
***Economic Analyses Alongside
Phase III Cooperative Group
Clinical Trials –
Practical Issues***

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Criteria for selecting trials for economic analysis

- 1. There's a reasonable possibility that the trial results could influence practice**
- 2. A change in practice could have non-trivial cost implications**
- 3. The expected differences in clinical outcome are likely to be relatively modest**

Criteria for targeting RCTs for an economic companion

- 1. There is a reasonable possibility that the trial results could influence practice**
 - comparator is standard of care**
 - experimental intervention is feasible in the routine care setting**
 - practitioners are likely to be interested in using the new therapy if it's effective**

Criteria for targeting RCTs for an economic companion

2. A change in practice could have non-trivial cost implications
 - i.e., the aggregate cost consequences of adopting one treatment over another as the standard of care are likely to be substantial...
 - because the difference in costs between treatment groups is large
and/or
 - the disease is so common that small differences in cost per patient could translate into large differences in cost for a population

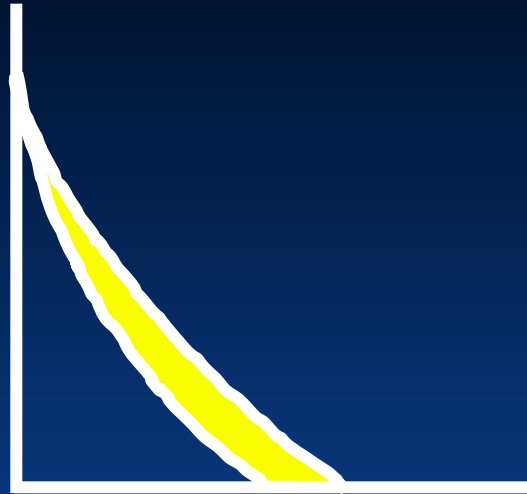
Criteria for targeting RCTs for an economic companion

3. The expected differences in clinical outcome are likely to be relatively modest

$$\text{CER} = \frac{\Delta \text{ Cost}}{\Delta \text{ QALYs}}$$

Why does cost-effectiveness vary with the setting?

Metastatic



$\Delta \text{ Cost} = \$20,000$

Adjuvant



$\Delta \text{ Cost} = \$20,000$

Special challenges in the metastatic setting

Difference in cost between arms may be sensitive to second and later line therapy

- **Requires information on treatment after progression**

Difference in cost between arms may be sensitive to costs of care during added months of life

- **Requires capture of total not just incremental costs**

Special challenges in the metastatic setting (cont'd)

- **QOL during additional months of life is likely to be compromised so that $\Delta\text{QALYs} < \Delta\text{LYs}$**
 - **Requires measurement of utilities to allow calculation of QALYs**

Process for targeting RCTs for an economic companion

Requires:

Systematic review of concepts to identify those that meet the pre-established criteria

Decision about whether to include an economic companion early in the protocol development process

True collaboration between the study chair and the individual leading the economic component

An economic companion must be designed and integrated during the clinical trial design phase

CALGB economic component prototype

Emphasis on incremental cost and effectiveness

**Collection of resource use on all patients relying on
clinical data collection mechanisms**

- chart reviews by CRAs**
- patient diaries [collected by QOL interviewer(s)
when there is also a QOL component]**

**Unit prices derived from bills of trial patients and
national sources**

**Collection of utility data from patients when cost-
utility analysis is an appropriate analytic approach**

RESOURCE UTILIZATION SUMMARY
First 25 Weeks

SWOG Study No. **S**

Protocol Step

Patient Label

SWOG Patient No. Patient's Name _____ (L,F,M)

Institution / Member _____ Physician _____

Amended data: Yes, mark amended items in red.

Check one summary period: 1- Week 13 (for Weeks 1-12)
 2- Week 25 (for Weeks 13-24)

I. LABORATORY TESTS and MEDICAL PROCEDURES

Were laboratory tests performed during this period?
 No Yes

Were medical procedures performed during this period?
 No Yes

Laboratory Tests	Total Number For Summary Period	Procedures	Total Number For Summary Period
CBC with or without differential		Chest X-ray	
Platelets <i>(Count as CBC unless only Platelets were ordered)</i>		MRI/Chest	
Chem -23 (SMAC) <i>(Count as Chem -23 unless individual tests ordered)</i>		MRI/Abdomen	
Alkaline Phosphatase		MRI/Brain	
LDH		CT/Chest	
Total bilirubin		CT/Abdomen	
SGOT/PT		CT/Brain	
GGT		Bone Scan	
Albumin		Bone X-ray	
Uric Acid		Audiogram	
Total Protein		EKG	
Serum Creatinine		Other, specify:	
Na+/K+			
Ca++/Mg++			
CO2/Cl-			
CEA			

RESOURCE UTILIZATION SUMMARY First 25 Weeks		SWOG Study No. S <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Protocol Step <input type="checkbox"/>	
SWOG Patient No. <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		Summary period: 1- <input type="checkbox"/> Week 13 (for Weeks 1-12) 2- <input type="checkbox"/> Week 25 (for Weeks 13-24)	
IV. OTHER MEDICAL CARE			
Did the patient receive other medical care during this period? <input type="checkbox"/> No <input type="checkbox"/> Yes			
A. Record Number of Days or Visits	Number of InPatient Days	ICU	Non-ICU
Protocol Mandated Chemotherapy			
Nonprotocol Mandated Therapy (See Below):			
2nd line Chemotherapy			
3rd line Chemotherapy			
Other Systemic Therapy, specify type: _____			
Radiation Therapy (record total # of different sites: _____)			
Hospital-based Hospice			
Other Hospital Admissions, specify reason: _____			

B. Record Number of Days or Visits	Number of Days		Number of Visits
Emergency Room Visits			
Home-based Hospice			
Nursing Home Stay			
Home Care Visits			
Physician Office Visits (not chemotherapy, radiation, or systemic therapy related)			
Pain Service Visits			
C. Record Number of Procedures	Number of Procedures		
Minor Procedures			
Semi-Permanent Catheter Insertion (e.g., Hickman)			
Thoracentesis			
Other, specify: _____			
Other Procedures, specify type: _____			

By: _____ Date: _____ SWOG 06-25-97 SW353

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about

I have some problems in walking about

I am confined to bed

Self-Care

I have no problems with self-care

I have some problems washing or dressing myself

I am unable to wash or dress myself

Usual Activities (*e.g. work, study, housework, family or leisure activities*)

I have no problems with performing my usual activities

I have some problems with performing my usual activities

I am unable to perform my usual activities

Pain/Discomfort

I have no pain or discomfort

I have moderate pain or discomfort

I have extreme pain or discomfort

Anxiety/Depression

I am not anxious or depressed

I am moderately anxious or depressed

I am extremely anxious or depressed

I would now like to think about your health in a different way. I'd like you to try to picture in your mind a scale that looks a bit like a thermometer. The best health you can imagine is marked 100 (one hundred) at the top of the scale and the worst health you can imagine is marked 0 (zero) at the bottom. I would now like you to tell me the point on this scale where you would put your own health **today**. What number, from 0 to 100 would you give to the state of your health?

What does it take?

Institution

- **CRA time to abstract resource use**
- **?CRA time for chart review beyond progression**
- **?provision of bills**

Stat center

- **Ability to conduct analyses of quality adjusted survival**

Economic team

- **Study chair effort**
- **Analyst effort**
- **Funds to support the cost of patient surveys if they can't be piggy-backed onto a QOL companion**