Lab & Pharmacy: Turning Daily Interaction into a Partnership

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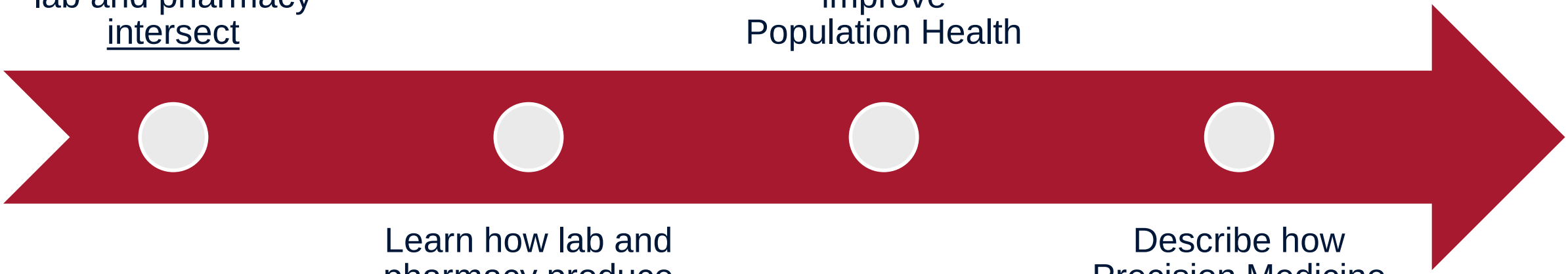
Objectives

Identify areas of healthcare where lab and pharmacy intersect

Learn how lab and pharmacy produce better outcomes together

Determine where lab and pharmacy collectively improve Population Health

Describe how Precision Medicine initiatives require both lab and pharmacy for success



Topic Outline

Make the Link Between Lab and Pharmacy

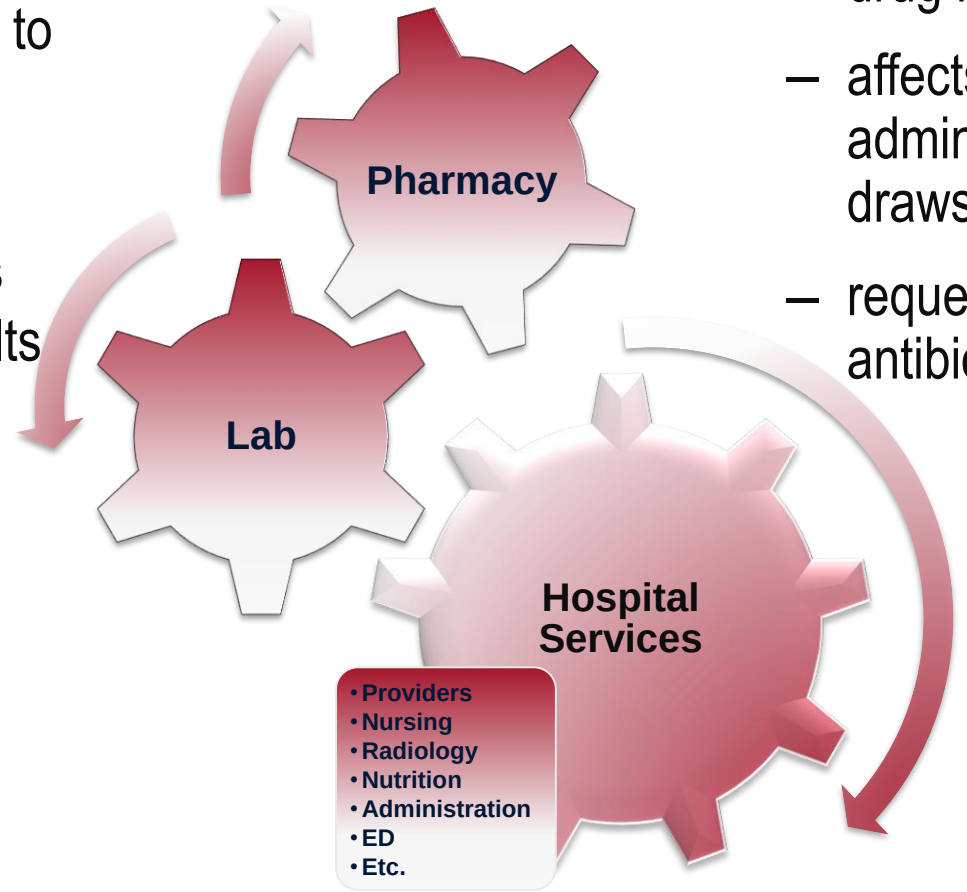
- Areas of Intersection
- Lab/Pharmacy Budgets & Workflows
- Therapeutic Drug Monitoring & Sensitivity
- EHR Build - Orders & Order Sets

Next Level Initiatives

- Population Health
- Precision Medicine (Pharmacogenomics)

Link: Areas of Intersection

- **Lab**
  - test results are used by pharmacy to determine drug effectiveness, adverse effects, toxicity
  - affects timing of dose adjustments that depend on receipt of lab results
  - genetic test results indicate drug effectiveness and dosing requirements
  - results for culture and sensitivities guide antibiotic use



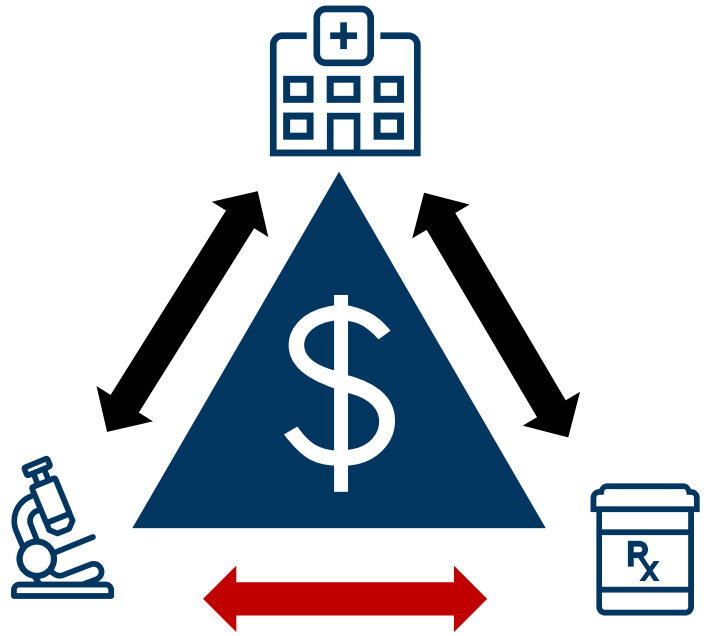
- **Pharmacy**
  - orders labs based on therapeutic drug monitoring
  - affects lab workflow by setting drug administration and times for lab draws
  - requests culture and sensitivity for antibiotic stewardship

Link: Budget Planning and Monitoring

Hospital

Composed of rolled up combined expenses

Hospital Combined Expense



Lab

Knows what tests are available internally or by reference labs

Lab Test Expense

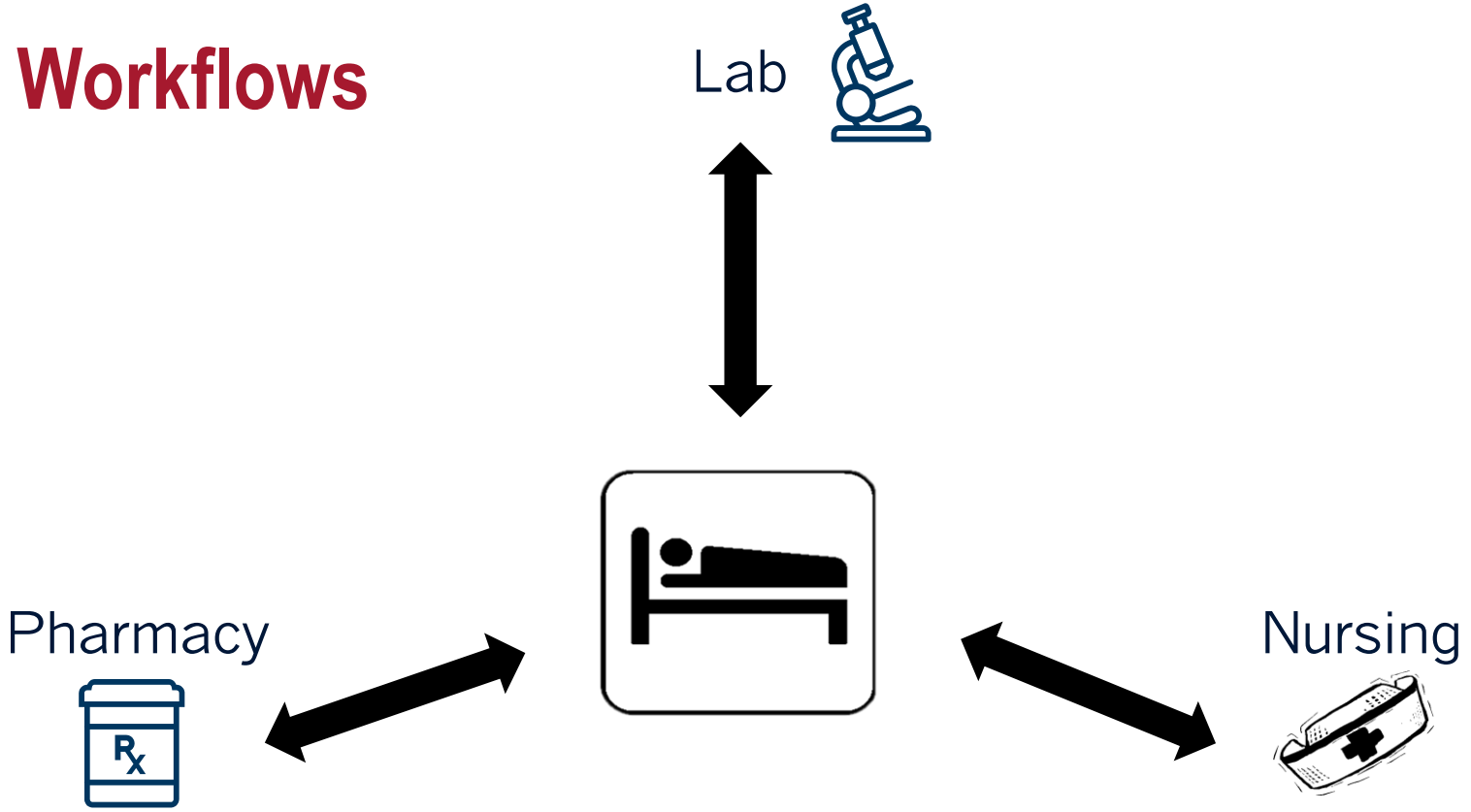
Pharmacy

Knows what drugs are being used throughout the hospital

Pharmacy Drug Expense

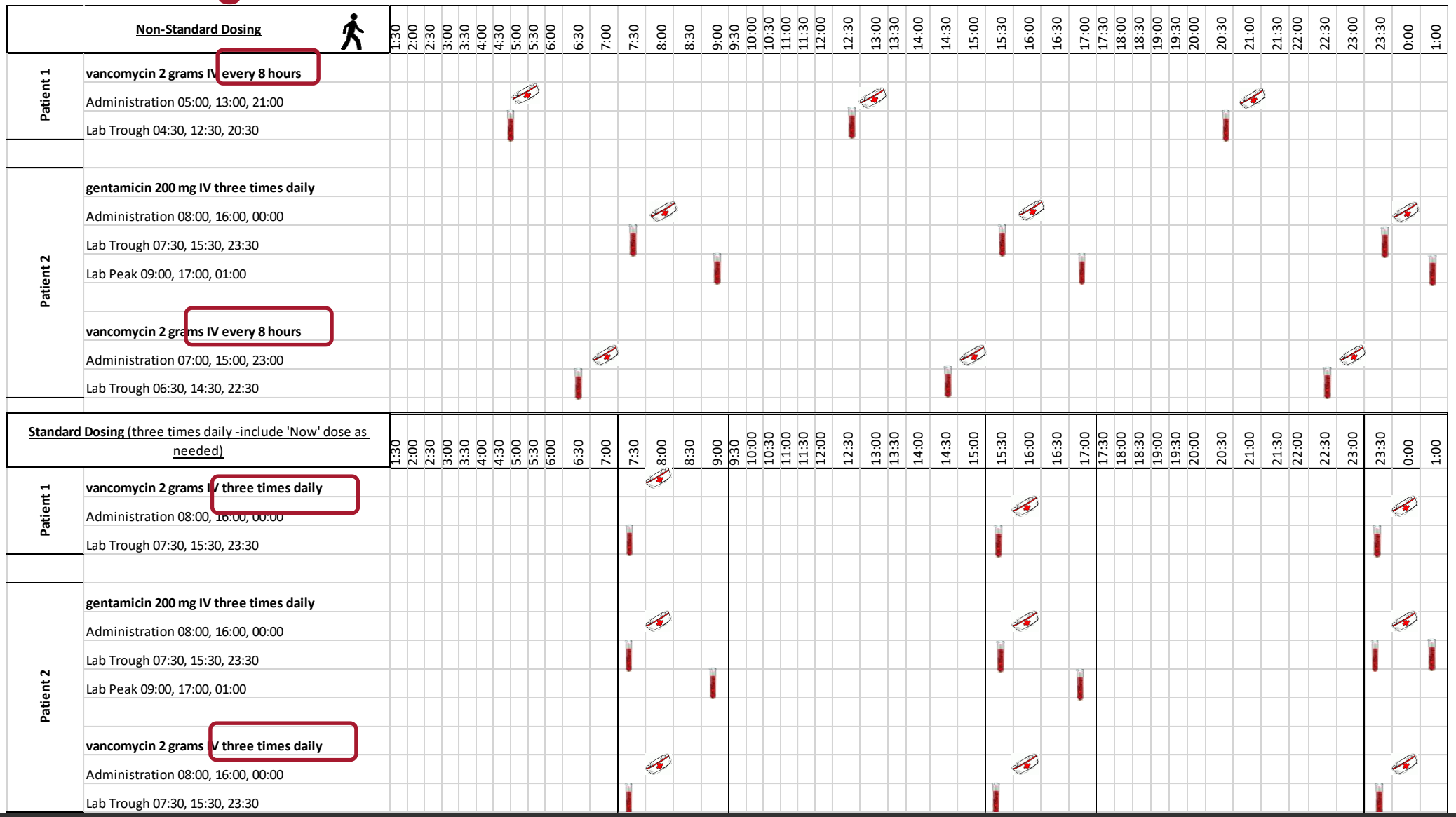
Both pharmacy and lab would benefit from the other's knowledge for better budget planning.

Link: Shared Workflows



- **Lab**: ↓ Blood draws, collection, cultures ↑ Time in the lab running tests
- **Pharmacy**: ↓ Drug deliveries ↑ Time monitoring patients
- **Nursing**: ↓ Trips to the dispensing cabinet ↑ Time at the bedside

Standard Drug Administration Times



Link: EHR Build – Orders and Order Sets

- Order set:
  - Guide clinicians to ensure critical components of care are not overlooked
  - Pre-defined template provides support in making clinical decisions
  - Grouped orders focus on a specific condition or procedure
- Development:
  - Only include formulary lab tests and drugs
  - Set default order details (method, dose, frequency)
- Benefits:
  - Points the provider to formulary items
    - Budget & inventory
  - Supports evidence based care
    - SCIP parameters (timing of antibiotic orders)
    - Stewardship initiatives
    - Stroke treatment turnaround times

Link: Therapeutic Drug Monitoring (TDM) & Sensitivity Tests

- Lab tests help enhance patient care and decrease drug spend
  - Ensure therapeutic concentrations
  - Minimize toxicity and side effects
  - Determine adherence
  - Avoid drug interactions

- Common opportunities for better utilization and cost savings
  - Remicade (inFLIXimab) and Humira (adalimumab) monitoring for concentration and neutralizing antibodies
  - Gleevec (imatinib) monitoring drug concentration
  - NS5A inhibitor testing for sensitivity

New addition: Precision Medicine
(*upcoming slides*)

Population Health & Precision Medicine

Next Level Initiatives

Population Health - Definition

- Landscape
  - Hospital Systems are becoming **increasingly responsible** for general health in their regions
- Definition
  - 'Population Health Management is … the analysis of that data into a single, actionable patient record, and the actions through which care providers can improve both clinical and financial outcomes'. [1]
  - '…improve the health outcomes of a group by monitoring and identifying individual patients within that group'. [1]
  - Involves: surveillance, management of risk factors, monitoring of drug side effects, increasing quality of life, providing preventative services
- **Lab and Pharmacy are essential** in these initiatives
  - Opioid & Antibiotic Stewardship, Precision Medicine

[1] https://www.usa.philips.com/healthcare/medical-specialties/population-health/what-is-population-health-management/

Precision Medicine - Definitions

- Precision Medicine
  - "An emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person"[1]
  - Improve health outcomes of the community by customizing care for the individual
    - Allows practitioners to target patient response to prescription drugs
    - Prevent adverse events and **readmissions** (i.e. *increase* care & *decrease* expense)

- Pharmaco**genet**ics (PGt)
  - How single genes influence response to drugs
- Pharmaco**genom**ics (PGx)
  - How multiple genes interact and influence response to drugs

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- Genetics
  - Broader term: Includes non-drug genes and variations
- Germline mutations
  - Inherited
- Somatic mutations
  - Acquired, tumor cells

[1] https://ghr.nlm.nih.gov/primer/precisionmedicine/definition
[2] https://labsoftnews.typepad.com/lab_soft_news/2019/03/momentum-in-pharmacogenetics-including-direct-access-testing.html

Precision Medicine - Considerations

Personalized care

- One size (drug) does not fit all
- Patients want to be treated as individuals

Growing public awareness and focus

- Ancestry.com, 23andMe
- People are taking a greater role in their own healthcare

Improved care and budgets

- Focus on patient care and budgets
- Cost savings for patients and healthcare entities
- Expand and enrich TDM and clinical monitoring

Enhanced stewardship initiatives

- Choose a therapeutic drug/dose combination more quickly
- Fewer therapy adjustments with reduced monitoring
- Minimizes toxicity and increases efficacy

Drug Metabolism

Traditional Dosing

- Based on average drug response in a population
- **Reality**: there is huge variability in metabolism and response
- **Risk**:
  - ~7 million **ED visits** per year due to adverse drug events (ADEs) at a cost of $3.5 billion
  - Patients are at risk for ADEs from incorrect drugs or doses that could have been prevented through PGx testing

Sources of Variation

- Pharmacogenetics
  - *Poor metabolizers*
  - *Intermediate metabolizers*
  - *Normal metabolizers*
  - *Ultrarapid metabolizers*
- Concomitant drug therapy
- Environmental factors
- Disease states

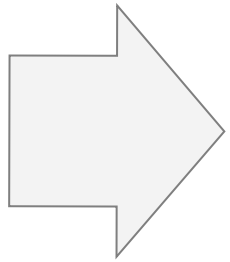
https://www.cdc.gov/MedicationSafety/Adult_AdverseDrugEvents.html

Opioid Epidemic

Problem:

Overdose deaths related to opioids
(data from the CDC[1]):

- 1999 - 2017 > 700,000 people died from drug overdoses
- 68% of all overdose deaths in 2017 involved an opioid (6x greater than in 1999)
- 130 Americans die each day from opioid overdoses



Collaboration is essential to combat this epidemic

- ***Lab***
  - test results will tell you what is being used in your population (umbilical cord, drug testing)
  - identifies available tests for PGx variants
- ***Pharmacy***
  - guides appropriate drug selection
  - evaluates PGx drug/dose adjustments

[1] https://www.cdc.gov/drugoverdose/epidemic/index.html. Accessed July 2019.

Antibiotic Stewardship Committee

Lab

- Guide PGx testing
- Perform culture and sensitivity tests
- Clarify viral vs. bacterial infection

Pharmacy

- Evaluate indication for drug treatment (bacterial infection, infection site)
- Determine drug/dose selection based on PGx

PGx vs. Emperic Dosing with TDM and Clinical Monitoring

- Note: PGx should not replace TDM and clinical monitoring

PGx + TDM and clinical monitoring

- Proactive genotyping provides a better chance to get the right drug & dose the first time
- Less monitoring is required for subsequent doses
- Precise dosing is more likely to prevent ADEs

Empiric (standard) dosing

- It could take longer to discover the patient-specific response
- Starting with a low dose may require more time to achieve therapeutic doses, putting the patient at risk
- A standard dose could be toxic to some patients

Patient Case

- Patient treated for GERD (heartburn)
- ***Pharmacy Assessment***: Headache and nausea after trying several PPIs (e.g. Prilosec, Nexium)
- ***Lab Evaluation***: PGx test for CYP2C19 metabolism
  - Patient was found to be a poor metabolizer
  - Low drug inactivation caused higher-than-normal levels of drug in the system, producing adverse drug effects
- ***Solution***: Medication switched to an H2 Blocker (Pepcid) - not activated by CYP2C19
- ***Result***: Headache and nausea issues were resolved and patient satisfaction increased

You'll never know *some* drugs are not working until they fail

Plavix (clopidogrel)

Antiplatelet medication prescribed to prevent stroke

Prodrug activated by CYP2C19

- If it's not activated it's not working
- No other drug monitoring or lab test available
- *Without genetic testing, the only way to know it is not working is if the patient is readmitted with a stroke*

WARNING: DIMINISHED ANTIPLATELET EFFECT IN PATIENTS WITH TWO LOSS-OF-FUNCTION ALLELES OF THE *CYP2C19* GENE

- Effectiveness of Plavix depends on conversion to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19.
- Tests are available to identify patients who are CYP2C19 poor metabolizers.
- Consider use of another platelet P2Y12 inhibitor in patients identified as CYP2C19 poor metabolizers.

Plavix package insert, revised September 2016
https://www.pharmgkb.org/chemical/PA450704/labelAnnotation/PA166104921

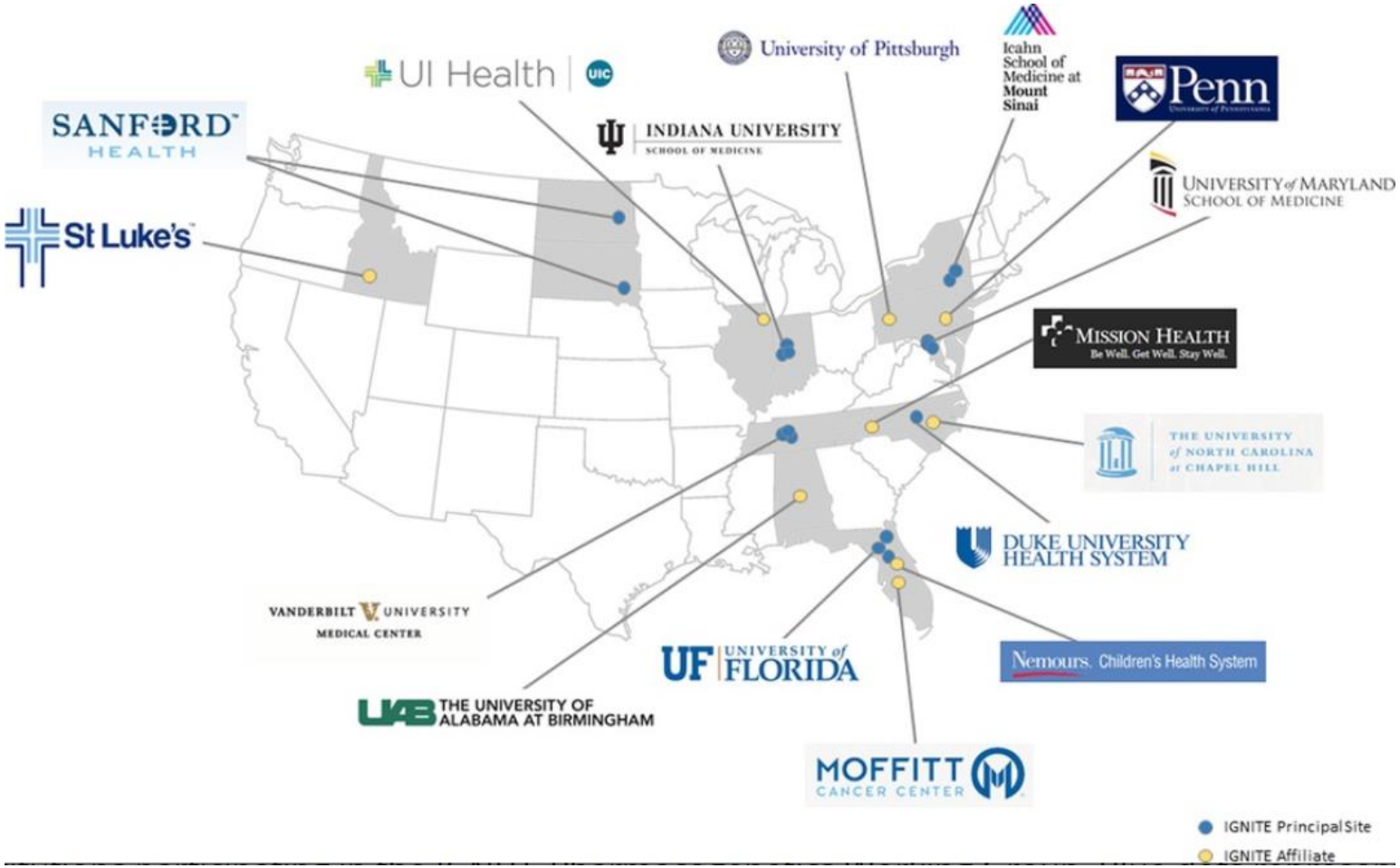
Genetic Testing Products

- The number of genetic testing products has grown from 10,000 (2012) to over 75,000 (2018)
- ~14 new tests per day enter the market
- ⬆Demand = ⬆Test Availability (and vice versa)
- Collaboration
  - Pharmacy helps determine what drugs to target
  - Lab helps choose and interpret the PGx test

Precision Medicine for Health Plans [online webinar]. Concert Genetics, Feb 13, 2019. https://www.concertgenetics.com/blog/webinar-precision-medicine-health-plans/. Accessed April 2019.

Highlight on Precision Medicine (Pharmacogenomics)

- This is a **new** and quickly **growing** concept in health care
  - Consulting and genetic testing companies
  - Research and implementation
  - IGNITE collaboration



https://ascpt.onlinelibrary.wiley.com/doi/full/10.1111/cts.12456

Lab and Pharmacy are Better Together

Benefiting the care environment

- Budgets
- Workflow
- Clinical decision support

Improving Population Health

- Stewardship initiatives
- Precision Medicine