Maximizing Outcomes Through Quality Improvement Tools Following Implementation of New Processes and Biomarkers

Laboratory Medicine and Healthcare Quality: Foundational Pillars for Excellence

A key enabler to achieving healthcare excellence is a coordinated healthcare workforce that unifies to challenge traditional thought and uses quality processes to achieve better outcomes. A multidisciplinary team approach has proven successful in the delivery of improved outcomes not only for patients, but also for a wide range of stakeholders, such as: clinicians, administrators and payors.

An ideal multidisciplinary team includes key representatives across clinical care including, but not limited to, physicians, nurses, and pharmacists. Standout additional team members with invaluable quality improvement expertise are the laboratorian and quality professional.

Healthcare quality is routinely practiced at the highest level by the core laboratory. Lab results are expected to be timely and accurate, despite incredibly high work volumes. The COVID-19 pandemic put a spotlight on this expectation, with laboratorians rising to the challenge.

Healthcare quality professionals have partnered with laboratorians on best practices and continuous improvement for concepts such as: efficiency, workflow, process improvement and more. The expertise of healthcare quality professionals and laboratorians can elevate outcomes, helping ensure success across projects and stakeholders.

The following example helps to illustrate this concept through use of a performance improvement tool that is commonly used by healthcare quality professionals and laboratorians to effectively identify, prioritize, and develop risk mitigation strategies associated with new processes.

Implementation of New Processes and Biomarkers:

With an emphasis on reducing both sepsis mortality rates and days of antibiotic therapy in the intensive care unit (ICU), procalcitonin (PCT) has increasing value. Procalcitonin is a biochemical marker released from the thyroid gland that has proven successful in the early detection and management of bacterial sepsis and has shown promise in reliably, safely and appropriately ending antibiotic treatment. In this hospital example, an integrated clinical care team determined the need to introduce PCT-guided therapy into clinical care.

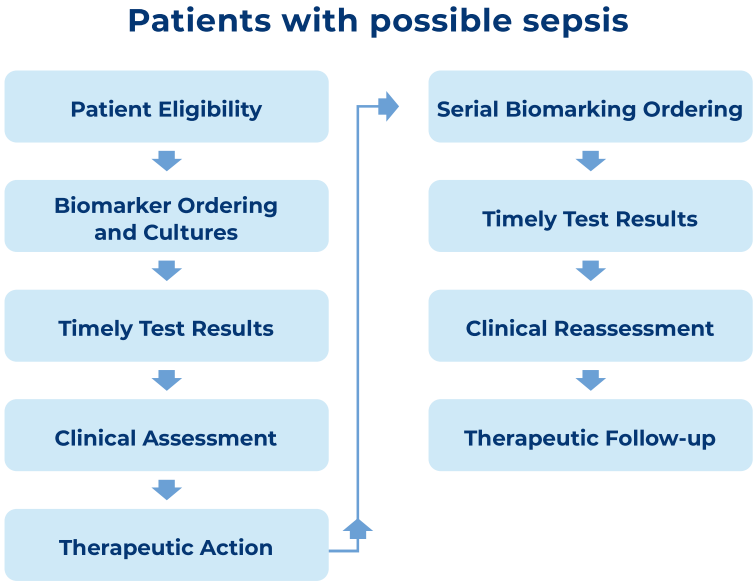
Interpretation of procalcitonin testing can be challenging. To ensure safe and accurate diagnosis of sepsis and discontinuation of antibiotic therapy there is a need for education and process changes to enable optimal outcomes, timely testing and communication of results, including delta values.

To establish safeguards against error, this hospital chose to use a quality tool commonly referred to as 'Failure Modes and Effect Analysis' (FMEA) to proactively design a procalcitonin testing process. A FMEA is a systematic method of identifying and subsequently preventing failures before they occur.

A multidisciplinary team facilitated by the hospital healthcare quality professional – including laboratory professionals, information technology, emergency department physicians and nurses, ICU physicians and nurses – collaborated to complete the FMEA.

Use of the FMEA tool includes the development of a process flow map which outlines each step within a process, including disciplines involved and possible errors (failure modes) at each step. The team then uses a numerical rating system to predict the severity, frequency and detectability for each failure mode identified. The resulting criticality scores help to rank the possible failure modes and guide the development of action plans to mitigate each relevant failure mode.

Below is a simplified version of a process flow map for procalcitonin testing.



Based on the process flow map and subsequent team collaboration, nine failure modes were identified, of which >50% were ranked at the highest severity level. The five high-ranked failure modes include:

Patient Eligibility | Timely Test Results | Clinical Assessment | Clinical Reassessment | Therapeutic Follow-up

Process	Process Description	Failure Mode	Causes	Effects	Severity	Frequency	Detectability	Score
Patient Eligibility	Patient with two or more SIRS (Systemic Inflammatory Response Syndrome) criteria AND Clinical Suspicion of sepsis [SIRS: temperature, tachycardia, respiratory rate >20]	No differential diagnosis of sepsis is considered	No Sepsis screening tool is used	Delay in sepsis care, increased Length of Stay or increased mortality	5	2	3	10
Biomarker Ordering and Cultures	Provider orders complete blood count (CBC), Chemistry profile, Lactic Acid and Procalcitonin testing, Blood Cultures drawn	All tests not ordered	No standard order set used or protocol available for sepsis care	Missing crucial information for actionable, informed care.	4	3	1	8
Timely Test Results	Results of test available in 30 minutes	Testing not ordered as STAT; Tube lost and not analyzed; pre/post-analytic errors in processing; critical values not communicated to provider	No standardized orders; Inefficient sample processing; sample mishandling; no protocol for critical value notification	Delayed decision-making, delayed sepsis care, increased Length of Stay or increased mortality	5	2	3	10
Clinical Assessment	A comprehensive review of risk factors, patient assessment and biomarker outcomes	Incorrect, dismissed or misunderstood interpretation	No training or educational communication on the use, impact and interpretation of Procalcitonin	Delayed care, increased mortality	5	2	3	10
Therapeutic Action	Antibiotics and fluids administered	Incorrect antibiotic selection or inadequate fluid bolus given	No consult with pharmacy; incorrect patient weight	Overuse of broad-spectrum antibiotics; poor perfusion of patient	3	3	2	8
Serial Biomarker Ordering	Follow-up testing ordered i.e. lactic acid and procalcitonin	Follow-up testing not ordered	No standard order set used or protocol available for sepsis care	No trend analysis, missing crucial information for actionable, informed care.	3	3	3	9
Timely Test Results	Results of test available in 30 mins	Testing not drawn at correct time, or ordered for incorrect timing	Testing ordered as routine and bundled with morning labs or other routine labs	Delta values incorrect causing misinterpretation of results	4	2	3	9
Clinical Reassessment	Plan for continued care i.e. discontinuation or continuation of antibiotic therapy	Incorrect, dismissed or misunderstood interpretation	Unclear reference ranges in lab reports; unclear delta values for procalcitonin; No training or educational communication on the use, impact and interpretation of Procalcitonin	Delay in discontinuation of antibiotic therapy; discontinuation of antibiotic therapy too early; increased Length of Stay or increased mortality	5	2	3	10
Therapeutic Follow-up	Discontinuation or continuation of antibiotic therapy	Inconsistent therapeutic action, Unchallenged therapeutic course when patients switch departments	Absence of best practice sharing; No standardized forum for continuing education or tracking of guideline-based care	Inconsistent decision-making and outcomes across common patients, increased length of stay, increased mortality	5	3	2	10

Severity Code
(5) Very high (permanent injury or death)
(4) High - (required increased medical management and/or increased length of stay)
(3) Moderate - (required additional monitoring with no harm to patient)
(2) Low - (no interventions/monitoring and no harm to patient)
(1) Very Low -(detected before it reached the patient)

Frequency
(5) Very High (more than 20 occurences per year)
(4) High (11-20 occurrences per year)
(3) Moderate (6-10 occurrences per year)
(2) Low (1-5 Occurrense per year)
(1) Remote (less than 1 occurrense per year)

Detectability
(5) Remote (error never detected)
(4) Low (error rarely detected)
(3) Moderate (error sometimes detected)
(2) High (error usually detected)
(1) Very High (error always detected)

Upon identification of relevant failure modes, safeguards and solutions can be identified using other quality tools such as the 'Five Whys' and 'Root Cause Analysis'. Once safeguards and solutions are identified and deployed, data must be collected to evaluate the success of the process. This data can further be used to inform decision-making and opportunities for process improvements. In the procalcitonin example above, process measures such as percent of "on-time" procalcitonin laboratory blood draws, or percent use of a standardized order set for sepsis admissions, must be developed with standard definitions and data sources to ensure reliable data collection. Outcome measures such as sepsis mortality in the ICU and days of antibiotic therapy in the ICU should also be measured to ensure the process is having the desired effect on patient outcomes. Balancing measures such as antibiotic resistance patterns or Clostridium difficile infection rates must also be monitored to ensure no unintended effects are present. Data collection and rigor should be done with improvement in mind, enabling an agile response to the success or failure of the process.

Keys to Success for Process Improvement:

In the representative PCT example, the multidisciplinary team was able to quickly align on implementation strategies for their process improvement. By speaking a common language centered on quality improvement and utilizing effective process improvement tools, they successfully prioritized risks and mitigation strategies while also achieving measurably better outcomes for patients with suspected and/or diagnosed sepsis.

The National Association for Healthcare Quality's (NAHQ) twice-validated Healthcare Quality Competencies Framework™ provides a common language for the healthcare quality profession. It was developed and validated by quality experts and practitioners across healthcare sectors for a comprehensive accounting of healthcare quality competencies. The framework is organized across eight domains, ranging from foundational, to proficient to advanced. Adoption of FMEA, and other tools in the Healthcare Quality Competencies Framework, enables multidisciplinary teams to "get to work" more easily and to deliver improved outcomes.

Upon delivering measurably better outcomes, healthcare teams are invited to apply to The UNIVANTS™ of Healthcare Excellence Award program. These prestigious global awards recognize integrated clinical care teams who, not unlike this PCT effort, have collaborated across disciplines to transform healthcare delivery. More details about the UNIVANTS of Healthcare Excellence award program, including criteria to apply and/or recognized best practices can be found at www.univantshce.com.

Conclusion:

Process improvement methods and tools mastered by both laboratorians and healthcare quality professionals can help facilitate healthcare transformation. Their collective expertise in strategic decision-making, tool selection and risk mitigation can ensure high quality outcomes.

NAHQ®
National Association for Healthcare Quality

Learn more here:
NAHQ.org or call **847.375.4720**

About NAHQ

The National Association for Healthcare Quality® (NAHQ) is the only organization dedicated to healthcare quality professionals, defining the standard of excellence for the profession, and equipping professionals and organizations across the continuum of healthcare to meet these standards. NAHQ believes that to reduce variability in healthcare delivery, we must first reduce variability in healthcare quality competencies, so we focus our efforts on healthcare quality competencies and workforce development. NAHQ published the first and only Healthcare Quality Competency Framework and validated it twice in the market. We offer the only accredited certification in healthcare quality, the Certified Professional in Healthcare Quality® (CPHQ), extensive educational programming, networking opportunities and career resources to help healthcare quality professionals enhance their competencies and their value. Learn more at **NAHQ.org**.

UNIVANTS™
OF HEALTHCARE EXCELLENCE

Learn more here:
www.univantshce.com

The UNIVANTS of Healthcare Excellence Award Program recognizes integrated clinical care teams who collaborate across disciplines and transform healthcare delivery, and ultimately patient lives. The UNIVANTS of Healthcare Excellence Award Program was created by Abbott Laboratories and is enabled by seven valued program partners including International Federation of Clinical Chemistry (IFCC), AACC, EHMA (European Health Management Association), Modern Healthcare, HIMSS (Health Information and Management Systems Society), NAHQ (National Association of Healthcare Quality) and IHE (Institute of Health Economics). Learn more at **univantshce.com**.

ADD-135632-GBL-EN