Patient Outcomes in Radiology: Some Issues and an Approach to Short-Term Health-Related Quality of Life

J. Shannon Swan, M.D.
Associate Professor of Radiology
Director, Division of Outcomes Research
Indiana University Department of Radiology

Acknowledgements

- 1R01 HL51370 (NHLBI)
  - J. S. Swan, P.I.
- 1R01 HS10277-01 (AHCPR)
  - J.S. Swan and François Sainfort, Co- P.I.'s
- GE- AUR Radiology Research Fellowship
- D.G. Fryback, F. Sainfort, W.F. Lawrence, D.A. Katz, D.M. Heisey, M.E. Hagenauer

What Are Outcomes ?

Traditional Definition:

- **Measurable changes in patient status that occur (or are avoided) and which can be attributed to some sort of therapeutic (or preventive) intervention**
- **Measuring outcomes: a process of making a quantitative description of patient status**
- **Measuring outcomes can be more general - we can also talk about the health of a population**

Measurement of Health Outcomes

- Outcome measures have evolved:
- From simple dichotomous assessments
  - Survival
  - Occurrence of a clinical event
- To patient-oriented measures
  - Satisfaction
  - Quality of life
  - Functional health status

Problems with Outcomes Research and Radiology

- The Bigger Picture: Design of studies to evaluate effects of diagnostic imaging as opposed to Tx
- The Smaller Picture: Measurement of outcomes from short-term procedures and treatments

Challenges to Outcomes Research in Radiology

- **Relative to Treatment Oriented Outcomes**
  - **Langlotz** CP. Overcoming barriers to outcomes research on imaging: Lessons from an abstract decision model *Acad Radiol* 1999; 6(suppl 1): S29-34 .
- **Measurement of Quality of Life in Radiology**
  - **Swan**, et. al. MR and conventional angiography: Work in progress toward assessing utility in radiology. *Acad Radiology* 1997; 4: 475-482.
  - **Swan JS, Langlotz CP**. Patient preference for magnetic resonance versus conventional angiography: assessment methods and implications for cost-effectiveness analysis. *Investigative Radiology* 1998; 33: 553-559.
  - **Swan**, et. al. A Time Tradeoff Method for Cost-Effectiveness Models Applied to Radiology. *MDM*. In Press.

Methodologic Challenges Relative to Treatment (Langlotz CP. *Acad Radiol* 1999)

- **Imaging studies must enroll a broader spectrum of patients**
  - **Tx trials have luxury of using patients with disease**
- **The benefits of imaging will be smaller than the benefits of treatment**
  - **Many patients in imaging trials don't have the disease**

Methodologic Challenges Relative to Treatment (Langlotz, AR 1999)

- For patients at extremes of disease likelihood, imaging tests are not optimal
  - If they have disease, tx. If not, don't test.
- Large temporal and causal distance between testing decision and patient outcome
  - Variability of radiologist ability
  - Lack of knowledge of how imaging influences tx decisions
  - Low or variable tx effectiveness

How to overcome these challenges ? (Langlotz, AR 1999)

- **Big randomized trials are not the only way, and their results are less meaningful if foundational studies are not done well**
- **Consider:**
  - **Feature analysis studies: decrease interobserver variability in later trials**
  - **Design of clinical prediction rules: so patients with varying pre-test likelihood can be stratified**
  - **Data synthesis studies: a lower cost way of gaining insights with decision analysis and meta-analysis**

Short-Term Outcomes

- Given that barriers to research can be to some extent overcome, there are well-tested ways to measure outcomes including overall and various domains of QOL.
- But what about the short-term outcomes, i.e. morbidity of imaging procedures, or other short-term treatments ?

Assessing Utility for Cost-Effectiveness Models in Radiology

Utilities Measurements for Radiology

- **The Reason**
  - **Radiology must address value in language of CEA**
  - **One of the steps - quality of life assessment**
  - **Patient preference for a health state = UTILITY**
  - **Studies now usually make assumptions**
  - **Result: can over or underestimate advantages of some procedures, therapies, etc.**

Utilities Measurements for Radiology

- **The Problem**
  - **Radiology does not fit the CEA paradigm easily**
  - **procedures are short-term: hard to link up to Quality-Adjusted Life-Years with events which take place over minutes to hours**

CEA: Units of Measurement

- **Cost: Dollars**
- **Effectiveness: Life Years or Quality-Adjusted Life-Years (QALYs) if a "CUA"**

$$\text{Incremental CE Ratio} = \frac{\Delta\text{COSTS}}{\Delta\text{QALYS}}$$

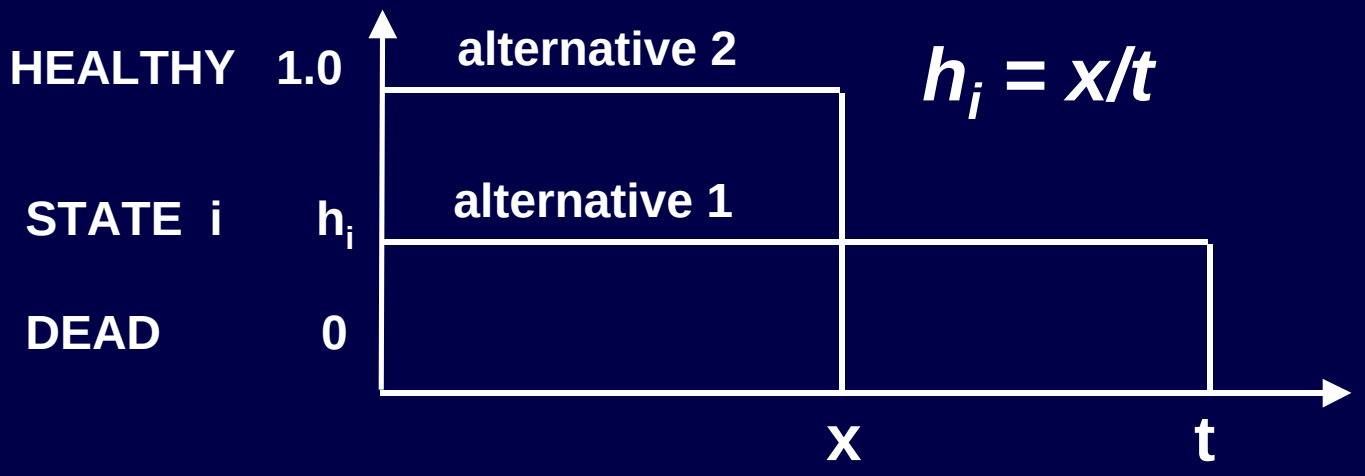
} aim for fewer $$/QALY

Quality-Adjusting Life

- Utility: value assigned to a health state or action
- 10 years lived at a utility value of 0.5 = 5 QALYs
  - Usually scaled as 0 = death to 1.0 = optimal health
  - Axioms associated
- Methods of Assessing Utility
  - Standard Gamble / Time Trade-off
    - » Direct interview
    - » Multi-attribute assessment instruments

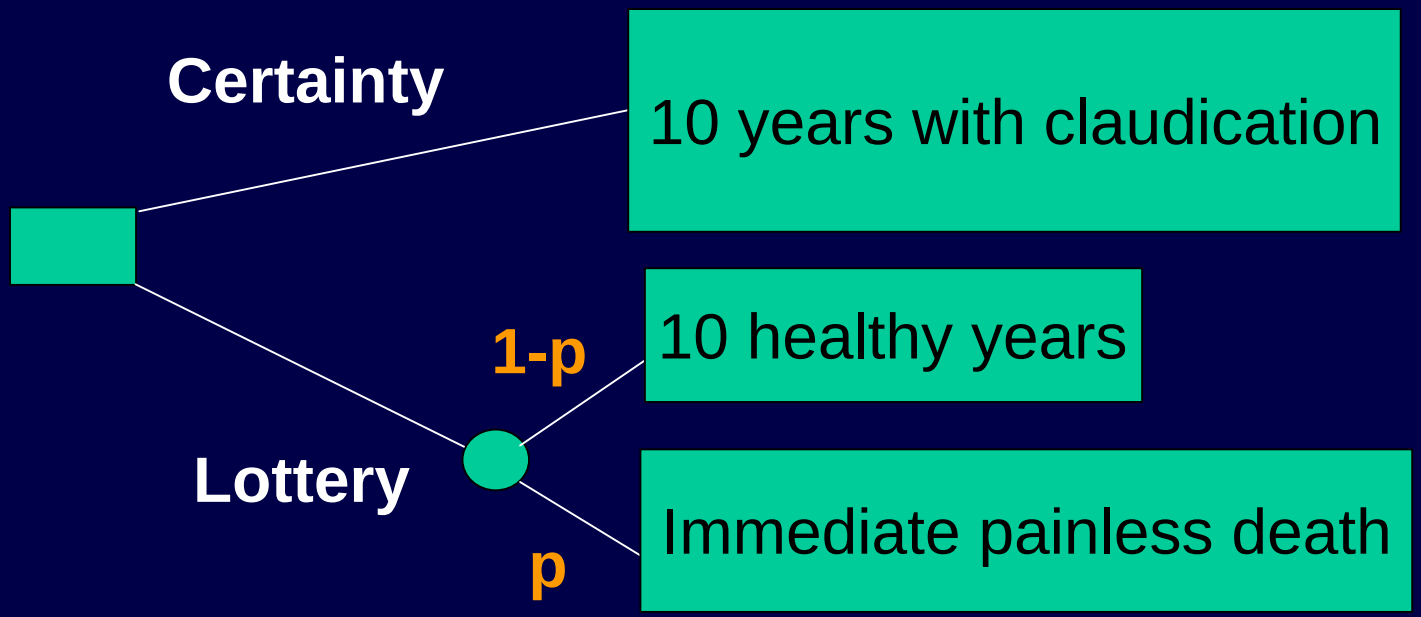
Time Trade-off

- For chronic states, two alternatives:
  - 1. State *i* for time *t* followed by death (LE of individual with a chronic condition)
  - 2. Healthy for time *x* < *t* followed by death.
  - 3. Indifference Point



$h_i = x/t$

Standard Gamble



- **Example: patient is given a choice between a certain period of life with claudication and a gamble between an equivalent period with a healthy life and a probability "p" of a painless death. "p" is varied until indifference is found. Utility for 10 years of claudication pain = 1-p (0<p<1) (After Yin, et al AJR 1995; 165: 1323-1328.).**

Example: Computing QALYs for a Fictional Treatment

Health State	Medical Therapy	Utility
Well	4 Years	1.0
Some Disability	1 year	.59
Bed Bound	0.5 year	.34

QALYS = [4 X 1.0 + 1 X .59 + 0.5 X.34] = 4.76

Years of Life = 5.5

A First Look at Assessing Utility in Diagnostic Radiology

- **Swan JS, Fryback DG, Lawrence WF, Katz DA, Heisey DM, Hagenauer ME, Seltzer P, Jacobson BK. MR and conventional angiography: Work in progress toward assessing utility in radiology. *Academic Radiology* 1997; 4: 475-482.**

Methods

- MRA vs. X-ray Angio: test case
  - difference in invasiveness
- No methods for short-term outcomes, so we modified existing instruments
  - Utility
    - » TTO, WTP, Rating Scale, Categorical Scaling
    - » TTO closest to real utility
  - "Functional Status" Measures
    - » pain, anxiety, role, social function, etc.

Methods

- **Patients**
  - **30 pts. enrolled in ongoing NHLBI grant**
  - **All pts. had both XRA and MRA**
  - **Interviews: months after the exams**
  - **Questionnaire pilot tested in 11 prior pts.**

Modified Time Trade-off (TTO)

- **Katz and Cohen**
  - **TTO in terms of additional life expectancy required for a patient to undergo a short term therapy**
- **Our use of Katz's method**
  - **"Assuming 5/10 years life expectancy (to assess for discounting) in excellent health from today, your doctor is concerned about new PVD. If you have the MRA/XRA now, assume we can guarantee you 2 years of additional healthy life. Would you have the test ?" (to indifference point)**

Utility: Results

Technique	Mean	Median	p WSR
TTO - MRA5	96.2*	10.5	XRA5-XRA10: NS
TTO - MRA10	84.9	10.5	MRA5-MRA10: NS
TTO - XRA5	142.6	60	XRA10-MRA10:NS
TTO - XRA10	126.3	52.5	XRA5-MRA5: NS
WTP - MRA	2.1+	0	p = .0137
WTP - XRA	7.4	0	
RS - MRA	-1.1	0	p = .0004
RS - XRA	-3.8	-3	

* = QALD, + = % annual income

Conclusions

- **Utility/QOL assessment is possible in the short-term scenario of radiologic tests, but QALY based methods need work**
- **MRA is strongly preferred to XRA by patients using multiple measures of preference, and functional status results indicate less morbidity**

The Next Step... Refinement of TTO technique

- “ **Wait Tradeoff** ”(AHCPR 1R01 HS10277)
  - An original method of Time Trade-off
    - » more realistic health state scenario for pt.
    - » does not require discounting
    - » easier to understand
    - » mathematically equivalent to classic TTO
    - » designed for tests and short-term tx
    - » administered via phone or face to face with computer cueing the coordinator

A Time Tradeoff Method for Cost-Effectiveness Models Applied to Radiology

J. Shannon Swan, MD, Dennis G. Fryback, PhD, Willliam F. Lawrence, MD, François Sainfort, PhD, Mary Ellen Hagenauer, BS ,

Dennis M. Heisey, PhD

Medical Decision Making, Jan. 2000, In Press.

Wait Tradeoff

- **Subject is given a choice between:**

  – **having an actual test now and receiving the results and treatment immediately**

  OR

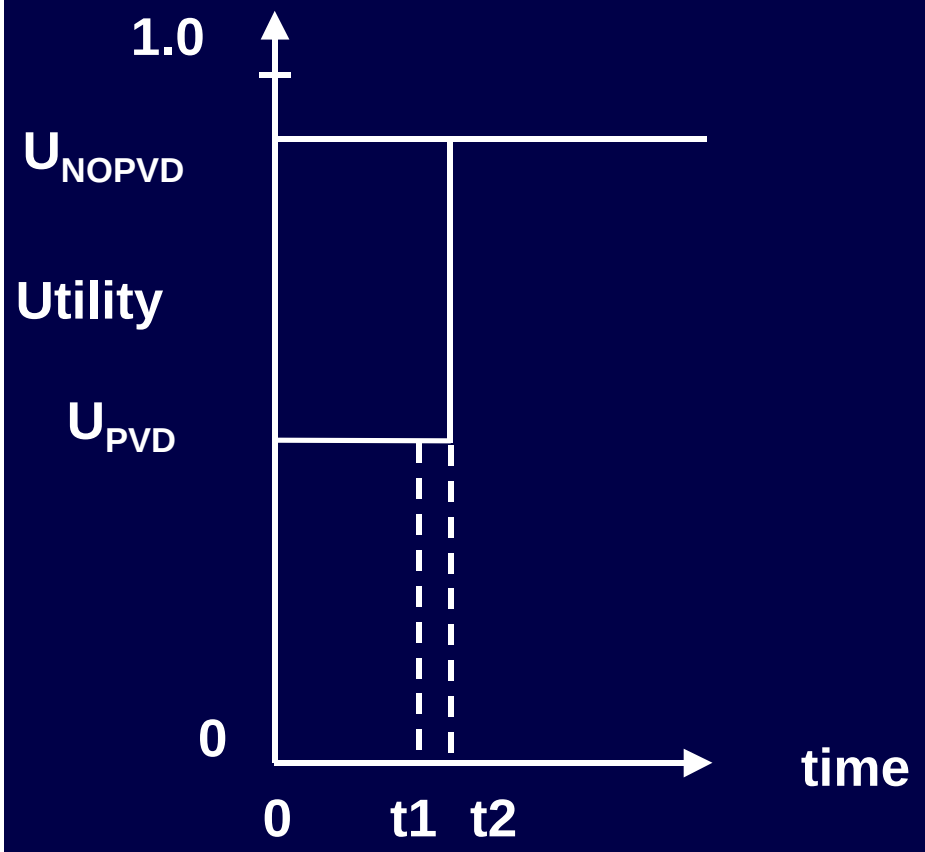
  – **having an "ideal test" (no pain, brief, and no risk) but having to wait with symptoms for the results and thus treatment**

Wait Tradeoff: Methods

- Begin interview assuming 4 week wait time for results and tx versus XRA (or MRA) now and immediate tx
  - Patients frequently wait ~ 4wks. for tx with non-emergent Hx in our institutions
- Use bisection to get indifference point
  - yes to 4 wks., then add 2 weeks until “no”, then bisect between 4 wks. and stop point until indifferent
  - If no to 4 wks., bisect toward indifference

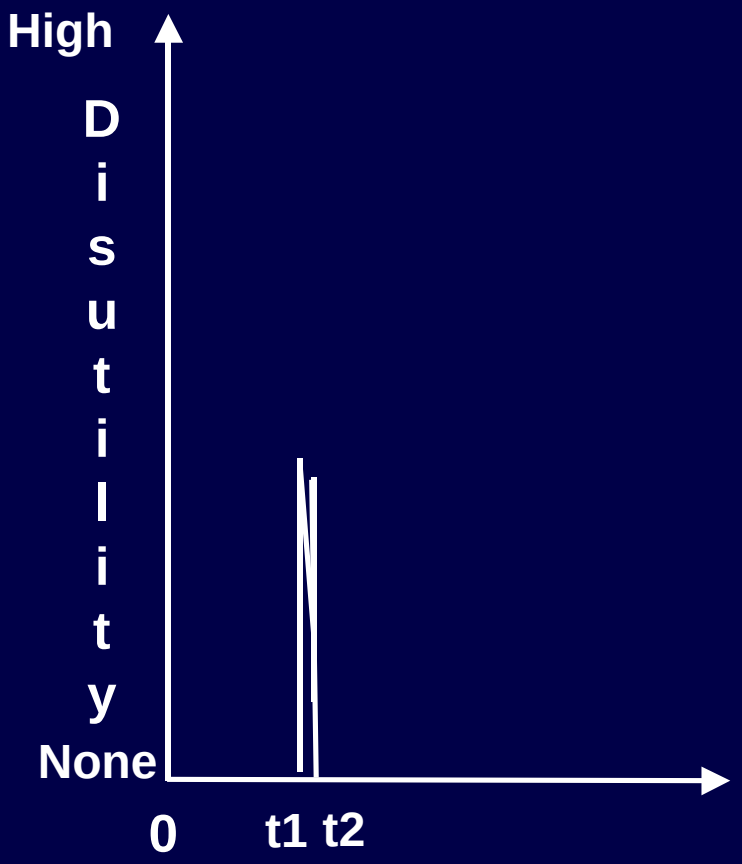
Overall Health experience of PVD Patient

Constant States

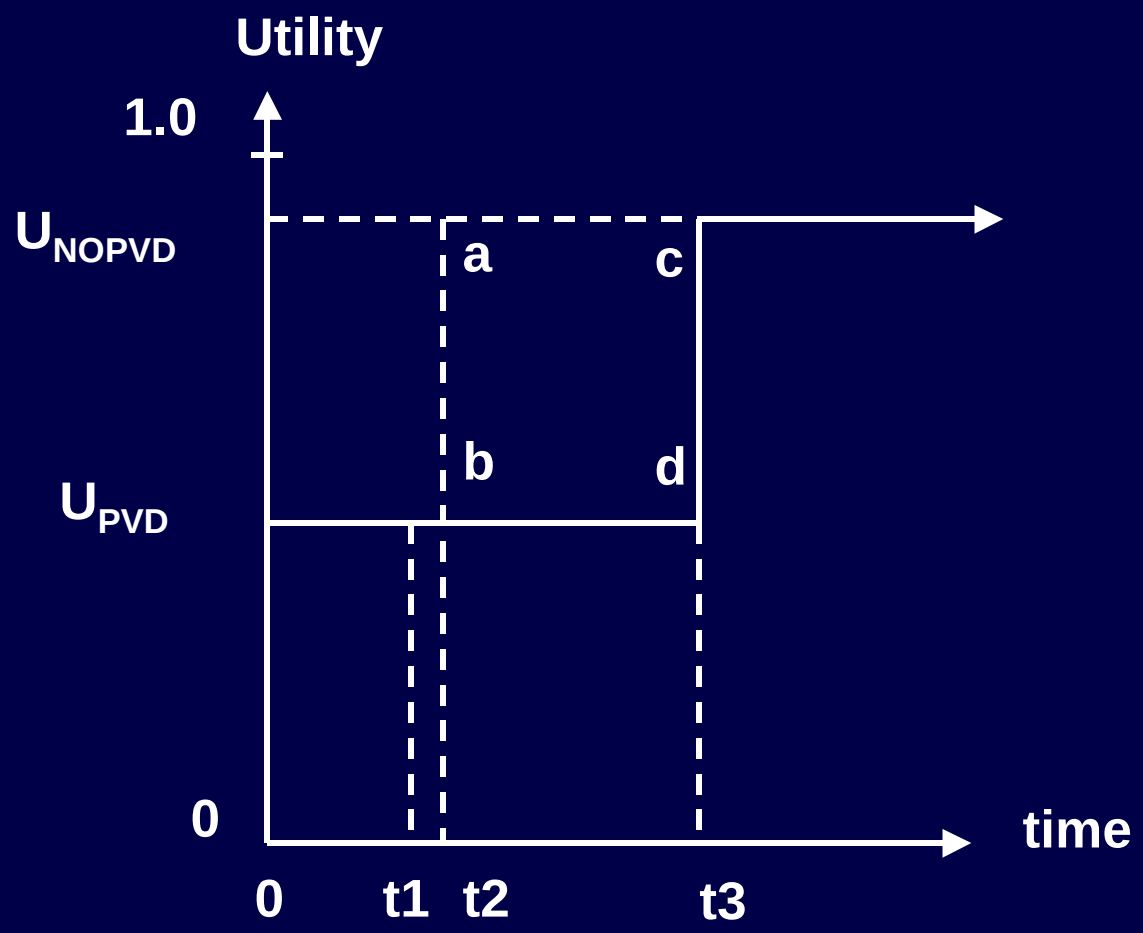


AND

Temporary States



Health Profile for Ideal Test



U_{NOPVD} = utility of not having PVD

U_{PVD} = utility of PVD

t2 - t1 = time of test

d2 = duration patient willing to wait

d2 = t3 - t2

Area of Rectangle (abcd) = disutility of actual test

Disutility of test = d2 x (U_{NOPVD} - U_{PVD}) [Eq. 1]

Wait Trade-off: Results

	XRA	MRA	Difference	WSR
Wait time (Days)	42.1	16.1	26.0	.0001
Disutility (QALD)*	15.16	5.80	9.36	.0001
Rate Scale (Mean)**	-3.73	-1.05	-2.68	.0001 (N= 38)

* calculated from Eq. 1 - expressed as Quality-Adjusted Life days (QALD) using $U_{PVD} = .57$ and $U_{NOPVD} = .93$ (Hunink, et. al)

** Likert Scale: 0 = neutral to -10 for most negative experience possible

WSR = Wilcoxon Signed Rank test

So, Why Does Utility Matter In This Case ?

- **Yin, et al.* : if one does not allow for disutility of XRA, MRA is not cost-effective**
- **9.36 QALD (our result) is substantially more disutility than the assumptions of Yin's model (17 years to accumulate disutility = to our measured value)**

***Yin D, Baum RA, Carpenter JP, Langlotz CP, Pentecost MJ. Cost effectiveness of MR angiography in cases of limb-threatening peripheral vascular disease. Radiology 1995; 194: 757-764.**

Conclusion

- Our methodology is improving
  - Keep aware of the limitations on imaging outcomes and how we can optimize evaluations where the larger outcomes picture is at stake
  - Short-term outcomes: “the smaller picture” but still important and in need of further clarification
- Radiology is not going to escape scrutiny
  - Adapt as needed, innovate when necessary and with strong linkage to reasonable methodology