Ethical Issues When Considering Insurance Coverage Based on Value in the Treatment of cancer

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Introduction

- Answer I gave to the definition in the poll of value in cancer care and treatment:
  - **“That the benefits in life extension and improved quality of life are obtained at a reasonable cost comparable to other typically funded treatments and at a reasonable cost/QALY.”**
- I believe many new Ca drugs fail to meet this standard
  - This is essentially a standard of cost-effectiveness (CE)

Outline of talk

- First—explain why this is so
  - Factors explaining value failure identify places in the system where changes could improve value
  - Will compare us with Britain where they do a better job assessing value.
- Second—value/CE is **one of two** broad resource allocation criteria.
  - Other is **equity**.
  - Explore briefly some equity considerations and whether they justify departures from value and CE, i.e. spending more on Ca drugs

Value

- First value question—how much resources to health care vs. other goods.
  - With a national health program can address that as a political question
    - As we do with defense spending.
  - Our non-system does not give us an institutional framework to ask and answer this.
- Second value question—how much to different HC needs and patients?
  - Value answer is CE—allocate HC resources so as to maximize health benefits from available resources

Value

- One way to approach CE is to set a limit of cost/QALY that will pay
  - NICE in Britain uses about $45,000/QALY
  - We spend twice as much on HC as GB
  - $100,000/QALY is measure economists often apply
    - Fits about $6-7,000,000 value of a statistical life used by government for health and safety regulations
- Cost/QALY cap in effect represents one answer to how much for HC vs other goods

Value

- Many new Ca drugs cost at least 2-3 times that limit of $100,000.
  - E.g. Avastin for breast or lung ca is between $200,000-$300,00/QALY.
  - NHS in Britain does not cover it.
  - Scott Ramsey—Pharm exec admitted “we don’t have any cancer products in our pipeline that will be priced at less that $300,000/QALY.”

Causes of Value Failure

- IP patent protection and monopoly pricing
  - In theory, 20 year protection, though in fact is substantially less.
  - Pharma can set any price it wants and believes it can get.
- Medicare is biggest purchaser of Ca drugs
  - Explicitly prohibited from negotiating prices under Plan D—though this may change
  - Though big payers can negotiate when are significant alternatives

Cont.

- Criteria for Medicare coverage—is it safe and efficacious in the diagnosis or treatment of disease or injury
  - No legal authority to weigh costs in the coverage decision.
  - So pharma knows it will not be denied coverage on grounds of costs
  - So no incentive not to develop new drugs because they will not be CE
    - Or to price so they will be CE

Cont.

- Most private insurance companies will follow Medicare's coverage decisions.
- Most Ca pts have HC insurance
  - Is good reason for insurance because can't budget for health expenditures
  - But means pts only concerned with out of pocket costs
    - Small fraction of real costs to the insurer and the HC system.
  - So little incentive for pts to reject non CE care.
- Some oncologists receive substantial income from using these new drugs for pts.
  - And is still a remnant of norm that should do what's best for your pt, without regard to cost.

Upshot

- Treatment decision makers (Drs and pts) have little incentive to weigh true costs against benefits
- Payers/insurers largely precluded from negotiating to lower costs.
- Pharmas have monopoly pricing to charge as much as can get

Monopoly Pricing

- Usual justification—necessary so companies will pay very high R & D costs
- New justification—reflects value of the health benefits
  - In competitive market—if own land now wanted for development, will raise the price.
    - Limited by what competitors will offer land for
  - With monopoly pricing—cost/QALY caps are **CAPS**, not the justified price.
  - You are drowning, will live 30 more years if I throw you a life ring
  - Can I charge you $100,000/QALY--$3million? Or is this exploiting your desperate circumstances?

Other Moral Justifications?

- Been showing why fail to get value in Ca care.
- But are there other moral/equity reasons that would justify these very high costs?
- One important equity consideration—priority to the worst off
  - Does this justify spending more on Ca pts near death who have exhausted less costly treatment?
    - E.g. $100,000 for 4 months average life extension?
  - Are worst off in sense need is most urgent—but that's not ethically relevant sense of worst off

Cont.

- Assume what are distributing is additional months/years of life
- Who are worst-off?
  - Those who will have had least life if not treated
  - This is not elderly Ca pt as opposed to other younger pts
  - Dying Ca pt is most urgent– will die soonest without treatment
  - But most urgent are not worst off

Cont.

- Illustrate with liver transplantation, where is absolute, not temporary, scarcity of livers
- Urgency is principal priority criterion.
  - Pt A is 65, will die in month, pt B is 35, will die in four months
  - Pt A is most urgent, but B is worst off—will have had many fewer years of life if doesn't get the transplant
- So urgent, dying Ca pts do not deserve special priority as worst off

Cont.

- Most of us will at some point become among the most urgent pts
  - Expected to die soon and little, but not nothing, can be done
  - If urgency justifies abandoning reasonable value/CE standards, result would be use of much high cost/marginal benefit care at end of life
    - This is arguably what we do
    - But question should be how we would allocate our heath care resources across our lives.
    - **NOT** asked when are near end of life

Special ethical priority to life extension?

- Aggregation problem—most people do give priority to big benefits (life saving) to a few over small benefits to many.
- Oregon's Medicaid prioritization problem
  - CE favored tooth capping over appendectomy
  - Why? Tooth capping much cheaper, so benefits greater cause can treat many pts.
  - Unwilling to let some die for getting many very small benefits for many pts.

Cont.

- Does rejection of unlimited aggregation support priority to end stage cancer pts?
- No--when is not a big benefit at stake, is not life saving like the liver transplant
  - Is small probability, of small period, of additional life.
  - So doesn't trump other benefits that would have to be foregone.

Rule of Rescue

- Won't let identified person in peril die when could rescue, even if very costly.
- Proposed as a psychological fact about people, not a normative principle to follow.
  - But Avastin does not "rescue" dying Ca pt.
  - Small chance of small life extension is not a big benefit
  - So psychological force of desire to rescue should be weaker—in effect, cannot rescue

Identified vs. Statistical Lives

- Are many cases where improving rates of Ca screening produces more QALYs than last chance, expensive treatments
  - Rule of rescue gives priority to identified over statistical lives, but is a case this is irrational
- Discounting--screening or behavioral prevention strategies produce future, not present benefits.
  - CE typically discounts cost **and** health benefits—so future benefits are of less value just because future
  - Acute care produce 100 QALYS, same dollars spent now buy 200 QALYs in 25 years from prevention
    - If can only afford one—should buy future prevention benefit

Cont.

- So determining value by CE, with standard discounting of health benefits, gives undue importance to present vs. future benefits.
  - And this will mean undue weight to expensive, last chance treatments
  - And too little weight to prevention

Recently Announced Policy Changes by Medicare

- According to news reports (NY Times, 1/27/09) Medicare has expanded its coverage of a number of cancer drugs for non-approved uses.
  - And weakened the general requirement for coverage for non-approved uses.
  - Expanded the reference guides that can be used to make coverage decisions
    - These guides are open to influence from industry and to conflicts of interest.

Cont.

- For the goal of value in cancer care—this is a step in the wrong direction
  - These are uses where the evidence both of benefit is limited, at best
  - These new covered uses have not been subjected to any cost effectiveness or safety evaluation
    - Nor did CMS do a cost analysis of the changes
  - Represent “last hope/last chance” response by physicians and pts to dying cancer pts
    - Even apart from costs, arguable whether this is a change that will benefit pts.

Adding a new tier to insurance coverage

- Most insurance plans have three tiers of drug co-pays, with highest tier generally not more than $50.
- New fourth tier policies typically require a percentage co-pay, e.g. 20%
  - With a $100,000 annual cost, this is $20,000
  - Many pts are not able to afford this cost
  - This may discourage some low value uses, but in an unethical way
    - Will limit uses, high **or** low value, on ability to pay

What is needed?

- Most fundamental need is willingness to ration even “last chance” care at the end of life
  - And not to cover very high cost/marginal benefit interventions
  - Needless to say, this will not come easily or soon
    - Requires major cultural change
  - Will not come without a national HC system—very heterogeneous system lacks means to ration

Cont.

- Smaller steps
  - Steps like covering these last chance therapies only in clinical trials or for registry pts
  - Authorizing CMS to negotiate prices of the drugs would be a step in the right direction
  - Transforming the “comparative effectiveness” program proposed in Congress to a “cost-effectiveness” evaluation program would be a much larger step