



# Applying CAST to a Healthcare Adverse Event: How Software Design Hides the Most Influential Clinical Cue

John Thomas  
Polly Harrington  
Nancy Leveson

Jasmine Ghorbani  
Patrick Samedy  
Melissa Marquez

Supported by Synensys:  
Stephen Powell, DHA  
Alana Keller, MBA

# Introduction

FDA-sponsored project to answer:

- Can root causes be missed by a Root Cause Analysis (RCA)?
- Can we improve healthcare adverse event investigations?
  
- Goal: Determine if systemic factors are being missed, if they are important, and what opportunities exist to improve
  
- How:
  - Identify an event that was already investigated with RCA
  - Apply CAST to the event
  - Compare the findings

# Adverse Event

- Highly respected medical center in US
  - Like all medical centers, adverse events can and do occasionally happen.
  - Every effort is made to learn from them and prevent future events
- Patient undergoing treatment for breast cancer
  - Including chemotherapy and immunotherapy
- Patient scheduled for surgery
- Many tests during Presurgical Testing (PST)
- One test, serum cortisol level, is critically low
  - All test results are provided in EHR
- PST provider does not identify the low cortisol level

# Adverse Event (2)

- PST refers patient to Urgent Care Center (UCC)
  - Possible pulmonary embolism based on symptoms
- UCC receives lab results from PST tests
  - UCC does not identify the low cortisol level or diagnose the adrenal insufficiency
- UCC refers patient to echocardiogram the next day
- Echocardiogram doesn't indicate a problem, doesn't lead to diagnosis

# Adverse Event (3)

- 10 days later, patient calls after-hours nursing service to report worsening symptoms
- Patient told to follow up with local (external) cardiologist next day
- Local cardiologist reviews PST test results, sees low cortisol level, refers patient to Emergency Department (ED)
- Patient calls oncologist to report being in ED with adrenal insufficiency
- Patient recovers and successfully undergoes the planned surgery

# Original Investigation

# Original Investigation

- Medical center investigates the event using standard Root Cause Analysis (RCA)
- Conclusions
  - PST provider reviewed the lab results too quickly, missing low cortisol level
  - Cortisol has diurnal reference range (different limits for am/pm samples). Some familiarity is needed to spot abnormal value
  - Sometimes a lab will call to alert providers to a critical value on test. Lab did not call because cortisol does not meet the definition of “critical value”
  - **No Medical Doctors (MDs) were involved in the event in any way that is substantial**
- Primary cause
  - **Human Performance:** PST provider (not MD) rushed during review, lacked expertise in evaluating cortisol levels

# Original Investigation (3)

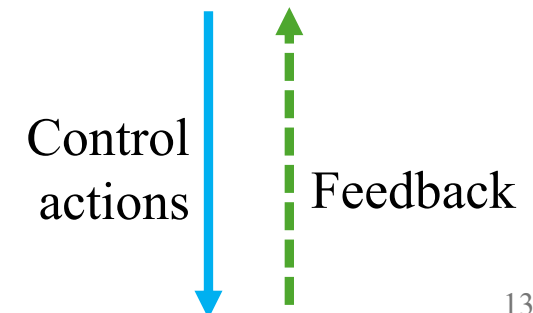
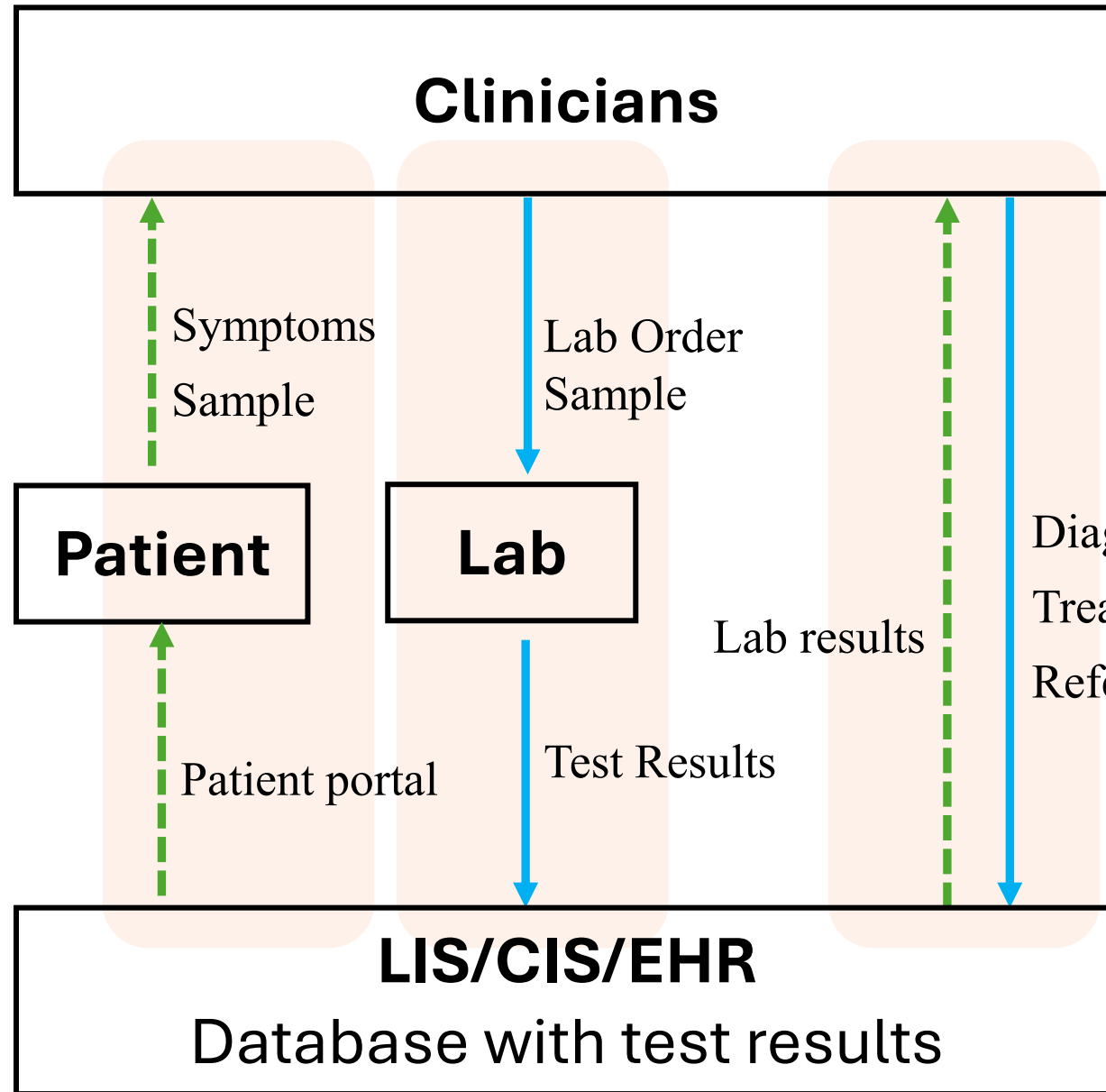
- Recommendations
  - **Remind PST providers to carefully review lab results like cortisol and document the reasons for the test**
  - EHR eventually updated to flag abnormal cortisol values by **always using the a.m. range** for cortisol (5-25)
    - Most cortisol tests are scheduled in the a.m.
    - **Text note added** to explain that providers must check the reference range and interpret results differently if it is not an a.m. test
  - Critical value policy reviewed. **No change necessary.**
  - Medical Quality Assurance group **declined to investigate** the role of MDs as none appear to have been involved in the event

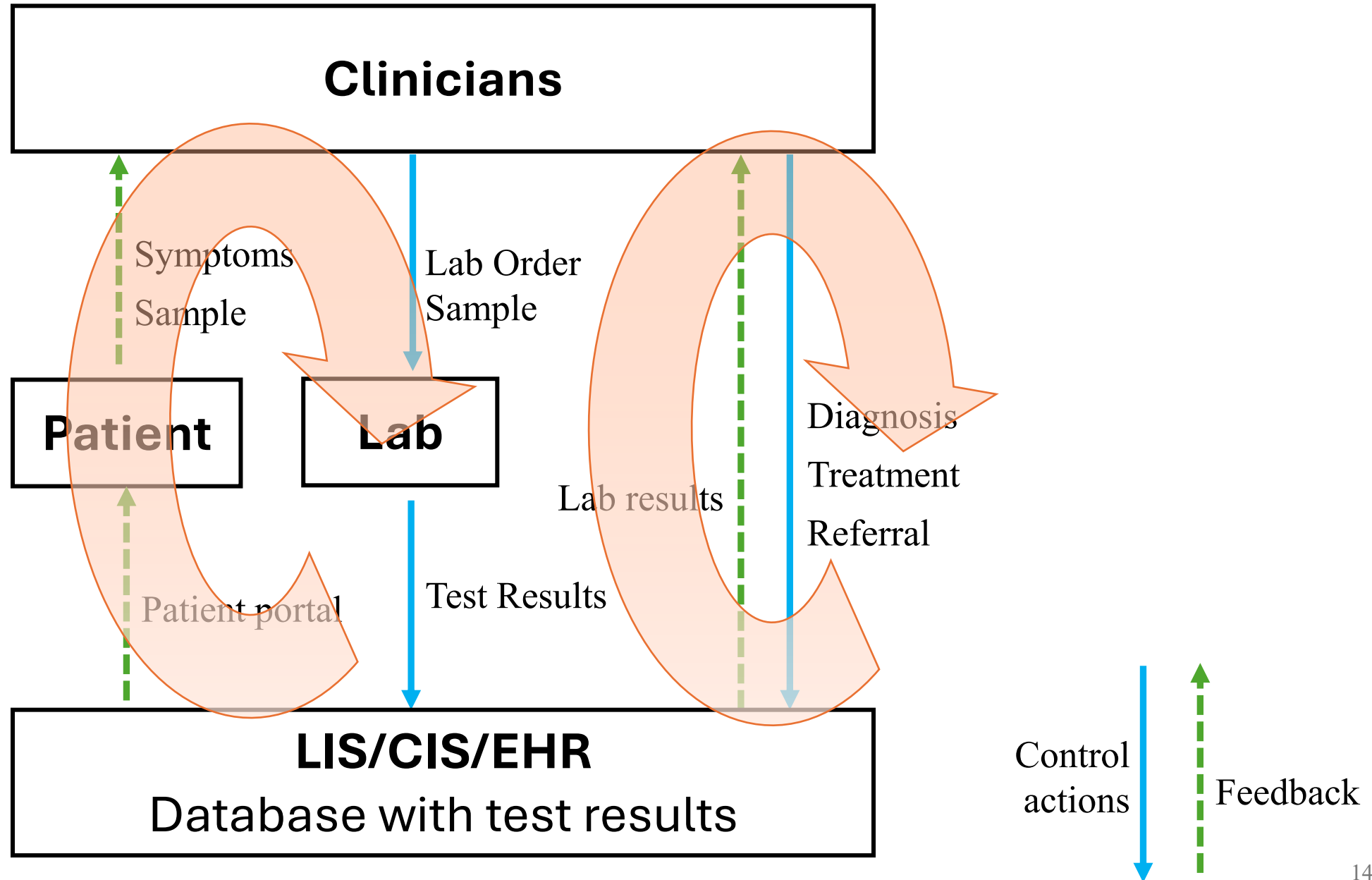
# Our Evaluation

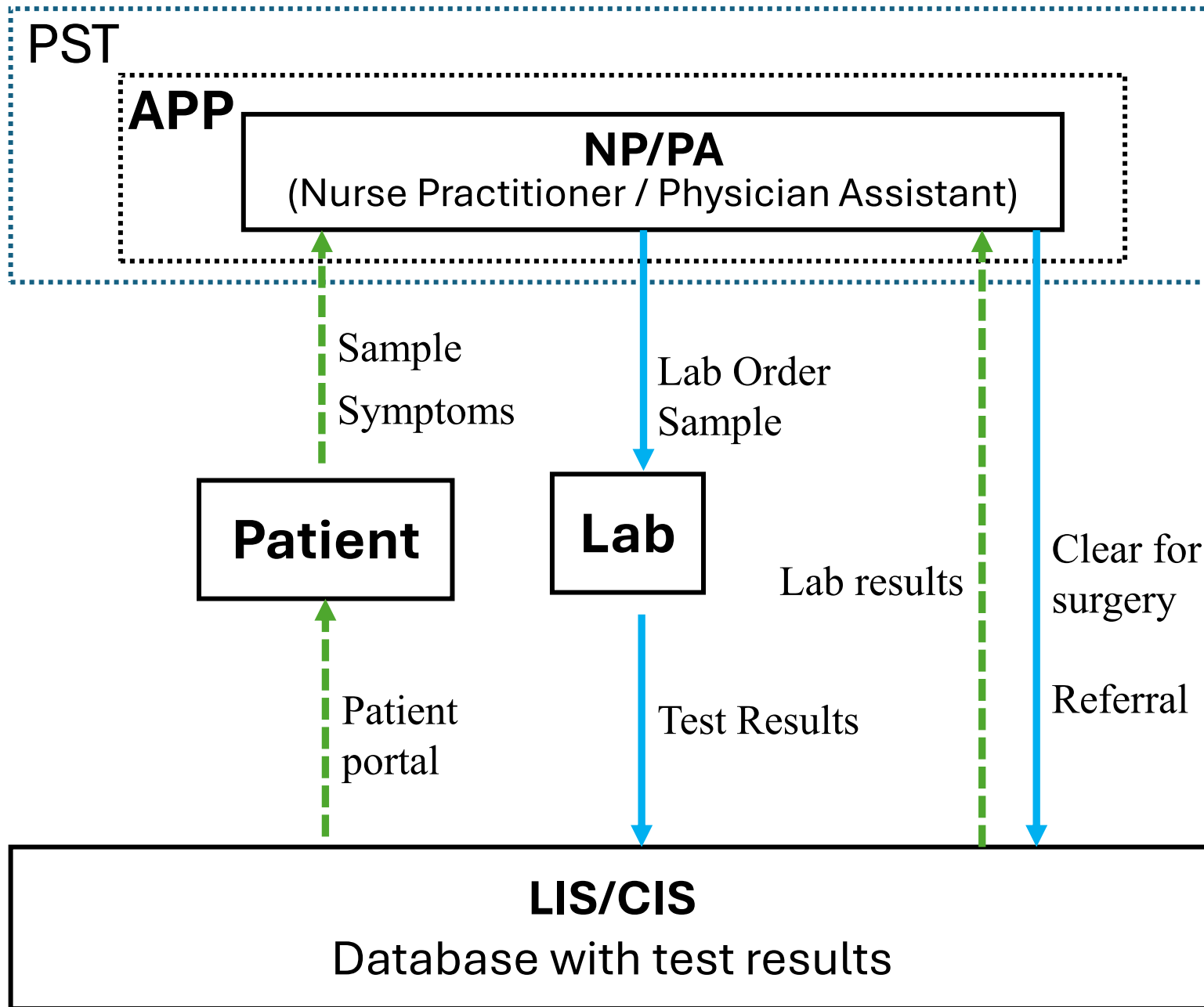
- While not perfect, the original investigation is **above average** compared to many RCAs we have seen in healthcare
  - Very common ignore the reasons for human error and deficiencies in the technology
  - To its credit, this RCA did recommend a technical change
  
- **HOWEVER:** Is there an opportunity to improve?

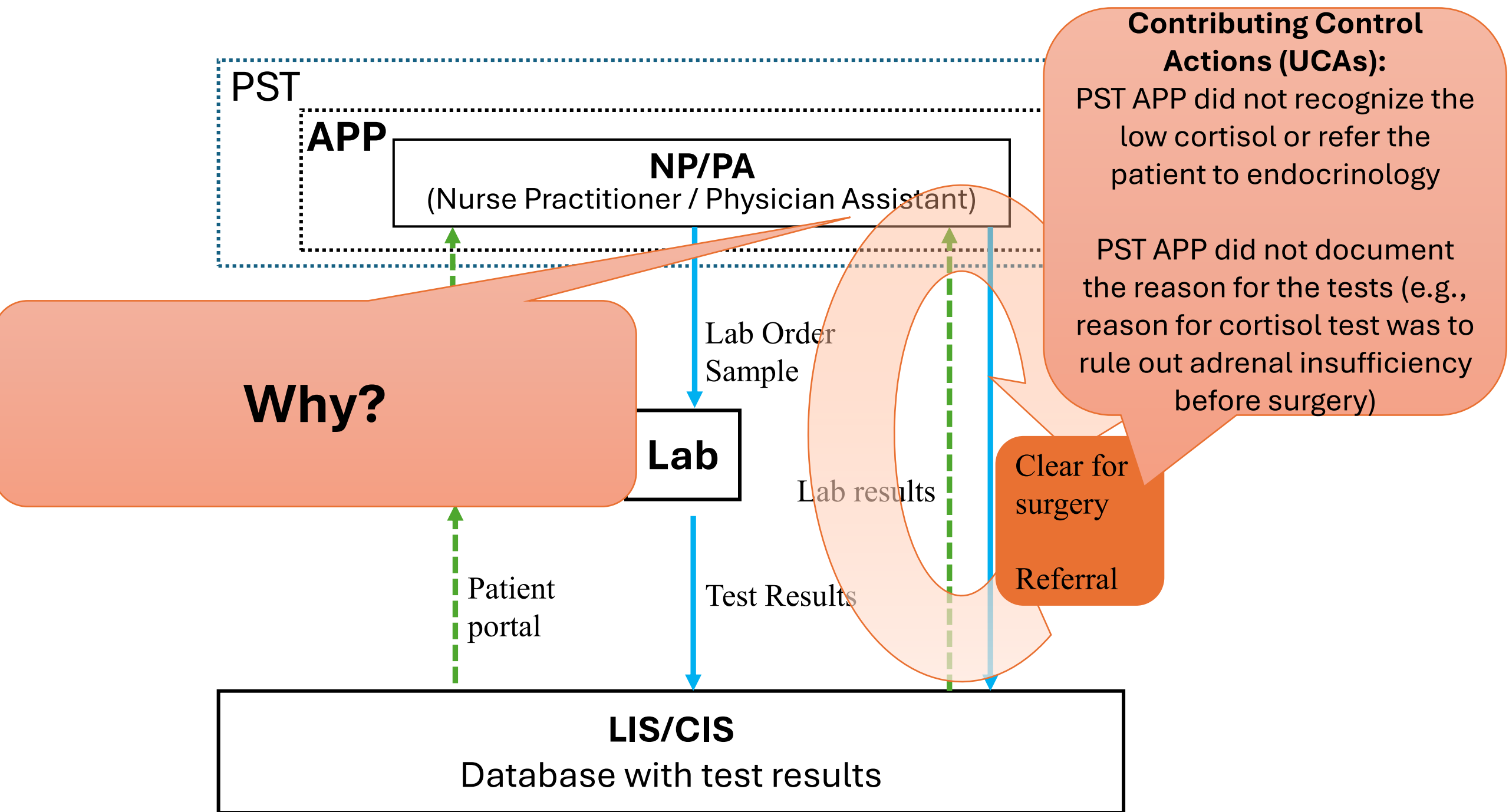
# CAST

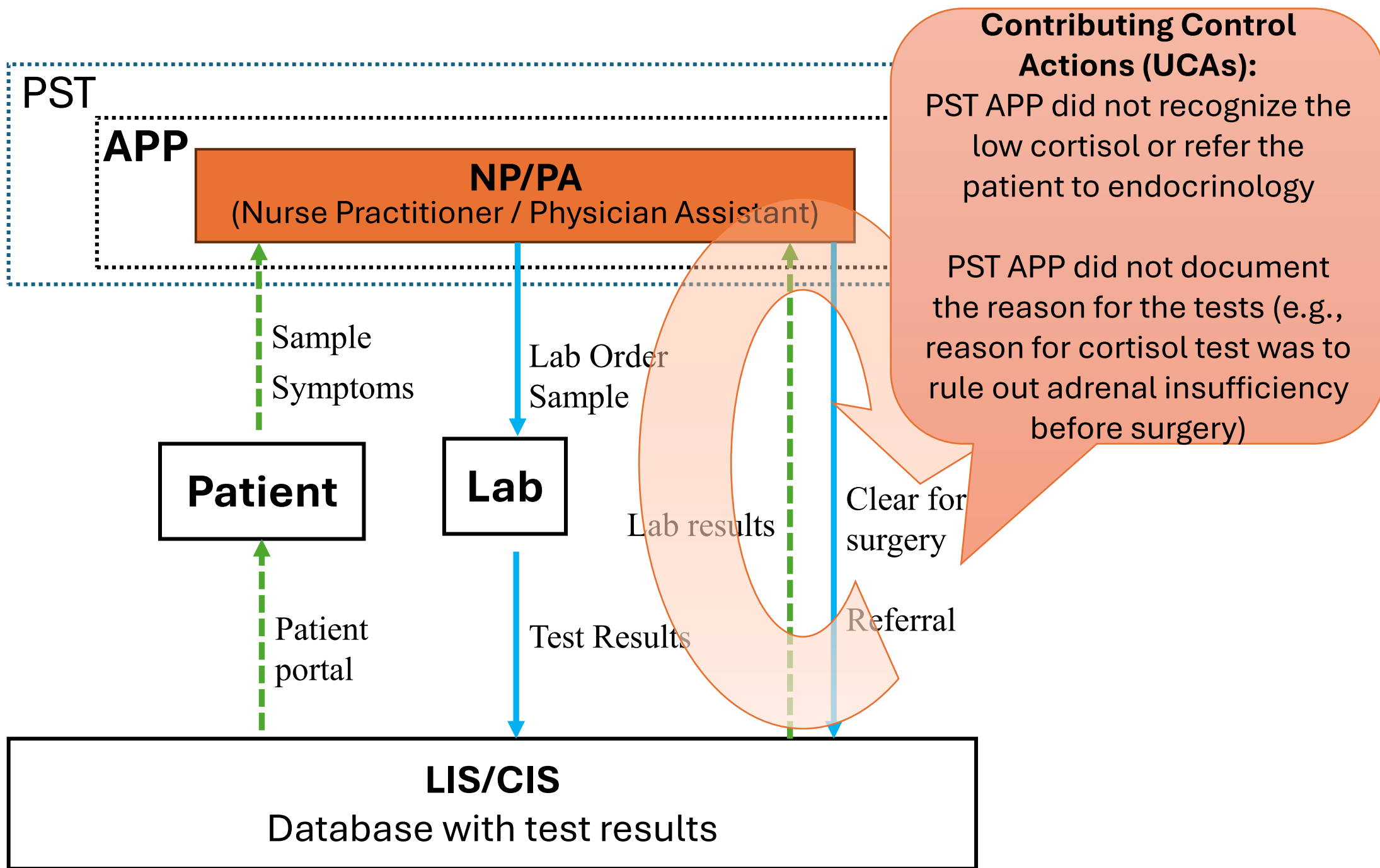
Causal Analysis using System Theory

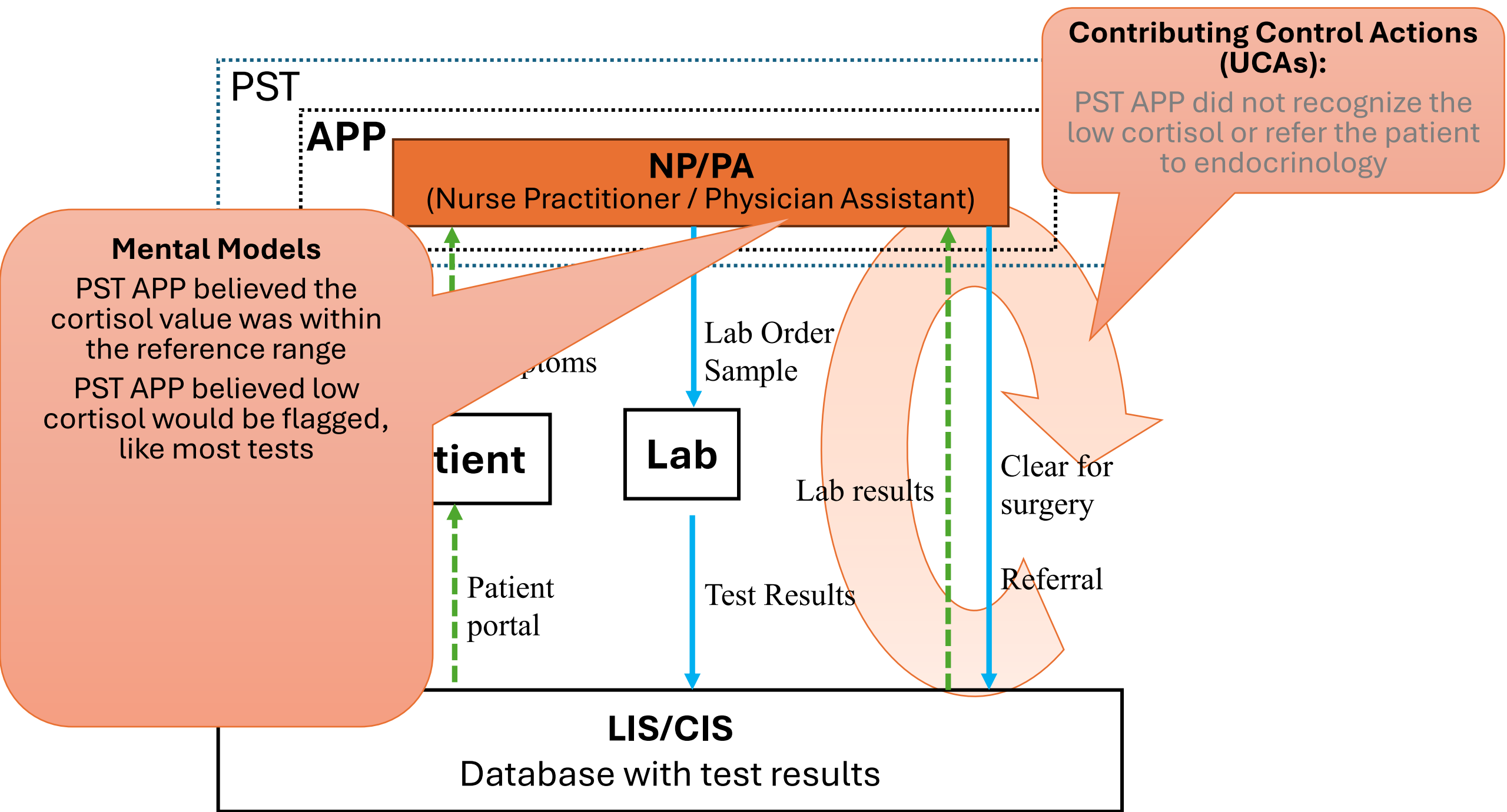


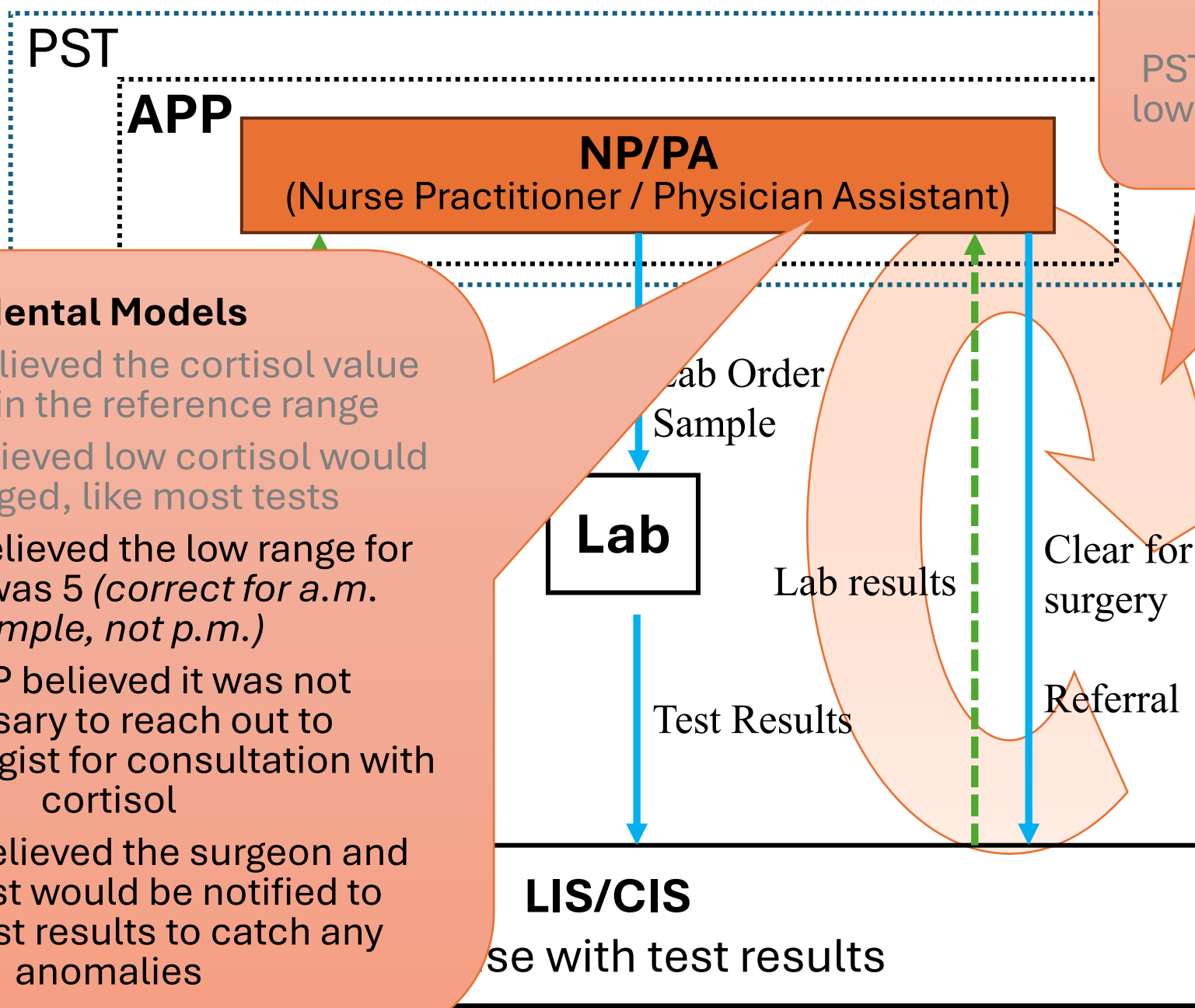












PST

APP

**NP/PA**  
(Nurse Practitioner / Physician Assistant)

**Contributing Control Actions (UCAs):**  
PST APP did not recognize the low cortisol or refer the patient to endocrinology

**Mental Models**

- PST APP believed the cortisol value was within the reference range
- PST APP believed low cortisol would be flagged, like most tests
- PST APP believed the low range for cortisol was 5 (*correct for a.m. sample, not p.m.*)
- PST APP believed it was not necessary to reach out to endocrinologist for consultation with cortisol
- PST APP believed the surgeon and oncologist would be notified to review test results to catch any anomalies

**Lab**

**LIS/CIS**  
Case with test results

Lab Order Sample

Lab results

Test Results

Clear for surgery

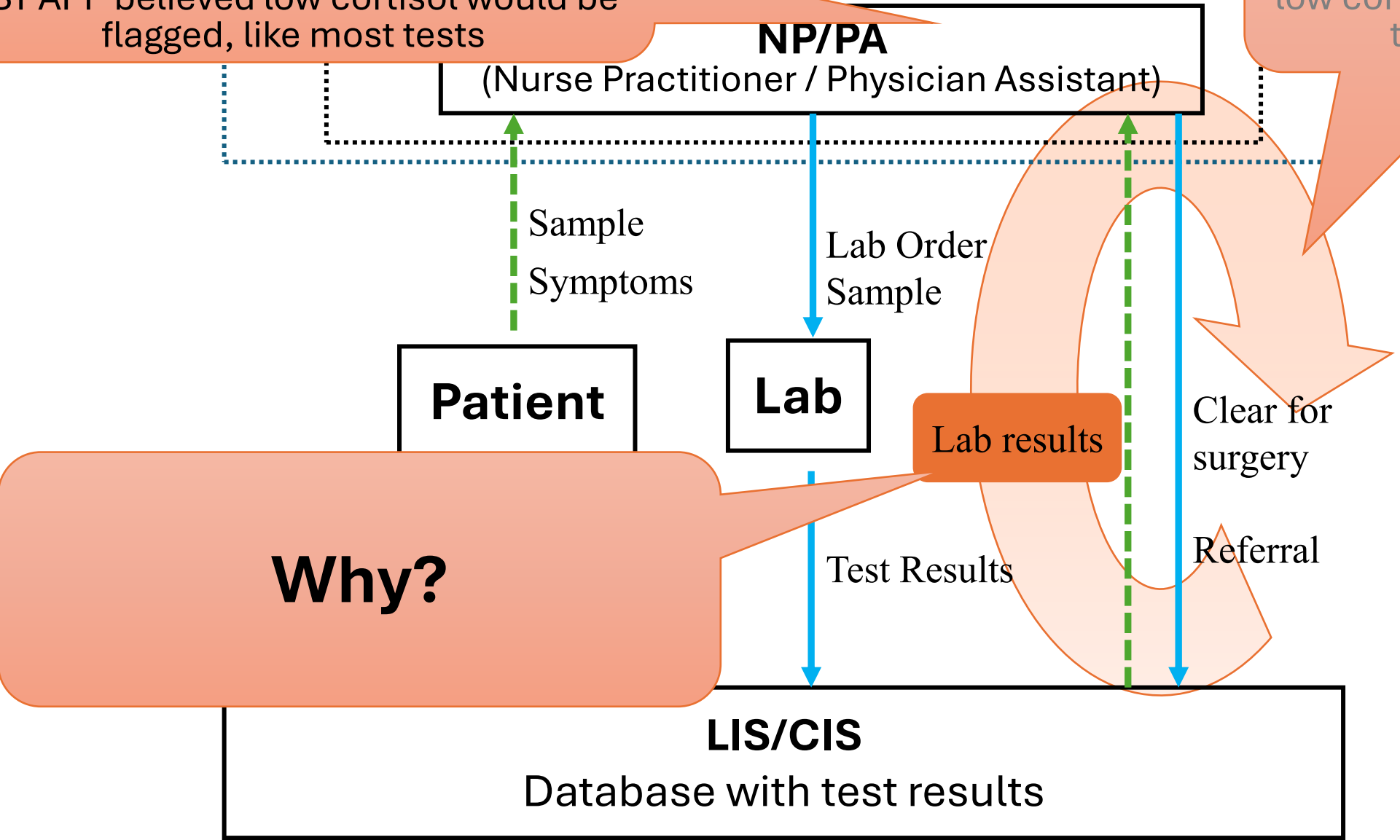
Referral

# Mental Models

PST APP believed the cortisol value was within the reference range  
PST APP believed low cortisol would be flagged, like most tests

# Contributing Control Actions (UCAs):

PST APP did not recognize the low cortisol or refer the patient to endocrinology



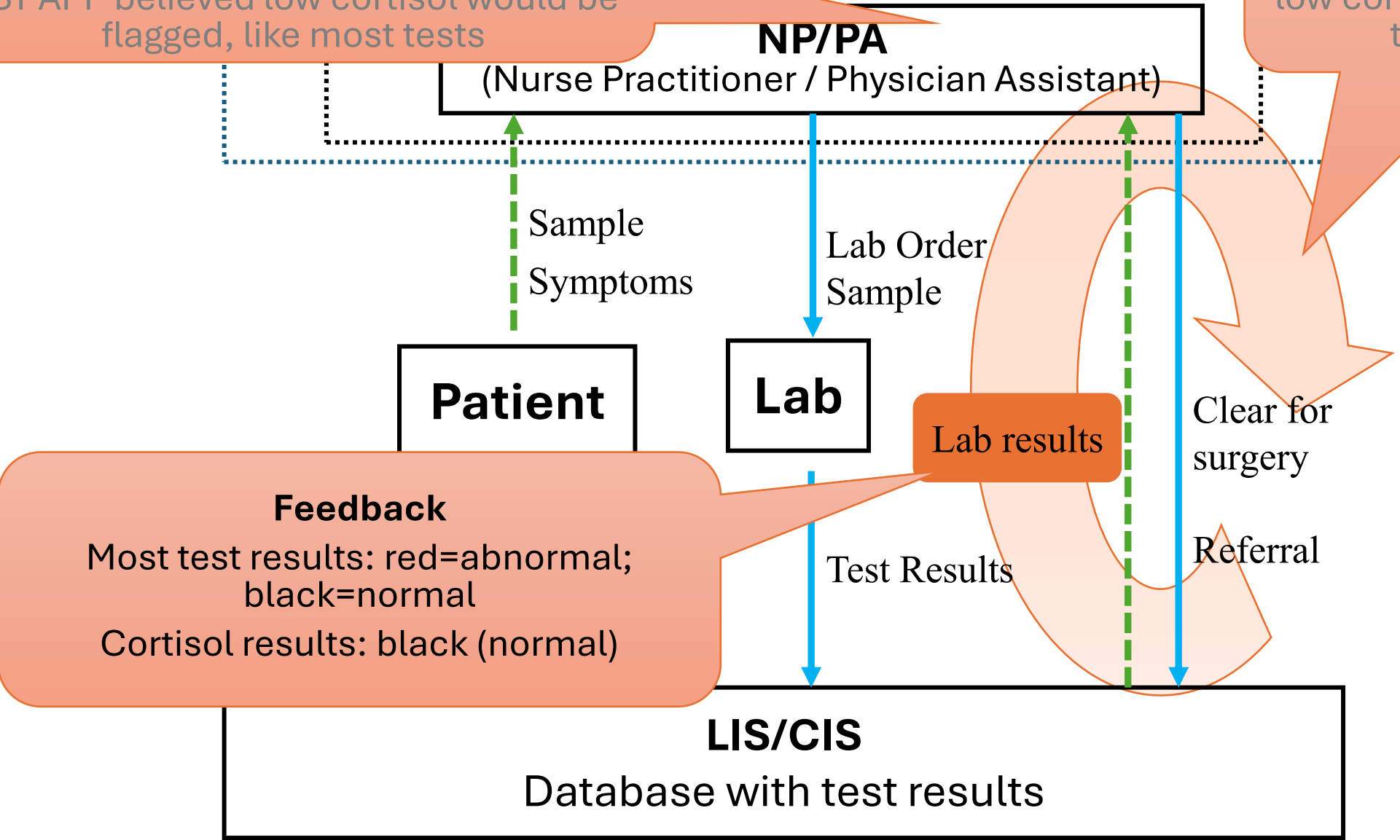
# Why?

### Mental Models

PST APP believed the cortisol value was within the reference range  
PST APP believed low cortisol would be flagged, like most tests

### Contributing Control Actions (UCAs):

PST APP did not recognize the low cortisol or refer the patient to endocrinology



### Feedback

Most test results: red=abnormal; black=normal  
Cortisol results: black (normal)

### NP/PA

(Nurse Practitioner / Physician Assistant)

**Patient**

**Lab**

Lab results

Clear for surgery

Referral

Test Results

### LIS/CIS

Database with test results

# Typical Test Results Screen (in EHR)

	2/22/24	3/12/24	3/29/24
eGFR (CKD-EPI 2021)	* 75	* 75	* 75
Anion Gap (Calc)	10		8
Z-score			
Insulin-Like Growth Factor-1, LC-M...			
Cortisol Level	* ↓ 0.5		* ↓ 0.9
Estradiol			
Growth Hormone			
Hemoglobin A1c.	* 5.5		* 5.5
Thyroxine (T4), Free	0.81	0.79	0.96
Thyroid Stimulating Horm...	* 1.72	* 1.34	* 2.64

# Actual Test Results Screen (in EHR)

	2/22/24	3/12/24	3/29/24
eGFR (CKD-EPI 2021)	* 75	* 75	* 75
Anion Gap (Calc)	10		8
Z-score			
Insulin-Like Growth Factor-1, LC-M...			
Cortisol Level	* 0.5		* 0.9
Estradiol			
Growth Hormone			
Hemoglobin A1c.	* 5.5		* 5.5
Thyroxine (T4), Free	0.81	0.79	0.96
Thyroid Stimulating Horm...	* 1.72	* 1.34	* 2.64

## Mental Models

MM-1: PST APP believed the cortisol value was within the reference range

MM-2: PST APP believed low cortisol would be flagged, like most tests

## NP/PA

(Nurse Practitioner / Physician Assistant)

Sample  
Symptoms

Lab Order  
Sample

Patient

Lab

Lab results

Clear for  
surgery

Test Results

Referral

## Feedback

FB-1: Most test results: red=abnormal;  
black=normal [MM-2]

FB-2: Cortisol results were black  
(normal) [MM-1]

## LIS/CIS

Database with test results

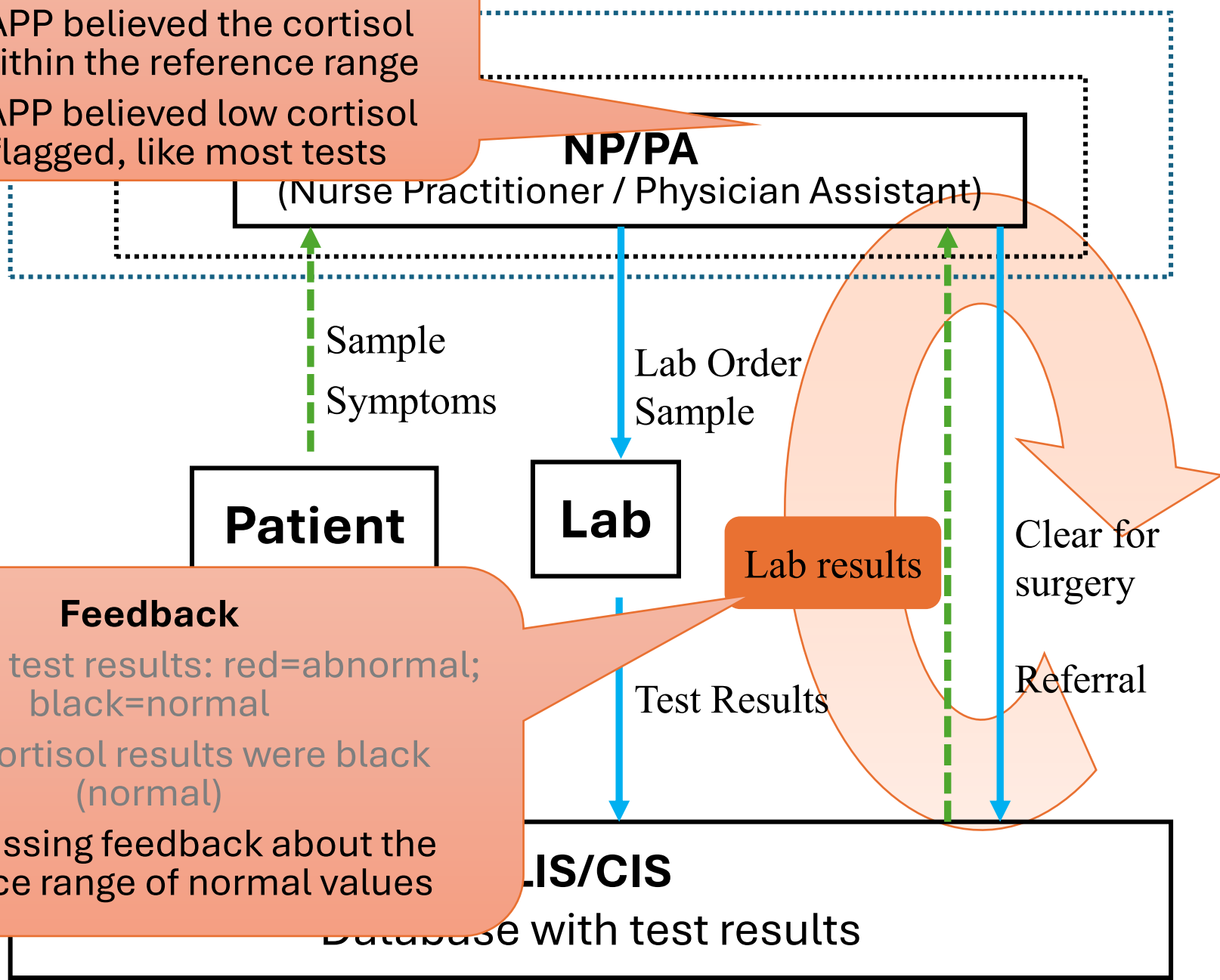
## Software Deficiencies

- 1) The design of lab results screen is inadequate to correct MM-1 (missing *red flag*)
- 2) The design of lab results screen is inadequate to correct MM-2 (black has dual meaning: *normal* OR *unknown*)

## Mental Models

MM-1: PST APP believed the cortisol value was within the reference range

MM-2: PST APP believed low cortisol would be flagged, like most tests



## Feedback

FB-1: Most test results: red=abnormal; black=normal

FB-2: Cortisol results were black (normal)

FB-3: Missing feedback about the reference range of normal values

# Actual Test Results Screen (in EHR)

	2/22/24	3/12/24	3/29/24
eGFR (CKD-EPI 2021)	* 75	* 75	* 75
Anion Gap (Calc)	10		8
Z-score			
Insulin-Like Growth Factor-1, LC-M...			
Cortisol Level	* 0.5		* 0.9
Estradiol			
Growth Hormone			
Hemoglobin A1c.	* 5.5		* 5.5
Thyroxine (T4), Free	0.81	0.79	0.96
Thyroid Stimulating Horm...	* 1.72	* 1.34	* 2.64

# Alternate screen with notes (less often used, but depends on the clinician)

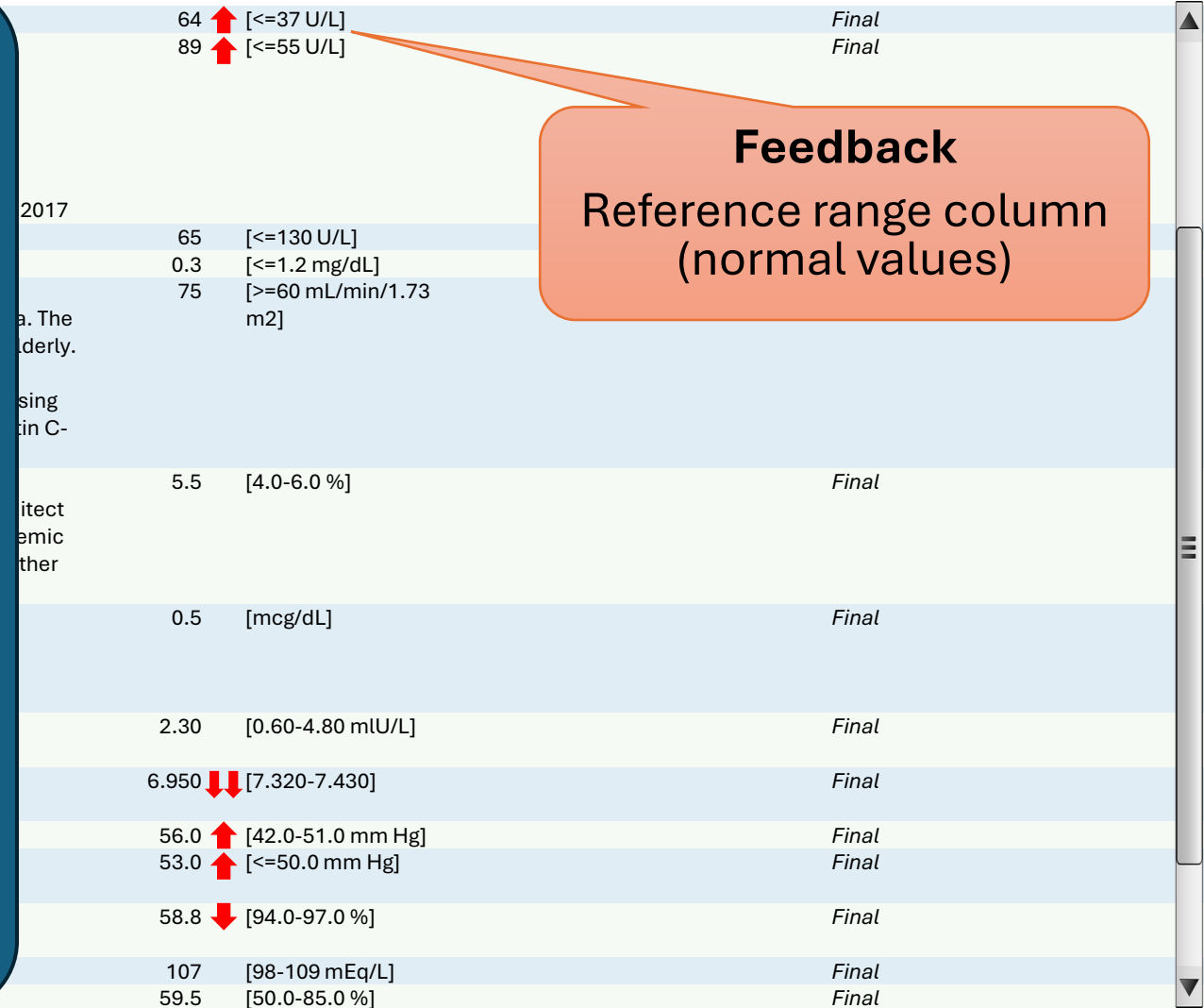
Quick: How many of these test results are abnormal?

	64	↑	[<=37 U/L]	Final
	89	↑	[<=55 U/L]	Final
2017				
	65		[<=130 U/L]	Final
	0.3		[<=1.2 mg/dL]	Final
	75		[>=60 mL/min/1.73 m2]	Final
a. The elderly.				
osing tin C-				
	5.5		[4.0-6.0 %]	Final
itect emic ther				
	0.5		[mcg/dL]	Final
	2.30		[0.60-4.80 mIU/L]	Final
	6.950	↓↓	[7.320-7.430]	Final
	56.0	↑	[42.0-51.0 mm Hg]	Final
	53.0	↑	[<=50.0 mm Hg]	Final
	58.8	↓	[94.0-97.0 %]	Final
	107		[98-109 mEq/L]	Final
	59.5		[50.0-85.0 %]	Final

# Alternate screen with notes

(less often used, but depends on the clinician)

Quick: How many of these test results are abnormal?



The screenshot shows a list of laboratory test results. An orange callout box labeled "Feedback" points to the reference range column, stating "Reference range column (normal values)".

Value	Reference Range	Status
64	[<=37 U/L]	Abnormal (↑)
89	[<=55 U/L]	Abnormal (↑)
65	[<=130 U/L]	Normal
0.3	[<=1.2 mg/dL]	Normal
75	[>=60 mL/min/1.73 m2]	Normal
5.5	[4.0-6.0 %]	Normal
0.5	[mcg/dL]	Normal
2.30	[0.60-4.80 mIU/L]	Normal
6.950	[7.320-7.430]	Abnormal (↓↓)
56.0	[42.0-51.0 mm Hg]	Abnormal (↑)
53.0	[<=50.0 mm Hg]	Abnormal (↑)
58.8	[94.0-97.0 %]	Abnormal (↓)
107	[98-109 mEq/L]	Normal
59.5	[50.0-85.0 %]	Normal

# Alternate screen with notes

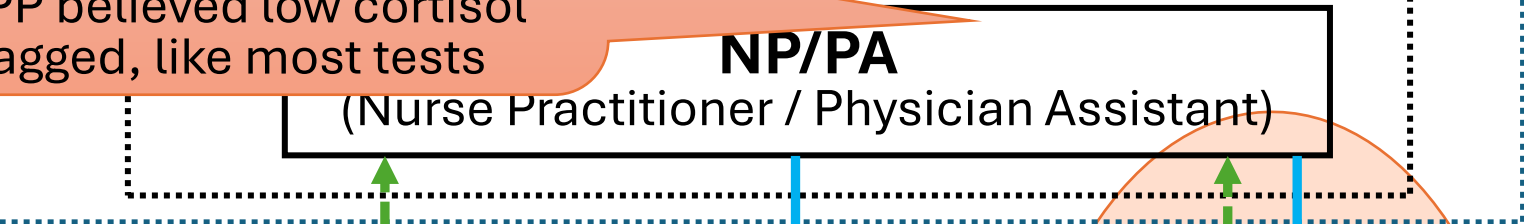
(less often used, but depends on the clinician)

Aspartate Aminotransferase (AST), Plasma	64	↑ [ $\leq 37$ U/L]	Final
Alanine Aminotransferase (ALT), Plasma	89	↑ [ $\leq 55$ U/L]	Final
Recommended healthy ALT level			
Males: 29-33 U/L			
Females: 19-25 U/L			
American College of Gastroenterology (ACG) Clinical Guideline: Evaluation of abnormal Liver Chemistries. 2017			
Alkaline Phosphatase (ALK), Plasma	65	[ $\leq 130$ U/L]	Final
Bilirubin, Total Plasma	0.3	[ $\leq 1.2$ mg/dL]	Final
eGFR (CKD-EPI 2021)	75	[ $\geq 60$ mL/min/1.73 m <sup>2</sup> ]	Final
The CKD-EPI (2021) is used to calculate the estimated GFR and is not adjusted to extreme body surface area. The CKD-EPI (2021) equation has not been validated for children less than 18 years, pregnant women, or the elderly. It has been developed in 2021 by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) and is recommended by the National Kidney Foundation and American Society of Nephrology Task Force Reassessing the Inclusion of Race in Diagnosing Kidney Disease. Inker LA, Eneanya ND et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. N Engl J Med 2021;385:1737-49.			
Hemoglobin A1c.	5.5	[4.0-6.0 %]	Final
Please note change in methodology as of 12/02/2021. The Hemoglobin A1c is performed on the Abbott Architect c8000. This assay measures the glycated fraction of total hemoglobin. It may not accurately reflect the glycemic control in patients with high levels of fetal hemoglobin (HgbF), recent transfusion, hemoglobinopathies or other conditions causing abnormal red blood cell turnover.			
Cortisol Level	0.5	[mcg/dL]	Final
Reference Range:			
A.M. 5.0-25.0			
P.M. 3.0-12.0			
Thyroid Stimulating Hormone (TSH)	2.30	[0.60-4.80 mIU/L]	Final
Includes reflex to Free Thyroxine for Thyroid Stimulating Hormone outside the reference range			
pH, Venous	6.950	↓↓ [7.320-7.430]	Final
Outside Reportable Range			
PCO2, Venous	56.0	↑ [42.0-51.0 mm Hg]	Final
PO2, Venous	53.0	↑ [ $\leq 50.0$ mm Hg]	Final
Please note change in reference range 2/15/2024.			
Oxyhemoglobin, Venous	58.8	↓ [94.0-97.0 %]	Final
Please note change in reference range 2/15/2024.			
Chloride, Whole Blood	107	[98-109 mEq/L]	Final
O2 Sat., Venous	59.5	[50.0-85.0 %]	Final

### Mental Models

MM-1: PST APP believed the cortisol value was within the reference range

MM-2: PST APP believed low cortisol would be flagged, like most tests



**NP/PA**  
(Nurse Practitioner / Physician Assistant)

Sample

Lab Order  
Sample

### Feedback

FB-1: Most test results: red=abnormal; black=normal

FB-2: Cortisol results were black (normal)

FB-3: Missing feedback about the reference range of normal values

FB-4: Alternate screen also missing reference range in expected location; notes are far from result value

Lab

Lab results

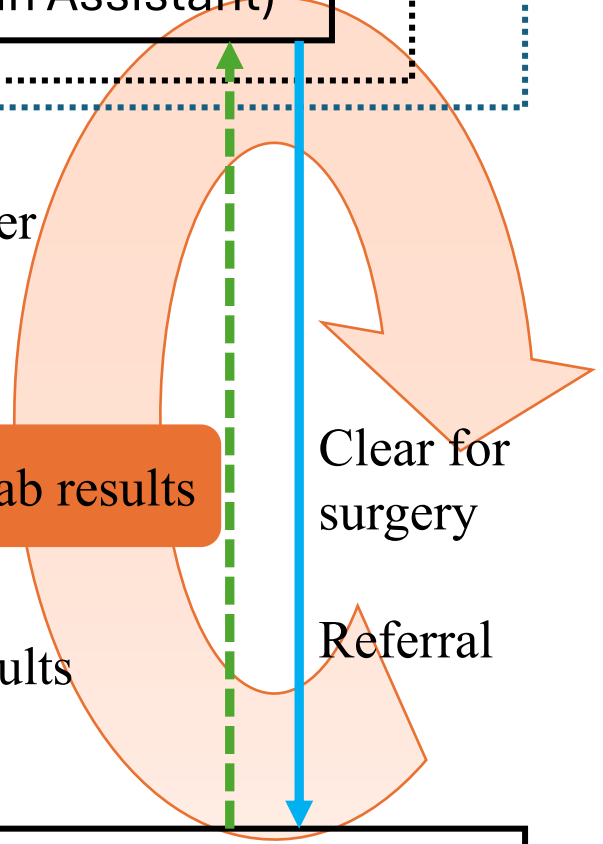
Test Results

Clear for surgery

Referral

**LIS/CIS**

Database with test results



# Actual Test Results Screen (in EHR)

## Feedback

The “\*” indicates there is a note that is hidden from view. Must hover the cursor here to see the hidden note. For cortisol, the hidden note contains the AM & PM reference ranges. However, most clinicians we interviewed could explain what the “\*” is for.

	2/22/24		
eGFR (CKD-EPI 2021)	*	7	
Anion Gap (Calc)			
Z-score			
Insulin-Like Growth Factor-1, LC-M...			
Cortisol Level	*	0.5	* 0.9
Estradiol			
Growth Hormone			
Hemoglobin A1c.	*	5.5	* 5.5
Thyroxine (T4), Free		0.81	0.79 0.96
Thyroid Stimulating Horm...	*	1.72	* 1.34 * 2.64

# Alternate screen with notes

(less often used, but depends on the clinician)

Aspartate Aminotransferase (AST), Plasma	64	↑	[<=37 U/L]	Final
Alanine Aminotransferase (ALT), Plasma	89	↑	[<=55 U/L]	Final
Recommended healthy ALT level				
Males: 29-33 U/L				
Females: 19-25 U/L				
American College of Gastroenterology (ACG) Clinical Guideline: Evaluation of abnormal Liver Chemistries. 2017				
Alkaline Phosphatase (ALK), Plasma	65		[<=130 U/L]	Final
Bilirubin, Total Plasma	0.3		[<=1.2 mg/dL]	Final
eGFR (CKD-EPI 2021)	75		[>=60 mL/min/1.73 m2]	Final
The CKD-EPI (2021) CKD-EPR (2021) eq				
It has been develop				
recommended by th				
the Inclusion of Rac				
Based Equations to				
Hemoglobin A1c.	5.5		[4.0-6.0 %]	Final
Please note change				
c8000. This assay me				
control in patients with high levels				
conditions causing abnormal				
Cortisol Level	0.5		[mcg/dL]	Final
Reference Range:				
A.M. 5.0-25.0				
P.M. 3.0-12.0				
Thyroid Stimulating Hormone (TSH)	2.30		[0.60-4.80 mIU/L]	Final
Includes reflex to Free Thyroxine for Thyroid Stimulating Hormone outside the reference range				
pH, Venous	6.950	↓↓	[7.320-7.430]	Final
Outside Reportable Range				
PCO2, Venous	56.0	↑	[42.0-51.0 mm Hg]	Final
PO2, Venous	53.0	↑	[<=50.0 mm Hg]	Final
Please note change in reference range 2/15/2024.				
Oxyhemoglobin, Venous	58.8	↓	[94.0-97.0 %]	Final
Please note change in reference range 2/15/2024.				
Chloride, Whole Blood	107		[98-109 mEq/L]	Final
O2 Sat., Venous	59.5		[50.0-85.0 %]	Final

**Feedback**

Which of these ranges should the clinician be using?

Was this an A.M. or P.M. test?

# Alternate screen with notes (less often used, but depends on the clinician)

Original recommendation: Always use a.m. values to flag cortisol.

## New Feedback

Always displays 5-25 a.m. range beside test result (even for p.m. tests)

Can cause *false negative flags*: no flag is shown, although out of range for p.m. test

Can cause *false positive flags*: flag incorrectly appears, even though in normal range for p.m. test

## New Clinician Mental Models?

MM-1: Incorrectly believes the listed reference range is accurate

MM-2: Incorrectly believes a flag will appear if abnormal

MM-3: Incorrectly believes a flag indicates abnormal result

MM-4: Incorrectly believes the test was an a.m. test (since the a.m. range is shown on screen)

Aspartate Aminotransferase (AST)		U/L]	
Alanine Aminotransferase (ALT)		U/L]	
Red Blood Cell Count (RBC)			
Male			
Female			
Ammonia			
Alkaline Phosphatase (ALP)		U/L]	
Bilirubin, Total		mg/dL]	
eGFR (CKD-EPI)		mL/min/1.73m <sup>2</sup> ]	
Theophylline			
CKD-EPI			
It has been recommended that the theophylline level be reported as a percentage of the baseline value.			
Hemoglobin A1c		%]	[4.0-6.0 %]
Please note change in methodology as of 12/02/2021. The Hemoglobin A1c is performed on the HbA1c8000. This assay measures the glycated fraction of total hemoglobin. It may not accurately reflect the glycated hemoglobin in patients with high levels of fetal hemoglobin (HgbF), recent transfusion, hemoglobinopathies or other conditions causing abnormal red blood cell turnover.			
Cortisol Level	21.2	[5.0-25 mcg/dL]	Final
Reference Range:			
A.M. 5.0-25.0			
P.M. 3.0-12.0			
Thyroid Stimulating Hormone (TSH)	2.30	[0.60-4.80 mIU/L]	Final
Includes reflex to Free Thyroxine for Thyroid Stimulating Hormone outside the reference range			
pH, Venous	6.950	↓↓ [7.320-7.430]	Final
Outside Reportable Range			
PCO2, Venous	56.0	↑ [42.0-51.0 mm Hg]	Final
PO2, Venous	53.0	↑ [≤50.0 mm Hg]	Final
Please note change in reference range 2/15/2024.			
Oxyhemoglobin, Venous	58.8	↓ [94.0-97.0 %]	Final
Please note change in reference range 2/15/2024.			
Chloride, Whole Blood	107	[98-109 mEq/L]	Final
O2 Sat., Venous	59.5	[50.0-85.0 %]	Final

# Alternate screen with notes (less often used, but depends on the clinician)

Aspartate Aminotransferase (AST), Plasma	64	↑	[<=37 U/L]	Final
Alanine Aminotransferase (ALT), Plasma	89	↑	[<=55 U/L]	Final
Recommended healthy ALT level				
Males: 29-33 U/L				
Females: 19-25 U/L				
American College of Gastroenterology (ACG) Clinical Guideline: Evaluation of abnormal Liver Chemistries. 2017				
Alkaline Phosphatase (ALK), Plasma	65			
Bilirubin, Total Plasma	0.3			
eGFR (CKD-EPI 2021)	75			
The CKD-EPI (2021) is used to calculate the estimated GFR and is not adjusted to extreme body surface area. The CKD-EPI (2021) equation has not been validated for children less than 18 years, pregnant women, or the elderly. It has been developed in 2021 by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) and is recommended by the National Kidney Foundation and American Society of Nephrology Task Force Reassessing the Inclusion of Race in Diagnosing Kidney Disease. Inker LA, Eneanya ND et al. New Creatinine- and Cystatin C-Based Equations to Estimate GFR without Race. N Engl J Med 2021;385:1737-49.				
Hemoglobin A1c.	5.5			
Please note change in methodology as of 12/02/2021. The Hemoglobin A1c is performed on the Abbott Architect c8000. This assay measures the glycosylated fraction of total hemoglobin. It may not accurately reflect the glycemic control in patients with high levels of fetal hemoglobin (HgbF), recent transfusion, hemoglobinopathies or other conditions causing abnormal red blood cell turnover.				
Cortisol Level	0.5		[mcg/dL]	Final
Reference Range:				
A.M. 5.0-25.0				
P.M. 3.0-12.0				
Thyroid Stimulating Hormone (TSH)	2.30		[0.00-4.80 mIU/L]	Final
Includes reflex to Free Thyroxine for Thyroid Stimulating Hormone outside the reference range				
pH, Venous	6.950	↓↓	[7.320-7.430]	Final
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PO2, Venous	53.0	↑	[<=50.0 mm Hg]	Final
Please note change in reference range 2/15/2024.				
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Please note change in reference range 2/15/2024.				
Chloride, Whole Blood	107		[98-109 mEq/L]	Final
O2 Sat., Venous	59.5		[50.0-85.0 %]	Final

**Feedback**

Double arrow indicates “critical” value. There is no screen to find out which tests have critical values defined or what the critical values or.

Cortisol will never flag a critical value, but there is no way to know that.

## Mental Models

MM-1: PST APP believed the cortisol value was within the reference range

MM-2: PST APP believed low cortisol would be flagged, like most tests

## Feedback

FB-1: Most test results: red=abnormal; black=normal

FB-2: Cortisol results were black (normal)

FB-3: Missing feedback about the reference range of normal values

FB-4: Alternate screen also missing reference range in expected location; notes are far from result value

FB-5: Both the normal and alternate screen are missing the time of the test, crucial for interpreting cortisol level.

## Software Deficiencies

3) The EHR screens lack the info necessary to interpret cortisol (do not include the time the sample was drawn)

*Note: other screens exist with "time of order", "time of report", "time result received". None of these is useful for interpreting cortisol level.*

**NP/PA**  
(Nurse Practitioner / Physician Assistant)

Lab Order  
Sample

Lab results

Clear for surgery

Test Results

Referral

**IS/CIS**  
use with test results

# Original Investigation (3)

How many of these problems were fixed by original recommendations?

- Recommendations
  - **Remind PST providers to carefully review lab results like cortisol and document the reasons for the test**
  - EHR eventually updated to flag abnormal cortisol values by **always using the a.m. range** for cortisol (5-25)
    - Most cortisol tests are scheduled in the a.m.
    - **Text note added** to explain that providers must check the reference range and interpret results differently if it is not an a.m. test
  - Critical value policy reviewed. **No change necessary.**
  - Medical Quality Assurance group **declined to investigate** the role of MDs as none appear to have been involved in the event



Oncologist (MD)

New/ongoing symptoms

Diagnosis and treatment

New

Consultation and

### Mental Models

Oncologist unavailable for interview, but also seems to have missed the low cortisol in the absence of a flag.

Common belief: responsibility for recognizing abnormal values lies with the ordering clinician (even if less qualified)

May have believed there was no need to double check PST lab results when notified of a referral (contrary to what others believed)

No investigation to understand the gaps here.

Patient

Order tests

Diagnosis and treatment

Patient

Test Results

### Contributing Control Actions (UCAs)

Oncologist did not notice or diagnose the critically low cortisol level

LIS/CIS

### Feedback

Oncologist was notified of patient symptoms and referral to UCC / ED

### Feedback

Surgeon was notified of the patient lab results, including cortisol, as well as the patient symptoms and PST referrals

### Process Deficiencies

Why is PST notifying the MDs (surgeon and oncologist) of PST test results and symptoms if they are just being ignored?

Surgery Department

Request for surgery  
Patient not clear  
Notification of concerns  
Request for consultation

Schedule or cancel surgery

PST

APP

NP/PA

(Practitioner / Physician Assistant)

### Mental Models

Surgeon unavailable for interview  
In the absence of a flag, likely also missed the low cortisol level

*Surgeon may have believed PST notifications and consultation requests do not require assistance with diagnosis*

No investigation to understand the gaps here.

Sample

Lab results

Clear for surgery

Referral

Test Results

CIS

with test

### Contributing Control Actions (UCAs)

Surgeon did not recognize the low cortisol lab result or diagnose the adrenal insufficiency prior to surgery

### Feedback

No objective feedback to indicate these deficiencies.

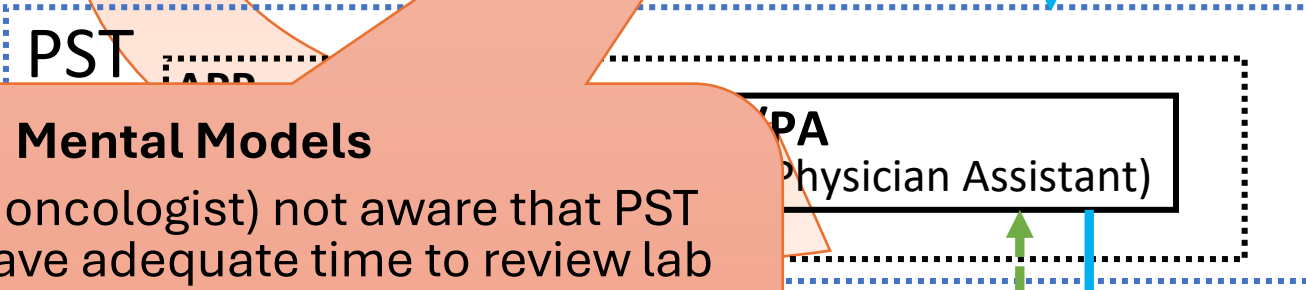
Complaints occasionally received, but with no effect.



Patient clear for surgery  
Patient not clear  
Notification of concerns  
Request for consultation



PST schedule



### Mental Models

Surgeon (and oncologist) not aware that PST APPs do not have adequate time to review lab results between patients, increasing their dependence on flags

Not aware that PST APPs do not have workspace to review lab results away from interruptions



Lab results  
Clear for surgery  
Referral



LIS/CIS

Database with test results

### Contributing Control Actions (UCAs)

Surgery Dept schedules back-to-back 30-minute consultations without any dedicated time for APP to review lab results

# Hospital Administration

Concerns  
Requests  
Reactive measures  
Proactive measures

Priorities  
Direction

Human and physical resources

# Department Leadership

Adverse events  
RISQ reports

actions  
(e.g., provide education)

Corrective actions

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions  
(e.g., provide education)

## Mental Models

Believed the template schedule achieved a reasonable balance to ensure safety and performance

Lab Group

ST

APP

NP/PA

(Nurse Practitioner / Physician Assistant)

UCC NPs

UCC MDs

Oncology

Setup  
Enter

## Feedback

Past complaints made about templates, but seen as subjective. The only strong feedback is adverse events. All past RCAs (including this one) did not identify the templates as a contributing factor.

Sample

Sample

Lab results

Diagnosis

Diagnosis

Clear for

R

bas

## Contributing Control Action

Administration provides templates that require scheduling back-to-back 30-minute consultations without time to review results

## Control Structure Gaps

Each mental model is essentially an assumption. A strong control structure will include feedback to correct these mental models, now or in the future.

## Feedback

No feedback exists to challenge the mental models

No feedback to indicate when flags are missing

## Contributing Control Action

Lab group configured LIS with no cortisol flag, only a hidden note about the range

al and departmental leadership

t reports  
Q reports  
e metrics



Corrective actions (e.g., provide education)



Lab Group

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

LIS/CIS

Database with test results

## Mental Models

Believed flags are optional, not required

Believed clinicians use the “final lab report” screen with detailed info, not the results overview screen

Believed clinicians are familiar with “\*” and will read the note

**Hospital and departmental leadership**

Adverse event reports  
RISQ reports  
Proactive metrics



Corrective actions (e.g., provide education)



**Lab Group**

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

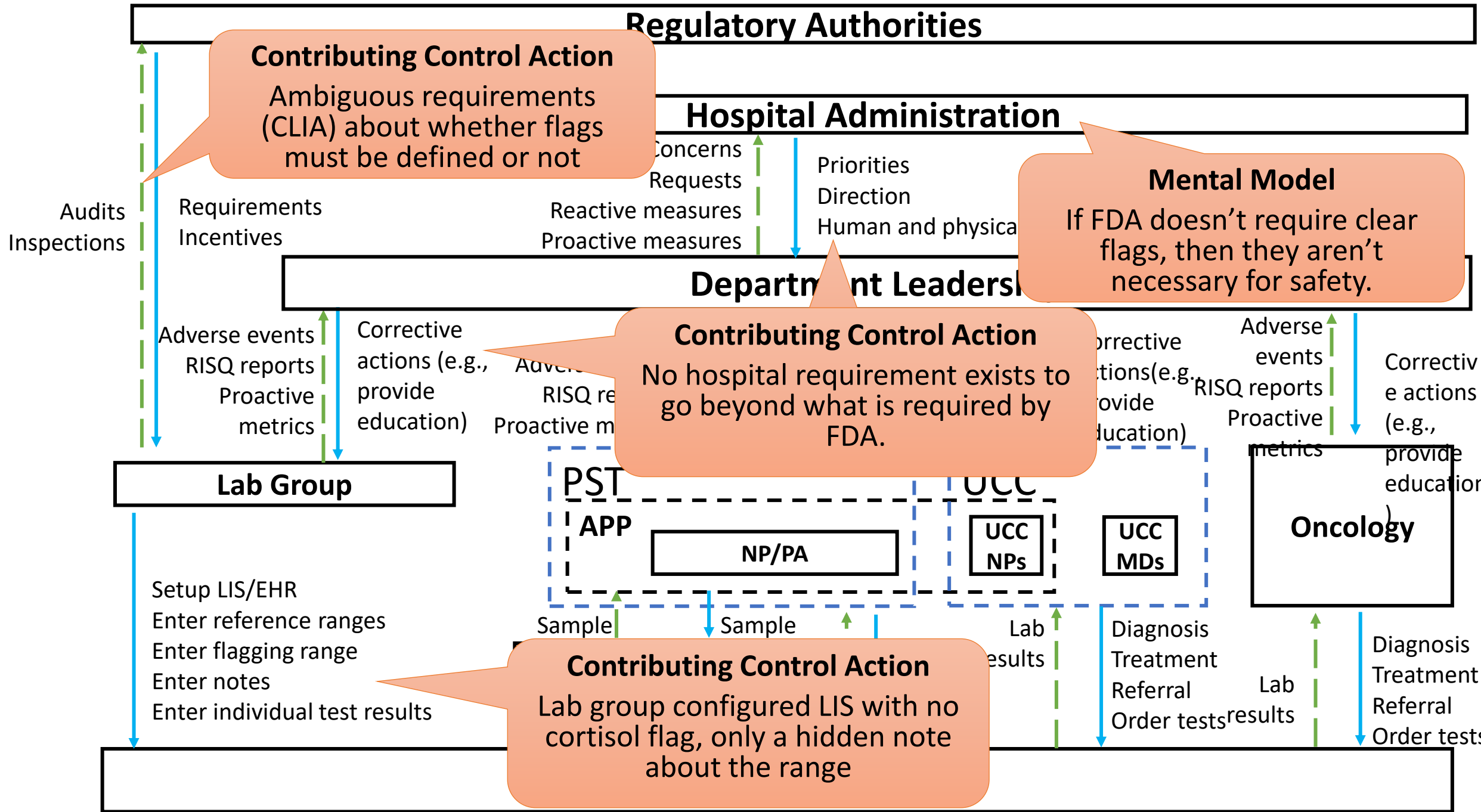


**LIS/CIS**  
Database with test results

**Context**  
Other institutions solved the diurnal (a.m./p.m.) reference range problem by splitting cortisol orders into an a.m. and p.m. order  
Weak or no feedback between institutions to share these best practices / lessons learned.



**Contributing Control Action**  
Lab group configured LIS with no cortisol flag, only a hidden note about the range



# Regulatory Authorities

## Hospital Administration

Audits  
Inspections

Requirements  
Incentives

Concerns ↑  
Priorities ↓

**CLIA Inspector**  
A test like cortisol does need to be flagged in order to meet CLIA requirements. I would have cited them if I saw this, and I would be a stickler for that.

resources

Adverse events  
RISQ reports  
Proactive metrics

action  
provide  
educ

RISQ reports ↓  
provide

RISQ reports ↓  
provide

Corrective actions (e.g. provide education)

Adverse events ↑  
RISQ reports ↓  
Proactive metrics

Corrective actions (e.g., provide education)

### Lab Group

**Another CLIA Inspector**  
As long as they have a note with the range, they would pass. A flag is not strictly required for a test like cortisol.

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

Sample ↑  
**Patient**  
Patient Portal

Sample ↓  
**Lab**  
Test results

Lab results ↑  
Clear for surgery  
Referral

Lab results ↑

**UCC MDs**

Diagnosis  
Treatment  
Referral  
Order tests

**Oncology**

Lab results ↑  
Diagnosis  
Treatment  
Referral  
Order tests

### LIS/CIS

# Regulatory Authorities

# Hospital Administration

# Department Level

# Lab Group

# APP

# NP/PA

# UCC

# UCC NPs

# UCC MDs

# Oncology

# Patient

# Lab

# Lab results

# Lab results

# Lab results

# Lab results

# LIS/CIS

## Mental Model: Disabled Flags

Do you have an idea of how many common lab tests have flags effectively disabled?

**Answer: No**

**Answer: "99.9% have flags enabled"  
0.01% have flags disabled**

Audits  
Inspections

Requirements  
Incentives

Concerns  
Requests  
Reactive measures  
Proactive measures

Priorities  
Direction  
Human and physical

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g.,  
provide education)

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g.,  
provide education)

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g.,  
provide education)

Proactive metrics  
education

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

Sample

Sample

Lab results

Diagnosis  
Treatment  
Referral  
Order tests

Diagnosis  
Treatment  
Referral  
Order tests

Diagnosis  
Treatment  
Referral  
Order tests

Patient Portal

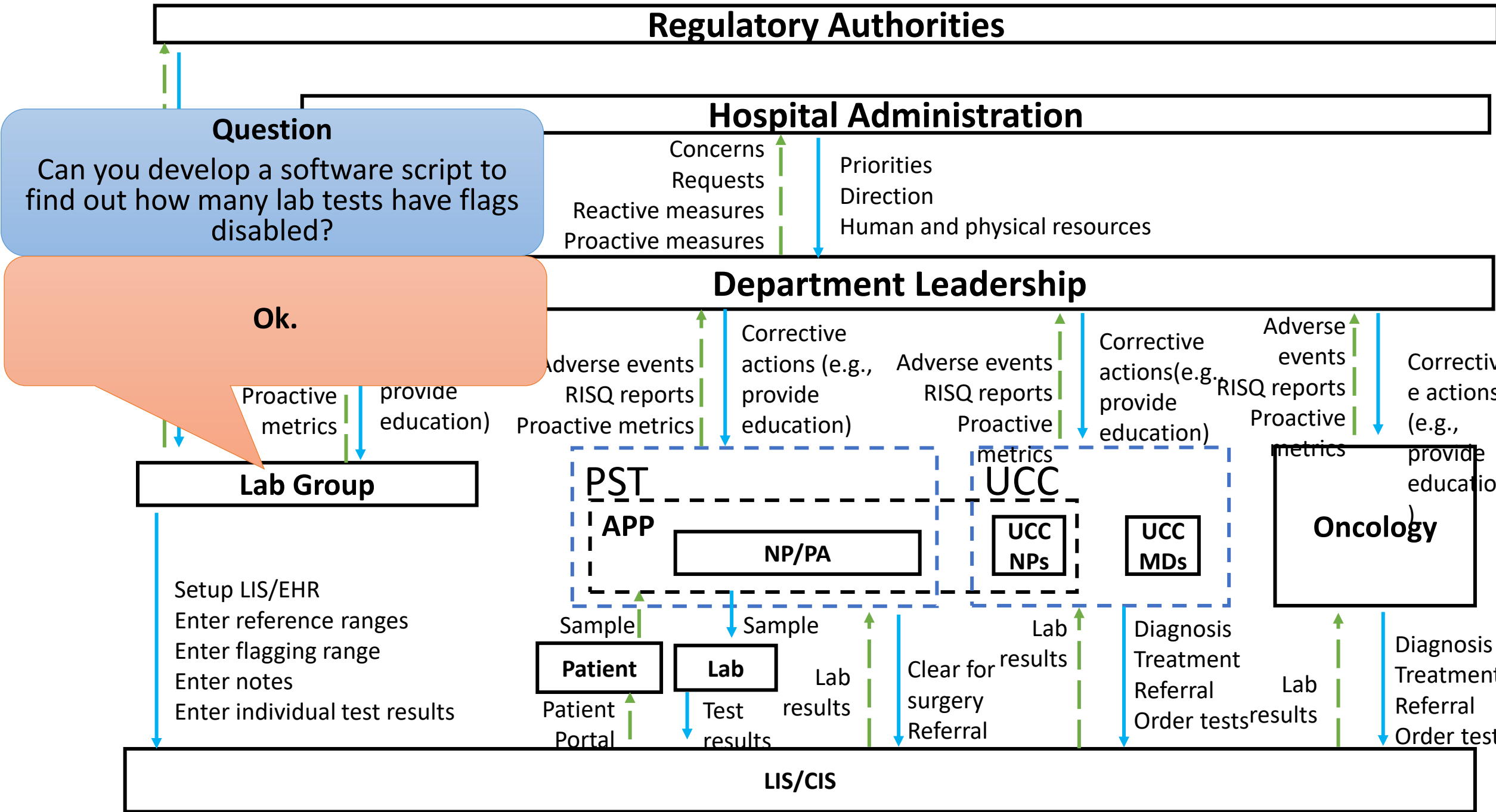
Test results

Lab results

Clear for surgery  
Referral

Lab results

Lab results



# Regulatory Authorities

## Hospital Administration

**Question**  
Can you develop a software script to find out how many lab tests have flags disabled?

Concerns  
Requests  
Reactive measures  
Proactive measures

Priorities  
Direction  
Human and physical resources

**15% of all common lab tests have flags effectively disabled**

## Department Leadership

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g., provide education)

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g., provide education)

Adverse events  
RISQ reports  
Proactive metrics

Corrective actions (e.g., provide education)

### Lab Group

Proactive metrics  
provide education

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

### PST

#### APP

### NP/PA

### UCC

#### UCC NPs

#### UCC MDs

### Oncology

### Patient

### Lab

Patient Portal

Test results

Lab results

Clear for surgery  
Referral

Lab results

Diagnosis  
Treatment  
Referral  
Order tests

Lab results

Diagnosis  
Treatment  
Referral  
Order tests

## LIS/CIS

# Regulatory Authorities

## Hospital Administration

Concerns  
Requests  
Reactive measures  
Proactive measures

Priorities  
Direction  
Human and

**No organizational function or responsibility to check for disabled flags or proactively fix them**  
**Not unique to this medical center-- common across many institutions**

**15% of all common lab tests have flags effectively disabled**

## Department Leadership

Adverse events  
RISQ reports  
Proactive metrics  
provide education)  
Corrective actions (e.g.,  
provide education)  
Adverse events  
RISQ reports  
Proactive metrics  
provide education)  
Adverse events  
RISQ reports  
Proactive metrics  
provide education)  
Corrective actions (e.g.,  
provide education)

### Lab Group

Setup LIS/EHR  
Enter reference ranges  
Enter flagging range  
Enter notes  
Enter individual test results

PST  
APP

NP/PA

UCC  
UCC NPs

UCC MDs

Oncology

Patient  
Patient Portal

Lab  
Test results

Lab results

Clear for surgery  
Referral

Lab results

Diagnosis  
Treatment  
Referral  
Order tests

Lab results

Diagnosis  
Treatment  
Referral  
Order tests

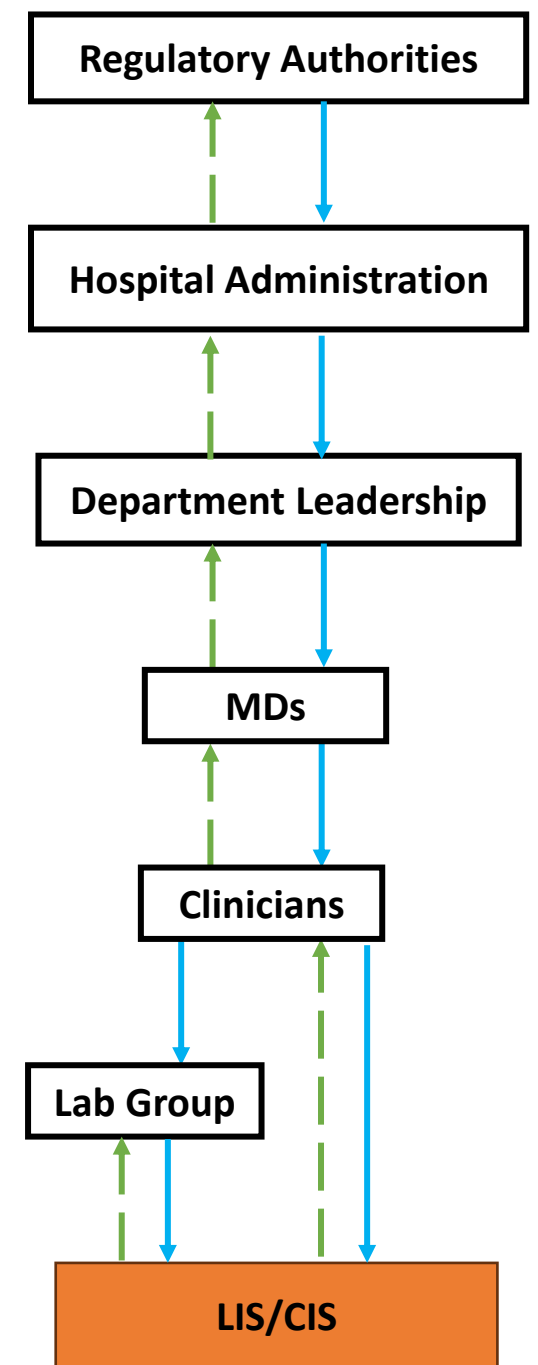
# LIS/CIS

# Recommendations

## Software & Configuration Changes

- Separate cortisol orders into a.m. / p.m. orders, so flagging is always correct
- Avoid visual indicators with dual meaning. All summary screens must distinguish abnormal, normal, and unknown.

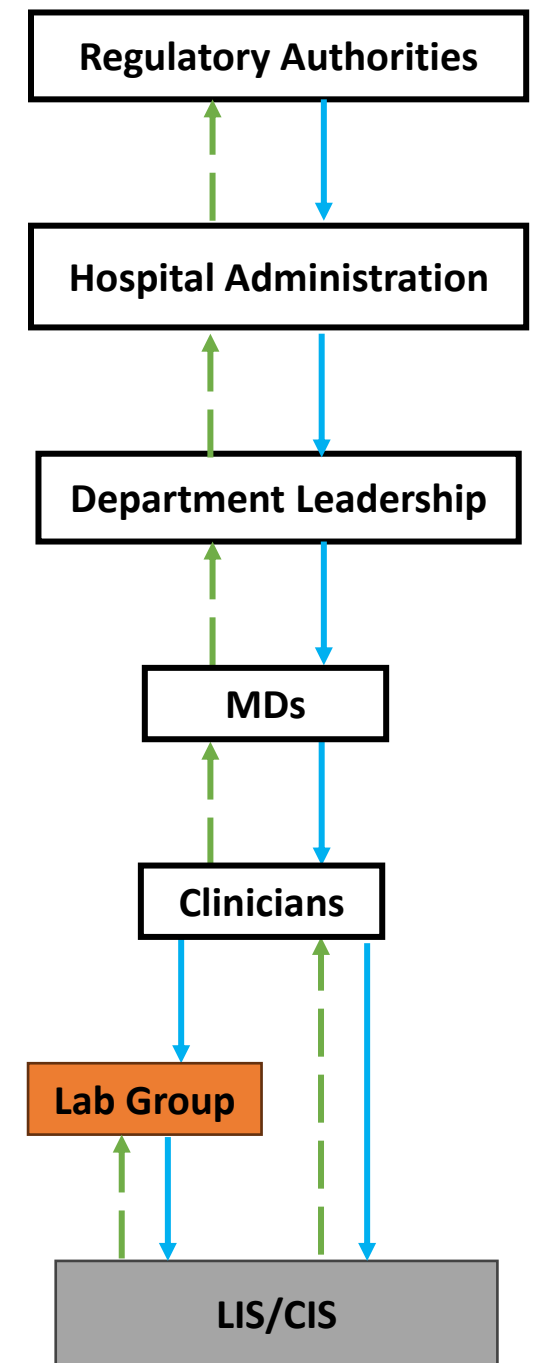
Significance	From	To
Abnormal result	Red	Red
Normal result	Black	Green
Unknown / not checked	Black	Black



# Recommendations (2)

## Lab Group

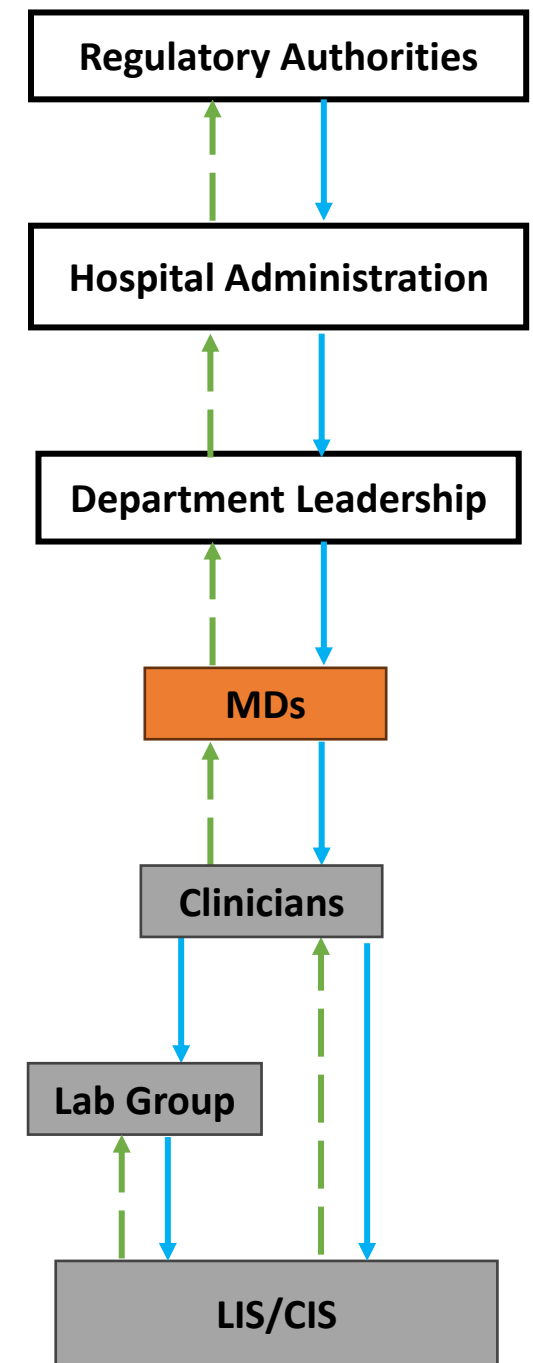
- Minimize the number of labs that rely on comments to convey reference ranges.
- Identify which labs currently rely on comments fields to convey reference ranges, review them periodically, and identify possible alternatives.
- Establish a clear policy about when flags may / may not be disabled in the future
- Define a process to compare the reference and flagging ranges with other institutions.
- Identify solutions to provide feedback on whether and when test results, including the notes, are actually presented to clinicians. For example, are >50% of notes never presented to clinicians?



# Recommendations (3)

MDs (Oncologist and Surgeon)

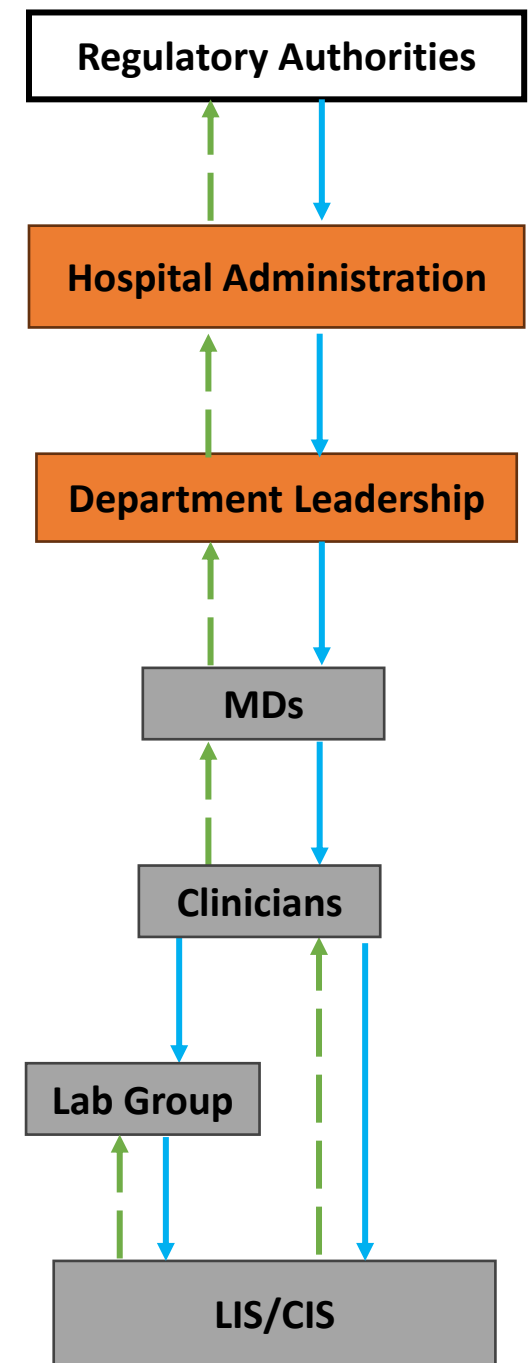
- The Quality Assurance group should **investigate why the oncologist was not able to identify** the low cortisol level and diagnose adrenal insufficiency.
- Tests (e.g., cortisol) for anticipated side effects **should be ordered by the team that is in charge of the patient's care** and treatment, not PST.
  - PST may repeat tests to verify the patient's current condition is stable.
- **Oncologists should assume the role of the primary care physician** and care coordinator for oncology patients. All tests, consults, and other healthcare visits should be sent to and reviewed by the oncologist.
  - If these policies already exist, then investigate why they were not effective and address the gaps.



# Recommendations (4)

## Department Leadership

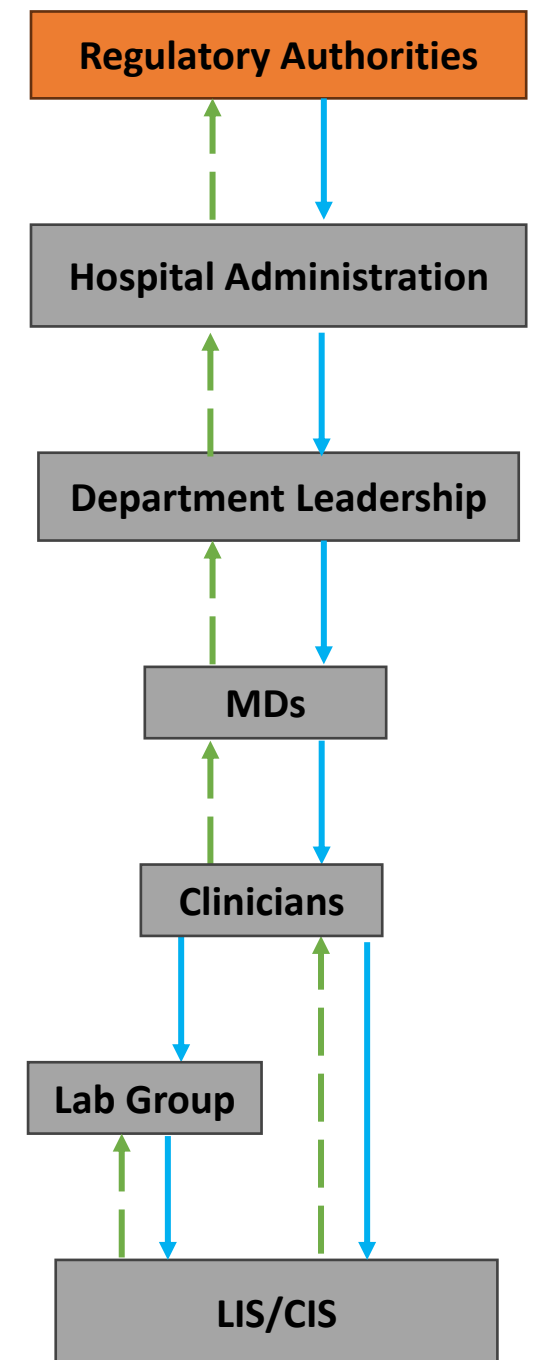
- Provide additional time for PST APP patient visits to enable careful review of lab results.
- Determine the extent to which PST APPs feel that leadership actions have prioritized quantity over quality and safety. If so, then determine why and address their concerns. Collect feedback from PST to determine if the solutions were effective.



# Recommendations (5)

Regulatory and certification bodies (e.g., CLIA)

- Regulations addressing hospital EHR systems (such as the ONC certification program) must be updated to clarify that lab results must distinguish:
  - Lab value that has no associated flags and requires manual interpretation
  - Lab value is within reference range
  - Lab value is within flagging range
  - Lab value is in critical range
- Improve the ability for auditors to identify missing reference ranges and flags quickly.
- Set up an industry-wide mechanism to compare practices across institutions, such as flagging ranges and defining separate cortisol a.m./p.m. tests. Make this information available to peer institutions as well as to regulators to understand the state of the healthcare system and the prevalence of various challenges.





# How much time did CAST take?

- Interviews: ~20 x 1hr each
  - As outside CAST facilitators, we needed to learn the full context at this facility
  - Much less time would be needed if CAST performed by medical practitioners
- CAST Analysis: ~10 hours
  - Includes quick sketch of control structure, UCA list, PM list, Context list
    - Almost entirely extracted from the interview notes
  - *Does not include activities for our research deliverable: searching for a suitable case study that can be published, turning results into a full research report, review by key stakeholders of the results, addressing comments before publication, and developing this public slide deck.*

# More info

- Full report with more info:

[https://psas.scripts.mit.edu/home/papers/2024 CAST of an Adverse Event Involving Labor.pdf](https://psas.scripts.mit.edu/home/papers/2024_CAST_of_an_Adverse_Event_Involving_Labor.pdf)