Procalcitonin Implementation Guide

Procalcitonin Implementation in Your Hospital

Implementing changes in a complex healthcare organization can be challenging. This implementation guide provides a road map for protocol development, integrating Procalcitonin (PCT) into clinical practice, and recommendations for evaluating the process and impact of testing.

Education and support

Research shows that behavior changes based on improving both knowledge and attitudes are more sustainable than manipulating behavior alone. Focus on practical “need to know” content, and then follow up with “nice to know” information or provide additional materials for self-directed study.

Resourses

Your Medical Science Liaison (MSL) will serve as a PCT expert and scientific resource guiding you and your team through PCT implementation. Your MSL will provide education, guidance on order sets and help with protocol development to ensure a full understanding of PCT kinetics, clinical applications and how it can aid in antibiotic decision making.

The MSLs provide clinical support throughout the implementation process (table below). Your facility will choose the teaching methods that will work best with your workflow. Options include instructor-led sessions which are most effective, along with, computer-based training, small group teaching and discussion, or a combination.

Pre-implementation	During Implementation	3-6 Months After Implementation
• Provide information and education to antibiotic stewardship committee, sepsis committee, ICU, ED, ID, pharmacy, lab	• Interdepartmental education (Similar to pre-implementation education)	• Grand rounds lecture by a physician guest speaker
• Procalcitonin kinetics, interpretation of results, scientific evidence	• Roving Q&A at all ordering departments	• Webinar, video clips for learning on demand
• Examples of order sets and protocols from hospitals that use PCT	• Review and learn from case studies	• Repeat interdepartmental education
• Abbreviated bibliography of recent PCT literature sent electronically with active links	• Pocket-size reference cards distribution	• Continuing literature support as requested
• References: hospitals, clinicians, lab personnel		

Implementation best practices

1. **Education, education, education**

   It is vital to provide tailored education to all clinicians involved with PCT testing including members of the Antibiotic Stewardship Committee, pharmacy, critical care, emergency medicine, hospitalists, infectious disease and laboratory.

2. **Pharmacy and Antibiotic Stewardship Committee involvement**

   Studies have demonstrated that when the antibiotic advisor is a pharmacist, antibiotic consumption improves.[1-3] In addition, an Antibiotic Stewardship Committee that reviews rapid diagnostic testing results and provides feedback to providers can help clinicians act upon the results.

3. **Order set/protocol development**

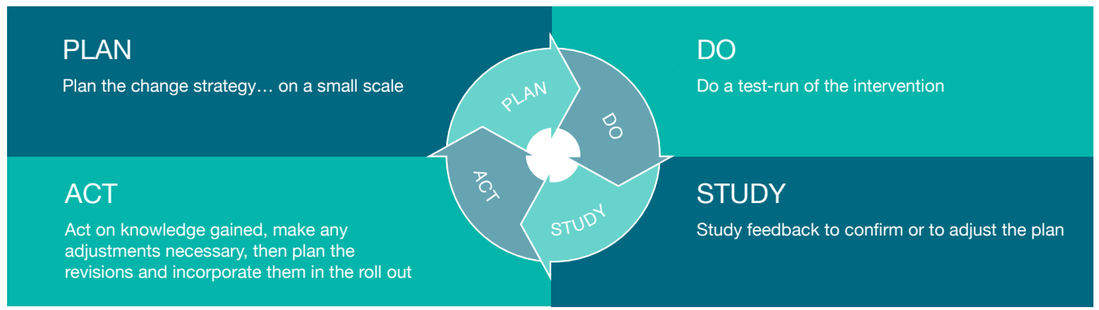
   Order sets standardize and expedite the ordering process and helps clinicians ensure that critical components of care are not overlooked. They also help to control test utilization and prevent unnecessary testing.

4. **Assess PCT testing impact: Pre- and post outcome assessment**

   A pre- and post-assessment measures the occurrence of predetermined outcomes before and after PCT testing is implemented. This allows the implementation team to assess the implementation strategy as well as the impact of PCT testing. This assessment should be based on predefined metrics, e.g. antibiotic consumption, adverse drug events, C-diff rates, hospital/ICU length of stay, health economics, etc.

5. **Assess compliance and offer feedback**

   Feedback and pharmacy oversight will help guide clinician practice which may lead to improved clinical and health economic outcomes.



Create an implementation strategy

- Recruit team members that are immediately affected by the change and who have the ability to influence others' reception of the protocol change

Physician leadership	Antibiotic Stewardship Committee	Clinical pharmacy
Clinical laboratory	Informatics	Quality management

- Determine how the test will be used clinically: antibiotic stewardship, differential diagnosis (rule-out bacterial infection), and which patient populations will be included (LRTI, COPD, sepsis, etc.)
- Establish Alert and Critical Lab Values.
- Develop and/or update order sets and protocols for each patient population.
- Establish a go-live target date.
- Define education plan and timeline for Antibiotic Stewardship Committee, Sepsis Committee, Critical Care Committee, Emergency Department, Pharmacy, Laboratory, etc.
- Define timeline and metrics for Pre / Post outcome assessment including duration of data collection, e.g. 4 months of baseline data prior to starting PCT, then collect 4 months of data after implementation has been completed. Define metrics, e.g. antibiotic consumption, adverse drug events, c-diff rates, hospital/ICU length of stay, health economic, etc.
- Create a Communication Plan that outlines how to communicate implementation details with end-users. Include go-live date, education dates, selected clinical applications, updates on order sets / protocol developments, etc.

Key steps to consider:

1. Add PCT as an order into EMR - this must be done early in the process to ensure it's available when you go-live.
2. Develop onscreen prompts for ordering PCT, e.g. suspected bacterial infection, LRTI, sepsis, fever, etc.
3. Consider PCT as a pre-checked item for baseline and follow-up draws.

✓ How will order be triggered?	✓ How will results be monitored?
✓ Does test need to be repeated in a specific time frame?	✓ Is trending or tracking required?
✓ Do standard documents need to be updated?	✓ Do we need custom elements?

Establish critical values and reference ranges

Key steps to consider:

1. Discuss whether to establish critical values and reference ranges. There is not one specific cut-off for PCT. The cut-offs are determined based on where and how PCT is used (ED, surgery, monitoring, neonatology, etc.). In addition, a trend can provide more information than one absolute value.

   Example:

   1. Repeat 6-12 hours after initial draw if baseline <0.25 (or another pre-defined low value per your hospital policy) and suspicion of infection is present.
   2. Draw Q am x2 to monitor trend.
   3. Determine who will be responsible for following PCT.
      - For clinical decision making: Intensivist/hospitalist/ED physician and/or clinical pharmacists
      - For antibiotic de-escalation: Intensivist/hospitalist and/or clinical pharmacist
      - From a quality standpoint: QI/QA
      - Who will monitor for spending/cost savings: Pharmacy for de-escalation, QI/QA for sepsis

2. Customize any additional elements based on organizational factors and potential barriers.
   - Are there any other labs that can be eliminated from current work-up?
   - After implementation, track if there are fewer orders for blood cultures, etc.

Feedback and evaluation

Encourage feedback throughout the implementation process. Once PCT has been incorporated into practice, survey staff members at all levels and ask them what went well, what didn't go well from their perspective, and how the process could be improved next time. Share what you learn with other implementation teams to facilitate future process improvements.

Support a culture of information sharing. Learn from others' experience, as they can learn from yours.

Long-term follow-up

Return to your baseline data. Collect data on the same parameters and compare pre- and post-implementation to determine if you met the goals described in the initial phase. Celebrate your successes! Bring the team together to analyze where you might fall short to explore revising your implementation plan to address any shortcomings.

Procalcitonin implementation planning checklist

Preparation	Yes	No	Not Required	Comments
Recruit team members				
Confirm administrative support				
Develop action plan with dates				
Set goals				
Review research				
Explore laboratory options				
Identify health economic benefits				
Assemble baseline data				
Custom elements				
Custom elements				

Development	Yes	No	Not Required	Comments
How test order will be triggered				
How results will be monitored				
Create new flow sheet or revision to existing				
Check policies, procedures, protocols, care paths for needed revisions				
Design education / support materials				
Custom elements				
Custom elements				
Custom elements				

Implementation	Yes	No	Not Required	Comments
Identify targeted compliance threshold				
Conduct trial run pilot				
Study process, feedback & revise plan as needed; confirm “go-live” date				
Train everyone involved in process just before go-live				
Go-live				
Custom elements				
Custom elements				

Evaluation	Yes	No	Not Required	Comments
Measure compliance and order patterns				
Collect feedback and review formal evaluation forms				
Evaluate entire process				
Make revisions as needed				
Collect data for longitudinal study				
Custom elements				
Custom elements				

Procalcitonin

Initiating antibiotic therapy for patients with suspected or confirmed lower respiratory tract infection (LRTI)[4]

PCT (ng/mL)	< 0.10	0.10 - 0.25	0.26 - 0.50	> 0.50
Ongoing Infection?	Very Unlikely	Unlikely	Likely	Very Likely
Interpretation	ABx Strongly Discouraged	ABx Discouraged	ABx Encouraged	ABx Strongly Encouraged

Important Considerations: Antibiotic therapy should be considered regardless of PCT result if the patient is clinically unstable, is at high risk for adverse outcome, has strong evidence of bacterial pathogen, or the clinical context indicates antibiotic therapy is warranted. If antibiotics are withheld, reassess if symptoms persist/worsen and/or repeat PCT measurement within 6-24 hours.

In order to assess treatment success and to support a decision to discontinue antibiotic therapy, follow up samples should be tested once every 1-2 days, based upon physician discretion taking into account patient’s evolution and progress.

PCT levels may not be elevated in patients infected by certain atypical pathogens, such as Chlamydophila pneumoniae and Mycoplasma pneumoniae.

Discontinuing antibiotics for patients with lower respiratory tract infection (LRTI), or suspected or confirmed sepsis[5,6]

Change in PCT Level

Decline from peak PCT > 80% and Clinical Improvement

OR

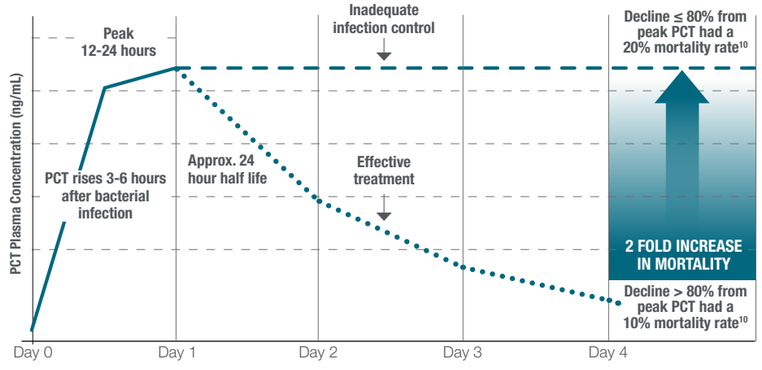
Current PCT Level

LRTI ≤ 0.25 ng/mL

Sepsis ≤ 0.50 ng/mL

Important Considerations: If clinical picture has not improved and PCT remains high, re-evaluate and consider treatment failure or other causes.

PCT values rise in relation to sepsis severity, providing clinicians with a valuable tool for assessing patients suspected of sepsis.[7-9]



PCT can be measured on serum or plasma; the liquid chosen should be consistent throughout a patient’s clinical course. Do not use citrate plasma tubes for specimen collection.

PCT Plasma Concentration (ng/mL)	Possible Interpretations 7-9,11
< 0.05 - < 0.10	Normal level.
< 0.5	Low risk for progression to severe sepsis and/or septic shock.
0.5 - 2.0	Systemic infection cannot be excluded. PCT levels should be measured again within 6 to 24 hours.
> 2.0	High risk for progression to severe sepsis and/or septic shock.

Please Note: PCT levels below 0.5 ng/mL do not exclude an infection, because localized infections (without systemic signs) may also be associated with such low levels. If the PCT measurement is done very early after the systemic infection process has started (usually < 6 hours), these values may still be low.

See next page for additional notes.

PCT values may be elevated in certain conditions independent of bacterial infection. These include, but are not limited to:

- Injuries including major trauma, burns and heat stroke
- Acute medical conditions such as biliary pancreatitis, chemical pneumonitis, viral hepatitis and/or decompensated severe cirrhosis (Child-Pugh Class 3), prolonged or severe cardiogenic shock, prolonged severe organ perfusion anomalies, and post-cardiac arrest
- Active medullary C-cell carcinoma, small cell lung carcinoma, and bronchial carcinoid
- Unusual infectious diseases including invasive fungal infections and acute plasmodium falciparum malaria
- Following interventions such as surgery with extra-corporeal circulation, treatment with drugs stimulating release of pro-inflammatory cytokines or resulting in anaphylaxis, peritoneal or hemodialysis

The PCT reference ranges are valuable guidelines for the clinician but they should always be interpreted in context of the patient's clinical condition. PCT serum concentrations are elevated in clinically relevant bacterial infections and continue to rise with the increasing severity of the disease. However, as an expression of individually different immune responses and different clinical situations, the same focus of infection may be associated with varying individual elevations in PCT concentrations. Antibiotic treatment should be started/continued on suspicion of infection, particularly in high-risk patients.

PCT results should be evaluated in context of all clinical and laboratory findings. If results do not agree with clinical finding, additional testing should be performed.

References

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