Introduction to Healthcare

Study Guide

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MODULE 1 – OVERVIEW OF HEALTH CARE SYSTEMS AND KEY CHALLENGES THEY FACE

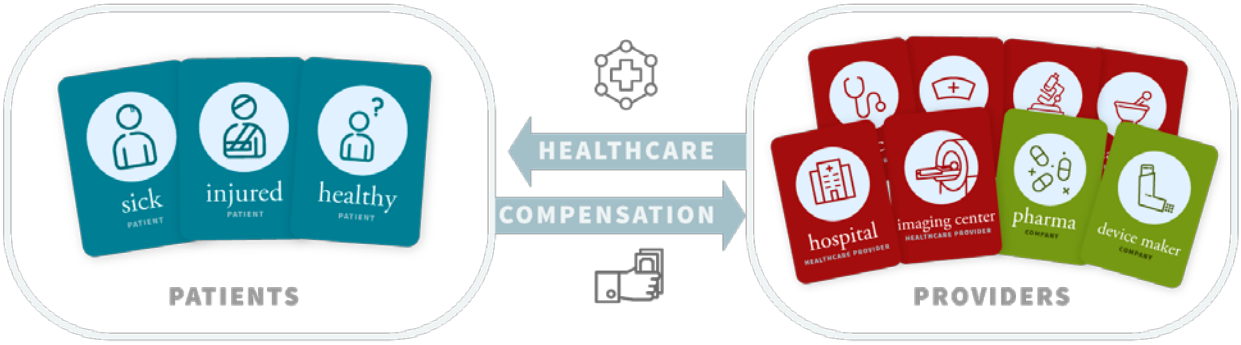
LEARNING OBJECTIVES

1. Identify key institutions and participants in the health care system and describe their major characteristics and roles
2. Describe a framework relating health care providers, intermediaries (insurers) and patients
3. Describe risk and risk pooling and its relationship to health insurance
4. Describe important challenges facing health care systems and the role they play in promoting discussions of future changes – high and rising costs, access to care, quality challenges
5. State implications of system structures for data analytics

THE BASIC STRUCTURE OF HEALTH CARE SYSTEMS

The simple interaction at the heart of any healthcare system - is an interaction between two parties.

- **Patients** - People who are sick or injured, people who are healthy but who want to get some preventive health care, people who would like to ask a question or get some information, people who have a concern about someone else they care about.
- **Providers** - Health care providers, the people who can help patients such as doctors, nurses, pharmacists, lab technicians, a pretty wide range of people. Sometimes also include institutions like hospitals or imaging centers, makers of health care goods and services like a pharmaceutical company or a medical device maker.



The goal for this interaction between patients and providers is to have "health care" flow from the providers to the patients; setting up a health care system to get health care from the providers to the patients in an effective and timely way.

The providers need to get compensated in order to provide health care and be sustainable. Thus, the transaction is needed in which health care gets provided, in return for some compensation.

A simple transaction between patients and providers worked in the past, then things happened that started to break this down, and couldn't continue with just this structure anymore. Health care providers grew and became more sophisticated.

Effects of Health Care's Growing Sophistication:

- People want more health care
- Healthcare becomes more expensive

With sophisticated health care, unplanned health care expenses became an issue which caused **problems**:

- Financial discomfort or hardship for patients affecting willingness to use health care
- Providers not getting paid affecting their ability to provide services

PROBLEM, RISK, AND RISK POOLING

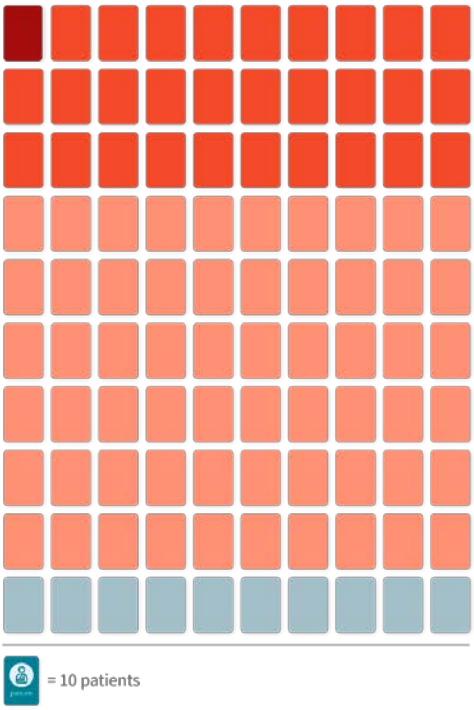
This problem is named ***"the problem of risk"***.

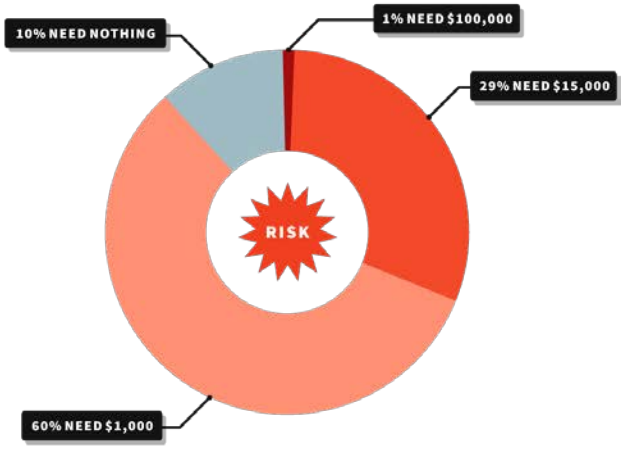
> Risk: The possibility of facing a financial loss associated with the use of healthcare

With health care being as sophisticated and costly as it is, it's very easy to find situations where someone can benefit from health care with a very big price tag that they would not be able to afford, and this risk starts to break the original transaction, and ability to treat healthcare is just a simple good or service.

A solution to the problem of risk is to ***pool the risk***.

> Risk pooling: Sharing risks among many members of a group. Shift the risk away from the individual and give the risk to the group, which is collectively better positioned to handle it.



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10 x $100,000 = $1,000,000
290 x $15,000 = $4,350,000
600 x $1,000  = $600,000
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                $5,950,000 / 1000 =
                $5,950 per person
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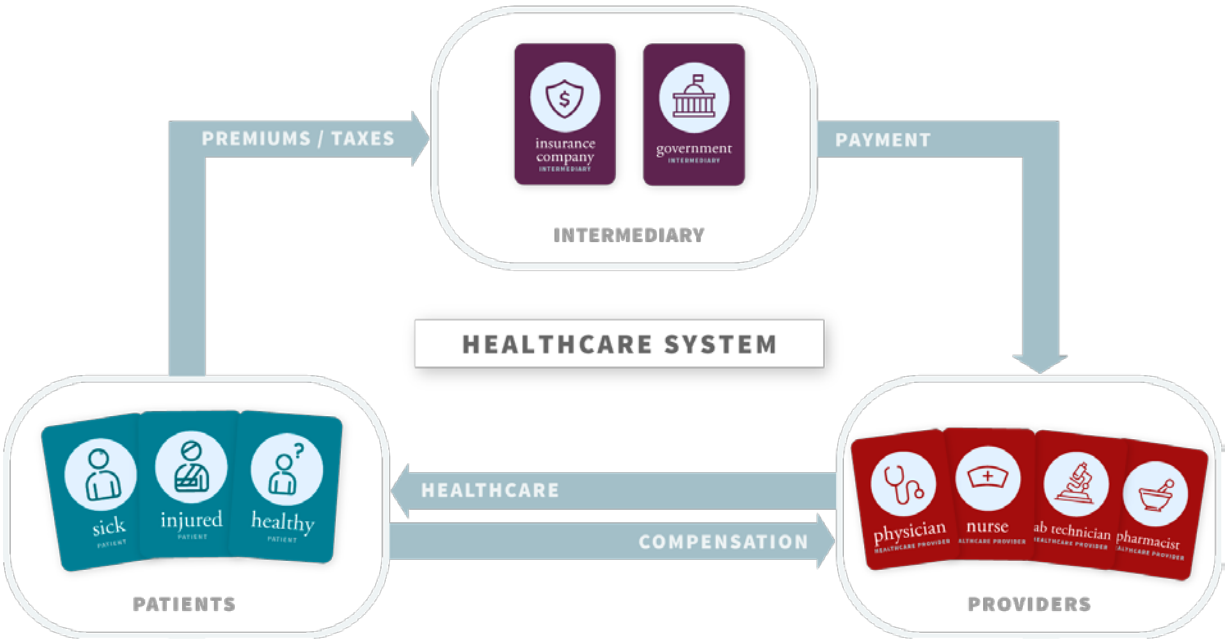
INTERMEDIARIES

Intermediaries: Entities that collect funds from a group of people, pool the funds and use them to pay for health care for the people who are covered. Also called; private insurance companies, insurers, payers, health plans, or plans.

Two Types of Intermediaries:

1. Insurance companies
    - Private companies
    - Insurance policy - a contract that provides for paying the medical bills of the holder, perhaps under some conditions.
    - Individuals pay a fixed, known amount for the insurance premium, and in return they get a policy that removes the risk that they're going to face a problematic medical bill that they'd have to pay themselves.
2. Government payers
    - Refer to as a public intermediary
    - The program agrees to cover healthcare costs for some group of people, and then it collects funds from the population to finance this.
    - The funds could be collected through the tax system, or in some cases it could be structured more as a premium



With intermediaries in the picture, funds can flow through the intermediaries from the patients to providers. On the one side, we have a group of people we'll call a population, some of whom become patients. The population pays money, either through premiums for private insurance, or through taxes or other fees to a government intermediary. Or maybe both. The intermediaries pool the risk and pay health care providers for providing care to patients. Normally a lot of the payments for providers go through intermediaries, so an arrow goes directly from the patients to the providers showing some payments that still go by this route.

Terminology

- Enrollees/members/beneficiaries: The people with a policy from the insurer
- Coverage: When people have a policy
- Premium: The price to buy a policy

OTHER PLAYERS IN THE HEALTH CARE SYSTEM

Regulatory Role of Government

- Oversight of private intermediaries
- Licensing and oversight of healthcare providers

Companies

- Provide goods and services used by providers and patients
- Develop drugs and devices, manufacture them, and sell them for use in the healthcare system.
- Operate in and around the healthcare system providing services to health care providers, or patients.
    - Create data systems and computer systems that can manage patient health records (electronic health records) or related applications.
    - Create applications for patients that they can use to manage their health

Others

- Professional societies and related organizations that work with providers
- Medical Associations that work with physicians
- Groups and professionals working on public health
- Philanthropies that help provide or finance care for people that might face challenges with that

TYPES AND ROLES OF INTERMEDIARIES

Intermediary roles:

1. Pool risk
2. Manage use and cost of health care
    - HMOs, PPOs, high deductible plans

Different intermediaries serve different parts of the population:

- In the US, the Medicare program is a large government program and one of its key roles is to cover people over age 65
- Sometimes intermediaries focus on particular geographic areas but don't operate throughout a country.

People have multiple choices of intermediaries, and opt for one or the other:

- In the UK, the National Health Service is a large public intermediary that is available to everyone. But there is also the option for people there to buy private insurance, foregoing the coverage offered by the NHS and opting to pay premiums for a private policy.

- In the U.S., most people under age 65 get their insurance from a private insurance company, and there are many different insurers that offer coverage, which individuals can choose between.

TYPES AND ROLES OF PROVIDERS

Providers can be organized into two groups:

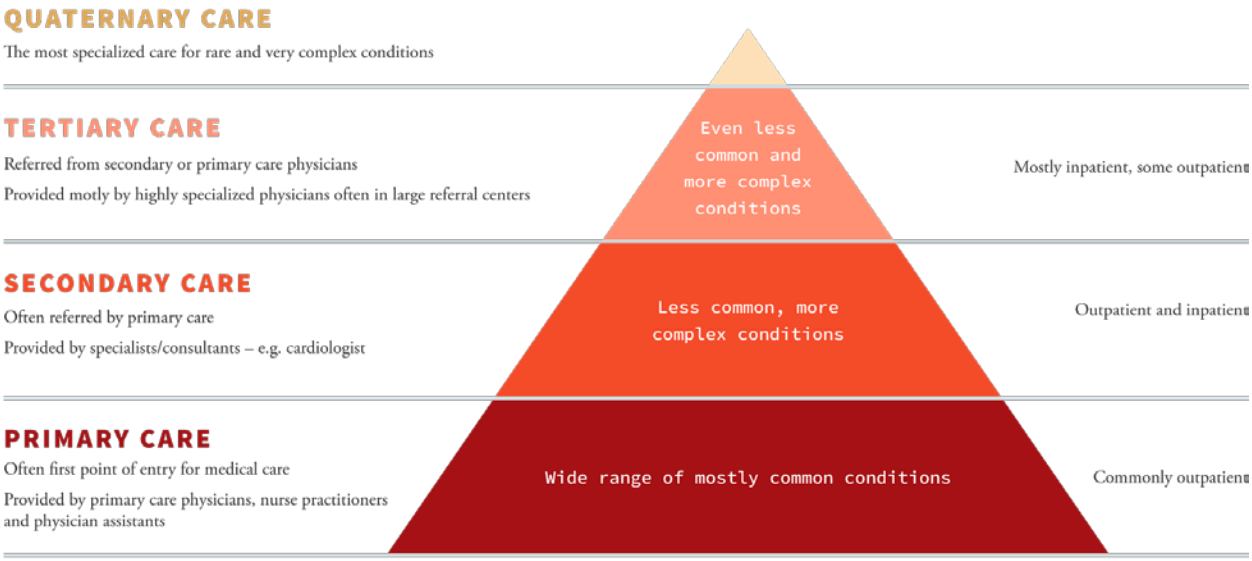
1. **Medical professionals**
    a. Physicians
        - Specialty - a particular area of medicine for which physicians have completed focused training.
        - Outpatient setting - outside a hospital, for example in a physician office or clinic. generally same day
        - Inpatient setting - in a hospital, generally where the patient stays overnight or longer
    b. Nurses
        - Includes nurse practitioners and physician assistants; Often think of people in this group as working as part of a team with physicians to deliver medical care
    c. Other professionals - Optometrists, midwives, pharmacists, dentists, therapists, emergency medical providers, and many others.
2. **Organizations**
    a. Physician Practices
        - The organizations providing the administrative and physical infrastructure

- Mainly think of practices as providing infrastructure for outpatient care

b. Hospitals
   - Organizations that house facilities for providing generally more complex care for inpatients.
   - Hospitals have beds, and often house more complex equipment, facilities for surgeries, advanced testing and imaging, and related

c. Independent Organizations
   - Ones that provide facilities in which some types of medical care can be provided but are not part of a physician practice or a hospital
   - There are a wide variety of these: Laboratories, ambulatory surgery facilities, diagnostic imaging facilities, pharmacies, rehabilitation facilities, long term care facilities, and many others.
   - Organizations can be owned and operated under different arrangements

Providers and Levels of Care



1. Primary Care - Often first point of entry for medicare. Provided by primary care physicians, nurse practitioners and physician assistants
2. Secondary care - Often referred by primary care. Provided by specialists/consultants.
3. Tertiary care - Referred from secondary or primary care physicians. Provided mostly by highly specialized physicians often in large referral centers.
4. Quaternary care - The most specialized care for rare and very complex conditions.

THREE KEY CHALLENGES FACING HEALTH CARE SYSTEMS

Health economists or health care policy analysts take a look at a measure of healthcare spending as a percent of the gross domestic product, the GDP, of a country.

- Percent of GDP allocated to health care
  = Healthcare spending / gross domestic product (GDP)

Spending has gone up steadily over time, Why?

- Populations getting older
- Population income and living standards have increased
- Price increases
- Increases in utilization resulting from technological advances

3 Challenges for Quality of Care

1. Underuse: One finds services that we would like everybody to be doing or getting, but we don't get enough of
2. Overuse: Situations where services don't create value, or even sometimes where they can lead to problems
3. Misuse: Making errors. Using a treatment when it should not have been used.

Access Challenges

- Lack of insurance coverage
- Socioeconomic disparities
- Differing levels of education
- Cultural issues
- Language barriers
- Lack of providers

LESSONS FOR AI AND DATA

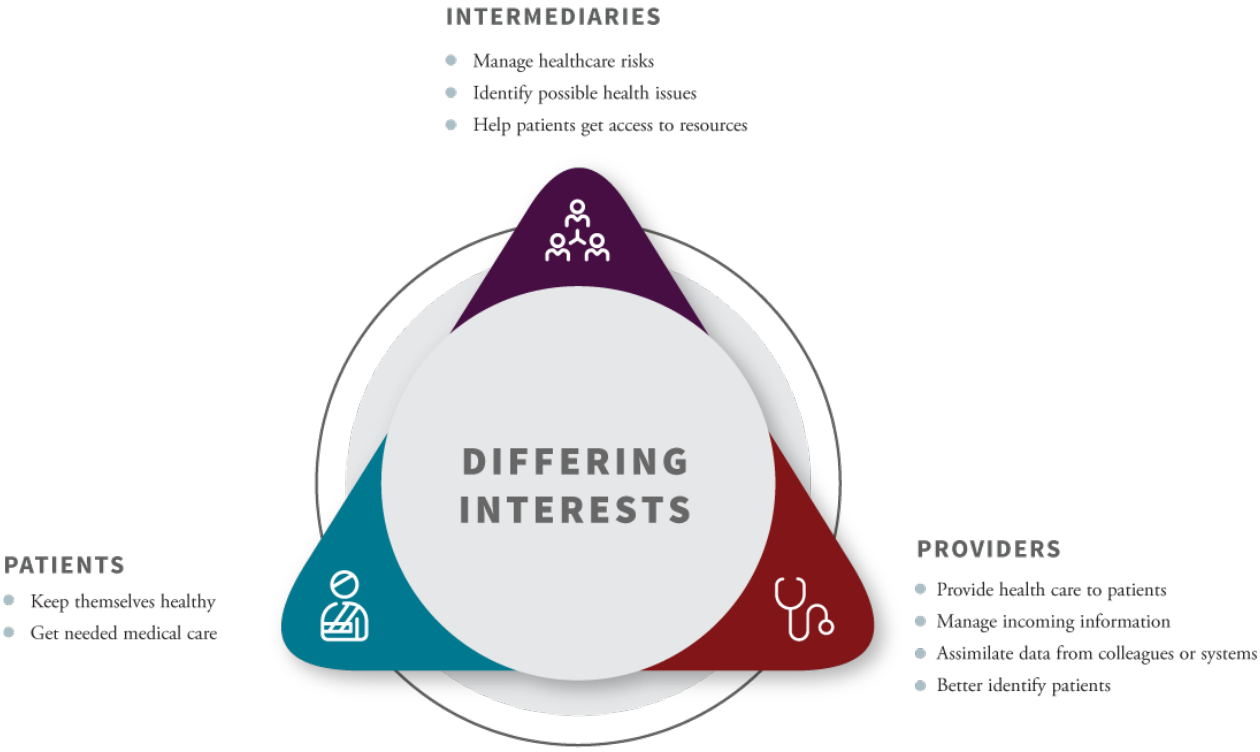
We can use the ideas about the healthcare system to make a couple of observations relevant to artificial intelligence and the data that might underlie AI work.

Wide Variety of players in the healthcare systems:

- Intermediaries - Looking for tools that can help manage healthcare risk. Tools that can help them identify possible health issues that they can see coming in their population where they could try to get involved and help those patients get access to resources that would help
- Providers - Trying to provide health care to their patients. Need a tool that manages incoming information from patients, and sorts that out into diagnoses and treatment plans. May benefit if they can better identify patients likely to need services in the future.
- Patients - Interest in keeping themselves healthy and finding out whether they might need medical care so there may be patient directed solutions

Data:

Paying attention to who will have data, and why they have it



1. Providers - electronic health records, or EHR data. The main purpose is to aid providers in working with patients. It may be heavily regulated because of privacy concerns.
2. Intermediaries - Interested in paying providers, may have records associated with that. Sometimes this can be very informative and tell things about what patients are getting services and how much they cost, but it'll be different from electronic health record data.
3. Government - Often keep track of the services that they're regulating. They might keep track of data on hospitals that they've licensed to operate. They might keep track of physician licenses to practice medicine.

4. Pharmacies - Pharmacies may collect data on the drugs that they sell.

It is important to pay attention to the fact that the data come from different sources, for different reasons, with different issues.

MODULE 2- PHYSICIANS, PHYSICIAN PRACTICES, AND PHYSICIAN PAYMENT

LEARNING OBJECTIVES

1. Describe the role of physicians and physician practices, ways that physician practices vary, and ways physicians and practices relate to intermediaries
2. Describe the basic operations of fee-for-service physician payment systems
3. Describe the basic operations of capitation-based physician payment systems
4. Describe some other approaches to physician payment, including salary models and episode-based payments
5. Describe how physician payment systems affect financial risk faced by physician practices, and incentives created by payment systems

PHYSICIAN PRACTICES

Physician practices are organizations in which physicians work, independent entities that are privately owned and operated.

- Solo practice contains one physician who is the owner and manager of the staff (one specialty)
- Group practices can contain 2-3 doctors in a partnership or up to 100's of physicians and can be called medical groups or physician organizations.
- Larger groups are much like corporations where doctors are hired as employees and do none or less of the management of the staff.

Physicians get paid through intermediaries that determine eligibility for care, process the insurance claims and pay the claims to the doctor's practices

Physician Network: a group of physicians or practices with whom the insurer works, and which the members covered by the insurer are required or encouraged to use

- In-network: If a payer (insurance company) and a practice agree on a payment arrangement, then we say the physicians in the practice will be "in-network" for the payer, and the payer covers all or contributes to the costs of their care.
- Out-of-network: Any doctors or groups not a part of network are called 'out-of-network' and patients will need to get prior authorization to see one of those doctors or pay out of pocket.

For larger groups, the management does all the work and negotiations with the insurer.

Network Organizer: do what larger practices can do except it is for multiple small practices

- **IPA (an Independent Practice Association)** – Most common network organizer.
- IPA collects physician groups and then goes to the insurance company on behalf of all of its members.
- The IPA members are considered 'in-network'. The IPA gets paid by the insurer who then pays the practices.
- Individual practices can mix and match a bit when it comes to working with IPAs.

PHYSICIAN PAYMENT

FEE FOR SERVICE

Fee for Service (FFS): The doctor bills and is paid for each service that he/she provides whether that be in the office or hospital.

Pay for volume: The more volume of services, the higher the pay.

Fee schedule: List of services with listed payment amounts

Allowed amounts: Also called negotiated rates. The agreed upon amounts an intermediary would pay a practice

Retrospective payment system: the amount of the payment is set after the services are delivered and responds to the services

The fee billed by the doctors' offices is listed on the 'charge-master', but the amount paid by the insurer is often lower.

Procedure Codes:

- CPT- Current Procedure Terminology
- HCPCS – Health Care Common Procedure Coding System
- ICD-10PCS - International Classification of Diseases, 10th revision, Procedure Coding system

Diagnoses Codes:

- ICD-10 - International Classification of Diseases

MEDICARE

Medicare: The US government payer that provides coverage for people over age 65, and some others

The Medicare fee schedule is based around the HCPCS system. at the core of that is the CPT listing of physician services.

A central idea in the Medicare Fee Schedule is that each service there should be assigned a weight that reflects the amount of work involved in doing it, what expenses a practice might incur to provide it, the amount of malpractice risk associated with it.

RVU (Relative Value Units): A weight assigned to service which allows a specific dollar amount to be paid for each service.

One service might have 2 RVUs assigned to it. 4 RVUs means that the latter should get twice as much weight in terms of the amount of work, practice expense, and malpractice risk involved.

Medicare fee schedule has all these enumerated services and the number of RVUs associated with each one. Then there is a conversion factor that converts RVUs for payment.

TOTAL RVU*	X	CONVERSION FACTOR	=	FEE SCHEDULE ALLOWED AMOUNT
2 RVUs		$35		$70
4 RVUs		$35		$140

*Note: In the Medicare Fee Schedule, Total RVUs reflect work, practice expenses, and malpractice risk, and are adjusted for geographic variations

Medicare's fee schedule is made by the government and is available to the public online.

CAPITATION

Capitation: Payment per person, per unit of time

Capitation payment model:

1. Identify panel of patients
2. Define scope of services
3. Practice and the intermediary agree on a fixed payment amount (called the PMPM amount, the per member per month amount)

NUMBER OF PATIENTS	X	PMPM AMOUNT	=	PAYMENT TO PRACTICE
1000 patients		$25		$25,000

If the patient needs services outside the scope of the agreement, like they need to be hospitalized or see a specialist, then the intermediary would pay for that separately.

We sometimes say capitation is the opposite of a fee-for-service system

Prospective payment: Payment amount is determined before any services are provided, and does not change depending on the services.

GLOBAL CAPITATION

PRIMARY CARE (PARTIAL) CAPITATION

The scope of capitation can be primary care or can be broader. At the broadest, we have what we call global capitation. Any medical care by any provider or place of service would be covered for that panel of patients.

The capitation rate or the PMPM amount depends on the scope. The PMPM for a broad arrangement like global capitation would be much higher than the amount for narrower, say primary care only, capitation. There is more risk so it is usually only done by larger healthcare organizations

PHYSICIAN PAYMENT MODELS

1. Episode Based Payments
    - Clinical dimension - the set of services or the medical conditions to be included, like fee for service
    - Time dimension - defines the beginning and the end of the episode
    - Each episode means one patient, one medical condition, and one period of time.
2. Salary Model
    - A fixed amount for working for some period of time, a month or a year, and carrying out agreed-upon duties during the time period

RISK IN PHYSICIAN PAYMENT AND MULTI-LAYERED PHYSCIAN PAYMENT ARRANGEMENTS

Physician payment and risk:

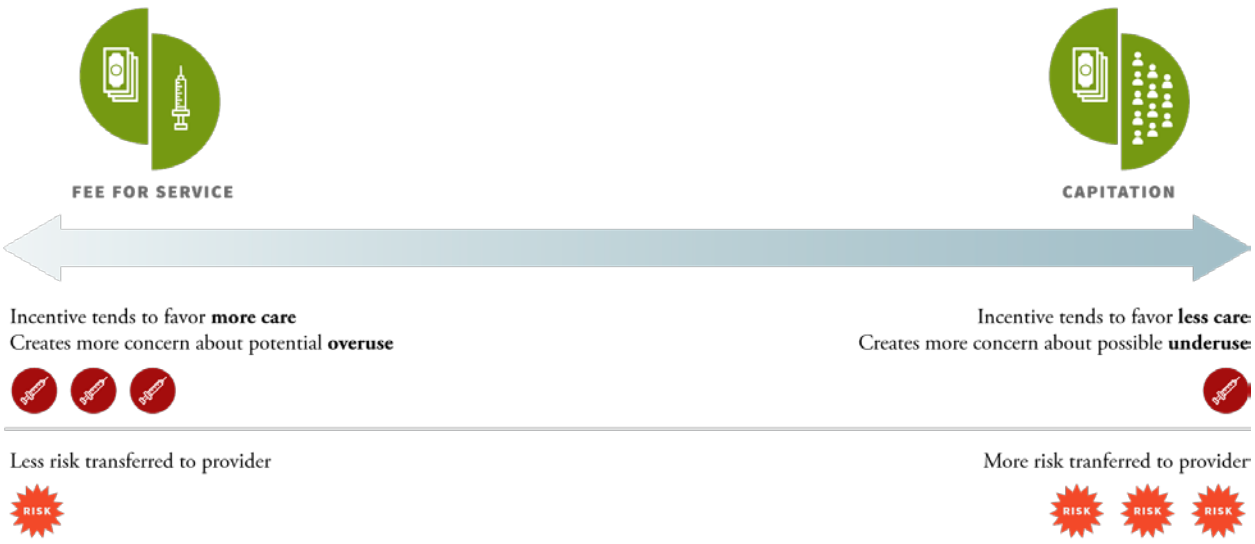
- When an intermediary pays a physician practice using capitation, even partial capitation, it can transfer risk from the intermediary to the provider.

- Physician group got a fixed amount of money and have to deal with it, even if they need to deliver a lot of care – which would be a risk.
- In large practices, predicting needs is easier statistically so the risk is less with capitation.

Multi-layered physician payment arrangements:

- **Example 1**: Consider the easiest case of a small practice contracting directly with an intermediary. The intermediary pays the practice directly, probably fee-for-service. Then the physicians in the practice, commonly the owners, would be paid based on the profits of the practice with some method they would devise for sharing those profits among the physicians.
- **Example 2:** Consider a larger group practice. The practice group administration may arrange for payment from the intermediary based on all the collective work of the physicians. This may be fee-for-service, or it may be some sort of capitation arrangement. Then, the group administrators may make separate and different arrangements to pay the individual doctors via salary plus bonuses or based on RVUs.
- **Example 3:** Consider the case of smaller practices that have joined an IPA. The IPA makes a deal with the payer for being paid based on the collective work of all of the participating practices. This might be a capitation arrangement or fee for service. Then once the IPA is paid, it in turn pays the practices according to arrangements between the IPA and the practice. This is probably fee-for-service if they are small practices. The practices then work out how the individual physicians will be compensated, perhaps based on the profits of the practice.

INCENTIVES



Payments based on fee-for-service will tend to create an incentive to do more services or more expensive ones. This ensures all of the things being done are what the patients need. People worry that fee-for-service might create incentives that lead to overuse of care and higher healthcare costs.

Capitation on the other hand goes the other way. Physicians have an incentive to do less for each patient. They have received a fixed payment and will do better financially if they incur fewer costs by providing less care. This might be good – it might incentivize them to seek more cost-effective ways of providing care that they might ignore under fee-for-service.

One might think that salaries are a solution to the fee for service model. Salary models really only work well when physicians are employees in a larger practice.

LESSONS FOR AI AND DATA

- Patients may see a physician in different practices resulting in multiple systems
    - Records and data systems at one practice will not contain a complete record of the care provided to the patient
- Payment systems are a valuable source of data, especially in fee-for-service model
- Different AI tools are needed depending on the size and structure of a physician practice

MODULE 3 - HOSPITALS, OTHER PROVIDER ORGANIZATIONS, AND RELATED PAYMENT SYSTEMS

LEARNING OBJECTIVES

1. Describe the main features of hospitals, types of care provided at hospitals, and the ways that hospitals and physicians are related
2. Describe the main features of different approaches to hospital payment, including DRG, per-diem, global budgets, and fee-for-service/charge-based systems
3. Identify other types of providers in addition to hospitals and physicians
4. Describe the main features of health care systems integrating multiple types of providers
5. Describe the main features of pay-for-performance structures
6. Describe the main features of electronic health and medical records

HOSPITAL OVERVIEW

Hospitals are organizations that provide facilities and staff to offer medical care. Can operate as private businesses, on a for-profit or a not-for-profit basis, and some hospitals are owned or operated by government organizations.

A defining characteristic of a hospital is the **provision of beds and infrastructure for inpatient care,** in addition, may have outpatient facilities.

Different Characteristics of Hospitals:

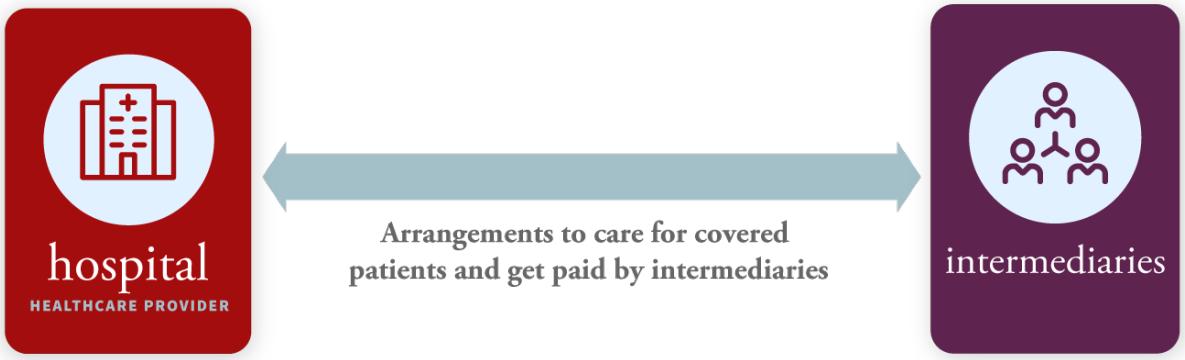
1. Level of services provides
    - Basic to more advanced all the way to tertiary and quaternary care
2. Focus of the hospital
    - Most hospitals are set up to treat a broad range of types of patients and cases called "general hospital"
    - Some hospitals that specialize in a particular area
3. Provision of teaching
    - Some hospitals operate programs to help train new doctors, and we refer to them as teaching hospitals, and sometimes we identify hospitals with a strong association with a medical school as academic hospitals

Relationship between hospital and physician:

1. Hospitals employs physician directly
2. Physician has a separate practice with an arrangement to practice at the hospital

Admitting Privileges: arrangements for physicians to provide services at a hospital

Physician practice and hospital would still be separate entities, separate businesses that are organized and probably paid separately.



Relationship between hospital and intermediaries:

- Arrangements with the intermediaries to take care of covered patients, and arrangements for getting paid when they do
- This can go a few different ways depending on the country and the health care system
- **Hospital Network:** A group of hospitals with whom an insurer works, and which enrollees are required or encouraged to use
- A hospital that contracts with an insurance company is considered 'in-network'

HOSPITAL PAYMENT

FEE FOR SERVICE AND PER DIEM

1. Fee-for-service: A fee is paid for each service provided to a patient
    - Hospitals maintain what we often call a "chargemaster," a list of all of the services the hospital can provide, and the amount the hospital charges for each
    - Cost-based reimbursement - hospitals present intermediaries with their costs for taking care of a patient and payment is based on the cost
2. Per diem: Payment per patient day
    - Hospitals and intermediaries set a fixed amount the hospital will be paid for a patient day in the hospital, regardless of the hospital's charges or the cost incurred for caring for that particular patient that day
    - Per-diem payments can vary:
        i. By type or complexity of services
        ii. By the day of the hospital stay

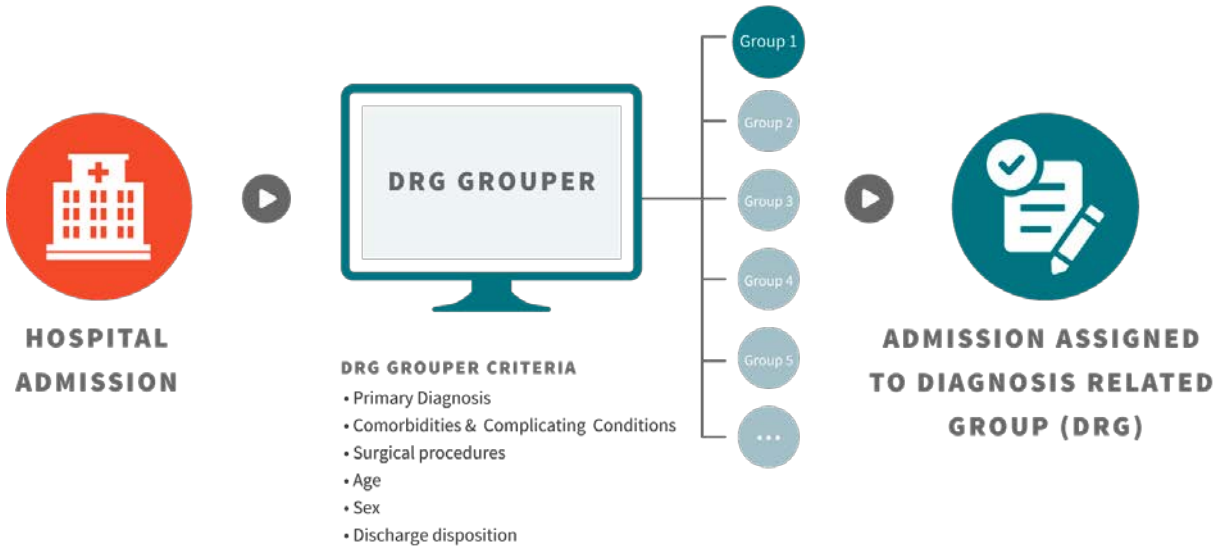
iii. If there are *carved out* services

Terminology

- Carve out: When specific services are paid separately from the per-diem

DRG SYSTEM

DRG (Diagnosis-Related Groups): A common system or method for paying hospitals, generally for inpatient care they provide. In a DRG system, hospitals are paid a flat payment for each specific discharge diagnosis, meaning **payment per hospital stay**.



DRG systems have a method for assigning patients to groups based on their diagnoses. This grouping is done by an algorithm, generally some software, that is sometimes referred to as a grouper.

Each DRG is associated with a specific allowed payment amount. One common way to associate each DRG with an allowable payment amount is to assign it a weight, reflecting something about the complexity or expected cost to the hospital of caring for a patient in the group. They use conversion factors to calculate the weights

Terminology

- **DRG weight:** A value assigned to a DRG reflecting complex
- **DRG Incentives:** Hospitals paid based on patient characteristics, not length of stay or services performed.

Evolution of DRG Systems:

- Adding more groups
- Incorporate consideration of treatments

The weights or payment amounts for each DRG generally are designed to be related to the average amount of care a patient in a group would need. For the patients who need extra care, DRG systems often provide for special extra payments when cases meet certain standards. We often called these outlier payments.

DRG systems comes under the terminology called prospective payment.

Terminology

- **Outlie payments:** Payments in addition to the DRG for patients using much more care than expected for their group
- **Prospective payment:** Payment is based on the patient condition at the outset of treatment, not on the actual treatments given.

GLOBAL GUDGETS

Global Budget is a way of paying for inpatient care, and they can easily extend to cover outpatient care provided by the hospital too.

Global budget model: A payment system where hospital is paid a fixed amount for a period of time

1. Often one year
2. To take care of a known or predicted population
3. To provide a defined scope of services

One general aspect of global budgets is that they often work best when they can capture a large share, maybe even all, of the business of a hospital.

Global budgets are harder to use when there are many intermediaries, each making their own deals with hospitals, though that is not to say that this hasn't been tried in a variety of situations.

HOSPITAL TOPICS

Topic 1: Payment arrangements for inpatient and outpatient care can vary

Hospitals provide a lot of inpatient care, but often do provide care to outpatients as well. Payment arrangements for these are often separate. Hospitals may use a fee-for-service, per-diem, DRG approach for their inpatient care but outpatient is likely fee-for-service.

For outpatient care, they may make separate agreements with insurance companies. Lab services, x-rays, ER visits, outpatient clinics are some examples. It could be fee-for-service, sometimes using a chargemaster approach DRG system, but for outpatient services. At any given hospital, payments for inpatient and outpatient services could be similar or could be completely different.

Topic 2: Payment arrangements for hospital-provided services and physician services can vary

Medical services:

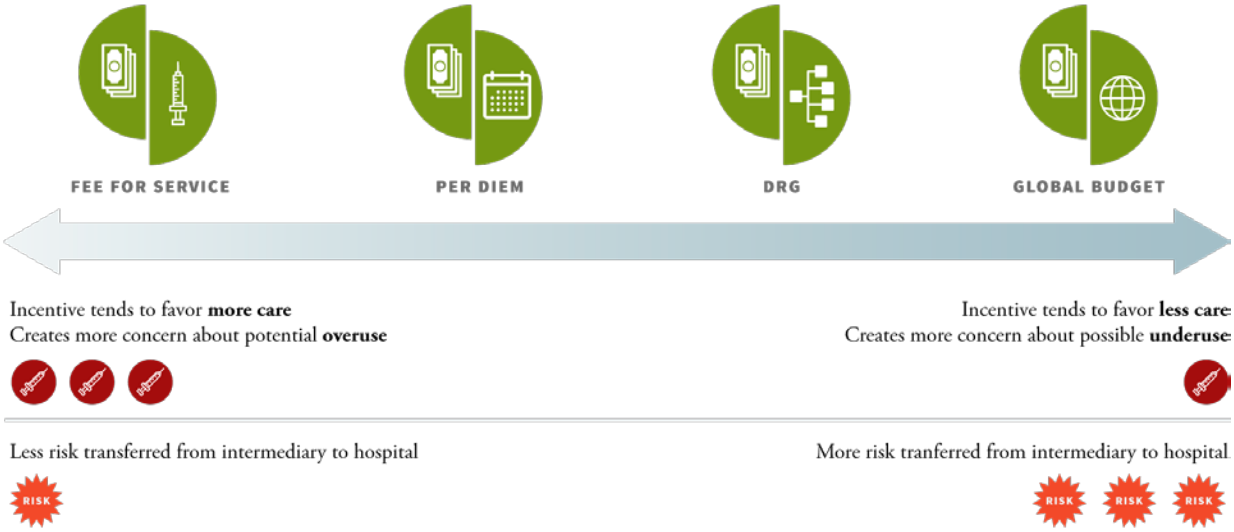
1. Professional component: payment for the physician or provider who provides the service
2. Facility component: payment to the facility for providing facilities, personnel, or infrastructure for the service

If a physician in private practice. When physicians provide care within the facilities of their practice, they're usually paid for both components at the same time.

In hospitals, inpatient and outpatient, the professional fee and the facility fee billed separately and paid separately. The DRG here covers the facility part. For surgery, there would be a surgeon bill, an anesthesiologist bill, and a facility bill

Topic 3: Amounts charged are often not the same as the amounts paid

Hospitals often send detailed bills to intermediaries, even when they might be paid using per diems or DRGs. Even in fee-for-service billing, there could be notable discounts from the charged amount.



Risk. Hospital payment systems can move risk around. Fee-for-service systems transfer the least, or maybe no risk. The intermediary keeps the risk associated with patients needing more or less medical care.

Per-diem systems transfer some risk**:** Hospitals would not be at risk when more people get sick and need hospital care, or when patients need to stay longer because they get paid for every day that the patient is in the hospital. But, the fixed payment per day (per diem) would leave the hospital on the hook for how much care gets delivered in the day.

DRG systems transfer more risk: Hospitals get a fixed payment per discharge, so now when a patient needs more days in the hospital, or when they need more services per day, the hospital has to bear the costs of that. Outlier payment components might help with this.

Global budgets would transfer the most risk**:** Here the hospitals got a fixed budget and accepts the risk associated with whether people get sick or not and the variations in the amount of care needed.

Incentives. Hospital payment systems create some incentives.

Fee-for-service would tend to create incentives to perform more services, which generate more revenue for the hospital.

Per diem systems similarly would tend to create incentives for hospitals to keep patients in the hospital longer.

DRG systems, create incentives to keep patients in the hospital a shorter amount of time. Once you paid the fixed amount per admission, the hospital benefits if they can get that patient out as soon as possible.

Global budgets would provide the strongest incentives to minimize the time spent and the amount that gets done for patients.

Toward the fee for service and per-diem end of the spectrum, we worry less about underuse of care, which might be good, but we might worry about creating overuse – patient staying the hospital longer than they need to for example. On the other end the opposite – we steer toward reduced overuse, but risk underuse – patients getting kicked out before they should be.

One important issue related to incentives for hospitals stems from the fact that hospitals and physicians are often in separate organizations, by physicians are in control of a lot of things that happen at hospitals. One reason that people sometimes like more integrated organizations, with physicians working more directly for the hospital say, is that it can get these incentives aligned. Despite the misalignment of incentives, though, there is evidence from studies that suggests that these incentives do function in these ways. When you use DRG systems, you do tend to get shorter stays, as opposed to fee-for-service or per-diems where you tend to get longer stays.

That leads to some interesting questions about system design.

NON-HOSPITAL FACILITIES

There are many kinds of professionals out there

- Nurses
- Technicians
- Physician assistants or nurse practitioners (NPs)
- Physical therapists
- Dentists, optometrists, chiropractors, nutritionists, podiatrists, and others

A common model would be a salary model, like salaried physicians in a group practice

Dentists, optometrists are set up like doctor's offices as fee for service.

There are also other kinds of organizations, besides physician practices and hospitals. There are independent labs, for example, and independent diagnostic facilities, ambulatory surgery, physical therapy facilities, long term care facilities, and many others.

From a system standpoint and a payment standpoint, these will often have similarities to hospitals in terms of arrangements and payments

LARGER PROVIDER ORGANIZATIONS

One growing area is hospital systems. Some hospitals operate more or less by themselves, but others have formed into larger organizations with many hospitals that are part of the same company.

In the US, quite a number of hospital systems have formed, some of which have just a couple hospitals, but in some of the large systems there may be dozens of hospitals, or more, that work together.

Another trend in the U.S. has been the integration of hospitals and physicians into the same organizations. We then sometimes call them PHOs – physician-hospital organizations. For example, the hospitals hiring physicians as employees, or buying physician practices, and bringing them all into the same organization.

As PHOs get larger, with broader representation of physicians, we start to apply a term like an ***integrated delivery network***, an *IDN*, or ***integrated delivery system IDS***.

- Integrated delivery network: an entity that owns, or closely integrates, many providers of different types to provide a broad range of care

- In principle, a true IDN is a self-contained and integrated healthcare ecosystem, with the ability to contain much or even all of the patient experience within it, delivering well-coordinated care.

The **Accountable Care Organizations (ACO).** These are kind of like PHOs or IDNs, but a little different.

PHOs and IDNs and others are what we would call **financially integrated organizations**.

- **Financially integrated organization:** providers work as part of the same business, with a unified bottom line
- **Clinical integration**: providers work together to deliver integrated and coordinated patient care

An ACO is an organization that works to create clinical integration across many providers, but without bringing everyone into the same financially integrated organization. The concept was originally designed for operation within the US Medicare program. The idea of an ACO is to create a structure that can have the breadth of services to meet the normal needs of a broad population. They can do that with each provider or organization voluntarily associating with the ACO, and coming together through some contractual arrangements, but staying in their own separate organizations. The ACO then can make participation and payment arrangements with intermediaries, in which the ACO collectively acts on behalf of the participating providers.

These larger organizations – PHOs, IDNs, ACOs, others like them – often form with the idea of trying to get better more coordinated care to happen. Larger organizations can often take broader capitation or related payment arrangements that can incentivize efficient care.

PAY FOR PERFORMANCE IN PROVIDER PAYMENT

Pay-for-performance (P4P) generally refers to the use of financial incentives or penalties based on whether or not a provider meets some set of performance expectations based on a set of predetermined measures.

P4P focused on whether providers meet performance standards focused on the quality of care. P4P models measure performance using clinical process measures – whether providers are following guidelines for example – or clinical outcome measures – whether actual outcomes of care meet standards. They may incorporate measures from surveys of patients' experiences.

P4P is often implemented as a performance-based bonus on top of whatever usual compensation methods might be in place.

Issues in Pay-for-performance system design:

- What set of measures to use?
- What is the goal or expectation to be met?
- Whether and how to adjust for variations in patient characteristics?
- How much money to put at stake?

PROVIDERS AND ELECTRONIC RECORDS

The original mode of record keeping about patient care was on paper, in what was commonly referred to as a **patient chart**.

Over time it became clear that digitizing this information could be valuable. The idea is that electronic records might be more easily maintained, be more easily searchable, maybe more easily used for communication from one provider to another, and so on.

Electric medical record (EMR): An electric version of a patient's medical record

Electronic health record, or EHR. EHRs and EMRs are similar. EMR might be used within a particular practice or setting, and EHR might incorporate data from multiple practices into a more comprehensive record.

PHR, a personal health record. This would commonly refer to an electronic application for patients to record their own personal health information, for their own use, or maybe to share with their providers.

LESSONS FOR AI AND DATA

A few lessons for us about the activities of organizations and their incentives, and a word about lessons for data that might be useful to point out.

There can be important differences in the goals of provider organizations, and their interest in tools and innovations, that are associated with their size and structure, and how they are paid. Not all provider organizations are equally interested in all innovations, or equally able to handle them even if they are interested.

Payment can matter. Practices getting fee-for-service or related types of payments may be open to pursuing new innovations, even high-cost ones, as long as they can bill for and be paid for that. On the other hand, it can happen that provider organizations getting fee-for-service or related payments may not be as eager to adopt new approaches that would reduce their provision of services, which might negatively affect their revenues.

Organizations with more risk, capitation, DRGs, can benefit from pursuing even things that are hard to bill fee-for-service for. They may also be particularly motivated to find cost-reducing things, and may not be as interested in innovations that would tend to increase resource use.

Larger and smaller organizations can also have different capacities to adopt and use new tools. Larger organizations may have substantial resources in house to manage computer systems and related things. Smaller organizations may not.

EMRs or EHRs can be useful sources of data, and the scale of organizations can affect the value. An issue with EMRs is that they may not capture care across multiple organizations.

Hospital payment data that you might get from intermediaries can also be useful and sometimes might be better than just using data from a single provider organization because it can capture bills from multiple providers. Regardless of the specific payment arrangements, hospitals may send pretty detailed bills with patient diagnoses, procedures, and related information to intermediaries.

MODULE 4 - INTERMEDIARIES, HEALTH INSURANCE PLANS, AND HEALTH CARE FINANCING

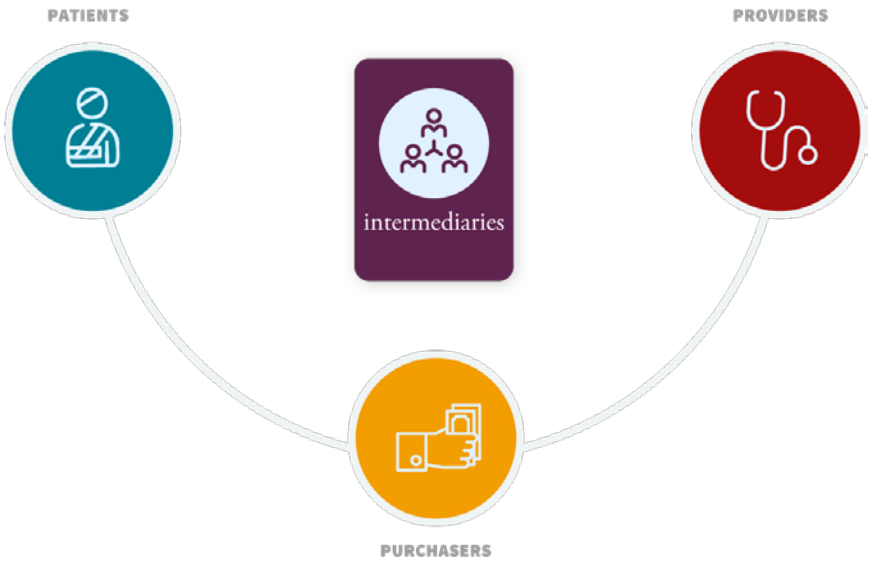
LEARNING GOALS

- Describe the main tools that intermediaries/insurers use to influence health care utilization, costs, and quality
- Describe stereotypical plan designs, including HMOs, PPOs, and “traditional” insurance models
- Identify the main sources of health coverage in the U.S., including private insurance plans and major government plans Medicare and Medicaid

INTERMEDIARIES OVERVIEW

Intermediaries are called plans, payers, and insurers. They are essential to the functioning of the healthcare system. Provide mechanisms for risk pooling, taking on risk from individuals in the population. Handle many payments to providers, and defining coverage rules that influence the ways patients can use care.

- Public intermediaries: Intermediaries run by, or under the auspices, of a government
- Private intermediaries: Intermediaries that operate as private businesses



Intermediaries face three different groups:

1. **Providers**: Intermediaries have to work out arrangements with health care providers to provide structure for taking care of patients covered by the intermediary and getting paid when they do so.
2. **Patients**: Intermediaries have to work out the terms under which they will cover health care, which often ends up influencing things like what services patients can get and how easy it is to get them.
3. **Purchasers:** The people who pay for coverage from them, their customers or buyers

The ways intermediaries work with providers and patients will influence the satisfaction people have with their products.

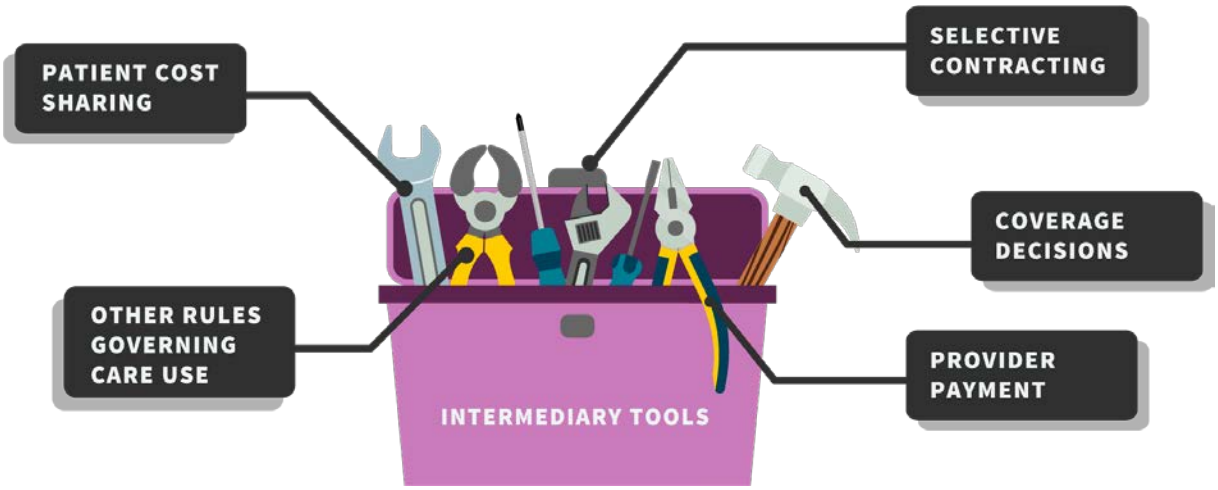
The ways intermediaries work with providers and patients also influences the amount of money they have to ask for.

Intermediaries are trying to figure out ways to work with patients and providers that both maintain those relationships and keep people happy with the care they can provide or get, and the terms under which they get it, and keep costs under control.

Broader forces that affect intermediaries:

- High and rising health care costs
- The need to provide high quality health care
- The need to enable access to care

INTERMEDIARY APPROACHES TO INFLUENCING HEALTH CARE UTILIZATION AND SPENDING



Intermediaries have a variety of tools they can use to influence health care use and spending.

Tool 1: The management of provider availability and networks. The key question is working out which providers the intermediary is going to work with.

In some places, large intermediaries or other government entities already exert influence on the provider space. Large public intermediaries in those places may find it natural to work with all or nearly all providers.

In the US, there is relatively little intermediary or government-led guidance. Providers are free to set themselves up where they want.

Terminology

- **Network or provider panel:** The set of providers organized by an intermediary to care for enrolled patients
- **Selective contracting:** Intermediaries selecting some but not all available providers to be included in their network

Some possible criteria for choosing providers:

- Quality
- Efficiency
- Payments required
- Location

Along with identifying a network, the plan sets the rules they will make for their members with respect to the choices of providers. Some intermediaries choose to be what we call "closed panel". **Closed panel** means a requirement that enrollees see providers in the panel, or else the intermediary won't contribute to the costs of care.

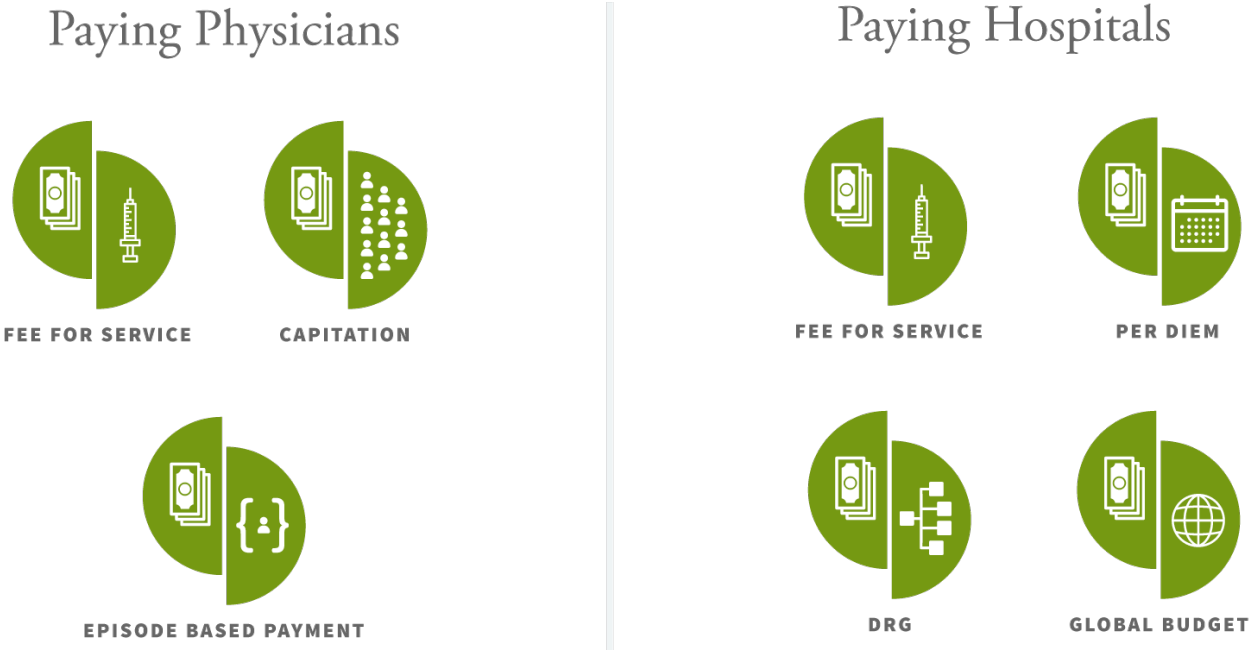
On the other side, a plan could go **open panel**. Here, the intermediary allows its members to go to pretty much any provider that they want to out there.

In between sometimes you we might say a plan has a **semi-open** or a **semi-closed panel**, where they set up a network, and then incentivize enrollees to go to providers in the network with maybe favorable cost-sharing, but maybe the plan would still pay something and help cover the cost if patients went out of the network.

Tool 2: Provider Payment Methods and Levels. Intermediaries are engaged in defining the structures governing payments to providers, as a tool they can use to influence care use and costs.

Depending on the context, this can be more or less a one-sided conversation. When intermediaries have a lot of power, say they are a large government intermediary, they may get a lot of control over the structure. On the other hand, sometimes the dynamic is more of a real negotiation – when both intermediaries and providers have some power, there can be more meaningful negotiations.

The structure of payment arrangements can have a couple of dimensions.



The first dimension - Form of the payment:

- For paying practices of physicians and other professionals, you have choices like fee for service, capitation, sometimes episode payments.
- For hospitals, the fee for service, per diem, DRG, global budgets are all methods that you'll see out there.

The second dimension - The level of payment.

- Fee for service, DRGs, any method, can be more or less costly if you set the fee schedule or the DRG payment amounts higher or lower
- One interesting interaction is between selective contracting and payment negotiations. Sometimes you will see selective contracting used to enhance a plan's bargaining ability with providers

Tool 3: Patient cost sharing. Intermediaries often use patient cost-sharing to influence care use and costs.

Cost sharing / Out-of-pocket payment: Money paid by patients to providers when they receive care.

Cost sharing structure:

- Deductible: an amount that a patient has to pay out of her own pocket before an intermediary will start contributing to the cost of the care.
- Copayments: a payment that a patient must make every time that they see a provider.

- Coinsurance: a percentage of the bill that the patient is responsible for when a provider is used.

Deductibles, copayments, coinsurance can come in a variety of combinations.

Variations in cost sharing:

- Across different types of services
- By level of spending (related to "out of pocket limit" or "out of pocket maximum")
- By network status of the provider
- By tier

The hope can be that by giving patients some incentives, they will steer themselves to more efficient, more thought-through choices about the care they really need and is worth it for them to get.

Tool 4: Utilization Review, Gatekeepers, and Other Methods of Directly Influencing Care. A set of tools to directly control or manage utilization.

1. Gatekeeper requirement. This refers to a requirement that patients must select or be assigned to a particular primary care physician, and then have to then see that physician as their first point of contact for any medical issue if the plan is to cover. Before they go see a specialist, for example, or get testing, they need to see and get a referral from the primary care doctor.
2. Utilization review. A general term that refers to plan efforts to monitor the utilization of patients and try to be involved in guiding decisions about care use. It is often said to come in 3 main types.
    a. One is pre-authorization, or "prior review." This is a requirement that, for certain services, the plan must approve of use before the service is delivered if the plan is going to cover it. Or they might do other things like maybe require the patient to try some less expensive therapy first before they go for the more expensive one. A plan could target pre-approval requirements at services where they were worried about the overuse of expensive but low-value things.
    b. The second version is a concurrent review. Plans monitoring care as it's being given and attempting to influence care. This is most often done for hospital stays whereby the insurance will contact the hospital if they think the patient is staying to long and the doctor/admin must justify why the patient is still there.
    c. The third area is a retrospective review. Happen also after the care is completed. Plans may take a look at the care that was delivered and may review that for appropriateness.

There are other things that can happen in the space of plans trying to influence care. They might monitor providers by collecting data on their use of certain services, or their quality scores, or other things, and then provide feedback to the providers that might influence the utilization of care. Working with patients, they might send reminders and other information to patients to try to influence the utilization of care.

Tool 5: Coverage Decisions. Influence care use and costs by limiting the services the plan will cover.

It is common for plans to seek to cover a pretty broad range of services, generally trying to cover services that are "medically necessary." That is, services that medical professionals would commonly say are warranted or indicated for the patient. Some may not elect to cover everything out there.

Example criteria for coverage decisions:

- Efficacy
- Cost or cost-effectiveness

One area where questions about this coverage decisions come up a lot lately is around new drugs, where there can be some high priced new treatments that raise interesting cost-effectiveness questions.

Tool Overview: Combinations and Tradeoffs.

Intermediaries are expected to be good at:

- Determining specific goals
- Determining the providers and people they work with
- Determining how to deal and compete with other intermediaries
- Designing their approach to meet their goals
- Mixing and matching existing tools and sometimes making new ones
- Adapting over time

Intermediaries can vary in different ways:

- Use different combinations of the tools
- Use the tools to greater or lesser extent

COMMON HEALTH PLAN DESIGNS

1. **Traditional insurance or traditional indemnity insurance.** This stereotypically involves minimal use of the tools.
    - Open panel
    - Fee-for-service
    - No gatekeepers
    - Limited use of utilization review
    - Often higher patient cost sharing.
2. **HMO.** HMO stands for health maintenance organization. It was meant to convey that these were health plans particularly focused on prevention and maintenance of health, perhaps distinguished from other traditional insurers that are focused on treating people once they got sick and less on keeping them healthy.
    - HMOs are in many ways the opposite of traditional indemnity insurance.
    - Defined network and closed panel
    - Stronger provider payment incentives
    - Gatekeep and utilization review common
    - Often less patient cost sharing
3. **PPO.** Stands for preferred provider organization. In-between traditional indemnity and HMOs.
    - Semi-open/semi-closed panel
    - Moderate provider payment incentives
    - Gatekeeper uncommon
    - Some patient cost sharing

"Managed care" is defined as plan designs where the intermediary exerts some efforts to manage the care of its enrollees through the use of the intermediary tools. HMOs and PPOs would be examples of managed care plans.

These are two illustrations of more recent developments in plan design:

1. High deductible plan.
    - Common structure: Similar to a PPO, but with higher deductible.
    - Has lower insurance premiums
2. Narrow network plan.
    - Common structure: Similar to an HMO or PPO, but with a smaller, more selected provider network.

DIFFERENT INTERMEDIARIES OFFERING HEALTH CARE COVERAGE

We commonly separate private insurers from public intermediaries.

Many countries use a combination of intermediaries, multiple public plans, multiple private plans, public and private plans, to suit their needs depending on histories, norms, and expectations of their populations, and a range of other factors.

Be clear that this is different from plan design, plan type. Some private insurance companies actually offer multiple choices of specific plans, each acting in different ways. Some public intermediaries do this too.

PRIVATE INSURANCE COMPANIES

Private insurance companies. These are the most common source of insurance for people under age 65 in the US. There are many different insurance companies that sell private insurance. Some of them are big essentially national in scope and many are smaller often more regional. They are subject to some oversight by government authorities.

Private insurance companies in the US offer a variety of different products- HMOs, PPOs, high deductible health plans, and many others, as they see opportunities to sell them.

The common thing in this market is for health insurance plans to cover a broad range of doctors, hospitals, testing, prescription drugs, and other services. And there are some types of services that are normally excluded, like long term care, optometric (eye care), dental care. You would buy separate coverage that specifically covers those items.

Private insurance in the U.S. is either bought by an individual or provided by an employer. The individual market is set up in each state. There may be subsidies to low-income people from the government. Note every employer offers coverage to their workers, and some people are self-employed, or not working, and don't get insurance from their employer. Thus, some people get private insurance by themselves, which is called, the "individual market." There are marketplaces that have been set up in each state, in which insurance is sold directly to individuals. One important feature of the individual market is that the government provides subsidies to some people with lower incomes to help them buy coverage.

MEDICARE

Medicare:

- Large public intermediary
- Covers people over age 65
- Covers the permanently disabled
- People with end-stage renal disease
- Largely financed through taxes, with some premiums from enrollees

Medicare is run by a government organization called the Center for Medicare and Medicaid Services (CMS).

Different structures and options:

1. Traditional Medicare (Part A and B)
    - Traditional indemnity coverage
    - Open panel
    - Little utilization review
    - No gatekeepers
    - Pays doctors using a fee schedule, and hospitals using a DRG system
    - High cost sharing
2. Medicare Advantage (Part C)
    - Medicare contracts with private insurance companies to take Medicare enrollees
    - A strong focus on just the Medicare market
    - Plans offered are often HMO or PPO plan types
3. Medicare Part D
    - Coverage for prescription drugs
    - Purchased as an add-on to traditional Medicare

- Often incorporated into Medicare Advantage plans

Medicare Supplement or Medigap: Supplemental insurance obtained by enrollees in traditional Medicare, to cover cost sharing or other things not covered by Medicare.

Medicare over time has been innovative in key areas, trying to achieve like acting as a pioneer in the creation of fee schedules and DRGs, and more recently encouraging the development of ACO models. At the same time, it has sometimes faced criticism for allowing too much choice and an outdated traditional insurance model in Parts A and B. But at the same time, they have been building Medicare Advantage, which brings in newer plan designs.

Medicare also offers good examples of interactions between private and public intermediaries. Overall, a lot we can see and learn from thinking about Medicare.

MEDICAID

Medicaid:

- Large public intermediary
- Covers lower income populations
- Overseen by both federal and state governments
- Largely financed by tax revenue

Medicaid offered in two main forms:

1. **Traditional Medicaid.** Original offering; generally traditional indemnity-style coverage
2. **Medicaid Managed Care.** More commonly found; HMOs or other managed care plans for Medicaid recipients

An important challenge with Medicaid over the years has been limited funding, and as a result, limited pay for the providers who take care of Medicaid patients, which has sometimes been a criticism and a political challenge for Medicaid.

Another challenge for Medicaid is that the limits for eligibility vary from one state to another. A result is that its ability to meet its goal of covering low income populations is met to differing degrees in different places, which can raise concerns.

Medicaid's greatest issues appear to stem from the challenges of raising sufficient funds for public programs in complex fiscal and political environments, particularly when the public program serves a subpart of the population that may face limitations in its political power.

LESSONS FOR AI AND DATA

Intermediaries' functions:

- Trying to figure out which tools to use and how to use them well
- Determine which providers to contract with
- Determine which providers in their network to drop
- Provide feedback to design payment approaches
- Determine complex medical care enrollees
- Determine which requests for pre-authorization should be approved
- Determine which hospital stays by their numbers are too long
- How to optimally set cost sharing
- Find most likely customers and market to them
- Process loads of bills for medical care claims
- Determine which claims to pay and which not
- Determine which, if any, have errors
- Determine which be fraud and which not

MODULE 5 - HEALTH CARE PRODUCTS AND PRESCRIPTION DRUGS, AND QUALITY MEASUREMENT AND IMPROVEMENT

LEARNING OBJECTIVES

- Describe the regulatory structure governing approval of prescription drugs
- Describe the role of patents and the role of generic drugs
- Describe the main institutions involved in negotiating drug prices and paying for pharmaceutical products
- Identify key organizing concepts for efforts to improve quality
- Identify structure, process, and outcome measures of quality
- Describe some different types of approaches to improving quality

HEALTH CARE PRODUCT REGULATION: OVERVIEW

Types of products and equipment

- Medical Devices
- Imaging Equipment
- Biologic Products
- Drugs

Most products or equipment used in medical care are regulated, in case of the US, FDA (Food and Drug Agency).

Drugs: Substances intended for use in the diagnosis, treatment, mitigation, cure, or prevention of disease.

Main groups of drugs:

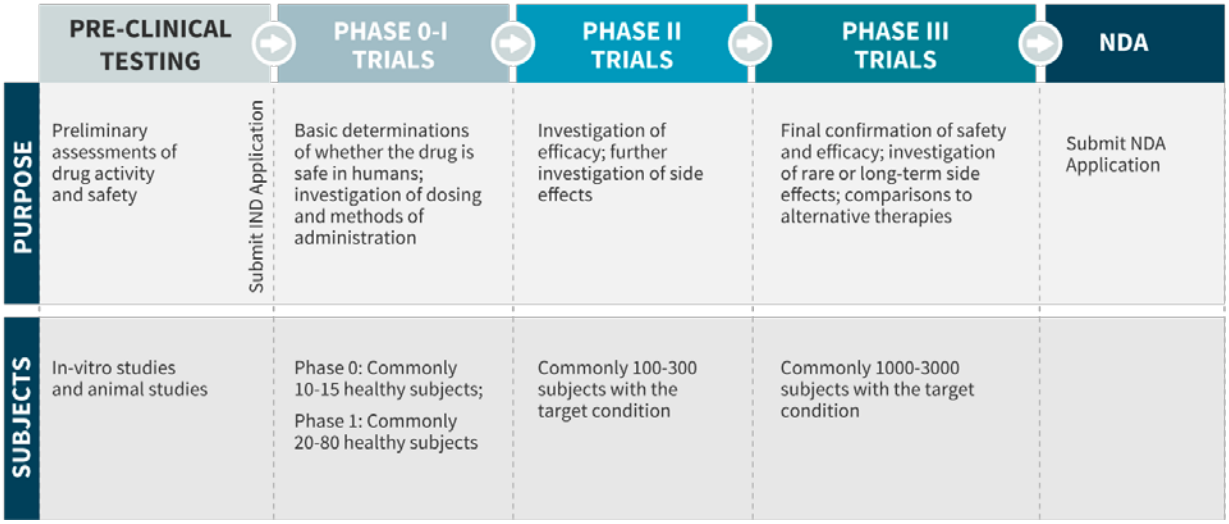
1. Prescription drug
    - Drugs that requires a prescription to obtain
2. Over-the-counter or OTC drugs
    - Drugs that do not require a prescription to obtain

From an approval and regulatory process, both prescription drugs and OTC drugs are regulated, but the processes are different. The process for prescription drugs is more involved, and prescription drugs have gotten a lot of attention lately.

PRESCRIPTION DRUG REGULATION AND PRICING

Prescription drug is a pretty complex area, with a lot of regulations. In the U.S., the Food and Drug Administration, or FDA, is tasked with overseeing prescription drugs - their specific mandate is to see that prescription drugs are safe and efficacious – they work. To sell a prescription drug in the U.S., one needs FDA approval.

Getting FDA approval involves a number of steps:



- Drug companies can start the normal approval process with the filing of something called an investigational new drug application, an IND for short.
- The FDA looks this over, and if approved, the company is allowed to begin the process of testing the new drug in humans. This involves a series of 3 different types of trials, called Phase I, Phase II, and Phase III trials.
    - Phase I trials are smaller, first steps, designed to test basic things about the drug including its safety in humans and dosages.
    - If Phase I trials are successful, then Phase II trials can be conducted on dozens or a few hundred people with the disease or condition of interest to test for effectiveness and side effects.
    - If Phase II trials are successful, then the company can move on to Phase III trials, with thousands of people to gather more data on effectiveness and outcome for longer terms.

If all of this goes well, then the company can file a new drug application or NDA. The FDA reviews this, and if approved, the company is finally able to begin marketing the drug – doctors can prescribe it and patients can buy it.

It takes a long time for drug approvals; 9 years is a general estimate number. It can be pretty expensive for the companies to do the work, many millions or even billions of dollars.

The FDA may continue to monitor drugs once they're on the market to assess their performance – sometimes people refer to these as Phase IV trials. FDA can regulate the labeling, manufacturing processes, and other aspects of the process of making and selling drugs.

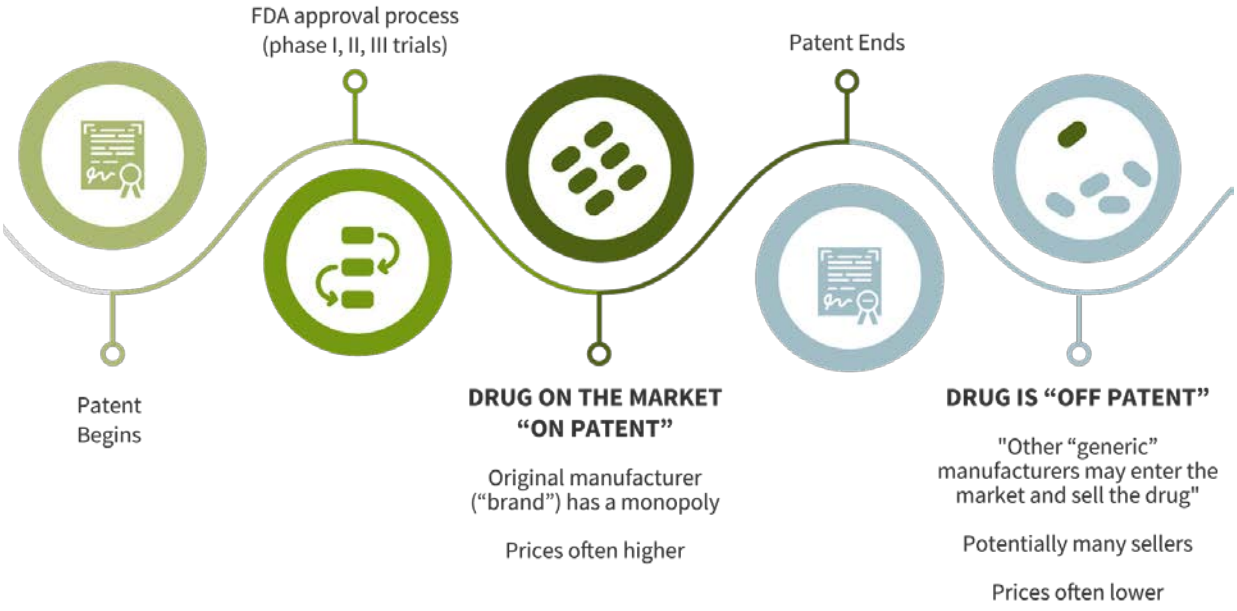
In other countries, the regulatory agencies are similar but it is a separate process.

PATENTS, BRANDED DRUGS, AND GENERIC DRUGS

For prescription drugs, an important distinction is between "branded" and "generic" drugs.

- **"Branded" drugs:** Drugs sold by the manufacturer that first brings the drug to market with patent protection
- **"Generic" drugs:** Drugs sold by additional manufactures after the primary manufacturer's patent expires.

A key part of this discussion has to do with patents.



Alongside the FDA approval process, a new idea for a drug can be seen as an invention and can be patented. When an inventor comes up with an invention and patents it, the inventor gets the right to be the only one selling the invention for a period of time, which can be called "market exclusivity."

The drug is brought to market with patent protection as a "branded" drug. They are sold as brand name products, which tend to be more expensive than generics.

After a while, patents expire, and other manufacturers may be able to figure out how to make the same drug. They could then start making it and selling it as well, which is called "generic drug" or just a "generic".

One important thing to note is the effect on price associated with the entry of generic drugs. While a drug is covered by a patent, and there is only the one seller allowed, prices tend to be higher. Once

generics enter the market, the arrival of more competition often leads to reductions in the prices charged for the drug, and these price changes are often notable.

INSURANCE AND FORMULARIES

When a patient is going to use a prescription drug, they need a prescription from a physician or other suitably authorized provider –The general rule is that you can't get a prescription drug without a prescription.

To get the drug, or sometimes we say to get the prescription "filled," the patient needs to take the prescription to a pharmacy. Pharmacies can be wholesale or retail, online or brick and mortar. Pharmacies are staffed by pharmacists, people with advanced training who are experts in different drugs and their uses, and how to handle them.

Most patients have insurance coverage to help them cover the cost of buying prescription drugs. It's common for insurance plans to have some provisions, that affect the drugs patients can use and the ways the insurer will cover them.

A key concept is the **formulary**; this is most generally the list of drugs that the insurance company will allow the patient to use and get reimbursed for.

Formularies can vary from one insurer to another, and formularies can be tiered.

- Tiered formulary: A formulary arrangement in which drugs are placed in different "tiers" with different levels of patient cost sharing

The insurer can create incentives for patients to use drugs in preferred tiers.

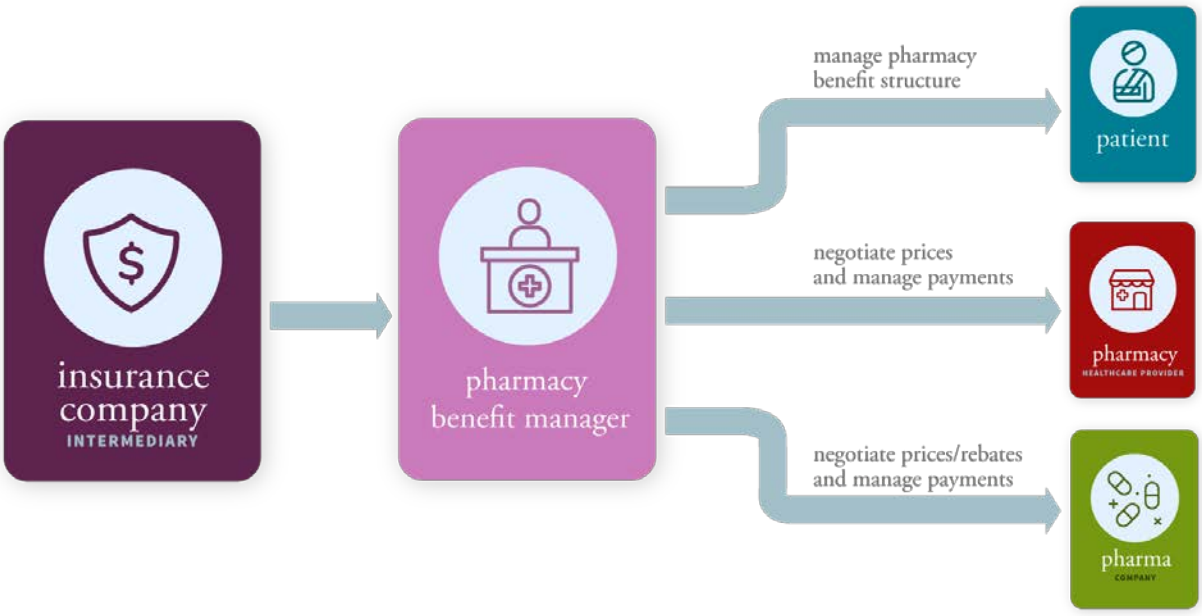
Plans may use utilization review, like pre-authorization, where a patient needs to seek pre-approval from the plan before getting the medicine. Plans may sometimes require "step therapy," where the plan might impose a requirement that a patient tries a more preferred drug first before they will cover a less preferred one.

INTERMEDIARIES, PHARMACY BENEFIT MANAGERS, DRUG PRICES, AND REBATES

An interesting and important set of interactions in the health care system revolves around negotiating prices and payments between insurers and drug manufacturers for prescription drugs and managing the prescription drug portion of insurance plans.

Two things intermediaries do with respect to prescription drug benefits:

1. Work out prices to be paid to manufactures when covered patients use prescription drugs
2. Set up the structure of insurance benefits for prescription drugs

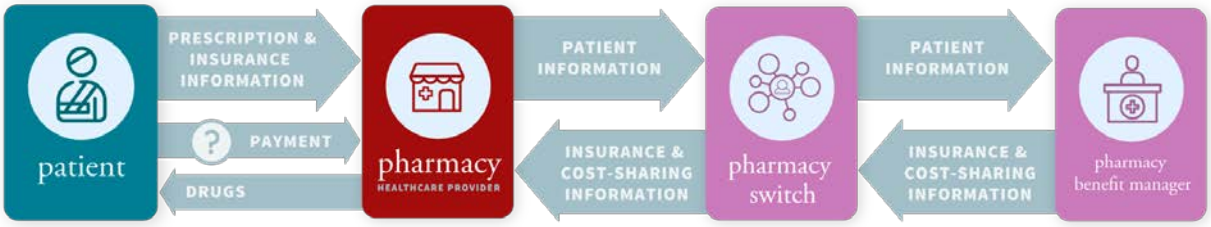


Most intermediaries commonly contract with a third party, called a **pharmacy benefit manager**, or **PBM**, to handle these things. PBMs can manage prescription drug coverage.

Three things PBMs can do:

1. Manage the design of prescription drug benefits (formularies or networks)
2. Manage payments to pharmacies
3. Negotiate prices with pharmacies and negotiate rebates with manufacturers

PBMs are an important player in this world. When trying to understand prices that insurers pay for prescription drugs, you have to always keep in mind the rebates. If you see, for example, the retail prices paid by PBMs to pharmacies, this may or may not be a reflection of the actual amount an insurer paid at the end of the day, net of rebates.



While we're talking about the interesting world of prescription drug benefits and the entities involved in them, there is one more interesting entity to note here, a company commonly called a **pharmacy switch**.

- **Pharmacy Switch:** A third-party vendor used by pharmacists to transmit claims from the pharmacy to the PBMs

They help the pharmacy determine all the rules about who pays what for what--as in co-pay. They can take the insurance information, figure out which PBM is handling the coverage for the patient, electronically get the info about cost-sharing or other rules from the PBM, and then turn around and send it back to the pharmacy.

The pharmaceutical space has lots of interesting things going on in it relevant to innovation and data. Drug discovery and FDA approvals are very interesting areas, with lots of opportunity for innovations in figuring out new targets and new areas for research, and in working on the data and studies that are part of the approval processes. On the insurance and payment side, prescription drugs can be quite expensive, so there is a lot of room for innovation that can help manage the use of drugs, figure out processes to make the best use of drugs when there are different choices, figure out which patients will be the best candidates for drugs and so on.

Insurers can have a lot of data, and pharmacies may have some. But PBMs and switches may as well, and may actually offer different angles of insight into what is happening.

QUALITY MEASUREMENT AND IMPROVEMENT

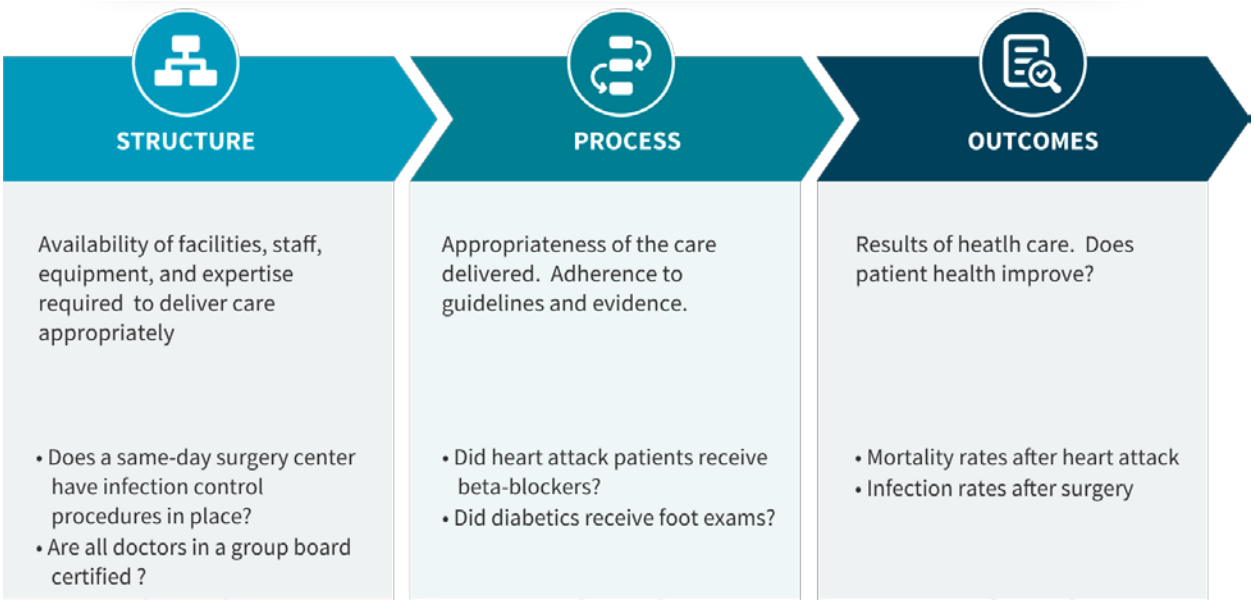
KEY ORGANIZING CONCEPTS OF QUALITY

Six domains of quality: widely known in a report on quality from the U.S. Institute of Medicine since renamed the National Academy of Medicine, published in the early 1990s. The acronym, sometimes people use STEEEP – safe, timely, effective, efficient, equitable, person-centered.

The six domains are:

1. Safe
2. Effective
3. Patient-centered
4. Timely
5. Efficient
6. Equitable

Overuse-underuse-misuse framework: When the healthcare system either uses too much health care, or not enough health care, or uses the tools at their disposal in the wrong way or at the wrong time.



Structure-Process-Outcomes: Also called as the Donabedian model. It was three process, which is structure, process and outcome.

Individual and Team: Health care is often delivered in teams, with multiple people and organizational structures. It is important for individuals to be well trained and focused on quality, of course. But it can also be very important to getting teams and organizations to work well.

QUALITY MEASUREMENT - STRUCTURE

Building and using quality measures has become a central component of efforts to improve quality, and we should look into some of the basic aspects of quality measurement.

When we talk about measuring quality, one thing we always need to keep in mind is whose quality are we measuring?

Different measurement levels:

- Measure quality for a provider or group of providers
- Measure quality for a health plan or intermediary
- Measure quality of care provided to an individual or a group of people

A very commonly encountered framework for thinking about quality measurement is **Structure-Process-Outcome**:

- How is care delivered?
- Does the health care system have a structure conducive to delivering quality?
- Are there enough providers, in the right places, with the right training and skills?
- In the equipment and infrastructure organized and financed in ways that enable them to work effectively?

Structural quality measures for providers:

1. Is a good EMR or EHR system in place?
2. Can an organization document that they have emergency protocols in place, can they document that they have protocols to prevent the spread of infections?
3. Are the physicians or other providers appropriately credentialed?
4. Are the facilities accredited, licensed, and certified appropriately?

Structural quality measures for health plans or populations:

1. Are there enough physicians and other professionals for the population being served?
2. Are there enough hospital beds?
3. Where are they located with respect to the population?

Data used for structural quality measurement can come from a variety of sources. Structural measurement is pretty commonly done. Often when you look at different measures, the more structural ones look like the easier ones to construct. At the same time, they may be the furthest from actual health outcomes, which is what we most care about, so quality measurement these days often goes beyond just structural quality.

QUALITY MEASUREMENT - PROCESS

One aspect of quality measurement in health care that has gotten a lot of attention focuses on processes of care are "**process measures**", or "**process measurement**".

The core idea is that if you have an outcome in mind that you want to achieve, then you can work to identify some processes that would lead to that outcome Then you design measurement around those processes, to track things like whether they are occurring and how often.

One very common way of approaching process measurement focuses on measuring whether generally accepted recommendations for clinical practice are followed. This would commonly involve specifying a population of people or patients of interest, specifying a particular treatment or procedure for which there is evidence of benefit, based on research or possibly on other things like professional opinion, and then creating a method to measure and track the share of the population that gets the recommended service.

One can define those populations, and then query databases or use some other method to see if people in those groups get recommended care or not. One can go gather data and assess whether the symptom/disease is happening. A variant is measuring care that should not be delivered, situations where evidence says not to do a particular type of procedure.

Process measures are probably the most common form of quality measures. Process measures can be created for different types of organizations.

There are a variety of sources of information for process measures. Often EMR or claims databases can be used to identify patients and track whether they got recommended care or not. There are registries that are sometimes used; registries are databases that try to collect and compile relevant information about all or at least many patients with a given condition or patients receiving a particular treatment, often for the purposes of having a resource for monitoring or improving quality.

QUALITY MEASUREMENT - OUTCOME

One very salient measure of quality is the **outcomes** of care.

The core idea here is that we define something we want to happen, or not happen, and see if it does or not. How is their health status, quality of life, or life expectancy impacted? This could also include things like whether their behavior changed, or their knowledge is improved.

Outcome measure examples:

1. Mortality Rates
2. Readmission Rate
3. Complication Rate
4. “Potentially Preventable” Admissions

- Sometimes these are called "ambulatory care sensitive admissions" or "potentially preventable admissions."

5. Patient-reported outcome measures
    - Called by their acronym P-R-O-M, or PROMs

Outcome measures have many attractive features, but can also face challenges. One key challenge is the possibility that, while variations in outcomes from one provider or health plan, to another may be the result of differences in actual underlying quality, they could also be the result of other things, some beyond the control of providers or plans. Depending on the situation, this can be an important factor – there can be major differences in the patients cared for across providers, though there are not always.

As a result, doing a good job of measuring outcomes usually involves adjusting for risk.

- **Risk adjustment**: Approaches designed to correct for differing characteristics of patients

QUALITIY IMPROVEMENT

Quality measurement. Doing a good job of this can take some real effort and involve multiple aspects. One aspect is finding the right set of measures to use. Structure, process, and outcome measures can all be useful in different circumstances, and often they are useful in combinations.

Measurement activities are being developed and implemented by a variety of different entities. Some measurement activities are undertaken by organizations working to improve quality. The National Center for Quality Assurance has developed a system of quality measurement for health plans called the Healthcare Effectiveness Data and Information Set, or HEDIS, that includes a range of measures (structure, process, and outcome) that can be used to compare health plans.

Government organizations may be involved in quality measurement such as the Medicare program that has developed tools for measuring the quality of health care providers.

Providers themselves are often measuring quality and assessing their own performance. Sometimes individual hospitals or doctor practices will implement quality measures.

What then to do with the quality data being collected? There are several different things being done.

Uses of quality data:

1. Monitoring and improving provider quality
2. Public reporting
3. Designing payment incentives

Measuring quality and using measures to try and drive improvement is an important area in the health care system, with many different aspects to keep eye on, lots of activity, and lots of opportunities for further investigation and innovation.

Quality has gotten a lot of attention and generated a lot of work. There remain a number of important opportunities for people with interests in data and measurement, and interests in AI. Some of the opportunities for innovation are in measurement. There are multiple domains of quality – as the STEEEP framework, like effectiveness or safety, and there are in others like equity or patient-centeredness and risk adjustment.

There may still be room for innovative ways to figure out how to use them to guide treatment choices, figure out the best choice of provider for patients, figure out the best network for a payer, figure out the best incentives to attach to quality measures, and other implementation steps that can further our pursuit of improved health care quality.

MODULE 6- ETHICS

OVERVIEW OF AI APPLICATIONS IN DELIVERY OF HEALTH CARE SERVICES AND ETHICAL ISSUES

There are many parts of a modern health care system, each of which collects and analyzes data. Health care providers and intermediaries such as health insurance companies and government programs such as Medicare and Medicaid generate huge amounts of data about patients.

Potential applications of artificial intelligence:

- Increasing the accuracy of diagnosis
- Robotic surgeries
- Identifying candidates for drug development
- Determining the best treatments to use for specific patients

Artificial intelligence raises ethical issues that should be considered by its developers and users and important stakeholders such as patients.

What are the ethical issues? Very broadly speaking, the questions we should ask are:

1. Do artificial intelligence tools help or harm patients, their families and caregivers, or health care providers?

2. Are these tools socially just or not?

These ethical issues can arise from different aspects of AI:

- The nature of the data that are used
- The way the data are collected
- The way that AI models are designed
- How their output is interpreted and used

A big ethical concern raised by AI is about **the privacy and security of digital data**, especially in the domain of health care because health care data are **sensitive**.

AI can lead to conclusions that are **biased based on systematic error** because their models are trained on data that are unrepresentative of populations or features of interest.

Systematic error in AI models is especially bad in the health care context, since the output of these models can affect important and even life-and-death decisions. Systematic errors can lead to unfair decisions, especially if they discriminate against whole categories of socially-disadvantaged people such as racial minorities, women, children, and people with low incomes.

One type of ethical concern that is particularly relevant to AI is due to the **lack of transparency** of AI models.

Currently there are few standards or regulations for evaluating safety and effectiveness of many AI-based products used in health care.

It is critically important for clinicians and health systems that use AI in ways that can influence health care decisions to understand the limitations of the AI techniques, data and models as they are applied to their specific patient populations.

One type of ethical concern that we will focus on in this course is the issue of **conflicting or competing interests**. This is an issue that arises particularly in the domain of health care.

ETHICAL FRAMEWORKS FOR HEALTH CARE AND FOR AI

There are many ethical, legal and regulatory factors that determine and constrain the financing and delivery of health care in ways that do not apply to other types of products and services.

Broad ethical frameworks that are applicable to developing and using AI in the health care context:

1. All professionals are ethically bound and guided by professional ethics through codes and guidelines
    - Professionals: Those entrusted with the well-being of people who seek their specialized expertise in times of need
2. Physician are allowed access to their patients' private health and financial information and are even allowed to do things that would be considered criminal in other contexts. The social contract that is implicit in the concept of professions allows such actions if they are necessary to serve the well-being of clients
3. A key feature of professions is that they are given a lot of leeway to self-regulate
4. Professionals have fiduciary duties (ethical obligations to serve the best interests of their clients)
    - Clinicians have to rely on regulators and drug and device manufacturers to ensure that the diagnostics and treatments that they provide to patients are safe and effective
    - The regulatory systems in place to evaluate drugs and devices, and the certification systems to evaluate hospitals and laboratories are critical to maintaining trust of both clinicians and patients. This becomes very important when thinking about how to develop artificial intelligence for health care applications, because these systems need to be trusted in order to be implemented successfully.

While clinicians and health care organizations are trying to serve the best interests of their patients, they have interests of their own and are subject to many competing or conflicting interests.

Most importantly in the context of health care delivery are financial interests. Understanding the interplay of these interests and how they are shaped by the structure of the health system is critical to understanding how AI models can be aligned or misaligned with these interests and affect patient care and well-being.

AI AND INCENTIVES IN HEALTH CARE DELIVERY AND PAYMENT STRUCTURES

Large, complex health care systems exist in an environment of explicit incentives intended to drive behavior of patients and health care providers. These incentives are often for the purpose of improving the efficiency of health care.

How to improve the efficiency of healthcare:

1. Improve the quality of care
2. Reduce health care costs or the utilization of health care resources

The existence of incentive structures that are built into health care systems through payment models means that physicians, hospitals and insurers need to measure things related to quality of care, costs and utilization. These incentive structures have also led to classifying and predicting features of patients and patient care.

AI is particularly good at classifying and predicting, especially using really large datasets, and especially in terms of probabilities. AI-based predictive analytics are feverishly being applied to health data for classifying and predicting.

"Big data": Really large numbers of patients and huge amounts of electronic information. These data can be collected from individual patients from medical records, digital images and monitors.

AI is not only useful for analyzing big data but actually necessary for improving the accuracy of classification and prediction. AI models are designed to predict or identify sources of risk. AI can be particularly good at identifying risk that is unexpected or less obvious, but has limitations when applied to health data, and these limitations have ethical implications.

Types of risk:

- The probability of facing a financial loss associated with the use of healthcare. Financial risks are largely measured and predicted from the perspective of health care systems, providers, and insurers.
- The probability of medical harm associated with the use of health care

Example of applications that use AI-based predictive analytics:

> An insurance company builds an AI model that uses insurance claims, electronic health records and consumer data to predict which of its members are likely to incur the highest costs of care over the next year.
>
> An ethical challenge in building this model arises because we know that vulnerable populations such as the poor, people with disabilities, and people from racial and ethnic minorities tend to incur disproportionately high health care costs. In order to minimize the chances that predictive models discriminate against patients in these vulnerable groups, it is important for the model to risk adjust accurately.
>
> The data that are available in health care domain rarely reflect what we actually want to measure. That means that our measurements used for predicting and classifying are **proxy measures**. When you use proxy measures, this introduces the possibility of systematic error, or bias because proxies are always imperfect. When the possibility of bias is introduced, there

is also the possibility of discrimination, which is bias that leads to negative consequences for certain groups.

It is important to recognize the limitations of the models that are created when you lack data that are necessary to really explain the outcome of interest.

Deep knowledge of the clinical characteristics of patients represented in datasets and familiarity with the limitations of available data are necessary to avoid ethical pitfalls in model design.

MORE EXAMPLES OF AI AND INCENTIVES IN HEALTH CARE DELIVERY AND PAYMENT STRUCTURES

An example of a common application of AI:

A large information technology company sells analytic services to health systems to integrate patients' health data with insurance claims data to help reduce inpatient admissions, emergency department admissions, and readmissions

This model has been developed to predict hospital readmissions within 30 days of discharge. These predictive analytics have been developed in response to the Medicare Hospital Readmissions Reduction Program, or HRRP, which fines hospitals when they have excess readmissions within 30 days, after adjustment for medical risks. The program was designed to create financial incentives to reduce avoidable readmissions.

There is evidence that the imposition of fines does reduce readmissions. However, there is also evidence that the way that admissions are reduced might also lead to the unintended consequence of poorer or inappropriate care, or no care at all.

How information from a predictive model gets used in actual practice is also ethically relevant

Here is another example:

A health system develops a model to predict costs of patients who have joint replacements

This application of AI would be developed in response to a type of incentive program designed to encourage value-based care, and is known as bundled payments.

- **Bundled payments**: focus on lowering costs of care by paying multiple providers for what are called "episodes of care" for certain conditions. Payment is bundled for all of the care and

providers as a group manage the costs. If the costs of caring for the patient exceed the bundled payment, the providers share the burden. If the costs are lower than the payment, providers share what is left.

- The intent of bundling payments for services included in an episode of care is to create incentives to improve patient outcomes in transition through better coordination of care. The intention is to align incentives of providers across a series of health care settings.

There are existing health disparities that could interact with the bundled payment programs to exacerbate these disparities. If predictive models do not include the right data, and do not risk-adjust appropriately, health disparities could be reinforced.

These are the main takeaway points:

- Health care systems deliberately use incentives
- These incentives make it useful to predict risk, AI can improve the accuracy
- Incentives can have unintended consequences
- It is important to understand and anticipate the impacts of proxy measures and the limits of health data on bias in models
- Important to understand how behavior of those who use the output of models could be affected in ways that could create unintended consequences

In short, fairly sophisticated and detailed knowledge of how health care services are delivered and paid for are necessary to understand how to build good and ethical AI models