

Title: Laboratory Medicine Best Practices Project (LMBP)
OMB Control Number: 0920-0848
Expiration Date: 3/31/2016

LMBP Quality Improvement (QI) Project Summary Form

Instruction: To assist you with completing this form, please refer to the Instructions

Submitter's Name: _____ Today's Date: _____
Position: _____
Institution: _____
Organization / Department: _____
E-mail: _____ Phone: _____
Mailing Address: _____
City: _____ State: _____ Zip Code: _____

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

If identified, please provide the name(s) of person(s) the data are attributed to:

If any information on the submission form is not familiar to you or needs explanation, please note "not familiar" as an answer choice.

Thank you for taking the time to submit your information.

Please call 206-528-3155 with questions. Email completed forms to futurelabmedicine@battelle.org.

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.

LMBP Quality Improvement (QI) Project/Study Summary Form
 (Note: Please complete separate form for each study/evaluation you conducted)

If you do not have room to fill in the answer, use the next page and refer to question number.

Background Information	QI Project/Study	QI Practice	Outcome Measures	Results/Findings/ Considerations
<p>1. LMBP Quality Problem (topic): _____</p> <p>2. a. Quality Problem/ Issue Description</p> <p>b. IRB approval obtained</p> <p><input type="checkbox"/> Waived <input type="checkbox"/> YES <input type="checkbox"/> NO {Stop here and submit form, our staff will follow up with you} **</p> <p>3. Funding Source(s):</p> <p><input type="checkbox"/> In-house <input type="checkbox"/> Manufacturer: Describe: <input type="checkbox"/> Grant/Contract: Describe: <input type="checkbox"/> Other – Describe:</p> <p>4. Facility Description</p> <p>a. Facility type</p> <p><input type="checkbox"/> Hospital: Type: _____ <input type="checkbox"/> Physician Office Laboratory <input type="checkbox"/> Public Health Laboratory <input type="checkbox"/> Blood Center <input type="checkbox"/> Independent laboratory <input type="checkbox"/> Other: _____ Specify _____</p> <p>b. Number of Beds</p> <p><input type="checkbox"/> N/A <input type="checkbox"/> <100 beds <input type="checkbox"/> 100-300 beds <input type="checkbox"/> >300 beds</p> <p>c. Total test volume per yr _____</p>	<p>5. a. QI Project Design:</p> <p><input type="checkbox"/> Observational: Pre-post (before-after) <input type="checkbox"/> Observational: Case – Control <input type="checkbox"/> Controlled Experiment/ Randomized Control <input type="checkbox"/> Time Series <input type="checkbox"/> Cohort <input type="checkbox"/> Other: _____ Specify _____</p> <p>b. Briefly describe aim for the design:</p> <p>6. QI Project Setting:</p> <p><input type="checkbox"/> Emergency Dept. <input type="checkbox"/> ICU/PICU/NIUC <input type="checkbox"/> Ob/Gyn <input type="checkbox"/> Hospital inpatient <input type="checkbox"/> Physician office <input type="checkbox"/> Hospital outpatient <input type="checkbox"/> Other-Describe:</p> <p>7. Sample Size and Description: (describe totals for new and usual practice)</p> <p>a. Sample is:</p> <p><input type="checkbox"/> Tests <input type="checkbox"/> Specimens</p> <p>b. Sample size for Original (Usual) Practice is:</p> <p>c. Sample size for New QI Practice (if applicable) is:</p>	<p>8. Describe Original (Usual) Practice: _____</p> <p>9. Describe New Intervention/ Practice: _____</p> <p>10. Practice Duration</p> <p>a. Original (Usual) Practice Start date (mo/yr): _____ / _____ End date (mo/yr): _____ / _____ Is Practice Currently Being Used? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>b. New QI Practice Start date (mo/yr): _____ / _____ End date (mo/yr): _____ / _____ Is Practice Currently Being Used? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>11. Resource Requirements/Costs:</p> <p>A. Staff:</p> <p><input type="checkbox"/> Medical technologist <input type="checkbox"/> Laboratory phlebotomist <input type="checkbox"/> Nursing personnel <input type="checkbox"/> Resident <input type="checkbox"/> Medical student <input type="checkbox"/> Physician</p> <p>B. Training: _____ _____</p> <p>C. Equipment/Supplies: _____ _____</p> <p>D. Cost: _____ _____</p>	<p>12. Outcome Measure(s) Description:</p> <p>a. Description: _____ _____</p> <p>b. How determined: _____ _____</p> <p>13. Measurement Duration</p> <p>a. Original (Usual) Measurement Start date (mo/dd/yr): ____/____/____ End date (mo/dd/yr): ____/____/____</p> <p>b. New QI Practice Measurement Start date (mo/dd/yr): ____/____/____ End date (mo/dd/yr): ____/____/____</p> <p>14 a. Recording method (how data were collected / note any differences between the original (usual) and new/intervention practices:</p> <p><input type="checkbox"/> Occurrence logs <input type="checkbox"/> Incident / adverse events reports <input type="checkbox"/> Audit – direct observation <input type="checkbox"/> Electronic information system monitoring <input type="checkbox"/> Other</p> <p>Please Describe each checked method: _____ _____ _____</p> <p>15. Potential Limitations to the QI Project/Study: _____</p>	<p>16. Results/Findings (as related to /outcome measure): _____</p> <p>17. Data Analysis- Significance (if applicable):</p> <p><input type="checkbox"/> For Pearson correlations <input type="checkbox"/> F-Test <input type="checkbox"/> T-Test <input type="checkbox"/> Fischer Exact <input type="checkbox"/> Chi-square <input type="checkbox"/> Odds Ratio <input type="checkbox"/> Rates <input type="checkbox"/> Other: _____</p> <p>18. Barriers to Implementation:</p> <p>19. Requirements to sustain the new QI practice:</p> <p>20. Lessons Learned:</p>

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		E. Other: _____		

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?

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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)

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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)

Instructions LMBP Quality Improvement (QI) Project Summary Form

Background Information

1. **a. LMBP Quality Problem (topic):** (As listed on www.futurelabmedicine.org website; e.g., [Rapid Identification of Bloodstream Infections, Reducing Hemolysis of Blood Samples Collected in Emergency Departments, Biochemical Markers of Acute Myocardial Infarction](#))

2. **a. Quality Problem or Issue:** Briefly describe the key problem(s) that the new practice (procedure/protocol) addresses plus details that support use of the practice such as citations, references. Example: Our institution had an aim to reduce our current blood culture contamination rate, to do this we assessed the use of phlebotomy teams to do blood draws compared to blood draws performed by house staff.

b. IRB approval obtained: Indicate if IRB approval was obtained or waived for submission of your project information. If no IRB approval was obtained, mark "no" and submit the form. A member of our team will contact you.

3. **Funding Source:** Describe the funding source for project/study (e.g. self-funded in-house, supported by manufacturer [name], external grant, other [describe]).

4. **Facility Description: Check the option that best describes your facility**
 - a. If a hospital, list the type: e.g., Academic Medical Center, Teaching, Non-teaching, VA/Military/Federal Government, Children's Hospital
 - b. If applicable, check the best option for number of beds at your facility
 - c. List your laboratory's total test volume per year

Prior to submitting de-identified information, you should consult with your institution's designated official or Institutional Review Board concerning required approvals or clearances.

If you have questions or need assistance, email us at futurelabmedicine@battelle.org or call 206-528-3155.

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QI Project/Study

5. **a. QI Project/Study Design/Type:** Describe the methods/approaches used for data collection/analysis (e.g., randomized controlled, observational, or other design.)
- a. **Observational or nonexperimental study designs:** studies in which study subjects (patients, participants, etc.) are not assigned to conditions/exposures, and are monitored through the natural course of development
 - i. **Pre-Post :** at least two measurements made on one characteristic; compares outcomes prior to a practice of interest and after at a point in time reasonably after (e.g. comparison of error rates before and after a new technology is implemented)
 - ii. **Case-control:** observation of exposed group to an intervention compared with non-exposed group
 - b. **Controlled Experimental / Randomized Controlled trial:** design in which study subjects (patients, tests, samples) are randomly assigned to a group exposed to the intervention/therapy/test or to a group that receives the control intervention/therapy/test
 - c. **Time-series:** a single defined study population studied over a period of time with periodic measurements prior to and after exposure to the intervention
 - d. **Cohort:** study design that involves repeated observations of the same variables over many time periods
- b. Briefly describe the aim of your project design (e.g., counting all inpatient care phlebotomy service blood collections, we compared the monthly rate of mislabeled collections before and after use of a bar coding mobile system)
6. **QI Project Setting:** Describe the unit(s) within the facility where the practice was implemented (if applicable); e.g., Emergency Department, ICU/PICU, Ob/Gyn, hospital inpatient, hospital outpatient, physician office, other (describe).
7. **Sample size and description:** The sample size is the number of observations used for the new and original practices. Describe your sample (tests, patient specimens, type of patient specimens, etc.) and the sample size. Example: Sample size was all in patient phlebotomy service blood collections; pre barcoding practice 181,758 specimens and post barcoding practice 184,043 specimens.

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QI Practice

8. **Describe Original (Usual) Practice:** Describe the original (usual) practice(s) or what was standard prior to the new practice/policy/technology implemented.

9. **Describe New Practice/Intervention:** Describe the new practice/policy/technology implemented. Include the characteristics and components for ongoing day-to-day operations. Example: A bar coding mobile system was implemented; this consists of handheld computers with barcode scanners, patient bar coded wristbands, mobile printers and integrated wireless radio interfaced with the hospital inpatient information system

10. **Practice Duration:** To the best of your ability, please record the start and end dates for both the New Practice/Intervention and the Original (Usual) practice. These are the dates on which the QI practice and Original practice were implemented and the dates on which they ended. Note: This is not the same as the study period, but the dates during which these practices were being used in the units(s) in which the study were done. Please mark whether or not you are still implementing the Original (Usual) or New Practice Intervention.

11. **Resource Requirements/Costs:** Describe the requirements and cost for starting and sustaining the practice, If you do not have this information list "Not Known."
 - A. **Staff: Describe staff used to implement the practice (all necessary personnel types)**
 - B. **Training:** describe staff training provided
 - C. **Equipment/Supplies (other resources):** Describe equipment/supplies and other resources (space, etc.) used to start and sustain the practice.
 - D. **Cost:** Provide costs for the start up and sustaining the practice
 - E. **Other:** List other relevant promotional activity or resource was used to implement the practice

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Outcome Measures

- 12. Outcome Measure(s) Description:** Describe how the impact of the practice was measured. Provide specific outcome(s) and corresponding specifications/definitions used to assess or track the impact of the practices implemented. Example: Outcome measure was **hemolysis rate** determined as the change in number of samples hemolyzed/total number of samples drawn
- 13. Measurement Duration:** For both the New Practice/Intervention and the Original (Usual) practice, please enter the dates between which data that contributed to the finding were collected. For example, if data were collected between June 1, 2011 and July 30, 2011, these dates would be entered as the start (06/01/11) and end (06/30/11) dates of measurement. If multiple outcomes are described by this study, or if intermittent data collection occurred, please describe those measures and dates of measurement on the additional page provided for answers.
- 14. Recording method:** Describe how the outcomes and results were recorded and data was collected: e.g. Occurrence logs, incident report, audit-direct observation, electronic information system monitoring, other (describe method).
- 15. Potential Limitations to QI Project/Study:** Describe any potential limitations or factors that may have influenced the results of this project. Examples: Implementation of another practice occurring at the same time as the new practice described; staff changes; new policy introduced during project period; new technology introduced during project period.

Results/Findings

- 16. Results/Findings (as related to study design/outcome measure):** For each outcome provided, summarize the results/findings of the study/project related to the practice implementation impact. Provide the total number of observations the results are based on, time period for observations and statistical tests results if performed. Include findings related to cost savings if applicable.
Example:
- Pre-Post finding: Pre- practice: 6/30 (20%) correct verbal verification Post practice: 24/30 (80%) correct verbal verification
 - Pre-Post finding: Mean time to treatment: Pre = 20 minutes (Standard Deviation 5.5 Minutes); Post = 12 minutes (Standard Deviation 3.5 Minutes)
- 17. Data Analysis –Significance (if applicable):** Describe any statistical tests conducted (e.g., for Pearson correlations, F-test, T-test, Chi-square, Other (describe)). List “None” if none was conducted.

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Additional Considerations

18. **Barriers to Implementation:** Describe any barriers (if applicable) encountered to implement the new practice. List “None” if no barrier was encountered.
19. **Requirements to sustain the practice:** Provide advice regarding what is needed to sustain the new practice over time and maintain momentum, such as ongoing funding, regular monitoring/feedback to foster improvement, staff time and other necessary resources.
20. **Lessons Learned:** Describe considerations, overall lessons, or otherwise useful information regarding sustaining the implemented new practice over time.