

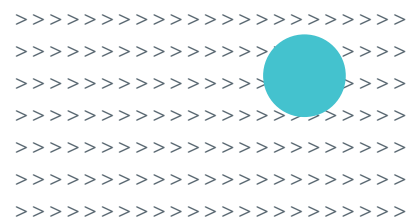
# REDUCING DIAGNOSTIC ERROR

## Related to the Laboratory Testing Process Change Package

Practices and Innovations from Leading Organizations

December 2018 V1.0





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- Advocate Health, Chicago, IL
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- Kaiser Permanente, Southern California
- MedStar Health, Columbia, MD
- North Mississippi Medical Center, Tupelo, MS
- Seattle Children’s Hospital, Seattle, WA
- Vanderbilt University, Nashville, TN

### **Consulted Subject Matter Experts**

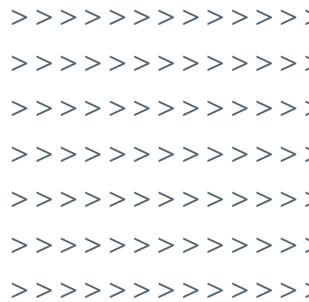
- Helen Haskell – Moms Against Medical Errors
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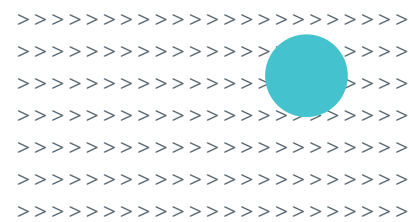
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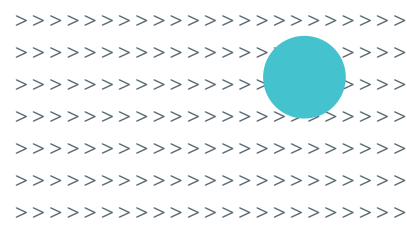
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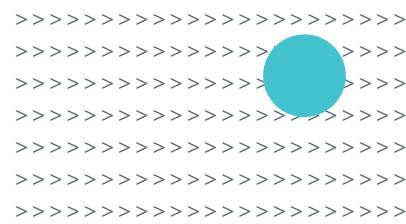
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## **Part 1: How to Use this Change Package**

This change package is proposed for hospitals in an effort to reduce diagnostic error related to the laboratory testing process through laboratory-driven systems change. It outlines best practices and scalable concepts for implementation that can improve the diagnostic process and reduce errors, thereby reducing harm to patients. A table of strategies and change concepts with specific actionable items that hospitals of all sizes can choose to adapt and implement is included. This change package is intended to be a complementary tool to literature reviews and other evidence-based resources and tools available.



## Part 2: Change Package Development

- 2017**  
Environmental scan, literature review and interviews with field experts
- JAN – MARCH 2018**  
Hospital site visits to best in class performers
- APRIL – JUNE 2018**  
First draft produced
- JUNE 20, 2018**  
Technical Expert Panel (TEP) in Baltimore, MD
- JULY – AUG 2018**  
Second draft produced
- SEPT 10, 2018**  
TEP II in Des Moines, IA
- OCT – NOV 2018**  
Third draft produced
- NOV 2018**  
TEP final review with written comment period
- DEC 2018**  
Hospital test group conducted, final change package delivered to CMS

Development of the change package focused on identifying key interventions and best practices used in leading organizations that could be scaled and adopted by hospitals across the United States (U.S.). In the absence of definitive or widely adopted diagnostic error data, an environmental scan and extensive literature review identified 34 organizations for preliminary study. The team selected these organizations based on their work with quality and safety initiatives, recommendations from subject matter experts, and published or presented work within the area of diagnostic error. Of these 34, ten organizations were identified as being leaders with recent and impactful work in diagnostic error initiatives. These ten were studied further through one-on-one interviews and group discussions focused on sharing their unique structure, strengths, culture, tools, policies and workflows that contributed to their high level of performance. Ultimately, seven organizations were chosen as “best in class” performers for site visits to further learn about their initiatives. These organizations represented diversity in size and geographic location and vary from community-based hospitals to academic medical centers and integrated health systems.

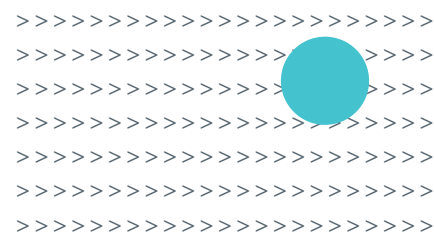
### Best in Class Hospitals who participated in this project:

- Advocate Health (recently renamed Advocate Aurora Health), an integrated health system based in Chicago, IL
- HealthPartners, an integrated nonprofit healthcare provider in Minneapolis/St. Paul, MN
- Kaiser Permanente, Southern California Region, an integrated managed care consortium and healthcare company
- MedStar Health, a not-for-profit healthcare organization based in Columbia, MD
- North Mississippi Medical Center, a regional referral hospital Tupelo, MS
- Seattle Children’s Hospital, a specialty hospital in Seattle, WA
- Vanderbilt University, an academic medical center in Nashville, TN

### Best in Class Performers were selected based on a combination of four factors:

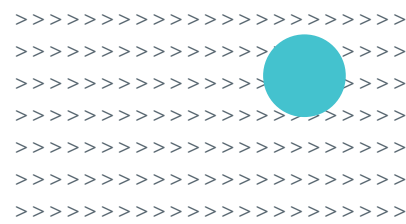
1. Consultation with subject matter experts in diagnostic error, organizational quality and safety
2. Leadership in published literature and national conference presentations related to the areas of study
3. Demonstration of active and progressive work on diagnostic error, specifically laboratory initiatives
4. Top performance in overall quality and safety, such as Leapfrog and Truven Analytics Top Hospital rankings

The development of this change package included discussions with more than 50 pathologists, clinical laboratory scientists, genetic counselors, physicians, nurses, operational managers, chief administrative leaders, quality and safety managers, national subject matter experts, patient safety organizations and patient advocates across six site visits and 17 telephone interviews. The development team held three extensive debriefing sessions to identify emerging themes and key action items. National experts and leading organizations validated the content. Additionally, Compass HIIN convened two interactive technical expert panel meetings, made up of site visit



participants, high performing organization leaders, national subject matter experts, patient advocates and the change package development team to further validate and refine the content. Finally, the change package was deployed and tested in a small group of hospitals to confirm that laboratory and quality improvement professionals found the content to be both useful and actionable. To achieve the overall aim of reducing diagnostic error related to the laboratory testing process, six key strategies for success, each of which includes change concepts and action items, are listed. The change package also provides links to toolkits and other relevant resources.

While the content has a focus on laboratory-related processes, the change package strives to set improvement goals which are ambitious and comprehensive to enable improvement throughout the diagnostic process as well as within an organization's overall quality and safety program. The intended audience is not only laboratory leaders and staff but also organizational leaders and clinical team members. The potential for implementation of these practices across the U.S. represents an opportunity to have a significant impact in improving the diagnostic process within organizations of all sizes and assist in achieving the CMS Partnership for Patients goal of making care safer by reducing all-cause harm (CMS 2018).



## ● Part 3: Diagnostic Error Introduction

### Background and Call To Action

Over the past decade, healthcare organizations have worked tirelessly on improving patient safety and quality of care. These efforts have addressed issues such as medication errors, healthcare-associated infections and post-surgical complications. Yet diagnostic error related quality and safety improvement efforts are less prevalent in the performance improvement community, despite research estimating diagnostic error accounts for 17 percent of preventable errors in hospitalized patients. A systematic review of autopsy studies covering four decades found approximately nine percent of patients experienced a major diagnostic error that went undetected while the patient was alive (Brennan & Newhouse et al 1991). More recent research compiled by Dr. Mark Graber in a 2013 narrative review cited studies, although using different approaches, consistently found diagnostic error incidence to be between 10-15 percent (Graber 2013). In addition to mounting research evidence illuminating the significant opportunity for improvement in reducing diagnostic errors, patients also cite the reduction of diagnostic errors as a high priority. A 2018 report reviewing more than 2 million safety events, root cause analyses and research requests revealed diagnostic errors as the number one patient healthcare concern that should be established as a priority (ECRI Institute, 2018). It is critical that the healthcare community raise their awareness of the magnitude of this problem and the impact it has on the quality and safety of our patients. Are you hearing the call to action?

### The Challenge

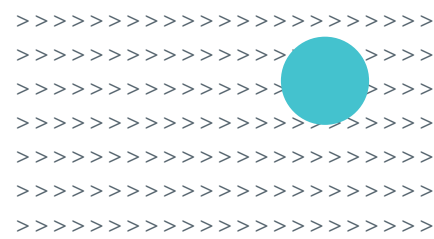
While the consensus to implement substantial efforts directed at reducing diagnostic error is growing, quality improvement efforts have been impeded by the lack of effective and appropriate measures and national benchmarking data.

There are many factors and steps that must be considered in the laboratory as it relates to the diagnostic process that could impact both (a) and (b) definition elements below. Diagnostic error data is retrospective and mostly selective (such as comparing clinical diagnoses to autopsy results, analyzing malpractice claims or performing surveys) (Schattner, 2016) which can be challenging for rapid-cycle improvement activities within a hospital.

As detailed in the 2015 National Academy of Sciences (NAS) quality report entitled Improving Diagnosis in Health Care, the committee wrote “a sole focus on diagnostic error reduction will not achieve the extensive change necessary; a broader focus on *improving diagnosis* is warranted.” Therefore, for the purposes of this change package, action items are innovative interventions to improve the diagnostic process (steps associated with determining and acting on a diagnosis as well as communicating the diagnosis to the patient). The change package also hopes to help catalyze the utilization of measurement from the standpoint of evaluating interventions and monitoring the steps within the diagnostic process. Hospital teams are challenged to customize measurements in ways that will positively impact the timeliness, accuracy and communication of diagnosis, with a focus on eliminating errors and improving patient outcomes. For example, metrics such as “failure to notify critical values to the clinical team” and “blood culture contaminations” represent current measurements which are easily tracked and may contribute to diagnostic error (as defined above) and undesired outcomes. A list of important measures related to diagnostic error is included in Appendix E for your consideration. Improvement in these areas of focus represents a methodology to improve the diagnostic process within an organization while research identifies alternative measures for directly assessing diagnostic error.

There appears to be even some variance in how diagnostic error is defined and a need for “common language” as the healthcare community commits to improvement. Perhaps the easiest way to understand diagnostic error is to consider diagnoses that are delayed, wrong/inaccurate or missed. The most widely accepted definition as defined by The National Academy of Medicine (formerly the Institute of Medicine) is as follows:

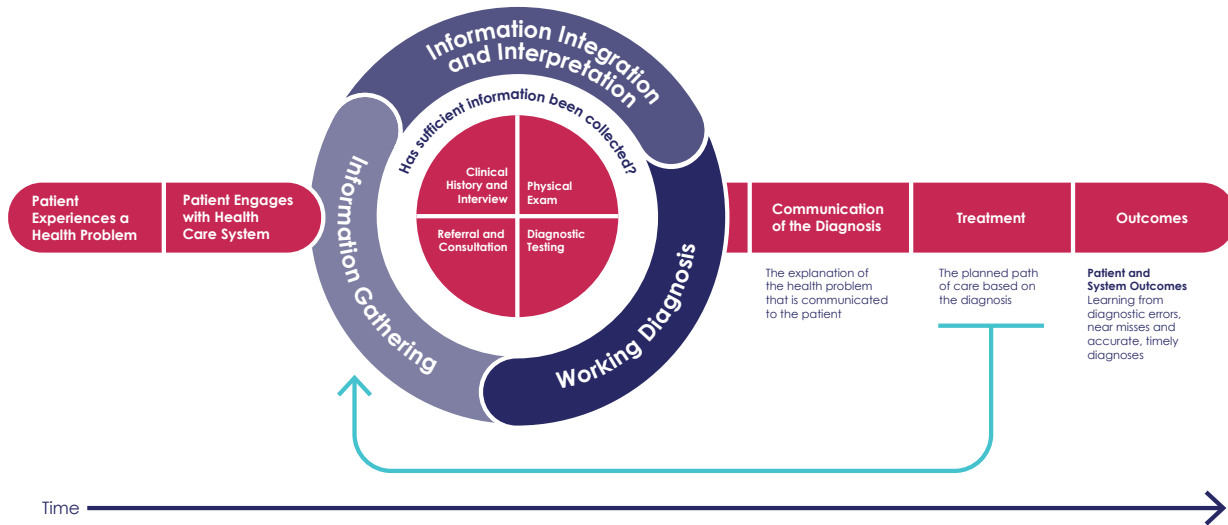




Diagnostic error is the failure to:

- (a) establish an accurate and timely explanation of the patient’s health problem (s) or
- (b) communicate that explanation to the patient

## The Diagnostic Process

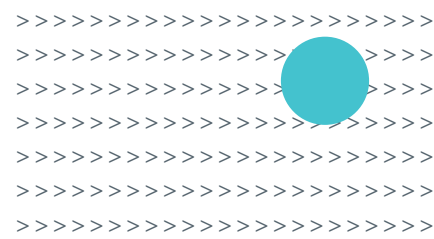


Source: National Academies of Sciences, Engineering and Medicine. 2015. Improving Diagnosis in Health Care. Washington, DC: The National Academies Press.

The diagnostic process is complex and is comprised of a significant number of steps where errors can occur. The process begins from the first symptom or health problem experienced by a patient, continuing through the patient’s engagement with the health system including information gathering, examination, testing, diagnosis and treatment, as well as communication with the patient and care team through outcomes. These errors can arise from cognitive or human failures including unconscious bias, system or process failures, culture lacking emphasis on patient safety issues or any combination of the three. Although the diagnostic process involves many areas of medicine and the health system the key to quality improvement may be in targeting a specific disease, care setting or modality. This change package focuses on opportunities that exist as part of the laboratory testing process. Due to the critical role laboratories have in the diagnostic process they are uniquely positioned to have a significant impact in decreasing diagnostic error. For example, laboratory testing is often used to confirm initial impressions or rule out differential diagnoses. It is estimated that at least 10 percent of all diagnoses are not considered final until laboratory testing is complete (Peterson et al 1992 and Wahner-Roedler et al 2007).

Inaccurate or delayed diagnosis is one of the most important safety concerns in healthcare. Laboratory testing errors, which may contribute to misdiagnoses, can occur in one or more of the three phases of the testing process: pre-analytical, analytical and post-analytical.

- Pre-analytical errors can result from incorrect test selection, incorrect patient identification, or the mishandling of specimens including collection, labeling, storage, transportation.
- Analytical errors can occur due to improper specimen processing, preparation or instrument failures resulting in incorrect results.
- Post-analytical errors can occur through delays, errors or omissions in reporting and communicating patient test results and misinterpretation of test reports by clinicians.



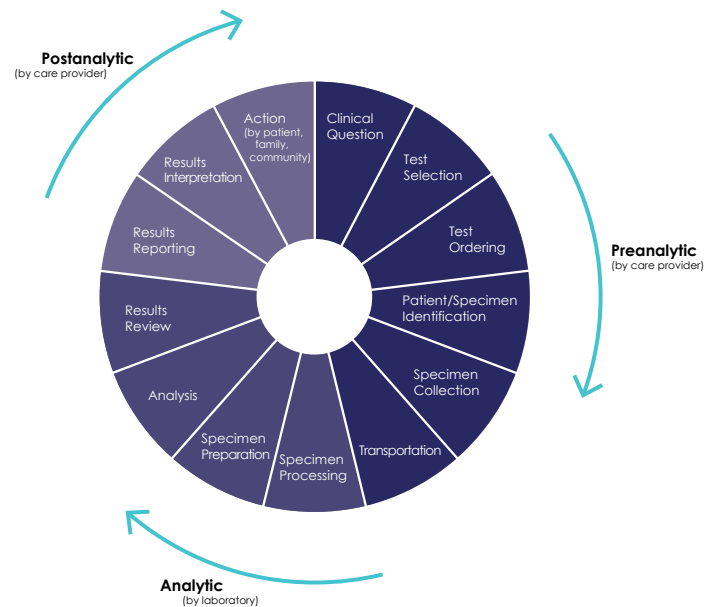
Efforts surrounding diagnostic error reduction in the previous two decades focused on the high rates and severity of errors in the analytical phase. These efforts caused a ten-fold reduction in the analytical error rate thanks to improvements in the reliability and standardization of analytical techniques, reagents and instrumentation (Plebani 2015).

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include requirements for all three phases of the testing process and are intended to assure the quality of laboratory testing, thus reducing laboratory errors and improving the diagnostic process. The Clinical Laboratory Improvement Advisory Committee (CLIAC), managed by the Centers for Disease Control and Prevention on behalf of the CLIA program, has also considered vulnerabilities in the diagnostic process and has provided many recommendations related to improving quality and reducing errors in all phases of the testing process.

All three phases of the total testing process can be targeted individually for improving quality, although it is acknowledged that most errors now occur in the pre- and post-analytical phases (Hammerling 2012). While safety initiatives have worked to address misidentification of patients, sample collection and sorting errors, the change package focuses on other errors that can impact the diagnostic process including, but not limited to, inappropriate test requests, unacceptable specimens, failures in reporting and communication, as well as other strategies identified at top performing organizations that impact patient outcomes.

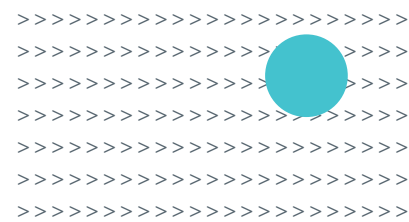
Laboratory professional staff can be an important asset, assuring appropriate test utilization by leveraging their expertise to assist clinicians in test selection and result interpretation. Several studies suggest this expertise is not always relied upon and, as a consequence, raises the risk of compromising timely and accurate diagnoses. While using the ‘pre-analytic’, ‘analytic’ and ‘post-analytic’ terms to describe phases within the laboratory, it is important to note the laboratory works in partnership with the entire care team. Members of the care team outside of the laboratory often participate in one or more of the activities during the laboratory total testing process: test selection, test ordering, specimen collection and identification, interpretation and communication to the patient. All these activities are opportunities for errors and harm to occur.

The concept of decreasing diagnostic error may sound daunting to organizations of any size but the goal to improve the diagnostic process is attainable and will, by virtue of improving the process, decrease diagnostic errors and reduce harm. Evaluation of the entire diagnostic process is a new and exciting dimension within the realm of quality improvement, one which is ripe for innovation and progression. As such, the change package is intended to reduce diagnostic error related to the laboratory testing process for organizations of all sizes across the United States.



Source: Lundberg GD. Acting on Significant Laboratory Results. JAMA. 1981;245(17):1762-1763. doi:10.1001/jama.1981.03310420052033

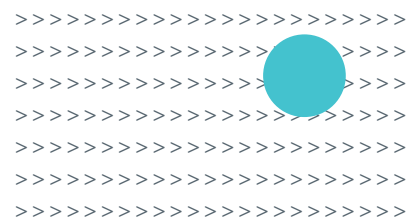
Image source: ECRI PSO Deep Drive Laboratory Testing presentation, courtesy of Dr. Mark Graber



## Part 4: AIM and Strategies

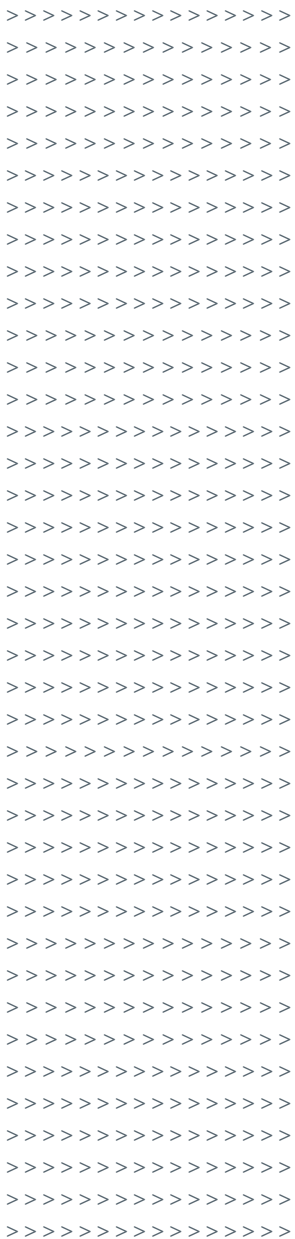
The change package was developed by way of a driver diagram, a tool which assists in translating a high-level improvement goal or AIM into a set of foundational strategies and change concepts. It is a guide toward transformation efforts which will support the aim of reducing diagnostic error related to the laboratory testing process. Strategies define necessary key forces while change concepts are the highly leveraged areas of change. Development of this diagram provides the pathway from change to successful outcomes. Action items provide detailed initiatives which are derived from the strategies and change concepts and can be scaled for implementation in your organization. Organizational stories from top performers have been incorporated as examples of successful work in the strategies and change concepts listed as well as links to additional resources.

AIM	Strategies	Change Concepts
<p><b>Reduce Harm Related to Laboratory Testing Diagnostic Error</b></p> <p><i>Diagnostic error is the failure to:</i></p> <p>(a) <i>Establish an accurate and timely explanation of the patient's health problem (s)</i></p> <p><i>or</i></p> <p>(b) <i>Communicate that explanation to the patient</i></p>	<p><b>Strategy 1:</b> Laboratory Performance</p>	<p>Laboratory regulatory standards and best practices</p> <p>Employ performance improvement concepts</p> <p>Pinpoint laboratory improvement opportunities</p> <p>Meaningful measurement</p> <p>Rapid-cycle improvement in the laboratory</p> <p>Monitor performance in the laboratory</p>
	<p><b>Strategy 2:</b> Teaming Opportunities</p>	<p>Organizational team development</p> <p>Key partnerships</p> <p>Champions</p> <p>Co-created design</p>
	<p><b>Strategy 3:</b> Implement Initiatives with your Team</p>	<p>Improve timeliness and accuracy of diagnostic processes</p> <p>Optimize test ordering</p> <p>Improve test results receipt and interpretation</p> <p>Ensure appropriate follow-up</p>
	<p><b>Strategy 4:</b> Systems-Based Best Practices</p>	<p>Peer-review best practices</p> <p>Awareness of cognitive bias</p> <p>Transparency and error reporting</p> <p>Care for the caregiver</p>
	<p><b>Strategy 5:</b> Patient and Family Centeredness</p>	<p>Engaging patients and families</p> <p>Educating and empowering patients and families</p> <p>Patient's critical role in quality improvement</p>
	<p><b>Strategy 6:</b> Clinical Informatics and Innovation</p>	<p>Data systems technical optimization</p> <p>Leveraging data to improve the diagnostic process</p> <p>Considerations for future innovation</p>



## Part 5: Change Concepts and Action Items

### Strategy 1: Laboratory Performance



#### 1.1 Change Concept: Laboratory Regulatory Standards and Best Practices

##### Action Items:

- Ensure compliance with state and federal regulations (e.g., CLIA)
- Review and enact findings from the CDC Laboratory Medicine Best Practices
- Review and use published findings and resources from the CDC Clinical Laboratory Integration into Healthcare Collaborative (CLIHC) to improve the testing process
- Review and use applicable best practices identified by relevant professional organizations and accrediting bodies including Clinical & Laboratory Standards Institute (CLSI), College of American Pathologists (CAP) and The Joint Commission (TJC)
- Review and implement Health IT’s SAFER Guides to enable healthcare organizations to address EHR safety
- Become compliant with Health Information Technology for Economic and Clinical Health Act (HITECH) standards for laboratory information technology interoperability
- Improve the testing process (consider implementing applicable items from AHRQ’s toolkit for Improving Laboratory Testing Process, although intended for outpatient offices may also provide additional insight applicable to the inpatient environment)



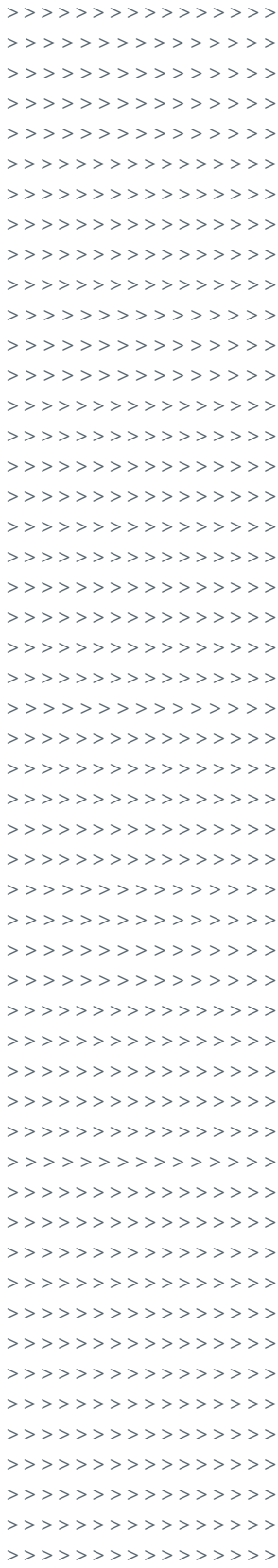
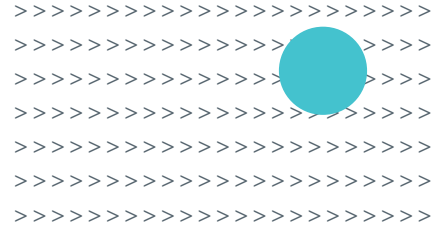
##### Resources:

- [ERCI National Clinical Guidelines](#) (Link)
- [CDC Laboratory Medicine Best Practices](#) (Link)
- [CLSI Standards](#) (Link)
- [HealthIT.gov’s SAFER Guides](#) (Link)
- [CMS’ EHR and HITECH Programs Promoting Interoperability](#) (Link)
- [AHRO’s Improving Your Laboratory Testing Process. A Step-by-Step Guide for Rapid-Cycle Patient Safety and Quality Improvement Toolkit](#) (Link) ([Appendix A](#))

#### 1.2 Change Concept: Employ Performance Improvement Concepts

##### Action Items:

- Train laboratory leaders on methods to design and implement effective and sustainable projects using rapid cycle improvement
- Engage all laboratory department staff in coordinated performance improvement activities



**Resources:**

- [IHI Open School provides classes on performance improvement](#) (Link)
- [IHI's Quality Improvement Essentials Toolkit](#) (Link)



**Success Story:**

North Mississippi Medical Center invested in off-site lean training for laboratory management which assisted in mapping processes and identifying improvement opportunities.

**1.3**

**Change Concept: Pinpoint Laboratory Improvement Opportunities**

**Action Items:**

- Review performance of high-priority tests (example: blood cultures to assist in diagnosing sepsis)
- Measure clinically significant delays in turnaround times for in laboratory and send out tests
- Track and evaluate the number of unacceptable specimens and reasons/causes to identify potential improvement opportunities
- Identify potential steps in laboratory processes which could be eliminated or expedited to reduce waste and opportunities for error to occur
- Review laboratory utilization stewardship opportunities (decreasing unnecessary utilization of obsolete, counterintuitive and expensive tests)
- Implement a formal quality improvement process to systematically evaluate and act on opportunities to improve accurate and timely diagnoses



**Success Story:**

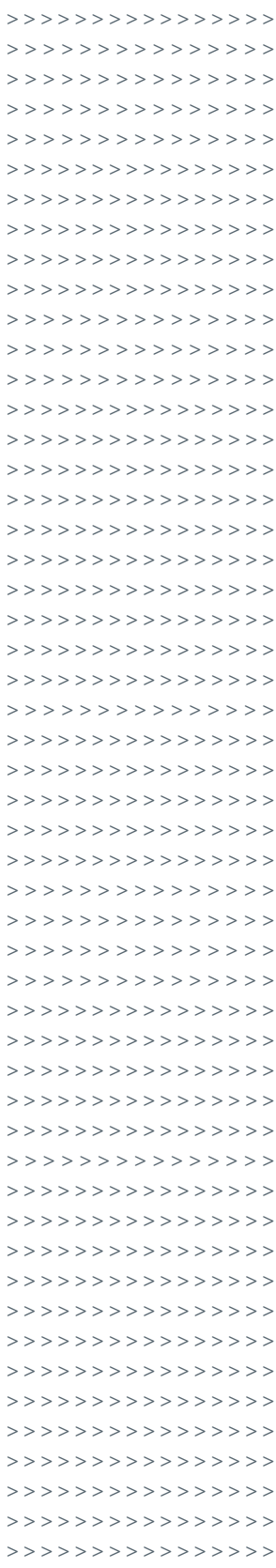
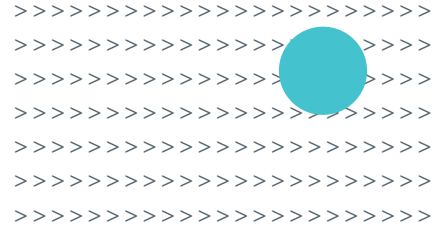
North Mississippi Medical Center reviewed each step in the processing of blood cultures as part of a sepsis project. By reviewing best practices for sample volume and plating as well as adjusting staff procedures to check for growth, they improved performance on their “Blood Collection to Initial Growth Reported” metric by more than four hours and “Blood Culture Collection to Final Report” metric by over 13 hours.

**1.4**

**Change Concept: Meaningful Measurement**

**Action Items:**

- Evaluate current state by establishing baselines for all performance metrics and goals for targeted areas of focus
- Consult your PI (performance improvement) experts to incorporate both process and outcome measures when possible
- Prioritize measurements that are clear and actionable
- Develop a communications plan and frequency for reporting results, ensuring feedback loops to all stakeholders



### 1.5 Change Concept: Rapid Cycle Improvement

#### Action Items:

- Determine priority improvement initiatives from opportunities identified
- Use small test of change (PDSA, Plan Do Study Act) as a framework to get started
- Just do it! *“Start where you are. Use what you have”* – Arthur Ashe

### 1.6 Change Concept: Monitor Performance in the Laboratory

#### Action Items:

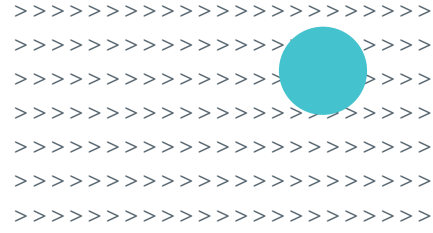
- Continue to measure while implementing improvement practices
- Optimize LIS and EHR event reporting tools for monitoring internal laboratory operations
- Leverage feedback reporting systems
- Create a scorecard to track and communicate performance and improvement resulting from interventions (remember to start small and add as you go)



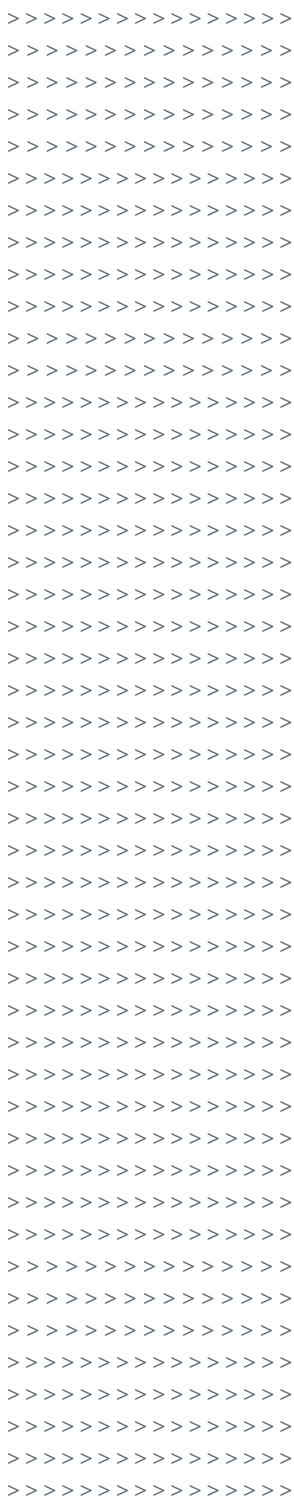
#### Success Stories:

Vanderbilt created a “Harm Index” to monitor harm related to the laboratory processes. Metrics include blood product errors, incorrect results reported in the EHR, delay in test resulting, failure to call critical laboratory values to clinical team, major discrepancies between intraoperative review and final diagnosis (due to sampling or interpretation).

Leading organizations visited including Kaiser Permanente, HealthPartners, Seattle Children’s, Vanderbilt and North Mississippi consistently review interventions for effectiveness and discontinue initiatives if they are not having an effective impact.



## Strategy 2: Teaming Opportunities



**2.1 Change Concept: Organizational Team Development**

**Action Items:**

- Engage multidisciplinary leaders from departments connected to the entire testing process (examples: pharmacy, nursing, emergency, providers, phlebotomy, risk management team and Chief Medical Officer)
- Use data to initiate and support dialogue by presenting metrics and outcomes centered around improving diagnostic processes presented in Strategy 1 (example: performance scorecard)

**★ Success Story:**

HealthPartners, Seattle Children’s, Vanderbilt and North Mississippi all utilized physicians (either laboratory directors or physicians with an interest in the laboratory) to build partnerships between the laboratory and ordering providers.

**2.2 Change Concept: Key Partnerships**

**Action Items:**

- Include stakeholders in evaluation of processes and identification of opportunities for reducing testing-related errors and associated harm across all clinical areas
- Engage external partners that provide consultative, telehealth and other services
- Review common testing-related diagnostic error metrics with partners (see Appendix E for metric examples)
- Select opportunities to implement change based on organizational prioritization and feasibility to garner buy-in

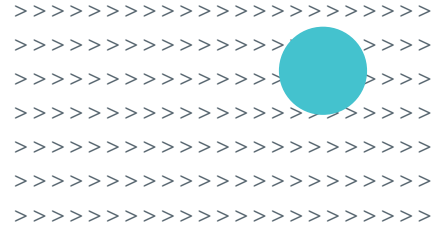
**2.3 Change Concept: Champions**

**Action Items:**

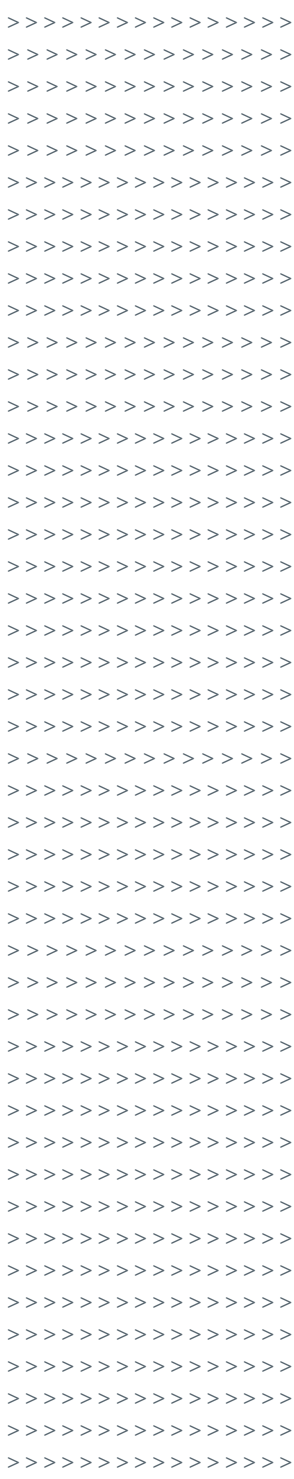
- Identify interested and passionate leaders across disciplines to facilitate dialogue and accelerate action on improvement initiatives
- Partner administrative, clinical and nursing leadership for shared accountability
- Develop communication structures to enable reporting at regular intervals to stakeholders and hospital leadership
- Raise awareness of the magnitude and impact of diagnostic errors within your own organization and the potential for interventions directed to improving health outcomes and reducing costs and liability

**★ Success Story:**

HealthPartners collaborated with providers to reduce administrative burden. Co-created initiatives decreased “inbox time” by over 30 percent and increased physician satisfaction.



## Strategy 3: Implement Initiatives with your Team



**3.1 Change Concept: Improve Timeliness and Accuracy of Diagnostic Process**

**Action Items:**

- Implement an annual review schedule and define accountability for assessment and revision of laboratory testing algorithms including reflex testing protocols
- Create ad hoc panels, diagnostic management teams and advisory groups of multi-disciplinary experts (including laboratorians) for management of specific diseases and disorders
- Implement and audit processes to measure timeliness of the diagnostic process with at least one component that includes laboratory measures (e.g., turn-around time)
- Develop testing and interpretation algorithms in collaboration with diagnostic management teams

**★ Success Story:**

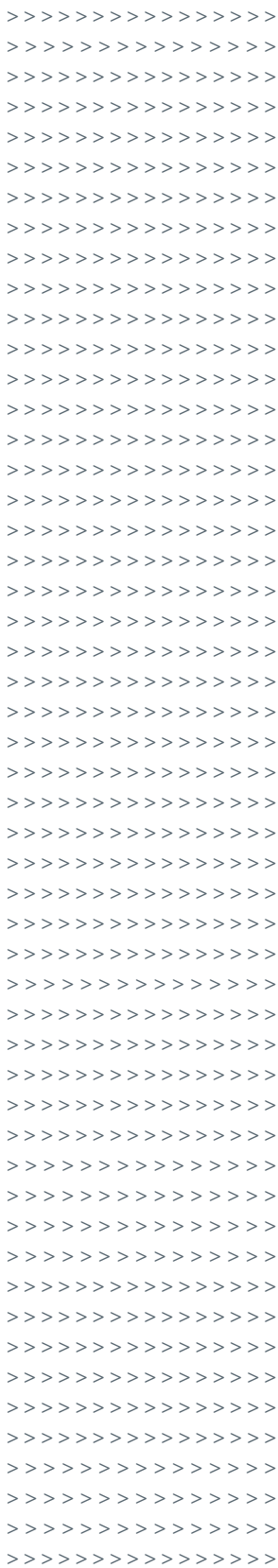
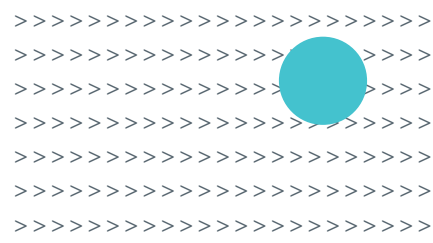
Vanderbilt Laboratory leadership collaborated with physicians and created diagnostic management teams (DMTs) for certain conditions. The Coagulation DMT created patient-specific, expert-driven interpretations of laboratory results enabling doctors to diagnose patients' conditions more quickly and accurately.

**3.2 Change Concept: Optimize Test Ordering**

**Action Items:**

- Develop interactive laboratory test menus
- Regularly review test menus to eliminate obsolete or non-effective tests from the list of tests available
- Privilege ordering of highly specialized testing by provider expertise or specialty when appropriate
- Develop and integrate a test menu to aid in test selection (example: a clinical directory of tests)
- Utilize clinical decision support software to provide guidance for ordering providers and assist them in optimal test selection
- Create electronic health record (EHR) hard stops to prevent automatic renewal of tests without review from the ordering clinician
- Develop an alert in the EHR to notify the ordering provider when a result is already available (example: provider alert if a patient already has a result from a “once in a lifetime” test to avoid duplication of the study, therefore reducing delays in diagnosis)
- Establish a process for clinicians to request a consult with a laboratorian to gain their expertise on tests (example: Pathologist, Laboratory Scientist or Reference Laboratory). Genetic Counselors also offer valuable knowledge on genetic test selection, interpretation, and communicating results to patients
- Create a protocol for automatic consultation between a laboratorian and the ordering clinician when ordering rarely used and/or expensive tests
- Join professional associations and study best practices on test utilization including Patient-centered Laboratory Utilization Guidance Service (PLUGS), an independent organization specializing in laboratory stewardship





**Resource:**

- [Patient-centered Laboratory Utilization Guidance Service \(PLUGS\) website](#) (Link)



**Success Stories:**

HealthPartners leveraged their EHR for strategies to improve appropriate test utilization including interactive laboratory formularies and prompts when newer or better tests were available for the provider to consider.

HealthPartners implemented a laboratory genetic counselor position – meant to be a resource rather than a roadblock – to assist providers in ordering and interpretation of uncommon tests. For expensive genetic testing this position paid for itself in less than one year. Seattle Children’s Hospital implemented a similar review process for genetic tests by laboratory genetic counselors. This review is associated with a 25 percent order modification/cancellation rate and associated cost-avoidance, which helps to justify additional resources to support the laboratory stewardship program. A white paper provided by HealthPartners detailing the use of the genetic counselor position is included in [Appendix B](#).

**3.3 Change Concept: Improve Test Results Receipt and Interpretation**

**Action Items:**

- Implement a process to identify high risk test results that have not been reviewed. Audit the process to identify gaps and prevent future delays in reviewing these results
- Promote consultation requests with a laboratory professional to assist providers with interpretation of test results
- Develop condition-specific and patient-specific laboratory reports that integrate testing and interpretation to assist in treatment decisions (example: coagulation)

**3.4 Change Concept: Ensure Appropriate Testing Follow-Up**

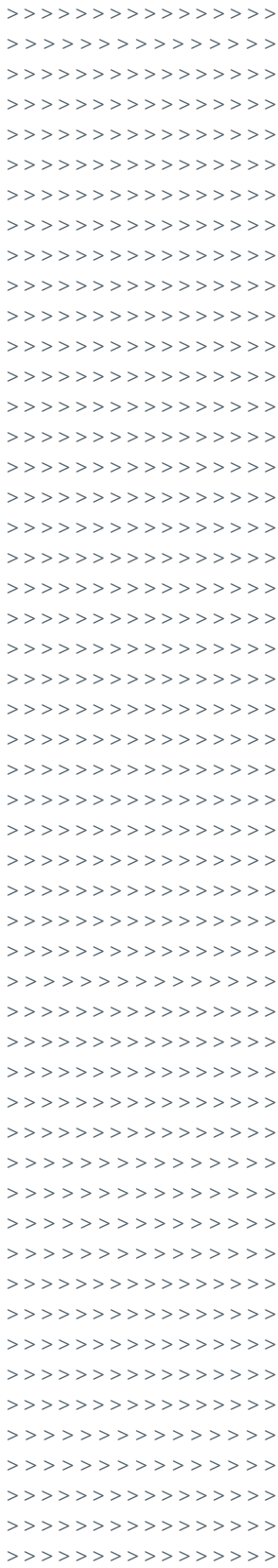
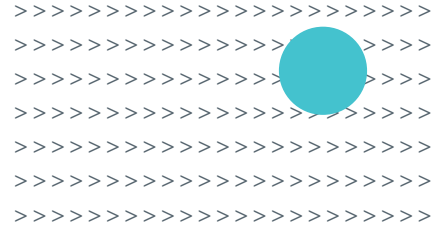
**Action Items:**

- Standardize protocols to safeguard closed-loop communication of life-threatening and urgent test results (example: critical results communication protocol)
- Develop a tracking system to ensure patients with abnormal test results receive follow-up evaluations, especially after an inpatient discharge and during transitions of care
- Leverage the use of EHRs to identify patients in need of follow-up care but that have not received it within the prescribed timeframe



**Success Story:**

Kaiser Permanente Southern California created SureNet, a system to identify care gaps including patients overdue for follow-ups of abnormal test results. This program has contributed to improved care for chronic kidney disease and colorectal cancer patients. Additional information on SureNet is included in [Appendix C](#).



**3.5 Improve Test Results Receipt and Interpretation**


**Action Items:**

- Implement a process to identify high risk test results that have not been reviewed. Audit the process to identify gaps and prevent future delays in reviewing these results
- Promote consultation requests with a laboratory professional to assist providers with interpretation of test results
- Develop condition-specific and patient-specific laboratory reports that integrate testing and interpretation to assist in treatment decisions (example: coagulation)

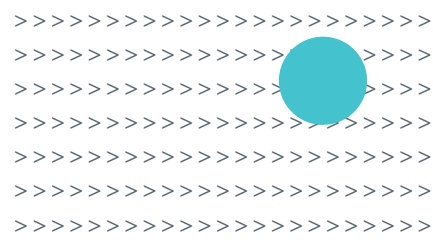
**3.6 Change Concept: Ensure Appropriate Testing Follow-Up**

**Action Items:**

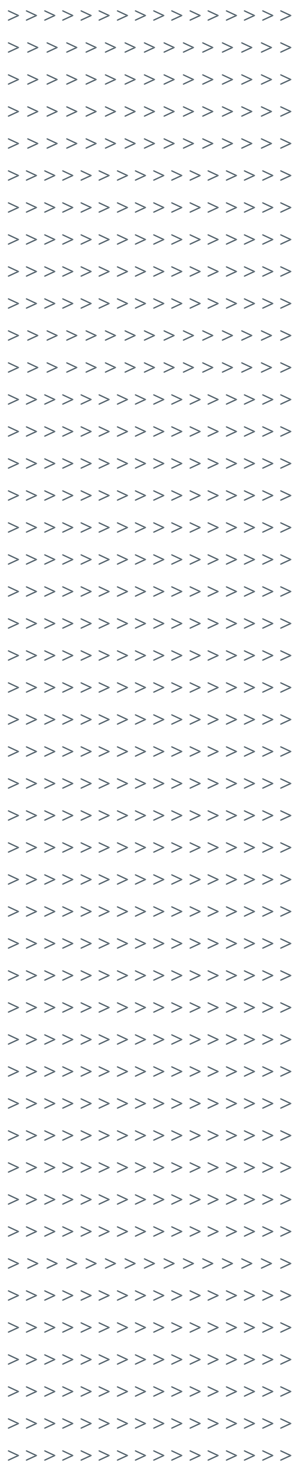
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 **Success Story:**

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## Strategy 4: Systems- based Best Practices



**4.1 Change Concept: Organizational Peer Review Best Practices**

**Action Items:**

- Redesign peer review to act as an educational tool not a disciplinary process based on “High Reliability” and “Just Culture” concepts
- Initiate multi-disciplinary peer review with a goal of progressing to inter-disciplinary peer review that includes a PFA (patient family advisor)
- Implement a simplified process for referring and reviewing peer review cases
- Take deeper dives in peer review beyond a “known complication” to review if the complication could have been prevented
- Design a mechanism to act on improvement opportunities unveiled in the peer review process so that lessons don’t get lost
- Identify and review near misses through the peer review process as an educational tool for the organization
- Provide a process for ongoing education for providers that supports ongoing process improvement based on peer review data findings


 **Resources:**

- [Just Culture Research Paper](#) (Link)
- An example of the process Advocate Health uses for Peer Review is included in [Appendix D](#).
- [AHRO’s Patient Safety Primer on High Reliability Organizations](#) (Link)

**4.2 Change Concept: Awareness of Cognitive Bias**

**Action Items:**

- Develop and assess diagnostic competencies through the education of health professionals with focus on diagnostic reasoning (example: cognitive bias training)
- Incentivize harm and bias education for non-employed or contract physicians

 **Success Story:**

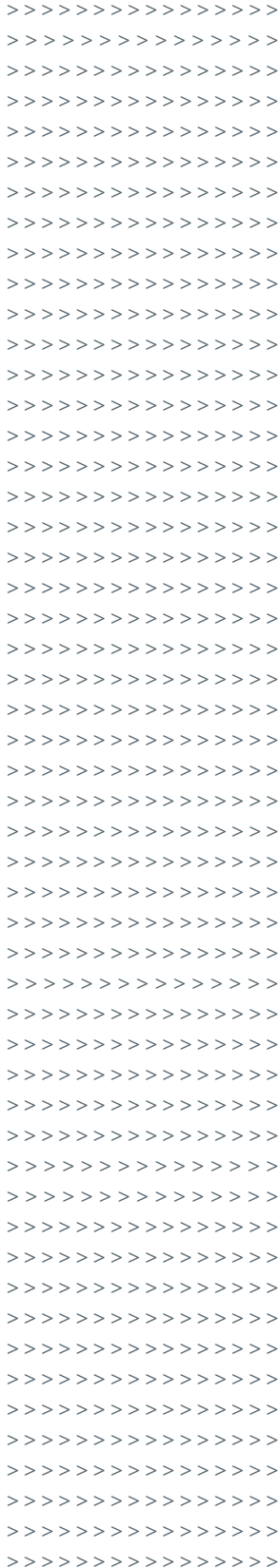
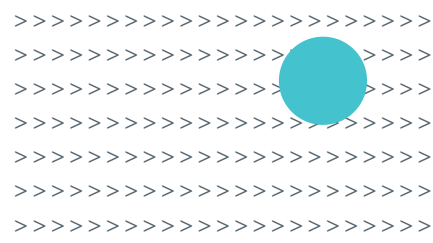
Advocate Health completed bias training for all physicians.

**4.3 Change Concept: Transparency and Error Reporting**


Dr. Lucian Leape stated that the single greatest impediment to error prevention in healthcare is *“we punish people for making mistakes.”*

**Action Items:**

- Ensure senior leadership demonstrates and communicates that transparency is an organizational value
- Research emerging literature on the relationship between decreasing malpractice claims/ payments and increasing transparency to support return on investment (ROI) propositions to leadership



- Educate your care team on medical liability in your state to dispel myths related to error reporting and transparency
- Develop and implement a process to allow anyone, including patients, to immediately report errors (example: an available hotline where anyone can anonymously report errors)
- Establish Root Cause Analysis and Sentinel Event Committees and ensure that patients are represented on each
- Be intentional about communicating to patients who have experienced harm regarding what has been done to ensure the same harm does not occur again
- Determine processes to make harm visible through immediate and open reporting, sharing near misses and preventable harm events with all staff and stakeholders
- Accept responsibility and take action when a harm occurs by using tools included in AHRQ CANDOR toolkit
- Research the concepts of Just Culture and implement them throughout the organization
- Embrace the human factors approach to event review and process redesign
- Provide positive feedback by acknowledging staff who identify, report and rectify preventable errors or near misses
- Measure and assess the culture of safety across the organization annually

 **Success Stories:**

Advocate Health developed a system to evaluate and classify serious safety events to assist in improvement efforts. Information on this system is included in [Appendix D](#).

MedStar initiated a “We Want to Know” program for their patients to share their stories and feedback.

MedStar empowered all employees to report errors and near misses as well as good catches. Employees who prevent medical errors are recognized.

 **Resource:**

- [AHRQ’s CANDOR Toolkit](#) (Link)

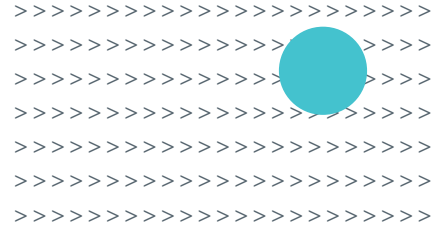
**4.4 Change Concept: Care for the Caregiver**

**Action Items:**

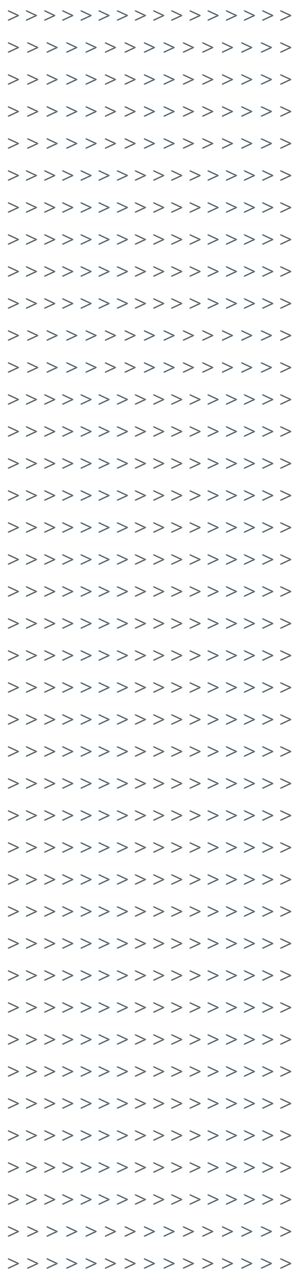
- Educate your team on the impact unintended harm has on healthcare providers (the second victim) involved in diagnostic errors and other unintended harm events
- Utilize tools within AHRQ CANDOR toolkit (module 6) in implementing a Care for the Caregiver program within your organization that allows for immediate support

 **Resources:**

- Compass HIIN has a [video series on CANDOR Training](#) (link) including Care for the Caregiver on their YouTube Channel
- Compass HIIN provides a [resource list](#) (link) which accompanies each workshop on their YouTube channel



## Strategy 5: Patient and Family Centeredness



### 5.1 Change Concept: Engaging Patients and Families

#### Action Items:

- Integrate patients and their families in diagnostic improvement efforts
- Engage patients and families as active participants at the center of the care team to build better relationships and outcomes
- Ask patients and families what matters or what is important to them and allow these priorities to guide the diagnostic process and care plan
- Establish care team bedside huddles and/or rounding with the patient and family
- Engage the patient community in practice improvement and education efforts and prioritize focus on efforts that matter to patients
- Understand the power of the patient narrative and capture their stories and perspectives to put a face on harm and share valuable lessons across the organization
- Explore tools established with evidence-based methods which support patients and families getting involved in their care



#### Resources:

- [AHRO's CANDOR Toolkit](#) (Link)
- [AHRO's Engaging with Patients and Families in their Health Care](#) (Link)
- [AIR's Partnership for Patient Strategic Vision Roadmap for PFE](#) (PDF) provides strategies and tactics to implement PFE

### 5.2 Change Concept: Educating and Empowering Patients

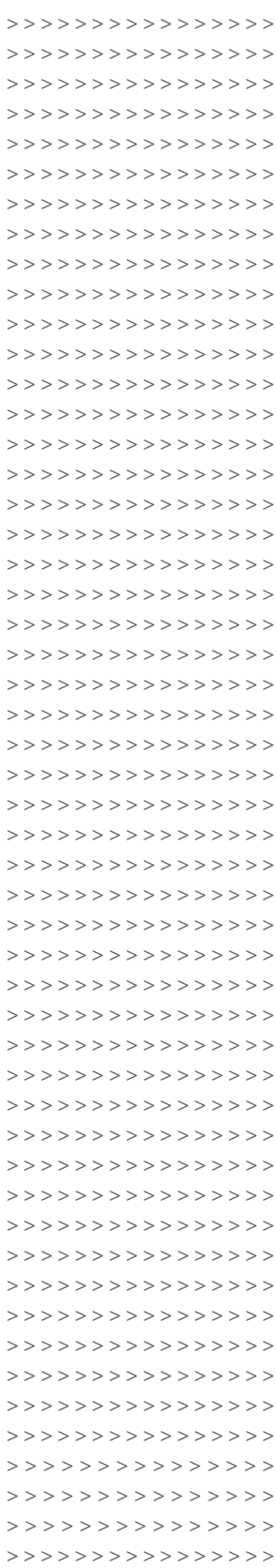
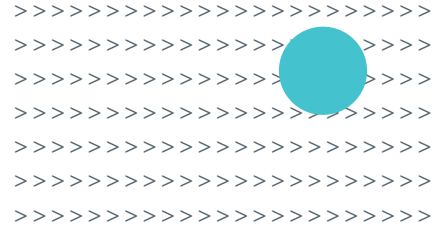
#### Action Items:

- Teach patients the importance of laboratory tests and what information can be gained by the results as it relates the patient's diagnostic process
- Facilitate shared decision-making throughout the organization with online resources (examples: labtestsonline.org and choosingwisely.org)
- Encourage use of patient portals or similar technology to review health records, test results and medical notes to improve timeliness and accuracy of medical information as well as improved bi-directional communication between provider and patient
- Explore ways to convey that you understand and value the patient as an expert in their health
- Create a system promoting, documenting and measuring patient reported outcomes
- Ensure patients and families feel comfortable asking questions and sharing feedback
- Create education materials that teach patients how to confidently communicate their symptoms and priorities to their provider
- Teach your team strategies for achieving active patient engagement (examples: motivating interviewing, teach-back, shared decision making)



#### Resources:

- [Lab Tests Online](#) (Link)
- [Choosing Wisely](#) (link) where there are downloadable resources to assist in the conversations between providers and patients regarding testing



**★ Success Story:**

Advocate Health developed a strategic, multiphase plan with a goal of having zero serious safety events by 2020 including higher accountability and greater patient and family engagement.

**5.3 Change Concept: Patient's Role in Quality Improvement**

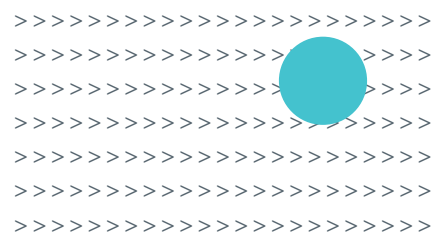
**Action Items:**

- Collaborate with Patient and Family Advisory Council (PFAC) on diagnostic process improvement projects
- Include patient and family advisors (PFAs) on process improvement/ quality improvement committees
- Co-develop policies and procedures with PFAs (examples: bedside rounding, hand hygiene, discharge planning)
- Include dedicated seat for a PFA in organizational governance

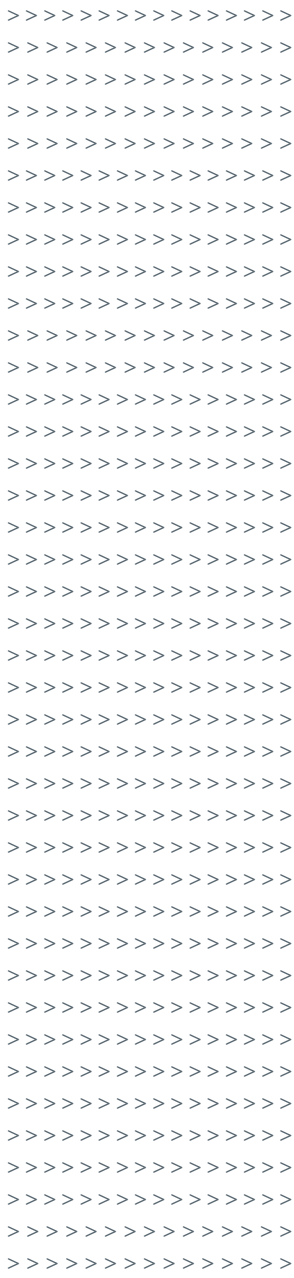
**★ Success Stories:**

MedStar asked patients and community members to participate on councils for performance improvement to ensure the patient's viewpoint was heard.

Advocate Health invited patient representatives to participate on the Root Cause Analysis (RCA) committees as valued members of the team.




# Strategy 6: Clinical Informatics and Innovation



**6.1 Change Concept: Data Systems Technical Optimization**

**Action Items:**

- Review the quality of interfaces between systems
- Ensure laboratory Information Systems (IS) teams consist of and are governed by laboratory personnel
- Review and implement AHRQ’s Health IT Evaluation toolkit
- Review and implement AHRQ’s Guide to Evaluating Health Information Exchange Projects

 **Resources:**

- [AHRQ’s Health IT Evaluation Toolkit](#) (Link)
- [AHRQ’s Guide to Evaluating Health Information Exchange Projects](#) (Link)

**6.2 Change Concept: Leveraging Data to Improve the Diagnostic Process**

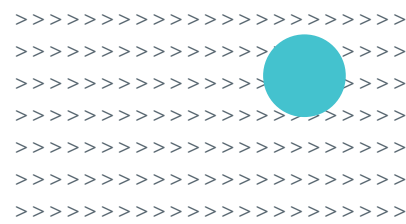
**Action Items:**

- Use currently reported data to identify inefficiencies, inconsistencies and opportunities for improvement
- Leverage the power of informatics to create timely, meaningful and actionable reports to understand what is driving current performance (example: highlight cross-departmental opportunities)
- Benchmark reports

**6.3 Change Concept: Considerations for Future Innovation**

**Action Items:**

- Consider the implications and potential use of artificial intelligence as the future of clinical decision support
- Consider the potential for integration of telehealth services to improve timely and accurate diagnosis
- Review blockchain technology and its potential impact on healthcare
- Prepare for the impact of data derived outside of the healthcare system
- Consider the use of data derived from non-traditional medicine
- Identify the availability and application of non-healthcare information which impacts health outcomes



## ● Part 6: Action Planning

Diagnostic error is a problem that has many variables. As such, there is a significant number of opportunities that can be embraced as we seek to fearlessly innovate and propel change. These can help us achieve the bold aim of reducing diagnostic error related to the laboratory testing process in our healthcare organizations. Because this is a relatively new area to quality improvement readers may find the need to educate and increase awareness around diagnostic error in their organization. Explore areas of safety, quality and performance opportunities unique to each organization and use them to create and communicate the urgent need for local change and amplify the “Call to Action.”

This change package provides a diverse array of change concepts and actions that can be implemented to drive improvement in the diagnostic process within an organization. Some tactics deal with ensuring an appropriate environment for change, while others are more technical tactics directly related to laboratory and provider interactions. Process changes are a critical component to success as systematized improvement efforts are made. Identifying vital process measures can help track and measure critical steps in the process that directly impact outcomes. If readers are unsure of where to start, focusing on key and fundamental processes is a great place to begin.

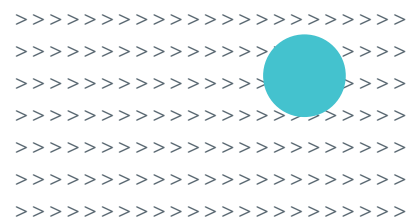
As hospitals progress in this work they will find there are opportunities to make investments in robust EHR platforms or data-mining tools that can provide electronic solutions to track follow-up gaps. Both incremental and more significant investments, based upon available resources, will likely reduce the risk of diagnostic errors.

There is a significant range of organizational sizes throughout the United States from critical access and community hospitals to integrated healthcare systems and large academic medical centers. In the development of this change package, the authors have thoughtfully considered all sizes of organizations. They have included a range of tactics that create opportunities for teams to scale change concepts and action items to their organization’s size and specific needs.

Similarly, this change package does not endorse one specific method for implementing the change package. Most organizations have methodology they utilize for their performance improvement activities. We recommend adapting the tactics and background as described in the change package in a way that leverages each organization’s proven performance improvement methodology. Readers looking for additional guidance can reference AHRQ’s helpful guide detailing improving laboratory testing processes as provided in Appendix A.

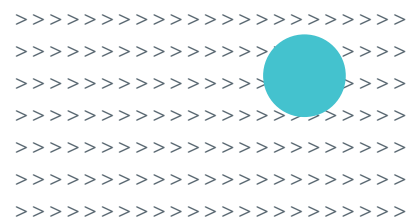
**The importance of selecting a single action and method to start on the journey to improve the diagnostic process cannot be overstated. In the foundational research for this change package, nearly every leading organization emphasized the importance of identifying an opportunity for improvement and beginning work on that area. An innovative spirit combined with small tests of change is all that is needed to get started. As a journey of a thousand miles begins with a single step, the road to diagnostic improvement begins with making a change in an area which can be improved. Just jump right in and do it!**





## ● Part 7: Appendices

- **Appendix A: AHRO’s Improving Your Laboratory Testing Process, A Step-by-Step Guide for Rapid Cycle Patient Safety and Quality Improvement Toolkit** (Link)
- **Appendix B: HealthPartners White Paper Discussing Utilization of Genetic Counselor for Test Selection and Interpretation** (PDF)
- **Appendix C: KPSC Outpatient Survey Net Overview** (PDF)
- **Appendix D: Advocate Health’s Advocate Peer Review Worksheet** (PDF) and **Advocate Health’s Advocate Safety Event Classification Worksheet** (PDF)
- **Appendix E: Laboratory Diagnostic Error Metrics** (PDF)



## ● Part 8: References

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