The justice of personalized medicine

Ethics / Medicine

- The Just Caring problem
- What is precision medicine
- Imprecision and uncertainty
- Who is paying?
- Limits and tradeoffs

Just caring problem

- **What does it mean to be "just and caring" when we have limited resources?**

- **Practical implications**
  - *Needs for limits on health care spending is unavoidable*
  - *Needs to make allocation decisions is unavoidable*
  - *Rationing means denying access to care to some patients*

- **Ethical implications**
  - *Human life is not priceless*

Just caring problem

What should be a benefit package that is guaranteed to all?

Among the emerging (costly) medical therapies, which should be included (excluded) in that package?

Some statistics

- In 1960, the US spent $26 billion (== $240 billion in 2022 $) on health care, or about 5.2 % of GDP
- In 2022, the US spent $4.4 trillion on health care, or about 18.2 % of GDP
- Canada, UK, and most European countries spend 8-12% of their GDP on healthcare

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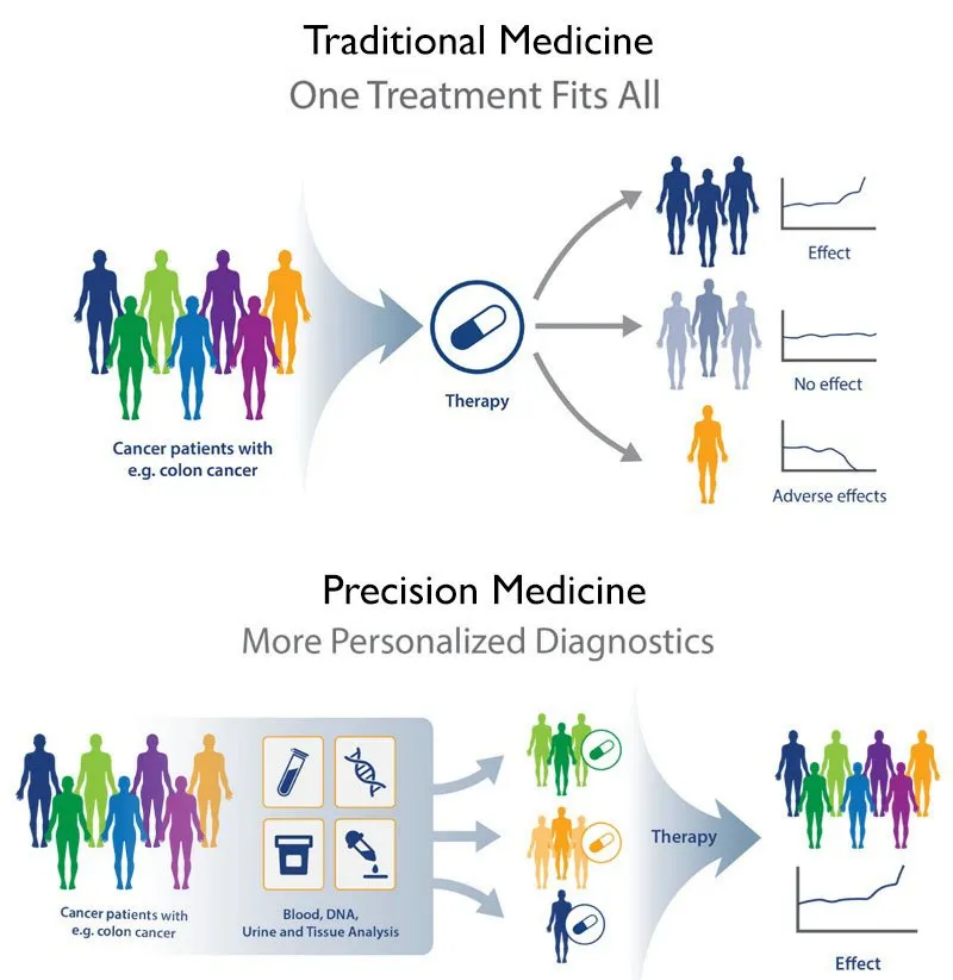
- In 2022, approximately 37% of the total health expenditures were consumed by the 17.3% of the US population over age 65 (57.8 million individuals)
- In 2030, approximately 21% of the US population will be over the age of 65

Justice / Ethics

How much health care are we ethically obligated to provide to:

- People with cancers
- People with hear disease
- ….
- Patients with dementia
- Sick children
- Patients with disabilities?

Personalized medicine



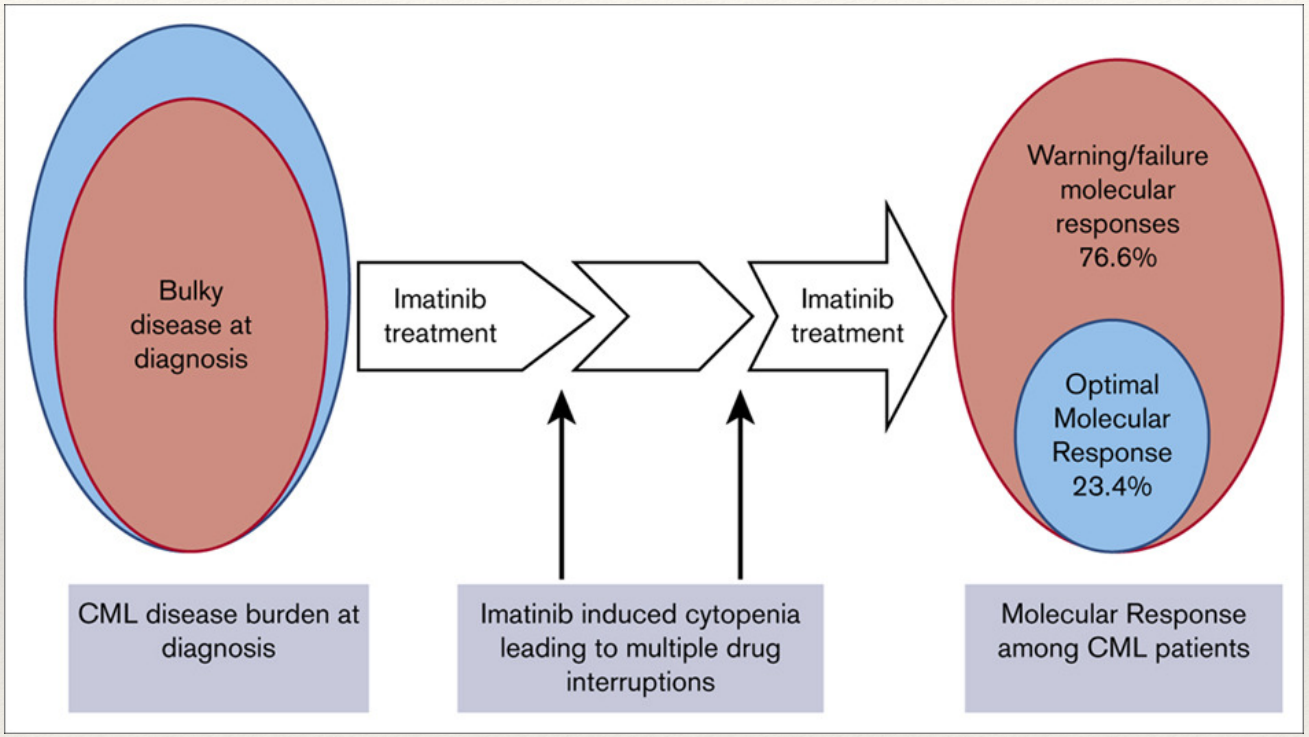
Where is the problem?
The example of cancer

- 1.89 million Americans were diagnosed with cancer in 2021 (projected to be 2.3 million in 2030)
- 610,000 Americans die of cancer each year (projected to be 640,000 in 2030)
- Cancer is largely a disease of older people (87% of cancer deaths are in individuals > 50 years old)
- Most cancers are treatable, if caught early
- Cost of cancer treatment is VERY expensive and increasing, in part as cancers are heterogeneous

Imatinib: success…

- Chronic Myelogenous Leukemia (CML) is caused by a mutation affecting an enzyme, tyrosine kinase ABL
- The mutation gives rise to a constitutively active kinase, which causes leukemia.
- Imatinib is a tyrosine kinase inhibitor.

Imatinib: ...failure



Nasser et al, Blood advances, 2021

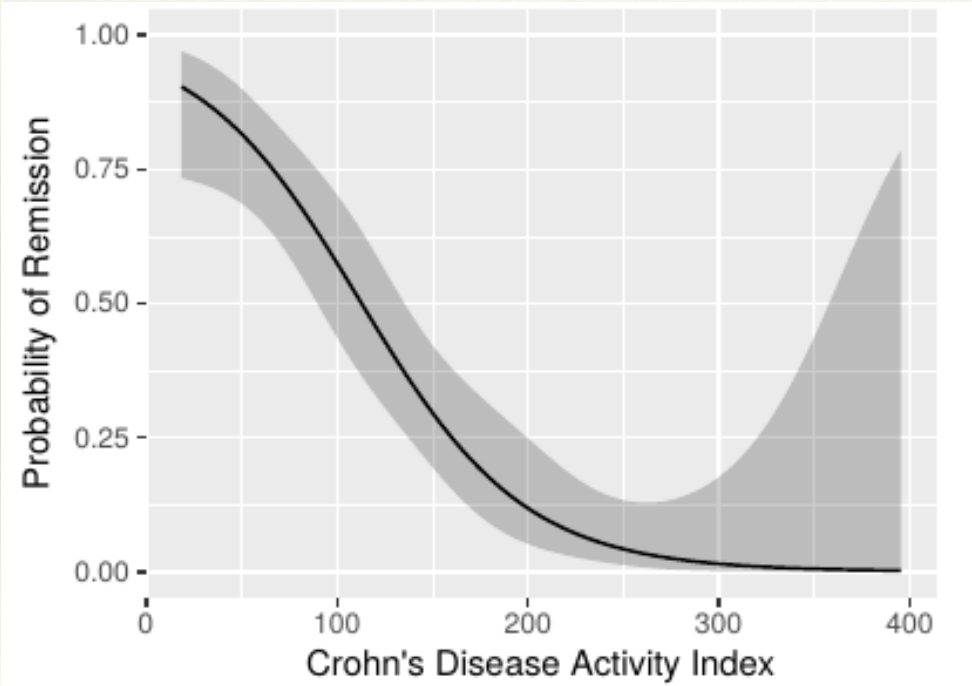
Cancer treatments

- 150+ cancer drugs approved by FDA since 2000
- Cost: $100,000 — $200,000 for a course of treatment
  - Extreme case: Kimtrak for uveal melanoma, a type of eye cancer; single-use vial given by infusion once every week. It was launched at $18,760 / vial, i.e. an annual cost of $975,520.
- None of the drugs are curative
- Median gain in life expectancy for patients measures in months

This is not just a cancer related problem

- Amyotrophic lateral sclerosis (ALS): 17300 diagnosed with ALS every year in the US
- Tofersen is a new drug that slows the progression of ALS.
- Only 2% of ALS patients who have mutations within the SOD1 gene can benefit from Tofersen
- Treatment is estimated to cost $375,000 per year.
- ***Are we ethically obligated to find comparable drugs for the other 98% of ALS patients?***

Wicked problem #1: The ragged edge



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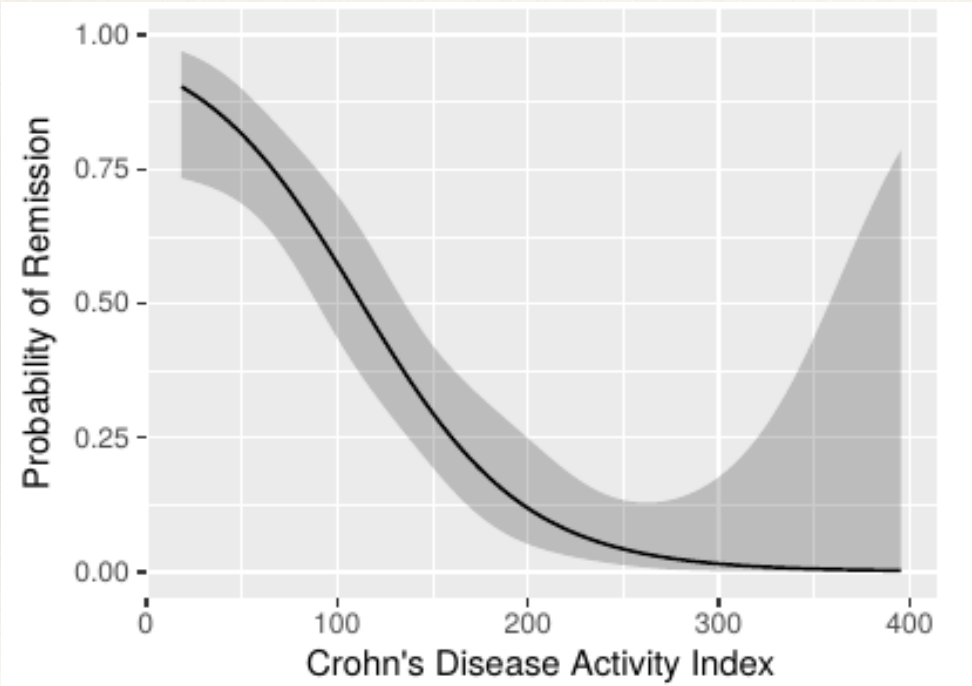

There is no sharp line that distinguishes those patients who are strong responders to a drug, to moderate responders, to minimal responders, and to non-responders.

Wicked problem #2: Funding research

Should we fund research that is aimed at identifying biomarkers for patients who are likely to benefit from a certain therapy / drug, as it implies that we will deny those drugs to individuals who are unlikely to benefit from access to them?

Wicked problem #3: Comparators

- For HIV positive patients, four drug combinations cost $35,000 per patient per year; As HIV positive patients can get up to 30 extra years of life, the aggregated cost is over a million dollars.
- For dialysis patients, we are paying almost $90,000 a year in the US; there are 570,000 of those patients. They will get seven to 10 extra years of life. The aggregated cost of doing that will be somewhere between 650,000 and 1.4 million.
- A left ventricular assist device (LVAD) cost $250,000 to provide individuals with LVADs. In the future, for artificial hearts we will pay half a million dollars, perhaps for as many as 50,000 Americans per year.

Justice?

- A utilitarian would say that only predicted super-responders should be treated /
- A libertarian would say that you have a right only to what you can pay for
- A deontologist or a virtue ethicist would be at loss as to what to think!

- ***Questions:***
  - Are we equal when it comes to health?
  - Do we equalize resources, outcomes?
  - Should people with bad health habit have the same right as people that tempt to live healthy life?