LABORATORY MEDICINE Best Practices

OMB Control No. 0920-xxxx
Exp. xx/xx/xxxx

Laboratory Medicine Best Practices Submission Form

Please provide information in the spaces below.

Name: _____ **Today's Date:** _____

Position: _____

Institution: _____

Organization / Department: _____

E-Mail: _____ **Phone:** _____

Mailing Address: _____

City: _____**State:** ___**Zip / Postal Code:** _____ **Country** _____

Do you want your organization to be identified ___ or remain anonymous? ___

I. About Your Organization

Type of facility	**Which of the following best describes the facility/organization type where the practice was implemented?** *(Check one)* ☐ Academic Medical Center ☐ Teaching hospital ☐ Non-teaching hospital ☐ VA/Military/Federal Government Hospital ☐ Outpatient Laboratory ☐ Physician Office Laboratory ☐ Public Health Laboratory ☐ Independent / Commercial Laboratory ☐ Blood Bank ☐ Other (please specify):
Size	**If a Hospital,** for how many beds is this hospital licensed? *(Check one)* ☐ <100 beds, ☐ 100-300 beds

	☐ >300 beds
Total Annual Test Volume	**What is the facility's annual total testing volume?** *(Check one)* ☐ <100,000 ☐ 100,000 to 500,000 ☐ 500,001 to 1,000,000 ☒ > 1,000,000
Topic Review Submission	**Which topic is this submission for?** *(Check one)* ☐ Patient Specimen Identification ☐ Critical Values Reporting ☐ Blood Culture Contamination

II. What you did?

Problem or Quality Issue	Provide a brief description of the key problem(s) that the practice addresses, plus details that support this statement, such as data on the magnitude and impact of the problem. Provided available citations to support any data.	
Summary of the Candidate Practice	Provide a description of the candidate practice to understand its requirements and components for ongoing day to day operations ***(For examples, See separate document "What are we looking for")***	

Impacts /Outcomes	**Describe how the impact of the practice was measured.** Provide names of outcomes and corresponding specifications/ definitions used to track the impact of the practices implemented ***(For examples, see separate document "What are we looking for")***	
Setting	Describe the setting within facility where practice has been implemented (if applicable). Examples include: • Emergency Department • ICU/ PICU • Outpatient clinics	

III. How you did it?

In completing this section, please provide information on both the candidate practice and comparison practice if available.		Candidate Practice	Comparison Practice
Study Population ***If the study population was laboratory specimens specify if all lab specimens were included or if the project/study only included specific specimens such as blood specimens.***	Provide a description of the study population for the study /quality improvement project **(if patients, specimens, and/or tests)** List the total number of tests, patients and or specimens and specific patient population or unit within the facility that practice was implemented (e.g., oncology, pediatric, general hospital)		
Funding Source	Describe the funding source for this study (e.g. self-funded in-house, supported by manufacturer, or extramural grant)		
Study/Project Design	Describe the methods/ approaches used for data collection / analysis. **If there was a comparison with another practice, describe the comparison practice (s) or what was standard prior to the candidate practice.**		

In completing this section, please provide information on both the candidate practice and comparison practice if available.		Candidate Practice	Comparison Practice
	Study design examples include: • Randomized Controlled • Quasi-Randomized Control (e.g., every 3rd patient) • Case-Control • Pre-/ Post- Implementation • Observational or time course • Individual Case Study (what went wrong write-up) • Other Design		
Start and End Date of Practices ***(if more than one comparison practice, continue to list these under the comparison column)***	Provide date (month/year) when the organization first implemented the practice. If initially implemented as a pilot, the date could be when the pilot began, and date (month/year) when organization ended the practice. If ongoing, please note	**Candidate Practice** Start Date (mo/yr): End Date (mo/yr): Yes, Practice is Ongoing	**Comparison Practice 1** Start Date (mo/yr): End Date (mo/yr): Yes, Practice is Ongoing **Comparison Practice 2 (if applicable)** Start Date (mo/yr): End Date (mo/yr): Yes, Practice is Ongoing
Measurement Time Period	List the length of time that the study was carried out and		

In completing this section, please provide information on both the candidate practice and comparison practice if available.		Candidate Practice	Comparison Practice
	outcomes of interest tracked – Provide dates (month and year) if available Example: 24 months (Jan. 2002-Jan. 2004)		
Recording Method	Describe how the outcomes and results were recorded. Examples: using an occurrence log, incident report, or audit-direct observation		
Data Analysis	Describe any analysis, including statistical tests conducted. If none, list none conducted		
Resources Used	Provide available information on the staffing and resources for implementing the practice: • **Staffing**: Number and type of individuals involved in carrying out the practice. • **Costs:** Start-up costs and ongoing costs for sustaining the practice • **Training**: Staff training required to implement the practice • **Supplies, Equipment, Space and other resources**		

In completing this section, please provide information on both the candidate practice and comparison practice if available.		Candidate Practice	Comparison Practice

IV. Did it work?

Results / Findings	For each outcome previously provided, summarize the results/findings of the study/project related to the impact practice implementation. Provide the total number of observations the results are based on, time period for observations and statistical tests results if performed. Example: 60 % improvement in correct verbal verification of patients. N=30 p value<0.0001 Pre practice: 6 (20%) checked Post practice: to 24 (80%) checked	
Study Bias	List any factors which may have influenced the results of this study/project. Undue influence, or bias, can occur if other practices or education was implemented during the same time as the practice of interest. Questions to consider are: • Were there other new activities introduced and ongoing during the same time period as the candidate practice? • Were there additional changes in staffing, technology and or process improvement during the time the candidate practice was implemented?	

V. Implementation Considerations

Sustaining This Practice	Provide advice regarding what is needed to sustain the candidate practice over time and maintain momentum, such as ongoing funding, regular monitoring/feedback to foster improvement, staff time, and other necessary resources.	
Barriers to Implementation	Describe any barriers (if applicable) encountered to implement the candidate practice. List "None" if no barriers were encountered.	
Technology Issues	Describe any technology problems encountered that affected the candidate practice's implementation	
Other Considerations and Lessons	Additional tips, considerations, overall lessons, or otherwise useful information that do not fit into the above categories.	

SUBMIT

Click on "SUBMIT" to e-mail this complete form to Ed Liebow (LiebowE@battelle.org)

VI. Topic Suggestions

The **Laboratory Medicine Best Practices Initiative** accepts suggestions for future evidence review topics from anyone.

All suggestions for future reviews are carefully considered based on a set of criteria. Priority is given to topics for which there is/are:

- A defined quality issue/problem (pre- and post-analytic) of broad stakeholder interest consistent with IOM domains (safety, timeliness, effectiveness, equity, efficiency, patient-centered)
- Potential practices that demonstrate impact on quality

To nominate a topic

Please fill in the form below as completely as possible and click on "submit" at the end. If you prefer, you may fill out the rich text format (rtf) version of the form, which can be edited in any text editing program (e.g., MS Word, Wordpad), and e-mail the completed form to [insert email address]

1. Briefly describe a question, or set of related questions, about the effectiveness of a laboratory related practice in the pre- or post- analytic testing phase that you would like to have evaluated.

   Examples:

   - What practices are effective at reducing blood culture contamination?
   - What practices are effective in improving test interpretation of elevated troponin?
   - What are appropriate blood cultures or other testing related to timely diagnosis and treatment of sepsis?

2. Briefly describe the quality issue(s)/gap(s) that your question addresses including why this is important.

Examples:

- Reduction of blood culture contamination rates can reduce costs of retesting, decrease treatment of false positive results, increase the timeliness and accuracy of bacteremia diagnoses and treatments, and, indirectly, reduce the rate of healthcare acquired infections
- Appropriate test result interpretation improves diagnosis and follow-up testing and or treatment

3. What are some current quality improvement practices to address this quality issue? Explain each practice and provide literature references or other sources that describe its effectiveness, risks and benefits.

Examples:

- Use of dedicated phlebotomy teams to draw blood culture specimens
- Use of clinical decision support (IT/Electronic health record interventions)

4. To what patient population does your question/quality issue apply? (Include details such as age, gender, diagnoses, or other factors is they are not general)

Examples:

- Inpatients
- Patients with signs and symptoms of acute coronary syndrome

5. To what care setting(s) is your question/quality issue applicable? (e.g. Emergency Department, Hospital inpatient, surgical, physician offices, nursing homes, public health laboratories, reference laboratories)

Public reporting burden of this collection of information is estimated to average 40 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA 0920-xxxx.