

The Ethics of the 'R'
word:
rationing and health
care in America



Rationing: Whole lot of politics

Total health care expenditures in the United States in 2008 came \$2.5 trillion. The implication of [White House] is that health care expenditures can be cut by almost 30 percent. That's a major amputation to the system. Mr. Summers tried to kill the pain by saying it all wouldn't have to be cut right away. That's only comforting if it's not your loved one's transplant that bureaucrats reject. The hypocrisy is enough to make a heart stop. [the]...White House has no problem telling doctors whether they can perform tonsillectomies or hysterectomies.

- www.washingtontimes.com/news/2009/apr/21/rationing

Rationing: Whole lot of politics

- *Rationing: The president and many Democrats claim health reform won't feature the kind of rationing seen in countries like Canada and the United Kingdom. Yet when given the opportunity to add language to prevent the newly established Center for Comparative Effectiveness Research from rationing health-care services on the basis of cost Democrats [said no]*

Without such safeguards, this government board will get in the way of doctors and patients, and it decide on its own which treatments are necessary.

- *NRO on line <http://healthcare.nationalreview.com/post/>*

Rationing: Whole lot of politics

- *Not to mention Dead Grandmas and euthanasia charges*
- *Reality is that hard choices are made all the time in health care by doctors, payors, hospitals and managed care organizations*
- *Obamacare puts a lot of faith on comparative efficacy data to find waste--the Dartmouth data. But that is not likely to work--example specialty pharma*
- *How does rationing work now--case of transplantation*
- *When we have to ration in the future or today what lessons can be learned.*

Example: Drugs cost a lot!

- An estimated 280 billion dollars spent on drugs in 2006.
- By 2010 drug spending expected to grow to 414 billion dollars.
- Specialty pharmacy accounted for 24% (54 billion dollars) of total drug spending in 2005.
- Expected to account for 44% in 2010.

Sources: Medco Drug Trends Report

Reality of personalized medicine

- “Specialty pharmaceuticals are:
 - a unique group of drug agents used to treat complex clinical conditions. Many specialty pharmaceuticals are biological in nature and administered through injection or infusion.”

Sources: C Daniel Mullins, Andrea R DeVries, Van Doren Hsu, Fanlun Meng, Francis B Palumbo. Health Affairs. Chevy Chase: Jul/Aug 2005. Vol.24, 4; pg. 1117

Cost/Spending/Growth

- Specialty pharmacy medications account for approximately 15% of U.S. drug expenditures.
- Annual Costs per patient can range from \$6,000 to \$350,000.
- Annual growth rate of 20%-30% on specialty pharmacy drugs.

Will costs improve in the future--

NO!

- Aging population will increase demand
- Continued NIH and private funding will deliver new things
- Genomics, neuroscience and regenerative medicine will pose real cost and management challenges

Costs are going up

- Genomics
 - Increasing cost of drugs, vaccines
 - Seen this already with HPV and some cancer drugs
 - Identification of high and low responders with probability
 - Identification of genetic groups as high benefit likely or high risk

The emerging challenge to managing pharmaceuticals

Neuroscience

- Explosion of new knowledge of brain and nervous systems (just no genome map project)
- Association of scans with psychiatric diagnoses and with responsiveness to drugs and implants
- Detection of early onset of serious illness AD
Parkinsonism, schizophrenia, depression, childhood scanning
- But, generates many new dilemmas



The emerging challenge to managing pharmaceuticals

- Neuroscience
- Detection of more mental health problems and more accuracy of diagnosis--linking diagnosis an therapy
- Identification of early symptoms pressure to prescribe earlier
- Enhancement and quality of life drugs will explode
- Low responders to drugs and implants identified and then what?



The emerging challenge to managing pharmaceuticals

- Regenerative medicine
- Stem cell therapies of all sorts likely to produce therapies
- Blurry line between drugs and procedures--cells as drugs
- Early efforts will create urgent appeals for coverage
 - Some will be very controversial
- How much chance of efficacy is worth paying for--quality of life, duration of therapy, age, function, symptom relief etc
- Price will be high to recoup a lot of cost



Cost/Spending/Growth Cont.

- In 2004, 108 specialty drugs in development. In 2005, manufacturers reported 800 products in development. 2007-- 1600
- Number of individuals utilizing specialty pharmaceuticals makes up about 1% of total U.S. population and accounts for 15% of total drug expenditures.

Sources: Medco Drug Trends Report 2007, IMS Health

Current Costs: rare diseases can destroy an insurance plan

- Cerezyme for Gaucher (Genzyme)
 - \$200,000 per pt
 - 10,000 patients effected
 - 4800 patients worldwide on drug
- Myozyme for Pompe (Genzyme)
 - \$400000/yr
 - 7500 patients effected worldwide

Current Costs: rare diseases

- Elaprase Hunter's syndrome (Shire)
 - \$800,000 per year
 - Effects about 2,000 people worldwide

What if the conditions **were not rare?**

- Cancer drugs 13% of total in 2002; 22% in 2006; 30% in 2011
 - Source:Express Scripts 2008
- Drugs for arthritis, MS, diabetes, osteoporosis expected to appear and grow in use over the next five years

Coverage

- Most insurance companies have a lifetime cap of 1 million dollars
- Shifting more costs of care onto patients through high deductibles, co-insurance, and less comprehensive coverage
- Often claims are denied because of fine-print clauses or procedural requirements
- "The insurance industry is not being held accountable for the quality of its products and services...Without providing adequate support for consumers and holding insurers to higher standards, we risk trading the problems of lack of health insurance for the equally serious ones of inadequate insurance."

Source: The Illusion of Coverage: How Health Insurance Fails People When They Get Sick, Access Project and Brandeis University, March 22 2007

Rationing now and soon

Paying for Penelope

Paying for a new cancer drug for colon cancer

Restricting erectile dysfunction drugs --grandpa's midnite
ramblings

Paying for cells to regenerate spinal cord

Paying for drugs for PTSD that scans show are unlikely to be
effective and may be a missed diagnosis

Paying for individual to have access to a drug who is a member of
a group that has triple risk of adverse event due to newly
identified genetic risk factor

Paying for cognitive enhancer

Ethics of allocation

- What is a just and fair distribution?
 - **Allocation** general distribution of any resource
 - **Rationing** distribution of scarce and highly valued resource
 - **Triage** rationing with an agreed upon goal



Ethics of Rationing

- What is **Just**?
 - Equal chance for all (sickest first, lottery, date of claim)
 - Equal outcome for all
 - Help those who merit/deserve benefit (can pay, stay healthy)
 - Help those who have greatest need
 - Create most good for greatest number
 - Save the largest number of lives
 - Save largest number of lives with quality of life

Fair Rationing

- What is Fair?
 - Transparent
 - Consent/buy in
 - Non discriminatory
 - Accountable
 - Evaluated—data driven
 - Due Process
 - Steam valve exists—buy outs

Ethics and Organ Transplantation

- Entry into Program
- Citizenship
- Age
- Access to primary care
- Celebrity
- Ability to pay
 - ESRD
 - Coverage of drugs
 - Most plans cover
- Who gets an Organ
- Medical urgency
- Tissue and blood type
- Size of donor/Rcpt
- Disability
- Compliance
- Sin

What principles are needed/ lessons to learn

- Vulnerable patients have special claims
- Duties of individuals and families to pay something
- Set terms for pay for innovation/innovative things
- Set terms for pay for long shot rescue
- Quality of life counts
- Justice demands saving most life of minimal quality with a bias toward the young