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 <insert Review Coordinator's phone number here> with questions. Email completed forms to <insert Review Coordinator's name and email address here>

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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

1. LMBP Quality Problem (topic):
_____

2. a.Quality Problem/ Issue Description

b. IRB approval obtained

- ☐ Waived
- ☐ YES
- ☐ NO {Stop here and submit form, our staff will follow up with you} **

3. Funding Source(s):
- ☐ In-house
- ☐ Manufacturer: Describe:
- ☐ Grant/Contract: Describe:
- ☐ Other – Describe:

4. Facility Description

a. Facility type
- ☐ Hospital: Type:_____
- ☐ Physician Office Laboratory
- ☐ Public Health Laboratory
- ☐ Blood Center
- ☐ Independent laboratory
- ☐ Other: Specify_____

b. Number of Beds
- ☐ N/A
- ☐ <100 beds
- ☐ 100-300 beds
- ☐ >300 beds

c. Total test volume per yr _____

QI Project/Study

5. a.QI Project Design:
- ☐ Observational: Pre-post (before-after)
- ☐ Observational: Case – Control
- ☐ Controlled Experiment/ Randomized Control
- ☐ Time Series
- ☐ Cohort
- ☐ Other: Specify_____

b. Briefly describe aim for the design:

6. QI Project Setting:
- ☐ Emergency Dept. ☐ ICU/PICU/NIUC
- ☐ Ob/Gyn ☐ Hospital inpatient
- ☐ Physician office ☐ Hospital outpatient
- ☐ Other-Describe:

7. Sample Size and Description: (describe totals for new and usual practice)

a. Sample is:
- ☐ Tests
- ☐ Specimens
- ☐ Patients

b. Sample size for Original (Usual) Practice is:

c. Sample size for New QI Practice (if applicable) is:

QI Practice

8. Describe Original (Usual) Practice:

9. Describe New Intervention/ Practice:

10. Practice Duration

a. Original (Usual) Practice
Start date (mo/yr): _____ /
End date (mo/yr): _____
Practice is Ongoing: ☐ YES ☐ NO

b. New QI Practice
Start date (mo/yr): _____ /
End date (mo/yr): _____
Practice is Ongoing: ☐ YES ☐ NO

11. Resource Requirements/Costs:

A. Staff:
- ☐ Medical technologist
- ☐ Laboratory phlebotomist
- ☐ Nursing personnel
- ☐ Resident
- ☐ Medical student
- ☐ Physician

B. Training:
_____
_
_____
_

C. Equipment/Supplies:
_____
_

D. Cost:
_____
_

E.

Outcome Measures

12. Outcome Measure(s) Description:

a. Description:
_____
_____

b. How determined:
_____
_____
_____

13. Measurement Duration

a. Original (Usual) Measurement
Start date (mo/dd/yr): ____/____/____
End date (mo/dd/yr): ____/____/____

b. New QI Practice Measurement
Start date (mo/dd/yr): ____/____/____
End date (mo/dd/yr): ____/____/____

14 a. Recording method (how data were collected / note any differences between the original (usual) and new/intervention practices):
- ☐ Occurrence logs
- ☐ Incident / adverse events reports
- ☐ Audit – direct observation
- ☐ Electronic information system monitoring
- ☐ Other

Please Describe each checked method:
_____
_____
_____

15. Potential Limitations to the QI Project/Study:
_____

Results/Findings/ Considerations

16. Results/Findings (as related to /outcome measure):

17. Data Analysis- Significance (if applicable):
- ☐ For Pearson correlations
- ☐ F-Test ☐ T-Test
- ☐ Fischer Exact ☐ Chi-square
- ☐ Odds Ratio ☐ Rates
- ☐ Other: _____

18. Barriers to Implementation:

19. Requirements to sustain the new QI practice:

20. Lessons Learned:

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Background Information	QI Project/Study	QI Practice	Outcome Measures	Results/Findings/ Considerations
		Other:_____		

OMB Control Number: 0920-0848
Expiration Date: 3/31/2016

Instructions
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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

3. **Funding Source: Describe** 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 of beds
   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.

OMB Control Number: 0920-0848
Expiration Date: 3/31/2016

Instructions
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QI Project/Study

5. **a. QI Project/Study Design/Type:** Describe 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.

OMB Control Number: 0920-0848
Expiration Date: 3/31/2016

Instructions
LMBP™ Quality Improvement (QI) Project Summary Form

QI Practice

8. **Describe Comparator Practice:** Describe the original 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 QI practice and the Original (usual) practice. This is the date on which the QI practice and Original practice was implemented and the date on which it 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.

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

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 QI practice 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 measure 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

Instructions
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Outcome Measures

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 min (Standard Deviation 5.5 Minutes); Post = 12 min (Standard Deviation 3.5 Minutes)

17. **Data Analysis –Significance (if applicable):** Describe any statistical tests conducted. List "None" if none were conducted. e.g., for Pearson correlations, F-test, T-test, Chi-square, Other (describe)

Additional Considerations

18. **Barriers to Implementation:** Describe any barriers (if applicable) encountered to implement the new practice. List **"None"** if no barriers were 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.