**Supplemental Table 8**

**Suggested Guidance for Future Studies**

The purpose of this Data Collection Form is to guide investigators of quality improvement interventions having an aim of assessing effectiveness of practices in support of appropriate test utilization. Utility of this form exists whether investigators choose to submit a paper for publication, or submit unpublished studies to the CDC LMBPTM initiative in support of future systematic review updates. A definition of appropriate test utilization is provided in the Future Research Needs section of the systematic review manuscript.

This Data Collection Form provides fields for the minimum information necessary to contribute meaningfully to the evidence base. It may, therefore, be used in companionship with validated reporting standards, such as SQUIRE reporting standards, which provides a framework for reporting studies designed to assess interventions with the aim of improving the quality and safety of care. Reporting standards should augment the data collection form with additional information fields as appropriate. Reporting standards serve to strengthen a study, and therefore the evidence base, by increasing the reliability, utility, and impact of studies through transparent and accurate reporting. Ultimately, reporting should help readers better understand what works, in what situations, and for whom, given test utilization management practices are implemented in multifaceted healthcare environments, dependent on characteristics of those ordering tests and the purpose of testing. A centralized repository of validated, published reporting standards (including SQUIRE) can be found at the Enhancing the Quality and Transparency of Health Research Network’s web site (<http://www.equator-network.org/>).

Investigations should be multidisciplinary, inclusive of laboratory professionals and other stakeholders involved in managing test utilization and with a role in implementing, using, and monitoring practice interventions. In general, practices to manage appropriate test utilization represent one, of many, ideal areas for clinical-laboratory collaboration. In instances where healthcare organizations choose to implement a practice (or a combination of practices) with goal of test utilization management, we recommend the quality and applicability of available guidelines (local and national) and protocols guiding utilization appropriateness be carefully assessed and validated in the local setting, to further evaluate potential patient harms relative to benefits. Decision to implement should include review by the institution’s medical executive committee (or equivalent), and involve a use-case (e.g., practice impact modeling) within the institution to assess impact before implementation, and involve feedback informing continuous quality improvement.

**Data collection form for QI projects examining the effectiveness of practices to support appropriate laboratory test utilization**

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| --- | --- | --- | --- | --- |
| **Background Information** | **QI Project/Study** | **QI Practice** | **Outcome Measures** | **Results/Findings** |
| LMBP Topic: Practices to support appropriate laboratory test utilization  A. Local test utilization quality gap/problem and intended improvement:  B. Study question:  C. Investigators  D. Country of study:  E. Funding: | F. Study design:  G. Facility setting  Name/location:  Type of facility:  Facility size:  Setting within facility:  H. Sample Information  Sample unit:  Sample size:  Sample strategy:  I. Data collection period:  J. Participate rate: | K. Description of alternate/intervention practice:  L. Criteria (and source) used for establishing occurrence of inappropriate test utilization:  M. Description of efforts to validate inappropriate test utilization criteria in local setting:  N. Resource requirements/costs  Staff targeted practice:  Training:  Equipment:  Supplies: | O Outcomes (systems, patient, and/or economic)  Primary:  Secondary:  Additional:  P. Recording methods: | Q. Findings/Effect Size  Primary outcome:  Secondary:  Additional:  R. Statistical methods for data analysis:  S. Study limitations/biases:  T. Investigator conclusions: |

1. Investigators should provide a description of the test utilization quality gap being investigated in the local healthcare setting, as well as the measurable target for improvement (i.e., how inappropriate test utilization is monitored and evaluated by performance measures/quality indicators). This item may include description of how investigators define appropriate test utilization, and description of the specific testing being inappropriately utilized (including level of complexity), including the clinical role of testing in the patient population of interest, (e.g. for screening, diagnostic, prognostic, or monitoring purposes) as well as description of the volume of targeted testing, as may be expressed quantitatively or qualitatively (e.g. the annual test volume, such as number of tests per year, or as “high-volume”, “medium-volume”, or “low-volume” testing).
2. Investigators should provide a concise statement of the research question (e.g. PICO, PICOS format).
3. Description of the professional position of investigators planning/executing the intervention. This may also include description of the organization’s leadership/management having a direct role in intervention planning/execution.
4. The effect of a test utilization management practice in a local setting may be influenced by a country’s healthcare system and standards for quality of care.
5. Funding, and its source.
6. Study designs for investigating the effect of an intervention may range from experimental (e.g., randomized controlled trials) to other types of comparative studies. Investigators are encouraged to use a study design that is feasible in the local setting, with an understanding that study design directly impacts study quality, therefore the quality of the evidence.
7. Information about the setting of the study should be provided, characterizing the type of facility, its size, and other important facility information. Facility types includes (more than one category may apply): academic/teaching/university hospital, Veterans Affairs (VA) hospital, public hospital, community hospital, children’s hospital, other specialty hospital (cardiac, orthopedic, etc.), primary care offices, outpatient clinics. Additionally, they may include an outpatient laboratory, a physician office laboratory, public health laboratory, a commercial/reference laboratory, or a blood bank. Facility size may be expressed as <100 beds (small hospital), > 100 but < 550 beds (medium hospital), >550 beds (large hospital, or may not be applicable (e.g. if facility is a reference laboratory). Investigators may indicate both the number of beds for which the facility is licensed, and the actual number of beds provisioned in practice, if these numbers differ. Setting within the facility may include inpatients, outpatient, both inpatient/outpatient, ICU, emergency department, physician office, etc.
8. This items should include a description of the unit of study, which may include patient population inclusion/exclusion criteria, or clinical provider information. It should indicate sample size, as well as sample strategy, which includes simple random samples, stratified random samples, cluster samples, convenience samples, and multi-stage samples.
9. The data collection period should be provided, indicating the specific dates and duration of the entire study period, including breakdown by pre-/post-intervention period. Breaks or gaps in the study period should also be indicated.
10. Participation rate should be indicated, including sample drop-out and missing data.
11. Investigators should provide a complete description of the intervention, and its component parts (as may include the frequency or intensity of component parts), such that the intervention could be reproduced by other investigators. This may include description of organizational factors that affected/influenced choice of the specific intervention (given that interventions should be developed to best fit the local test utilization challenge), and description of any changes to the intervention during the study period. Investigators may indicate how they categorize the practice, in the context of this systematic review, using practice definitions provided in the glossary (Supplemental Table 1), or through use of background references (cited in Introduction section of manuscript).
12. Investigators should indicate the source of criteria used in identifying occurrences of inappropriate utilization through test utilization audits. As described by Hauser & Shirts 2014, sources of criteria for establishing the presence of inappropriate test utilization range from “ 1) guidelines endorsed by an organization (i.e., government, professional society), 2) primary literature, 3) local consensus without specific literature cited, 4) rules developed and validated within the article, and 5) individual opinion.”(1) Multiple sources may apply.
13. Investigators should indicate any efforts to validate the criteria identified in item L within the local context/setting in which the criteria are being applied. As generally described (van Walraven et al.1998), this may include investigator assessment of the quality of evidence on which criteria are based, and attempts by investigators to include expert opinion in the development/application of the criteria.(2) Validation of criteria in the local setting provides better assurance criteria leads to the right test, for the right patient, at the right time within the local setting, and better enables readers to assess how reliably criteria were applied by investigators.
14. Investigators should discuss resources required to support the intervention, including training, equipment, and supplies.
15. Investigators should indicate the primary outcome of interest, as well as any secondary outcomes of interest. Outcomes may be operational (systems/process) outcomes, economic outcomes, or patient health/clinical outcomes. Further, in relation to targeted health outcomes, other linked outcomes may be characterized as intermediate or surrogate outcomes. Additional discussion on outcomes (and cited references) provided in the Limitations section of the manuscript.
16. Investigators should provide a complete description of the data recording methods used for test utilization auditing, and describe the source for data used to assess the effectiveness of the intervention on targeted outcomes. This may include indication of the test utilization audit sample size, and may include description of validity/reliability of recording method used to capture inappropriate utilization, as well as description of methods to assure data quality/adequacy.
17. Investigators should provide estimates comparing study groups, such as differences between means or proportions or ratios of proportions or odds. Also, corresponding *P*-values or confidence limits should be provided. Studies should report enough information to permit calculation of standardized effect measures (e.g., *OR* or Cohen’s *d* with standard error), to allow more robust analyses within systematic reviews.
18. Investigators should describe the statistical methods or tests used to determine *P*-values or calculate confidence intervals in the answer to R. If hypothesis testing was performed, provide the definition of statistical significance used to interpret *P*-values. If interval estimation was used, provide their degree of confidence.
19. Investigators should provide description of limitations of the study, and indication of study-level biases (e.g., issues impacting study internal validity). Additionally, investigators may indicate unusual challenges encountered during the study period, including barriers encountered to intervention implementation. This may include discussion of possible influence of context/setting on outcome, as well suggestions to improve future studies.
20. Investigators should provide their overall conclusions concerning the success of the intervention in the local setting, and the usefulness of the intervention in impacting the test utilization quality gap. Investigators may highlight the strengths of the study, and they may wish to discuss conclusions in relation to other existing evidence. The generalizability (external validity) of the study should also be addressed.
21. 1. Hauser RG, Shirts BH. Do we now know what inappropriate laboratory utilization is? An expanded systematic review of laboratory clinical audits. Am J Clin Pathol. 2014 Jun;141(6):774-83. PubMed PMID: 24838320.
22. 2. van Walraven C, Naylor CD. Do we know what inappropriate laboratory utilization is? A systematic review of laboratory clinical audits. JAMA. 1998 Aug 12;280(6):550-8. PubMed PMID: 9707147.