Overview of Clinical Care

6.871/HST.956: Machine Learning for Healthcare

February 3, 2022

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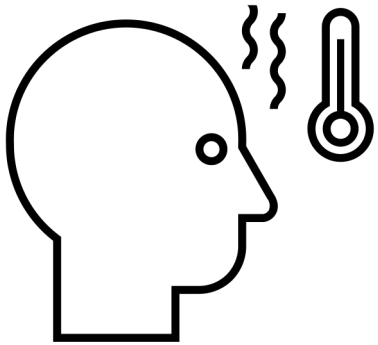
Overview of Clinical Care

- Topics of discussion
  - Stakeholders in healthcare
  - Diagnostic process
  - Access to clinical data

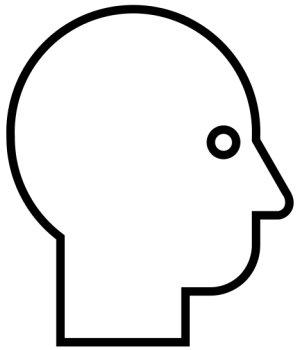
Healthcare Oversimplified



Patient presents with a **sign** OR **symptom**

Physician treats patient for underlying illness, manifesting with **sign** or **symptom**

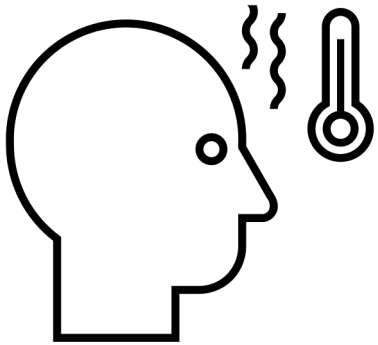
Treatment is provided



Patient returns to (previous or new) state of health

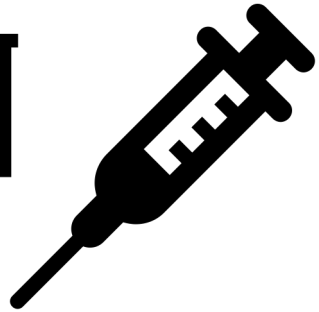
Stakeholders in Healthcare

Providers

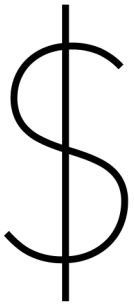


Patient

Physician



Treatment



Payer

Policymaker

"The Four Ps" of healthcare

Stakeholders in Healthcare

- Major – "The Four Ps"
  1. Patients
  2. Providers
  3. Payor
  4. Policymakers
- Other
  - Industry
  - Research community
  - Regulators
  - Etc.

Stakeholders have different goals and expectations from the healthcare system

Lübbeke, Anne, Andrew J. Carr, and Pierre Hoffmeyer. "Registry stakeholders." *EFORT open reviews* 4.6 (2019): 330-336.

A Patient's Perspective

- Tell us about a time that
  - Healthcare worked
  - Healthcare didn't work
    - And ML may have been helpful?

A Patient's Perspective

- I woke up this morning and my urine was red. I got scared, I've never seen that before.
- I went to the ER with my wife.
  - What are the goals of the patient?
  - What are the expectations of the patient?
- I took a number and waited for it to be called. I then saw the nurse and told them what had happened. The nurse took my information and told me to wait until I was called.
  - What is the purpose of triage?
  - What information is used to triage patients?

Triage note

- Jim Jones
- DOB: 10/18/1957
- Address: 8035 King Street, Boston, MA
- History of presenting illness: Gross hematuria x1 episode this AM.
- Exam:
  - Appears anxious
  - Vitals: HR 85, BP 130/90, temperature 37.8, RR 20
- Time of arrival to ER: 13:14

A Patient's Perspective

- I woke up this morning and my urine was red. I got scared, I've never seen that before.
- I went to the ER with my wife. The nurse took my information and told me to wait until I was called.
- **About an hour later, I got called in to see the doctor.**

A Provider's Perspective

- After clicking "Submit" for the orders in the last patient's chart, the next chart in the triaged order is "picked up" by the ER physician.
  - What are the goals of the provider?
    - Do the goals of the ER differ than other clinical settings?
  - What are the expectations of the provider?
  - What are potential tasks that the physician may perform in their interaction (beginning to end) with the patient?

Tasks of a Physician

- Prevention
  - Smoking cessation strategies to decrease risk of bladder cancer
- Diagnosis
  - Cause of blood in the urine (gross hematuria)
- Treatment
  - Antibiotics of urinary tract infection
- Prognosis
  - Expected course after treatment
- Documentation
- And more!!

A Provider's Perspective

- After placing orders in the last patient's chart and signing the encounter, the next chart in the triaged order is "picked up" by the ER physician.
- **The physician assesses the triage note and begins the diagnostic process**

Diagnostic process

- How does it work?
  - Varies by specialty
  - Varies by individual

Diagnostic process

- My approach (in two steps)

1. Access knowledge **database** on the different possible diagnoses i.e. **differential diagnoses** related to that **sign** or **symptom**
2. Obtain **data** to narrow differential diagnoses, **n number of times**, until enough **data** is gathered to make a diagnosis

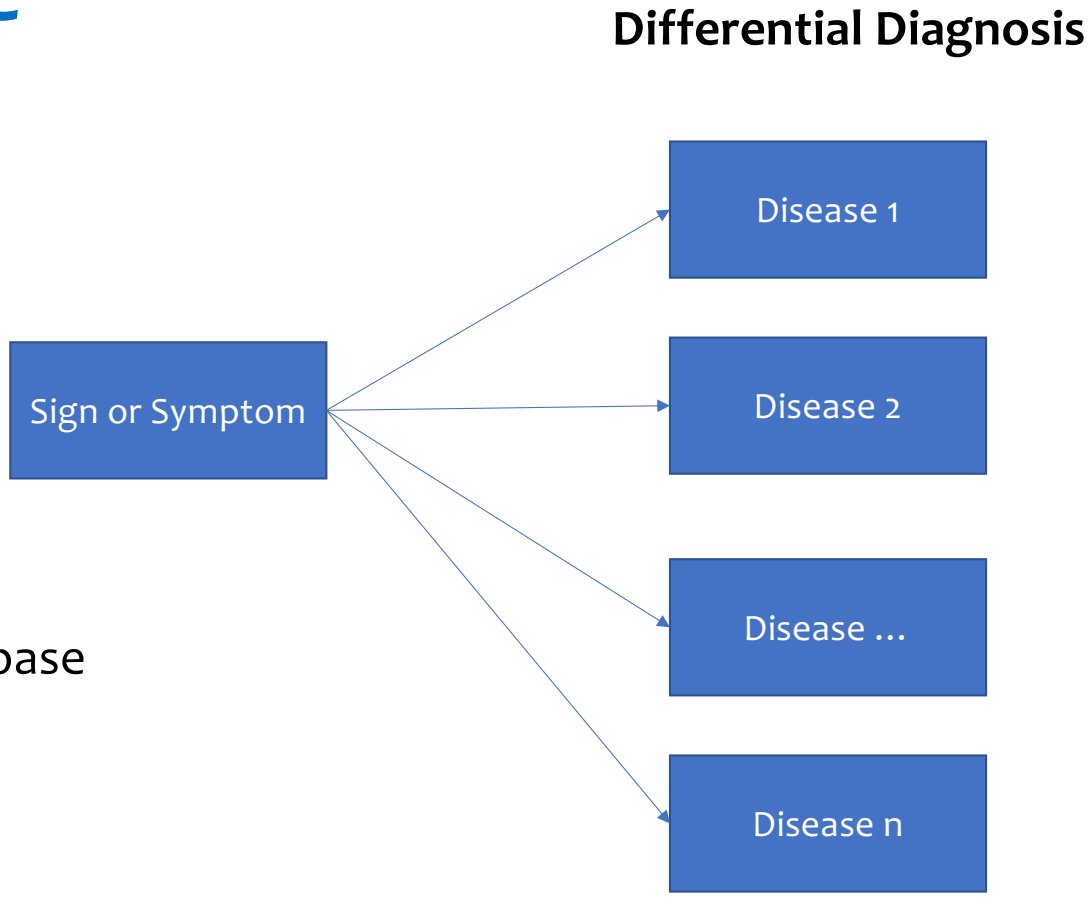
Diagnostic process

- My approach

1. Access knowledge **database** on the different possible diagnoses i.e. **differential diagnoses** related to that **sign** or **symptom**

Knowledge Database

- +/- prior experience
- Medical school (4 years)
- Residency (5 + 3 years)
- +-/ Fellowship (2 years)
- Attending (until I retire)
  - Build & **update** the knowledge database
  - **"The key to becoming a medical specialist, in any discipline, is experience."**



Diagnostic process

- My approach

1. Access knowledge **database** on the different possible diagnoses i.e. **differential diagnoses** related to that **sign** or **symptom**
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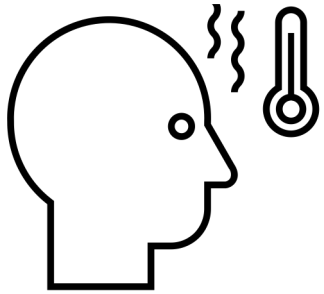
Iterative process

What data are obtained in healthcare?

Types of data in healthcare

- History
  - Symptoms and their details, past medical/surgical history, medications, allergies, family history, etc.
- Physical exam
  - Height, weight, BMI, vital signs (temperature, blood pressure, heart rate, etc), tenderness, erythema (redness), etc.
- Labs
  - Complete blood count, serum electrolytes, urine culture, blood culture, etc.
- Imaging
  - Chest x-ray, CT scan, bone scan, MRI, ultrasound, etc.
- Pathology
  - Biopsy, surgical pathology
- Genetics
  - Germline testing, etc.

Diagnostic Process in Action



A **65M** is referred to you for **gross hematuria symptom**

1. Access knowledge **database** on the different possible diagnoses i.e. **differential diagnoses** related to that **sign** or **symptom**

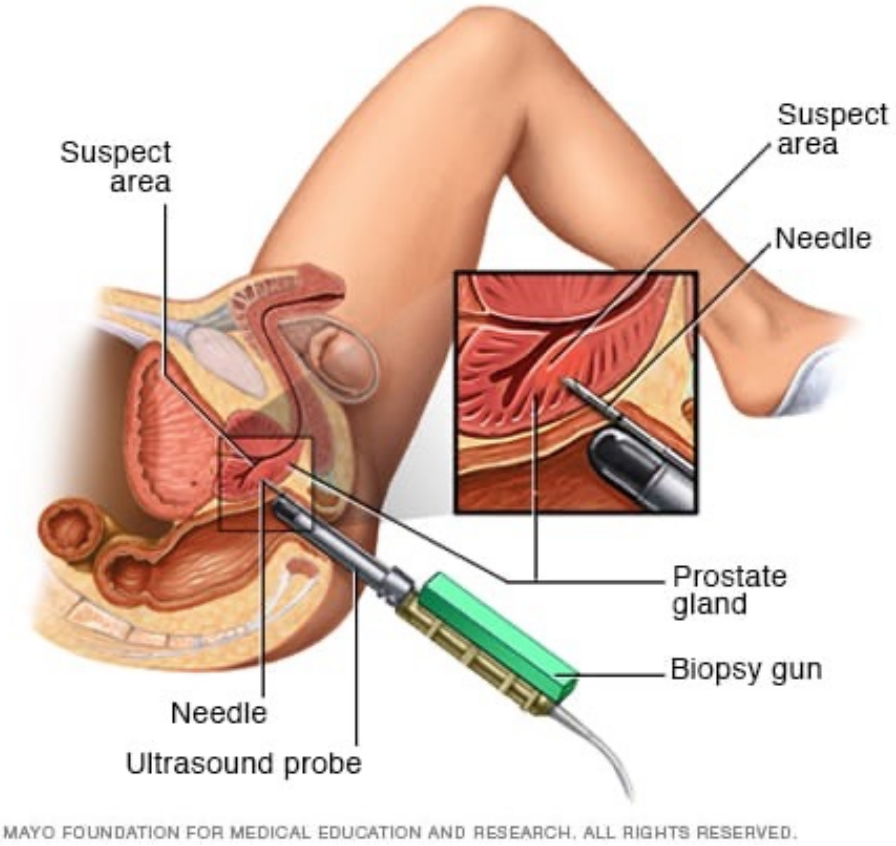
- Malignant
  - Anywhere along the urinary tract
    - Kidney
    - Ureter
    - Bladder
    - Prostate
    - Urethra
- Non-malignant
  - Infection
  - Stone
  - Trauma
  - Benign prostatic hyperplasia (BPH)
  - Etc.

Narrow the Differential Diagnoses

- Obtain **data** to narrow differential diagnoses
- Malignant
  - Anywhere along the urinary tract
    - Kidney – CT scan
    - Ureter – CT scan
    - Bladder - Cystoscopy
    - Prostate – Digital rectal exam (DRE), PSA, Prostate biopsy
    - Urethra - Cystoscopy
- Non-malignant
  - Infection – History, urine culture
  - Stone – CT scan
  - Trauma - History
  - Benign prostatic hyperplasia (BPH) – History, DRE
  - Etc.
- **Testing can be invasive, associated with risks, and costly**
  - **Selective testing is needed to minimize these**

Invasive

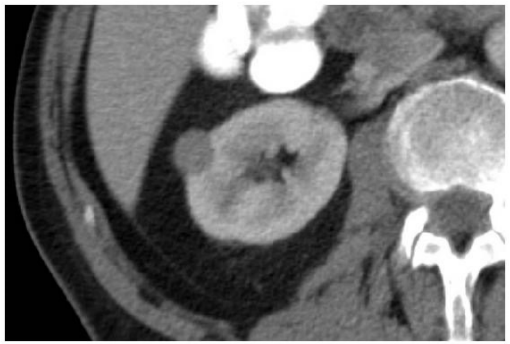
- Prostate biopsy
  - Patient discomfort



https://www.mayoclinic.org/tests-procedures/prostate-biopsy/about/pac-20384734

Risks of CT scan

1. Increased possibility of cancer induction from x-ray radiation exposure.
2. May demonstrate a benign or incidental finding, leading to unneeded, possibly invasive, follow-up tests that may present additional risks
   - 20-30% of small renal mass are benign



https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/what-are-radiation-risks-ct
https://www.hindawi.com/journals/au/2008/415848/fig9/

Radiation exposure from CT scan

- Radiation exposure measured in millisieverts (abbreviated mSv)

Diagnostic Procedure	Typical Effective Dose (mSv)[1]
Chest x-ray (PA film)	0.02
Lumbar spine	1.5
I.V. urogram	3
Upper G.I. exam	6
Barium enema	8
CT head	2
CT chest	7
CT abdomen	8
Coronary artery calcification CT	3
Coronary CT angiogram	16

Radiation dose from CT procedures varies from patient to patient.

https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/what-are-radiation-risks-ct

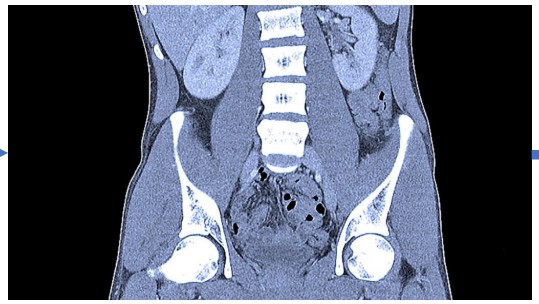
Risk of cancer with a CT scan

Overall risk of cancer

Baseline risk of fatal cancer: 1 in 5

400 in 2000

1 CT = ≈10 mSv



401 in 2000

↑ risk of cancer 1 in 2000

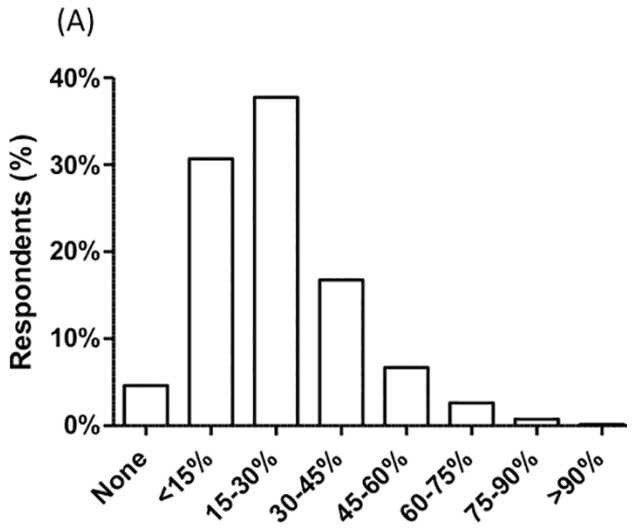
https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/what-are-radiation-risks-ct

https://www.medicalnewstoday.com/articles/abdominal-ct-scan

Costs of Unnecessary Tests

- ≈30% of US health spending in 2009 ($750 billion) was wasted on unnecessary services, excessive administrative costs, fraud, and other problems
- Survey of 2,106 physicians from the American Medical Association

In your specialty, what percent of overall care do you think is unnecessary?



- **20% of overall care unnecessary**
  - Most common cited reasons for overtreatment
    - Fear of malpractice (84.7%)
    - Patient pressure/request (59.0%)
    - Difficulty accessing medical records (38.2%)

McGinnis, J. Michael, et al., eds. "Best care at lower cost: the path to continuously learning health care in America." (2013).
Lyu, Heather, et al. "Overtreatment in the united states." *PloS one* 12.9 (2017): e0181970.

Characteristics of an ideal test

- Non-invasive
- Low-risk
- Inexpensive
- **Reflect the truth**
  - **Sensitivity**
  - **Specificity**
  - **Positive predictive value**
  - **Negative predictive value**

Test Performance

- Purpose of test is to determine the **ground truth**
  - In healthcare, the ground truth is the underlying illness that may explain the patient's **symptom** or **sign**
- Test results are often classified as **positive vs. negative**
  - In healthcare, we want to correctly classify patient (ie: disease present or absent).

Test results may or may not reflect the **ground truth**

Test Performance Characteristics

		DISEASE (GROUND TRUTH)	
		Present	Absent
TEST RESULT	Positive	a	b
	Negative	c	d

Test Characteristics in Healthcare

- In healthcare, when would you want a sensitive test?
- In healthcare, when would you want a specific test?
- What happens if the test result is continuous?
- How does prevalence of disease influence test characteristics?

Narrowing the Differential Diagnoses

- **Selected testing is important**
  - Consider invasiveness, safety, cost, and ability to reflect truth when selecting tests
  - **Other important considerations?**
    - Most likely diagnosis (highest probability)
      - In the population (of my clinical setting)
      - In this patient
    - Most serious diagnosis
      - "Cost" of delayed/missed diagnosis

Cause of diarrhea?
Resource-rich country
vs.
Resource-poor country

Differential Diagnosis of Gross Hematuria

	Prevalence
Kidney cancer	+
Ureteral cancer	+
Bladder cancer	+
Prostate cancer	++++++
Urethral cancer	+
Infection	+++++++
Stones	+++++++
Trauma	+
BPE	+++++

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

Differential Diagnosis of Gross Hematuria

	Prevalence	Associated with GH
Kidney cancer	+	+
Ureteral cancer	+	+++
Bladder cancer	+	++++++
Prostate cancer	++++++	+
Urethral cancer	+	+
Infection	+++++++	++++
Stones	+++++++	+
Trauma	+	+++
BPE	+++++	++++

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

Updating the differential diagnosis

- A study of the ER population at this hospital has shown that
  - Prevalence of prostate cancer and bladder cancer are 30% and 5%, respectively
  - 1% of patients with prostate cancer present with gross hematuria, compared to 80% of patients with bladder cancer
- What is the probability that a patient from the ER at this hospital with gross hematuria has
  - Prostate cancer?
  - Bladder cancer?

values for illustrative purposes

Bayes' Theorem

- $P(A \mid B) = P(A) \times P(B \mid A) / P(B)$
- P(disease|test) = P(disease) x P(test|disease) / P(test)
- P(disease|symptom) = P(disease) x P(symptom|disease) / P(symptom)

- What is the probability that a patient from the ER at this hopsital with gross hematuria has
  - Prostate cancer?
  - Bladder cancer?

Hall, G. H. "THE CLINICAL APPLICATION OF BAYES'THEOREM." *The Lancet* 290.7515 (1967): 555-557.

Updating the differential diagnosis

- What is the probability that this patient with gross hematuria has
  - Prostate cancer? p(PCa|GH)?
  - Bladder cancer? p(Bca|GH)?

	Gross hematuria YES	Gross hematuria NO	1000 patients with mutually exclusive diagnoses
Prostate Cancer			
Bladder Cancer			
…			
nth differential diagnosis			
Total			

Updating the differential diagnosis

- What is the probability that this patient with gross hematuria has
  - Prostate cancer? p(PCa|GH)?
  - Bladder cancer? p(Bca|GH)?

	Gross hematuria YES	Gross hematuria NO	1000 patients with mutually exclusive diagnoses
Prostate Cancer			=p(prostate cancer) * 1000 =0.30*1000=300
Bladder Cancer			=p(bladder cancer) * 1000 =0.05*1000=50
…			
nth differential diagnosis			
Total			1000

Updating the differential diagnosis

- What is the probability that this patient with gross hematuria has
  - Prostate cancer? p(PCa|GH)?
  - Bladder cancer? p(Bca|GH)?

	Gross hematuria YES	Gross hematuria NO	1000 patients with mutually exclusive diagnoses
Prostate Cancer	=300*0.01 =3		300
Bladder Cancer	=50*0.80 =40		50
…			
nth differential diagnosis			
Total			1000

Updating the differential diagnosis

- What is the probability that this patient with gross hematuria has
  - Prostate cancer? p(PCa|GH)?
  - Bladder cancer? p(Bca|GH)?

	Gross hematuria YES	Gross hematuria NO	1000 patients with mutually exclusive diagnoses
Prostate Cancer	3	297	300
Bladder Cancer	40	10	50
…			
nth differential diagnosis			
Total			1000

Updating the differential diagnosis

- What is the probability that this patient with gross hematuria has
  - Prostate cancer? p(PCa|GH)?
  - Bladder cancer? p(Bca|GH)?

	Gross hematuria YES	Gross hematuria NO	1000 patients with mutually exclusive diagnoses
Prostate Cancer	3	297	300
Bladder Cancer	40	10	50

Bayes' Theorem

$P(A \mid B) = P(A) \times P(B \mid A) / P(B)$

P(disease|test) = P(disease) x P(test|disease) / P(test)

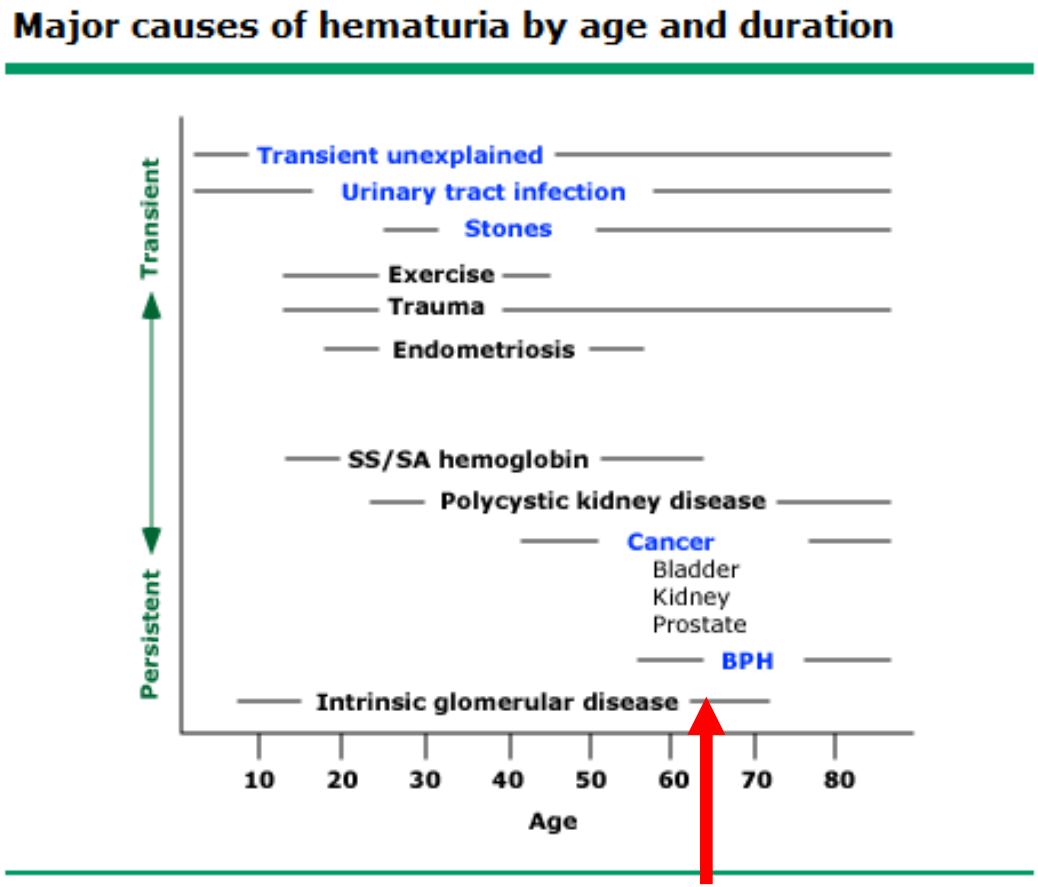
p(Pca|GH) = 0.3 x (3/300) / P(test)
=0.003/P(test)
P(Bca|GH) = 0.05 x (40/50) / P(test)
=0.04/P(test)

Narrowing the Differential Diagnoses

2. Obtain **data** to narrow differential diagnoses, **n number of times**, until enough **data** is gathered to make a diagnosis

- A **65 year old male** is referred to you for **gross hematuria**?
- What **data** has already been provided to narrow the differential diagnosis in this patient?
  - Age
  - Sex
  - Symptom = gross hematuria

Narrowing the Differential Diagnoses



Mostly likely diagnosis varies by Age

UpToDate®

Differential Diagnosis of Gross Hematuria

	Incidence	Associated with GH	Age 65	Male
Kidney cancer	+	+	+++	+++
Ureteral cancer	+	+++	+++	+++
Bladder cancer	+	++++	+++	+++++
Prostate cancer	++++++	+	+++	+++++
Urethral cancer	+	+	++	
Infection	+++++++	++++	+	-
Stones	+++++++	+	+	+
Trauma	+	+++		
BPE	+++++	++++	+++	+++++

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

Narrowing the Differential Diagnoses

2. Obtain **data** to narrow differential diagnoses, **n number of times**, until enough **data** is gathered to make a diagnosis

- A **65 year old male** is referred to you for **gross hematuria**?
- What **more** **data** do you want?
  - History
  - Physical exam
  - Labs
  - Imaging
  - Other

History (abbreviated)

- HPI: GH x 1 day, no LUTS, no pain, no trauma.
- PMHx: none
- Current smoker: 1ppd x 10 yrs

Physical exam

- Digital rectal exam: smooth, non-tender prostate, estimated size 20g

Differential Diagnosis of Gross Hematuria

	Incidence	Associated with GH	Age 65	Male	Smoker
Kidney cancer	+	+	+++	+++	+++
Ureteral cancer	+	+++	+++	+++	+++++
Bladder cancer	+	++++	+++	+++++	++++++++
Prostate cancer	++++++	+	+++	+++++	+
Urethral cancer	+	+	++		+
Infection	+++++++	++++	+		
Stones	+++++++	+	+	+	
Trauma	+	+++			
BPE	+++++	++++	+++	+++++	

- Most likely diagnosis: bladder cancer

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

A Multivariable Model

Table 1 Univariable and multivariable logistic regression analyses assessing the association between predictor variables and the presence of bladder cancer in 1,182 patients

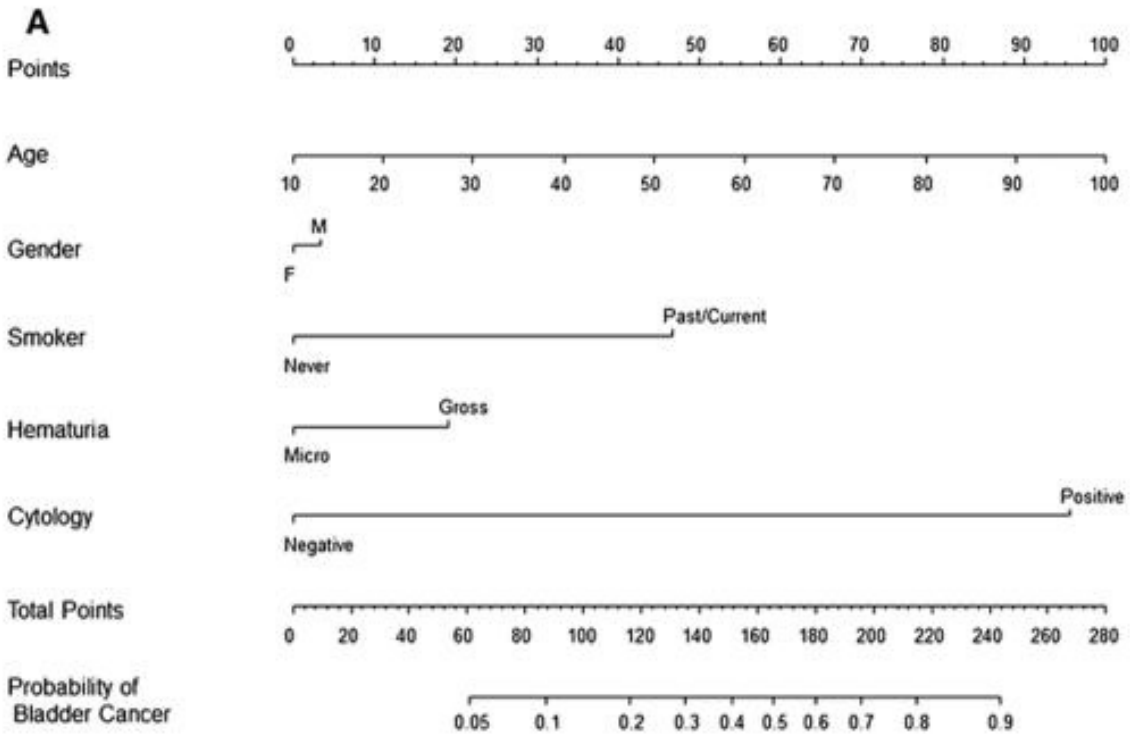
Predictors of bladder cancer	Univariable				Multivariable			
	OR	95 % CI	*p* value	AUC (%)	OR	95 % CI	*p* value	AUC (%)
Age (continuous)	1.04	(1.03, 1.06)	<0.0001	64.7	1.03	(1.02, 1.05)	<0.0001	83.1 %
Gender (male vs. female)	1.49	(1.04, 2.15)	0.03	52.3	1.10	(0.72, 1.68)	0.66	
Smoker (past/current vs. never)	3.38	(2.49, 4.58)	<0.0001	64.6	3.72	(2.58, 5.37)	<0.0001	
Hematuria (gross vs. microscopic)	2.47	(1.85, 3.30)	<0.0001	60.3	1.71	(1.21, 2.41)	0.002	
Cytology (positive vs. negative)	16.12	(10.98, 23.66)	<0.0001	70.6	14.71	(9.70, 22.28)	<0.0001	

AUC estimates are based on internal validation using 200 bootstrap samples

AUC area under the curve, *CI* confidence interval, *OR* odds ratio

Cha, Eugene K., et al. "Accurate risk assessment of patients with asymptomatic hematuria for the presence of bladder cancer." *World journal of urology* 30.6 (2012): 847-852.

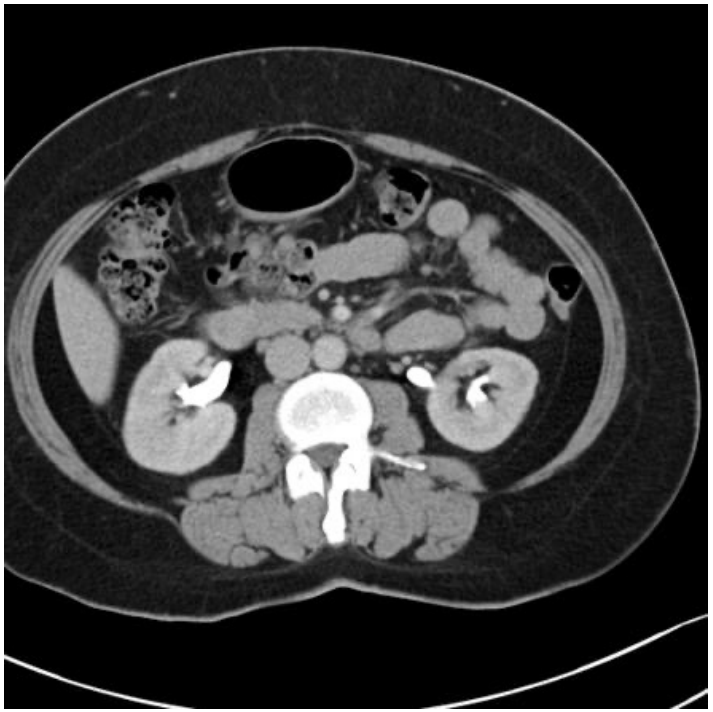
Nomograms



- A graphical representation
- Allows clinician to estimate individualized risk estimates based on patient and disease characteristics

Balachandran, Vinod P., et al. "Nomograms in oncology: more than meets the eye." *The lancet oncology* 16.4 (2015): e173-e180.
Cha, Eugene K., et al. "Accurate risk assessment of patients with asymptomatic hematuria for the presence of bladder cancer." *World journal of urology* 30.6 (2012): 847-852.

Imaging



- Sensitivity for stones: 98%
- Sensitivity for kidney cancer: 75%
- Sensitivity for bladder cancer: 2%

- **How do you explain this to a patient?**

https://radiopaedia.org/cases/normal-ct-intravenous-urogram?lang=us

values for illustrative purposes

Differential Diagnosis of Gross Hematuria

	Incidence	Associated with GH	Age 65	Male gender	Smoker
Kidney cancer	+	+	+++	+++	+++
Ureteral cancer	+	+++	+++	+++	+++++
Bladder cancer	+	++++	+++	+++++	+++++
Prostate cancer	++++++	+	+++	+++++	+
Urethral cancer	+	+	++		+
Infection	+++++++	++++	+		
Stones	+++++++	+	+	+	
Trauma	+	+++			
BPE	+++++	++++	+++	+++++	

- The ER discharges the patient
  - **Have the goals of the ER been met?**
  - **Have the goals of the patient been met?**

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

A Patient's Family Member's Perspective

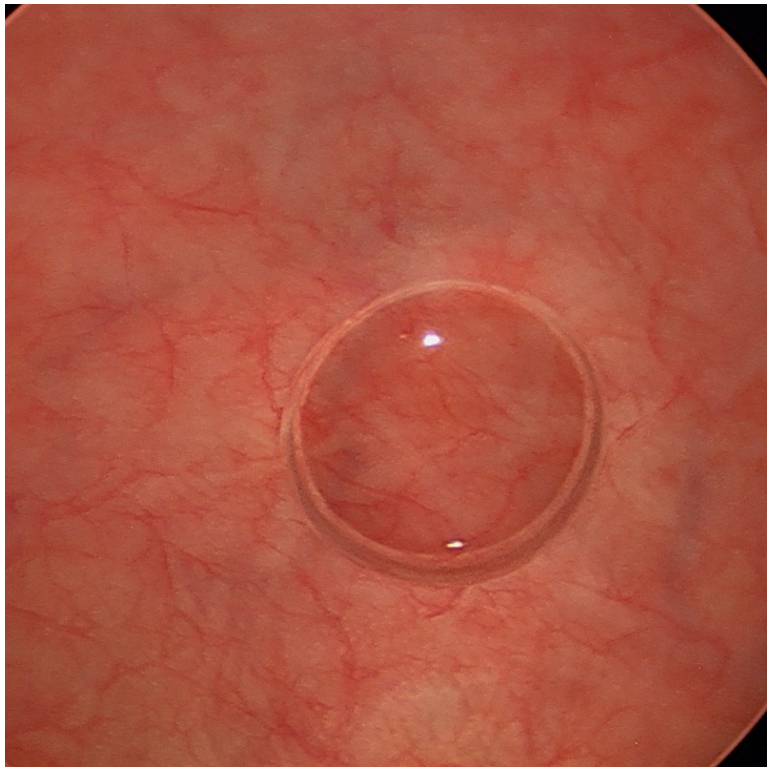
- Jim saw blood in his urine this morning so we went to the ER. They did a bunch of tests and couldn't find anything. They said a urologist would need to see us.
- 5 days later…
- The urologist's secretary left a voicemail. I called back but it went to the office voicemail.
- 3 days later…
- The urologist's secretary gave us an appointment to see the urologist to take a look inside the bladder.

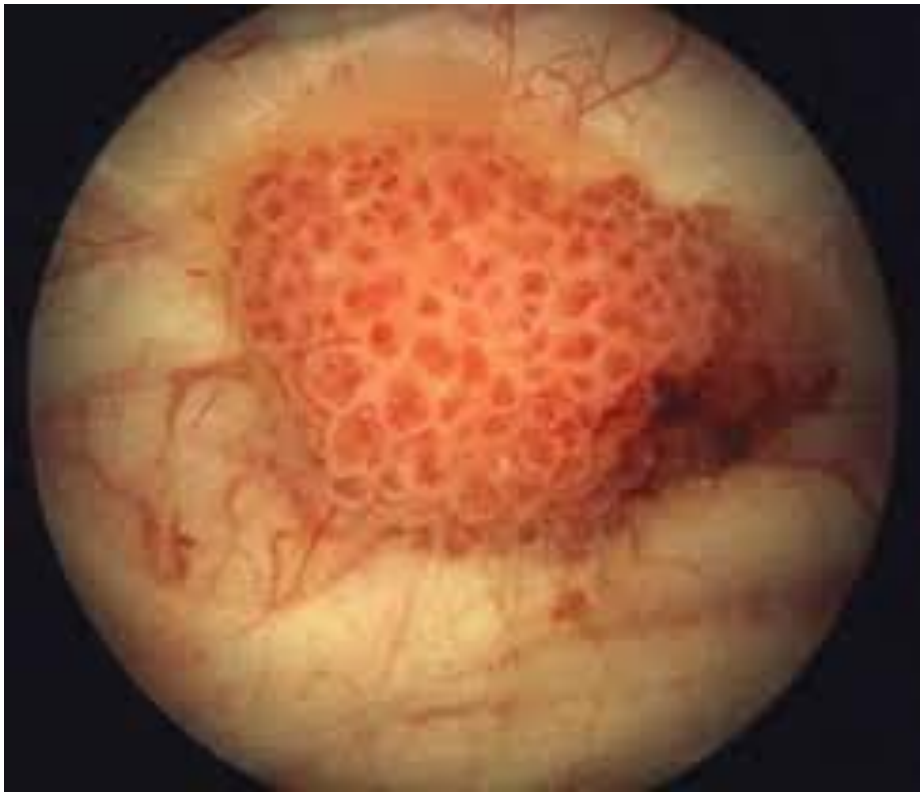
A Provider's Perspective

- Night before clinic, review medical record
  - Diagnostic process
    - Re-interpretation of tests (e.g. imaging)

	Incidence	Associated with GH	Age 65	Male gender	Smoker
Kidney cancer	+	+	+++	+++	+++
Ureteral cancer	+	+++	+++	+++	+++++
Bladder cancer	+	++++	+++	+++++	+++++
Prostate cancer	++++++	+	+++	+++++	+
Urethral cancer	+	+	++		+
Infection	+++++++	++++	+		
Stones	+++++++	+	+	+	
Trauma	+	+++			
BPE	+++++	++++	+++	+++++	

Cystoscopy





https://vivwong.com.au/faqs/cystoscopy-procedures/
https://www.livescience.com/34701-bladder-cancer-symptoms-treatment.html

A Provider's Perspective

Cystoscopy Note

- MRN
- Name
- DOB
- Clinical Note: Mr. Jones is a 65M who presented to the ER with a 1 day history of gross hematuria. A CT urogram was normal. He presents for cystoscopy.

A Provider's Perspective

Cystoscopy Note Continued…

- Procedure Note: A well lubricated flexible cystoscope was inserted into the urethra. The visualized anterior and posterior urethra were normal. The prostate demonstrated moderate lateral lobe enlargement. Upon entering the bladder, we performed cystoscopy. Both ureteric orifices were identified and normal. We noted 1 papillary tumor along the right lateral wall. The flexible cystoscope was then removed. The procedure was well tolerated and there were no immediate complications.

A Provider's Perspective

Cystoscopy Note Continued…

- Assessment: 1 papillary tumor along the right lateral wall. We discussed the role of TURBT given the appearance of a bladder tumor. Specifically, we discussed the diagnostic and therapeutic role. We discussed the potential risks and complications of the procedure, including, … The patient had an opportunity to ask questions and then signed the consent.
- Plan:
  1. TURBT with paralysis, post-operative gemcitabine
  2. PSA to assess risk of prostate cancer

Differential Diagnosis of Gross Hematuria

	Incidence	Associated with GH	Age 65	Male gender	Smoker
Kidney cancer	+	+	+++	+++	+++
Ureteral cancer	+	+++	+++	+++	+++++
Bladder cancer	+	++++	+++	+++++	+++++
Prostate cancer	++++++	+	+++	+++++	+
Urethral cancer	+	+	++		+
Infection	+++++++	++++	+		
Stones	+++++++	+	+	+	
Trauma	+	+++			
BPH	+++++	++++	+++	+++++	

+ not to scale, for illustrative purposes

Labs

- PSA 1.2 ng/mL

Differential Diagnosis of Gross Hematuria

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Bladder cancer	+	++++	+++	+++++	+++++
Prostate cancer	+++++++	+	+++	+++++	+
Urethral cancer	+	+	++		+
Infection	+++++++	++++	+		
Stones	+++++++	+	+	+	
Trauma	+	+++			
BPE	+++++	++++	+++	+++++	

+ not to scale, for illustrative purposes
BPE: benign prostatic enlargement

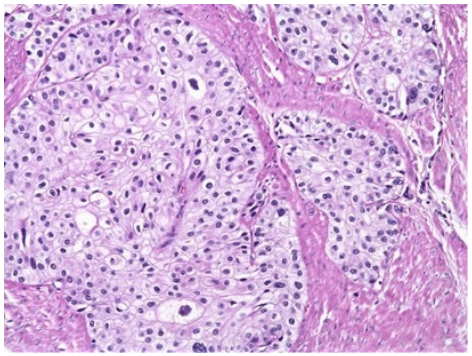
Date of surgery (TURBT)

A Patient's Perspective

- I had a bladder tumor resection today. The doctor thinks it's cancer. They said it will take a week for the pathology report to come back.

A Provider's Perspective

- Over the next few days, the specimen is processed and plated on slides
- The pathologist reviews the slides and initiates their diagnostic process



Compared with knowledge **database**

Diagnosis is reported as observed pattern most consistent with knowledge database.

Report is generated

https://www.nature.com/articles/modpathol200926

Pathology Report

- Accession Number: AAAA1111
- Report Status: Final
- Type: Surgical Pathology
- Procedure Date: 02/05/2022
- Ordering Provider: Apprentissage Profond, M.D.
- CASE: AA-AA-1111
- PATIENT: Jim Jones
- Specimen(s) Received Bladder tumor, transurethral resection
- Data-driven Hospital Department of Pathology 1111 Main Street

Pathology Report

FINAL DIAGNOSIS: A. Bladder tumor, transurethral resection:

1. Poorly differentiated carcinoma, arising in an invasive papillary urothelial carcinoma with focal micropapillary differentiation, high grade (WHO 3 of 3). See comment.
2. Muscularis propria is present and involved by the tumor.

Comment: The tumor cells are negative for pancytokeratin, CK7, CK20, TTF-1, chromogranin and synaptophysin. Case also reviewed by a colleague (Dr. AB, M.D., who concurs.

Clinical History: Bladder cancer.

Gross Description: A. Bladder tumor, transurethral resection: Received in formalin are multiple friable, tan-white/brown tissue fragments measuring 3.0 x 2.6 x 1.5 cm in aggregate. The specimen is entirely submitted in cassettes A1-A5.

Final Diagnosis by AB, M.D.,

Electronically signed on Thursday February 8, 2022 at 06:40:43PM

A Provider's Perspective

- MRN
- Name
- DOB

- Urologic Oncology Clinic Note
- ID: Mr. Jones is a 65 year old male who underwent a TURBT on 02/05/2022. He returns today for follow-up.
- HPI: Patient reports that he is doing well since surgery. He denies any pain or lower urinary tract symptoms.
- Pathology: (copy/paste report)

A Provider's Perspective

Assessment: Mr. Jim Jones is a 65 year old male found to have muscle-invasive bladder cancer. We discussed that standard of care for this disease is neoadjuvant chemotherapy followed by radical cystectomy and urinary diversion.

We discussed the potential risks and complications of these, including …

We also discussed alternative treatment options, including …

The patient was given an opportunity to ask questions. They would like to proceed with neoadjuvant chemotherapy followed by radical cystectomy and creation of ileal conduit.

Plan:

1. Complete staging: CT chest
2. Medical oncology consult

Questions

6.871/HST.956: Machine Learning for Healthcare