THE HEALTH CARE DILEMMA 2016: COSTS, SELF-INTEREST, AND OPTIMIZING CARE

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Conflict of Interest Declaration

- Dr. McKinney is:
  - Employed the Association of American Medical Colleges
  - For many years Chair of the Duke School of Medicine Conflict of Interest Committee
  - Has a past history of NIH funding
  - A member of a data safety monitoring boards for Gilead Sciences (now pro bono)
    - A consultant for the National Football League Players Association (now pro bono)
Goal of the talk

- First, I’ll discuss the overall cost of medical care in the US
- We’ll consider some breakthrough medical treatments and their costs
- Then, we can all think about how we might start to bring the cost of medical care under control
Sisyphus

“Hey, Sisyphus, when you’ve got a minute I’d like to discuss this progress report with you.”
Health Care Expenditures as % GDP – United States 1960-2014

Life expectancy at birth (2012/14): US 78.8  Taiwan 79.8
Healthcare expenditures

- What does it mean?
- In 2014, US healthcare spending was $3 Trillion
- That translates to $9,523 per person
- For comparison, the average rent for a one-bedroom apartment in Durham, NC, in 2014 was $9,600
Meaning of health care expenditures

- Employers pay an average of $17,545 for employee’s family health insurance coverage, with employee contribution of $4,955 (Kaiser – 2015)
- The ACA requires companies with ≥50 employees provide coverage to employees and dependent children to age 26, not spouses
Breakdown of expenses - 2014

- Hospitals $970 B (38%) (Proportions quite constant)
- Physicians $604 B (24%)
- Drugs $298 B (12%) (12% increase over 2013)
- Nursing Care & Residential $156 B
- Other services $150 B
- Dental $114 B
- Devices & Equipment $103 B
- Other Professional services $84 B
- Home Health $83 B
Who pays? (2014)

- Medicare 22%
- Medicaid 17%
- Private insurance 34%
- Out of pocket 11%
- Misc: DoD, VA, workman’s comp, Social programs, etc. 16%

Source: Keehan et al, Health Affairs 2016;35:1522
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- Misc: DoD, VA, workman’s comp, Social programs, etc. 16%
- Federal impact on health care spending is large – roughly 55%
The Doctor’s Dilemma

- I’m going to present a series of breakthrough treatments from the last few years
- Costs are an issue in each case
- Who should determine when, or how, to use the treatments?
  - After the case studies, I’ll present why this the doctor’s dilemma …
The story of Ivacaftor

- A prime example of “Precision Medicine”
- Ivacaftor is marketed as Kalydeco by Vertex Pharmaceuticals
- Developed using financial support for the research by Cystic Fibrosis Foundation & the NIH
Ivacaftor

- Cystic fibrosis is a relatively common genetic disease, autosomal recessive (most common life shortening genetic disease in Caucasians)
- 70,000 cases living worldwide
- US: 30,000 cases - ~1,000 new diagnoses/year
- It’s a defect of a trans-membrane conductance regulator, so that sodium and potassium are not exchanged normally
- Shortens life expectancy and quality of life
Ivacaftor

- Ivacaftor only works for certain Cystic Fibrosis genes
- In the right patients, using Ivacaftor for 48 weeks took pulmonary function from an average FEV1 of 64% to ~75%, a perceivable change (vs. 0.2% decline in placebo controls)
- Pulmonary exacerbations were 50% as frequent
Kalydeco (the product)

- The price of Kalydeco is $311,000 per year
- The price of providing Kalydeco to all ~4,000 U.S. patients who could benefit:
  - $1,244,000,000 per year ($1.2 billion dollars/year)
- One drug, one small group of patients, 10% improvement in pulmonary function tests
The CF Foundation paid Vertex Pharmaceuticals (and its predecessors) $150M over 10 years to develop Kalydeco

In 2014, sold the rights to any royalties for $3.3B (20X the foundation’s annual budget)

Was profiting from insurance companies (i.e. an involuntary broad pool of patients) correct?
Hepatitis C

- Hepatitis C causes a chronic infection that in some cases leads to cirrhosis, liver failure, and can be fatal.
- For many years, the standard treatment was long, expensive, and made the patients feel miserable. It often didn’t work.
  - Interferon and ribavirin.
Hepatitis C

- In 2013 Gilead Sciences introduced Sovaldi (sofosbuvir), and then Harvoni (which added ledipasvir)
- To gastroenterologists and ID docs, these drugs were nearly miraculous – an 8-12 week course produced a cure in nearly all patients with minimal side effects
- Treating a person not only cures, it makes them non-contagious
The problem? Gilead Sciences set the price for Sovaldi at $80,000 per course, for Harvoni at $110,000 per course.

2.7-3.9 million Americans are infected with Hep C.

The total cost of curing them all, for drugs alone (no physician costs) would be $385 B [NY state annual budget is $120 B for FY 2016].

For further perspective, $385 B is roughly $100 B more than ALL drugs bought in 2014.
So far

- I believe I’ve made the case that there are some medical breakthroughs that are both tremendous advances and serious incremental costs.
- Hard choices will need to be made.
- Let’s consider one more area that’s likely to affect a significant portion of this audience.
Cancer Drugs

- Most new cancer drugs don’t cure, they either change a surrogate marker (like tumor size) or extend life, often with poor quality of life.
- There have been a few breakthroughs.
- Imatinib (Gleevec) for chronic myeloid leukemia (from Johnson – Washington Post March 2016)
  - Gleevec took life expectancy from 5-6 years after diagnosis of CML to a normal life span.
Gleevec – Novartis

- Approved in 2001 for CML - $26,400 / year
- In 2016? >$140,000 /year
  - This is despite the fact that competitive drugs are on the market for the same indication
- About 4,500 people are diagnosed with CML in the US each year – makes this an orphan disease
Gleevec

- Original price ($26,000/year) was set according to Novartis to deal with small patient population, recouping R&D expenses, and the price of competitors (at the time)
- Not expected to be a big deal (?$100M/year)
- Last year, $4.7 B in sales
- 2 new drugs with similar effectiveness have been approved – work for some Gleevec failures, so initial price was higher
**Rising drug prices**

New drugs treating chronic myeloid leukemia were introduced at prices higher than Gleevec's. Their prices have gradually risen since, and Gleevec's price has increased at a greater clip.

Company:  
- **Novartis**
- **Bristol-Myers Squibb**

**Note:** Amounts reflect median monthly payments by patients and their private insurance plans. They do not include rebates and discounts. Amounts are adjusted for inflation to 2014 levels.

Source: Truven Health Analytics data analyzed by Stacie Dusetzina
KEVIN UHRMACHER/THE WASHINGTON POST
The good news – living longer

Prevalence of chronic myeloid leukemia
The number of people living with the disease in the United States has been growing since 2010, increasing demand for the drugs.

Source: Cancer journal

WEIYI CAI/THE WASHINGTON POST
The real expense to patients

- Patients on Medicare Part D prescription drug plan (with no supplemental insurance or low-income subsidy) have a co-pay of $525/month (as of 2010) for imatinib
In the future

- Gleevec lost exclusivity in 2016
- Manufacturing cost is $108 per year
- Generic drug could be available with 50% margin over cost at $216 per year
In the future

Will a price drop happen?

- Sun Pharmaceuticals made it through the licensing process – given 6 months exclusivity as sole generic
- In August, 2016, the Red Book price of Gleevec was $146,000/year, Sun imatinib $140,000.
- In Canada? $8,000
- In India? $400

- Teva and Apotex are about to market generics
  - Multiple generics typically will drop price by 50%
Another new cancer drug

- Pfizer’s Xalkori approved for ROS-1 positive Non-small cell lung cancer
- About 180,000 cases of NSCLC per year in the US, 1% ROS-1 positive
- 66% of patients saw tumor shrinkage, lasted 18 months in a typical patient
- The cost?
Another new cancer drug

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- About 180,000 cases of NSCLC per year in the US, 1% ROS-1 positive
- 66% of patients saw tumor shrinkage, lasted 18 months in a typical patient
- The cost? $172,000 per year
What’s happening

- We’ll come back to this – basically, we’re rationing by not giving access to all these breakthrough medicines to everyone
- CMS and the insurance companies are trying to act as the brakes, for better or worse, by limiting access
- The working poor have the least access to these medications, particularly in non-Medicaid expansion states
Why haven’t we changed the rules?

- One reason: People and organizations have learned to succeed in the current models.
- Those that are succeeding will be resistant to change.
- Any changes to our current payment schemes to lower costs will have negative effects for some constituency.
Who has an incentive to lower cost?

- I’m talking about actors in the health care system other than patients (who do have an incentive!)
- Not the physician, at least not directly
  - Can be placed at risk – managed care models
  - New quality models
  - Patient advocacy
Who has an incentive to lower cost?

- We all know that proceduralists get paid by the procedure – they want to do more of them
  - Surgery, stents, etc.

- We know that unused equipment doesn’t pay for itself – hence physicians who own expensive billable equipment use it more often
Consider the effect of stars

- Some health systems and hospitals use a star system to rate their physicians (and are rated similarly).
- To boost ratings, most doctors will do more treatment and diagnostics, rather than less.
  - “I waited two hours for my doctor and all I was told was it’s probably a virus.” - a visit that won’t get a five-star rating
  - Difficult patients may give bad scores, and as a result doctors might try to avoid them.
Who has an incentive to lower cost?

- Industry does – healthcare is a non-productive expense
  - Would love to move the costs to the government, but not allowed by ACA
- Government has an incentive, but when it moves it confronts push-back from well-financed lobbies
- Insurance companies just pass-through expenses, adding a margin for the service
- All of us should be asking for change
Lowering the pressures to change

- Insurance acts as a buffer – we insure the routine as well as the extraordinary
  - Otherwise, people might not engage in preventive care
  - Not the auto insurance model
- Physicians make the choices that affect costs in most cases
  - Physicians often don’t know the cost of care
    - Don’t want to know
    - Hard to figure out anyway, with insurance company deals
Healthcare & markets

- Healthcare has not behaved like a normal market, where competition lowers costs
- In lowering cost, someone loses
  - Lower reimbursement: doctors, hospitals, nurses, staff
  - Lower drug/device profit: pharmaceutical companies, device manufacturers, decrease incentives to innovate
  - Move from private marketplace to single payer, the enormous insurance industry would suffer
The marketplace

- While there is a marketplace for insurance products, the consumer is poorly placed to affect prices around medical events.

- When you are sick, you want care, and the best care possible. There isn’t time to price or value shop.
Building a lower cost model?

- It’s not clear where to begin
- The government controls ~60% of health care expenditures, but too rarely exerts authority
  - Political pressures
  - Specific rules – for example, CMS is not allowed to consider cost when approving a new drug for patient use
  - In the UK, NICE determines if the drug is cost effective before agreeing to pay
Insurance Companies

- The most serious run at cost controls came with managed care in the 1990s
- Insurance companies were burned by their attempts to control cost and act as gatekeepers
  - Who do you want making decisions? An insurance clerk you’ve never met, or your personal physician?
  - A fairly blunt instrument
  - BMT for breast cancer story
The Doctor’s Dilemma

- Physicians are supposed to advocate for their individual patients
- At the same time, they are being asked to take steps to lower cost
- Quality ratings and outcomes measures assess process and often expect more care
- Incentives are not currently aligned
- Put physicians at risk? Fixed payment per pt/year?
My bias

- Start with the overhead costs of insurance (~25% of health care costs)
  - Go to single payer insurance with private delivery – the system used in Canada
- Make costs transparent – easier when there’s a single payer
- Expand health care savings plans to cover larger deductibles
- Improve support for poor patients
Ideas for the future

- Consider a NICE equivalent
  - Limit $ per QALY unless the individual has supplemental private insurance
- Figure out some way to measure quality that isn’t game-able and reward physicians and hospitals for accepting sicker patients and for achieving better outcomes (Note: this approach is coming fast)
  - Fixed payment per patient, with supplements for difficulty and for outcome measures
Precision Medicine

- Not a cost effective model
- Cost per patient to justify research for small patient numbers become huge
  - Cancer drugs already demonstrate this
- Conceptually pretty, currently economically unfeasible
At some point, we need to decide instead of walking around it:

- Do we support equal access?
- Do we restrict by income?
- How much is healthcare a right?

Rationing is inevitable, but how to do it rationally?
End of Life Care

- 30% of all healthcare dollars go for the 5% of patients who die within the year.
- 1/3 of that cost is in the last month.
- How do we decide when the returns are diminishing? Who gets to decide?
- In the developing world, these aren’t issues because they don’t have options.
Are there solutions?

- At present, no
- We need to entirely change the way we do the business of medicine
- We can nibble at the edges by moving to single payer, establishing a NICE equivalent – but really we need to decide what is the healthcare we want, and then, what is the healthcare we can afford
- We haven’t done it yet.