Health Services Research and Development Service QUERI Economic Analysis Guidelines

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The VA Quality Enhancement Research Initiative (QUERI) develops and tests interventions to improve the quality of VA care, and methods to enhance implementation and dissemination of these interventions. Economic analysis can provide important information needed to evaluate these quality improvement efforts. However, not all QUERI projects will benefit equally from an economic analysis. Evaluations of interventions that are costly, are expected to have large effects on health care utilization, or are nearly ready to be implemented widely (e.g. the clinical effectiveness has been shown)ⁱ are most appropriate for economic analyses. These analyses are usually conducted alongside the primary trial to ensure coordinated measurement of clinical and economic outcomes. QUERI economic analyses measure costs and often outcomes and place this information in context, depending on the audience for the analysis. In some cases, more than one economic study will be appropriate to answer the questions of different audiences.

Types of analysis

There are several common forms of economic analysis that are appropriate for QUERI studies, including cost-identification, a cost-effectiveness analysis (CEA), and a budget impact analysis (BIA), also called a business case analysis. These are complementary but answer different questions and thus employ different designs – cost-identification will determine the cost of an intervention, the CEA estimates the cost-effectiveness of an intervention, and the BIA estimates the costs of adoption and dissemination of an intervention for a particular payer in a specific health-care system. A CEA calculates the dollars that must be spent to gain an additional unit of benefit from the intervention, usually the quality-adjusted life year (QALY) over the patients lifetimes. A BIA reports the cost to the payer, for example the VA, of the adoption of a proposed intervention over 1 to 5 years.¹ Cost-identification of an intervention does not consider outcomes or dissemination consequences. In all of these methods, the costs of the implementation strategy - including dissemination and sustainability, should be considered (and definitively included in or excluded from the analyses). A CEA is estimated at the individual patient level, the BIA is estimated at the payer level. Below we describe cost-identification, two forms of CEA, BIA, and an additional form of analysis, the assessment of low value care or waste which might be appropriate for disinvestment or de-implementation.

1. Cost-identification

A variety of methods are employed to determine intervention costs. Microcost methods ² are usually employed to estimate the cost of providing the clinical intervention and will include: personnel costs (with benefits, time in patient-care meetings, etc.); supplies and durable medical equipment; and IT equipment, software and maintenance costs attributable to the intervention.

ⁱ Note: when the efficacy of a clinical intervention has not yet been shown, it is rarely appropriate to undertake a cost-effectiveness or budget impact analysis.

When the intervention changes the quantity but not the character of health services, standard unit costs or average cost methods may be used. In a few cases, reasonable estimates may be available from published studies, but a cost analysis specific to the intervention and health care system under study will have more credibility.

Cost-identification of an intervention does not include the costs of implementation or dissemination unless specifically described. Because cost-identification is interested in the costs to provide the service at the time of the analysis, it does not employ discounting for future costs. Cost-identification is usually the first basis for other forms of economic analyses.

Microcost methods are also used to determine the cost of the implementation effort. There are several issues to consider: how long will the implementation program last? If it were implemented more broadly in the VA system, would the same program be used? How might implementation costs vary by station? Will costs change over time? (That is, might the implementation effort become more efficient with increased experience?)

2. Cost-effectiveness analysis (CEA)

In the 1990s a U.S. Public Health Service (USPHS) task force defined standard methods for conducting CEA. The task force used the term 'reference case' to refer to standard CEA, also called cost-utility analysis, which analyzes the costs and outcomes of an intervention relative to usual care. The result is expressed as a ratio called the incremental cost-effectiveness ratio (ICER). The numerator of the ICER is the difference in costs generated by the people in the intervention arm and the costs of those in the comparator arm. The denominator is the difference in outcomes, expressed as QALYs.

The standard CEA assumes the audience or the perspective for the study is society as a whole. As a result, it considers the cost to all relevant parties impacted by an intervention, and might include patients, family members, providers and the health care system. Therefore, a CEA conducted from a societal perspective would measure the effect of an intervention on subsequent health care utilization incurred by patients in the intervention (and their families), costs incurred by other health care systems, and other non-health care costs incurred by patients and their families. Standard CEA considers average costs, not incremental costs. The standard CEA thus includes fixed costs, facility overhead, and depreciation. A CEA done from a payer perspective would limit the costs included to only those incurred by the payer or patient, respectively.

In a standard CEA, outcomes are translated into a specific measure of benefit, the Quality Adjusted Life Year (QALY). Typically new interventions are more effective and more expensive than usual care.ⁱⁱ When this occurs, an incremental cost-effectiveness ratio is calculated. This provides information about whether the benefits of the intervention justify the costs. QALYs are treated as equal, regardless of the patient characteristics. Interventions are judged equivalently, regardless of their relation to the current standard of care. However, QALY

ⁱⁱ If the new intervention is both more effective and less costly, then the intervention is deemed "dominant" and the CEA is not required.

estimates, unless gathered during a clinical trial, are difficult to find as those in the literature may not match the disease, disease severity or the time frame of a particular study.

An alternative way to represent the ICER is to estimate the net benefit. Here an arbitrary dollar value is assigned to each QALY gained, such as \$75,000 or \$100,000 per QALY. The net benefit is calculated as the value of QALYs gained from the intervention (relative to the comparator) minus the cost of the intervention.

Standard CEA considers costs and benefits through a lifetime horizon often via modeling because long-term costs and benefits are rarely measured prospectively for several decades in a clinical trial. These are discounted to reflect the decline in economic value that results from delay. Two related modeling approaches are Markov models and discrete event models, with Markov modeling being the more common. Simple models can be done using a spreadsheet. More extensive models typically employ specialized software applications.

CEA should include sensitivity analyses because there is uncertainty with respect to information and assumptions in CEA. Sensitivity analysis is an important way in which to evaluate the effect of this uncertainty on study findings. For more information on the USPHS task force and its recommendations, see Trainings and Resources 3.b. For an example of a CEA using QALYs, see Pyne et al.³

3. Cost-effectiveness analysis (CEA) without Quality-adjusted life years (QALYs)

CEA can also be conducted using clinical outcome units in the denominator. This leads to costeffectiveness phrased in clinical terms such as "dollars per heart attack avoided." This type of study could be very useful when comparing across several treatment options for a single condition, however a condition-specific/outcome-specific study is less useful to decision makers when making resource allocation decisions across many potential programs. For example, dollars per heart attack avoided is difficult to compare to dollars per person vaccinated. QALYs were developed to provide an outcome measure that would be consistent across all diseases and treatments. See Knapp, 2011. ⁴

4. Budget impact analysis (BIA)

A BIA (or business case analysis) considers costs from the perspective of the payer, comparing the costs of adoption and implementation of two or more interventions, over the short-term (e.g. 1-5 years).¹ Because the comparison is short-term, discounting of future costs and benefits is unnecessary and only variable costs are taken into account. If a long-term horizon is chosen, then discounting could apply and fixed costs would be included. The best guide is to use the time horizon of greatest value to the managers who will use the results.

A BIA does not report clinical outcomes, but assumes the benefit of the new intervention is equal to or greater than the benefit of the comparator. It must take into account any impact of the intervention on the payer's costs, which may include changes in the cost of treatment, the number and characteristics of treated patients, and changes in health plan enrollment.

In most cases BIA uses the current state of care as a comparator. Thus costs are tallied under the usual care scenario and under the alternative scenario in the study. The difference between those total costs is the incremental cost to the payer over the time horizon specified. Like CEA, every BIA should include a sensitivity analysis that varies its parameters through a range of reasonable values.

A BIA will be more applicable to managerial decisions if it considers how much funding is needed to adopt the intervention given the current staffing and configuration of equipment and facility at sites where adoption is being considered. For example, an intervention that reduces hospital stays may save little if the effect is too small to allow reassignment of ward staff. Space and staffing constraints often make it unexpectedly expensive to adopt a new program. Unused capacity may make a program more economically feasible. Such considerations are often specific to a particular facility, making it difficult to generalize from a small sample of sites. The analyst may also wish to consider whether the analysis would change if the payer were to buy or make new services required by the intervention. See Gidwani. ⁵

5. Implementation

In all of the above analyses inclusion or exclusion of the costs of implementation should be described in the research plan. These costs must be specifically differentiated from research, intervention and dissemination costs so that the effectiveness and cost-effectiveness of the implementation strategy might be separately evaluated. To date, very few comparative economic evaluation analyses of implementation interventions have been reported. ^{6,7}However, there is increasing demand for QUERI economic analyses to involve the estimation of the costs of the implementation intervention strategy used to enhance the uptake of an effective program or practice (e.g., Hybrid Type III implementation intervention studies- see Curran et al 2012⁸). An excellent example of the estimation of implementation costs is found in Liu.⁹

	Cost-identification	CEA	BIA
Research Question	What does it cost to provide a specific intervention	What are the incremental costs and benefits of a new/enhanced intervention compared to a comparator?	What will it cost to adopt this new intervention across our health care system?
Economic Measures	Direct costs of the intervention including personnel, equipment, technology, pharmacy	Direct and indirect costs of intervention delivery, health care, and patient time and services related to the intervention	Variable costs of intervention adoption and implementation
Clinical Measures	None	morbidity, mortality, QALYs	None
Perspective	Payer	Payer, patient or societal	Payer
Timeframe considered	Current	Lifetime	1-5 years

Table 1 Comparison of the basic elements of economic analyses

6. Disinvestment or de-implementation

The QUERI Program generates new knowledge about how to implement evidence-based research findings into clinical practice. It is, for the most part, focused on improving quality and safety of care through the identification of gaps in care and the implementation of new or known evidence-based practices. Another approach to improving the quality and safety of care is the de-implementation of practices that are known to be wasteful or of low-value. Examples of these low-value practices are preventable hospital readmissions, hospital-acquired infections, annual PAP smear testing (rather than guideline recommended every three years) and preoperative chest x-rays for an asymptomatic healthy patient. These types of low-value services were estimated by the Institute of Medicine to produce over \$210B of costs in the US health care system in 2009.

Disinvestment in low-value care is the focus of the American Board of Internal Medicine/Consumer Reports' "Choosing Wisely" Initiative, the National Priorities Partnership, and the British National Health Service's NICE program. Links to the web sites for these programs are found below in: **Training and Resources 4. Disinvestment Resources.** Queri researchers that want to identify practices appropriate for disinvestment, should review the work done to date in the above disinvestment programs (outlined below), identify unwarranted variation in current practice, and identify the overuse and misuse practices within their areas of concentration. Researchers will want to consider the politics associated with the practices identified as low-value or wasteful and potential unintended consequences associated with proposed changes in practice. Researchers should work closely with their operations partners before moving forward in these areas. For Implementation researchers, it is important to note that this is an emerging field and the theoretical frameworks for disinvestment/deimplementation strategies are undeveloped.

Cost

All of the above analyses should determine what other types of care will be affected by the intervention. For example, if the intervention were adopted, would it attract new patients to enroll, or encourage existing patients to obtain more of their care through VA? If so, then the analysis should consider how these will affect cost. Note that from the societal perspective of a CEA there may be little net impact on cost if people switch from one health care system to another. However, from the VA's perspective, as in a BIA (business case), however, such changes will matter.

Presentation issues

The report of an economic evaluation must document data sources, methods, and assumptions. It should describe when costs are incurred and when benefits are realized. In particularly it is important to note which assumptions were varied in the sensitivity analysis, over what range, and how changes in the assumptions changed the results from the base case.

Due to variation in costs across VA stations, researchers sometimes develop simple spreadsheet programs for use by VA managers. These programs enable a manager to enter local details about costs and possibly other parameters as well.

Training and Resources

Training and resources for VA employees. Non-VA researchers will not have access to some items.

1. Archived cyber-seminars

VA researchers present many cyber-seminars on topics related to economic analysis within QUERI. Here is a sample of recent topics:

- Patient preferences and utilities
- Analysis alongside a clinical trial
- Assessing outpatient VA health care use
- Disinvestment in Implementation Research
- Creating a decision model
- Budget impact analysis
- Systems thinking for implementation

Future and past cyber-seminars, including archived recordings, may be found on the HSR&D web site at <u>http://www.hsrd.research.va.gov/cyberseminars/default.cfm</u>.

2. Resource centers

Health Services Research & Development (HSR&D) funds four resource centers.

- a. The Health Economics Resource Center (HERC) (<u>www.herc.research.va.gov</u>) documents economics data and provides publications and training on economic methods. (Visit the corresponding intranet web site to download most documents.)
- b. VA Information Resource Center (VIReC) (<u>www.virec.research.va.gov</u>) documents most other VA datasets, including many within the Decision Support System, and presents cyberseminars on informatics topics.
- c. Center for Information Dissemination and Education Resources (CIDER) (www.cider.research.va.gov) coordinates the HSR&D cyber-seminar series and manages web sites for HSR&D headquarters in Washington, DC.
- d. Center for Implementation Practice and Research Support (CIPRS) (<u>http://www.queri.research.va.gov/ciprs/default.cfm</u>) assists researchers in developing quality-improvement research within the QUERI program.

3. Journal articles and book chapters

a. Costing and the stages of implementation

Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. Feb 2004;8(6):iii-iv, 1-72.

Liu CF, Rubenstein LV, Kirchner JE, et al. Organizational cost of quality improvement for depression care. *Health Serv Res.* Feb 2009;44(1):225-244.

McInnes DK, Solomon JL, Shimada SL, et al. Development and evaluation of an internet and personal health record training program for low-income patients with HIV or hepatitis C. *Med Care*. Mar 2013;51(3 Suppl 1):S62-66.

McIntosh E. Economic evaluation of guidelines implementation strategies. In: Changing professional practice: theory and practice of clinical guidelines implementation. Thorson T, Mäkelä M, eds. Copenhagen: Danish Institute for Health Services Research and Development, 1999. DSI Report no. 99.05. URL: http://www.dsi.dk/projects/cpp/monograph/DSI9905.pdf (accessed 13 Nov. 2009).

Severens JL. Value for money of changing healthcare services? Economic evaluation of quality improvement. *Qual Saf Health Care* 2003;12(5):366-371.

Smith MW, Barnett PG. The role of economics in the QUERI program: QUERI Series. *Implement Sci.* 2008;3:20.

Vale L, Thomas R, MacLennan G, Grimshaw J. Systematic review of economic evaluations and cost analyses of guideline implementation strategies. *Eur J Health Econ* 2007;8(2):111-121.

b. Cost-effectiveness analysis methods (without reference to implementation)

Drummond MF, Jefferson TO. Guidelines for authors and peer reviewers of economic submissions to the British Medical Journal. *BMJ* 1996;313:275-283.

Gold MR, Siegel JE, Russell LB, Weinstein MC. Cost-effectiveness in health and medicine. New York: Oxford University Press, 1996.

The following three papers summarize contents of the Gold et al. book cited above.

Russell LB, Gold MR, Siegel JE, Daneils N, Weinstein MC. The role of cost-effectiveness analysis inhealth and medicine. Panel on Cost-Effectiveness in Health and Medicine. *JAMA* 1996;276(14):1172-1177.

Siegel JE, Weinstein MC, Russell LB, Gold MR. Recommendations for reporting costeffectiveness analyses. Panel on Cost-Effectiveness in Health and Medicine. *JAMA* 1996;276(16):1339-1341. Weinstein MC, Siegel JE, Gold MR, Kamlet MS, Russell LB. Recommendations of the Panel on Cost-Effectiveness in Health and Medicine. *JAMA* 1996;276(15):1253-1258.

c. Budget impact analysis

Luck J, Parkerton P, Hagigi F. What is the business case for improving care for patients with complex conditions? *J Gen Int Med* 2007;22(Suppl 3):396-402.

Mauskopf JA, Sullivan SD, Annemans L, et al. Principle of good practice for budget impact analysis: report of the ISPOR Task Force on Good Research Practices – Budget Impact Analysis. *Value in Health* 2007;10(5):336-347.

Nicholson S, Pauly MV, Polsky D, et al. How to present the business case for healthcare quality to employers. *Appl Health Econ Health Policy* 2005;4(4):209-218.

Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of goodpractice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value Health.* Jan-Feb 2014;17(1):5-14.

d. Sensitivity analysis

Briggs A, Goeree R, Blackhouse G, O' Brien B. Probabilistic analysis of cost-effectiveness models: choosing between treatment strategies for gastroesophageal reflux disease. *Medical Decision Making* 2002;4:290–308.

Briggs A, Schulpher M, Claxton K. Decision modelling for health economic evaluation. Oxford: Oxford University Press, 2006.

Doubilet P, Begg CB, Weinstein MC, Braun P, McNeil BJ. Probabilistic sensitivity analysis using Monte Carlo simulation. A practical approach. *Medical Decision Making* 1985;5(2):157-177.

4. Disinvestment Resources

http://www.nice.org.uk/usingguidance/donotdorecommendations/index.jsp http://www.nehi.net/publications/56-how-many-more-studies-will-it-take/view http://www.qualityforum.org/Setting_Priorities/NPP/Input_into_the_National_Quality_Strategy. aspx http://www.iom.edu/Global/Perspectives/2012/CEOChecklist.aspx http://www.abimfoundation.org/Initiatives/Choosing-Wisely.aspx

Choosing Wisely partners include: American Academy of Allergy, Asthma & Immunology ; American Academy of Family Physicians American College of Cardiology American College of Physicians American College of Radiology American Gastroenterological Association American Society of Clinical Oncology American Society of Nephrology American Society of Nuclear Cardiology National Physicians Alliance

Consumer Reports and the medical societies developed summaries of the lists including: <u>Allergy tests: When you need them and when you don't</u> (American Academy of Asthma, Allergy and Immunology)

<u>Bone-density tests: When you need them and when you don't</u> (American Academy of Family Physicians)

<u>Chest X-rays before surgery: When you need them – and when you don't</u> (American College of Radiology)

Chronic kidney disease: Making hard choices (American Society of Nephrology)

EKGs and exercise stress tests: When you need them for heart disease -- and when you don't (American Academy of Family Physicians)

Hard decisions about cancer: 5 tests and treatments to question (American Society of Clinical Oncology)

<u>How should you treat heartburn and GERD?</u> (American Gastroenterological Association) <u>When do you need an imaging test for a headache?</u> (American College of Radiology) <u>When do you need antibiotics for sinucitie?</u> (American Academy of Asthma, Allergy and

<u>When do you need antibiotics for sinusitis?</u> (American Academy of Asthma, Allergy and Immunology)

<u>When do you need antibiotics for sinusitis?</u> (American Academy of Family Physicians) <u>When do you need a Pap test?</u> (American Academy of Family Physicians)

When do you need imaging tests for lower back pain? (American Academy of Family Physicians)

References

- 1. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis-principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. *Value Health.* Jan-Feb 2014;17(1):5-14.
- 2. Smith MW BP, Phibbs CS, Wagner TH. . *Microcost methods of determining VA healthcare costs*. Menlo Park, CA: Health Economics Resource Center;2010.
- 3. Pyne JM, Fortney JC, Tripathi SP, Maciejewski ML, Edlund MJ, Williams DK. Costeffectiveness analysis of a rural telemedicine collaborative care intervention for depression. *Arch Gen Psychiatry*. Aug 2010;67(8):812-821.
- 4. Knapp H, Fletcher M, Taylor A, Chan K, Goetz MB. No clinic left behind: providing cost-effective in-services via distance learning. *Journal for healthcare quality : official publication of the National Association for Healthcare Quality*. Sep 2011;33(5):17-24.
- 5. Gidwani R, Goetz MB, Kominski G, et al. A budget impact analysis of rapid human immunodeficiency virus screening in Veterans Administration emergency departments. *The Journal of emergency medicine*. Jun 2012;42(6):719-726.

- 6. Vale L, Thomas R, MacLennan G, Grimshaw J. Systematic review of economic evaluations and cost analyses of guideline implementation strategies. *Eur J Health Econ.* Jun 2007;8(2):111-121.
- 7. Grimshaw JM, Thomas RE, MacLennan G, et al. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*. Feb 2004;8(6):iii-iv, 1-72.
- 8. Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care*. Mar 2012;50(3):217-226.
- 9. Liu CF, Rubenstein LV, Kirchner JE, et al. Organizational cost of quality improvement for depression care. *Health Serv Res.* Feb 2009;44(1):225-244.