

# When Things Go Sideways: Managing Shortages and Physical Disasters

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February 27, 2026

First Coast ID/CM Symposium

# Disclosures

- Avsana Labs- scientific advisory board member
- bioMérieux- grant funding (past)

# Objectives

- Recognize the terms conventional, contingency, and crisis management as they pertain to managing laboratory supplies shortages.
- Identify stepwise laboratory-based operational approaches to mitigate negative impact on patient care during shortages and physical disasters.
- Understand the role of laboratory leaders in organizing a collaborative clinical response with stakeholders outside the laboratory for infectious disease testing during extreme shortages and other crises.

# Shortages come in all flavors

**Insufficient  
reagents/supplies**

**Infrastructure**

**Personnel**

**Patient specimen  
access/movement**

**Instrumentation**

# Causes for shortages

## Temporary Shortages (days-weeks)

### Reagents/Tests

- Local increased test demand, not forecasted
- Vendor backorders
- Delayed deliveries

Instrumentation being down

Unexpectedly high staff call-outs

**Physical Disasters**

## Prolonged Shortages (months)

- Manufacturing component sourcing issues
- Recalls (already discussed)
- Widescale increased test demand, not forecasted
- Lack of eligible workforce

<u>Conventional Management</u>		<u>Contingency Management</u>	<u>Crisis Management</u>
<b>Baseline Operations</b>	<b>Heightened Emphasis on Best Practices</b>		
<ul style="list-style-type: none"> <li>- Continuous emphasis on quality of specimen collections</li> <li>- Encourage clinically indicated test ordering and diagnostic stewardship</li> <li>- Supply inventory managed to minimize waste, align with storage space, optimize cash flow</li> </ul>	<ul style="list-style-type: none"> <li>- Increase staff re-education and system-wide prioritization of blood culture collection quality</li> <li>- Diagnostic stewardship programs implemented throughout the system, simultaneously</li> <li>- Re-distribute near expiration date bottles to high-use areas</li> </ul>	<ul style="list-style-type: none"> <li>- Centralize supplies and re-set unit inventory levels</li> <li>- Set temporary clinical guidance to reduce testing, beyond what is typically recognized as best practice or stewardship</li> </ul>	<ul style="list-style-type: none"> <li>- Restrict or greatly reduce access to inventory</li> <li>- Set temporary clinical guidance to significantly reduce testing which is not supported by routine best practice standards</li> </ul>



**Inventory Levels**

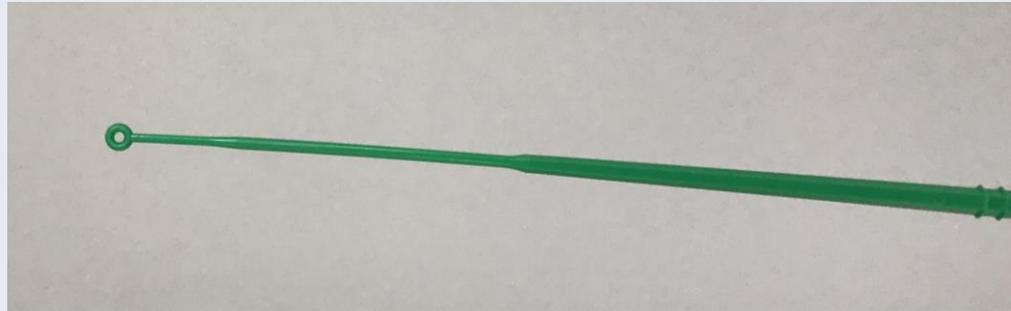


**Target Reduction of Use**



**Interventions Implemented**

# Example 1: Calibrated sterile plastic loop shortage (vendor backorder)



## What it's used for:

- Sterile loop to streak specimens for culture
- Quantitative loop for inoculating urine for urine culture

## Alternative:

- Single use sterile loops, same specimen volume
- Different manufacturer
- Different product number

## Would you perform a verification before implementing this loop alternative?

Yes



No



# Verification Requirements

- CLIA '88
- Required when a non-waived test system is introduced into the laboratory
- Technical Consultant\Supervisor or Laboratory Director are responsible for ensuring the procedure used for verifying the performance specifications is adequate
- Should include: accuracy, precision, reportable range, reference intervals, as applicable
- No universal design, no prescriptive sample # for verifications
- Accrediting bodies may have stricter requirements

<https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/6064bk.pdf>

## What it's used for:

- Sterile loop to streak specimens for culture
- Quantitative loop for inoculating urine for urine culture

## Alternative:

- Single use sterile loops, same specimen volume
- Different manufacturer
- Different product number

## Requirements to implement:

- **Streaking cultures:**
  - **Not needed**
  - **Certificate of analysis indicating product sterility**
- **Inoculation of urine for cultures:**
  - **Abbreviated or streamlined verification**
  - **Check specimen volume delivery**
- **Training:**
  - **Probably none**
  - **Does the loop feel or act different?**

## External notification:

- None

## EMR/LIS changes:

- None

## Conventional Management

### Baseline Operations

- Continuous emphasis on quality of specimen collections
- Encourage clinically indicated test ordering and diagnostic stewardship
- Supply inventory managed to minimize waste, align with storage space, optimize cash flow

### Heightened Emphasis on Best Practices

- Increase staff re-education and system-wide prioritization of blood culture collection quality
- Diagnostic stewardship programs implemented throughout the system, simultaneously
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## Contingency Management

- Centralize supplies and re-set unit inventory levels
- Set temporary clinical guidance to reduce testing, beyond what is typically recognized as best practice or stewardship

## Crisis Management

- Restrict or greatly reduce access to inventory
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### Inventory Levels

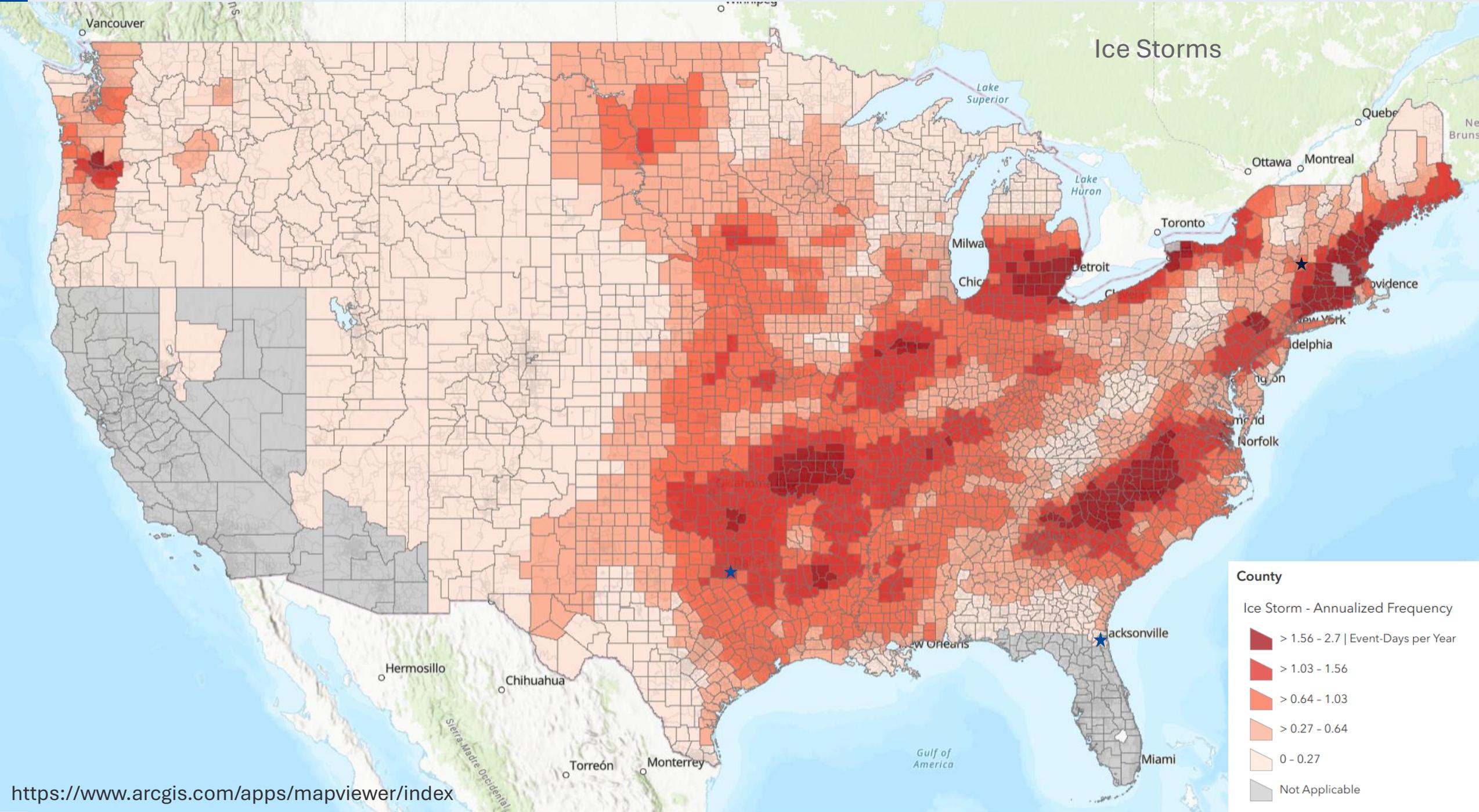
### Target Reduction of Use

### Interventions Implemented

## Example 2: Delayed Receipt of Blood Agar Plates



# Ice Storms



**County**

Ice Storm - Annualized Frequency

- > 1.56 - 2.7 | Event-Days per Year
- > 1.03 - 1.56
- > 0.64 - 1.03
- > 0.27 - 0.64
- 0 - 0.27
- Not Applicable

# Winter Precipitation

	Lane miles	Fleet
Florida- statewide (public roads)	278,661  Duval county- 7,760 center lane miles	11 plows 120 de-icing trucks 26 salter/sanders
Dallas District (7 counties)	11,670 –state maintained 50,880- county/local	100 vehicles (mostly brine/ salters, some plows)
TX statewide	>201,000- state maintained >500,000- county/local	500 plows
NYC, NY	19,000	>700 salt spreaders 2,200 garbage trucks with plows attached

# Ice Storm Disaster:

## Transportation Barriers

Supplies/Reagents not received on time

Sendout testing can't get out

Staff can't get to work/can't get home

## Infrastructure Barriers

Power outages

Internet outages

Diminished access to clean water

# ~~Ice Storm Disaster:~~

*Tropical Storms  
Hurricanes*

## Transportation Barriers

Supplies/Reagents not received on time

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Staff can't get to work/can't get home

## Infrastructure Barriers

Power outages

Internet outages

Diminished access to clean water

*Flooding*

*Structural Building Damage*

*Failure of Environmental Controls*

*Potentially Extended Durations*

# Step-wise approach: Checklist

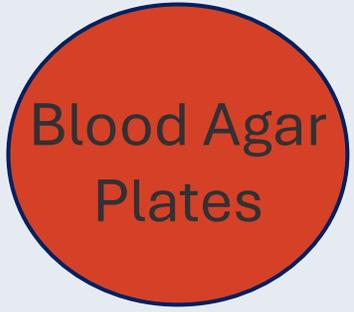
- Inventory all the current uses vs current supplies
- Project the extent of the shortage
- Available alternatives
- Determine feasibility and timeline
  - Regulatory requirements to implement each option
  - EMR/LIS changes required
  - Impact on test or clinical performance
- Identify the best approach: clinical and operational
  - Involve clinical experts, leadership, supply chain, as necessary
- Lab staff training/readiness to shift
- Notification and further collaboration with external stakeholders

## What it's used for:

- Almost all routine bacterial cultures
- Subculturing
- Purity plates for AST

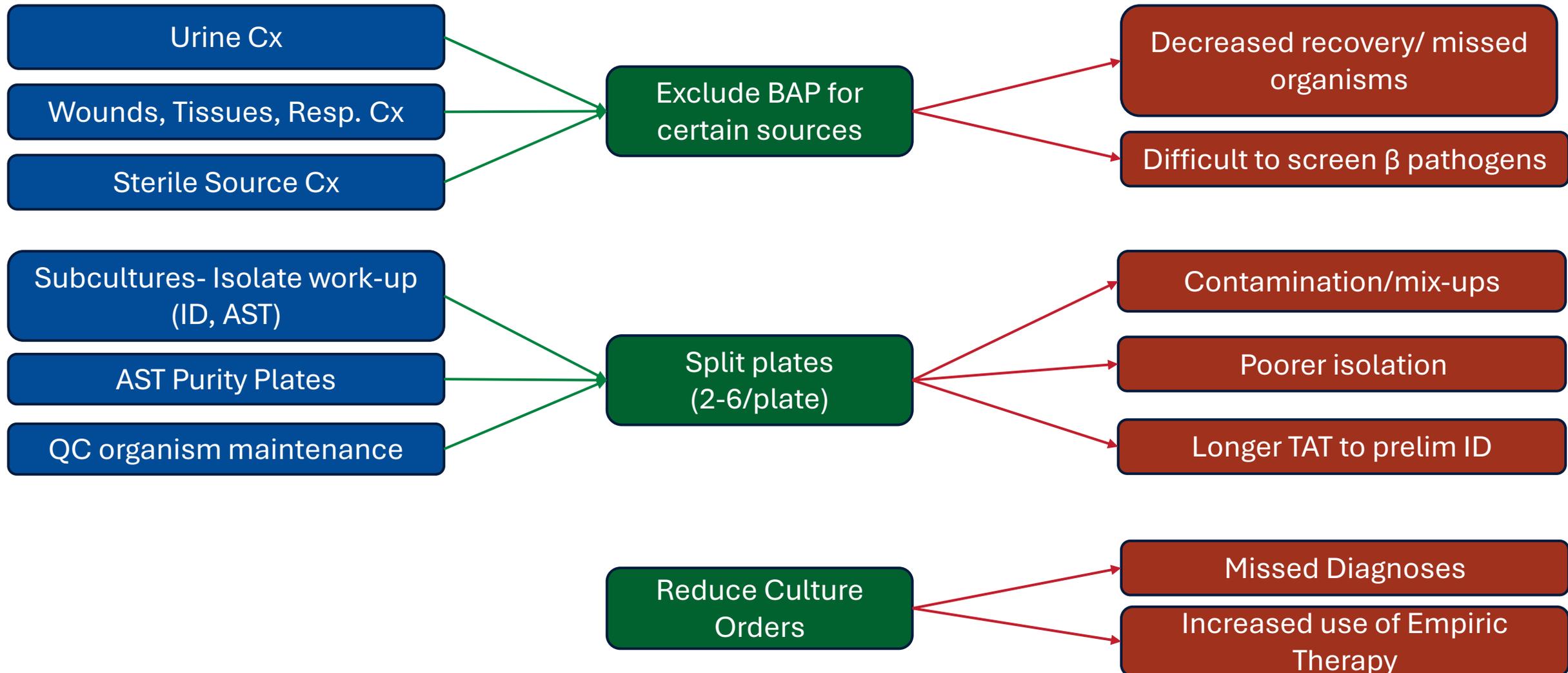
## Alternative:

- Sharing with nearby labs
- **Reduce use**



Blood Agar  
Plates

# Reduce Use: Weigh the Risks and Benefits

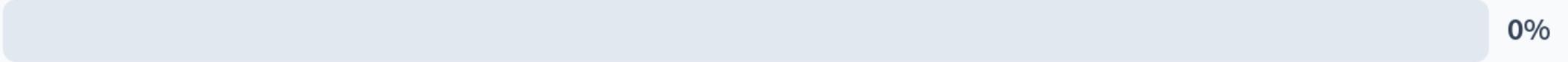


## In your lab/system approach would you choose first? (must be implemented within 24hr)

Exclude BAP for certain sources



Split plates for subcultures or purity plates



Reduce Culture Orders



## What it's used for:

- Almost all routine bacterial cultures
- Subculturing
- Purity plates for AST

## Alternative:

- Sharing with nearby labs
- **Reduce use**

## Requirements to implement:

- Staff notification
- Documentation:
  - Adjust procedures (?)
  - Alternative documentation of process, rationale, and duration

## External notification:

- Depends
  - Notify if recovery of certain pathogens may be reduced
  - Overall culture use reductions → partnership with ordering providers

## EMR/LIS changes:

- None

## Conventional Management

### Baseline Operations

- Continuous emphasis on quality of specimen collections
- Encourage clinically indicated test ordering and diagnostic stewardship
- Supply inventory managed to minimize waste, align with storage space, optimize cash flow

### Heightened Emphasis on Best Practices

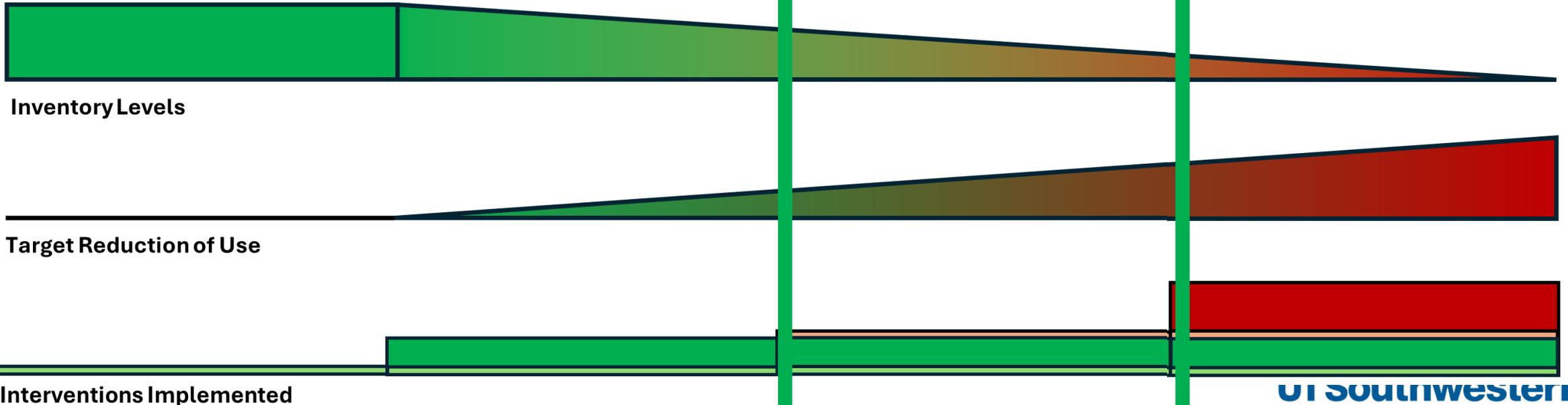
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## Crisis Management

- Restrict or greatly reduce access to inventory
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## Example 3: Ice storm continued.... Staffing levels at 50%



.... And send-out testing is not an option due to transportation delays

## What strategies would you consider implementing? (2-12hr to implement)

Nobody has responded yet.

Hang tight! Responses are coming in.

# Individualized aspects to weigh for your lab/institution

<u>Decision Making</u>	<u>Survival Strategy</u>		<u>Potential Negative Impact</u>
Lab operations	Mandatory double shifts	→	Fatigue, risk poorer quality; not sustainable
Provider notification*	Increased batching	→	Delayed results
Notification +/- clinical expert input*	Reduce frequency of reading cultures	→	Delayed results
Clinical expert input + notification	Reduce length of cultures before finalizing	→	Decreased yield
Clinical expert input; Notifications; LIS support	Temporarily cease to offer certain tests	→	Missed/delayed diagnoses, billing impacts
Stakeholder/User Buy-in	Reduce Test Orders	→	Missed/delayed diagnoses

\*Shared decision making if extent of delay will be significant (consider clinical implication and extent of delay)

## Conventional Management

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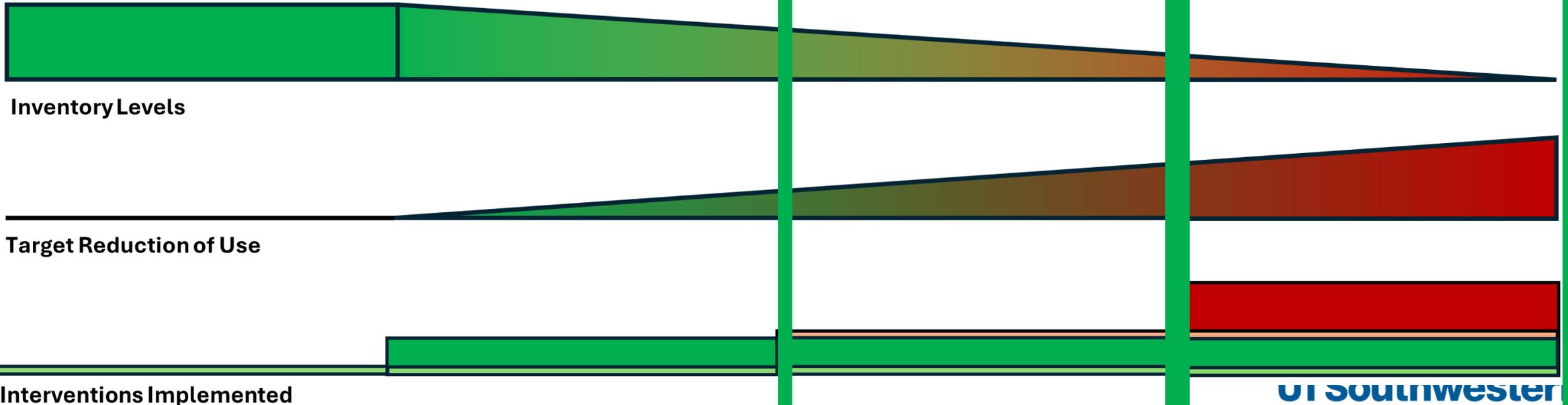
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## Example 4: Nasopharyngeal swab and transport media device shortage



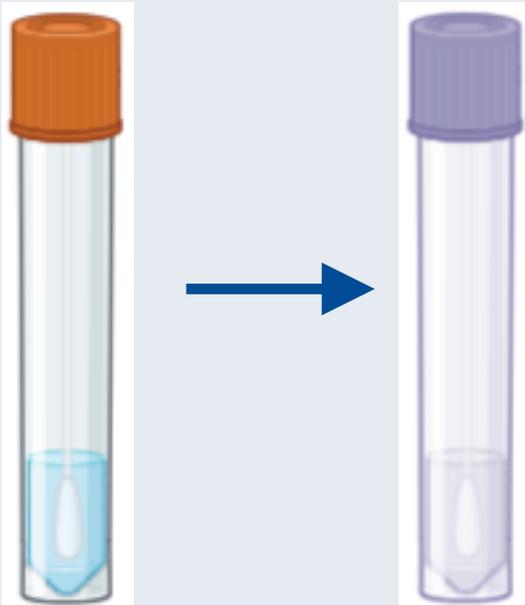
## What it's used for:

- **Upper respiratory specimen collection for:**
  - Respiratory panel PCR
- **Non-NP sample testing? (lesions, ocular, etc.)**

## Alternatives:

- Find a different source for the same product
- **Find an equivalent, different product**
- Find a non-equivalent, alternative product
- Reduce collections

## Requirements to implement:



## External notification:

## EMR/LIS changes:

## How extensively would you verify the equivalent, different product?

Full re-verification for each test that uses the device

0%

Abbreviated re-verification for each test that uses the device

0%

Verification of the device using a sampling of specimens for each associated test

0%

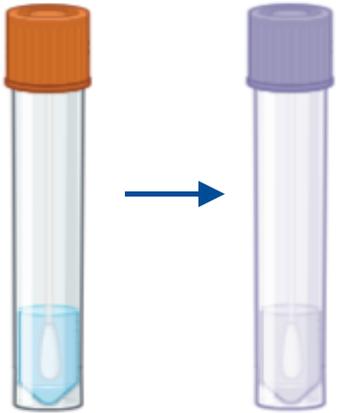
Perform QC testing only to assess impact of matrix changes

0%

No verification of the device, as long as it is listed in the manufacturer's IFU for each associated test

0%

# Some degree of verification is usually performed



Reasons to be thorough	Reasons to be minimalist
How sure are we that the product is “equivalent”?	There’s a shortage! <ul style="list-style-type: none"><li>- No time, resources, or supplies to be performing extensive verifications</li></ul>
The product is experimental	The product is broadly used
High consequence lab results → need to fully understand and defend the impact on test performance	Low risk of changing test performance <ul style="list-style-type: none"><li>- In the IFU</li><li>- Composition is almost identical or highly comparable</li></ul>
Ensure adequate documentation for future inspections	<ul style="list-style-type: none"><li>- Swab is made of same material, looks/feels similar</li></ul>

## What it's used for:

- Upper respiratory specimen collection for:
  - Respiratory panel PCR
- Non-NP sample testing? (lesions, ocular, etc.)

## Alternatives:

- Find a different source for the same product
- **Find an equivalent, different product**
- Find a non-equivalent, alternative product
- Reduce collections

## Requirements to implement:

- **Find an equivalent, different product**
  - Verification usually performed
- Procedure and lab catalog updates
- Staff notification required (e.g. acceptable collection devices)

## External notification:

- Notification to collection staff

## EMR/LIS changes:

- Update EMR-based collection instructions

## Conventional Management

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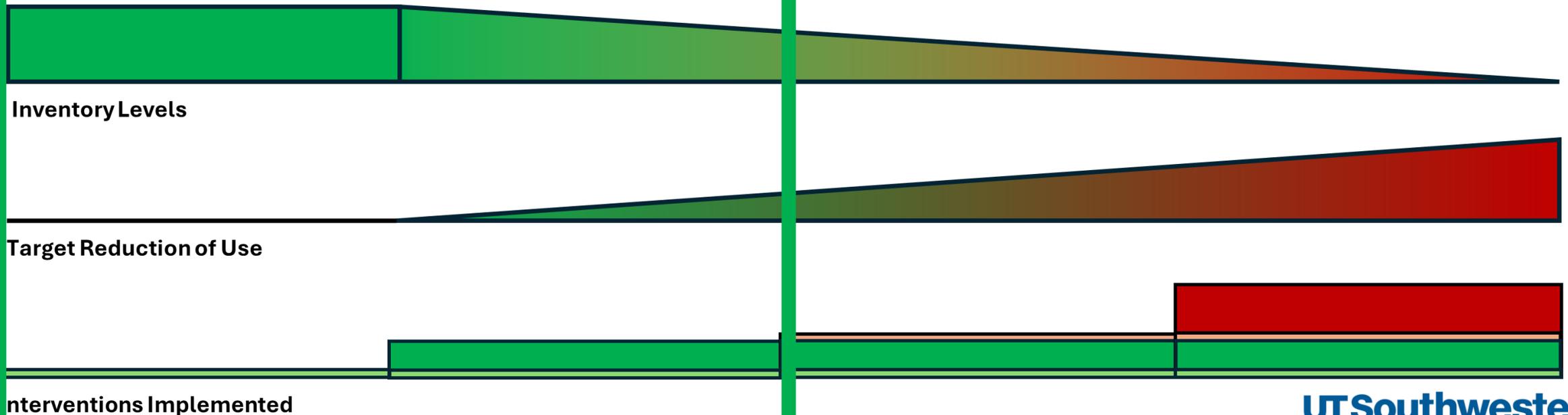
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Interventions Implemented

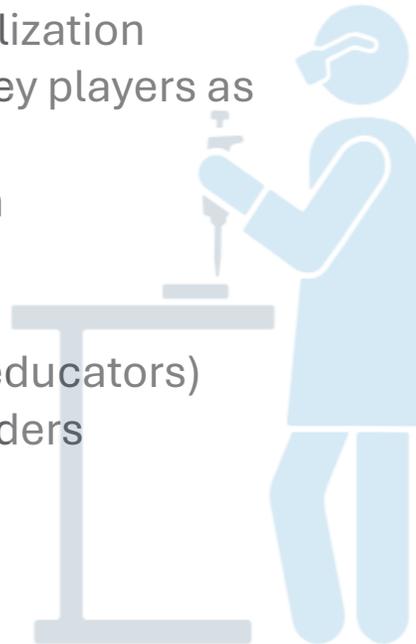
## **Example 5: Severe global blood culture bottle shortage**

**Significant shortage of a critical test  
High potential to negatively impact patient care**

# Why should lab lead these efforts? Why not alone?

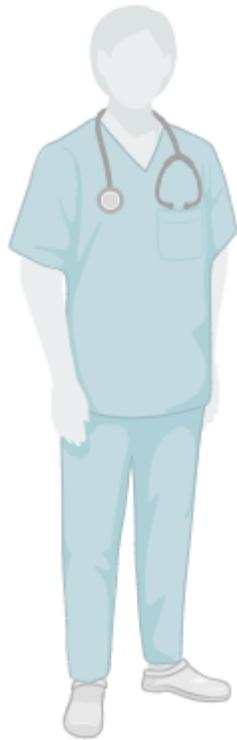
## Lab

- Experts in the tests we offer
- Experience in managing inventory, data, reporting tools, monitoring utilization
- Routinely work with non-lab key players as part of routine lab operations
  - Institutional supply chain
  - Vendors
  - IS/IT
  - Educators (e.g., nursing educators)
- Collaborate with key stakeholders



## Clinical stakeholders

- Clinical experts in the impact of interventions for lab testing (infectious disease diagnostics)
- Mitigate clinical impact → ensure patient safety
- Who does the ordering- how do we collaborate
- Who does the collecting- how do we collaborate



## What it's used for:

- Detecting bacteremia and fungemia

## Alternatives:

- Alternative platform and manufacturer
- Send out testing (?)
- Reduce use

## Considering the options:

- How long is the shortage expected?
- How severe is the shortage?
- How much supplies do you currently have on hand?

## External notification:

- YES

## Requirements to implement:

- Alternative platform → high cost, contracting, long wait list for instrumentation, full verification required

## EMR/LIS changes:

- YES

1

## Determine the Baseline and Scope of the Shortage

- Quantify baseline inventory
- Determine typical use and calculate days of supply on-hand
- Contact your local blood culture bottle vendor representative to request estimates of the extent of expected shortages and weekly allocation for your system

2

## Coordinate Inventory Management

- Communicate with hospital and clinical leadership. Obtain support
- Collaborate with supply management
- Obtain accurate blood culture bottle inventory
- Centralize and reallocate supplies
- Work with the vendor to expedite and escalate orders
- Investigate alternative blood culture testing and supplies options

## Coordinate Clinical Guidance

2

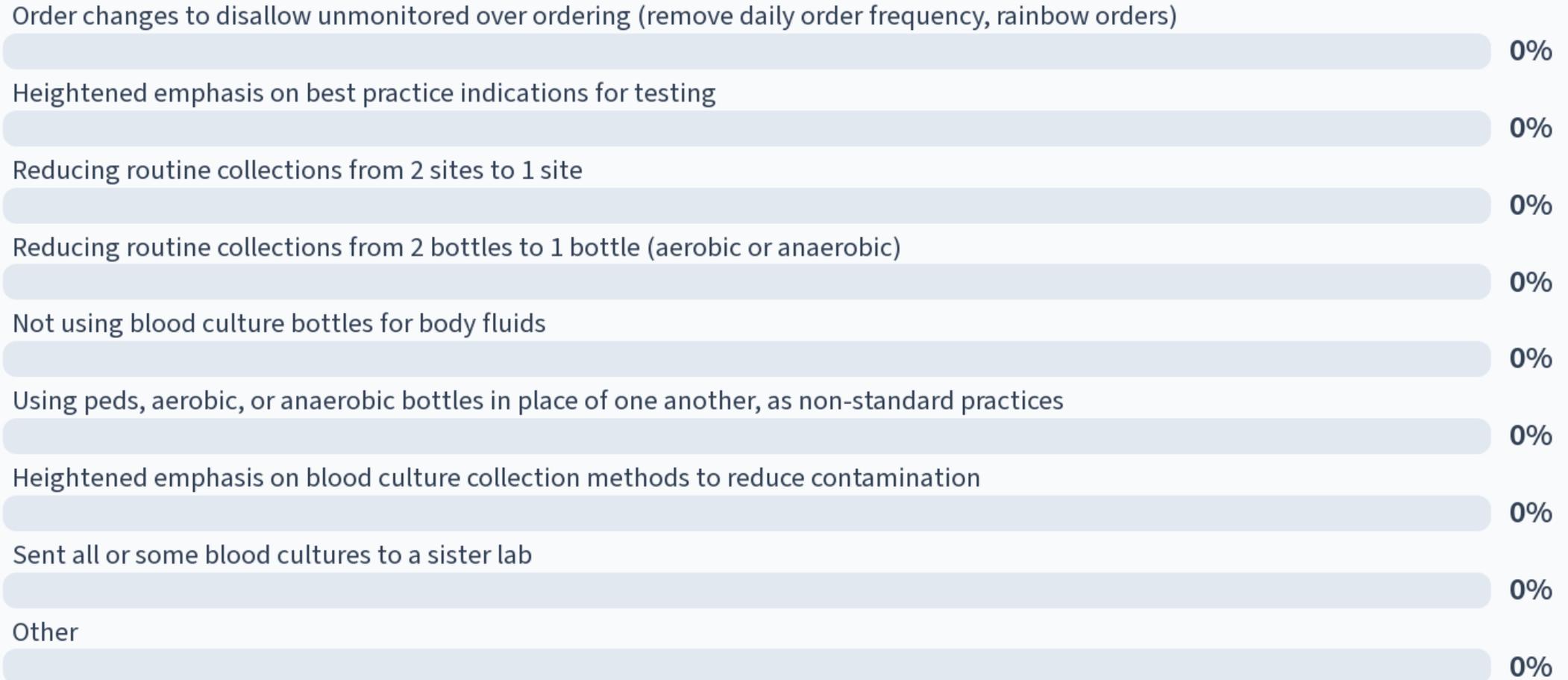
- Communicate with hospital and clinical leadership. Obtain support
- Create a core, multi-disciplinary clinical guidance workgroup. Collaborate with clinical stakeholders
- Develop blood culture shortage clinical guidance based on the severity of the shortage (e.g., conventional, contingency or crisis management)
- Partner with information technology teams and clinical leadership to implement utilization interventions

3

## Continuously Monitor and Respond to Changes

- Continuously monitor blood culture bottle inventory, use, and supplies receipt
- Meet with and update hospital and clinical leaders at an agreed upon frequency
- Monitor safety and quality signals to detect any need to adjust the clinical guidance or utilization interventions
- Set inventory and blood culture bottle use targets and adjust clinical guidelines as needed to respond to changes in inventory

## Which was the most effective strategy at your institution during the blood culture shortage?



## Conventional Management

### Baseline Operations

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### Heightened Emphasis on Best Practices

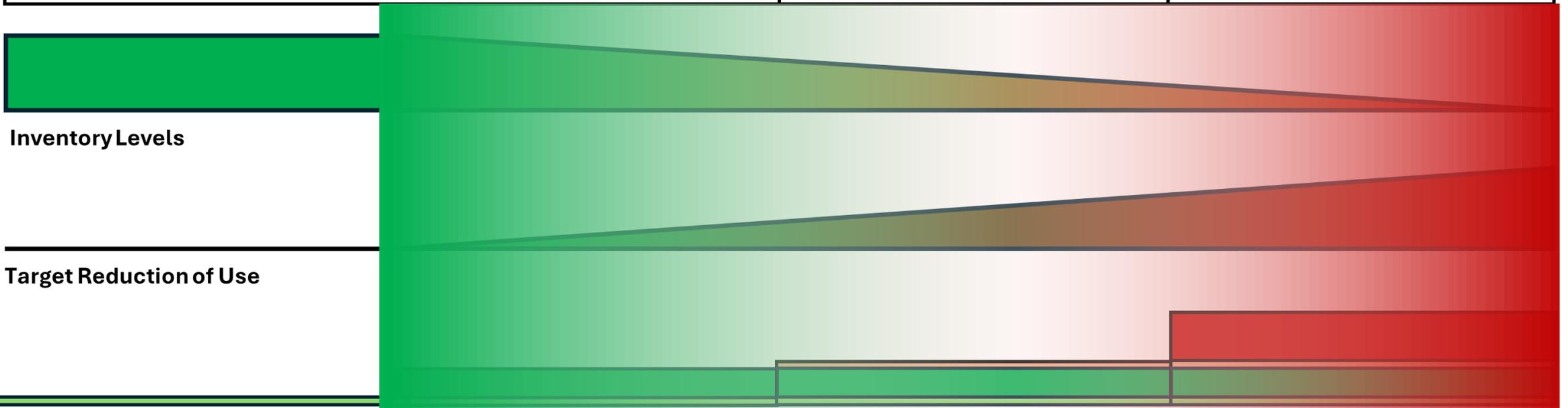
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Interventions Implemented

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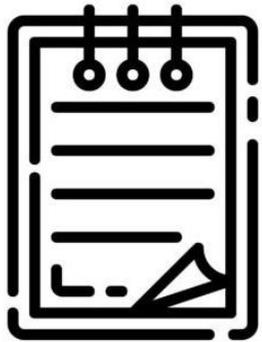
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- Reducing contamination
- Optimizing collection volume
- Avoid over-collecting
  - Automatic repeat orders
  - JIC collections
- Reduce inappropriate/low yield clinical indications

- Other broth or agar only for body fluids
- Anaerobic bottles only for following *S. aureus* positive patients.

- 1 site instead of 2
- 1 bottle instead of 2
- Reduced blood volume bottles (peds bottles vs adult)
- Empiric treatment without testing

# How to implement supply shortage interventions?



Memos/Guidelines



Computerized  
Clinical decision support



Targeted and consistent education



- Support from institution leadership
- Multi-modal communication
- EMR-based restrictions
- EMR-based education
- Interim institutional guidelines
- Targeted communication (department meetings, handshake on the floors, etc.)

### Summary of low-yield BCx in non-neutropenic adults

LOW-YIELD INITIAL BLOOD CULTURES	LOW-YIELD FOLLOW-UP BLOOD CULTURES
<ul style="list-style-type: none"> <li>• Non-severe CAP</li> <li>• Post-op fever within 48hs</li> <li>• Isolated fever</li> <li>• Isolated leukocytosis</li> <li>• Persistent fever without clinical change and negative blood cultures in last 48-72 hours</li> <li>• Persistent leukocytosis without clinical change and negative blood cultures in last 48-72 hours</li> <li>• Non-severe CAP</li> <li>• Non-severe cellulitis</li> <li>• Post-operative fever within 48hs from surgery</li> <li>• Lower UTI (cystitis, prostatitis)</li> <li>• Surveillance blood cultures (e.g., before procedures, line placement, TPN initiation, etc.) in patients without suspicion for bacteremia</li> </ul>	<ul style="list-style-type: none"> <li>• Repeat blood cultures to document clearance of bacteremia caused by organisms other than <i>Staphylococcus aureus</i>, <i>Staphylococcus lugdunensis</i>, or <i>Candida</i> in patients without infective endocarditis/endovascular infection (e.g., cardiac device infection, septic thrombophlebitis) who showed clinical response and source control has been achieved</li> <li>• Repeat blood cultures to rule out blood culture contamination in immunocompetent patients without prosthetic implants</li> </ul>

### Blood Culture Order History Expand

(From admission, onward)

	Ordered
> Culture, blood [1877905] Once	08/22/23 0808
> Culture, blood [1895342] Once, Status: Canceled	09/19/23 1505
> Culture, blood [1904563] Once, Status: Canceled	09/25/23 0924
> Culture, blood [1904579] Once	10/11/23 1112
> Culture, blood [1904580] Once, Status: Canceled	10/11/23 1112
> Culture, blood [1937582] Once	02/08/24 1030
> Culture, blood [1937594] Once	02/16/24 1333
> Culture, blood [1937596] Once, Status: Canceled	02/16/24 1545
> Culture, blood [1948519] Once	02/22/24 1028
> Culture, blood [1948539] Once	03/19/24 0924
> Culture, blood [1948541] Once	03/19/24 0925
> Culture, blood [1969479] Once	08/08/24 1406
> Culture, blood [1969490] Once	08/29/24 0915
> Culture, blood [1969491] Once	08/29/24 0915

### Blood Culture Results (Last 10 days)

Procedure	Component	Value	Units	Date/Time
Culture, blood [1969490]				Collected: 08/29/24

Frequency:  **Once**

At:

Specimen Type: **Blood**

Specimen Source:

Limited frequency

\*\*\*STOP!\*\*\* Blood cultures are in progress or resulted within the last 72 hours, no additional blood cultures can be ordered at this time.

Comments: [+ Add Comments](#)

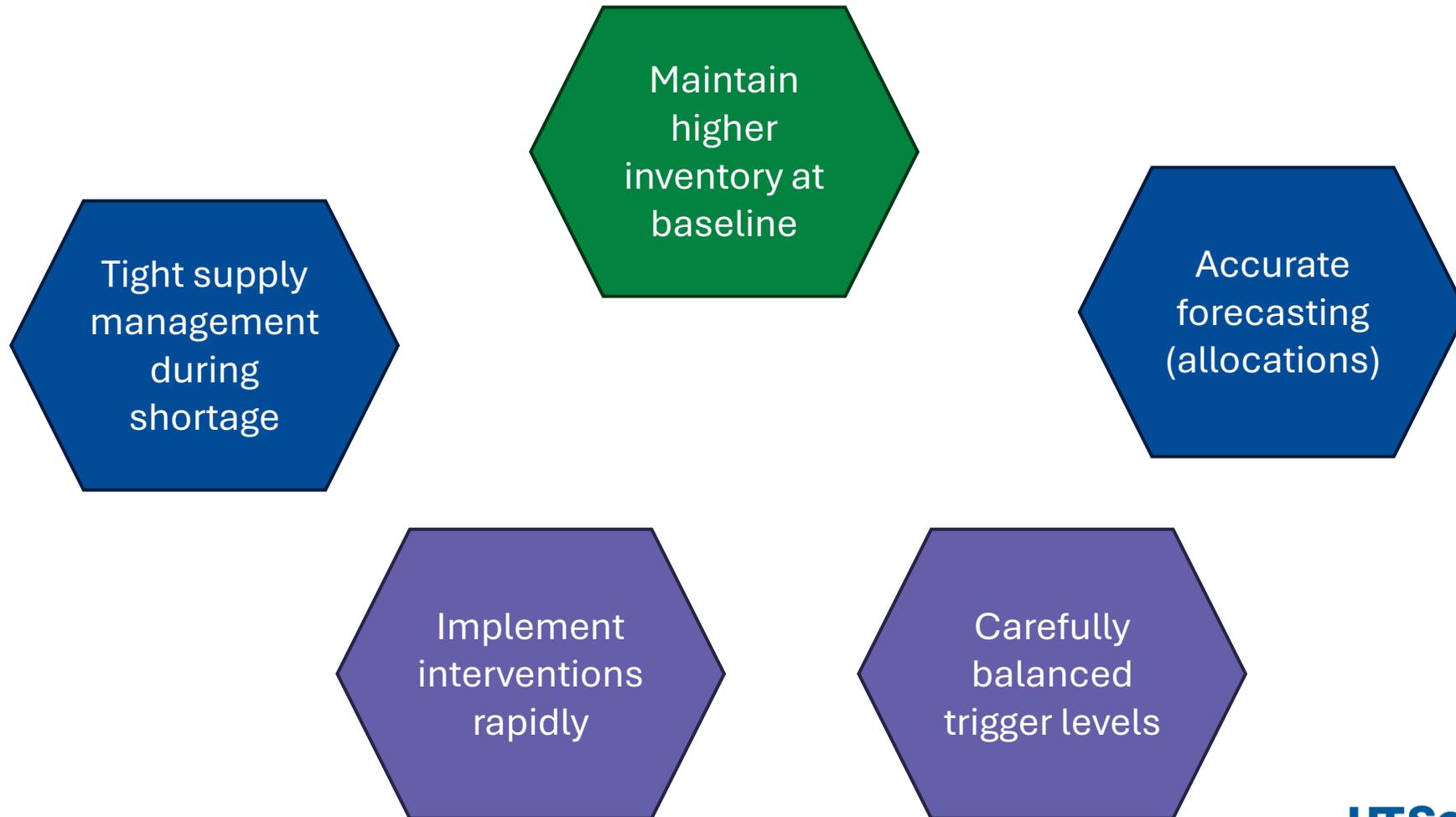
Reference Links: [Obtaining Blood Cultures - Aerobic, Anaerobic, TB and Fungal \(Adult and Pediatric\)](#)

Add-on: No add-on specimen found

CC Results: [+ My List](#) [+ Other](#)

- (a) limit to two BC in 24 hours,
- (b) only repeat BC if 72 hours have passed from the prior sets,
- (c) do not repeat BC for coagulase negative *Staphylococcus* bacteremia when considered a contaminant
- (d) do not repeat BC for Streptococcus bacteremia,
- (e) do not repeat cultures for Gram-negative rod bacteremia unless an unknown source, immunosuppression, or clinical worsening.

# How to avoid contingency and crisis management?



# Characteristics to justify higher inventory levels

- Critical tests (high clinical or operational impact, require fast TAT)
- No/few alternatives
- Alternatives cannot be swiftly employed (e.g., capital purchases)
- Long reagent stability, extended expiration dates





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Thank you.

Questions?