Standard Operating Procedures for:

Preparing, Publishing and Revising National Academy of Clinical Biochemistry Laboratory Medicine Practice Guidelines

Including Review and Approval of External Society/Organization Guidelines for Endorsement and Support by AACC/NACB

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List of Acronyms Used

AACC	American Association for Clinical Chemistry
ACCP	American College of Chest Physicians
AGREE	Appraisal of Guidelines for Research and Evaluation
AHRQ	Agency for Healthcare Research and Quality
BOD	Board of Directors
COI	Conflict of interest
CPG	Clinical Practice Guidelines
EBLMC	Evidence-Based Laboratory Medicine Committee
EBM	Evidence-Based Medicine
ESAC	Education and Scientific Affairs Committee
GDG	Guideline Development Group
G-I-N	Guidelines International Network
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
IOM	Institute of Medicine
LMPG	Laboratory Medicine Practice Guideline
NACB	National Academy of Clinical Biochemistry
PICO	Patient-Intervention-Comparator-Outcome
ROC	Receiver Operating Characteristic
SOP	Standard Operating Procedures
SR	Systematic Review
STARD	Standards for the Reporting of Diagnostic Accuracy Studies

Standard Operating Procedures for Developing and Revising
National Academy of Clinical Biochemistry
"Laboratory Medicine Practice Guidelines"

Including Review and Approval of External Society/Organization Guidelines for Endorsement and Support by AACC/NACB

I. PURPOSE

This document's purpose is to provide guidance for members of the National Academy of Clinical Biochemistry (NACB) and others who will develop new Laboratory Medicine Practice Guidelines (LMPGs), be involved in the revision of previously published LMPGs or be involved in the review and approval of other societies' and organizations' clinical practice guidelines (CPGs) external to NACB and the American Association for Clinical Chemistry (AACC).

II. BACKGROUND

NACB BOD's Manual includes a policy on LMPGs that requires the creation and use of a Standard Operating Procedures (SOP) Instrument for NACB Guideline Development Groups (GDGs) (1). The first NACB SOP for development and revision of LMPGs was created in 1997 by Dr. Lawrence Kaplan. At that time, LMPGs were known as Standards of Laboratory Practice or SOLPs. This version was subsequently revised by Drs. Robert Dufour and William Winter in 2003 as well as further revised by Dr. Catherine Hammett-Stabler in 2004. This revision was accepted and adopted by the NACB Board of Directors (BOD) in 2005 (2). In 2009, Dr. Shirley Welch (then current chair of NACB's Education and Scientific Affairs Committee or ESAC) deferred further revision pending integration of NACB's ESAC and AACC's Evidence-Based Medicine (EBM) Committee into a single joint group representing both organizations. In 2010, a new combined AACC/NACB Evidence-Based Laboratory Medicine Committee (EBLMC) was created that reported to both organizations and was chaired by Dr. Stephen Kahn.

The EBLMC was charged with updating and revising the 2005 SOP. Due to the significance and potential impact of two Institute of Medicine (IOM) reports published in 2011, initiating this effort was deferred until 2012. The 2011 IOM reports of relevance are *'Clinical Practice Guidelines We Can Trust'* (3) and *'Finding What Works in Health Care – Standards for Systematic Reviews.'* (4). These two reports were created as part of a response to a legislative mandate from the U.S. Congress, through the *Medicare Improvements for Patients and Providers Act (MIPPA) of 2008*, requesting that steps be taken to implement recommendations from IOM's report on *Knowing What Works in Health Care (2008).* In this series of actions, Congress commissioned the Secretary of HHS to develop evidence-based, methodological standards for systematic reviews (SRs) and clinical practice guidelines (CPGs) (3).

III. **OVERVIEW**

NACB LMPGs are documented practice recommendations developed using evidence-based approaches to address questions regarding the appropriate use of diagnostic laboratory testing in a specific scientific and/or clinical discipline. LMPGs include recommendations intended to improve the use of diagnostic laboratory tests in a manner that optimizes patient care based on practice recommendations informed by a systematic review of evidence. When feasible and appropriate, the LMPG should also address benefits and harms of alternative laboratory test utilization approaches. When possible, LMPGs will be developed in collaboration with other relevant clinical societies and/or organizations. NACB LMPGs will be developed to address, incorporate and/or conform to the standards explicitly stated in the 2011 IOM report on developing trustworthy clinical practice guidelines to the greatest extent that is feasible (3). The 2011 IOM standards for establishing trustworthy guidelines are:

a. Establishing transparency
b. Management of conflict of interest (COI)
c. Guideline development group composition
d. Clinical practice guideline-systematic review intersection
e. Establishing evidence foundations for and rating strength of recommendations
f. Articulation of recommendations
g. External review
h. Updating

A detailed version of these 8 IOM standards for developing trustworthy clinical practice guidelines (CPGs) is provided in Appendix One. Please note that CPGs and LMPGs are considered similar guidelines although not truly identical.

The creators of this current LMPG SOP revision recognize that not all elements of the IOM standards articulated in the 2011 report may always be applicable to the development of each LMPG. But LMPG committees are encouraged to strive towards significant adherence of LMPG development to these standards. In this way, it is hoped that the overall NACB LMPG development process will continue to evolve and improve over time. Key information and guidance relating to these standards is also incorporated into other sections of this SOP.

In fact, there is a wealth of valuable information available to guideline developers. The scope of this material cannot be easily summarized nor substantially incorporated into this SOP. But an additional group and resource for guideline developers is the Guidelines International Network (i.e., G-I-N). The G-I-N library contains many resources and materials that can be accessed at http://www.g-i-n.net/library. One of the groups AACC and NACB worked with resulting in AACC's endorsement of 2012 guidelines for antithrombotic therapy published in *Chest* was the American College of Chest Physicians (ACCP). A listing of ACCP Guideline Development Workshop Materials in provided in Appendix Two.

LMPGs represent the efforts of a committee of experts selected from disciplines involved in the care of patients within the LMPG topic area. Committee members may include clinical laboratory scientists, physicians, and other allied professionals as deemed appropriate by the LMPG chair. The LMPG chair will then make a formal recommendation of the LMPG committee membership that will be subject to the review of the EBLMC as well as approval by the EBLMC and NACB BOD. Selection will be based upon the needs of the topic area. Representatives from allied professional organizations are also sought to broaden the scientific input in developing the LMPG as well as broadening applicability and distribution of LMPG recommendations.

Guidelines will be based on a systematic review of the literature and will provide both criteria identifying the quality of the evidence and the strength of each recommendation. Consensus recommendations are acceptable and will be clearly identified. Initial draft guidelines will be peer reviewed. Comments received and the resolution of each will be documented. After final revisions, the guidelines are approved by the sponsoring society or societies, published in a peer-reviewed journal, and made available for distribution on the NACB web site.

IV. PROCEDURES

a. Role of the NACB Board of Directors

The NACB BOD will maintain a policy on development of LMPGs in their Policy Manual. The NACB BOD will make a final decision on when the LMPG SOP needs further revision, when a developed LMPG is officially approved by the NACB, and who will be approved to chair a LMPG committee. These actions may also come as a result of recommendations from the AACC/NACB Evidence-Based Laboratory Medicine Committee (EBLMC).

b. Role of the Evidence-Based Laboratory Medicine Committee

The EBLMC is responsible for conducting the revisions of the LMPG SOP. The EBLMC is responsible for recommending approval of an LMPG to the BOD or endorsement of an external clinical practice guideline by NACB and AACC. The EBLMC may recommend individuals as chairs for specific LMPG projects as well as LMPG committee members. The NACB BOD may also obtain recommendations and/or volunteers for these positions outside of the EBLMC. It is recommended that, regardless of approach, the EBLMC and NACB BOD work collaboratively. While the EBLMC can develop a LMPG SOP and propose that it be accepted as final, the decision as to whether a version is approved as final is the purview of the NACB BOD.

The EBLMC is responsible for interacting with the LMPG chair and committee members in a way that supports their efforts while ensuring that there is a full degree of compliance with the

requirements described in this SOP. This includes a member of the EBLMC serving as a member on each LMPG committee. EBLMC's involvement and guidance with a LMPG chair and committee will begin at the earliest stages of topic proposal and will continue through all phases of development including presentation, final approval and publication.

c. Selection of Topics for LMPG Development

Topics may be proposed by the EBLMC, the BOD, or any member of NACB. Final approval of a topic for a LMPG is made by the NACB BOD. Both the EBLMC and NACB BOD will work collaboratively so that, on an annual basis, at least one new potential LMPG topic is identified for further development.

Oversight of the entire LMPG program is under guidance of the EBLMC. EBLMC will use relevant criteria in addition to those listed below to evaluate proposals based on topic significance, the availability of the evidence on which to base guidelines, availability of individuals and other organizations with expertise in the proposed area and the absence of other guidelines that already specifically address the laboratory issues to be explored.

Topics for LMPG development will be sufficiently narrow in scope to allow a reasonable timeframe for the systematic review of the literature and guideline development. Topic selection should consider the ability to clearly identify the criteria for successful completion and, potentially, result in a significant impact on laboratory practice and care. Guidelines may also be helpful in areas with large variation in clinical practice where best practices are not yet established. Impact factors will also include areas in which there are documented problems or controversies in laboratory practice and in what practice settings. Additional impact factors include existing guidelines with conflicting recommendations or the potential to provide useful guidance as well as process improvement metrics for future users of the LMPG.

EBLMC and/or the BOD will develop a list of potential chairs for a potential LMPG at least one year before the scheduled presentation of draft guidelines or before the publication of final guidelines. It should be recognized that activities of LMPG committees resulting in collaborations with or input from outside organizations in guideline development presentations of draft recommendations for discussion, and professional debate (e.g., at a conference or other venue) prior to finalizing the guideline, will likely add a year or more to the above timeframe. This may include requests to the Agency for Healthcare Research and Quality or potential other groups for conducting systematic reviews.

d. Selection of the LMPG chair

The proposed LMPG chair should be a laboratory scientist, either a current or eligible member of NACB, with expertise in the topic being addressed, strong contacts with other laboratory and

clinical experts in the field, and exceptional leadership and organizational skills. The NACB BOD will approve the selection of the LMPG chair. This individual may be recommended by the EBLMC. While this is not mandatory, the BOD should ensure that an individual not recommended by EBLMC, but proposed as a LMPG chair, also has the support of the EBLMC.

e. Responsibilities of the LMPG Chair

The LMPG chair will recommend potential committee members to the EBLMC (and, finally, to the NACB BOD). One LMPG member should be named as the Vice-Chair of the LMPG committee. It is strongly recommended that the LMPG Chair and Vice-Chair obtain and read (3) (the IOM guideline manual) or, minimally, become well familiarized with the eight IOM standards of trustworthy guidelines detailed in Appendix One. Using the current online training tool, either the LMPG Chair or Vice-Chair will become trained in the use of the AGREE II instrument as described in Section IV k, LMPG Development and Review.

The LMPG Chair, in consultation with the EBLMC Chair, should identify other laboratory and/or clinical societies to approach as appropriate co-sponsors in LMPG development. The LMPG Chair should contact the leadership of these relevant societies to determine their interest in co-sponsorship and for recommendations of members to serve on the LMPG Committee or as Expert Reviewers. Potential LMPG Committee members should be made aware of the responsibilities of the LMPG Committee (as described below) and be willing and able to make the commitment needed to develop a suitable LMPG in the time frame assigned. The LMPG chair should discuss prospective external committee members with the EBLMC Chair prior to making the final selection. The committee should be of sufficient size to allow adequate representation of all appropriate areas of expertise, but not so large as to impede the committee's actions. In general, a committee size of 8 - 10 should be most effective. Again, one member should be an EBLMC member. The LMPG committee, the EBLMC and the NACB administrative staff should maintain a close and collaborative relationship throughout all phases of guideline development.

The LMPG Chair is responsible for the recruitment of other professional societies as co-sponsors, selection of a LMPG committee, preparation of draft guidelines, organization of any presentations of the draft guidelines, development of final guidelines, and preparation of the final guideline and monograph. The LMPG Chair should review Appendix Three, Financial Concerns Regarding LMPG projects. Using these guidelines, the Chair will develop a budget for review in working with the NACB administrative staff as described. The Chair will also review the guidelines in 2-3 y intervals to determine currency and to recommend when another revision and of what degree should be undertaken by the NACB.

The LMPG chair is responsible for the coordination of efforts between the LMPG Committee, the EBLMC and any editorial groups that will be asked to consider publishing all or part of the

LMPG when it is finalized. For a majority of past LMPGs, the relevant editorial group has been that of *Clinical Chemistry*. The LMPG chair and committee will also work with the relevant editorial group and EBLMC from the earliest stages of LMPG development with three goals in mind for LMPG publication:

1) Ensuring that the timeframes for submission of LMPGs for publication include sufficient time (minimum of 60 days) so that draft LMPGs can be posted for an adequate period for public review and comment, additional revision and then, submission for publication;
2) Ensuring that the EBLMC and any other groups will also have sufficient time to review and evaluate the draft LMPG (minimum of 60 days which can overlap with #1);
3) Ensuring that the relevant editorial group, e.g. that of *Clinical Chemistry*, will have sufficient time to take a formally EBLMC-reviewed and BOD-approved draft LMPG through the appropriate peer review process for acceptance and publication in a scientific journal.

f. Selection of a Multidisciplinary LMPG Committee

The LMPG chair will recommend committee members to EBLMC and NACB BOD. The LMPG committee should be made up of clinical laboratory based professionals and clinician experts, and may also include other healthcare professionals or relevant members of stakeholders interested in the LMPG topic such as patients. The LMPG committee will also include a current member of the EBLMC. Assignment of a willing EBLMC member will be completed through collaborative discussion between the LMPG committee chair and the EBLMC chair.
The process for developing a LMPG must be transparent, objective and unbiased. Committee members will make full disclosure of all topic-related consultancies, external funding, and prior product evaluations and will recuse themselves in situations where conflicts may exist (1).

g. Responsibilities of the LMPG Committee

The LMPG Committee is responsible for determining the LMPG's scope and the topic areas to be addressed by the guidelines. Their first step is to develop a LMPG proposal to be submitted to the EBLMC for consideration using the guidance in this SOP, information from materials listed in Appendix Two for guideline proposal information and considering the 6 domains and the 23 key elements of the AGREE II on-line tool. LMPG proposals should include the following sections:

- Roster of LMPG Committee members including the Chair and Vice Chair
- Identification of collaborating organizations, if relevant, and information regarding role and qualifications of all LMPG Committee members
- Background
- Defined conditions and target populations

- Identification of the primary target audience for which the final LMPG is intended
- Questions to be answered (See reference 5)
- Incidence, prevalence and indication of the disease burden
- Costs associated with complications
- Potential impact of the evidence report on technology to decrease healthcare costs or to improve health status or clinical outcome
- Identification of criteria that will be used to monitor the impact of a LMPG
- Demonstrated commitment by nominating organizations
- Proposed system for choosing and weighing evidence and grading recommendations
- Proposed budget for LMPG development
- References

LMPG developers should familiarize themselves with the recommended attributes of LMPGs and, when relevant, CPGs (3). In brief, these attributes are validity, reliability/reproducibility, clinical applicability, clinical flexibility, clarity, multidisciplinary process, scheduled review and documentation. The EBMLC committee will work with the LMPG committee to refine the proposal before the proposal is submitted to another group or beginning the internal systematic review of the evidence (SR). A useful example of a guideline proposal form and sample proposal from ASCO is available in their Guidelines Methodology Manual, available at http://bit.ly/XDWIb3by selecting the Guidelines link on this website and doing a website search for ASCO Guidelines Methodology Manual.

h. Conduct of the Systematic Review of Evidence

Once a proposal is accepted by the EBLMC and approved by the NACB BOD, the next key issue to determine is how a systematic review will be conducted and by whom (i.e., the LMPG committee or an external group, e.g., AHRQ). The LMPG committee is responsible for seeing that the research to evaluate the evidence in the areas to be addressed has or will be conducted and, if so, by whom. The LMPG committee should determine if the evaluation of the evidence through a SR(s) has already been completed and published by another group(s) or organization(s); will be developed into a proposal for conducting a SR to another group(s) or organization(s); or will be undertaken and conducted by the LMPG committee. Regardless of the SR approach taken, information on the method used to review the literature must be described and incorporated into the final LMPG publication. The description must include the methods used to conduct the literature search, sources used (such as references contained in primary articles found by the search, published guidelines, etc.)

If the LMPG committee plans to develop the LMPG based on recently published SRs, the specification of these resources and how they will be used to develop the LMPG should be detailed in the initial LMPG proposal submitted to the EBLMC for their consideration and, if deemed a worthwhile proposal, submitted to the NACB BOD for approval.

If the LMPG committee plans to submit a SR proposal for consideration by the AHRQ, the plan including the proposed topic and key questions should be part of the initial LMPG proposal submitted to the EBLMC and BOD for approval. If AHRQ accepts the proposal for development into a SR, the LMPG chair and other subject matter experts will be involved in this process, to review the draft evidence report and refine the questions as needed. The process is outlined on the AHRQ website (6) at http://www.ahrq.gov.

If the LMPG Committee performs the SR (whether by choice or because AHRQ declined to accept a SR proposal), specific actions to be taken by the LMPG Committee are as follows.
Once a list of topics for the LMPG is identified, a literature search is conducted using an indexed electronic database such as PubMed or another tool that searches Index Medicus. Evidence-based medicine collections, such as the Cochrane Collaboration, should also be searched. Additionally, currently published guidelines, such as those found electronically at the National Guideline Clearinghouse, should be reviewed before beginning the process to assess currently accepted guidelines that may relate to laboratory medicine. All references reviewed should be documented, regardless of acceptability or strength. Sample forms previously used by NACB for the evaluation of the literature, suggested format for this documentation, information and details on preparing the original draft of the guidelines (with appropriate supporting references and evaluation of strength of evidence) and evidence summary tables are provided in Attachment One. Sample forms being used by the NACB Pain Management LMPG are provided in Attachment Two.

i. Evaluation of the Strength of Recommendations

In developing laboratory management practice guidelines, the LMPG Committee must systematically evaluate the evidence included in the SR to arrive at an overall strength for each recommendation in the guidelines as well as grade the quality of the evidence used to arrive at the recommendation. One of several approaches to evaluating the strength of recommendations and grading reviewed evidence is GRADE (Grading of Recommendations, Assessment, Development and Evaluation), which was presented in a series of 2008 articles beginning in the April edition of BMJ (7). GRADE is increasingly being adopted by organizations worldwide, but may not be well-suited to diagnostic laboratory test recommendations. The 2011 IOM report on trustworthy guidelines also provides examples of roughly a dozen different clinical organizations' systems for rating the strength of recommendations and grading the evidence (3). One common feature shared by all of these organizations is their use of each organizations' own single, standardized system for determining the strength of a recommendation and grading the quality of the evidence used to arrive at this recommendation.

In general, NACB has adapted the approach used by one of the organizational systems described in the 2011 IOM report. NACB LMPG Committees have often used this system. It is that of the US Preventive Services Task Force as modified and described in Appendix Four.

Each LMPG Committee does, however, have the ability to change the classification system if mandated by the other societies co-sponsoring the guidelines. The draft and final guidelines must clearly describe the process used to determine the strength of evidence, and the strength of each recommendation must be clearly defined. Otherwise, LMPG committees are encouraged to use the modified US Preventative Services Task Force system. Recognition of a standardized system for rating the strength of recommendations and grading of the evidence is a worthwhile goal. It is also a consistent characteristic of the leading clinical practice guideline developing organizations in the U.S. and worldwide.

j. Public Presentation of Key LMPG Information

The purpose of public presentation of draft LMPGs is to allow public comment and discussion of the recommendations made by the committee. The venue must allow adequate time for the presentations with subsequent discussion to assure that all issues have been appropriately considered before preparation of the final guidelines for publications. Most guidelines require a two-day period for presentation and public comment during the Arnold O. Beckman Conference, the AACC Annual Meeting or another venue. If another venue is used, the amount of time allotted for the presentation and discussion should range from 8-10 hours for a complete review of a LMPG. Less time will be needed if only a sub-set of the guidelines is presented. EBLMC suggests that the time allotted be evenly (50:50) distributed between the presentations and the time devoted to public comments.

Presentation: The presentations should be focused. Since attendees should have accessed or have received an electronic copy of the draft guidelines in advance with proposed recommendations, it is generally necessary to provide only a small amount of background to the rationale for the guidelines. The majority of the presentation should focus on the actual guidelines and their strength of evidence. Arrangements should be made in advance to record and transcribe the comments and for identification of the commentator so that appropriate consideration can be given to all points made, as well as recognition of the discussants in the final published version of the guidelines.

k. LMPG Development and Review

i. LMPGs Developed by NACB or in Collaboration with Other Groups

As LMPGs go further into development, the draft guideline should be organized with a standardized and widely-accepted structure. While there is more than one guideline evaluation system that is used across many different clinical societies and organizations, the NACB will employ the second edition of the AGREE (Appraisal of Guidelines for Research and Evaluation) instrument (8). An analysis of the use of the AGREE II instrument to evaluate guidelines has recently been published (9). Developing drafts of NACB LMPGs will include a preamble, which should address the 23 points listed in the AGREE II Instrument for guideline

appraisal (8). Methods used to evaluate the literature and a description of the grading system must be clearly described in the LMPG. Either the LMPG Chair or Vice-Chair will be trained in the use of the AGREE II Instrument available on the AGREE Enterprise website. Members of the EBLMC will also be trained in the use of the AGREE II Instrument as previously described. The quality of the evidence and strength of the recommendations will follow a scientifically accepted and evidence-based format. LMPGS should also consider the essential elements of guidelines described by Oosterhuis, et.al. (10). Primary research articles should be cited rather than reviews or book chapters. The structure of the LMPG's format, vocabulary and content, such as statements regarding evidence and target populations, should facilitate and enhance implementation using tools such as computer-assisted clinical decision systems by the end-users (3). It is critical that a methodological quality control mechanism be consistently applied to LMPGs in development and in appraisal of the near-final products. The use of the AGREE II instrument serves such a purpose. Other examples may be available from the G-I-N web site's library (http://www.g-i-n.net/library).

ii. Guidelines Developed by Other Groups

Periodically, NACB and/or AACC are contacted by other organizations for collaboration in the development of clinical practice guidelines by these groups. Should this collaboration be an opportunity to assign a NACB and AACC member to an outside group, recommendations of members who are willing to serve and have the requisite expertise should be provided from the EBLMC to the NACB BOD and, if relevant, AACC leadership. If the AACC and/or NACB is asked to consider reviewing another society's or organization's practice guidelines for approval and endorsement, the EBLMC should identify a minimum of three reviewers to fulfill this role. These individuals should be provided a minimum of 30 days to review the draft guideline and use the AGREE II instrument for this purpose. Additional guidance on review of other societies' guidelines is also available from the ACCP's G-I-N Guideline Development Workshop (11) and the American Society of Clinical Oncology (ASCO) Guideline Procedures Manual, Expert Panel Version 4.0 (12) which can be downloaded in PDF format from the ASCO website, www.asco.org. Should the reviewers agree that the guideline is worthy of approval, they should formulate a recommendation through the EBLMC to the NACB and AACC BODs who may then consider formal endorsement.

l. Public Posting of LMPGs

Draft guidelines will be posted on the NACB webpage for public comment for a specified period of time, i.e., a minimum of 60 days. Comments will be made using the on-line comment documentation process. This process will document comment receipt and final resolution. The final LMPG will be submitted to EBLMC for review and approval before being presented to the NACB Board of Directors for final approval. This submission should include the LMPG committee's response, clarification and explanation of their reply to each and every comment provided by other readers and reviewers of the draft guideline.

m. Guideline Finalization and Approval

The EBLMC will have a minimum of 60 days to review a draft LMPG for approval. Once reviewed, the EBLMC will make a recommendation to the NACB BOD, which holds final authority and responsibility for approving all LMPGs developed by NACB alone or in collaboration with other organizations. The NACB BOD-approved LMPG shall then be formally delivered to the AACC BOD. Once approved, the final LMPG will be posted on the NACB website.

n. Requirements for Publication of LMPGs

NACB will publish LMPGs in *Clinical Chemistry* or in a relevant clinical specialty journal deemed more appropriate for the clinical topic or subject matter. In matters of submission of proceedings of NACB meetings to *Clinical Chemistry*, all submissions will be evaluated using the standard peer editorial review policies of the journal. If the NACB chooses to publish meeting proceedings, practice guidelines or standards in a relevant clinical specialty journal, NACB will consult with AACC (that is the AACC President, AACC Board of Directors or the designee of the AACC President) to ensure that AACC is aware of and supports the NACB decision, particularly regarding the depiction of AACC's name and involvement with the meeting and proposed published materials. NACB will not publish meetings proceedings, practice guidelines or standards of practice in competing journals of *Clinical Chemistry* such as journals in the fields of clinical chemistry, pathology or laboratory medicine without approval from the NACB BOD as well as approval from the AACC President or AACC BOD.

Overall, publication of the LPMG or a summary in a peer-reviewed journal is encouraged. The LMPG chair may also submit LMPG to the AHRQ for consideration of listing on the website of the National Guidelines Clearinghouse. LMPG Chairs are responsible for working with the EBLMC chair, the NACB administrative staff and the relevant editorial group with this goal in mind from the earliest phases of LMPG development. The LMPG chair is responsible for ensuring that the LMPG in development is given sufficient time for public posting of comments and review by EBLMC for potential approval. The minimum time period for this is 60 days. The LMPG chair will work with the above stakeholders to ensure that there is sufficient lead time to accommodate the a scientific journal's editorial peer of all or part of the LMPG. LMPGs may be published in their entirety or in portions in the following vehicles:

i. Peer reviewed journals
ii. Web-based versions
    1. AACC/NACB
    2. Other organizations' website

Editorial requirements for the published format of a LMPG are detailed in Appendix Five

o. Suggested Timeline for Preparation of LMPGs

The timeframe for LMPG development can vary widely and is dependent on many factors. A focused LMPG based on a previously conducted SR may take 6 – 12 months to develop. A LMPG based on a SR that is requested to be conducted by another organization such as AHRQ may take at least 3 years from the time of the initial proposal to final posting/publication of a LMPG. Based on the past experience of NACB LMPG committees, the LMPG process can often take roughly two years to complete. This time frame includes one face-to-face meeting of the committee and/or initial presentation of potential recommendations in a venue for debate and discussion. Subsequent meetings would be completed by e-mail or by conference call including additional calls or meetings with any co-sponsoring specialty society or organization. Unless specifically approved by the BOD, it is anticipated that the representative delegate of an outside society attends such meetings at the expense of that society. A sample timeline for LMPG development is illustrated in Appendix Six.

p. Planning for Future Guideline Dissemination, Implementation and Updating

When practical, developers and implementers of LMPGs should explore collaboration and interaction with designers of clinical decision support systems to facilitate wider implementation and broaden the impact of the LMPG. The LMPG committee, the EBLMC and the NACB BOD as well as any other external organizations that collaborated in LMPG development should consider and, ideally, identify ways to determine the LMPGs impact in both the short and long term. Together with support from AACC's Communications department, LMPG committees and chairs are required to identify a five year plan (or shorter in a rapidly changing area of laboratory medicine) for updating specific recommendations as well as to consider if the complete LMPG should be updated in roughly the five year time frame. The plan and schedule for future review should be documented upon completion of efforts on the current LMPG. Requirements regarding securing permission to obtain reprints or translate LMPGs are detailed in Appendix Seven.

REFERENCES and RESOURCES

1. NACB Policy on Laboratory Medicine Practice Guidelines, Page 25, NACB Board of Directors Manual, April 2007 Revision.

2. NACB Standard Operating Procedures for Preparing, Publishing and Editing NACB LMPGs, March 2005 Version.

3. Clinical Practice Guidelines We Can Trust, Institute of Medicine, The National Academies Press, Washington, D.C., 2011.

4. Finding What Works in Health Care – Standards for Systematic Reviews, Institute of Medicine, The National Academies Press, Washington, D.C., 2011.

5. Price CP and Christenson RH (Eds.). Evidence-Based Laboratory Medicine; Principles, Practice and Outcomes. Second Edition. Washington DC, AACC Press, 2007.

6. Agency for Healthcare Research and Quality website at http://www.ahrq.gov

7. Guyatt GH *et al*. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336: 924 – 26.

8. The AGREE Enterprise Website. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument. www.agreetrust.org

9. Brouwers MC *et al*. AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ* 2010; 182(18): e839-42.

10. Oosterhuis WP *et al*.. Evidence-based guidelines in laboratory medicine: principles and methods. Clin Chem 2004;50: 806-818.

11. American College of Chest Physician's Guideline Development Workshop Materials, ACCP, 2012.

12. American Society of Clinical Oncology Guidelines Procedures Manual, Expert Panel Version 4.0, available at www.asco.org., ASCO, 2011.

Appendix One
Standards for Developing Trustworthy Clinical Practice Guidelines
Institute of Medicine of the National Academies Report at a Glance (*)

Note: *These standards are listed as described in the 2011 IOM Report. NACB LMPG Committees as well as NACB and AACC leadership will strive to follow these standards when practical. However, in development of a specific LMPG, it may not be feasible or possible to incorporate every principle within each of the eight standards described below. However, it is important and relevant for LMPG committees to be aware of these principles as they articulate prevailing wisdom on development of trustworthy clinical practice guidelines in the U.S. at the time this SOP was finalized. For the purposes of this NACB LMPG SOP, the terms CPGs and LMPGs can be considered "generally equivalent" with each under the auspices of a guideline development group (GDG).*

Standard 1
Establishing transparency

1.1 The processes by which a CPG is developed and funded should be detailed explicitly and publicly accessible.

Standard 2
Management of conflict of interest (COI)

2.1 Prior to selection of the Guideline Development Group (GDG), individuals being considered for membership should declare all interests and activities potentially resulting in COI with development group activity, by written disclosure to those convening the GDG

- Disclosure should reflect all current and planned commercial (including services from which a clinician (NOTE: or laboratorian) derives a substantial proportion of income), non-commercial, intellectual, institutional and patient/public activities pertinent to the potential scope of the CPG.

2.2 Disclosure of COIs within GDG

- All COI of each GDG member should be reported and discussed by the prospective development group prior to the onset of their work.
- Each panel member should explain how their – COI could influence the CPG development process or specific recommendations.

2.3 Divestment

Members of the GDG should divest themselves of financial investments they or their family members have in, and not participate in marketing activities or advisory boards of, entities whose interests could be affected by CPG recommendations.

2.4 Exclusions

- Whenever possible, GDG members should not have COI.
- In some circumstances, a GDG may not be able to perform its work without members who have COIs, such as relevant clinical specialists who receive a substantial portion of their incomes from services pertinent to the CPG.
- Members with COIs should represent not more than a minority of the GDG.
- The chair or co-chairs should not be a person(s) with COI.
- Funders should have no role in CPG development.

Standard 3
Guideline development group composition

3.1 The GDG should be multidisciplinary and balanced, comprising a variety of methodological experts and clinicians, and populations expected to be affected by the CPG.

3.2 Patient and public involvement should be facilitated by including (at least at the time of clinical question formulation and draft CPG review) a current or former patient and a patient advocate or patient/consumer organization representative in the GDG.

3.3 Strategies to increase effective participation of patient and consumer representatives, including training in appraisal of evidence, should be adopted by GDGs.

Standard 4
Clinical practice guideline-systematic review intersection

4.1 CPG developers should use systematic reviews that meet standards set by the IOM's Committee on Standards for Systematic Reviews of Comparative Effectiveness Research/

4.2 When systematic reviews are conducted specifically to inform particular guidelines, the GDG and systematic review team should interact regarding the scope, approach and output of both processes.

Standard 5
Establishing evidence foundations for and rating strength of recommendations

5.1 For each recommendation, the following should be provided:

- An explanation of the reasoning underlying the recommendation including
- A clear description of potential benefits and harms,

- A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
- An explanation of the part played by values, opinion, theory and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A description and explanation of any differences of opinion regarding the recommendation.

Standard 6
Articulation of recommendations

6.1 Recommendations should be articulated in a standardized form detailing precisely what the recommended action is and under what circumstances it should be performed.

6.2 Strong recommendations should be worded so that compliance with the recommendations (S) can be evaluated.

Standard 7
External review

7.1 External reviewers should comprise a full spectrum of relevant stakeholders, including scientific and clinical experts, organizations (e.g., health care, specialty societies), agencies (e.g. federal government), patients and representatives of the public.

7.2 The authorship of external reviews submitted by individuals and/or organizations should be kept confidential unless that projection has been waived by the reviewer (s).

7.3 The GDG should consider all external reviewer comments and keep a written record of the rationale for modifying or not modifying a CPG in response to reviewers' comments.

7.4 A draft of the CPG at the external review stage or immediately following it (i.e., prior to the final draft) should be made available to the general public for comment. Reasonable notice of impending publication should be provided to interested public stakeholders.

Standard 8
Updating

8.1 The CPG publication date, date of pertinent systematic evidence review, and proposed date for future CPG review should be documented in the CPG.

8.2 Literature should be monitored regularly following CPG publication to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the CPG.

8.3 CPGs should be updated when new evidence suggests the need for modification of clinically important recommendations. For recommended intervention causes previously unknown substantial harm, that a new intervention is significantly superior to a previously recommended intervention from an efficacy of harms perspective, or that a recommendation can be applied to new populations.

Appendix Two
ACCP Guideline Development Workshop Materials*

A. Folder – Breakout 1 - Systematic Literature Search
B. Folder – Breakout 2 – Study Selection, Quality Assurance
C. Folder – Breakout 3 – Meta-Analysis
D. Folder – Breakout 4 – Evidence Tables and Evidence Profiles
E. Folder – Educational Program Modules for Conducting an Evidence Review (Contains Six Modules)
F. Folder – Reference Guides
G. Folder – Session I – Welcome and Guidelines in EBM
H. Folder – Session II – Scope and PICO Questions
I. Folder – Session III – Development Process Overview
J. Folder – Session IV – Conflict of Interest
K. Folder – Session IX-X – Guidelines – CSs – Review Process
L. Folder – Session VI – Guideline Writing
M. Folder – Session Vii and VIII – Values, Preferences and Resources
N. Folder – Session XII - Dissemination & Implementation
O. Folder – Session XIII – Quality Improvement
P. Folder – Session XV – Evaluations
Q. PDF – Guideline Methodology Course Material
R. PDF – Course Disclaimer

- Each one of the above folders contains PDF versions of PPT presentations, samples of forms and other instructional materials.
- Copies of these files can be obtained from the NACB Administrative Office. Selected forms for illustrative purposes are included later in this SOP

Appendix Three
Financial Considerations for LMPGs

The following should be considered as costs associated with developing and publishing an LMPG. These are based on the experience gained from previous LMPG's. Each LMPG Chair is encouraged to work with NACB staff liaisons to identify all costs for development and publishing of an LMPG for the purposes of budgetary planning. It is expected that the LMPG Chair will work closely with the NACB administrative staff in the NACB office to ensure that guidelines are developed within fiscal constraints. The following expenses should be identified at the appropriate stages of an LMPG development process.

Development Costs

Expenses covering committee activities, including conference calls, and one face-to-face meeting, and minor supplies should be identified.

Electronic Publication

Expense associated with posting the document on the web.

Budget Development

A preliminary draft LMPG budget should be developed by each LMPG committee and submitted with the initial draft LMPG proposal to the EBLMC for review and referral to the NACB BOD for approval.

Appendix Four
Strength of Recommendations and Grading of the Evidence

(Modified from US Preventive Services Task Force Recommendations for Preventive Services)

Strength of Recommendations:

A. The NACB strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B. The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C. The NACB recommends against adoption; there is evidence that it it is ineffective or that harms outweigh benefits.

I. The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

Grading the Quality of the Evidence:

NACB grades the quality of the overall evidence on a 3-point scale:

I: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

II: Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.

III: Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Appendix Five
Writing Style Format Conventions for LMPGs

NOTE: Reference numbers in Appendix Five refer to the reference list at the end of Appendix Five

Laboratory Medicine Practice Guidelines (LMPG) are published periodically by the National Academy of Clinical Biochemistry (NACB) as a result of the LMPG consensus process in a selected area of clinical laboratory medicine. Recommendations are derived from the process previously described and have final approval by the NACB Board of Directors. Writing is clear, concise, and grammatically correct. The guidance below is based on the most likely example, a LMPG being published all, or in part, in the journal of Clinical Chemistry.

Manuscript review. Manuscripts are evaluated by the Editor and will be copy edited according to NACB style (note at present the NACB follows the style used by *Clinical Chemistry*). No direct attribution of authorship should be given in the final document.

Copyright agreements*.* Manuscripts are published with the understanding that the copyright is transferred to the NACB. See Appendix Seven.

Translation from English into another language. LMPGs may not be translated into another language, or transmitted in any form without express written permission of the American Association for Clinical Chemistry (AACC, 1850 K Street, NW Suite 625, Washington, DC 20006). Permission will ordinarily be granted provided the logo of the AACC and the NACB, along with the following notice appear prominently at the front of the document:

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Manuscript Preparation

Use wide (2 cm) margins and double or triple spacing throughout the text, references, tables, figure legends, and footnotes. Place references, tables, and figure legends on separate pages, in that order. Number every page, starting with the title page, in the top right-hand corner. For guidance on manuscript preparation and style, consult *The ACS Style Guide: A Manual for Authors and Editors* (1) or the *CBE Style Manual* (2). Use the International System of Units (SI) (3) consistently throughout. Values expressed in conventional units may be added in parentheses after the value in SI units.

Title page. Prepare the title page on a separate sheet with the Editor's and all Committee Members first and last names in full.

LMPGs Including Review of Studies on Diagnostic Accuracy of Laboratory Tests In reviewing studies of diagnostic accuracy of laboratory tests, LMPG committee should identify an appropriate resource for evaluating the quality of reporting of studies of diagnostic accuracy. Examples of these types of statements or tools are the STARD statement (7) and QUADAS-2 (8).

Abbreviations. Define all nonstandard abbreviations the first time they are used in the text. Avoid unnecessary new abbreviations.

Acknowledgments. In an appendix, list the corporate sponsors of the LMPG and acknowledge the contributions of manuscript contributors, reviewers, and persons commenting during the consensus process.

Figures. Number figures consecutively using Arabic numerals. Use figure legends that are descriptive and concise. Figure print quality will be sufficient to ensure ease of reproduction and reading clarity.

Tables. Number tables consecutively with Arabic numerals. Give every column a heading, with clearly defined units as appropriate.

References. Number references in their order of appearance. Numbers for reference citations in the text should be typed on the line, in parentheses, adopting the style used in the journal *Clinical Chemistry*. References to CLSI Guidelines should be included where appropriate. In the reference list, name all authors of a paper unless there are more than seven, in which case list the first six plus "et al." Indicate any references that are editorials, abstracts, letters to editors, technical briefs, or reviews. Abbreviations for journal names are those used by *Chemical Abstracts* and *Biological Abstracts.* Do not use italic or boldface type in the reference citations. Examples of reference format follow:

1. Linnet K. Necessary sample size for method comparison studies based on regression analysis. Clin Chem 1999; 45: 882-94.
2. Fuentes-Arderiu X. and Miró-Balagué J. State of the art instead of biological variation to set requirements for imprecision. Clin Chem 2000; 46: 1715-16 (letter to the editor).
3. Siminovitch KA. Molecular characterization of human anti-DNA antibodies. In: Farid NR, Bona CA, eds. The molecular aspects of autoimmunity. San Diego: Academic Press, 1991:59-72.
4. Bailar JCIII, Mosteller F, eds. Medical uses of statistics, 2nd ed. Boston: NEJM Books, 1992:449pp.
5. Harley JB Gaither KK. Autoantibodies. In: Klippel JH, ed. Systemic lupus erythematosus (Zvaifler JH, ed. Rheumatic disease clinics of North America, Vol. 14). Philadelphia:WB Saunders, 1988:43-56.

6. Haughton MA. Immunonephelometric measurement of vitamin D binding protein [MAppSc thesis]. Sydney, Australia: University of Technology, 1989:87pp.
7. **STA**ndards for the **R**eporting of **D**iagnostic accuracy studies (STARD)at http://www.stard-statement.org (2008).
8. QUADAS-2 at http://www.bris.ac.uk/quadas/quadas-2 (2011).

Reference to unpublished work. Personal communications, unpublished work, and papers that have not been accepted must be cited parenthetically in the text and not as numbered references.

Studies of diagnostic accuracy. Follow accepted minimum criteria for methodological standards (4): (a) Specify spectrum of evaluated patients (age and sex distributions, eligibility criteria, and summary of symptoms or disease stage). (b) Analyze pertinent subgroups of subjects (e.g., symptomatic and asymptomatic patients). (c) Avoid verification bias (usually by application of "gold-standard" test to all subjects rather than to a clinically selected subset). (d) Categorize test results and patients independently to avoid reviewer bias (usually by performance of tests with blinding to patient information and vice versa). (e) Provide confidence intervals (or SE) for indices of diagnostic accuracy such as sensitivity/specificity, likelihood ratios, and areas under receiver-operating characteristics (ROC) curves (5). (f) Indicate the number of indeterminate test results and their use (if any) in further data analysis. (g) Provide laboratory data on analytical precision of the test (usually day-to-day CV at two or more concentrations) or reproducibility of observer interpretation [e.g., for a dichotomous (e.g., positive / negative) test]. See below for statistical treatment of data.

Statistics. Use of appropriate and meaningful statistics in the LMPG is the responsibility of the contributing authors and the editorial committee. Literature citations for statistical methods will be included in the LMPG list of references.

Appendix Five References

1. Dodd JS, ed. The ACS style guide : a manual for authors and editors, 2nd ed. Washington, DC: American Chemical Society, 1997:460pp. (Address: 1155 16th St., NW, Washington, DC 20036.)
2. Scientific style and format (the CBE manual for authors, editors, and publishers, 6th ed). Northbrook, IL: Council of Biology Editors, 1994:825pp. (Address: 60 Revere Dr., Suite 500, Northbrook, IL 60062.)
3. Taylor BN, US ed. The international system of units (SI). NIST Special Publication 330, Gaithersburg, MD: National Institute of Standards and Technology, 1991:62pp. (Periodically revised; for sale by Supt. Of Documents, Code No. NSPUE2, US Government Printing Office, Washington, DC 20402-9325.)
4. Reid MC, Lachs MS, Feinstein AR. Use of methodologic standards in diagnostic test research. Getting better but still not good. JAMA 1995; 274:645-51.

5. Zweig MH, Campbell G. Receiver-operating characteristics (ROC) plots a fundamental evaluation tool in clinical medicine [Review]. Clin Chem 1993; 39:561-77. Note that in Figs. 4-12 in this paper, the labels for the x-axis at the top and bottom are reversed. The (correct) dual labeling of the x-axis solves the problem of whether to plot specificity or 1 – specificity on the x-axis.

Appendix Six
Example Timeline for LMPG Development

TIME LINE	ACTIVITY	PERSON RESPONSIBLE
27-30 months before draft guideline presentation	Identify topics and potential chairs. Submit recommendations to the EBLMC and NACB BOD	EBLMC Chair
24-27 months before	Approve topic and LMPG Chair.	NACB BOD
	The LMPG Chair receives a copy of this SOP, reviews the recommendations of the process, and agrees to the requirements of the position.	EBLMC Chair
24 months before	Contact appropriate professional societies regarding co-sponsorship of guidelines. Directed committee members to the NACB web site (www.nacb.org) to review published LMPG's and familiarize themselves with the type of presentation of the issues used in LMPG's. Provide Committee members with a copy of this SOP	LMPG Chair
21-24 months before	Develop preliminary list of topics for inclusion in guidelines. Submit list to EBLMC Chair for approval. Develop preliminary budget for the guideline development and submit to EBLMC for approval by the NACB BOD.	LMPG Chair and Committee members
18-21 months before	LMPG Committee meets (Face-to-face or conference call) to determine final list of topics for inclusion, divide responsibility for preparation of draft guidelines, and set deadlines for submission of draft sections to LMPG Chair. Preliminary discussions of potential sites for public presentation of the guidelines; if this does not include the AACC annual meeting, the LMPG Chair must formally propose the alternative meeting venue to the EBLMC Chair who will present the recommendation to the NACB BOD for approval. Prepare final budget based on recommendations from the NACB administrative staff to the NACB BOD	LMPG Chair and Committee members
15-18 months before	Prepare initial draft of guideline sections with references.	Committee members
	Distribute drafts to committee members for review.	LMPG Chair
14-15 months before	Revise drafts based on committee review. Submit to LMPG chair for review.	Committee members
	Identify appropriate speakers to present the guidelines at public presentation(s) and the venue(s) appropriate for presentation. Present these recommendations to the EBLMC Chair.	LMPG Chair
12 months before	Circulate revisions to all LMPG Committee members for comments and further revisions. Assign "strength of recommendations".	LMPG Chair; Committee members

	Submit proposal for presentation to identified venue with copies to the EBLMC Chair. Remember to allow adequate time for public comments (see below). For the AACC Annual Meeting, the format may be a half or full day symposium or interactive workshop. LMPGs may also be used as the basis for staging of an Arnold O. Beckman Conference.	LMPG Chair
6-9 months before	Prepare final draft of guidelines. Send to selected expert reviewers. Submit documents in Word format to NACB administrative staff for posting on the NACB web site. Notify EBLMC Chair of progress.	LMPG Chair
5-6 months before	Draft guidelines posted on NACB web site; E-mail sent to NACB members announcing posting with comment period.	NACB administrative staff EBLMC Chair
3-4 months before (optional)	Revise draft guidelines using comments from expert reviewers and comments from web site.	LMPG Committee members
6 weeks before	Distribute (print or electronic) draft guidelines to attendees at public presentations. Print copies must be received by the NACB administrative staff no less than 4 weeks prior to the meeting.	LMPG Chair; NACB administrative staff
	Verify details of program location (recording, audio-visual needs, etc.) with Meeting Department. Contact all speakers to assure travel plans are made. For presentations held at the AACC annual meeting, much of this process will have been handled by the AACC Meeting's department. Remind all speakers that they are invited to attend the annual NACB Awards Luncheon as guests of the Academy. For presentations made at an Arnold O. Beckman conference, the AACC staff liaison for this conference will assist with these details.	LMPG Chair
Presentation	The LMPG Committee members should attend to distribute the draft guidelines and to assist in capturing feedback from the audience.	LMPG Chair All Committee Members
1-3 months after	Review and evaluate all comments (public, experts, email). Revise draft guidelines as needed.	All Committee Members
5-6 months after	Prepare final version of guidelines. Send to EBLMC Chair.	All committee members
	Submit to BOD for approval.	EBLMC Chair
	Final review and approval. Submit for publication.	BOD
7-9 months after	Complete Monograph. Send to NACB administrative staff and EBLMC Chair.	LMPG Chair
9-10 months after	Publication of Monograph (electronic and print).	EBLMC

Appendix Seven
Permissions, Reprints, Translations

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Attachment One
Examples of the NACB Forms Previously Used for Recording Systematic Review Information

NACB LMPG 201X Data Abstraction Forms
Reference List

Clinical Question:

Databases Searched:

Search Terms/Hits:

Group Abbreviation use first letter of each word (ID = Infectious Disease), or first two letters of single word groups (ie Cardiac = CA) followed by chronological number of citation search hits.
Use standard citation format. [authors last name First initial. Title. Journal. Year;Volume:Page Numbers.]

		Abstract Review				Full Text Review				
Group/No.	Citation	Include? 1	2	3	Reviewers	Include? 1	2	3	Reviewers	Comments
CA 5	*Smith JA, Miller K. Outcomes of X. Clin Chem 1999;45:2005-2010.*	*v*	*N*	*v*	*JN, CR, MD*	*v*	*v*		*FM, KL*	*CR felt outcomes not quantitative*

NACB LMPG 201X Data Abstraction Form
Systematic Review (Data Abstraction Form 1)

Clinical Question: *(eg. Is Test X useful in screening for Y disorder?)*

Citation	Design	Application/ Population	N Study/Control	N Evaluated Study/Control	Outcome	Outcome Measurement	P value
CA 5 Smith JA et al	*RCT*	*Screening pts (ambulant) in ED*	*N = 23 walk-in ED Control = 25 outpatient clinic pts*	N = 20 ED pts Control N = 25	*Length of Stay*	*Time from admit to discharge*	P = 0.03

NACB LMPG 201X Data Abstraction Form
Systematic Review (Data Abstraction Form 2)

Clinical Question: *(eg. Is Test X useful in screening for Y disorder?)*

Citation	Design	Comparable Initial Groups?	Comparable Groups Maintained?	Comparable Performance Test on Subjects vs Controls?	Comparable Measurement of Outcomes?	Appropriate Analysis?	Comments
CA 5 Smith JA et al	*RCT*	*Both outpts, but ED may be more acute*	*Same groups maintained*	*RN and LPN tested in both groups*	*Time from admit to discharge measured both*	*Different N in study vs control*	*Use of control pts outside ED not comparable*

NACB LMPG 201X Data Abstraction Form
Systematic Review Summary

Clinical Question:

Volume of Literature					FINAL		
Aggregate Internal Validity	Aggregate External Validity	Coherence Consistency	Overall Link to Outcome	Net Patient Benefit?	Recommendation	Reviewers	Comments
Fair	*Poor*	*Good*	*Fair*	*Small*	*B*	*JN, RB, FM*	

NACB LMPG 201X Data Abstraction Form
Reviewer List

Clinical Question:

Reviewer's Initials	Name
JD	*Joe Doctor*

Attachment Two (b)

Pain Management LMPG Chapter: 0

Clinical Question: 0

Primary Reviewer: 0

Reviewer #2: 0

Reviewer #3: 0

Source		Setup/Study Design				Intervention Study			Diagnostic Study		Results/Outcome						Critical Appraisal of the Study			Other Comments
Citation	Funding Source/ Competing Interest	Setting (Multicenter, Countries, etc)	Study Objectives	Study Population (Inclusion/ Exclusion Criteria)	Study design (Cited by	Intervention(s)	Primary Outcome	Secondary Outcome Measure(s)	Diagnostic Test/Method	Reference Test/Method	Number of Patients/ Samples (Included/ Excluded)	Study Duration	Patient/Sample Characteristics	Summarize Outcome/Results	p-value/ Significance of Outcome/ Results	Author's Conclusion	Appropriate Analysis/ Conclusions	Recommendation (Grading of the	Reviewer #	Other / Addendum
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