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Rare Diseases and Orphan Products
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How should we allocate the budget: Efficiency or fairness first

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GROUP OF EIGHT AUSTRALIA

AACSB ACCREDITED

EFMD EQUIS ACCREDITED

ASSOCIATION AMBA ACCREDITED

SUMMARY

Objective of economics

Best allocation of finite resources

BUT methods have mixed success

- Simple competitive markets ✓✓
- Social infrastructure - ??

- Economic evaluation

  ← Unsupported assumptions *wrt* values, motivations

- Empirical evidence

  → Need for revision of theory/practice

  → Fairness first paradigm

  ie theory, methods commence with fairness

CONTENT

1. Economic evaluation
2. Failed theory
3. Empirical evidence: personal values
4. Empirical evidence: social values
5. Fairness *vs* Efficiency paradigms

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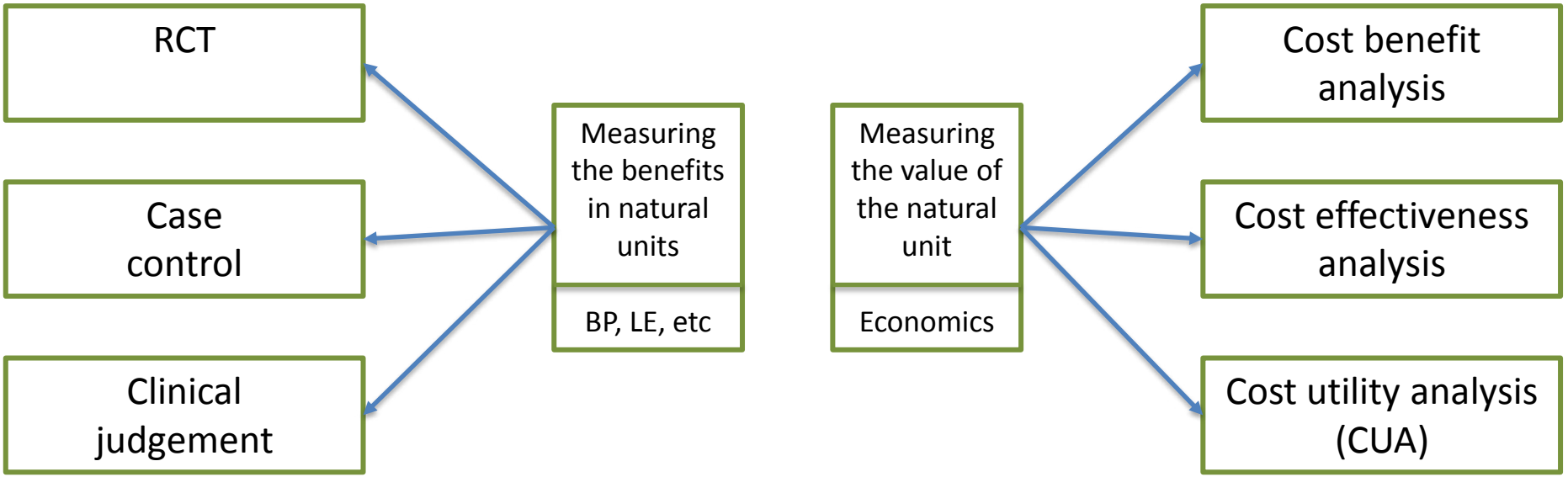
1. OVERVIEW OF ECONOMIC EVALUATION

THE EVALUATION FRAMEWORK



COST UTILITY ANALYSIS

- QALY = (life years)*(utility) = unit of output
  = Quality Adjusted Life Year
  'utility' = strength of preference
- Decision criteria
  minimise cost/QALY
  → maximum QALYs from a budget

FOCUS OF COST UTILITY ANALYSIS

- An ‘equity efficiency’ trade-off is recognised

BUT

- ‘Efficiency’: Methods well developed → maximise QALYs
- Fairness: No methods developed, commonly ignored
- Conclude
  - CUA = ‘efficiency first paradigm’

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2. WHERE ECONOMIC EVALUATION FAILS

PROBLEMATIC THEORY AND IMPLEMENTATION

- Implementation – imperfect methods
  - *eg* Measuring utility: seriously defective (EQ-5D)
  - Theory = 'foundations' of evaluation methods
    ← problematic assumptions = focus below
    (bad theory → measurement irrelevant/ambiguous use)

ASSUMPTIONS of CUA

1. Personal motivation … maximise utility
2. Social motivation (what we want for others)
   … Maximum QALYs (ie LY weighted utility)

Result

← Social = personal goal scaled up

PROBLEM 1 INDIVIDUAL MOTIVATION

- Is maximising utility the only motivation?
  - Habit/duty/religion/conformity/marketing ??

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  - Choice identifies utility

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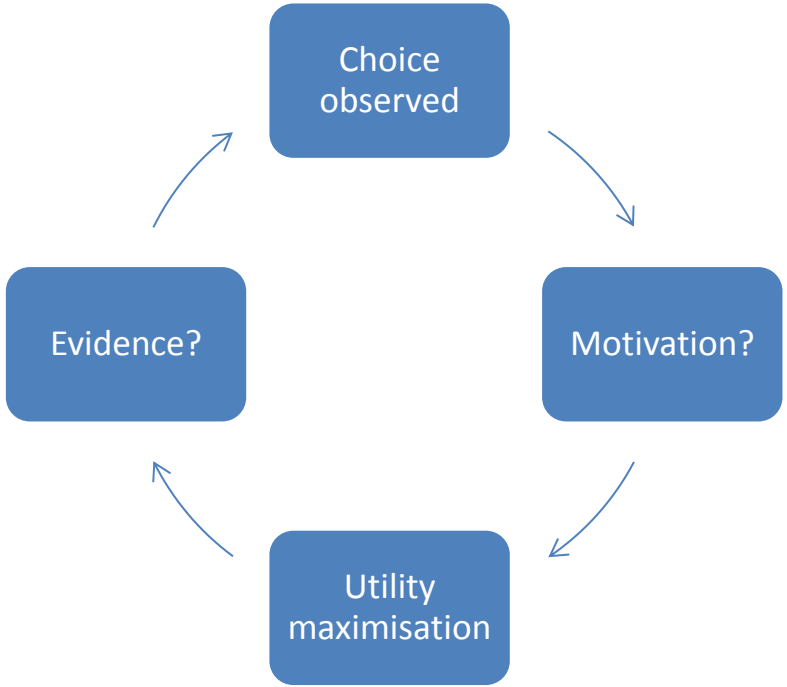
- Criterion behaviourally barren

THE REVEALED PREFERENCE TAUTOLOGY



CONCLUDE

- CUA ⇐ empirical evidence of individual motivation
- Motivation ← behaviourally barren tautology
- Behavioural economics = a response

PROBLEM 2 SOCIAL PREFERENCES

- Do people want maximum QALYs
  - Maximisation ignores distribution

4 people: (5+5+5+0)>(3+3+3+3)

15 QALYs > 12 QALYs

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- Do people want maximum QALYs
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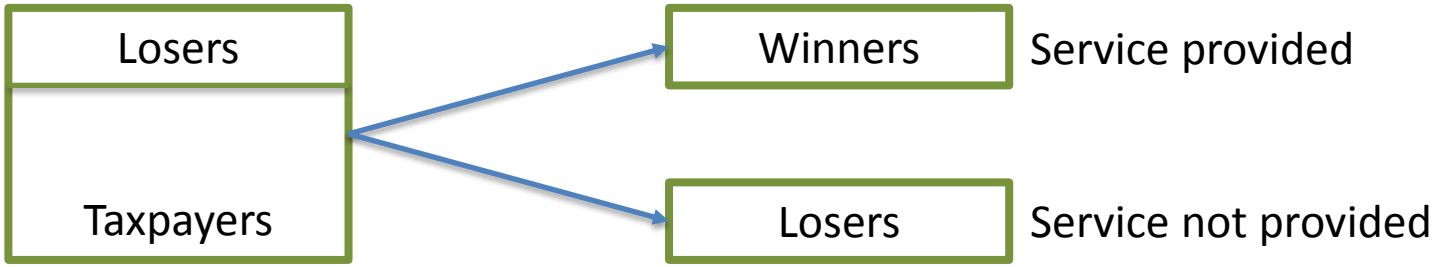
    4 people: (5+5+5+0)>(3+3+3+3)

    15 QALYs > 12 QALYs
  - CUA → winners/losers



JUSTIFICATION FOR NON-PROVISION TO LOSERS

- Rhetorical: more QALYs (health) better than less losers … lose!
- Ethical … utilitarianism: an assumed goal
- Evidence of population support … na

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3. EMPIRICAL EVIDENCE: VALUES

SURVEY EVIDENCE FROM AUSTRALIA n=455

Which ethical principle

- Australians are not hedonic utilitarians

  ‘Action producing happiness is always right’

agree	22.8%
disagree	57.4%

  ‘Maximising happiness is more important than any other principle’

agree	14.3%
disagree	65.9%

SURVEY EVIDENCE FROM AUSTRALIA n=455

- There is a strong commitment to ‘duty’, ‘role in community’ (solidarity/communitarianism)

  ‘I must fulfil duties even if it makes me less happy’

agree	92.0%
disagree	8.0%

  ‘Having duties is a natural part of being a member of society’

agree	95.0%
disagree	5.0%

DUTY = LONG RUN SELF INTEREST ??

‘People help others only because they gain something personally’

agree	18.2%
disagree	60.7%

CONCLUDE

- Personal motivation
  ≠ pure self interest
- Social motivation therefore:
  unlikely to be the sum of individual self-interest
- Task: what personal motivations are relevant to social decisions

EVIDENCE FROM ANTHROPOLOGY

Behaviour ← social role/social inter-relations

- Social behaviour
  - Motivation
    - Reciprocal altruism (‘weak reciprocity’)
      - Help others expect reciprocal treatment
    - Strong reciprocity
      - Punish others for selfishness in absence of self interest

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  - Evidence: Behavioural economics
    - Ultimatum game: Personal loss to punish unfair behaviour
    - Dictator game: Share with others at personal loss; no possible penalty

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    - Ultimatum game: Personal loss to punish unfair behaviour
    - Dictator game: Share with others at personal loss; no possible penalty
  - 'Sharing is a core feature of human society' (Kameda 2002)

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4. EMPIRICAL EVIDENCE

Allocating the budget: Results from 4 surveys

SIMILAR METHODS

- Web based allocation exercises
- Fixed budget:

  allocate between
  - low cost QALY … CUA includes
  - higher cost QALY … CUA excludes
- Budget rises, sharing possible

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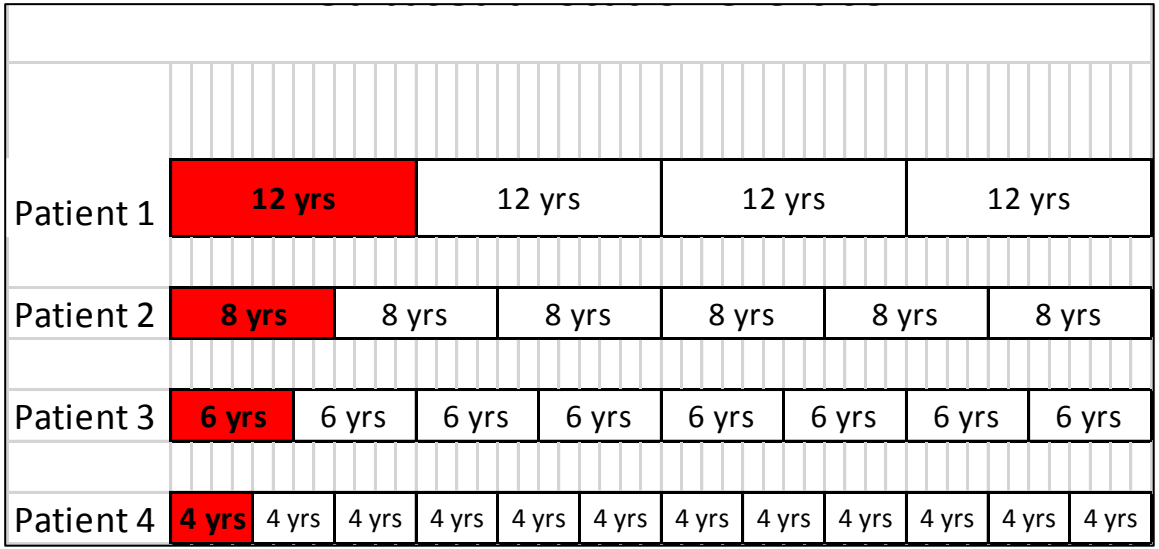
Sharing Survey 1

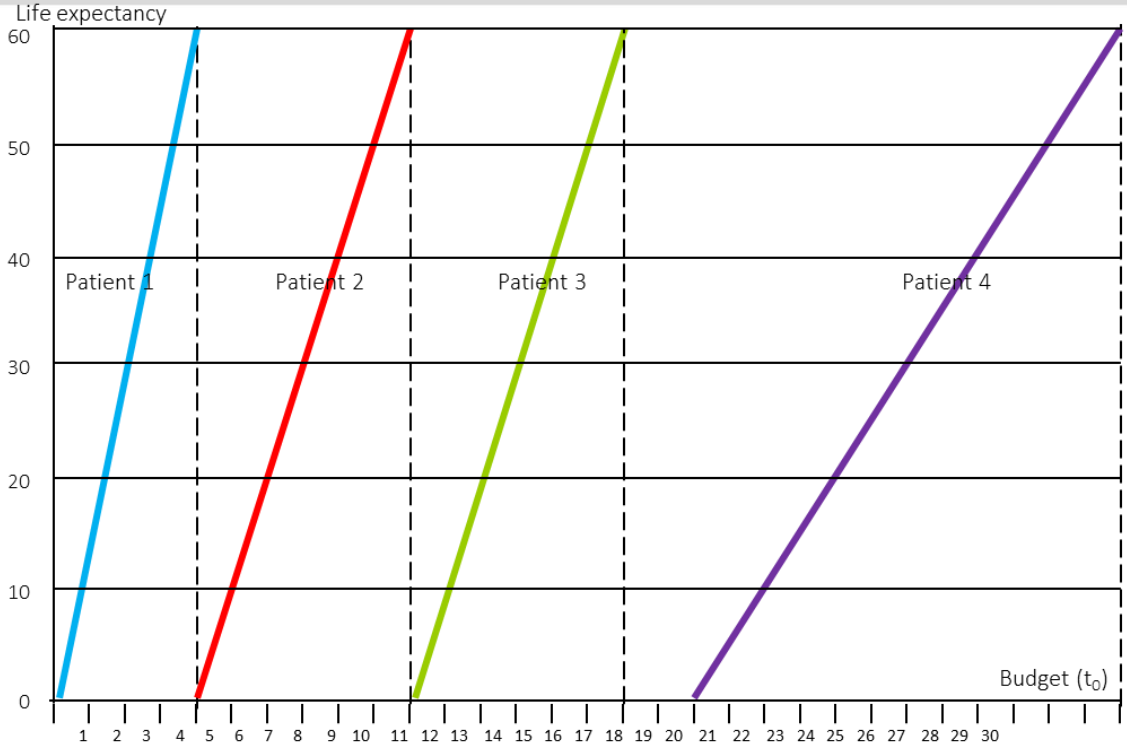
Maximising health versus sharing: measuring preferences for the allocation of the health budget

Richardson J, Sinha K, Iezzi A, Maxwell A
Social Science and Medicine 2012 75(8):1351-1361

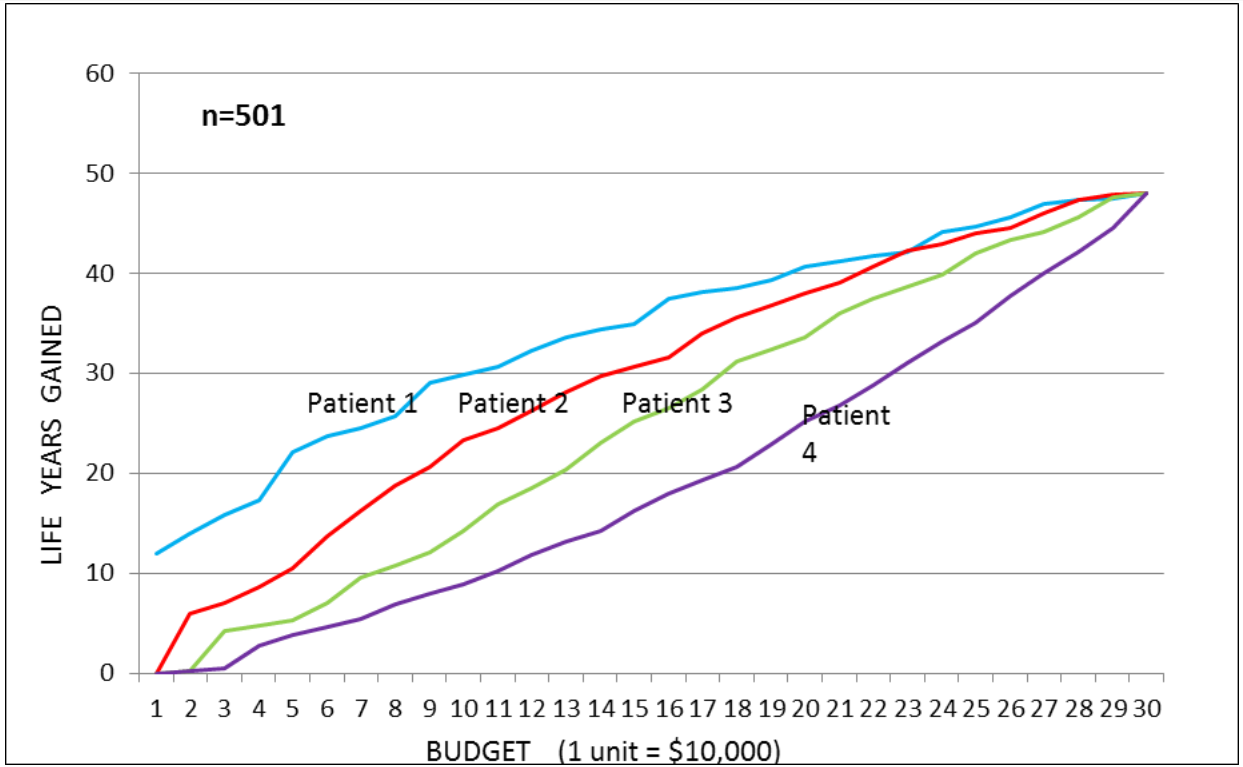
WEB BASED ALLOCATION EXERCISE (n=532)



CEA AND LIFE YEARS ALLOCATED



SURVEY RESULT



CONCLUSION, SHARING SURVEY 1

- Cost is relevant
  But
- Sharing with most costly treatment immediate

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SHARING 2 LIFE EXTENSION

Sharing and the provision of “cost ineffective” life extending services to less severely ill patients

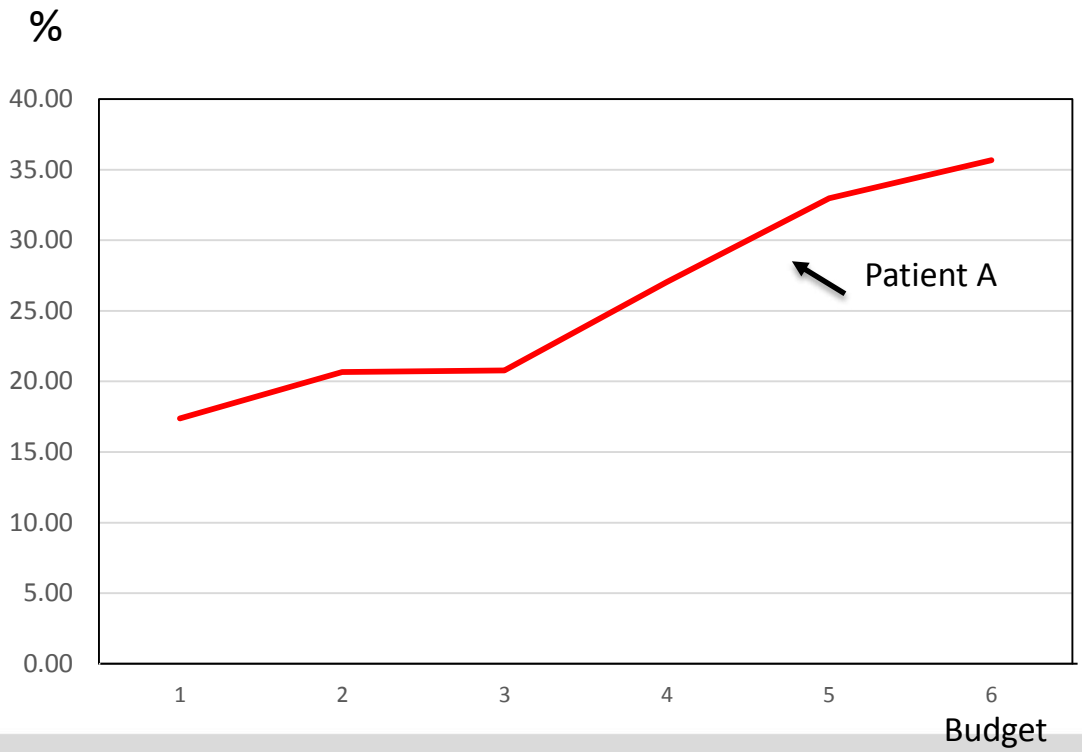
Richardson, Iezzi, Maxwell *Value in Health* 2018 (in press)

DESIGN

	A	B
Life Expectancy	10	2
Cost/LY	2,000	1,000
Budget = progressively increases		
n= 430		

SHARING LIFE YEARS

% LY to A
(LE longer
cost/QALY higher)



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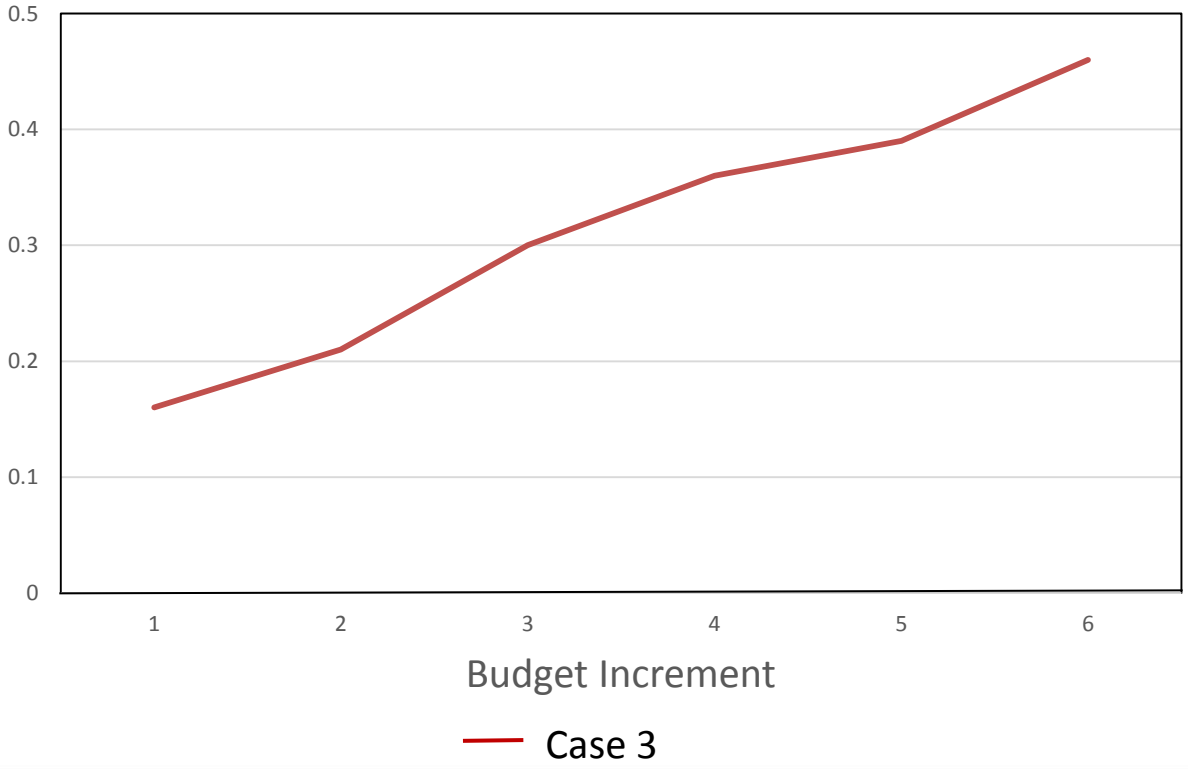
SHARING 3 QoL

Sharing in a communal health scheme when services improving the quality of life are not cost effective and patients are not severely ill

Richardson, Iezzi, Maxwell
Medical Decision Making 2018 (under review)

SHARING QUALITY (n=203)

% share of Budget to Patient A: cost/QoL=3 x B QoL 50 vs 30



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SHARING SURVEY 4: Orphan Products

Sharing in a communal health scheme when services improving the quality of life are not cost effective and patients are not severely ill: Results of a population survey

Richardson, Iezzi, Maxwell
PharmacoEconomics 2017; online 2016

SURVEY (n=432)

- Allocate a budget
  - Illness A: 5 patients (no treatment – die; budget ↑ → QoL ↑)
  - Illness B: many patients (budget ↑ → QoL ↑)
- Cost varied: ↑ QoL A = 20, 15, 10, 5, 2 x Cost ↑ QoL B
- Size Group B varied: n = 100, 300, 600

TRADE-OFF

- Budget to A → less for B
- Small benefit/$ *vs* large benefit $
- Small total benefit *vs* large total benefit

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Sailor at Sea Hypothesis

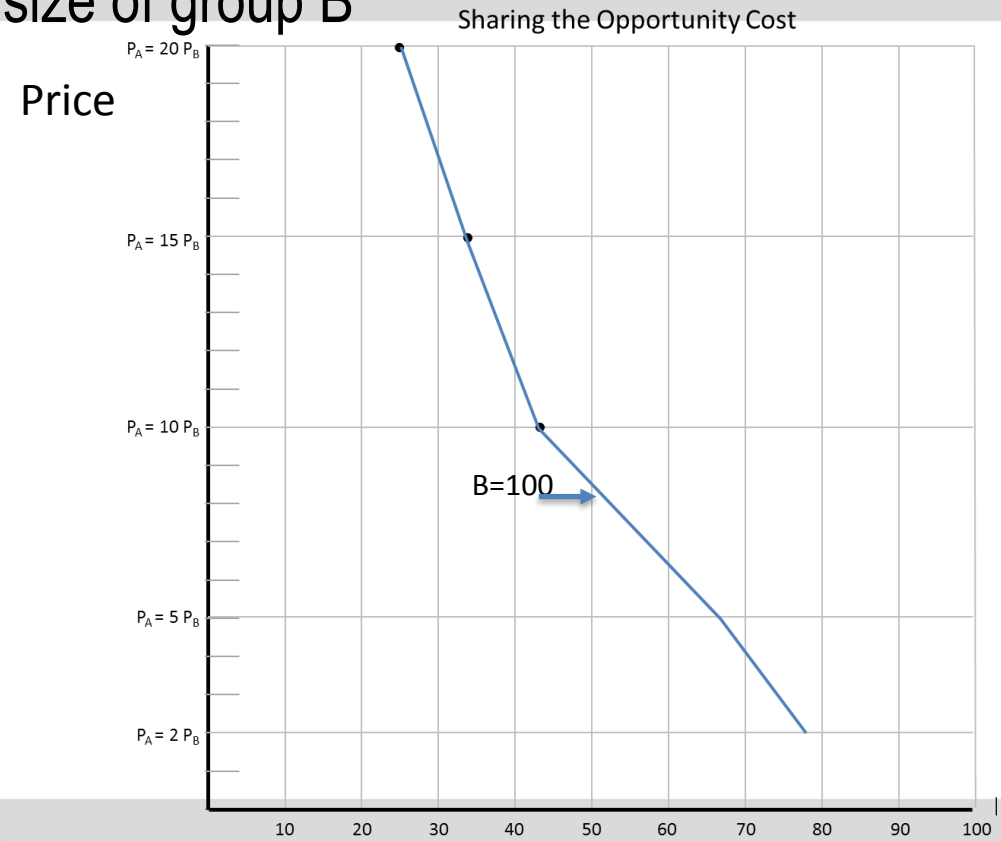
- Small numbers in group A → low loss/person B
- Urgent benefit A *vs* non urgent effect B
- Hypotheses
  - Immediate sharing (CUA → no budget for A)

    Number of B ↑ → loss/person B ↓
    → sharing ↑

    Cost A ↑ → sharing ↓

ALLOCATION TO HIGH COST PATIENT (B)

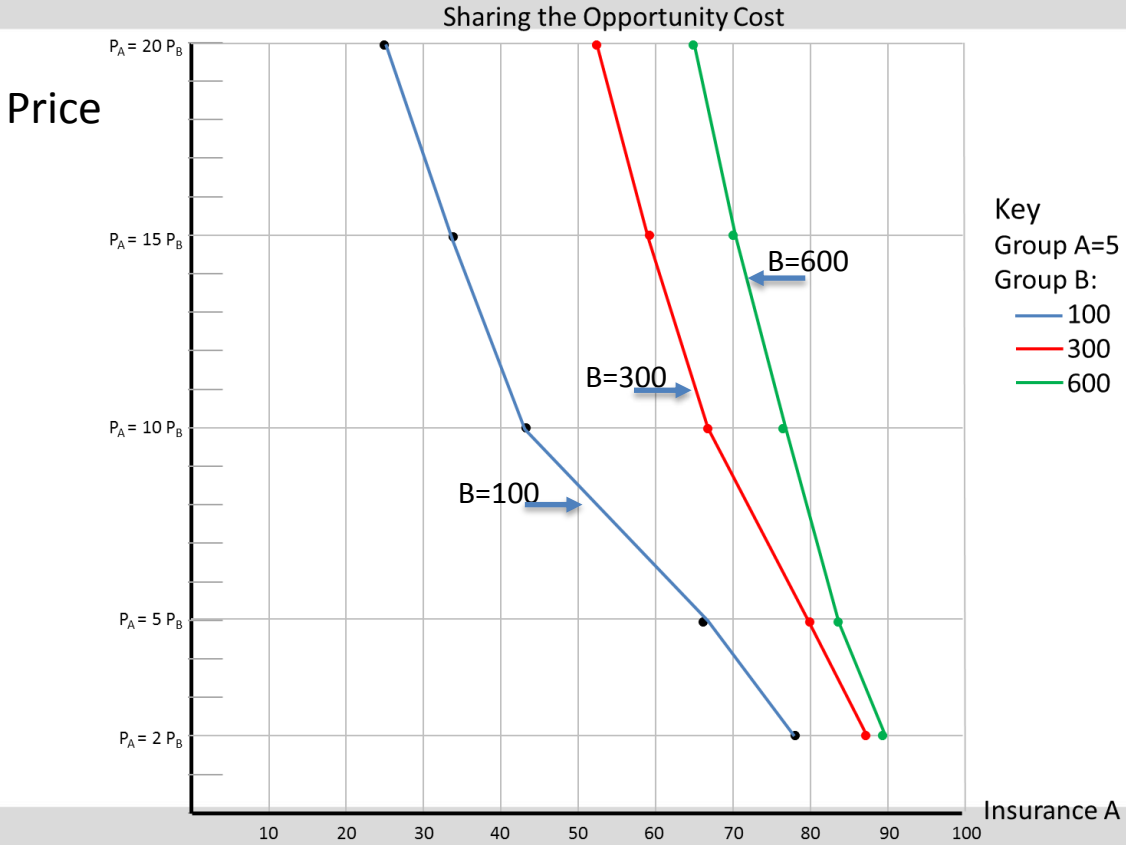
Price and size of group B



Group A=5

Group B: _____100

INSURANCE A BY PRICE A AND SIZE OF GROUP B



CONCLUSION SHARING STUDIES

- Sharing allows
  - Partial treatment of high cost/QALY services
  - In exchange for small loss for less severe patients
- Rationing ← intensity of care
  ⇍ exclusion of individuals

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- Sharing allows
  - Partial treatment of high cost/QALY services
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- Rationing ← intensity of care
  ⇍ exclusion of individuals
- Implication
  - Evaluation theory/methods need revision

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5. FAIRNESS *vs* EFFICIENCY PARADIGMS

REASONS FOR CHANGE

1. Motivation as a citizen in a social context
   ≠ motivation as an individual (Aristotle)

   Individual, utility maximisation

   a) An inadequate explanation of behaviour
   b) (Wrongly) extrapolated to social context

2. Utilitarianism: excludes individuals
   rejected by public
   never empirically supported

REASONS FOR CHANGE FROM ECONOMIC THEORY (Cont)

3. Exclusion of patients
   - Violates medical practice
   - Violates social preferences
4. Community support
   - Sharing
   - Other fairness variables in literature

TWO PARADIGMS

- Extra Welfarism (Present theory)
  - Focus: Services (← simple theory of a market)
  - Objective: Maximise efficiency of service mix
  - Rationing: Exclude services
- Communitarianism
  - Focus: Patients
  - Objective: Universal entitlement
  - Rationing: Intensity of care

TWO PARADIGMS

Attribute	Present (Extra Welfarism)	Communitarianism
Analytical Focus	Maximisation	Optimisation (Fairness)
Social objective	Max utility	Fair sharing
Criterion for funding	Cost/QALY < threshold, T	Presumed entitlement
*Exclusions	Yes Cost/QALY >T	No (except extreme cases)
*Caveat	Ad hoc adjustment for undefined equity	Systematic adjustment for cost effectiveness
Funding formula	If criterion met, then 100% funding	Level of treatment varies =f[fairness variables, cost, effectiveness]
*Role of cost	Pivotal: max benefit ← min cost/QALY	Secondary: alters allocation, ie the intensity of care
Ethical basis	Utilitarianism	Communitarianism satisfaction of community preferences

CHALLENGES (HOPEFULLY) FOR FUTURE RESEARCH

- Agreement/quantification of fairness
- A budget allocation rule?
- Who makes decisions?

AN ETHICAL JUSTIFICATION FOR SHARING/FAIRNESS BASED PARADIGM

- Utilitarianism … historical not empirical
  numerous alternatives exist
- Deontological ethics (duty etc)
  … population support
- Communitarian ethics
  … population support
  … the Golden Rule (Christianity)
  (reciprocal altruism)

FINAL COMMENT

Could economists be fundamentally wrong for so long?

YES Evaluation theory ↛ empirical error learning

Wrong allocation formula

↛ stock exchange crash

↛ bridge collapse

→ contradictory observations

– Epistemology The 'method a priori': legacy of philosophical rationalism

– Alternative: 'Empirical Ethics'

- investigate population values

- *s.t.* ethical critique

– Ultimate arbiter: (laundered) social values

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Thank You

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Vielen Dank