



## LMBP Data Abstraction Tool

# LMBP Data Abstraction Coding Manual

This manual summarizes the rules and guidelines for using the standardized abstraction form to record evidence for systematic reviews for best practices in laboratory medicine. The purpose of systematic data abstraction (and the development and use of the data abstraction form) is to assure that all studies are reviewed using the same guiding criteria, reducing bias in the assessment of the study quality.

This abstraction form has been designed with sufficient flexibility to allow the evaluation of different laboratory medicine practices in different settings and studies with varied designs. Two reviewers abstract each study using this form to develop evidence databases and evidence tables. This form provides the information regarding the intervention/practice of interest, target population, setting, outcomes, and results. Also the abstraction form provides the basis for drawing conclusions about individual studies.

The abstraction form was developed on the basis of the original systematic review method (1), and from similar instruments used by other types of systematic reviews (2).

If you have questions or would like a copy of the abstraction coding manual, you can email Laboratory Medicine Best Practices (CDC) at [lbpinform@cdc.gov](mailto:lbpinform@cdc.gov)

The abstraction form consists of 2 parts:

**Part I: Descriptive Information** includes the following sections: Bibliographic Information, Information about Quality Improvement (QI) study, QI Intervention/Practice, Outcome Measures, and Results/Findings.

**Part II: Study Quality** includes information about the limitations of the execution of study.

It takes about 1-2 hours to read and abstract a study report. Please note drop-down options are available to answer some questions. Text boxes are provided to ease the readability of the form but not to limit the amount of information you can provide. If you need to include additional information, you can add your comments using sticky notes or comment options.

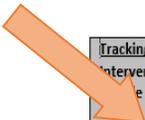
## Part I: Descriptive Information

### Tracking Information:

Each data abstraction table has a separate section providing brief basic information regarding a particular abstraction table including,

- Intervention(s)/ Practice(s) name: Use the intervention/practice name that has been selected for review topic, e.g., using computerized physician order entry (CPOE), test review, clinical decision support system (CDSS), test utilization
- Reviewer’s name: Enter the name of the data abstractor
- Author’s last name: Enter first author’s last name
- Article ID: Enter allotted study ID number
- Date of Abstraction: Enter the date when data abstraction of the study performed

### 1: Bibliographic Information/References Column



| <b>Tracking Information:</b>             |   |   |   |  |
|--|---|---|---|--|
| Intervention(s)/Practice(s): .....       |   | Reviewer Name : .....   |   | Author Last Name: .....  |
| Article ID #: .....                      |   | Date of Abstraction: (mm/dd/yy): .....  |   |  |
| Bibliographic information                | Study Description   | Practice Description:   | Outcome Measures  | Results (Effect Size)  |
| <b>A. Short Name for Study Citation:</b> | <b>H. Study Design:</b> (Select one from drop down options) <ul style="list-style-type: none"> <li>• Before-after</li> <li>• Randomized Control Trial (Individual or Group)</li> <li>• Non-randomized comparison study</li> </ul> | <b>O. Intervention/Alternate practice:</b> <ul style="list-style-type: none"> <li>-Name of the practice/ intervention</li> <li>-Practice description: (Provide a rich description of practice (copy or paraphrase if</li> </ul> | <b>S. Outcome Measure</b><br>Description of Outcome measures:<br>List Name of the outcome measures in each category | <b>U. Sample size:</b><br><b>Total sample size</b><br><br>For each outcome/Intervention/ group:<br><br>Intervention (n): |

This section captures the bibliographic information of candidate studies, including:

#### **A. Short Name for Study Citation**

Use the format “Author\_ Year\_ Title\_” indicating the last name of the author(s), year of publication or receipt of unpublished data, and the title of the paper.

e.g., Goddard, K.; Austin, S. J. 2011. Appropriate regulation of routine laboratory testing can reduce the costs associated with patient stay in intensive care.

#### **B. Type of document**

Note that technical reports can be either published or unpublished. Select the option that reflects best how the document was made available for dissemination from the drop-down options.

1. Published
2. Unpublished

#### **C. Published documents**

**C 1. Document type:** Choose the published document type from the drop-down options.

1. Professional guidelines
2. Peer-reviewed publication
3. Book / book chapter
4. Technical Report
5. Conference proceeding
6. Other: (Specify)

**C 2. Name the source of publication:** Name the source where the document is published, e.g., name of the journal, book.

**D. Unpublished document**

**D1. Document type:** Choose the document type from the drop-down options.

1. In-house audit or quality-control initiative
2. Technical report
3. Manuscript
4. Conference presentation
5. Other (specify)

**D2. Permission to be identified (unpublished only):** For unpublished studies indicate whether the author has given permission to be identified. Select the option from below,

1. “Yes” if the author agrees to be identified
2. “No” if they wish to remain anonymous (Note: If you select this option please refer to the item ‘11’ for state’s region and division designation guidance)

**D3. Complete Citation or Identifying Information for Unpublished Source:** Enter the full citation using standard AMA style. Guidance can be found at

[http://www.nlm.nih.gov/bsd/uniform\\_requirements.html](http://www.nlm.nih.gov/bsd/uniform_requirements.html).

**D 4. Date of Receipt:** Enter the date of receipt of the document.

**E. Author Affiliations**

Record the affiliations of all authors. If the document has no authors identified, the affiliation of the “First Author” should be the information of facility or healthcare organization and/or system provided in the study. The affiliation for the “second author” should be the alternate point of contact for the facility or health system that provides the unpublished study.

**F. Funding Source(s)**

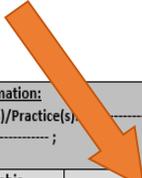
Identify (name) the actual source of funding for the research conducted. Whether it was funded by the same organization or from outside source.

**G. Other references**

Enter any other references that are linked with this study, e.g., if the methods to conduct this study are published as a separate paper or multiple publications reporting long term effects of a specific practice over the period of time.

(Note: Bibliographic information does not contribute towards the study quality scoring.)

**2: Study Description Column**



|  |   |   |   |  |
|--|---|---|---|--|
| <b>Tracking Information:</b><br>Intervention(s)/Practice(s): .....; Reviewer Name : .....; Author Last Name: .....;<br>Article ID #: .....; Date of Abstraction: (mm/dd/yy): ..... |   |   |   |  |
| <b>Bibliographic information</b>   | <b>Study Description</b>  | <b>Practice Description:</b>  | <b>Outcome Measures</b>   | <b>Results (Effect Size)</b>   |
| <b>A. Short Name for Study Citation:</b>   | <b>H. Study Design:</b> (Select one from drop down options) <ul style="list-style-type: none"> <li>• Before-after</li> <li>• Randomized Control Trial (Individual or Group)</li> <li>• Non-randomized comparison study</li> </ul> | <b>O. Intervention/Alternate practice:</b><br>-Name of the practice/ intervention<br>-Practice description:<br>(Provide a rich description of practice (copy or paraphrase if | <b>S. Outcome Measure</b><br>Description of Outcome measures:<br>List Name of the outcome measures in each category | <b>U. Sample size:</b><br><b>Total sample size</b><br><br>For each outcome/Intervention/ group:<br><br>Intervention (n): |

This section is used to abstract information on the study, setting, and sample characteristics that may be important for contextualizing the results and also to abstract information on the sources of evidence included in the study.

**H. Study Design**

Select from the drop-down options that best captures the study design on which the findings are based.

1. Group Non-randomized Comparison Study (with ≥1 comparison group)
2. Case Control (Groups defined by outcome, AKA Retrospective cohort study)
3. Prospective Cohort Study
4. Retrospective Cohort Study
5. Cross-Sectional Study
6. Time-series Study
7. Before-after Study
8. Descriptive Analysis (e.g., implementation study, feasibility study)
9. Other designs with concurrent comparison groups
10. Other (specify)

[Note: Refer to the Attachment 1 to select the study design]

**I. Facility description**

**I1. Location of the Facility:** For Published Study or Unpublished Study with permission to identify [City, State, and Country]: Record the location of the facility or an organization in which the study was

conducted. Include the City, State, and Country separated by commas. If multiple locations are represented, separate locations using a semi-colon.

For *Unpublished Study with NO permission* to identify [Region, Country], record the region and country of the facility or an organization in which the study was conducted. In the United States, states can be defined by their census region and division. Use the region and division designations contained in the parentheses for the 50 United States:

|                             |                      |                       |
|-----------------------------|----------------------|-----------------------|
| Alabama (R3D6)              | Indiana (R2D3)       | North Carolina (R3D5) |
| Alaska (R4D9)               | Iowa (R2D4)          | Ohio (R2D3)           |
| Arizona (R4D8)              | Kansas (R2D4)        | Oklahoma (R3D7)       |
| Arkansas (R3D7)             | Kentucky (R3D6)      | Oregon (R4D9)         |
| California (R4D9)           | Louisiana (R3D7)     | Pennsylvania (R1D2)   |
| Colorado (R4D8)             | Maine (R1D1)         | Rhode Island (R1D1)   |
| Connecticut (R1D1)          | Maryland (R3D5)      | South Carolina (R3D5) |
| Delaware (R3D5)             | Massachusetts (R1D1) | South Dakota (R2D4)   |
| District of Columbia (R3D5) | Michigan (R2D3)      | Tennessee (R3D6)      |
| Florida (R3D5)              | Minnesota (R2D4)     | Texas (R3D7)          |
| Georgia (R3D5)              | Mississippi (R3D6)   | Utah (R4D8)           |
| Hawaii (R4D9)               | Missouri (R2D4)      | Vermont (R1D1)        |
| Idaho (R4D8)                | Montana (R4D8)       | Virginia (R3D5)       |
| Illinois (R2D3)             | Nebraska (R2D4)      | Washington (R4D9)     |
| New Mexico (R4D8)           | Nevada (R4D8)        | West Virginia (R3D5)  |
| New York (R1D2)             | New Hampshire (R1D1) | Wisconsin (R2D3)      |
| North Dakota (R2D4)         | New Jersey (R1D2)    | Wyoming (R4D8)        |

**12. Name of the facility (ies) or organization(s) where study performed:** Enter the name of the facility or group (e.g., Hospital A, or in case of unpublished data enter the source of data, e.g., College of American Pathologists.

**13. Facility/Organization Type.** Select from the pull down options for the type of facility in which the study was conducted. Options include:

1. Academic Medical Center
2. Non-teaching Hospital
3. VA/Military/Federal Government Hospital
4. Outpatient Laboratory
5. Physician Office Laboratory
6. Public Health Laboratory
7. Independent / Commercial Laboratory
8. Blood Bank
9. Other (please specify)

**I4. Facility Size.** Select from the pull down list the options that best describes the size of the facility in which the study was conducted. Options (for hospitals) include:

1. <100 beds
2. 100-300 beds
3. >300 beds
4. Information not provided

**I5. Total Annual Test Volume.** Enter the option that best corresponds to the annual test volume of the facility in which the study was conducted. Use the “Other” field to provided additional information, if appropriate. Options include:

1. <100,000
2. 100,001-500,000
3. 500,001 – 1,000,000
4. 1,000,000
5. Information not provided
6. Other (please specify)

If total annual test volume standard options do not describe available annual test volume information, or to include information about annual test volume that is not inclusive of all laboratory testing (e.g., specific test volume, anatomic pathology, microbiology, chemistry) use this text field to describe available test volume information.

**I6. Setting within facility / organization where practice implemented.** Select from the drop-down list the options for the setting within the facility or organization that best describes where the practice – as tested – was implemented. Options include:

1. Hospital Inpatient
2. Hospital Outpatient
3. Emergency Department
4. ICU
5. Physician Office
6. Other - please specify

### **J. Sample description**

The sample type can vary in different studies, e.g., patients, healthcare professionals, specimens, tests, others. So provide the following description according to the type of sample described in a particular study.

**J1. Sample size.** Provide the total number of patients/healthcare professional/specimens/tests who were initially contacted to participate in the study, number of participants/specimens actually participated in the study and how many completed the study in both intervention or experiment group\*.

**J2. Sample type.** Provide a brief description of the sample in intervention group according to the sample type. For example if the intervention is targeted to the patients then provide the type of patients that were exposed to the alternate practice or intervention, e.g., pediatric, diabetics, patients with cardiovascular diseases, general patients. Similarly, if intervention is implemented for specific

diagnostic testing or specimen then provide the description of type of tests (glucose tolerance test, molecular sequencing) or type of specimen (e.g., blood, stool, spinal fluid).

**J3. Population demographics.** Provide information regarding population demographics as described in the study, e.g., gender, age. Include any other description of the specimens, and/or tests that are summarized in the study being coded.

\* ‘Intervention group’ also known as ‘experiment group’ is defined as a group of people/tests/specimens exposed to an intervention.

#### **K. Specific inclusion/exclusion criteria for sample collection**

Describe any other specific inclusion/exclusion criteria used for sample selection/rejection in the study. For example, whether a study implemented intervention (e.g., test review) only for the test that costs \$1,000 or more, or whether a practice was evaluated only among patients in emergency department.

#### **L. Sampling strategy**

When more than one group is included in a study, provide the detailed strategy used for selecting intervention and comparison groups\*\*, for example, whether the intervention and comparison groups were exposed to the intervention randomly or the intervention group volunteered to receive intervention (i.e., convenient sample).

\*\*Comparison group definition is provided below in “Comparison group” section of this document.

#### **M. Comparison group**

Comparison group, many times also referred as “control group,” represent the group that is not exposed to the intervention of interest; changes in this group are used to estimate what would have happened if the intervention had not been carried out. It can represent the same group of individuals before the implementation of the intervention (e.g. before and after study design) or a separate group of individuals that is not exposed to the intervention as in experimental studies where the comparison group is generally referred to as the control group (e.g., randomized or non-randomized control trials). Include details of comparison group, e.g., number, location, demographic information.

**Note:** Describe non-representativeness: Describe, if necessary, sources of deviation from test or sample representativeness. This text field allows the abstractor to record any sample information they feel restricts our confidence that the study results generalize to all tests and populations.

#### **N. Attrition rate**

Severe, unexplained, or differential attrition after assignment/agreement to participate may invalidate randomization and may adversely affect generalizability from an original study sample. Attrition may also be considered when the expected number of units in an analysis (subjects, samples, or tests) is not included in a study. Select from the drop-down list the option that best describes whether all expected units are included in the analysis:

1. Minimal attrition is represented in this study (<50%)
2. Attrition occurred, but authors attest there are no problems resulting from it
3. Attrition occurred, and the authors acknowledge it affected the quality of the randomization
4. Attrition is obvious but it is not discussed or acknowledged by author

**Note:** Calculate attrition rate based on the total number of participants contacted to participate in the study, how many actually participated and stayed till the last Follow-up period. In addition, collect information regarding any other potential bias reported in the study or that the reviewers detect. Are there other selection bias issues not identified above? This might include a very low participation rate, i.e., <50% (or a high refusal rate), an all-volunteer sample (as opposed to a convenience sample selected by the investigators), an inappropriate control or comparison group, or extremely restricted sampling inappropriate for measuring the effectiveness of the intervention being studied.

### 3: Practice Description Column



| <b>Tracking Information:</b><br>Intervention(s)/Practice(s): .....; Reviewer Name: .....; Author Last Name: .....;<br>Article ID #: .....; Date of Abstraction: (mm/dd/yy): ..... |   |  |   |   |
|---|---|--|---|---|
| Bibliographic information   | Study Description   | Practice Description:  | Outcome Measures  | Results (Effect Size)   |
| <b>A. Short Name for Study Citation:</b>  | <b>H. Study Design:</b> (Select one from drop down options) <ul style="list-style-type: none"> <li>• Before-after</li> <li>• Randomized Control Trial (Individual or Group)</li> <li>• Non-randomized comparison study</li> </ul> | <b>O. Intervention/Alternate practice:</b><br>-Name of the practice/ intervention<br>-Practice description: (Provide a rich description of practice (copy or paraphrase if | <b>S. Outcome Measure</b><br>Description of Outcome measures:<br>List Name of the outcome measures in each category | <b>U. Sample size: Total sample size</b><br>For each outcome/Intervention/group:<br>Intervention (n): |

This table column provides information on the practices described in the study. Note that a study may include a single practice or multiple practices. If multiple practices are evaluated in one study, collect detailed information for each practice treating as a separate intervention.

#### **O. Intervention/Alternate Practice**

**O1. Name of the practice/intervention.** Assign a short, standardized name for the practice being documented. In the event that an appropriate short name has not been pre-determined, reviewers need to assign one.

**O2. Intervention/practice description.** \* Provide a rich description of the practice (copy or paraphrase if necessary). Ideally, the practice could be replicated from description. As such, include in the description any information available about the practice:

- **What** was done: How the intervention was applied such as what components of the intervention/practice were implemented, e.g., single practice was implemented (e.g., computerized physician/provider order entry or a combination of practices was introduced (e.g., CPOE plus Education), or if it is a part of bigger intervention (e.g., implemented as combination of multicomponent intervention)
- **When** it was implemented: Practice time period/ duration, or the start/end date. Note whether it is an ongoing practice (i.e. if the practice was still ongoing at the time of the data collection) or has been completed (i.e., implemented for a shorter time period and was completed at the time of data collection);
- **Who:** description of staff involved, staff responsible for using the intervention practice;
- **How** it was done: How the intervention and control groups were selected, how the intervention group was exposed to the alternate practice (e.g., randomly, convenient

sample), if any training was needed associated with implementing this practice, associated costs (both implementation and maintenance), and any specific materials, new staff, technology, additional supplies, equipment, space, or other resources necessary to implement and maintain the practice;

Note: **Where:** information of setting within the facility (this information will be captured in study description section).

**\*Intervention/Practice:** In LMBP reviews, an intervention is defined as any kind of new practice(s) designed to improve the QI projects by reducing errors in pre- and post-phases of laboratory medicine in order to improve overall healthcare quality. For LMBP reviews intervention practice may also be referred as ‘alternate practice’

**P. Practice implementation duration (MM/DD/YYYY)**

Record any information about the practice/intervention duration, e.g., month and year that the practice for this study was implemented. Although the program formats the data as MM/YYYY, data must be entered using the MM/DD/YYYY format. If the day and month are not reported, enter your best estimate of the start of data collection or enter length of practice implementation time if available, e.g. practice was implemented for 4-month period during summer of 2011.

**Ongoing Practice:** In case of ongoing practice/intervention then record start date and for end date indicate that it is still ongoing practice. Please select from the drop-down list of options whether the practice likely continued beyond the period of data collection.

**Q. Information on involved staff and test schedule**

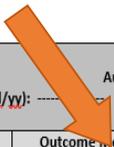
**Q1. Staff.** Include the number and type of individuals involved in implementing and carrying out the practice: In addition to staff routinely carrying out the practice, some practices require additional staff or staff with unique abilities (e.g., information technology staff, hardware support, staff with specialized medical training) to develop, plan and/or implement a practice. Include here information on the staff necessary to implement and carry out the practice.

**Q2. Test schedule.** Indicate schedule if provided; otherwise report ‘information not provided’.

**R. Intervention description to Comparison group**

Provide brief description of the type of exposure provided to the comparison group, such as if the comparison group was treated (i.e., partially exposed to the intervention) or true comparison (i.e., not exposed to any intervention). In case of before and after the intervention in a same group, provide the information of already existed pre intervention practice(s) sometimes also referred to as “**usual practice(s)**” existed in the same group before the implementation of the intervention.

### 3: Outcome Measures Column



| <b>Tracking Information:</b><br>Intervention(s)/Practice(s): .....;      Reviewer Name : .....;      Author Last Name: .....;<br>Article ID #: .....;      Date of Abstraction: (mm/dd/yy): ..... |   |   |   |  |
|---|---|---|---|--|
| Bibliographic information   | Study Description   | Practice Description:   | Outcome Measures  | Results (Effect Size)  |
| <b>A. Short Name for Study Citation:</b>  | <b>H. Study Design:</b> (Select one from drop down options) <ul style="list-style-type: none"> <li>• Before-after</li> <li>• Randomized Control Trial (Individual or Group)</li> <li>• Non-randomized comparison study</li> </ul> | <b>O. Intervention/Alternate practice:</b><br>-Name of the practice/ intervention<br>-Practice description:<br>(Provide a rich description of practice (copy or paraphrase if | <b>S. Outcome Measure</b><br><br>Description of Outcome measures:<br>List Name of the outcome measures in each category | <b>U. Sample size:</b><br><b>Total sample size</b><br><br>For each outcome/Intervention/ group:<br><br>Intervention (n): |

#### S. Outcome Measures

The LMBP evidence-based recommendations for laboratory best practices are based on these predetermined outcome(s), which may also be referred to as “**recommendation outcome(s)**.” The recommendation outcomes usually include “**intermediate/surrogate outcome(s)**” defined as well established proxy for a **health outcome** that occurs in the causal pathway between an intervention and the final health outcome, such as error rates during the pre-analytic phase of laboratory medicine, usage of appropriate practices, and patient satisfaction rate. Whereas “health outcome” is defined as overall improvement in health due to the intervention/practice implementation such as a decrease in morbidity and mortality rate and decrease in overall healthcare costs. These outcomes are predetermined by the systematic review teams to answer the research questions for intervention/practice effectiveness.

**S1. Description of the outcome measure(s).** Provide the list of intermediate outcomes (e.g., decrease in hospital stay, decrease in inappropriate test orders) and health outcomes reported in the study along with a rich description of the outcome measure. For example, how they calculated the hospital stay for the analysis (e.g., # of days patient stayed in the hospital, readmission to ED) or how the decrease in inappropriate test orders was calculated (e.g., decrease in duplicate tests). This information can be copied directly from the source material. **{Note:** Record if the validity/reliability of the exposure /outcome is discussed in the study to make sure that the outcome measure used to evaluate the practice/intervention is consistent or reproducible. Face validity asks if the measure likely captures the construct it is intended to measure. Outcome measures may be subject to bias (intentional and otherwise).}

#### T. Data collection information

**T1. Data Collection Method.** Record the data collection method or how the data was obtained for calculating the outcome effect size. For example whether it was collected from healthcare facility records including, log of occurrences, adverse events reports, direct observation or self-reported, e.g., interview. Pick the right option from the drop down window, otherwise select option ‘information not provided’ if the source of data is not provided in a study.

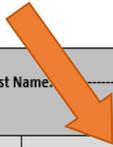
**T2. Data Collection Period.** Collect information about data collection dates for both intervention and comparison groups (if applicable). Also record information about all follow-up periods for data collection.

**Base line (MM//DD/YYYY):** Record the month and year that data were first collected for this study. Although the program formats the data as MM/YYYY, data must be entered using the MM/DD/YYYY format. If the day and month are not reported, enter your best estimate of the start of data collection.

**Follow-up (MM/DD/YYYY):** Record the month and year that data were last collected for this study. Although the program formats the data as MM/YYYY, data must be entered using the MM/DD/YYYY format. If the day and month are not reported, enter your best estimate of the end of data collection. In case there are multiple follow-up period, collect data for all follow-up periods. In the effectiveness analysis the teams can decide if they want to include all data points to show the trends of effectiveness at different time periods or they want to select the last data point in the analysis.

**{Note: Collect any additional information reported by the author that can be useful for understanding the record being coded.}**

### 4: Results Column



| <b>Tracking Information:</b><br>Intervention(s)/Practice(s): .....;      Reviewer Name : .....;      Author Last Name: .....<br>Article ID #: .....;      Date of Abstraction: (mm/dd/yy): ..... |   |   |   |  |
|--|---|---|---|--|
| Bibliographic information  | Study Description   | Practice Description:   | Outcome Measures  | Results (Effect Size)  |
| <b>A. Short Name for Study Citation:</b>   | <b>H. Study Design:</b> (Select one from drop down options) <ul style="list-style-type: none"> <li>• Before-after</li> <li>• Randomized Control Trial (Individual or Group)</li> <li>• Non-randomized comparison study</li> </ul> | <b>O. Intervention/Alternate practice:</b><br>-Name of the practice/ intervention<br>-Practice description:<br>(Provide a rich description of practice (copy or paraphrase if | <b>S. Outcome Measure</b><br><br>Description of Outcome measures:<br>List Name of the outcome measures in each category | <b>U. Sample size:</b><br><b>Total sample size</b><br><br>For each outcome/Intervention/ group:<br><br>Intervention (n): |

This column provides the quantitative results of intermediate and health outcomes that evaluate the intervention effectiveness, including the effect size and significance of the results. Also, this section provides the additional information about important factors that play significant role in making decisions regarding intervention recommendation.

**{Note: The practices, outcome measures, and study population groups and sub-groups should all link directly to those identified in the previous sections. No new study populations, practices, and outcome measures can be “created” in this section, only the quantitative results related to those previously identified outcomes should be recorded in this section.}**

#### **U. Sample size**

Provide the number of patients/healthcare professional/specimens/tests included in the final data during both before (pre- intervention) and after (post- intervention) the implementation of intervention/ new practice to improve the quality error in control and intervention or experiment group, e.g. the number used in analysis to calculate the effectiveness of the practice for both intervention and comparison group.

**{Note: “Sample Sufficiency” is an important factor to be considered for study appraisal. Many of the outcomes of interest are rare events. If too few observations (usually <20) are obtained or if the measurement period is insufficient to capture these events the measure may provide an inaccurate**

representation of the effect of the practice. Even among more common events, there may also be considerable variation in the number or rate of events over time. The period of measurement should be sufficiently long to allow robust estimates of the impact of the practice.}

### **V. Findings and Effect Sizes\***

List findings or effects\* of intervention for all intermediate and health outcomes reported in the study. Always include the exact unit(s) and effect measure(s)\* (e.g., mean, mode, ratio) for each outcome as reported in the study. Also include any estimate of dispersion provided (e.g., standard deviation, standard error, variance) if provided with the findings. For study comparing one comparison group with multiple practices, create different study arms for each practice and report effect size of each practice separately. For example, a study comparing the effectiveness two practices, bar coding and technician education, with same comparison group for reducing error rates, report effect size for reduced error rates for each practice separately. Provide the data for each intervention and comparison group used in calculating effect sizes of each outcome. Also provide data points for all follow-up periods, if applicable.

**{\* Effect is the change in an outcome that results from an intervention; Effect measure is the outcome measurement used to assess the effect; Effect size is the estimated magnitude of the effect.}**

**V1. Direction of effect.** For all statistical comparisons, confirm the direction of effect. That is, effect is in desirable direction (positive impact), in undesirable direction (negative impact) OR no change (no impact). Be aware that direction of effect can be mediated by item wording. In other words, a practice can have a positive impact by reducing errors or increasing accuracy. Note that this variable captures the simple direction of effect, not whether the effect is statistically significant. Note also that as a standardized convention, positive impacts will be coded positively (i.e., when a practice results in a reduction in errors there is a positive effect from the practice). Following this convention, in a pretest-posttest design an increase in error rates over time would be coded as a negative impact of the intervention. Select only one:

1. Positive impact from the practice
2. No difference
3. Negative impact from the practice (i.e., comparison group/pretest group returned a more positive result)

**V2. Type of statistical test.** If a statistical test was conducted, is the result of the test significant? Enter the type of statistical test summarized in Finding. Select only one:

#### *Quantitative effect sizes*

1. Change in number of target population/tests
2. Change in proportion of target population/tests
3. Multi-category frequency or %
4. Means and SDs
5. T-value (independent)
6. Probability with N/degrees of freedom
7. Dependent T-test
8. One-way ANOVA (2 groups, 1 degree of freedom)
9. One-way ANOVA (>2 groups, >1 degree of freedom)
10. Factorial Design (MANOVA)
11. Covariance Adjusted (ANCOVA)

12. Chi-square statistic (1 degree of freedom)
13. Chi-square (> 2x2 table)
14. Nonparametric
15. Correlation coefficient (zero-order)
16. Means and variances
17. Means and standard errors
18. Means and t-test (independent)
19. Multi-factor ANOVA
20. Multivariate analysis

*Other findings*

21. Cost
22. Implementation
23. Feasibility
24. Dissemination

**V3. Effect size significance.** Enter if the author provides the information about the significance of results in the paper, e.g., p-value, confidence interval (CI) to see if the effect size was statistically significant or not. Pick one from the following options,

1. Effect size is statistically significant
2. Effect size is not statistically significant
3. Significance not reported (Note: In this case, if sufficient data are provided, try to calculate the p-value or CI on your own)

**W. Sub group analysis**

Were secondary results of interest reported (including subpopulation differences, dose-response relationships, or others)? If yes, describe those results. Include page and table numbers. *Describe breakout:* If findings are based on a subset of the available data, provide a rich description of the subset of data on which the finding is based.

Note that this is not a practices comparison, but a comparison of a given practice in different settings, populations, or facilities. To be coded as a breakout, the breakout variable should result in mutually exclusive groupings (even if data on only one of the groups is reported). An example might be when a study that uses inpatient data provides separate estimates for the ICU and for the emergency room. Another might be when an inpatient study breaks out the data on time of day or shift.

***Examples:***

- *The effect was stronger among inpatients compared to patients admitted in ED (management working as gatekeepers to order lab tests resulted in 70% decrease in duplicate orders compared to 50% decrease in emergency ward.)*
- *The intervention had less effect among physicians' blood collection behaviors (using prepackaged prep kit for venipuncture) compared to phlebotomy team.*
- *The combination of test review and Clinical Decision Support System (CDSS) was more effective than test review only in reducing test error rates.*

{Note: Enter finding page number (if available): Enter page number(s) or other information that

would facilitate finding the evidence being summarized in the original document.}

### **X. Additional information**

Enter any additional information re: feasibility and other key issues were addressed in the paper (if available) from each study to address potential barriers and other implementation concerns that can guide stakeholders if they want to adopt the practice in their organizations. To flag issues that might be of importance in describing the intervention or its implementation, check off any of the following issues that are described by the author. Check all that apply. Include the page numbers where this information can be found in the paper.

- Barriers to implementation: Describe in this field any problems or difficulties noted by the authors in implementing the practice. These can include unanticipated or excessive training needs, problems with technology (hardware and/or software issues), unanticipated or excessive implementation costs, and/or other issues related to institutional support for the practice.
- Cost associated with intervention implementation (include monetary, non-monetary or human resources).
- Potential harms and benefits of the intervention (includes health and social consequences). Problems sustaining the practice: Describe in this field any problems or difficulties noted by the authors in sustaining the practice. These can include unanticipated or excessive staffing needs, problems with technology (hardware and/or software issues), unanticipated or excessive maintenance costs, and/or issues related to institutional support for the practice.
- Formation or use of existing coalitions to develop, implement, or evaluate interventions
- Ethical constraints.
- Other (*Describe*): Use this field to record source for any additional information used or additional information useful for understanding the record being coded. Also record all qualitative information about the effectiveness of the practice of interest. Collect any additional information on confounding factors or biases reported in the study that could influence the effectiveness of the intervention. Collect any information about generalizability concerns (e.g., type of setting and population, method of allotment of intervention among intervention and control group, an inappropriate control and comparison group, or extremely restricted sampling inappropriate for measuring the effectiveness of the practice being studies) or other issues regarding barriers to implementation described in the paper.
- Not discussed (i.e., no other data were presented)

## **Part II: Evaluation of Study Quality**

After the data abstraction and standardized information is entered into the abstraction form, individual studies are rated for study quality (good, fair, or poor) based on following four dimensions using a 10-point scale:

- **Study Characteristics (Maximum 3 points)**- (i.e., sample characteristics, setting characteristics, potential study biases)
- **Practice Characteristics (Maximum 2 points)** (i.e., what/when/how was it done, who implemented the intervention)
- **Outcome Measure(s) (Maximum 2 points)** - (i.e., measure description, validity and reliability of exposure and measurement variable, how/when data for these measures was collected)
- **Interpretation of Results (Maximum 3 points)**- (i.e., sample sufficiency, statistical analysis, other confounders/ biases/ generalizability issues)

If all four dimensions receive the maximum number of points, the overall study quality rating for an individual study would be a “10.” This 10-point scale supports the following categorical study quality ratings

**Good:** 8-10 points total (all four dimensions)

**Fair:** 5-7 points total

**Poor:** ≤ 4 points total

### **Evaluating Study Quality**

The four study quality dimensions are rated separately, with a rating score assigned up to the maximum for a given dimension. The rating scores for each dimension are added to reach a single summary score reflecting overall study quality. Anytime points are deducted from a study, a justification for the deduction is recorded and included in the evidence summary. In this scheme, a “poor” quality rating indicates a study has significant flaws, implying biases that may invalidate results. Thus, individual studies with a “poor” quality rating are excluded from consideration as evidence for a “best practice” recommendation.

### **Dimension 1. Study Description (3 points maximum)**

Assess the study quality by evaluating:

1. Study setting
2. Sample characteristics (representativeness sufficient for practice)
3. Potential study biases (study design, time period/duration and sample selection methods)

#### **Criteria for point deduction**

Deduct no points if sufficient information provided

Deduct 1 point for each variable: if limited information regarding

**1.1 Study Setting (1 point)**

If limited description is provided for the

- a. Location
- b. Facility

where the study was conducted.

**1.2 Sample characteristics (1 point)**

If limited description is provided for the

- a. **Population demographics** sample description
- b. **Sampling frame** or universe of selection for the study population? For example, if the authors did not specify the selection for the study population? Or described if it is representative of the entire eligible population or a probability sample at the point of observation?
- c. The authors did not specify the **screening criteria** for study eligibility is not (if any)?

**1.3 Potential study biases (1 point)**

Potential biases may produce study results interpreted as inconsistent with the true results - study design (e.g., in case of before and after study designs the absence of a comparison group makes it impossible to know what would have happened without the intervention), and sample selection methods (e.g., in case of non-randomized sample selection can result in objectively/ unbalanced representation of participants, i.e., some members of the population to be less likely to be included than others which can affect the external validity of the results).

In addition, if there are other selection bias issues not otherwise addressed by the authors? For example,

- a. Very low participation rate (low attrition rate),
- b. Convenient sample (all volunteers),
- c. An inappropriate control and comparison group (not comparable), or
- d. Extremely restricted sampling inappropriate for measuring the effectiveness of the practice being studied (generalizability bias).

**Dimension 2. Practice/ Intervention Description (2 points maximum)**

Assess the description of the practice and its adequacy.

**Criteria for point deduction**

Deduct 0 points: The practice is well described (what, when, how, who, where).

Deduct 1 point each if the practice and its basic characteristics are not sufficiently identified.

**1.1 Description of Intervention/Practice (1 point)**

If limited information is provided about the practice/intervention implementation. For example,

- a. What was done in both groups i.e., intervention and comparison group or in case of single group, before and after comparison re: the practice

- b. Duration of practice implementation: Start and end dates for practice implementation in case of completed practice or start date for ongoing practice, duration of time period if dates were not provided (e.g., practice was implemented for 3 months in summer 2010)
- c. How the intervention/practice was done: Information of method of intervention allotment among intervention and comparison group, required staff, materials, training, cost, and technology to implement?
- d. Who applied the practice (e.g., physicians, residents/internist, nurses, PA)?
- e. How long the practice/intervention was implemented?

**2.2 Description of control group (1 point)** (e.g., what type of exposure, demographics –if applied)

### **Dimension 3. Outcome Measure(s) (2 points maximum)**

Outcome measures capture the result of implementing a practice. Evaluation criteria reflect their face validity for capturing the outcome(s) of interest, and whether the methods used to record results provide an incomplete or inaccurate record of the impact of a practice. Most studies use multiple outcome measures. Their evaluation should concentrate on measures that most directly address the review question, which relates to health care quality (Institute of Medicine domains: safe, timely, effective, patient-centered, efficient, and equitable), and may ignore secondary measures, especially those gauging implementation feasibility.

#### **Criteria for point deduction**

1. Deduct 0 points/no deduction (if all information is available)
2. Deduct 1 point if: no or limited information about the following:

#### **3.1 Measure description (1 point)**

- a. Did not report the measure description? (e.g., how they calculated hospital stay for the analysis)
- b. Validity of exposure/outcome variable not expressed (e.g., consistent or reproducible)?
- c. Results were obtained using different measures or recording practices for two groups.

#### **3.2 Data collection method (1 point)**

- a. Data recording method not described. (e.g., resource utilization, log of occurrences, adverse events reports, direct observation, interview, self-report, etc.)
- b. Data collection time period not reported.
- c. Confounder, if any, due to:
  1. The practice itself (that is, the outcome is a direct result of the practice which was not available or applicable to both the comparison practice and the tested practice);
  2. The context in which the practice was implemented (that is, the outcome is unlikely to be clearly attributed to the practice).
  3. Method of recording the outcome is unreliable.

### **Dimension 4. Results/Findings (3 points maximum)**

Results are affected by each of the previous three dimensions of quality. With this dimension, a narrow set of criteria specific to the result are evaluated relating to (1) sample sufficiency, (2)

appropriateness of statistical analysis and, (3) uncontrolled deviations along with results/conclusions bias.

### **Criteria for point deduction**

Many of the outcomes of interest are rare events. If too few observations are obtained or if the measurement period is insufficient to capture these events the measure may provide an inaccurate representation of the effect of the practice. Even among more common events, there may also be considerable variation in the number or rate of events over time. The period of measurement should be sufficiently long to allow robust estimates of the impact of the practice.

Deduct 0 points/no deduction (if all information is available)

Deduct 1 point for each if:

**4.1 Sample size (1 point):** If points were deducted for the Sample Sufficiency Rating, please provide a rationale for the deduction.

- a. Sample may be too small to allow a robust estimate OR not enough sample size to calculate the statistical power OR Measurement period insufficient to allow robust estimate of practice impact
- b. If sample size is not reported

**4.2 Statistical analysis (1 point):**

- a. No information regarding statistical analysis
- b. Data do not permit effect size calculation OR insufficient data to allow or verify calculation of an effect size
- c. No controlling for design effects in statistical model

**4.3 Uncontrolled Deviations and Results/Conclusions biases (1 point):**

- a. The units of analyses were not comparable prior to exposure between intervention and control group
- b. Unexplained attrition >30% OR Uncontrolled differential attrition
- c. Did the authors identify and discuss potential biases or unmeasured/contextual confounders that may account for or influence the observed results and explicitly state how they assessed these potential confounders and biases? Please describe these factors and, if possible, comment on the likely direction of bias. OR
- d. If there are additional biases NOT COVERED IN OTHER CATEGORIES that the authors did not address, please list these as well.

*Example:*

*A study of an educational program to decrease the error rate during a period when the control group was also likely to receive considerable education about the intervention could underestimate the effectiveness of the program.*

**References:**

1. Christenson RH., Snyder SR., Shaw CS., Derzon JH., Black RS., Mas D.et.al., Laboratory medicine best practices: systematic evidence review and evaluation methods for quality improvement. [Clin Chem](#). 2011 Jun;57(6):816-25. doi: 10.1373/clinchem.2010.157131. Epub 2011 Apr 22.
2. Zaza S., Wright-De Aguero LK., Briss PA., Trumen Bl., Hopkins DP., Hennesey MH. et. al., Data collection instrument and procedure for systematic reviews in the Guide to Community Preventive Services. Task Force on Community Preventive Services. [Am J Prev Med](#). 2000 Jan;18(1 Suppl):44-74

