Evidence-Based Care Guideline Development Process Manual

7th Edition

Created by the **CCHMC EVIDENCE COLLABORATION**

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Introduction

An Evidence-Based Care Guideline *(EBCG)* is developed to provide an efficient way to share evidence regarding care around a specific condition. An EBCG answers multiple health or clinical questions regarding disease management. Each EBCG is designed to assure evidence is captured through a high-quality process using a standardized format and to provide a resource that informs evidence-based decision making *(EBDM)* at the point of care *(POC) (Appendix 1 EBCG Template, Appendix 2 User Checklist)*. The development process and EBCGs are designed to meet criteria for quality in development of evidence-based care recommendation statements from the National Guideline Clearinghouse *(NGC)* and Appraisal of Guidelines for Research and Evaluation *(AGREE)*.

Possible reasons to develop an EBCG for disease management include, but are not limited to:

- Key patient issues have been identified *(e.g., clinical, safety)*
- The care being provided to a specific patient population may not be based on the best available evidence
- The outcomes for a specific patient population are less than ideal
- There is variation in practice
- There is new evidence to be considered for a product, drug, or device
- There are questions concerning a product, drug, or device currently in use
- Patients/families are dissatisfied with specific care or outcomes
- There are potential benefits to efficiency and cost-effectiveness, if practice is changed
- There is an absence of CCHMC evidence-based documentation that addresses the issue
  (e.g., guidelines, other BESts, policies/procedures, Knowing Notes, or Health topics)
- There is alignment of the identified issues with strategic initiatives with a high likelihood of implementation

Producing and implementing an EBCG requires time and careful consideration of resources. With a manager responsible for budgetary decisions, discuss whether resources are available to support the development and potential implementation and monitoring of the evidence-based practice changes that result from this evidence exploration process.

The development of an EBCG is a rigorous process of evaluating current evidence, which will either validate or suggest a need for changes in current practice. Implementation of the evidence and care recommendations follows development of the EBCG; and it is important to consider implementation throughout the development process. Implementation considerations might include:

- There is enough evidence to support a practice change; if not, consensus has been attained.
- The benefits of and resources required for the practice change outweigh the financial investment.

In order to ensure success and improve outcomes, you must select and engage team members, develop evidence-based care recommendations, identify measures, plan for implementation, and evaluate and monitor the outcomes. Developing evidence statements without a process for use and sustainment may not promote a change in practice.

The maintenance of an EBCG includes ongoing literature search and review of evidence to ensure content validity of the care recommendations. The EBCG may need to be revised when new evidence indicates the need for modification. Team leader responsibilities include EBCG maintenance, unless otherwise delegated to another team member.

At CCHMC, tools for working with a team to identify the EBCG topic, areas for improvement, responsibilities, and expected outcomes may be found at the following webpages:

Quality Improvement Tools *(e.g., key driver diagram, PDSA test cycles)*
Other Resources *(e.g., team charter)*

SELECTION OF TEAM LEADER & MEMBERS

Identification of a multidisciplinary team, including key stakeholders, increases likelihood of successful development and implementation of each EBCG. Benefits include team discovery of new evidence, collaborative solutions for use of new evidence in care/decisions, team perspectives from a variety of disciplines, families, or patients, and reduced bias in recommendation statements.

Multidisciplinary Team

A. Team Leader / Author

1. Identification

a. Has available resources *(e.g., time, commitment, administrative staff)*

b. Possesses skills to guide a team
(e.g., leadership skills, communication skills, organizational skills)

c. Can interface with relevant parties to communicate progress

2. Roles & Responsibilities

a. Identify and disclose personal conflicts of interest

b. Assists in recruiting a development team *(i.e., Stakeholders, Team Members, Patients/Family Members/Parents)* to balance conflicts of interest that may have undue influence on recommendations

c. Keeps process moving and on track

d. Coordinates development of the EBCG

e. Coordinates meetings

f. Maintains the body of evidence through ongoing literature search and review to ensure content validity of the EBCG

- If non-CCHMC staff or students are involved in the development of the EBCG, a CCHMC employee must do the following:
    a. serve as the Team Leader/Author
    b. be actively engaged in the development process
    c. provide oversight throughout the process
    d. function as the point-of-contact with the Evidence Collaboration
    e. be responsible for quality and initial development
    f. be responsible for revision of the EBCG *(see Maintaining the Evidence)*

B. Team Member / Co-Author

1. Identification

a. Meets Content Reviewer Criteria *(See below)*
***PLUS* is involved in the development of the care recommendation**

b. Has available resources
(e.g., time to attend meetings and relay information to constituents, support and commitment from manager for the work required)

c. Has the commitment to complete assignments
(e.g., time and skills for critical appraisal, searching for further evidence, drafting recommendation statements, providing feedback on developing draft)

2. Roles and Responsibilities
    a. Identify and disclose personal conflicts of interest
    b. Completes assignments, such as critical appraisal *(i.e., evidence evaluation)* or drafting recommendation statements
    c. Communicates work to those he/she represents, serving as a representative of colleagues who are not present at meetings
    d. Informs team leadership of unavoidable absences and keep oneself informed of team progress

C. Patient/Family/Parent or Other Parent Representative

1. Identification
    a. Has interest/experience in the clinical topic
    (e.g., parent, patient, family)
    b. Represents a Parent Organization
    (e.g., Family Advisory Council, external parent organizations or foundations, parent support groups)
2. Roles & Responsibilities
    a. Identify and disclose personal conflicts of interest
    b. Verifies topic is of interest for patients/parents
    c. Provides feedback from the patient/parent perspective
    (e.g., adherence, cost, feasibility, generalizability, accuracy, value/attitudes/beliefs)

Other EBCG Development Support

D. Content Reviewers:

1. Identification
    a. Are invested in this topic, questions, issues, or concerns
    (e.g., family members, inter-professional staff, business units, community, researchers, managers or supervisors)
    b. Oversees or provides care or decision making for this population
2. Roles and Responsibilities
    a. Review EBCG for subject matter content
    b. Advise as needed
    c. Identify and disclose personal conflicts of interest

E. Support / Consultant

1. Identification
    a. Anderson Center for Health Systems Excellence – Evidence-Based Decision Making *(EBDM)*
    b. Center for Professional Excellence – Evidence-Based Practice *(EBP)* and Research
    c. Edward L. Pratt Research Library
    d. Others – management, administrative assistants
    – quality improvement coordinators, clinical outcomes managers, data analysts
    – others trained in EBDM

2. Roles & Responsibilities
    a. Identify and disclose personal conflicts of interest
    b. Provide assistance, as needed, to team leader or members
    c. Assist with and/or teach literature search and search methods
    d. Provide expertise in evidence evaluation

CARE RECOMMENDATION DEVELOPMENT PROCESS

Multiple clinical questions and recommendation statements are developed and identified in the EBCG process. The EBCG focuses on a patient group or population for which management decisions are recommended. The EBCG identifies a topic or diagnosis for the EBCG population. In overall disease management EBCG, recommendations may be made to diagnose and/or assess patients, in addition to recommendations made for interventions or therapies.

The development process includes working through the five steps of evidence evaluation:
(Appendix 3 – Overall Process Algorithm)

- **Developing clinical questions *(Step 1)*:**
  The clinical questions identify the patients or population, intervention*(s)*, comparison, and outcome*(s)* which define the criteria for an electronic literature search.
- **Conducting a literature search *(Step 2)*:**
  Systematic searches of the literature are conducted to find all relevant articles for given topics.
- **Evaluating and appraising individual studies/articles *(Step 3)*:**
  Evaluation of the evidence includes critically appraising each study included in the project.
- **Synthesizing the evidence *(Step 4)*:**
  Individual studies are synthesized, describing how the studies relate to the recommendation.
- **Developing care recommendations *(Step 5)*:**
  Care recommendations are developed as answers to the clinical questions, in light of the evidence synthesis and other dimensions, such as health benefits or cost-effectiveness.

The evidence evaluation system developed at CCHMC is known as **LEGEND** *("Let Evidence Guide Every New Decision")* and is found on the EBDM website[1]. The LEGEND system is used at CCHMC for the care recommendation development process, including the evidence appraisal forms, the table of evidence levels, grading a body of evidence, judging the strength of a recommendation, a glossary, and a study design algorithm.

EBDM REVIEW PROCESS

Once the document has been developed, the completed EBCG is submitted for review. Two independent reviewers, trained in EBDM, evaluate the EBCG against a defined set of quality criteria. A completed EBCG is posted both internally *(CenterLink)* and externally *(www.cincinnatichildrens.org/evidence or www.ngc.gov)*.

IMPLEMENTATION AND EVALUATION OF THE RECOMMENDATIONS

Implementation includes identifying how recommendations are put into practice. Involving identified stakeholders in the implementation process will increase the likelihood of success. Implementation will be evaluated and monitored through outcome and process measures *(Conclusion: Putting Evidence into Practice)*.

[1] EBDM website – LEGEND *(CenterLink)*
EBDM website *(CCHMC)*

Evidence-Based Decision Making Steps

Once a topic has been selected for development of an EBCG, multiple clinical questions and recommendation statements are developed and focus on a patient group or population *(e.g., a disease process or condition)* for which management decisions are recommended. Development of each clinical question and related evidence-based care recommendations follows the five evidence-based decision making steps.

STEP 1: DEVELOPING A CLINICAL QUESTION

Identify and refine each clinical question using the PICO format *(Patients/Population, Interventions, Comparisons, and Outcomes of interest)*. Key components of a clinical question define the criteria for a more precise electronic literature search.

Components of a clinical question include the following:

P Patient / Population

Identify the condition-specific group *(Population)* for which outcome improvement is desired.
Some examples of population characteristics may include but are not limited to:

- Age
- Gender
- Disease / Condition
- Care Setting

Example: *Among school-aged children with candy cravings who are studying,*

I Intervention

Identify specific *Intervention* that may affect the desired outcome.
Intervention may be a clinical intervention or a process change.

Example: *does eating peanut M&Ms*

C Comparison

Identify the current clinical practice *(may be no treatment)*.

- Describe current practice, if known by team, based on collective experience.
- Conduct an electronic survey of current practice, if not fully aware of current practices.
- Conduct chart reviews to determine current practice, if other methods are not sufficient.

Example: *compared to plain chocolate M&Ms*

O Outcome

Identify clinical or functional outcomes or results that are desired. *Outcome* is measurable.

Example: *improve homework completion and/or grades?*

Once all components have been identified, the clinical question can be written:

Example: *Among school-aged children with candy cravings who are studying, do peanut M&Ms compared to plain chocolate M&Ms improve homework completion and/or grades?*

Scope of the Clinical Question:

Consider how general or specific the clinical question is.
If the clinical question is too general, the resulting volume of literature may be high, but not necessarily appropriate.
If the clinical question is too narrow, the resulting volume may be too low or nonexistent.

To be submitted for review and posting by CCHMC *(see Review & Posting)*, the EBCG must be developed within the scope of care provided by or in collaboration with CCHMC.

Other versions of the PICO question include PICO(TT) or PICO(TS):

PICOTT:
Population, Interventions, Comparators, Outcomes, Timing, Type of study

PICOTS:
Population, Interventions, Comparators, Outcomes, Timing, Setting

WE HAVE THE CLINICAL QUESTIONS, NOW WHAT?

Once the clinical questions are developed, the team asks whether the questions are important and merit continuing development of care recommendations and possible EBCG.

For each clinical question, the following table may be helpful guidance for the team in these decisions:

Status of the **Evidence Base** and **Our Knowledge** and **Use** of it in **Practice**	**Team Action**
A. If the evidence is sufficient, we all know what the evidence is, and our practice is consistent or standardized…	Let's not spend our limited time on this question; we're doing a pretty good job with this.
B. If at least some of us are aware of some good evidence, but our division doesn't really have it down yet in terms of dissemination to all providers, change in practice, and standardization of care…	It could be helpful to systematically search, appraise and synthesize the evidence, so that we could distill it down into a specific and unambiguous recommendation that we could codify into practice.
C. If there is little to no evidence, but there is credible expert consensus (external and/or internal), and we could agree on recommendations in order to standardize care…	It could be helpful to approve consensus recommendations in order to standardize care.
D. If there is a large body of evidence, but it's not clear how much of it is good evidence and/or whether the results are consistent, and/or there is no good synthesis of this large body of evidence to easily get answers…	**If there is strong interest in the question…** It could be helpful to systematically search, appraise and synthesize the evidence, so that we could distill it down into a specific and unambiguous recommendation that we could codify into practice.
	If there is little interest in the question… Let's not spend our limited time with this question at this point in the process.
E. If there is no evidence and there's a lack of consensus…	With no recommendation to implement, consider research or dissemination of the need for research related to this question.

Proceed to Step 2: Conducting the Literature Search

Refer to the EBDM website for additional information related to this step and other EBDM resources:

CCHMC employees Users not employed by CCHMC

STEP 2: CONDUCTING A LITERATURE SEARCH

For each clinical question, a literature search is conducted. Additional resources for conducting the literature search may be accessed on the EBDM website[2] or via the Edward L. Pratt Research Library, such as personnel, software, databases, or educational workshops.

A. Identify the criteria *a priori* for considering studies for the evidence review
In order to establish the *a priori* criteria, some investigation into what evidence is available is merited. Some *a priori* criteria may be the same for all clinical questions.

1. Types of Studies
   Study designs being considered for inclusion in the systematic review
2. Types of Participants
   Patients/Population(s) which were considered for inclusion in the systematic review
   (What populations were applicable to this review? For example, only pediatric studies were planned for inclusion.)
3. Types of Interventions
   Interventions and Comparisons which were considered for inclusion in the systematic review
4. Types of Outcomes
   Outcomes which were considered for inclusion in the systematic review
5. Exclusion Criteria, if any
   Additional criteria for exclusion that go beyond simply the opposite of the inclusion criteria

B. Using the criteria above and the clinical question*(s)* developed in Step 1,

Identify search terms that may be helpful in conducting the electronic literature search, including the following:

1. Keywords or MeSH Headings
   Use the patient population and/or intervention as keywords to begin the search
   (i.e., Medical Subject Headings; e.g., patient population, setting, intervention).
2. Limits, Filters, and Search Date Parameters
   Limits and/or filters *(e.g., English language, publication dates, ages, etc.)* may assist in focusing the search results.

C. Perform electronic literature searches using search terms identified above.
(Appendix 4 Beyond the Basics Search Techniques, Appendix 5 Constructing a Search Strategy, Appendix 6 Literature Search Algorithm)

1. Databases used for search may include, but are not limited to:
   a. MedLine *(Search engines for MedLine include OVID or PubMed)*
   b. CINAHL
   c. *The Cochrane Library* / Cochrane Database for Systematic Reviews
   d. PsychInfo
2. Relevant CCHMC Evidence-Based Documents should be considered for inclusion in the Evidence Synthesis *(Body of Evidence)*.

   Available CCHMC resources include Evidence-Based Care Recommendations
   Evidence-Based Care Guidelines & Best Evidence Statements (BESt) – www.cincinnatichildrens.org/evidence
3. Clinical Practice Guidelines may also be found on association websites or other sites, including the National Guideline Clearinghouse.

[2] CCHMC employees
Users not employed by CCHMC

4. Search results may be exported/imported into electronic reference manager, such as EndNote or RefWorks.

   For additional help with this item or institutional access to EndNote or RefWorks, if you are a CCHMC employee, refer to these resources from Pratt Library: EndNote or RefWorks

D. Document the Search Strategy on the EBCG template in the Search Strategy table of the appendix *(Appendix 2: Evidence Search Strategy and Results)*, once you know you have the correct searches completed, including the following:

1. Database*(s)*
2. Search Terms
3. Limits, Filters, and Search Date Parameters
4. Date of Most Recent Search

Other Resources *(documented in "Other" row of the Search Strategy table)*:

5. Any solicitation of information from ListServs or other personal correspondence/communication
6. Search results from organizations that provide secondary syntheses
   (e.g., Clinical Evidence, Up-To-Date)
7. Reference list searches
   (e.g., hand-searching of reference lists from related articles)
8. Relevant CCHMC Evidence-Based Documents
   (e.g., Evidence-Based Guidelines, Best Evidence Statements/BESt)

   If CCHMC guidelines or BESts are found and are applicable to this EBCG, include in the Discussion/Synthesis of the Evidence and include the citation in reference list.

E. Reduce search results by discarding duplicates and applying the *a priori* inclusion/exclusion criteria *(defined in section A above)*. Based on the titles and/or abstracts:

1. Discard search results that obviously do not satisfy the *a priori* criteria for inclusion and any results that meet the exclusion criteria
2. Retain search results that may meet inclusion criteria

F. Retrieve full text of articles retained based upon title/abstract review above *(E)*.

G. Apply *a priori* inclusion criteria to the full text articles and retain only the articles that meet the *a priori* criteria.

H. Document the Search Results & Methods in the appendices of the EBCG
(Appendix 2: Evidence Search Strategy and Results)

1. Required documentation
   a. Total number of articles *identified* in database searches and other sources *(See C above)*
   b. Total number of articles meeting the inclusion criteria
      The final number of articles meeting inclusion criteria may be determined after critical appraisal (see Steps 3–4).
2. Optional documentation
   a. Number of articles identified from electronic databases
   b. Number of articles identified from reference lists or hand searches
   c. Number of articles discarded or excluded
      Reasons for discarding:
      - duplicates *(n=#)*
      - does not meet inclusion criteria *(n=#)* or met exclusion criteria *(n=#)*
      - other reasons not identified here
   d. Number of articles reviewed in full text and critically appraised

WE HAVE THE EVIDENCE SEARCH RESULTS, NOW WHAT?

Once the evidence has been found that meets inclusion criteria for the review, the team continues with critical appraisal of the evidence.

<table>
<tr><td colspan="2">For clinical questions with evidence:</td><td>Proceed to Step 3:

Critically Appraising the Individual Studies / Articles</td></tr>
<tr><td rowspan="2">For clinical questions with insufficient evidence for your population:</td><td>The team may want to work on developing a recommendation based on consensus</td><td rowspan="2">Proceed to Step 5: Developing a Care Recommendation

See Step 5. B. 4. Writing Consensus-Based Recommendations</td></tr>
<tr><td>The team may want to suggest further research, if the team is unable to work on developing consensus</td></tr>
</table>

Refer to the EBDM website for additional information related to this step and other EBDM resources:

CCHMC employees Users not employed by CCHMC

STEP 3: APPRAISING AND COMPILING RESULTS OF THE INDIVIDUAL STUDIES / ARTICLES

Evaluation of the evidence includes critically appraising each study you selected as applicable to your clinical questions in step 2.

A. Determine the domain of the clinical question[1]:

Which of the following domains does your PICO/clinical question address?

1. Therapy / Treatment / Prevention / Harm
2. Diagnosis / Assessment
3. Prognosis
4. Meaning / Knowledge, Attitudes, Beliefs *(KAB)*
5. Etiology / Risk Factors
6. Prevalence / Incidence
7. Cost-Analysis / Decision-Analysis

B. For each individual study/article:

1. Determine the study design[3]
2. Choose the relevant Evidence Appraisal Form[4]
3. Read each individual article:
   Use the questions in the top section of the evidence appraisal form as a guide to continue with critical appraisal for each individual article.
   a. Verify that each study helps to answer the clinical question.
   b. If individual studies do not help to answer the clinical question, then critical appraisal of those studies is discontinued.
4. Complete evidence appraisal form for all individual studies that help to answer the clinical question.
   a. Comment fields may be used to highlight methods, results, or conclusions to help with synthesizing the evidence and developing care recommendations in later steps.
   b. Consider how the individual study contributes to the answer for the clinical question and use the "Additional Comments" field to document your conclusions.
   c. These conclusions may be used in later steps of synthesizing the evidence and/or developing the care recommendation statement.
5. Assign the Evidence Level[5] *(abbreviated table at the end of each evidence appraisal form)*

C. Compiling results for comparison of the individual articles

1. The purpose is to have all individual article information meeting the inclusion criteria in one place for comparison of all articles to each other.

[3] LEGEND – Evaluating the Evidence Algorithm
[4] LEGEND – Evidence Appraisal Forms Table
[5] LEGEND – Table of Evidence Levels

2. The columns of an evidence table may include, but are not limited to:
    a. Population *(e.g., Patients, Setting, Sample/Sample Size)*
    b. Intervention / Comparison
    c. Outcomes
    d. Results
    e. Conclusions
    f. Evidence Level
3. Extract information from each article into the Evidence Table of Included Studies.
4. The Evidence Table of Included Studies is documented on the EBCG template in the appendix. *(Appendix 3: Evidence Table of Included Studies)*

WE HAVE THE EVIDENCE APPRAISED, NOW WHAT?

Once the individual studies / articles are appraised, the team synthesizes this evidence.

The evidence synthesis includes articles meeting the inclusion criteria and how they influence the recommendation(s).

Proceed to Step 4: Synthesizing the Evidence

Refer to the EBDM website for additional information related to this step and other EBDM resources:

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STEP 4: SYNTHESIZING THE EVIDENCE

A. The purpose is to synthesize evidence to concisely answer the clinical question.

1. What does the evidence included in the table tell you about the clinical question?
    a. Based on the evidence table of included studies related to the clinical question, discuss themes, concepts, commonalities/similarities, differences, or evidentiary gaps from the articles reviewed and appraised.
    b. This synthesis is not a narrative of each article, but a synthesis of the articles combined forming the "Body of Evidence."
2. How does the evidence inform the clinical question?

B. For each recommendation statement, an evidence synthesis is documented on the EBCG Template as the "Discussion / Synthesis of the Evidence related to the recommendation*(s)*."
(Appendix 5 for each recommendation statement)

1. The evidence synthesis of the Body of Evidence is used to develop a care recommendation for the clinical question.
2. A description of the quality *(including applicability)*, quantity *(including completeness)*, and consistency of the aggregate available evidence. *(See Step 5: Grade for the Body of Evidence)*
3. A description and explanation of any differences of opinion regarding the recommendation.
4. Articles meeting the inclusion criteria should be included in the evidence synthesis, including how these studies influence the recommendation(s).
5. References are cited in the text of the discussion/synthesis with the evidence level included.

WE HAVE THE EVIDENCE SYNTHESIS AND EVIDENCE TABLE, NOW WHAT?

When the evidence has been summarized and synthesized, the team proceeds to the next step to develop a recommendation.

Proceed to Step 5: Developing a Care Recommendation

Refer to the EBDM website for additional information related to this step and other EBDM resources:

CCHMC employees Users not employed by CCHMC

STEP 5: DEVELOPING A CARE RECOMMENDATION

The care recommendations are developed explicitly with the supporting evidence and other dimensions *(below)*, demonstrating how the body of evidence answers the clinical question. Consider the target population in developing the care recommendation.

A. Identify Target Population for the EBCG

- The population *(e.g., patients, public)* to whom the recommendation is meant to apply is specifically described. This includes defining any inclusion or exclusion criteria for the population to which the recommendation statement applies *(e.g., age group, presence/absence of comorbidities, care setting)*.

B. Write the Care Recommendation Statement

1. To be easily identifiable, the recommendation will begin with one of the following phrases reflecting the strength of the recommendation *(based on the dimensions listed in item **C** below)*:

a. It is recommended that …
It is recommended that …not…

b. It is strongly recommended that …
It is strongly recommended that …not…

In order to designate 'strongly recommended,'
review and documentation of the Dimensions are required – see Section C below.

c. There is insufficient evidence and a lack of consensus to make a recommendation on…

Review and document the rationale for the decision of "insufficient evidence and a lack of consensus."

2. Consider the Dimensions *(See section below C. Judge the Strength of the Recommendation)* in development of the recommendation statement.

3. To be specific and unambiguous, the recommendation will include an action verb and state:

a. Who are being addressed *(e.g., which patients / caregivers)*

b. What is being recommended *(e.g., which specific treatment, test, or prognostic marker)*

c. When

d. Where *(e.g., in course of disease/location – home, clinic, ED, hospital bed, ICU)*

4. Document citations for the recommendation at the end of the statement:

a. Examples of formatting citations include:

1. Primary Author, Year, [Evidence Level] *{e.g., (LastName Year [3b])}*

2. Local Consensus, [Evidence Level] *{i.e., (Local Consensus [5])}*

3. APA *(American Psychological Association)* formatted citation ***PLUS*** [Evidence Level]
{e.g., (APA formatted citation [4a])}

b. One effective way to present citations is to order them by ***(1)*** evidence quality level, ***(2)*** year of publication, then ***(3)*** alphabetical by first author. This order presents cited evidence of the highest quality level first and then in order of year and author. If quality levels are low or equal, citations are in order of year and author.

c. If using bibliography software to manage citations, such as EndNote or RefWorks, the reference list will be completed as citations are added to the EBCG Template.
If not, enter references manually, alphabetically by first author, into the References section of the EBCG Template.

d. All citations used in the EBCG are included in the References.

5. To develop recommendations based on local consensus:

a. Local consensus is pursued if the evidence, or lack thereof, falls into one of these categories:

1. Published, appraised articles give inconsistent results
2. Published, appraised articles are not valid, reliable, or applicable for answering the question
3. Insufficient or no evidence was found related to the clinical question

b. Identify all disciplines that may have an impact or effect on the care recommendation.

c. Identify potentially supporting or opposing viewpoints about what recommendation to make.

d. Draft a recommendation statement to begin the consensus process.

e. Elicit input on draft statement from all representing groups, divisions, or disciplines and provide feedback to the development team.

f. Attempt to come to an agreement regarding a recommendation statement.

1. If agreement is reached and appropriate viewpoints were considered, a consensus recommendation is finalized:
"It is recommended that …" or
"It is recommended that …not…"
2. If the team agrees that there is insufficient evidence and lack of consensus to make a care recommendation, then the statement is:
"There is insufficient evidence and lack of consensus to answer the clinical question or make a care recommendation."
3. For a formal consensus process, helpful techniques may include Nominal Group Process or Delphi Technique.

g. Describe the consensus process in the section for Discussion/Synthesis of the Evidence.
(Appendix 5 of EBCG Template)

6. Notes *(as appropriate)*

a. A Note follows and is associated with a recommendation.

b. A Note is sometimes used to:

1. discuss specific evidence related to the recommendation
(e.g., number needed to treat (NNT), data clarifying the recommendation)
2. emphasize key points/issues related to the recommendation
(e.g., safety, harm, applicability, dimensions for judging the strength of a recommendation)
3. mention exceptions to the recommendation

c. References for the notes are cited at the end of the note, as appropriate.

7. Additional Recommendation Statements for each clinical question
    a. For many clinical questions, one recommendation statement is developed.
    b. For some clinical questions, multiple recommendations may be developed from the synthesized evidence. This evidence would help to answer the clinical question, but may cover multiple outcomes and, thus, multiple recommendations.

C. Judge the Strength of the Recommendation Statement

To judge the strength of the recommendation, consider the following dimensions[6]:

1. Body of Evidence *(BOE)*
    a. Individual studies combine to form the BOE *(i.e., the evidence synthesis)* and are used in development of the care recommendation, based upon the synthesis of the evidence.
    b. The BOE addresses the clinical question and is relevant to the recommendation statement.
    c. Grading allows consideration of the quality, quantity, or consistency of the BOE
        1. Quantity: the aggregate of quality ratings for individual studies
        2. Quality: the magnitude of the effect or the numbers of studies
        3. Consistency: the extent to which similar findings are reported using similar and different study designs
    d. Grades of high, moderate, low, or grade-not-assignable[7] are used to describe the quality of the body of evidence. *(A more detailed grade description is provided online – see footnote[2])*
        1. High:
            i. Sufficient number of high-quality studies with consistent results
            ii. Further research is unlikely to change our confidence in the answer to the clinical question
        2. Moderate:
            i. Multiple studies of lesser quality or with inconsistent results OR a single well-done study
            ii. Further research is likely to have an important impact on our confidence in the precision of the answer to the clinical question, and may even change the answer itself
        3. Low:
            i. Expert opinion, case reports, case studies and general reviews
            ii. There is local and/or published consensus, but no research, to answer the clinical question
            iii. Further research is very likely to have an important impact on the answer
        4. Grade-not-assignable:
            i. Insufficient design or execution, too few studies, and inconsistent results
            ii. There is insufficient evidence and lack of consensus to answer the clinical question
    e. If the studies are not easily categorized by quantity, quality and consistency, additional concepts on the LEGEND tool for Grading the BOE are provided to guide the user in determining the grade for the body of evidence.
    f. Using evaluation criteria for determining the BOE grade increases user confidence in the resulting recommendation.

[6] LEGEND – Judging the Strength of a Recommendation
[7] LEGEND – Grade for the Body of Evidence

2. Safety / Harm

   Identify any potential adverse effect*(s)* for the safety or harm of the patient population, if the recommendation is implemented.

   a. Minimal adverse effects
   b. Moderate adverse effects
   c. Serious adverse effects

3. Health benefit to patient

   Identify any potential health benefit*(s)* for the patient population, if the recommendation is implemented.

   a. Significant health benefit
   b. Moderate health benefit
   c. Minimal health benefit

4. Burden on patient to adhere to recommendation

   Identify the potential burden of adherence for the patient population
   (e.g., cost, hassle, discomfort, pain, motivation, ability to adhere, time)

   a. Low burden of adherence
   b. Unable to determine burden of adherence
   c. High burden of adherence

5. Economic impact to healthcare system

   Identify the economic impact to the system, if the recommendation is implemented
   (e.g., balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)

   a. Cost-effective to healthcare system
   b. Inconclusive economic effects
   c. Not cost-effective to healthcare system

6. Directness

   Identify the directness to which the BOE directly answers the clinical question *(PICO)*

   a. Evidence directly relates to the recommendation for this target population
   b. There is some concern about the directness of the evidence as it relates to the recommendation for this target population
   c. Evidence only indirectly relates to the recommendation for this target population

7. Impact on morbidity/mortality or quality of life

   Identify the potential impact on morbidity / mortality or quality of life, if the recommendation is implemented.

   a. High impact on morbidity/mortality or quality of life
   b. Medium impact on morbidity/mortality or quality of life
   c. Low impact on morbidity/mortality or quality of life

D. Complete your dimension review in Appendix 5 of the EBCG template in the table with the Discussion / Synthesis of Evidence related to each recommendation statement*(s)*.
When applicable, provide rationale on the EBCG for judgment and selection of the dimensions, including citations.

WE HAVE THE RECOMMENDATION*(S)* WRITTEN, NOW WHAT?

A. Confirm that the BOE and Recommendation address the Clinical Question.

B. Consider if the BOE and recommendation are compelling enough to make a change and to dedicate resources.

Proceed to Putting Evidence Into Practice

Refer to the EBDM website for additional information related to this step and other EBDM resources:

CCHMC employees Users not employed by CCHMC

Conclusion
Putting Evidence into Practice

Once the BOE is determined and the recommendation is developed you now need to explore whether these are compelling enough to implement. You need to weigh the resources and effort needed for implementation against the outcome which implementation will produce. Considerations regarding the proposed practice change and resources may need to be re-discussed with primary stakeholders.

Rationale for pursuing implementation of the EBCG recommendation*(s)* may include:

- Implementation of the recommendation*(s)* provides an opportunity to improve the desired outcome*(s)* or to decrease variation in practice.
- The strength of the recommendation*(s)* influences support for a change.
- Evidence indicates a need for change.
  (e.g., outcomes for patients, staff, or organization; implementation of new practice or technology; incorporation of innovation; standardizing practice)
- Potential benefits of practice change*(s)* merit short- and long- term costs and investment of resources.
  (e.g., efficient and fiscally responsible use of resources, cost-effectiveness)
- Recommendation*(s)* and evidence remain consistent with priorities established when the project was approved and/or throughout development of the EBCG.
  (e.g., supports current strategic initiatives, unit level resources commitment)
- Implementation of the recommendation*(s)* may improve safety and will not cause harm.
- Barriers can be identified and mitigated to sustain the practice change.

Based on your decision for implementation, complete the **Implementation** section on the EBCG:

A. Applicability & Feasibility Issues *(see example below)*

This section briefly describes items that may positively or negatively impact the successful implementation of the EBCG such as:

1. Define potential facilitators and barriers within the practice setting that may help or hinder the implementation
   (Facilitators – e.g., leadership support, strong evidence)
   (Barriers – e.g., systems not in place, resources not available, baseline data not available, not currently an organizational priority, unfamiliarity with the quality improvement process)
2. Determine potential resource needs
   (e.g., cost, equipment availability, appropriate staff availability)
3. Identify tools or processes which need to be developed, adapted, or revised for incorporation of the recommendation into practice
   (e.g., clinical pathways, order sets, EPIC/EMR, family education materials, Knowing Notes, Health Topics)
   (See Relevant CCHMC Tools for Implementation below)

B. Relevant CCHMC Tools

Available CCHMC resources *(www.cincinnatichildrens.org)* which may need to be updated include:

1. Internal policies and procedures
2. Knowing Notes or Health Topics
   If available, copy and paste the www.cincinnatichildrens.org web address for these items into the BESt.

3. If there are no existing tools for implementation, including a statement such as, "No CCHMC Tools for Implementation were found."

C. Outcome Measures and Process Measures

1. This section briefly describes the desired outcomes resulting from implementation of the EBCG and how the recommendation*(s)* are measured including:
    a. Identify specific outcomes and related processes addressed in the EBCG which may be affected by implementation of the recommendation*(s)*.
        i. Consider outcomes used in the evidence for the recommendation*(s)* *(Cite if applicable)*
        ii. Current/baseline data may be reported in this section, if available.
    b. Think about the rationale for measuring these outcomes or processes.
        i. Why are you measuring the outcome/process?
        ii. What are you trying to change?
        iii. How would you measure the outcome/process?
        iv. How will you know you have improved the outcome/process?
    c. Write the outcome measures and process measures along with the rationale on the EBCG. *(See example below)*
        i. Identify measures that could be used to evaluate the outcomes and processes affected by implementation of the recommendation.
            1. Process measures evaluate the way care is provided. These may include technical *(e.g., procedures, therapies, wait time, cost)* or interpersonal *(e.g., communication, compassion)* processes.[8]
            2. Outcome measures *(e.g., patient satisfaction, health status, illness, injury, rehospitalization, morbidity, mortality, incidence, prevalence)* evaluate the effectiveness of processes that constitute health care delivery. [1]
            3. Consider work flow when choosing outcome measures and process measures to not over-burden clinicians. *(If outcome assessment requires additional monitoring beyond what is already captured in normal work processes, consider using tools that have already been validated to monitor those outcomes, if available.)*
        ii. Include a rationale for choice of each measure *(i.e., outcome and process)*.
2. If no recommendation is made *(e.g., insufficient evidence)*, include a statement such as "This team did not consider outcome or process measures, due to no recommendation being developed."

[8] Singh, D. (2012). Delivering health care in America: A systems approach (5th ed.) Burlington, MA: Jones and Bartlett.

EXAMPLE
Clinical Question:
Among school-aged children with candy cravings who are studying, do peanut M&Ms compared to plain chocolate M&Ms improve homework completion and/or grades?
Recommendation Statement:
It is recommended that a single serving of peanut M&Ms be provided to school-aged children during homework sessions to enhance homework completion and increase grade point average (GPA) *(Hershey 2010 [1a], Charlie 2008 [2a], Chocolate Factory 2009 [2a])*. NOTE: When using M&Ms as a study tool, increasing exercise is encouraged to counteract any concerns for weight gain *(Lelane 1990 [3a], Fonda 1988 [4b], Simmons 2001 [4b])*. NOTE: Effect sizes with plain chocolate M&Ms were small and did not approach significance. However, a similar trend to peanut M&Ms was noted *(Chocolate Factory 2009 [2a])*.
Applicability Statement:
Availability of M&Ms may vary by household and budget. Additionally, implementation may be affected by the child's desire or time to adhere to homework sessions. Consider allergies in the implementation of this recommendation.
Outcome Measure Statement:
For school-aged children, homework completion will be at 90% and GPA will improve by 0.5 points in three months.
Process Measure Statement:
Peanut M&Ms will be included on the weekly household grocery list. During homework sessions, children will receive one serving of peanut M&Ms. Homework completion will be monitored weekly. Grades (GPA) will be monitored quarterly.

RESOURCES AT CCHMC FOR IMPLEMENTATION OF AN EVIDENCE-BASED CARE RECOMMENDATION

CCHMC tools are available: Quality Improvement Tools *(e.g., AIM, KDD, PDSA)*

Other Resources *(e.g., team charter)*

At CCHMC, consultation may be available for strategic initiatives. For needed improvement guidance, contact Clinical Outcomes Managers or Quality Improvement Coordinators *(QIC)*.

Completing Supporting Information

All steps to develop evidence-based care recommendations are done. Remaining items need to be added to complete the EBCG, including the Supporting Information section. Continued use of the User Checklist will guide you through the completion of the EBCG. The EBCG Template, User Checklist, & Reviewer Checklist *(Appendix 1, Appendix 2, Appendix 8)* are adapted from internationally recognized criteria *(AGREE: Appraisal of Guidelines for Research & Evaluation)*.

A. Title

- A good title *(typically less than 12 words long)* will use descriptive terms and phrases that accurately highlight the core content of the EBCG, including all key words and avoiding non-essential words and word repetition.

B. Reference List

- Check all references and citations for evidence levels, formatting, and consistency.
- If using bibliography software to manage citations, such as EndNote or RefWorks, the reference list will be completed as citations are added to the EBCG Template.

  If not, enter references manually, alphabetically by first author, into the References section of the EBCG Template.

C. Background / Purpose of EBCG Development

Background or purpose information includes your rationale for choosing the topic.
These questions may help in developing your rationale:

1. Why was this EBCG developed?
2. Why is this topic important?
3. Is this connected to a strategic initiative or other organizational priority?
4. What needs or issues encouraged pursuing a recommendation for your topic?
5. Who is the target user of the EBCG?
   (e.g., specialty, discipline, primary care, parent, etc.)
6. What brought you to these clinical questions?

D. Definitions

1. Definitions may be useful to provide:
   a. Additional information for the target users
   b. Specialty-specific terms, if appropriate
2. Definitions may be developed based on provider knowledge of the topic or evidence derived from the EBCG development process.
   In the latter case, if citations are used to support definitions, provide an evidence level with the accompanying citation*(s)*.
3. If you choose not to complete this section, then the header can be deleted from the template.

E. Group/Team Members

List members *(including Name, Credentials, Specialty/Area of Expertise)* who participated in the EBCG development or content review, such as:

Multidisciplinary Team

1. Team Leader/Author
2. Team Members/Co-Authors
3. Patient/Family/Parent or Other Parent Organization *(e.g., Family Advisory Council)*

Other EBCG Development Support

4. Ad Hoc Advisors/Content Reviewers *(e.g., internal expert review)*
5. Support Personnel/Consultants

F. Known Conflicts of Interest *(CoI)*

Indicate financial or intellectual conflicts of interest *(Appendix 9)*

1. Group / Team members *(multidisciplinary team and content reviewers/ consultants)* complete and sign CoI forms
2. Check the appropriate boxes and complete stated conflicts, if any:
    a. "No financial or intellectual conflicts of interest were found."
    b. "*{State found conflicts.}*"
3. CoI forms are submitted with the EBCG and archived with the EBCG.

Reviewing and Posting the EBCG

A. User Review & the User Checklist

1. Review your EBCG, using established criteria included in the User Checklist *(Appendix 2)*.
2. Peer, consultant, or other stakeholder review (e.g., EBP mentor, Anderson Center consultant, support personnel) of the EBCG prior to submission is recommended. List those who give feedback as Content Reviewers.
3. Verify format and style are consistent and professional throughout the EBCG, including but not limited to:
   - **a.** Conducting spell check on the document text
   - **b.** Defining acronyms the first time used in text
   - **c.** Numbering tables, figures, and appendices in the order of appearance in text
   - **d.** Assuring that journal names are consistently used in the references
     (e.g., use either the full name or the abbreviation for all references)
   - **e.** Choose a consistent reference style for all citations in the text and all references in the reference list
     *(e.g., APA formatted citation or EBDM format (i.e., AuthorLastName Year) **PLUS** Evidence Level (i.e., [#a/b]))*
4. Submit your EBCG for Evidence Collaboration Review to EBDMinfo@cchmc.org.

B. Evidence Collaboration Review Process & the Reviewer Checklist

1. The EBCG will be reviewed by two independent Evidence Collaboration Reviewers, using established criteria included in the Reviewer Checklist *(Appendix 8)*.
2. Reviewers commonly suggest improvements to the EBCG draft. Some changes are required to pass the review process.
3. Team members are expected to remain engaged during this process to assist with any revisions. The review process may require multiple iterations of revision.
4. If changes are ***not*** made based on reviewer comments/suggestions, please respond with how those comments/suggestions were considered *(e.g., using Comments or other means)*
5. Failure to meet established criteria may result in rejection of the EBCG. These two conditions would need to be met in order for a EBCG to be rejected:
   a. One or more of the following three circumstances is true:
      - Author has not demonstrated substantial improvement toward meeting checklist criteria.
      - EBCG has failed fourth review *(i.e. the reviewers are seeing the document for the fourth time)*. Warning was provided at third review that substantial improvement must be made.
      - Six months since latest submission

   AND

   b. Combined agreement of the reviewers as to whether there is good reason to reject, instead of working toward a final product.

   Authors may decide at any point in the review process to withdraw the EBCG from consideration for approval.

6. Once the review process is completed, the Team Leader will be notified that the EBCG is approved.

C. External Review Process *(Future process to be added)*

D. Posting Process

1. The Evidence Collaboration's Information and Knowledge Management group will categorize the EBCG, once approved for posting *(i.e., topic, discipline/specialty, and type of guidance)*.
2. Authors will be provided with a final page proof of the EBCG to review prior to posting.
3. The EBCG is posted on:
   a. Cincinnati Children's website *(www.cincinnatichildrens.org/evidence)*
   b. Agency for Healthcare Research and Quality *(AHRQ)*
      – National Guideline Clearinghouse *(NGC - www.ngc.gov)*
      (The NGC may not accept EBCGs which do not meet established criteria.)

Refer to the EBDM website for additional information related to this step and other EBDM resources:

CCHMC employees Users not employed by CCHMC

Maintaining the Body of Evidence & Revising the EBCG

Peer-reviewed literature should be monitored regularly to identify the emergence of new, potentially relevant evidence and to evaluate the continued validity of the EBCG. If a EBCG is not revised at the end of ***five years*** from the date of posting, it will expire and be removed from all sites *(Refer to posting section)*.

The team leader is responsible for maintaining the body of evidence and keeping the EBCG up-to-date. A EBCG may be revised at any time, if the team finds new evidence. Revising a EBCG follows the same process as EBCG development, including review and posting of the EBCG. When revising a EBCG, always use the newest template *(CenterLink EBDM)*.

A. Ongoing Literature Search and Review

1. Searching for new evidence related to the EBCG may occur on a regular basis.

- **a.** Frequency of searches may be determined by the:
  - **i.** volume of new articles published related to the clinical question/topic
  - **ii.** amount of time available to review new evidence
  - **iii.** available team members to "share" the evidence review process
- **b.** The evidence review may be triggered by a seminal study.
- **c.** Automatic searches may also be set up in the search engines *(e.g., Ovid, PubMed, EBSCO)* to send notification of newly published articles related to the clinical question via email or RSS feed *(Really Simple Syndication)*.
  Help sections of search engines provide direction in setting up automatic searches.
  If you are a CCHMC employee, the Edward L. Pratt Research Library may provide additional help with this item.

2. Review titles and abstracts in the search results for references that are relevant to the clinical question *(See the EBDM Step 2 section)*

3. If *NO* new evidence found:

- **a.** Update the following in the EBCG and resubmit:
  - **i.** Search dates in the Search Strategy section
  - **ii.** Review History table *(see B. Review History below)*
- **b.** If searches are more frequent with no new evidence, updates may be submitted annually.
- **c.** The EBCG would be reposted following a Publication Review Process.

4. If new evidence is found and related to the clinical question/topic:

- **a.** Repeat the evidence evaluation process *(Repeat Steps 3 through 5)*
- **b.** Determine action, if any, related to the recommendation*(s)* and EBCG
  - **i.** Does the evidence support the recommendation*(s)*?
    If so, add references and update the discussion/synthesis with the new evidence
  - **ii.** Is there invalidating evidence that would change the recommendation*(s)*?
    If so, revise the recommendation statement*(s)* and the EBCG

B. Review History

Once a EBCG is complete, the original publication date is included in the EBCG Review History table at the end of the EBCG by the author. An ongoing evidence review is necessary to maintain currency of evidence and the recommendation statement*(s)*. Review history events are inserted as a new row in the table, ordering them with the most recent event as the top row. Each entry provides publication dates, events, and outcomes of the events.

If there are changes to a clinical question, the EBCG should be revised.

Review history events include:

1. Original Publication
    - **a.** The first publication date of the EBCG will be included in the Review History table. For the original EBCG, this date will match the date on the first page of the EBCG and be the only entry in the table.
    - **b.** The Outcome would be described as – New EBCG developed and published.
2. Subsequent Events
    - **a.** Literature Search

      Outcomes
        - **i.** No new evidence found.
        - **ii.** New evidence with no recommendation change.
        - **iii.** New evidence with recommendation change.
    - **b.** Amendment *(Edits not as a result of a literature search)*

      Outcomes
        - **i.** Health topic or other implementation tool added.
        - **ii.** Format changes made.
        - **iii.** Outcome Measures changed *(and/or)* Process Measures changed.
        - **iv.** New team members added.
        - **v.** Other changes not altering the recommendation or evidence. *(Please provide description)*

C. Reviewing and Posting a Revised EBCG *(EBCG Manual: Conclusion – Reviewing and Posting the EBCG)*

1. If new evidence was found and changes were made to the recommendation*(s)*, then the revised EBCG will be submitted for Checklist Review.
2. If new evidence was found and changes were not made to the recommendation*(s)*, then the revised EBCG will be submitted for Checklist Review.
3. If no new evidence was found, then the revised EBCG will be submitted for Publication Review.

Refer to the EBDM website for additional information related to this and other EBDM resources:

CCHMC employees Users not employed by CCHMC

Appendix 1
Evidence-Based Care Guideline (EBCG) Template

Date

Evidence-Based Clinical Care Guideline for *Management of…* [1]

Definitions *for terms marked with * and an* ***Abbreviations*** *list may be found in Appendix 1.*

Target Population for the Recommendations

Inclusions:

-

Exclusions:

-

Target Users for the Recommendations

Target users include, but are not limited to,:

- Clinicians caring for inpatients / outpatients
- Emergency Medicine Physicians
- Primary Care Providers
- Residents
- Patient Care Staff, including:
  - nurse practitioners
  - nurses
  - allied health
  -
- Patients and families
- Community-based caregivers (e.g. daycare, school personnel)
-
-

Guideline Recommendations

Click on the **{Evidence & Dimensions}** *hyperlink for Discussion/Synthesis of the Evidence and Table for Dimensions for Judging Recommendation Strength related to individual recommendation statements.*

Assessment and Diagnosis

Clinical Assessment

1. **It is recommended …*(AuthorLastName Year [Level])*.**

   Note 1: Text …*(Arnott 2003 [2a])*.

[1] Please cite as: Name of Team / Authors (Year). Cincinnati Children's Hospital Medical Center: Evidence-based clinical care guideline for title. http://www.cincinnatichildrens.org/svc/alpha/h/health-policy/ev-based /title.htm, Guideline number, pages 1-number, *hyperlink the document*.

Note 2:

{Evidence & Dimensions}

2. **It is recommended …*(Local Consensus [5])*.**

{Evidence & Dimensions}

Laboratory Studies

3. **It is recommended …*(AuthorLastName Year [Level])*.**

Note:

{Evidence & Dimensions}

Radiology Studies

4. **It is recommended …***(Hoberman 2003 [2a])*.

{Evidence & Dimensions}

Management Recommendations

Medications

5. **It is recommended…** *(Colombel 2000 [3a], Baert 2003 [4b])*.

{Evidence & Dimensions}

Table 1: Name of Table

Admission Criteria

6. **It is recommended…**

{Evidence & Dimensions}

Discharge Criteria

7. **It is recommended…**

{Evidence & Dimensions}

Monitoring

8. **It is recommended …**

{Evidence & Dimensions}

Follow up

9. **It is recommended …**

   {Evidence & Dimensions}

Other Therapy

10. **It is recommended …**

    {Evidence & Dimensions}

Consults and Referrals

11. **It is recommended …**

    {Evidence & Dimensions}

Education

12. **It is recommended …**

    {Evidence & Dimensions}

Health Topics on Cincinnati Children's website[2]:

- Name of Health Topic(s)

[2] Cincinnati Children's Health Topic website: www.cincinnatichildrens.org/health/info

Algorithm for …

References

*Evidence Level in [ ], Table of Evidence Levels in **Appendix 4***

1. **Arnott, I. D.; McNeill, G.; and Satsangi, J.:** An analysis of factors influencing short-term and sustained response to infliximab treatment for Crohn's disease. *Aliment Pharmacol Ther,* 17(12): 1451-7, 2003, *[2a]* _____**E** _____.
2. **Baert, F.; Noman, M.; Vermeire, S.; Van Assche, G.; G, D. H.; Carbonez, A.; and Rutgeerts, P.:** Influence of immunogenicity on the long-term efficacy of infliximab in Crohn's disease. *N Engl J Med,* 348(7): 601-8, 2003, *[4b]* _____**E** _____.
3. **Colombel, J. F. et al.:** Genotypic analysis of thiopurine S-methyltransferase in patients with Crohn's disease and severe myelosuppression during azathioprine therapy. *Gastroenterology,* 118(6): 1025-30, 2000, *[3a]* _____ **E** _____.
4. **Hoberman, A.; Charron, M.; Hickey, R. W.; Baskin, M.; Kearney, D. H.; and Wald, E. R.:** Imaging studies after a first febrile urinary tract infection in young children. *N Engl J Med,* 348(3): 195-202, 2003, *[2a]* _____ **E** _____.
5. **Local Consensus:** During guideline development timeframe. *[5]*.

Appendices

Appendix 1
Background, Objectives, and Definitions/Abbreviations

Background / Purpose of Guideline Development

Discuss prevalence, etiology, cost of care (US), descriptive or general information, etc.

Challenges in the management of … include: …

Objectives

The objectives of this guideline are to:

- improve …
-

Definitions

Term*(s)* and definition*(s)*

Abbreviations *(if any)*

Abbreviation*(s)* and *Description(s)*

Clinical Questions *(in PICO format)*

In children aged …

I	*(Intervention)*	
C	*(Comparison)*	
O	*(Outcome)*	

I	*(Intervention)*	
C	*(Comparison)*	
O	*(Outcome)*	

D	*(Diagnostic Test)*	
C	*(Comparison)*	
O	*(Outcome)*	

P	*(Prevention)*	
C	*(Comparison)*	
O	*(Outcome)*	

Appendix 2
Evidence Search Strategy and Results

Clinical Question: Clinical question

Criteria for considering studies for this review

Types of Studies	Study designs which were considered for inclusion in the systematic review
Types of Participants	Patients/Population(s) which were considered for inclusion in the systematic review *(What populations were applicable to this review? For example, only pediatric studies were planned for inclusion.)*
Types of Interventions	Interventions and Comparisons which were considered for inclusion in the systematic review
Types of Outcomes	Outcomes which were considered for inclusion in the systematic review
Exclusion Criteria, if any	Additional criteria for exclusion that go beyond simply the opposite of the inclusion criteria

Search Strategy

Search Methods

To select evidence for critical appraisal by the group for this guideline, the databases below were searched using search terms, limits, filters, and date parameters to generate an unrefined, "combined evidence" database. This search strategy focused on answering clinical questions relevant to condition and employing a combination of Boolean searching and "natural language" searching on human-indexed thesaurus terms as well as "natural language" searching on words in the title, abstract, and indexing terms.

Search Databases	Search Terms	Limits, Filters, & Search Date Parameters	Date of Most Recent Search
☐ MedLine via PubMed or Ovid	• X • X	Publication Dates or Search Dates: • mm/yyyy to mm/yyyy ☐ English Language ☐ Pediatric Evidence Only: • X ☐ Other Limits or Filters: • X	mm/dd/yyyy
☐ CINAHL	• X	Publication Dates or Search Dates: • mm/yyyy to mm/yyyy ☐ English Language ☐ Pediatric Evidence Only: • X ☐ Other: • X	mm/dd/yyyy
☐ Cochrane Database for Systematic Reviews	• X	Publication Dates or Search Dates: • mm/yyyy to mm/yyyy ☐ English Language ☐ Pediatric Evidence Only: • X ☐ Other: • X	mm/dd/yyyy
☐ PsychInfo	• X	Publication Dates or Search Dates: • mm/yyyy to mm/yyyy ☐ English Language ☐ Pediatric Evidence Only: • X ☐ Other: • X	mm/dd/yyyy
☐ Other:	• X	Publication Dates or Search Dates: • mm/yyyy to mm/yyyy ☐ English Language	mm/dd/yyyy

		☐ Pediatric Evidence Only: • X	
		☐ Other: • X	

Search Results

The citations were reduced by: eliminating duplicates, review articles, non-English articles, and adult articles (e.g., limits/filters above). The resulting abstracts and full text articles were reviewed by a methodologist to eliminate low quality and irrelevant citations or articles. During the course of the guideline development, additional articles were identified from subsequent refining searches for evidence, clinical questions added to the guideline and subjected to the search process, and hand searching of reference lists. The dates of the most recent searches are provided above.

The initial search for evidence identified ### articles.
articles met the inclusion criteria above.

The following optional Information may be inserted above to account for the articles identified in the search:

articles were discarded, as they were duplicates (n=###) or not related to the clinical question of interest based on title (n=###) and abstract (n=###) review.
articles were reviewed in full text and critically appraised. ### articles were excluded/discarded for the following reasons: XXX (n=###), XXX (n=###), XXX (n=###), or XXX (n=###).

Appendix 3
Evidence Table of Included Articles
(i.e., articles meeting inclusion criteria)

PER CLINICAL QUESTION						
First Author & Year	Column Title	Column Title	Column Title	Column Title	Column Title	Evidence Level

Appendix 4
LEGEND Evidence Evaluation System
(Let Evidence Guide Every New Decision)

Full tables of the LEGEND evidence evaluation system are available in separate documents:

- Table of Evidence Levels of Individual Studies by Domain, Study Design, & Quality *(abbreviated table below)*
- Grading a Body of Evidence to Answer a Clinical Question
- Judging the Strength of a Recommendation *(Appendix 5 – Dimensions and Rationale)*

Table of Evidence Levels *(see link above for full table)*:

Quality level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Table of Grade for the Body of Evidence *(see link above for full table)*:

Grade	Definition
High	Sufficient number of high quality studies with consistent* results
Moderate	A single well-done study or Multiple studies of lesser quality or with some uncertainty
Low	Studies with insufficient quality including case reports, case studies, general reviews, and local consensus

Table of Language and Definitions for Recommendation Strength *(see link above for full table)*:

Language for Strength	Definition
It is strongly recommended that… It is strongly recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens. (or visa-versa for negative recommendations)
It is recommended that… It is recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.
There is insufficient evidence and a lack of consensus to make a recommendation…	

Appendix 5
Discussion/Synthesis of the Evidence and Tables of Dimensions for Judging Recommendation Strength by Recommendations

Given the dimensions below for each recommendation and that more answers to the left of the scales indicate support for a stronger recommendation, the recommendation statements reflect the strength of each recommendation as judged by the development group. *(Note that for negative recommendations, the left/right logic may be reversed for one or more dimensions.)*

Recommendation 1

Discussion/Synthesis of the Evidence			
Evidence discussion/synthesis text here.			
Dimensions of Judging the Recommendation Strength			
1. Grade of the Body of Evidence	☐ High	☐ Moderate	☐ Low
Rationale:			
2. Safety / Harm (Side Effects and Risks)	☐ Minimal	☐ Moderate	☐ Serious
Rationale:			
3. Health benefit to patient	☐ Significant	☐ Moderate	☐ Minimal
Rationale:			
4. Burden to adhere to recommendation	☐ Low	☐ Unable to determine	☐ High
Rationale:			
5. Cost-effectiveness to healthcare system	☐ Cost-effective	☐ Inconclusive	☐ Not cost-effective
Rationale:			
6. Directness of the evidence for this target population	☐ Directly relates	☐ Some concern of directness	☐ Indirectly relates
Rationale:			
7. Impact on morbidity/mortality or quality of life	☐ High	☐ Medium	☐ Low
Rationale:			

Recommendation 2

Discussion/Synthesis of the Evidence			
Evidence discussion/synthesis text here.			
Dimensions of Judging the Recommendation Strength			
1. Grade of the Body of Evidence	☐ High	☐ Moderate	☐ Low
Rationale:			
2. Safety / Harm (Side Effects and Risks)	☐ Minimal	☐ Moderate	☐ Serious
Rationale:			

3. Health benefit to patient	☐ Significant	☐ Moderate	☐ Minimal
Rationale:			
4. Burden to adhere to recommendation	☐ Low	☐ Unable to determine	☐ High
Rationale:			
5. Cost-effectiveness to healthcare system	☐ Cost-effective	☐ Inconclusive	☐ Not cost-effective
Rationale:			
6. Directness of the evidence for this target population	☐ Directly relates	☐ Some concern of directness	☐ Indirectly relates
Rationale:			
7. Impact on morbidity/mortality or quality of life	☐ High	☐ Medium	☐ Low
Rationale:			

Recommendation 3

Discussion/Synthesis of the Evidence			
Evidence discussion/synthesis text here.			
Dimensions of Judging the Recommendation Strength			
1. Grade of the Body of Evidence	☐ High	☐ Moderate	☐ Low
Rationale:			
2. Safety / Harm (Side Effects and Risks)	☐ Minimal	☐ Moderate	☐ Serious
Rationale:			
3. Health benefit to patient	☐ Significant	☐ Moderate	☐ Minimal
Rationale:			
4. Burden to adhere to recommendation	☐ Low	☐ Unable to determine	☐ High
Rationale:			
5. Cost-effectiveness to healthcare system	☐ Cost-effective	☐ Inconclusive	☐ Not cost-effective
Rationale:			
6. Directness of the evidence for this target population	☐ Directly relates	☐ Some concern of directness	☐ Indirectly relates
Rationale:			
7. Impact on morbidity/mortality or quality of life	☐ High	☐ Medium	☐ Low
Rationale:			

Additional tables would be included for each recommendation statement.

Appendix 6
Implementation

Applicability & Feasibility Issues

Relevant Cincinnati Children's Tools

Policies, Procedures, Knowing Notes, or Health Topics OR None were found.

Outcome Measures and Process Measures

Appendix 7
Future Research Agenda

1. In children…
2. In children…
3. In children…

Appendix 8
Team Members & Conflicts of Interest

Multidisciplinary Team Members

Team Leader/Author/Chair:

Firstname Lastname, Credentials, Specialty/Area of Expertise

Team Members/Co-Authors:

Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Organization/Hospital (if other than Cincinnati Children's)

Patient/Family/Parent or Other Parent Organization:

Firstname Lastname, Parent/Parent Organization

Other BESt Development Support

Content Reviewers:

Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Chair of Division/Dept, MD/DO, Department or Division, Cincinnati Children's Hospital Medical Center
Chair of other relevant Division/Dept, MD/DO, Department or Division, Cincinnati Children's Hospital Medical Center
Kimberly Collins, Medical Education (if CME was offered)

Support/Consultants:

Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center
Firstname Lastname, Credentials, Specialty/Area of Expertise, Cincinnati Children's Hospital Medical Center

Conflicts of Interest were declared for each team member and:

☐ No financial or intellectual conflicts of interest were found.
☐ The following conflicts of interest were disclosed:
Firstname Lastname – State found conflicts.
Firstname Lastname – State found conflicts.
Firstname Lastname – State found conflicts.

The guideline was developed without external funding.
Conflict of interest declaration forms are filed with the Cincinnati Children's EBDM group.

Appendix 9
Evidence-Based Clinical Care Recommendation Development Process

The process by which this guideline was developed is documented in the Guideline Development Process Manual; relevant development materials are kept electronically. The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic search and critical appraisal of the literature, using the Table of Evidence Levels described with the references and in Appendix 4, and examined current local clinical practices. The guideline has been reviewed and approved by clinical experts not involved in the development process. The guideline has also been distributed to leadership and other parties as appropriate.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference, and clinical expertise. During formulation of these recommendations, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

Review Process

This guideline has been reviewed against quality criteria by two independent reviewers from the Cincinnati Children's Evidence Collaboration.

If the guideline was not externally appraised using the AGREE II criteria, delete the following sentence, list and percentages.

The guideline was also externally appraised by three independent reviewers using the AGREE instrument *(Appraisal of Guidelines for Research and Evaluation)* and the results by domain are:

- Scope and Purpose XXX%
- Stakeholder Involvement XXX%
- Rigor of Development XXX%
- Clarity and Presentation XXX%
- Applicability XXX%
- Editorial Independence XXX%

Revision Process

The guideline will be removed from the Cincinnati Children's website, if content has not been revised within five years from the most recent publication date. A revision of the guideline may be initiated at any point within the five year period that evidence indicates a critical change is needed. Team members reconvene to explore the continued validity and need of the guideline.

If this is the initial development of the guideline, delete the following paragraph. If this is a revision, please include:

The most recent details for the search strategy, results, and review are documented in this guideline. Details of previous review strategies are not documented. However, all previous citations and content were reviewed for appropriateness to this revision Experience with the implementation and monitoring of earlier publications of this guideline has provided learnings which have also been incorporated into this revision.

Review History

Date	*Event*	*Outcome*
	Original Publication	New guideline developed and published

Permission to Use the Guideline

This Evidence-Based Care Guideline (EBCG) and any related implementation tools (if applicable, e.g., screening tools, algorithms, etc.) are available online and may be distributed by any organization for the global purpose of improving child health outcomes.

Website address: http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/recommendations/default/

Examples of approved uses of the EBCG include the following:

- copies may be provided to anyone involved in the organization's (outside of Cincinnati Children's) process for developing and implementing evidence-based care guidelines;
- hyperlinks to the Cincinnati Children's website may be placed on the organization's website;
- the EBCG may be adopted or adapted for use within the organization, provided that Cincinnati Children's receives appropriate attribution on all written or electronic documents; and
- copies may be provided to patients and the clinicians who manage their care.

Notification to Cincinnati Children's (EBDMInfo@cchmc.org) is appreciated for all uses of any EBCG or its companion documents which are adopted, adapted, implemented, or hyperlinked.

Please cite as:

Name of Team / Authors (Year). Cincinnati Children's Hospital Medical Center: Evidence-based clinical care guideline for title. http://www.cincinnatichildrens.org/service/j/anderson-center/evidence-based-care/recommendations/default/, Guideline number, pages 1-number, *hyperlink the document*.

For more information:

About this guideline, its companion documents, or the Cincinnati Children's Evidence-Based Care Recommendation Development process, contact the CINCINNATI CHILDREN'S's Evidence Collaboration at EBDMinfo@cchmc.org.

Note/Disclaimer

These recommendations result from review of literature and practices current at the time of their formulations. This guideline does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this guideline is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Appendix 2
User Checklist

for developing and posting of a EBCG

EBCG Title: _____

Check each box, once item has been completed on the EBCG Template.

☐ Title succinctly describes the topic.
[EBCG Manual: Conclusion – Completing the Supporting Information (page 23)]

☐ Target Population is defined.
[EBCG Manual: Step 5 (page 15)]

☐ Target Users are clearly defined.

☐ Recommendation*(s)* is*(are)* adequately specific and actionable.
- *Notes are used to add clarity to the recommendation(s), if applicable.*

[EBCG Manual: Step 5 (page 15)]

☐ Citations are included with the recommendation*(s)* and note*(s)*.
[EBCG Manual: Step 5 (page 15)]

☐ Recommendation*(s)* is*(are)* easily identifiable and begin*(s)* with the appropriate recommendation phrase to signify the strength of the recommendation.
[EBCG Manual: Step 5 (page 15)]

☐ Reference List is complete and references/citations are consistently formatted.
[EBCG Manual: Step 5 (page 15)]

☐ All citations have been assigned a quality level, and level legend is present.
[EBCG Manual: Step 3 (page 12)]

Appendices

☐ The Background or Purpose of EBCG Development provides rationale for choosing the topic.
[EBCG Manual: Conclusion – Completing the Supporting Information (page 23)]

☐ Definitions provided as appropriate.
- *Mark any terms included in this section with an asterisk (*) where first used in the Clinical Question (PICO).*

[EBCG Manual: Conclusion – Completing the Supporting Information (page 23)]

☐ Clinical question/s is/are presented in PICO format as a question.
[EBCG Manual: Step 1 (page 7)]

☐ Systematic search strategy and results are documented.
[EBCG Manual: Step 2 (page 9)]

☐ The Evidence Table of Included Articles is provided.
[EBCG Manual: Step 3 (page 12)]

☐ Discussion/Synthesis of Evidence demonstrates how the Body of Evidence informs the Clinical Question.
[EBCG Manual: Step 4 (page 14)]

☐ Discussion of the quality, quantity, and consistency of the Body of Evidence is included.
[EBCG Manual: Step 4 (page 14)]

☐ The supporting evidence is relevant to the recommendation statement(s).
[EBCG Manual: Step 4 (page 14)]

☐ Dimensions for judging the strength of a recommendation have been appropriately considered, including Body of Evidence, health benefits, side-effects, risks, and others.
[EBCG Manual: Step 5 (page 15)]

☐ Team member*(s)*, including credentials, specialty and/or area of expertise is present, with a CCHMC employee listed as Team Leader/Author.
[EBCG Manual: Conclusion – Completing the Supporting Information (page 24); Introduction (page 4)]

☐ Known Conflicts of Interest are declared by each team member.
*[EBCG Manual: Conclusion – Completing the Supporting Information (Conflict of Interest) (page 24) and **Conflict of Interest** form]*

Implementation

☐ The potential resource implications of applying the recommendation(s) have been considered.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]

☐ Processes or tools have been identified which need to be developed, adapted, or revised for incorporation of the recommendation into practice.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]

☐ Relevant CCHMC Tools are identified *(if any)*.
- *If no documents, then "None were found." under that section title.*

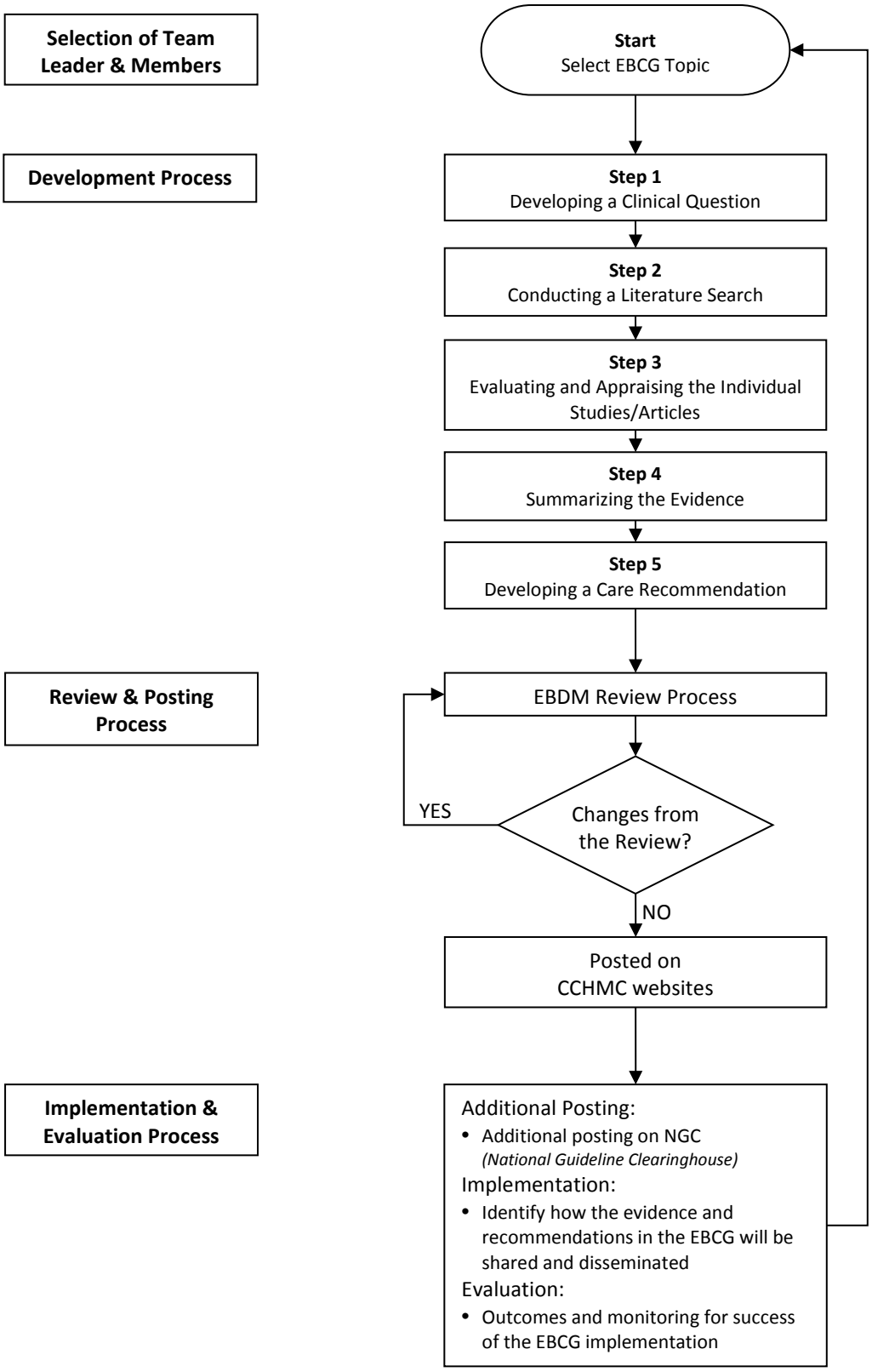
[EBCG Manual: Step 2 (page 20)]

☐ Outcome Measures and Process Measures are identified with the rationale for each measure.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Outcome Measures and Process Measures) (page 21)]

Submit completed EBCG and User checklist to EBDMinfo@cchmc.org for quality review/posting by Evidence Collaboration.

Appendix 3
Overall Process Algorithm



Appendix 4
Beyond the Basics
Six Rules of Thumb to Improve Literature Search Success and Efficiency

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the topic being reviewed or developed. The search strategy may be revised to improve the output as needed.

RULES OF THUMB	NOTES
Search only one database at a time.	Because of differences in database design, one search strategy does not necessarily work for all databases. A possible exception is text-word-only searches, but even this is problematical in full-text databases like Cochrane's DSR.
Use MeSH (Medical Subject Headings).	Because it is a controlled vocabulary applied by indexers on the basis of the actual content of the article, the MeSH terms describe the article and cover vagaries of the language better than text words and are, therefore, more reliable.
	MeSH is available for MEDLINE and CINAHL searches, but not (or only partially) for Cochrane searches.
	MM is available for EBSCO / CINAHL searches.
Limit Cochrane searches to titles, abstracts, and keywords.	Because Cochrane doesn't use a controlled vocabulary, and also because of the comprehensive description of everything included and excluded for the systematic review, a search of the complete document gives an undesirably high proportion of irrelevant citations.
Use Clinical Queries.	Clinical Queries is a study design filter by domain.
Use the age limit filters.	Though these filters generally work better than text words, one disadvantage of this rule of thumb is that an age group which includes adolescents will include adult articles which have one or more adolescents in the study population.
	Text words can be additionally used, if further filtering is needed. When using text words, use all relevant permutations: • infan$ or infan* • child$ or child* • pediatr$ or pediatr* • paediatr$ or paediatr* • neonat$ or neonat* • teen$ or teen* • adolesc$ or adolesc*
Understand and use Boolean search operators.	To keep it simple, use one type of operator per search and combine the search results thereafter. *[and, or, not]*

Appendix 5
Constructing a Search Strategy

Define the information need and state it in words as a question:

Expressing your information problem in words forces you to think about what you need and determine terms you will use in subsequent steps. For clinical questions remember the elements represented by the mnemonic device:

PICO (**P**opulation, **I**ntervention, **C**omparison, **O**utcome)

- *For example:*
  Among infants with cleft lip, are some feeding techniques or equipment more successful than others in providing necessary nutrition?

Break down the need into its component parts:

Extract the important concepts or keywords from the question.

- *For example:*
  Using the question formulated above, the components are "cleft lip" and "feeding techniques or equipment" and "infants."

Identify synonyms for each concept:

Consult the thesaurus or vocabulary list for controlled vocabulary terms (subject headings or descriptors).
The Medline thesaurus is called Medical Subject Headings or MeSH.

Consider whether a general term or a more specific term is appropriate.

- *For example: Would "bottle feeding" be more appropriate than the general term "feeding methods?"*

Often it is wise to use both controlled vocabulary terms and text words *(words used by the author in the title or abstract of an article)*, and then combine the results of both searches.

Some concepts can be identified as specific aspects of primary concepts. They do not stand alone as search terms.

- *For example: Diagnosis, therapy, and etiology are aspects of a disease or condition.*
  These aspects are best searched in Medline by applying subheading(s) to the primary search term.

Construct logical relationships between concepts:

The logical connectors are "AND," "OR," and "NOT."

- "**AND**" is used to connect terms that must both be in a record. "AND" narrows a search. Each time you add a term using "AND" you have narrowed the search another step.
- "**NOT**" is another way to narrow a search. "NOT" is used to eliminate records containing a given term.
- "**OR**" is used to connect or group synonyms. "OR" broadens a search.

Only one of the terms specified must be present in the record for a record to be selected.

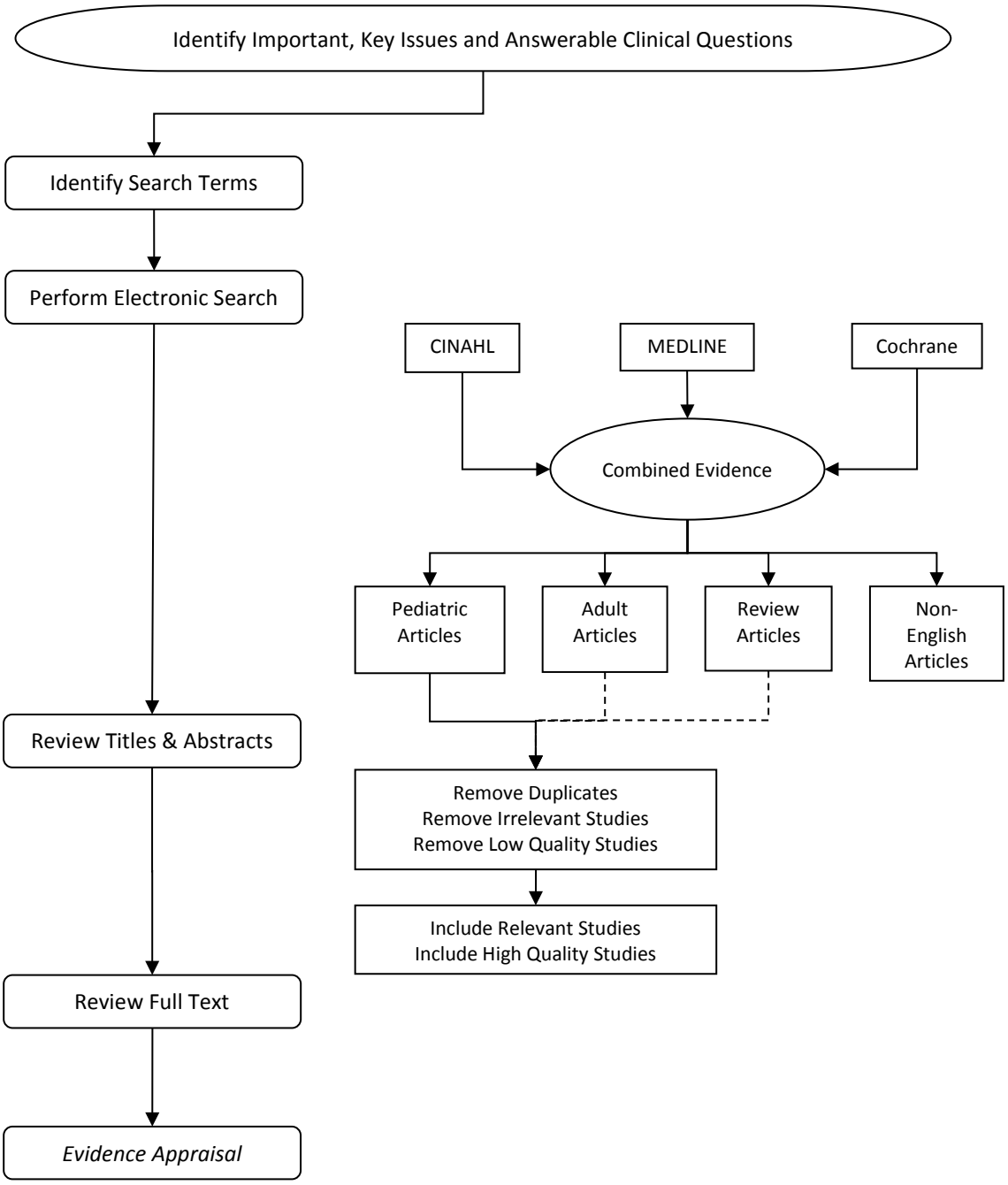
"**Exploding**" a term is a special instance of the "OR" connector that is used with databases such as Medline that use a hierarchically arranged thesaurus. You may retrieve specific and general terms in the hierarchy by using the "Explode" command.

Identify limiting features:

Aspects of the records may be used to limit retrieval. Common limiting aspects are age of subjects, language, species, publication type, or date of publication.

- *For example: You might search "cleft lip" AND "feeding methods," then limit the results to infants, English language, human, and 1990 -2002. You could also limit by eliminating ("NOT") letters or reviews as publication types.*

Appendix 6
Literature Search Algorithm



Appendix 7
Evidence Table for Included Studies

i.e., Articles meeting Inclusion Criteria

TITLE, IF APPLICABLE						
First Author & Year	**Column Title**	**Column Title**	**Column Title**	**Column Title**	**Column Title**	**Evidence Level**

 April 27, 2015

Appendix 8
Reviewer Checklist

for evaluating readiness for posting of an EBCG

EBCG Title: _____

Met	Not Met		
☐	☐	1.	Target Population is defined. *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	2.	Target Users are clearly defined. *Comment:* _____
☐	☐	3.	Recommendation*(s)* is*(are)* adequately specific and actionable. • *Notes are used to add clarity to the recommendation(s), if applicable.* *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	4.	Citations are included with the recommendation*(s)* and note*(s)*. *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	5.	Recommendation*(s)* is*(are)* easily identifiable and begin*(s)* with the appropriate recommendation phrase to signify the strength of the recommendation. *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	6.	Reference List is complete and references/citations are consistently formatted. *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	7.	All citations have been assigned a quality level, and level legend is present. *[EBCG Manual: Step 3 (page 12)]* *Comment:* _____

Appendices

Met	Not Met		
☐	☐	8.	Clinical questions are presented in PICO format. *[EBCG Manual: Step 1 (page 7)]* *Comment:* _____
☐	☐	9.	Systematic search strategy is documented. *[EBCG Manual: Step 2 (page 9)]* *Comment:* _____
☐	☐	10.	The Evidence Table of Included Articles is provided. *[EBCG Manual: Step 3 (page 12)]* *Comment:* _____
☐	☐	11.	Discussion/Synthesis of Evidence demonstrates how the Body of Evidence informs the Clinical Question*(s)*. *[EBCG Manual: Step 4 (page 14)]* *Comment:* _____
☐	☐	12.	Discussion of the quality, quantity, and consistency of the Body of Evidence is included. *[EBCG Manual: Step 4 (page 14)]* *Comment:* _____
☐	☐	13.	The supporting evidence is relevant to the recommendation statement***(s)*.** *[EBCG Manual: Step 4 (page 14)]* *Comment:* _____
☐	☐	14.	Dimensions for judging the strength of a recommendation have been appropriately considered, including Body of Evidence, health benefits, side-effects, risks, and others. *[EBCG Manual: Step 5 (page 15)]* *Comment:* _____
☐	☐	15.	Team member*(s)*, including credentials, specialty and/or area of expertise is present, with a CCHMC employee listed as Team Leader/Author. *[EBCG Manual: Conclusion – Completing the Supporting Information (page 24); Introduction (page 4)]* *Comment:* _____

☐ ☐ 16. Known Conflicts of Interest are declared by each team member.
*[**EBCG** Manual: Conclusion – Completing the Supporting Information (Conflict of Interest) (page 24) and **Conflict of Interest** form]*
Comment: _____

Implementation

Met **Not Met**

☐ ☐ 17. The potential resource implications of applying the recommendation(s) have been considered.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]
Comment: _____

☐ ☐ 18. Processes or tools have been identified which need to be developed, adapted, or revised for incorporation of the recommendation into practice.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Applicability & Feasibility Issues) (page 20)]
Comment: _____

☐ ☐ 19. Outcome Measures and Process Measures are identified with the rationale for each measure.
- *If no recommendation is made (e.g., insufficient evidence), then this section will not apply.*

[EBCG Manual: Conclusion – Putting Evidence Into Practice (Outcome Measures and Process Measures) (page 21)]
Comment: _____

☐ ☐ 20. I, the reviewer, was not involved with the development of this EBCG.
Comment: _____

☐ Meets all criteria *(may be posted)*
☐ Does not meet all criteria *(return to EBDMinfo@cchmc.org for required changes)*

EBCG is attached with tracked changes: ☐ Yes ☐ No, not attached

Additional Comments / Suggestions: _____

. _____ . **Reviewers' Names**

. _____ . **Date Reviewed**

Appendix 9
Conflict of Interest Disclosure

In accordance with IOM (Institute of Medicine) and AGREE (Appraisal of Guidelines for Research and Evaluation) criteria, development Team members and key professional support staff must declare whether they have any conflict of interest. Any situation that would or would be perceived as capable of influencing the decision for any recommendation within the evidence work is considered a conflict.

Name: _____ Credentials *(e.g. RN, MD):* _____
Division: _____

Title or Topic of Guideline or Best Evidence Statement: _____

Role on Proposal: ☐ Team Member
☐ Key Professional Support Staff *(e.g. members of Evidence Collaboration)*

Please check all that apply:

A. ☐ **No significant financial interests* exist** related to this Evidence-Based Care Guideline (EBCG) or Best Evidence Statement (BESt) development or revision which would require a disclosure.

B. ☐ **No significant intellectual interests exist** related to this Evidence-Based Care Guideline (EBCG) or Best Evidence Statement (BESt)

C. ☐ **A disclosure is required.** I hereby disclose the following significant interest(s): *(Check all that apply)*

- ☐ Salary or other payment for services *(e.g., consulting fees or honoraria, royalties)*
- ☐ Equity interests *(e.g., stocks, stock options, or other ownership interests)*
- ☐ Other significant financial interests that could possibly affect or be perceived to affect the specific EBCG or BESt development, implementation or reporting activities
- ☐ Intellectual interests *(e.g., patents, copyrights, authorship of article or research involvement that bears directly on recommendations, influence of expertise)*
- ☐ Other interests pertinent to the potential scope of these activities *(e.g., non-commercial, institutional, and patient/public activities)*

If C is checked, you must attach a signed, written statement (in an envelope marked "Confidential") identifying the business entity involved, the nature/type of the interest, and the amount of the interest that is related to the specific EBCG or BESt development, implementation or reporting activities.

☐ I attest that I have listed all relevant financial, intellectual, professional, and personal conflicts that have occurred within the previous 12 months and that I will immediately update this information if changes occur.
By checking this box, I agree to the terms of this electronic disclosure.

Signature *(please type your signed name)*: _____
Date: _____

Send completed form via e-mail to EBDMinfo@cchmc.org.

* Financial Interest does not include:

1. Salary, royalties, or other remuneration received directly from CCHMC.
2. Equity interests that, when aggregated for the Covered Individual and his/her family, do not exceed $5,000 in fair market value and do not represent a five (5) percent or greater ownership interest in a single entity.
3. Salary, royalties, or other payments that, when aggregated for the Covered Individual and his/her Family are not expected to exceed $5,000 in the prior or next twelve (12) months.
4. Interests arising solely by reason of investment by mutual, pension, or other institutional investment funds over which the Covered Individual does not exercise control.
5. Royalties for publishing scholarly works or other writings.

