

Evidence-Based Care

Guideline Development and Update Process

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Evidence-Based Care Guideline Development and Update Process

EXECUTIVE SUMMARY

Background:

Patients, purchasers, regulators, and others expect practice to be based on sound judgment and best evidence. The proportion of medical practice that has a basis in published scientific research has been measured at approximately 50% (Borrill, 2003; Ellis, 1995; Hardern, 2003). It has been postulated that even when sound research does uncover more efficacious forms of treatment, incorporation of this into routine patient care takes about fifteen to twenty years (Balas, 2000).

With this in mind, Cincinnati Children's Hospital Medical Center (CCHMC) established the Center for Health Policy & Clinical Effectiveness (HPCE) to assist with the pursuance of evidence-based care. One mechanism for achieving this goal has been through the development and implementation of Evidence-Based Care Guidelines (EBCGs). The development of these EBCGs is supported by the Board of Trustees and the strategic plan at Cincinnati Children's Hospital Medical Center and is congruent with its vision to be the leader in improving child health. The Center for HPCE strives to support the activities of clinicians in the development of disease- or procedure-specific EBCGs, providing guidance and assistance as needed.

Evidence-Based Care Guideline Definition:

As defined in the 1990 Institute of Medicine report, "Practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." (Lohr, 1990). The report goes on to delineate eight "attributes of good guidelines." The AGREE Collaboration's guideline appraisal tool has operationalized the attributes concept (AGREE, 2001).

Evidence-Based Care Guideline Development Phases:

The EBCG progresses through several phases before it is completed. A summary of these phases follows.

Selection Phase:

EBCGs are targeted to specific patient populations. A request for development of an EBCG may come from HPCE or other stakeholders. Before selecting an EBCG for development, preliminary data is reviewed from the hospital's information systems as well as input from other data sources. A Team Leader is identified who champions the initial phases of the guideline development.

Preparation Phase:

Once an EBCG has been selected for development, a review of the preliminary data from the Selection Phase is conducted. Target population and current practice are defined. Potential gaps in knowledge, applicable clinical questions and potential opportunities for improvement are identified. Potential outcomes related to the target population and current practice are explored with stakeholders.

Based on the clinical questions, a comprehensive search of the literature is conducted. The resulting abstracts are reviewed by a methodologist to eliminate low quality and irrelevant citations. An interdisciplinary team is identified by key leaders to participate in the development of the EBCG. Inclusion of Family Advisors is essential to the success of the work. Team members are contacted and invited to participate and the first meeting is scheduled.

Development Phase:

At the first meeting, the interdisciplinary Team members are oriented to the guideline development process, the role of evidence, and critical appraisal. Goals and outcomes are confirmed, and timelines are defined. The Team engages in a series of meetings exploring and critically evaluating best evidence. A high-quality EBCG and a hand-off to implementation and improvement Teams are the end result of the Team's work. The hand-off includes development or revision of relevant implementation tools*. Areas for potential research projects and publication are also developed.

External Review Phase:

Once the EBCG is developed and all members have agreed upon its content, a formal external review of the EBCG by clinical and methodological experts is conducted.

Implementation Phase:

While the EBCG is being finalized, the planning for education, communication, implementation, monitoring, and improvement begins. Historically, these phases were the responsibility of HPCE. Currently (2006) these activities are transitioning to the caregivers responsible for the relevant patient outcomes. This phase includes identification of the target audience and the tools required to implement the guideline, and the schedule for implementation. Also included are the monitoring tasks of data collection, and outcome feedback to users, as well as improvement activities.

Review and Revision Phase:

This phase can be initiated at any point that evidence indicates a critical change is needed. Revision of one or more recommendations, other text of the guideline, or the guideline in its entirety will commence upon identification of invalidating evidence. In addition, periodic updates to the guideline will be conducted to improve guideline quality, incorporate all relevant, recent, valid evidence, and reflect current clinician experience as well as patient values and preferences. This process may be conducted by e-mail or meetings, as determined by the character of the new information.

Summary:

An EBCG is a clinical tool developed to address medical or surgical care for a specific target population. This tool is developed by an interdisciplinary team to improve patient outcomes, to promote quality care based on current knowledge and research, and to reduce variation in practice that is either not scientifically defensible or clearly inappropriate. The steps for this activity are explained in more detail in this document. This effort is guided and supported by HPCE. Progress is evaluated and reported as described in more detail in each phase.

*Implementation tools may include but are not limited to:

- Clinical Pathway – Inpatient and/or Emergency Department Highlights
- Order Set(s) – Inpatient and/or Emergency Department
- Algorithm(s) – Inpatient and/or Emergency Department
- Education Record; Discharge Instructions
- Patient/Family Pathway
- Health Topics

References:

1. Balas, E. Andrew and Suzanne A. Boren. Managing Clinical Knowledge for Health Care Improvement. *Year of Medical Informatics* National Library of Medicine, Bethesda, MD:65-70, 2000.
2. [Borrill, Z; Houghton, C; Sullivan, P J; Sestini, P.](#) Retrospective analysis of evidence base for tests used in diagnosis and monitoring of disease in respiratory medicine. *BMJ*. 327(7424):1136-1138, 2003.
3. [Ellis J. Mulligan I. Rowe J. Sackett DL.](#) Inpatient general medicine is evidence based. A-Team, Nuffield Department of Clinical Medicine. *Lancet*. 346(8972):407-10, 1995
4. [Hardern, R D; Leong, F T; Page, A-V; Shepherd, M; Teoh, R C M](#) How evidence based are therapeutic decisions taken on a medical admissions unit? *Emergency Medicine Journal*. 20(5):447-448, 2003.
5. Lohr, MJ, Field, MJ. Eds. *Clinical practice guidelines. Directions for a new program*. IOM - Institute of Medicine; National Academy Press, Washington DC: pg 8, 1990.
6. AGREE - Appraisal of Guidelines for Research and Evaluation, The AGREE Collaboration, 2001. Website: <http://www.agreecollaboration.org>

ROLES AND RESPONSIBILITIES

The development of an EBCG is a scientifically rigorous process. It requires dedication, commitment, and active participation of all involved. Administrators and HPCE support this activity in light of its linkage with the mission of Cincinnati Children's Hospital Medical Center.

An interdisciplinary team is charged with developing an EBCG. This development process will take several months from inception to implementation. The actual work of the Development Team is outlined in this manual according to each phase of the work. A member from HPCE will work with the Team Leader to guide and support this effort. Support will be provided to maintain momentum, to provide training for all involved and to facilitate the process.

Highly effective Teams are clear about the roles and responsibilities for all people on the Team or supporting the Team. These roles and responsibilities remain consistent even though the people change. Clarity about roles and responsibilities helps build support, trust and positive momentum for Teamwork.

Division Director and Sponsors:

- Evaluate system barriers requiring administrative input
- Assure time for staff participation
- Approve mission
- Provide known parameters that may affect Team decisions
- Allocate resources as needed for project work
- Assess and support implementation of the Team's results

Team Leader:

- Assists HPCE staff with activities in the Selection and Preparation Phases
- Leads Team through the project
- Coordinates and manages the Team's work to assure goals are met
- Establishes professional, collaborative atmosphere for work of Team
- Communicates progress to relevant parties.

Team Member:

- Participates in scheduled EBCG meetings
- Contributes specialized knowledge or expertise to the project, serving as a representative of colleagues who are not present at meetings
- Communicates work to those he/she represents
- Informs Team leadership of unavoidable absences and keeps self informed of Team progress
- Completes accepted assignments which may include: critical appraisal, searching for further evidence, drafting recommendation statements, providing feedback on developing draft.

Health Policy and Clinical Effectiveness Team Members:

Clinician Methodologist

- Provides guidance to the Team on evidence-based care, including assuring that best evidence is the basis for the recommendations.
- Guides the Team to understand, utilize, and grade evidence in the development of clinical recommendations
- Works closely with the Facilitator and Team members to distill the evidence-based discussions in drafting the guideline

Facilitator

- Works with Clinician Methodologist and Epidemiologist to identify literature for critical appraisal
- Trains, guides and supports Team Leader and members in the EBCG process, these activities may include:
 - facilitating meetings
 - communicating and follow-up of action-items between meetings
 - compiling evidence-based draft recommendations into a formatted guideline document
 - assuring AGREE criteria are met
 - assuring eligible CME credit is awarded
 - serving as liaison to Team Leader and other HPCE members (one contact point for leader)

Epidemiologist

- Assists with development of clinical questions and search criteria in the Preparation Phase
- Reviews evidence to eliminate low-quality and irrelevant citations and selects literature to be reviewed by Team.
- Conducts on-going evidence review during guideline Development and Review and Revision Phases.
- Conducts on-going evidence review for invalidating evidence after guideline publication

Medical Librarian

- Conducts electronic searches based on submitted clinical questions.

Implementation and Education Management

The HPCE department will help assure that new or revised implementation tools are aligned with the guideline evidence.

Education Coordinator

- Assists with implementation tool development and guides education of physicians and staff in the use of implementation tools, consistent with the EBCG recommendations.

Implementation Leader

- Responsible for evidence-based development and updates to implementation tools
- Responsible for implementation of EBCG

Outcome Data Management

Data Analyst: Provides preliminary information in the Selection and Preparation Phases and outcome information in the Monitoring Phase

Outcomes Coordinator: Develops, coordinates and monitors outcome measurement

Medical Reviewer: Assists with data definition and reviews patient information for data management

External Review Editor

- Coordinates guideline review by external experts

SELECTION PHASE

The Selection Phase is important in determining that the work involved in developing, monitoring and evaluating an EBCG is feasible, worthwhile, and meets two or more of the selection criteria. Collecting data to evaluate criteria such as improvement opportunities or sufficient volume to positively impact the target population assures that an appropriate topic is chosen. Key stakeholders, including a committed, informed, and interested physician leader, must commit to the choice of the project before work begins.

Step 1: Identify Potential Projects

- Selection Criteria:
 - committed, informed and interested physician leader
 - high likelihood of implementation
 - available resources for development
 - sufficient case volume
 - quality improvement potential
 - potential financial impact
 - availability of data
 - research interest
 - managed care interest
 - national interest
 - potential increase in market share
 - division commitment
- Target population is defined for each potential project, utilizing as needed:
 - ICD-9-CM diagnosis/procedure codes, or CMS DRGs, APRDRGs
 - Conduct a pilot feasibility chart review to determine if the target population has been and can be identified appropriately using the above described coding methods

Output:

Potential project list
Identifiable target population

Step 2: Project Selection

- Using the preliminary data analysis and feasibility and resource considerations, make a decision on the next project for development/study.
- Share roles and responsibilities with relevant key stakeholders. Confirm commitment, as appropriate, from Division Director or sponsor.
- Identify and obtain commitment from a Team Leader for the chosen topic
- Set up a plan for proceeding with the Preparation Phase with Team Leader and HPCE staff

Output:

Project status determination
Commitment from Division Director and sponsor
Team Leader identified

Proceed to Preparation Phase

PREPARATION PHASE

The Preparation Phase includes the groundwork activities of topic definition, evidence search, and baseline data collection. The Team Leader is an integral part of the activities in the Preparation Phase. Before the Development Team meets, the Team Leader, together with HPCE staff, work to clearly define the topic, answerable clinical questions, and target population. A mission statement based on these definitions may be drafted. Additional data may be collected to continue to assess the ability of tracking the population and to establish a comparison data set to represent the time period before EBCG implementation. Assessing selected medical literature and CCHMC data brings the purpose of the EBCG into focus and points to areas where practice may be impacted or a research contribution may be made. The Preparation Phase is also a time to make a final assessment of the appropriateness of the topic and availability of evidence before much work is invested. This groundwork provides focus to the EBCG development process and allows for a scientific evaluation of the EBCG after implementation.

Step 1: Literature Search

- Formulate clinical questions including input solicited from those with relevant expertise.
- Perform a pediatric literature search exploring the condition, procedure, target population and clinical questions (See Appendix 1 – Conducting a Comprehensive Literature Search).
- Review resulting abstracts to eliminate low quality and irrelevant citations
- For clinical questions with insufficient evidence **and** if evidence from the adult literature could be extrapolated to pediatrics condition above, search the adult literature, selecting only high quality evidence (see Appendix 2 – When to Consider Adult Studies)
- Identify key gaps in knowledge and areas for improvements which could be addressed with EBCG implementation and evaluation
- Map selected citations to the relevant clinical questions
- Print and sort articles in preparation for reading assignments

Output:

Answerable clinical questions
Literature selected and articles prepared for readers
Preliminary research agenda

Step 2: Baseline Data Collection

- Assess need for chart review to pinpoint opportunities in process or key outcomes, which could lead to improvement and/or research questions.
- Submit data request to Data and Analysis Group
- Summarize data for Team review

Output:

Data summary

Step 3: Mission Statement

- Clearly define the target population
- Clarify the clinical questions or other issues which the EBCG will address
- Draft the mission statement including the target population, purpose, Team members, expectations, timeline, preliminary expected outcomes and research potential

Output:

Draft mission statement

Step 4: Team Selection

- With the Team Leader, select the appropriate Team members consisting of physicians, nurses, educator, and other healthcare providers. This Team also includes Family Advisors and other non-healthcare community-based providers (such as teachers or day-care providers), as appropriate to the guideline topic.
- Set a date, time, place and agenda for the first meeting and for the proposed subsequent meeting schedule
- Distribute agenda, draft mission statement, and other preparatory information as appropriate

Output:

Interdisciplinary Team identified

First meeting scheduled

Proposed subsequent meeting schedule

Step 5: Education Plan

- Identify Implementation Leader(s) who will be responsible for patient outcomes related to the guideline topic

Output:

Commitment from Implementation Leader

Step 6: CME

Contact CME Coordinator to complete application for CME approval.

- Identify and/or conduct needs assessment
- Identify overall goal
- Identify what outcomes/changes in practice will occur
- Identify topic objective(s)
- Develop pre/post-test
- Complete conflict of interest documentation for Clinician Methodologist and Facilitator (CME faculty)

Output:

Approved application for Category I CME approval, and/or contact hours, as feasible, for represented disciplines

Pre/post test

Proceed to Development Phase

DEVELOPMENT PHASE

The Development Phase consists of a series of meetings, the number of which will depend upon the project scope. The Team rigorously reviews existing literature, EBCGs, and national, local, and internal experiences. Other steps which may be a part of this phase are development of specific, measurable outcomes, relevant implementation tools, and potential areas for research or publication. A member from HPCE will work with the Team Leader, implementation leader, and the Outcomes Coordinator to guide and support these activities.

Step 1: Initial Meeting(s)

- The Team is oriented to roles and responsibilities, expectations, the development procedure, the timeline and the CME process.
 - Roles and responsibilities for non-physicians may or may not be different from those of the physicians (e.g. critical appraisal more by physicians, implementation tool development more by non-physicians)
 - If this is a Review and Revision Team, discussion of the development procedure should not be omitted but should be clarified as it relates to the original document.
- The Team is oriented to evidence-based care (EBC) concepts and activities. This includes discussing how to critically appraise an article, **the terminology and its importance (e.g. randomization, concealment, intent-to-treat, etc.)**, and the grading scale and its relevance. Future meetings may include short tutorials on these subjects as just-in-time training.
- Review and refine mission statement
- Review baseline data if available - internal, local, and national experience
- Confirm or revise measurable goals and outcomes expected to be achieved by the development and use of the EBCG, to including clinical, satisfaction and/or financial impacts
- The Clinician Methodologist or Team Leader may present the first set of articles, setting an example for future presentations.
- Make assignments for:
 - *Literature review (See Appendix 3 –Evidence Review Forms)
Literature is divided into sections by category/clinical questions and members are assigned to review each section, and to grade and summarize results. At each meeting, results are presented to either the entire Team or a subgroup of the Team for discussion and identification of best evidence-based care.
- Confirm meeting and initial presentation schedule

Output:

A final mission statement
Measurable goals and outcomes
Persons identified for assignments
Presentation dates for assignments
Meeting schedule

Please note: It may take up to two hours to cover the content of this agenda. This may require an extended meeting time or a second meeting.

Step 2: Subsequent Meetings

- Present remaining literature reviews
- Present just-in-time tutorials on EBC or critical appraisal topics.
- Explore current goals, outcomes and questions for continued validity in relation to work accomplished to date
- Review data for continued applicability
- Begin draft EBCG statements based on reviewed evidence
- Begin integration of AGREE criteria (See Appendix 4 – Appraisal of Guidelines for Research and Evaluation: AGREE Instrument)
- Regular reports from the Education group

Output:

Ongoing presentations of annotations and grading of literature reviewed
EBCG recommendations documented based on evidence reviewed
Ongoing evaluation of the EBCG development process meeting AGREE criteria

Step 3: Preliminary Implementation Activities

- With previously identified Implementation Leader(s) begin to identify and discuss organizational barriers to implementation (see Appendix 4 – Appraisal of Guidelines for Research and Evaluation: AGREE Instrument, questions 19 and 20).

Output:

Organizational barriers identified.

Step 4: Final Development Activities

- Finalize EBCG draft
- Distribute EBCG drafts to Team members and ad hoc members as appropriate
- Communicate with Outcomes Coordinator regarding need for development or revision of outcomes and measures
- Communicate with Implementation Leader regarding need for development or revision of implementation tools and implementation plan.
- Integrate AGREE criteria

Output:

Final draft approval of guideline from all stakeholders in the EBCG

Step 5: Wrap-up

- Submit final EBCG to stakeholders.
- Distribute, collect and analyze Team evaluation forms (see Appendix 5 – Questionnaire and Feedback on Evidence-Based Care Guidelines)
- Submit CME documentation to Medical Staff Office

Output:

Final approval from Team and ad hoc members on the EBCG
Team evaluation
CME hours awarded

Proceed to External Review Phase

EXTERNAL REVIEW PHASE

Once the EBCG is finalized by Team members and stakeholders, the EBCG is sent to an external editor who selects methodological and clinical experts to formally evaluate the EBCG using the AGREE instrument.

In order to minimize the practical time for the external review process, the following concepts will be applied:

- Approval of the EBCG by the Team and stakeholders should be obtained as soon as is practical after the final Team meeting.
- Posting of the EBCG will proceed concurrently with the external review phase and changes can be made later based on this feedback.

Output:

Externally reviewed EBCG

Proceed to Implementation Phase

IMPLEMENTATION PHASE

“Guidelines alone have had regrettably little impact in the absence of concrete efforts to translate them into tools usable in everyday practice.” (Lohr, 1998) (see Appendix 6 – Implementation Checklist).

Step 1: Information Dissemination

- Create articles or other communication vehicles for dissemination of new or revised guidelines and implementation tools when ready
- Post guideline, and implementation tools when ready, on the internet and National Guideline Clearinghouse, and, when appropriate, on the intranet.
- Send changes for website to Marketing for and summarize substantive changes for quarterly Evidence-Based Care e-Newsletter

Output:

Communication to target audiences

The final EBCG and implementation tools posted on the intranet, internet and National Guideline Clearinghouse (NGC)

Quarterly e-Newsletter from Marketing

Step 2: Tool Development

- Assist Implementation Leader or designee as needed in the identification of appropriate tools guideline implementation (see separate document: [Implementation Tools](#))
- Assist Implementation Leader or designee as needed in the development of the identified tools, addressing systems issues and barriers
- Help assure that the developed tools are aligned with the guideline evidence

Output:

Evidence-based implementation tools

Step 3: Education Plan

Once the guideline is disseminated and the implementation tools are developed, an education plan is finalized by the Implementation Leader(s) or designees with guidance from Clinical Effectiveness.

Output:

Education Plan which must include at least the following:

- specific EBCG highlights for presentation
- desired practice changes indicated by EBCG
- available implementation tools
- specific EBCG outcomes, as available
- an implementation schedule

Step 4: Monitoring & Improvement

Once the guideline is implemented, data is collected that measures the outcomes identified during the development phase. This phase may be conducted by the Development Team or by other groups such as a task force, a quality improvement group or a data monitoring group. HPCE will serve as a communication conduit or provide guidance for evidence related issues.

Output:

Outcome measure(s) and concurrent feedback to EBCG users
Improvement opportunities identified and addressed
Organizational barriers are resolved or reported

Reference:

[Lohr, K.N., Eleazer, K., & Mauskopf, J.](#) Health policy issues and applications for evidence-based medicine and clinical practice guidelines. *Health Policy*. 46(1):1-19, 1998.

Proceed to Review and Revision Phase A

REVIEW AND REVISION PHASE – A. On-going review for invalidating evidence

After the EBCG has been published, it will be entered into the literature review schedule for invalidating evidence. This schedule assures that new literature for each guideline is searched every 3 to 6 months. In addition, all Team Members are advised, and periodically reminded, to forward important new evidence to the guideline Facilitator at any time. Revision of one or more recommendations, other text of the guideline, or the guideline in its entirety will commence upon identification of invalidating evidence.

Step 1: Literature Search and Review

- The Epidemiologist will search and stratify new literature according to the review schedule. Individual Team Members and/or HPCE staff will forward important literature and/or evidence to the Facilitator when it is identified. The Facilitator will forward these to the Epidemiologist.
- The Epidemiologist will review, grade and extract invalidating evidence from the literature identified (See Appendix 7 – Ongoing Literature Search for Invalidating Evidence).

Output:

Summary of any invalidating evidence

Step 2: Revision of the guideline document

- The Facilitator will e-mail guideline Team Leader, HPCE physicians and cc all guideline Team Members with summary of any invalidating evidence and the citation/reference(s) when and if identified in Step 1.
- Based upon the response to the e-mail request, **one** of the following two courses will be pursued:
 1. Text will be written by one or more of the following: Team Leader, HPCE physicians, Team Members, or Facilitator and coordinated by the Facilitator. Resulting draft will be e-mailed to all parties mentioned above. A non-response indicates assent.
 - or**
 2. One or more meetings of some or all of the Team Members will be convened by the Facilitator in order to review the evidence and discuss changes to the guideline.
- The Facilitator will coordinate finalization of guideline changes. The date of the change will be listed at the beginning of the guideline with a description of the scope of the change. Example:

Original Publication Date: July 20, 1998
Revision Publication Date: September 3, 2002
Xyz recommendation updated: August 6, 200X
- Communicate with Outcomes Coordinator regarding revision of outcome measures to reflect EBCG changes, if necessary.
- Communicate with Implementation Leader regarding revision of implementation tools to reflect EBCG changes, as appropriate.
- Communicate with Implementation Leader regarding revised guideline implementation and education of physicians and staff in the use of implementation tools, as appropriate.
- Repeat external review, implementation, and review and revision phases, as appropriate.
- Note that this process may also apply to technical changes, not related to evidence, in which case the date entry will read:

(Technical changes: January 19, 200X)

Implementation Phase (continued)

Output:

EBCG document which is up-to-date

Reposting of revised guideline (including National Guideline Clearinghouse,
excluding technical changes)

Proceed to Review and Revision Phase B

REVIEW AND REVISION PHASE – B. Full review and update

The process repeats with a literature review from previous date of publication as if beginning the preparation and development phases again. With this phase a complete update will be conducted of format, including quality elements such as AGREE criteria, as well as incorporating relevant, recent, valid evidence reflecting current clinician experience and patient values and preferences which 1) supports existing recommendations, 2) changes or invalidates existing recommendations and/or 3) generates new recommendations.

Step:

- Perform literature search covering time period since last publication date
- Review, grade and extract evidence from the literature that has been collected
- Meet with Team leadership to amend the EBCG and implementation tools to incorporate the relevant, recent, valid evidence reflecting current clinician experience and patient values and preferences as appropriate and to bring into standardized CCHMC HPCE format
- Identify appropriate previous and new Team members as needed and meet to finalize guideline draft
- Communicate with Outcomes Coordinator regarding revision of outcome measures to reflect EBCG changes, if necessary
- Communicate with Implementation Leader regarding revision of implementation tools to reflect EBCG changes, as appropriate
- Communicate with Implementation Leader regarding revised guideline implementation and education of physicians and staff in the use of implementation tools, as appropriate
- Repeat external review, implementation and review and revision phases as appropriate

Output:

A reviewed and revised EBCG

Hand-off to Implementation Leader and Outcomes Coordinator for implementation, education, ongoing monitoring and new or revised outcomes

Proceed to Research and Publication Phase

RESEARCH AND PUBLICATION PHASE

The EBCG development process often identifies gaps in knowledge or in published syntheses of trials which may lead to research and/or publication opportunities.

Step 1: Research Agenda

- Formulate questions and research hypotheses in order to design variables for chart review (see guidelines)

Output:

Collection of pertinent questions with hypothesis identified

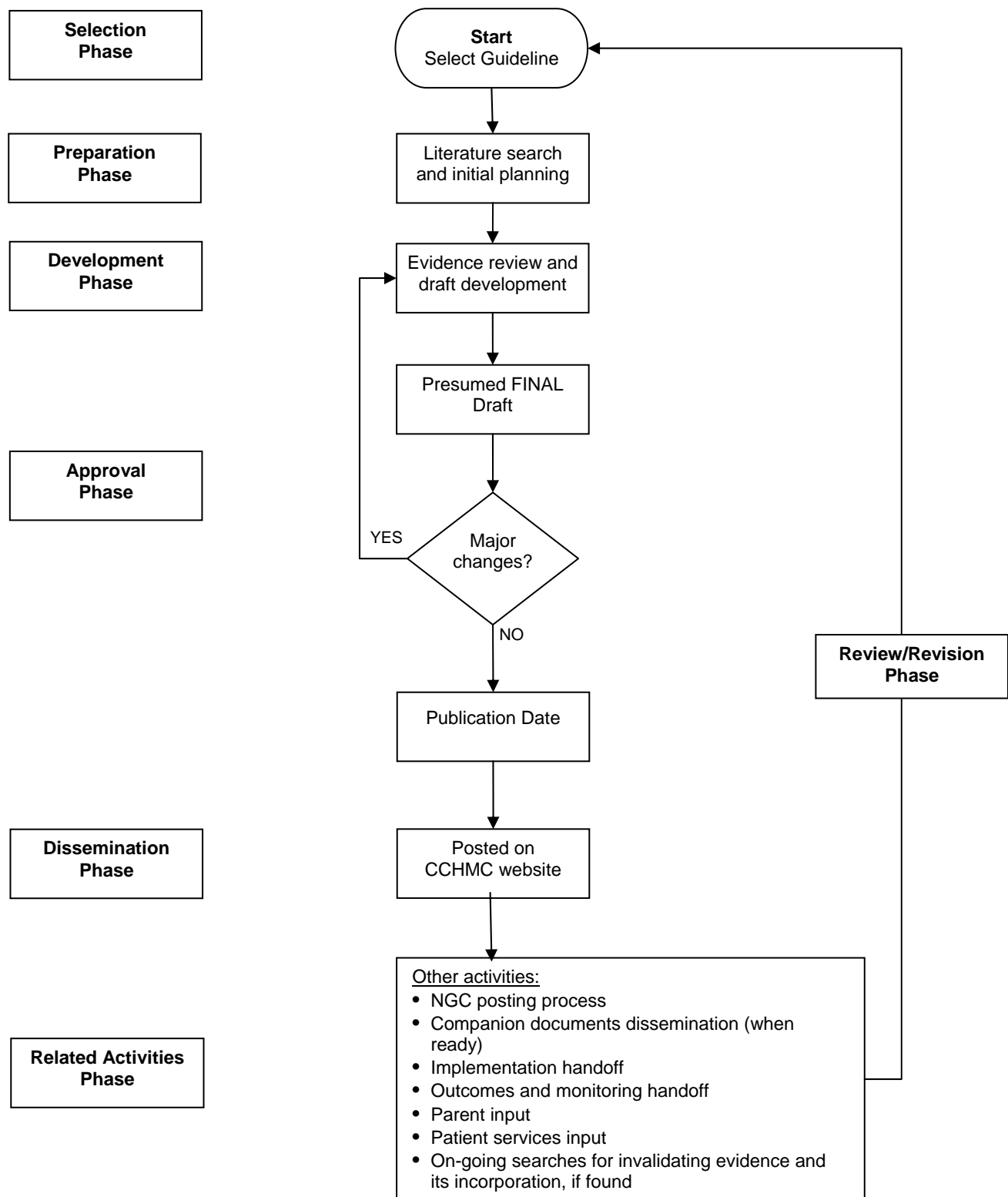
Step 2: Possible avenues of research or publication

- Identify individual(s) interested in answering a question in the research agenda.
- Identify individual(s) interested in pursuing grant opportunities
- Identify individual(s) interested in conducting an internal research project
- Identify individual(s) interested in publishing a systematic review or meta-analysis
- Identify individual(s) interested in an improvement project

Output:

Publication or clinical trial

Algorithm for Evidence-Based Guideline Development and Update



Conducting a Comprehensive Literature Search

Clinicians need simple, patient specific, user-friendly EBCGs. Many encounters with patients involve multiple decisions and the purpose of the Cincinnati Children's Hospital Medical Center's EBCGs is to address the most important ones.

The key clinical decisions surrounding most clinical encounters can be categorized into four general areas: treatment, diagnosis, prognosis, and etiology or harm¹. In order to build high-quality EBCGs for pediatric care, we have developed an algorithm and search-strategy to be utilized in the development of information and evidence for review by our EBCG Teams.

The Medline, Embase (through Cochrane Controlled Trials Register), CINAHL, and *The Cochrane Databases* will be used to develop an unrefined, "combined evidence" database to be applied in the EBCG development. *The Cochrane Database* will undergo a separate but similar topical search because of its architecture and limitations in electronic transfer.

Searching strategies will be focused on answering clinical questions relevant to the EBCG being developed and will employ a combination of Boolean searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. Strategies used in the searching algorithms developed for the National Library of Medicine's PubMed interface by Haynes, et.al.² will also be utilized.

The citations developed will then be reduced by: eliminating duplicates, subsetting review articles and non-English articles, and subsetting non-pediatric or adult articles (limited by age group, MeSH heading, or textword "pediatric"(tw) and "child*"). The results of the search, at this stage of the algorithm, will be reviewed by an EBCG methodologist. The methodologist will review the titles and abstracts of the resulting citations and will match the citations to the clinical questions.

The evidence from the refined search will be presented to the guideline Team members for review. Participants will be oriented to the search strategy and divided into review groups charged with an answerable clinical question(s). In order to further narrow the spectrum of material developed in the initial stages of searching, the participants on the EBCG Team may be asked to identify, categorize, and prioritize the important decisions and issues pertaining to the EBCG. Specifically, the participants will be queried as to the important decisions surrounding the treatment, diagnosis, prognosis, harm/etiology and the costs, risks, and benefits associated with the clinical issue being addressed by the EBCG.

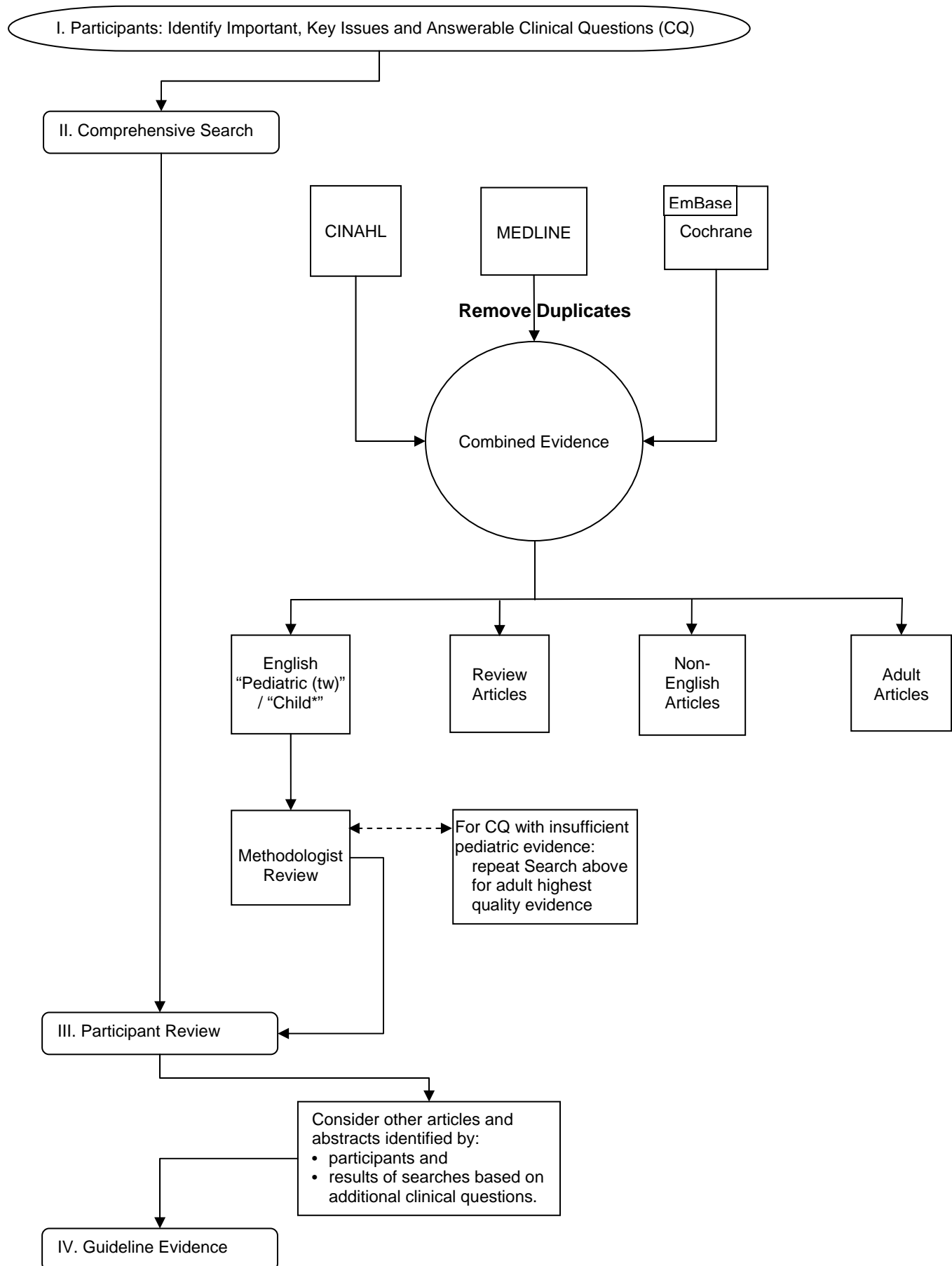
After assessment of the information needs of the participants and the results of the initial search are reviewed by the Team Leader and members, additional searches of the Medline, Embase, CINAHL, and Cochrane Databases may be conducted. Committee participants will also be asked to recall important abstracts and presentations from scientific meetings that may pertain to issues related to the EBCG at hand. Whenever possible, the written abstracts will be made available to the EBCG participants and authors will be contacted as needed. At subsequent meetings, EBCG participants will be encouraged to bring to the Team's attention important abstracts or articles that may have been missed in the searching algorithm.

A diagrammatic representation of the search process used to develop evidence to be utilized in constructing EBCGs is presented in the figure on the next page.

References:

1. Sackett D, Straus S, Richardson W, Rosenberg W, Haynes R. Evidence-Based Medicine How to Practice and Teach EBM. 2nd ed. New York: Churchill Livingstone; 2000.
2. Haynes R, Wilczynski N, Walker C, Sinclair J. Developing optimal search strategies for detecting clinically sound studies in MEDLINE. J. Am. Med. Inform. Assoc. Nov.-Dec.1994; 1(6).

FIGURE



When to Consider Adult Studies**1. Condition #**

Based on the results after conducting the search of the pediatric literature

- Identify any clinical questions for which there is insufficient pediatric evidence
- These clinical questions meet condition #1

2. Condition #2

For each clinical question formulated during the preparation phase, answer the following question:

- Is it plausible that results from adult studies regarding this clinical question could be extrapolated to pediatrics?
- The clinical question meets condition #2 if the answer is “yes”

3. Adult literature search

For any clinical questions meeting BOTH conditions #1 and #2:

- Extend the search to the adult literature for those clinical questions.
- Review resulting citations to select **only** the highest-quality relevant studies. See table below for definition of “highest quality “ by domain.

Definition of “Highest-Quality” Study Design by Domain

to be used for selection of adult studies when insufficient pediatric evidence is available

Domain	Study Design
Therapy/Prevention, Etiology/Harm	<ul style="list-style-type: none"> • Systematic review of randomized controlled trials (RCTs) (with homogeneity) • Individual RCT with narrow confidence interval
Prognosis	<ul style="list-style-type: none"> • Systematic review of inception cohort studies (with homogeneity) • Clinical decision rule validated in different populations • Individual inception cohort study with $\geq 80\%$ follow-up
Diagnosis	<ul style="list-style-type: none"> • Systematic review of (with homogeneity) • Clinical decision rule based on validating cohort studies with good reference standards from different clinical centers • Validating cohort study with good reference standards
Differential diagnosis/symptom prevalence study	<ul style="list-style-type: none"> • Systematic review of prospective cohort studies (with homogeneity) • Prospective cohort study with good follow-up
Economic and decision analysis	<ul style="list-style-type: none"> • Systematic review of analyses based on clinically sensible costs or alternatives • Analysis based on clinically sensible costs or alternatives

adapted from Oxford Center for Evidence-Based Medicine, 2001

Appendix 3
Evidence Review Forms
– A – Treatment

Reviewer: _____

Today's Date (mm/dd/yy): _____

Article Title: _____

Year: _____ First Author: _____ Journal: _____

Intervention / Condition Under Study: _____

1. What is the Type of Study? (Please check all that apply)

- | | |
|--|---|
| 1. <input type="checkbox"/> Meta-Analysis [M] | 6. <input type="checkbox"/> Review Article [S] |
| 2. <input type="checkbox"/> Systematic Review [M] | 7. <input type="checkbox"/> Expert Opinion [E] |
| 3. <input type="checkbox"/> RCT [A] / [B] | 8. <input type="checkbox"/> Basic Lab. Research [F] |
| 4. <input type="checkbox"/> Prospective Study [C] | 9. <input type="checkbox"/> Decision Analysis [Q] |
| 5. <input type="checkbox"/> Retrospective Study [D] } a. <input type="checkbox"/> Cohort | 10. <input type="checkbox"/> Other Article Type [O] |
| | (please specify) _____ |
| | b. <input type="checkbox"/> Case/Control |
| | c. <input type="checkbox"/> Case Series |

2. What is the sample size? _____ # **Study Patients** (Case group or cohort study)
_____ # **Control patients** (If study involved control groups)

3. Was there a sponsor or funding agency for the study? ☐ **No** ☐ **Yes**, Whom? _____

4. What are the Eligibility Criteria? _____

5. What are the Exclusion Criteria? _____

ARE THE STUDY RESULTS VALID?

Did the experimental and control groups begin the study with a similar prognosis?

6. Were patients randomized to treatment groups and was that randomization concealed? ☐ **Yes** ☐ **No**
Comments: _____
7. Were patients analyzed and accounted for in the groups to which they were randomized? ☐ **Yes** ☐ **No**
Comments: _____
8. Were the groups similar at the start of the trial, with respect to known prognostic factors? ☐ **Yes** ☐ **No**
Comments: _____

Did the experimental and control groups begin the study with a similar prognosis?

9. Were patients/parents and clinicians masked to which treatment was being received? ☐ **Yes**
☐ **No**
Comments: _____
10. Aside from the experimental treatment, were the groups treated equally? ☐ **Yes**
☐ **No**
Comments: _____
11. Was the follow up complete? ☐ **Yes** ☐ **No**
Comments: _____

ARE THESE VALID STUDY RESULTS IMPORTANT?

12. What are the main tables or graphs of results in the article? _____ (e.g., page or table numbers...)

13. What are the main results of the study? (Complete Table Below)

TREATMENT OUTCOMES	Control Event Rate [CER]	Experimental Event Rate [EER]	Difference (ARR) [CER – EER]	Number Needed to Treat (NNT) [1 / ARR]
Primary Efficacy Outcome: _____				
Secondary Efficacy Outcome: _____				
Other Outcomes: _____				
Other Outcomes: _____				
Harm Outcomes: _____				
Net Cost: _____				

CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

Is this article useful for this patient population?

14. Were the patients in this study similar to this patient population? ☐ Yes ☐ No
Comments: _____

15. Are the results described clinically significant? ☐ Yes ☐ No
Comments: _____

16. Were all important outcomes considered? ☐ Yes ☐ No
Comments: _____

17. Are the likely benefits worth the potential harm and costs? ☐ Yes ☐ No
Comments: _____

Additional Comments or Notes: _____

– B – Diagnosis

Reviewer: _____

Today's Date (mm/dd/yy): _____

Article Title: _____

Year: _____ First Author: _____ Journal: _____

Intervention / Condition Under Study: _____

1. What is the Type of Study? (Please check all that apply)

- | | |
|--|---|
| 1. <input type="checkbox"/> Meta-Analysis [M] | 6. <input type="checkbox"/> Review Article [S] |
| 2. <input type="checkbox"/> Systematic Review [M] | 7. <input type="checkbox"/> Expert Opinion [E] |
| 3. <input type="checkbox"/> RCT [A] / [B] | 8. <input type="checkbox"/> Basic Lab. Research [F] |
| 4. <input type="checkbox"/> Prospective Study [C] } a. <input type="checkbox"/> Cohort | 9. <input type="checkbox"/> Decision Analysis [Q] |
| 5. <input type="checkbox"/> Retrospective Study [D] } b. <input type="checkbox"/> Case/Control | 10. <input type="checkbox"/> Other Article Type [O] |
| | (please specify) _____ |
| | c. <input type="checkbox"/> Case Series |

2. What is the sample size? _____ # **Study Patients** (*Positive Gold Standard Test Result*)
 _____ # **Control patients** (*Negative Gold Standard Test Result*)

3. Was there a sponsor or funding agency for the study? ☐ **No** ☐ **Yes**, Whom? _____

4. What are the Eligibility Criteria? _____

5. What are the Exclusion Criteria? _____

ARE THE STUDY RESULTS VALID?

6. Did the clinicians face diagnostic uncertainty? ☐ **Yes** ☐ **No**
 Comments: _____

7. Was there a masked/blinded comparison between the new test and the "Gold Standard?" ☐ **Yes** ☐ **No**
 Comments: _____

8. Did results of the test being evaluated influence the decision to use the "gold standard" test? ☐ **Yes** ☐ **No**
 Comments: _____

ARE THESE VALID STUDY RESULTS IMPORTANT?

9. What likelihood ratios are associated with the range of possible test results? _____
 Comments: _____

DIAGNOSTIC TESTS	Sensitivity	Specificity	Likelihood Ratio (LR) * High probability (+) test result	Likelihood Ratio (LR) Low probability (-) test result
New test 1: _____				
New test 2: _____				
New test 3: _____				
Gold standard: _____				

* LR =>

$$\text{Likelihood Ratio +} = \frac{a}{b} \div \frac{a+c}{b+d} = \frac{\text{Sensitivity}}{(1-\text{Specificity})}$$

$$\text{Likelihood Ratio -} = \frac{c}{d} \div \frac{a+c}{b+d} = \frac{(1-\text{Sensitivity})}{\text{Specificity}}$$

LIKELIHOOD RATIO CALCULATIONS	Disease Positive	Disease Negative
Positive Test Result	a	B
Negative Test Result	c	D

CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

Is this article useful for this patient population?

10. Will the reproducibility of the test result and its interpretation be satisfactory in this setting? ☐ Yes ☐ No
 Comments: _____

11. Are the results applicable to my patient? ☐ Yes ☐ No
 Comments: _____

12. Will the results change my management? ☐ Yes ☐ No
 Comments: _____

13. Will patients be better off as a result of the test? ☐ Yes ☐ No
 Comments: _____

14. Is it likely that the new test will be used in everyday practice? ☐ Yes ☐ No
 Comments: _____

15. Are the results described clinically significant? ☐ Yes ☐ No
 Comments: _____

Additional Comments or Notes: _____

– C – Prognosis

Reviewer: _____

Today's Date (mm/dd/yy): _____

Article Title: _____

Year: _____ First Author: _____ Journal: _____

Intervention / Condition Under Study: _____

1. What is the Type of Study? (Please check all that apply)

- | | |
|--|---|
| 1. <input type="checkbox"/> Meta-Analysis [M] | 6. <input type="checkbox"/> Review Article [S] |
| 2. <input type="checkbox"/> Systematic Review [M] | 7. <input type="checkbox"/> Expert Opinion [E] |
| 3. <input type="checkbox"/> RCT [A] / [B] | 8. <input type="checkbox"/> Basic Lab. Research [F] |
| 4. <input type="checkbox"/> Prospective Study [C] | 9. <input type="checkbox"/> Decision Analysis [Q] |
| 5. <input type="checkbox"/> Retrospective Study [D] } a. <input type="checkbox"/> Cohort | 10. <input type="checkbox"/> Other Article Type [O] |
| | (please specify) _____ |
| | b. <input type="checkbox"/> Case/Control |
| | c. <input type="checkbox"/> Case Series |

2. What is the sample size? _____ # **Study Patients** (Case group or cohort study)
 _____ # **Control patients** (If study involved control groups)

3. Was there a sponsor or funding agency for the study? ☐ No ☐ Yes, Whom? _____

4. What are the Eligibility Criteria? _____

5. What are the Exclusion Criteria? Were some patients excluded? _____

ARE THE STUDY RESULTS VALID?

6. Was the patient sample representative of the population of interest? ☐ Unknown ☐ Yes ☐ No
 o Was the method for sample selection clearly described? ☐ Yes ☐ No
 Comments: _____
7. Were the patients sufficiently homogeneous with respect to prognostic risk? ☐ Yes ☐ No
 o Are there subgroups in the sample with very different prognosis compared to other subgroups
 Subgroups in the study? ☐ Yes ☐ No
 o Are the patients and their management similar to the patients of interest? ☐ Yes ☐ No
 Comments: _____
8. Was the follow-up sufficiently complete? ☐ Yes ☐ No
 Comments: _____
9. Were objective and unbiased outcome criteria used? ☐ Yes ☐ No
 Comments: _____

ARE THESE VALID STUDY RESULTS IMPORTANT?

10. What percent of the study sample were followed to the primary endpoint of interest? ____%
 Comments: _____
11. Were the endpoints quantifiable and precisely measurable? ☐ Yes ☐ No
 Comments: _____

12. Was the assessment of the endpoint made independent of knowledge of prognostic factors? ☐ Yes ☐ No

Comments: _____

13. Does the prognosis change as the patient ages?

☐ Yes ☐ No

Comments: _____

14. What is the primary prognosis endpoint? What is the 95% confidence interval?

_____ (_____-_____)

Comments: _____

CALCULATING SE & CI	Standard Error [SE]	Confidence Interval [95% CI]
Proportion (rate of some prognostic event) where: * the number of patients = n * proportion of these patients who experience the event = p	Square root = $\sqrt{\{p \times (1-p) / n\}}$	
n from your evidence: _____		
p from your evidence: _____	_____	_____

CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

Is this article useful for this patient population?

15. Can the study results be used in my everyday practice?

☐ Yes ☐ No

Comments: _____

16. Was the follow-up sufficiently long?

☐ Yes ☐ No

Comments: _____

17. Are the results described clinically significant?

☐ Yes ☐ No

Comments: _____

Additional Comments or Notes: _____

Appraisal of Guidelines for Research and Evaluation (AGREE)

AGREE APPRAISAL QUESTIONS

SCOPE AND PURPOSE

-
1. The overall objective(s) of the guidelines is (are) specifically described.
 2. The clinical question(s) covered by the guideline is (are) specifically described.
 3. The patients to whom the guideline is meant to apply are specifically described.

STAKEHOLDER INVOLVEMENT

-
4. The guideline development group includes individuals from all the relevant professional groups.
 5. The patients' views and preferences have been sought.
 6. The target users of the guideline are clearly defined.
 7. The guideline has been piloted among target users.

RIGOUR OF DEVELOPMENT

-
8. Systematic methods were used to search for evidence.
 9. The criteria for selecting the evidence are clearly described.
 10. The methods used for formulating the recommendations are clearly described.
 11. The health benefits, side effects, and risks have been considered in formulating recommendations.
 12. There is an explicit link between the recommendations and the supporting evidence.
 13. The guideline has been externally reviewed by experts prior to its publication.
 14. A procedure for updating the guideline is provided.

CLARITY AND PRESENTATION

-
15. The recommendations are specific and unambiguous.
 16. The different options for management of the condition are clearly presented.
 17. Key recommendations are easily identifiable.
 18. The guideline is supported with tools for application.

APPLICABILITY

-
19. The potential organizational barriers in applying the recommendations have been discussed.
 20. The potential cost implications of applying the recommendations have been considered.
 21. The guideline presents key review criteria for monitoring and/or audit purposes.

EDITORIAL INDEPENDENCE

-
22. The guideline is editorially independent from the funding body.
 23. Conflicts of interest of guideline development members have been recorded.

OVERALL ASSESSMENT

Would you recommend these guidelines for use in practice?

Strongly Recommend

Recommend (with provisos or alterations)

Would not recommend

Unsure

Strongly Agree	4	3	2	1	Strongly Disagree
Comments					

Appendix 5

Health Policy & Clinical Effectiveness Questionnaire and Feedback on Evidence-Based Care Guidelines

In order for us to continually improve our process for the development of Evidence-Based Care Guidelines, we need input regarding our effectiveness and areas in which we can make improvements. We would appreciate your confidential feedback.

Date: _____

Name (optional): _____

Guideline Team: _____

1. Do you feel that your Team accomplished the goals as stated in the Team mission statement?

- ☐ Yes (If yes, skip to #3)
☐ No

2. Possible reasons for not accomplishing goals?

3. Do you have any suggestions as to how your Team could have been more productive?

4. Do you feel that you have received adequate support from Clinical Effectiveness? (Circle one.)

Yes, completely

Somewhat

Not at all

5

4

3

2

1

5. What could Clinical Effectiveness do to be more helpful?

6. Would you be willing to participate in another Evidence-Based Guideline Team?

☐ Yes

☐ No (*see #8*)

7. Reason (*optional*)

8. Do you have any suggestions you would like to have considered in regards to guideline development, implementation or monitoring?

9. Do you have any recommendations for future evidence-based guidelines?

Thank you for taking the time to participate in this survey!

Please return to:

Cincinnati Children's Hospital Medical Center
Center for Health Policy and Clinical Effectiveness:
3333 Burnet Avenue MLC 7014
Cincinnati, OH 45229

OR

Reply by email to:

HPCEInfo@chmcc.org

Appendix 6

Implementation Checklist

Information Dissemination

- ☐ Articles and/or other communication vehicles disseminated to target audiences
Comments: _____

The final EBCG and implementation tools are posted on

- ☐ the intranet
☐ the internet
☐ National Guideline Clearinghouse (NGC)

- ☐ Information for quarterly e-Newsletter sent to Marketing

- ☐ Other: _____

Tool Development

Evidence-based implementation tools

- ☐ Clinical Pathway – Inpatient and/or Emergency Department
☐ Order Set(s) – Inpatient and/or Emergency Department
☐ Algorithm(s) – Emergency Department
☐ Education Record
☐ Discharge Instructions
☐ Patient/Family Pathway
☐ Health Topics
☐ Other: _____

Education Plan

- ☐ Identify specific implementation tool target users, based on guideline target users
☐ Identify specific care settings (units, departments, community)
☐ Plan an implementation schedule (including timeline and content)
☐ Other: _____

Monitoring & Improvement

- ☐ Identify task force, quality improvement Team, and/or data monitoring group
☐ Confirm appropriate outcome measure(s)
☐ Confirm outcome data feedback process to EBCG users
☐ Identify and address improvement opportunities
☐ Resolve or report organizational barriers
☐ Other: _____

Appendix 7

On-going Literature Search for Invalidating Evidence

For the on-going literature searches for invalidating evidence, a time-efficient model is used which varies from the comprehensive search used prior to a full guideline review and revision (See Appendix 1). The time-efficient model is described below (Shekelle, 2001; Gartlehner, 2004). For an algorithm demonstrating the role of the two search process, see the following page.

For the condition of interest the following seven general pediatric journals are searched:

- Arch Dis Child
- Pediatrics
- Arch Pediatr Adolesc Med
- J Peds
- BMJ
- NEJM
- JAMA

and relevant specialty pediatric journals are searched.

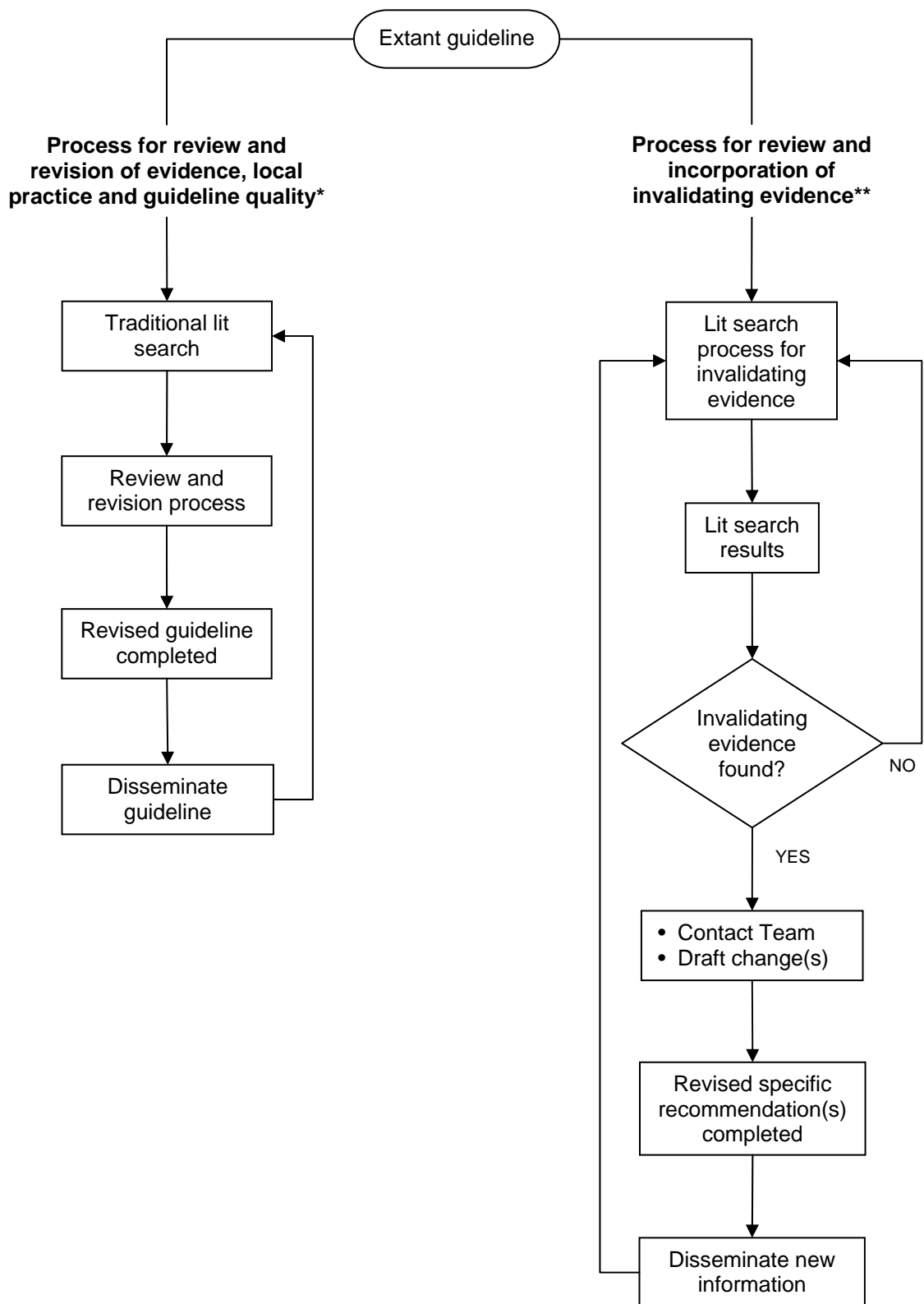
The following articles types are searched for:

- Editorials
- Commentaries
- Letters to the Editor

using keywords for the condition of interest.

References:

1. [Shekelle, P. G.; Ortiz, E.; Rhodes, S.; Morton, S. C.; Eccles, M. P.; Grimshaw, J. M.; and Woolf, S. H.:](#) Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? *JAMA*. 286(12): 1461-7, 2001.
2. [Gartlehner, G.; West, S. L.; Lohr, K. N.; Kahwati, L.; Johnson, J. G.; Harris, R. P.; Whitener, L.; Voisin, C. E.; and Sutton, S.:](#) Assessing the need to update prevention guidelines: a comparison of two methods. *Int J Qual Health Care*. 16(5): 399-406, 2004.



*Cycle time > 1yr.

**Cycle time < 1yr.