**Integrated Process Model Tables.** These tables correspond to the manuscript “An Integrated Process for Co-Developing and Implementing Written and Computable Clinical Practice Guidelines” published in the American Journal of Medical Quality (citation).

**Figure 1: Overview of Integrated Process for Developing Written and Computable Guidelines**

*Note: red italicized font represents informatic activities*

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pre-guideline development: set up operational framework</td>
</tr>
</tbody>
</table>
| 1    | Define clinical problem/need; topic selection  
*Assess clinical need for CDS, additional products* |
| 2    | Establish Steering Committee: partners, SMEs  
*Establish informatics team* |
| 3    | Establish Guideline Panel, systematic review team; COI  
*Set-up collaboration platforms, identify tooling* |
| 4    | Scope Guideline  
*Formalize computable clinical practice guideline (CPG) concepts* |
| 5    | Identify, assess, and synthesize evidence  
*Specify clinical concepts, data elements, decisional flows* |
| 6    | Formulate/craft recommendations  
*Create semi-structured version, use cases, workflows; Develop and test computable CPG artifacts* |
| 7    | Draft the guideline manuscript/recommendations  
*Finalize computable CPG artifacts, create documentation* |
| 8    | Conduct internal, external & peer reviews/public comment  
*Validate CPG, create derivatives (measures & interventions)* |
| 9    | Publish and disseminate guideline  
*Release computable CPG* |
| 10   | Implement guideline  
*Incorporate into clinical information systems, CDS, & tools* |
| 11   | Evaluate Guidelines Outcomes & Impact  
*Data (CQM, etc.)* |
| 12   | Update guideline  
*Communication* |
|      | Assess goals for communication  
*Evaluation* |
|      | Create team for evaluation  
*Create team for communication* |
|      | Draft Outcomes Logic Model & evaluation plan  
*Draft plan for communication* |
|      | Collect process evaluation data  
*Create team for evaluation* |
|      | Update evaluation plan – Logic Model  
*Plan outreach, assess media interest* |
|      | Tailor & finalize evaluation for local implementation  
*Launch & track communication outreach* |

Footnote: If the reader has any accessibility issues with document, please contact the corresponding author on the main linked manuscript.
Figure 1 Key:

Development = Dev Topic
Subject = Subj
Subject Matter Expert = SME
Informatics = INFO
Evaluation = EVAL
Communication = COMM
Implementation* = IMPL

*Can be at local levels (e.g., a single hospital system), regional level (e.g., large group practice in a particular state), or beyond (using shared resources, such as a computable guideline’s repository)

Note: Resources listed in last column may be broken when this article is published.
## Future State Tables – Phase 0: Pre-Guideline Development – Set up Operational Framework and Integrated Process for Co-Developing Written and Computable Guidelines

<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
</table>
| 1. Identify functional and operational (including informatics and information technology) needs and requirements and limitations for developing written and computable guidelines in the organization. | a. Get leadership buy-in  
b. Review experience in the field and identify internal and external stakeholders (Informatics, Implementation, Guideline SMEs, and end-users.  
c. Consult with SMEs in the field (Informatics, Operational, and Guidelines SMEs and End-users to identify needs, requirements, barriers, and expectations for guideline development.  
d. Brainstorm on processes, people, and place. | Organizational management  
INFO SME  
IMPL SME | Requirement list | |
| 2. Assess current resources and capacity for guideline development in the organization. | a. Assess technical capacity for guideline development.  
b. Assess staffing, roles, and responsibilities. Identify necessary work roles and stakeholders for communication, evaluation, and implementation.  
c. Assess costs of developing computable guidelines and all its elements (i.e., COMM, IMPL, EVAL). | Organizational Management | A needs assessment of the organizational capability for computable guideline development | |
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>d. Assess evaluation needs and begin tracking process. Review evaluation requirements. Identify resources needed to conduct evaluation. Identify persons to conduct process, outcome, and impact evaluation activities.</td>
<td></td>
<td>EVAL SME</td>
<td></td>
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<tr>
<td>3. Develop organizational framework for developing a written and computable guideline.</td>
<td>a. Develop framework for project organization, planning, and control for integrating informatics standards and protocols in guideline development.</td>
<td>Organizational leadership and Management Guidelines Lead INFO Lead</td>
<td>Established process, framework, &amp; procedures for</td>
<td>Decision Tool (Appendix A)</td>
</tr>
<tr>
<td></td>
<td>b. Establish management committee for decision-making to specify technologies, systems, staff, and materials that the organization can maintain or contract out.</td>
<td></td>
<td>• computable guidelines model</td>
<td>Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action</td>
</tr>
<tr>
<td></td>
<td>c. Identify education, training and support, plus incentives to help staff adapt to the new ways of operating.</td>
<td></td>
<td>• informatics framework</td>
<td></td>
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<tr>
<td></td>
<td>d. Establish standard operating procedures (SOPs) for implementing the operational framework in organizations.</td>
<td></td>
<td>• management of process</td>
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<tr>
<td></td>
<td>e. Revise general standard operating procedures (SOPs) for guideline development to include computable guideline development processes and rules (guideline methodology, software, language, and rules (if any) for developing and rating</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
<td>*Responsible Entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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<td></td>
<td>the strength of the guideline recommendations (based on the evidence) consistent with computable guidelines (e.g., logical, computer interpretable format).</td>
<td></td>
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<td>f.</td>
<td>Establish steps and rules for finalizing draft recommendations (e.g., voting of members, public comment), voting/comment options (e.g., agree/disagree, agree if modified in strength or wording), and timing relative to entire guideline text finalization.</td>
<td></td>
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<tr>
<td>g.</td>
<td>Establish procedures for how monitoring of research advances will occur while text is being written so that important findings aren't missed, rendering the document outdated by the time of publication.</td>
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</tbody>
</table>
### Future State Tables - Phase 1: Define Clinical Problem / Assess Clinical Need / Select Topic

**Assess Clinical Need for the Computable CPG / Additional Products**

<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th><em>Responsible entity, Expertise Needed</em></th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
</table>
| 1. Identify and assess clinical need to identify topic(s) and define clinical questions for a new or updated guideline. | a. Determine process steps and tools to identify and assess clinical need that may include the following:  
  - Assess the landscape of evidence (e.g., literature, patient data).  
  - Evaluate surveillance data, implementation outcomes from program data, or aggregated patient data, electronic case reports as needed.  
  - Consult with experts or request input from stakeholders, e.g., community, authors. | Guideline office/ lead Topic SME EVAL SME IMPL SME | Criteria and process for assessing clinical need and for selecting topics and searching literature. | Guidelines and Recommendations: A CDC Primer, 2012  
A Quality-Driven Approach for Translating Evidence into Action  
Canadian Task Force on Preventive Health Care  
CMS Measures Management System Blueprint |
| 2. Prioritize topics (if there is more than one proposed topic). | a. Establish process for prioritizing topics – aligned to end-user need or organization priorities. | Guideline office/ lead | Criteria to identify and prioritize key clinical topics | NICE process for selecting & prioritizing guidelines |
| 3. Assess topic and research questions (guideline objective), and communication, informatics, implementation, and evaluation needs. Decide whether to produce a | a. Establish guideline development processes considering clinical need, feasibility, cost, implementability, etc.  
  b. Assess topic for communication needs and products. Ensure communicators are aware of guideline development timeline. Assess topic for informatics needs and support. Assess need/opportunity for | Guideline office/ lead Topic SME EVAL SME INFO SME IMPL SME Economist COMM SME | Completion of Decision Tool (Appendix A) | USPSTF Procedure Manual  
Decision Tool (Appendix A) |
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>computable version of the guideline.</td>
<td>development of computable guidelines OR clinical data elements related to topic, such as metrics, population-level measures, and electronic case reports. Define key concepts, data elements, and terminologies relevant to the topic.</td>
<td></td>
<td>&quot;</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Assess topic for implementation, feasibility, and support.</td>
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<tr>
<td>4. Obtain leadership approval of topic and funding.</td>
<td>a. In-house – as per organizational protocols (no standard process), obtain leadership approval of topic and assure funding is available internally and with partners.</td>
<td>Organizational leaders</td>
<td>Topic and funding approval</td>
<td></td>
</tr>
</tbody>
</table>


## Phase 2: Establish Guideline Oversight Committee / Explore international Collaboration / External Partners / SMEs

## Phase 3: Establish Workgroups: (Guideline Panel, Informatics, CDS Implementors, Systematic Review Team)
Assess Informatics Team / Set up Collaboration Platforms and Tools

<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Convene an oversight committee/group, determine goals, roles, and responsibilities, and assess conflict of interest.</td>
<td>a. Select multidisciplinary members from organizational leadership and broad stakeholder representation, which will vary across different organizations.</td>
<td>Guideline lead</td>
<td>Established protocols and criteria for oversight committee membership, management, selection of chair and members, roles and responsibilities of SMEs (SUBJ, INFO, EVAL, COMM, IMPL SMEs)</td>
<td>Managing conflicts of interest in the development of health guidelines. (NIH) Jan. 11, 2021</td>
</tr>
<tr>
<td></td>
<td>b. Establish:</td>
<td>Guideline lead</td>
<td></td>
<td>GIN-McMaster Guideline Development Checklist-Conflict of Interest</td>
</tr>
<tr>
<td></td>
<td>• Goals, composition, and charge of an oversight committee</td>
<td></td>
<td></td>
<td>Disclosing Competing Interests in CDC Guidelines, Oct. 2015</td>
</tr>
<tr>
<td></td>
<td>c. Assess &amp; manage conflict of interest.</td>
<td>Guideline Lead</td>
<td></td>
<td>A Quality-Driven Approach for Translating Evidence into Action</td>
</tr>
<tr>
<td></td>
<td>d. Establish informatics team, including knowledge engineer (KE) SMEs, and informatics technical SMEs.</td>
<td>Guideline Lead</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>e. Ensure at least one communication, evaluation, and implementation SMEs are on oversight committee to inform stakeholders of guideline creation or update and timeline.</td>
<td>COMM lead</td>
<td></td>
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<tr>
<td></td>
<td>EVAL Lead</td>
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<tr>
<td></td>
<td>IMPL SME</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. Establish project management plan, including time frame and</td>
<td>a. Develop project management plan for integrating informatics standards and</td>
<td>Oversight Committee representing: SUBJ SME</td>
<td>Buy-in on process &amp; procedures for:</td>
<td>Agile development tools, e.g., kanban, scrum</td>
</tr>
<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
<td>*Responsible entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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</tr>
</tbody>
</table>
| milestones, for specific guideline topic. | protocols to develop computable CPGs. | INFO SME EVAL SME COMM SME IMPL SME | • standard or living guidelines model  
• informatics framework  
• membership management | ScrumAlliance  
Scrum Presentation  
Lean Knowledge Works  
Lean Enterprise  
Github  
CDS Connect Repository  
MagicApp  
Introduction to living guidelines and recommendations |
<p>| b. Choose collaboration mechanisms and processes to share knowledge, e.g., SharePoint, Microsoft Teams, Confluence, DropBox, Google Docs. | | | | |
| c. Establish code repositories, e.g., Github. | | INFO SME | | |
| 3. Establish an evaluation team. | a. Determine the types of evaluation to be conducted (e.g., process, product, outcome). | Oversight committee chair, Work group lead, Selected members from workgroup with expertise in evaluation | Evaluation team formed | |
| | b. Identify those with evaluation expertise (within and outside of the organization) who will guide and conduct the evaluation, e.g., members of the guideline workgroup, 1-2 individuals with evaluation expertise, or an evaluation workgroup that collaborates with guideline workgroup. | | | |
| | c. Determine roles and responsibilities of members of the evaluation team. | EVAL Team including IMPL SME | | |
| | | Roles and responsibilities listed | | |</p>
<table>
<thead>
<tr>
<th><strong>Activities</strong> (What to do)</th>
<th><strong>Tasks</strong> (How to do it)</th>
<th><strong>Responsible entity, Expertise Needed</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Establish guideline workgroup(s).</td>
<td>a. Identify the need and types of multidisciplinary workgroups, e.g., main guideline workgroup, external reviewer’s group, evidence review group.</td>
<td>Oversight Committee</td>
<td>Success Indicators for selecting chair and members, member type (SUBJ, INFO, EVAL, COMM etc.), and their roles &amp; responsibilities</td>
<td>National Academies of Sciences- Standards for Systematic Reviews, Cochrane Handbook, A Quality-Driven Approach for Translating Evidence into Action</td>
</tr>
<tr>
<td></td>
<td>b. Ensure that informatician has experience in guideline development, or provide them with guideline training, as needed.</td>
<td>INFO SME</td>
<td>Criteria for incorporating informatics in systematic reviews (living evidence profile)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Define goals, composition, and charge of the guideline workgroup(s).</td>
<td>Oversight Committee</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Identify and select members and obtain and manage COI.</td>
<td>Oversight Committee</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. Establish criteria for if/when to include health care organization (HCO) for implementation issues.</td>
<td>Oversight Committee</td>
<td>Criteria for if/when to include HCO members for assessment of implementation feasibility in guideline development</td>
<td></td>
</tr>
</tbody>
</table>
| 5. Identify and establish collaborations and/or partnerships. | a. Identify and assess the type of collaborations and partnerships needed:  
• Internal (organizational units)  
• External to organization (other agencies, stakeholders, community groups, including international). | Oversight Committee | Success Indicators for identifying partners and types of partnerships, communication, and roles and responsibilities of partners. |  |
<p>| | b. Establish partner/collaborator rules of management and communication. |  |  |  |</p>
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
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<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Conduct kickoff meeting with relevant stakeholders.</td>
<td>a. Hold kickoff meeting to assess communication needs, issues, risks, intended audience, and to understand science/underpinnings of guidelines.</td>
<td>Oversight Committee COMM SMEs</td>
<td>Kickoff meeting accomplished</td>
<td>Stakeholder Communication Analysis (Appendix B)</td>
</tr>
<tr>
<td></td>
<td>b. Obtain agreement of external communication standards, protocol, clearance, and identify communication workgroup members.</td>
<td></td>
<td>Description of communication standards and protocols, and communication workgroup members</td>
<td></td>
</tr>
<tr>
<td>7. Develop communication plan and estimated timeline of activities to do before, during, and after release of guideline, including a plan for tracking results.</td>
<td>a. Consider steps to inform communication/dissemination plan for guideline, e.g., focus groups, surveys, community forums, listening sessions.</td>
<td>COMM Lead</td>
<td>Draft communication plan</td>
<td>Communication SOPs: A Checklist for Effective Communication and Dissemination (Appendix C)</td>
</tr>
<tr>
<td></td>
<td>b. Facilitate information sharing between communication and guideline workgroups.</td>
<td></td>
<td></td>
<td>Developing Effective Communication Products</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A Framework for Disseminating Evidence-Based Health Promotion Practices</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Strategies for disseminating recommendations or guidelines to patients: a systematic review</td>
</tr>
<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
<td>*Responsible entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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</tr>
<tr>
<td>8. Set-up collaborative platforms and tools.</td>
<td>a. Decide on collaboration platforms for information sharing and tools for producing computable guidelines CPG artifacts.</td>
<td>Guideline Lead INFO Lead</td>
<td>Collaborative platform established</td>
<td></td>
</tr>
</tbody>
</table>
### Future State Tables - Phase 4: Scope Guideline
### Identify Computable Clinical Practice Guideline (CPG) Concepts

<table>
<thead>
<tr>
<th><strong>Activities (What to do)</strong></th>
<th><strong>Tasks (How to do it)</strong></th>
<th><strong>Responsible entity, Expertise Needed</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>b. Identify key studies to support scope and future planning.</td>
<td>COMM SME</td>
<td></td>
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<tr>
<td></td>
<td>c. Research past communication, dissemination, and lessons learned to improve COMM planning. Work with guideline leads to map out COMM plan and audience issues and needs.</td>
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</table>


<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Develop draft scope</td>
<td>a. Use preliminary assessments to set guideline objectives, key research questions. Develop PICO or PICOTS to reflect guideline objectives, and which research questions must be answered to arrive at a recommendation. Determine if any published guideline recommendations on the topic need to be maintained.</td>
<td>Scoping Group</td>
<td>Draft scope developed</td>
<td>NICE Scoping checklist</td>
</tr>
</tbody>
</table>
|                        | b. Make initial scoping decisions:  
  - Develop and select key questions  
  - Use structured format, based on the defined PICO or PICOTS components  
  - Select criteria to prioritize questions  
  - Define outcomes of interest | Oversight Committee Scoping Group INFO SMEs | " | AGREE-II Tool |
<p>|                        | c. Discuss key research questions and scope with INFO SME, and what information is needed and how to frame it for a computable guideline. | Oversight Committee Scoping Group INFO SMEs | Revised PICO or PICOTS and informatics needs | |
|                        | d. Consult with IMPL SME to evaluate plausible clinical workflows impacting scope of intervention and settings. | Oversight Committee Scoping Group IMPL SMEs | Revised Intervention with time frame (T) and Settings (S) for PICOTS | |
| 4. Develop a visual analytic model showing a causal | a. Develop a graphical representation of how the proposed key research | Guideline Lead EVAL Lead | Visual analytic model (draft) | IOM: Clinical Guidelines |</p>
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
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<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pathway for the proposed research questions and intervention(s) in PICO.</td>
<td>question(s) and intervention(s) under consideration as reflected in the PICO or PICOTS are linked to their intended outcomes. The linkages represent critical premises in logic that require confirmation by evidence review to support related recommendations.</td>
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</tr>
<tr>
<td>5. Consult with INFO SME to inform and refine scope.</td>
<td>a. Convene internal and external consultations, if needed, to provide feedback on proposed scope.</td>
<td>Scoping Group Stakeholders IMPL SME Oversight Committee INFO SME</td>
<td>Summary of feedback</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Consult with INFO SME to further inform and refine scope of overall guideline (and data needed) for potential CDS, draft clinical use cases, and identify relevant computable CPG artifacts and concepts. Determine feasibility of data elements.</td>
<td></td>
<td>Refined scope, and draft framework, terminology, and use cases. Use cases cover the scope of recommendations to be digitized.</td>
<td></td>
</tr>
<tr>
<td>6. Finalize guideline scope after consultation with oversight committee and partners.</td>
<td>a. Oversight Committee (and guideline partner organizations, if relevant) review and approve all drafts.</td>
<td>Oversight Committee Partners INFO SME</td>
<td>Final scope as reflected in PICO or PICOTS and logic model</td>
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<tr>
<td></td>
<td>b. Use scope to determine guideline type (new, interim, update, adaptation etc.).</td>
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<tr>
<td>7. Develop a logic model and evaluation plan.</td>
<td>a. Develop the logic model in collaboration with oversight committee to produce a shared purpose, transparency through the implementation process, and a</td>
<td>EVAL Team Guideline Team</td>
<td>Draft evaluation plan</td>
<td>Logic Models: CDC Approach to Evaluation CDC: A Framework for Program Evaluation</td>
</tr>
<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
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<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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<tr>
<td>common understanding of the intended evaluation outcomes. A logic model is a graphic road map that presents the shared relationships among the resources, activities, outputs, outcomes, and impact for your proposed guideline. (1) A statement of the intervention; (2) Inputs or program resources: needed for guideline intervention and evaluation, e.g., staff, budget, partners; (3) Activities: What we do to produce desired guideline outcomes, based on theory, evidence, or best practice; (4) Outputs: The direct tangible results of activities, e.g., health care professionals trained in use of computable guidelines; (5) Short-term/Proximal Outcomes: The immediate effects of the guideline, e.g., reach, awareness or knowledge and, satisfaction with guidelines among intended audience; (6) Intermediate Outcomes: The behavior, normative, and policy changes, e.g., health systems in place to implement computable guidelines; clinicians using computable guidelines. (7) Long-term/Distal Outcomes: the desired health outcomes of the</td>
<td></td>
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<td>Indicators: CDC Approach to Evaluation</td>
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<td>CDC Division for Heart Disease and Stroke Prevention Evaluation Plan</td>
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<td></td>
<td>Framework for Program Evaluation in Public Health: A Checklist of Steps and Standards</td>
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<td></td>
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<td></td>
<td>Western Michigan University: Evaluation Checklists</td>
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<td>Checklist of Key Considerations for Development of Program Logic Models</td>
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<td>A science impact framework to measure impact beyond journal metrics</td>
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<td>An organizing framework for translation in public health: The knowledge to action framework</td>
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<td>Developing Your Evaluation Plans: A Critical Component of Public Health Program Infrastructure</td>
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<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
<td>*Responsible entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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<td>guideline, e.g., blood pressure control in a health center population. (8) Environmental context: within which the guideline is implemented (e.g., emergency situation such as COVID-19, emerging issues, cultural or geographic factors, demographics of communities or persons, new trials, economic or political conditions, historical events) (9) Impact: (may/may not include) Ultimate impacts of the intervention(s) that could take years to achieve, e.g., heart disease deaths</td>
<td></td>
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<td>Conceptual frameworks and empirical approaches used to assess the impact of health research: an overview of reviews An organizing framework for translation in public health: The knowledge to action framework From ClinicalTrials.gov trial registry to an analysis-ready database of clinical trial results.</td>
</tr>
<tr>
<td>b. Draft a preliminary high-level evaluation plan based on logic model with a description of evaluation target audience, time frame and frequency, expected proximal, intermediate, and distal outcomes, resources needed.</td>
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<tr>
<td>c. Draft a detailed evaluation plan for assessing the guideline process, products, and outcomes.</td>
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<tr>
<td>8. Update draft of communications plan.</td>
<td>a. Update first draft of communication plan.</td>
<td>COMM SME</td>
<td>Updated draft of communication plan</td>
<td>The new P Process: Steps in Strategic Communication A Framework for Disseminating Evidence-Based Health Promotion Practices</td>
</tr>
<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
<td>*Responsible entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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<td>Strategies for disseminating recommendations or guidelines to patients: a systematic review</td>
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</tbody>
</table>
### Activities (What to do)

1. Select evidence review methods and infrastructure most appropriate for the guideline under development.

### Tasks (How to do it)

- **a.** Determine responsibilities for: systematic or other evidence reviews, (living or dynamic updating, digitized).
- **b.** Consider which analytic approaches are best suited to the guideline goals, e.g. Global evidence maps, scoping studies, prospective meta-analyses, network meta-analyses, individual patient-level data, meta-analysis, and/or “real world evidence,” including real time patient-level data evidence.
- **c.** Consider analyzing real time emerging information to develop rapid guidelines for emerging issues.
- **d.** Consider conducting predictive analytics.

### Responsible entity, Expertise Needed

- Evidence Review Group
- INFO SME
- Evidence Review Group

### Success Indicators

- Evidence review methods and rationale selected
- Overarching lead describes responsibilities for each group (SUBJ, INFO, IMPL, COMM, EVAL)

### Resources and tools (Examples)

- Systematic Reviews: the process: Guides/Manuals
- National Academies of Sciences- Standards for Systematic Reviews
- Coursera Course (free): Introduction to Systematic Reviews and Meta-Analysis
- Cochrane Community: Living Systematic Reviews
- Living systematic review: 1. Introduction—the why, what, when, and how
- Development of Rapid Guidelines: GIN-McMaster
- Systematic review automation technologies PRISMA 2015
- Prisma Flow Diagram Generator
- Brown Center for Evidence Synthesis in Health
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
</table>
| 2. Decide how information and evidence regarding critical questions identified in Phase 4 will be addressed. | a. Identify PICO or PICOTS questions for which a systematic review adds greatest value. | Evidence Review Group Guideline development group | Determination of final PICO or PICOTS questions, sources for information, and metrics | The Global Evidence Mapping Initiative  
Design and implementation of Metta, a metasearch engine for biomedical literature retrieval intended for systematic reviewers. |
| | b. Identify and justify sources of information and evidence used to address critical questions that will not be addressed by systematic reviews (e.g., values, IMPL issues). | “” | “” | “” |
| | c. Decide on appropriate effect metrics for quantitative data. | “” | “” | “” |
| 3. Identify evidence and extract information. | a. Develop a formal systematic review protocol that outlines steps to identify the evidence:  
• Define inclusion/exclusion criteria  
• Refine PICO questions. Also consider T (time interval) and S (settings) for the intervention. | Evidence Review Group | Quality search protocol established with clear systematic methods  
Systematic review in process | Introduction to Systematic Reviews and Meta-Analysis  
Epistemonikos  
AHRQ Systematic Review Data Repository  
Covidence  
Distiller SR |
<table>
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<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>b.</td>
<td>Identify search parameters (database, years, language, MeSH terms, etc.)</td>
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<td>RevMan</td>
</tr>
<tr>
<td>b.</td>
<td>Determine number of reviewers</td>
<td></td>
<td></td>
<td>OVID Scopus</td>
</tr>
<tr>
<td>b.</td>
<td>Conduct a systematic review to search for and gather evidence per research question(s). Types of evidence can include:</td>
<td></td>
<td></td>
<td>McMaster Health Information Research Unit: Evidence-Based Health Informatics Guide to Community Preventive Services/Task Force on Community Preventive Services Evidence Ecosystem concept and advances in evidence synthesis and dissemination - Cochrane When and how to update systematic reviews: consensus and checklist, Developing WHO rapid advice guidelines in the setting of a public health emergency The System for the Unified Management, Assessment and Review of Information (SUMARI) Machine-learning information-extraction systems (e.g., RobotReviewer, ExaCT)</td>
</tr>
<tr>
<td>c.</td>
<td>Current systematic and living reviews</td>
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<tr>
<td>c.</td>
<td>Other similar guidelines</td>
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<tr>
<td>c.</td>
<td>Primary studies and reports (published and grey literature)</td>
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<td>c.</td>
<td>Patient level data (pulled from real-time analysis of data in EHRs, etc.)</td>
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<td>c.</td>
<td>Modeling (may be appropriate for certain types of questions)</td>
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<tr>
<td>c.</td>
<td>Expert opinion (may be relevant for emergency situations and questions with limited data).</td>
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<tr>
<td>d.</td>
<td>Screen articles at the abstract and full text level and evaluate quality of screening process.</td>
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<tr>
<td>d.</td>
<td>Abstract relevant study information (i.e., demographic, interventions, effect sizes, key findings) into</td>
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<tr>
<td>Activities (What to do)</td>
<td>Tasks (How to do it)</td>
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<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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</table>
| 4. Assess evidence.     | a. Evaluate and rate the quality of each individual study using pre-defined quality appraisal criteria for each element. For example:  
  - Study design and quality of execution  
  - Internal validity  
  - External validity (generalizability)  
  - Precision (e.g., confidence interval, credible intervals, certainty)  
  - Other potential biases (e.g., funding source).  
  b. Conduct a meta-analysis, if appropriate.  
  c. If evidence derived from sources other than studies is included (e.g., patient data from EHRs), have a transparent discussion regarding its validity or biases, limitations, and uses relative to study results. | Evidence Review Group | Individual study rating schema established and applied to gathered evidence | AMSTAR quality assessment checklist  
The EPC Approach  
AHRQ  
GRADE  
GRADEPro  
GRADE-CERQual  
The Cochrane Collaboration-Qualitative Research Appraisal  
Robins-I  
Cochrane-RevMan)  
PRISMA and PRISMA-P  
Prisma Flow Diagram Generator  
Critical Appraisal Skills Programme (CASP)  
Dr. Evidence |
<table>
<thead>
<tr>
<th><strong>Activities (What to do)</strong></th>
<th><strong>Tasks (How to do it)</strong></th>
<th><em><strong>Responsible entity, Expertise Needed</strong></em></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.</strong> Synthesize evidence and define a process for writing draft text for manuscript for Phase 7.</td>
<td>d. Conduct economic analysis, if appropriate.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>a. Synthesize published and unpublished evidence into tables/evidence profiles for each key question, including quality of evidence, magnitude of effect, and assessment for heterogeneity.</td>
<td>Evidence Review Group</td>
<td>Developed evidence tables</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Evaluate and rate the quality of the body of evidence using pre-defined criteria (for each research question).</td>
<td>Guideline Oversight Committee</td>
<td>Established body of evidence rating schema and applied to all evidence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Develop a process for drafting text for manuscript through organization’s oversight committee for all guidelines.</td>
<td></td>
<td>Established process for writing manuscript text (see Phase 7)</td>
<td></td>
</tr>
</tbody>
</table>
| | a. Specify computable CPG artifacts. | INFO SME | Computable CPG artifacts specified. | Overview: [FHIR Clinical Guidelines (v1.0.0) (STU 1)](hl7.org)  
Examples of artifacts: [FHIR Clinical Guidelines (v1.0.0) (STU 1)](hl7.org) |
## Future State Tables - Step 6: Formulate (Craft) the Recommendations
Create Semi-structured version, use cases, workflows; develop & test computable CPG artifacts

<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
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</thead>
<tbody>
<tr>
<td>1. Develop, rate, and prioritize recommendations.</td>
<td>a. Review rules (if any) for process for wording of recommendations (e.g., one person followed by comments, group effort, and sentence structure) that is consistent with computable guidelines (e.g., logical, computer interpretable format).</td>
<td>Guideline multidisciplinary panel including INFO SMEs and IMPL SMEs</td>
<td>Clear, concise, and unambiguous recommendations</td>
<td>Approaches to scoring recommendations (e.g., GRADE, USPSTF).</td>
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<tr>
<td></td>
<td>b. Review the evidence and formulate draft recommendation(s). Decide if any current recommendation should be maintained and cited.</td>
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<td>GRADE Evidence to Decision (EtD) Framework</td>
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<tr>
<td></td>
<td>c. Describe information in support of the recommendation(s) (e.g., rationale for group decisions, benefit vs. harm considerations, patient values and preferences).</td>
<td></td>
<td></td>
<td>GRADE ADOLOPMENT</td>
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<tr>
<td></td>
<td>d. Rate recommendation strength/class of recommendation (e.g., strong, weak) and direction (e.g., for, against) based on quality/Level of evidence.</td>
<td></td>
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<td>Bridge-Wiz</td>
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<td></td>
<td>e. Based on pre-determined steps, finalize draft recommendations</td>
<td></td>
<td></td>
<td>Building better guidelines with BRIDGE-Wiz, 2012</td>
</tr>
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<td></td>
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<td>Moving from evidence to developing recommendations in guidelines: article 11 in Integrating and coordinating efforts in COPD guideline development, 2012</td>
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<td>Guidelines into Decision Support (GLIDES)</td>
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<td>Developing clinical practice guidelines, 2012</td>
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<td>IOM: Clinical Guidelines We Can Trust, 2011</td>
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<td>Reviewing clinical guideline development tools, 2017</td>
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<td>How &quot;Should&quot; We Write Guideline Recommendations? 2010</td>
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<td>Clinical Practice Guideline Development Manual, Third</td>
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### Activities
(What to do)

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<tr>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
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</thead>
<tbody>
<tr>
<td>(e.g., voting of members, public comment) and voting/comment options (e.g., agree/disagree, agree if modified in strength or wording) and timing (relative to entire guideline text).</td>
<td>“</td>
<td>“</td>
<td>Edition: A Quality-Driven Approach for Translating Evidence into Action, 2013</td>
</tr>
<tr>
<td>f. Drawing upon previous rating of each recommendation, prioritize which recommendations are suitable for developing computable CPG using various criteria, e.g., strength of evidence and magnitude of the effect (strong evidence and strong recommendation), feasibility of implementing in a computable format, and importance of the recommendation in reaching the intended population regardless of evidence strength.</td>
<td>“</td>
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</tbody>
</table>
| 2. Create case presentations, use cases, user stories for recommendations where clinical decision support is appropriate. | a. From patient-centered characteristics, refine and expand clinical decision support design artifacts, use cases & their diagrams, case presentations, user stories.  
- Case presentation  
- Use cases & user stories  
- Use case diagrams | INFO SMEs IMPL SMEs | Case presentation  
User stories  
Use case diagrams | User stories as lightweight requirements for agile clinical decision support development  
DigitalGov User Experience Resources  
DigitalGov Use Cases  
Usability.gov Scenarios |
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<tr>
<th><strong>Activities</strong> (What to do)</th>
<th><strong>Tasks</strong> (How to do it)</th>
<th><strong>Responsible entity, Expertise Needed</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools</strong> (Examples)</th>
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<tr>
<td>3. Represent written</td>
<td>a. Based on analysis,</td>
<td>Guideline writing group</td>
<td>Decision trees and</td>
<td>Digital Adaptation Kits</td>
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<tr>
<td>recommendations (as</td>
<td>translate related/bundled</td>
<td>Guideline office/lead</td>
<td>concept maps created</td>
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<tr>
<td>appropriate) into logical</td>
<td>recommendations into</td>
<td>Methodology SMEs</td>
<td></td>
<td>Opioid Prescribing</td>
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<tr>
<td>diagrams for use in creating</td>
<td>algorithmic decision</td>
<td>INFO SMEs</td>
<td></td>
<td>Recommendation #5:</td>
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<tr>
<td>computable guideline.</td>
<td>trees, data capture</td>
<td>IMPL SMEs</td>
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<td>Lowest Effective Dose</td>
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<td>needs, concept maps or</td>
<td>Other SMEs</td>
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<td>decision analyses (if</td>
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<td>Computer Interpretable Clinical</td>
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<td></td>
<td>applicable).</td>
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<td>Guidelines, 2014</td>
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<td>b. Create a semi-</td>
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<td>Computer-interpretable clinical</td>
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<td>structured diagram (L2)</td>
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<td>guidelines: A methodological</td>
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<td>representing the steps</td>
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<td>review, 2013</td>
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<td>involved in implementing</td>
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<td>From clinical practice</td>
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<td>the recommendation at</td>
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<td>guidelines to computer-</td>
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<td>the clinical level.</td>
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<td>interpretable guidelines. A</td>
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<td>Diagram should</td>
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<td>literature overview, 2010</td>
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<td>incorporate previous</td>
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<td>Modeling a Nursing Guideline</td>
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<td>analyses to model the</td>
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<td>with Standard Terminology and</td>
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<td>work, such as decision</td>
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<td>Unified Modeling Language for a</td>
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<td></td>
<td>trees.</td>
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<td>Nursing Decision Support System:</td>
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<td></td>
<td>A Case Study</td>
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<tr>
<td>internal review(s) of Phase</td>
<td>present recommendations</td>
<td>Methodology SMEs</td>
<td>recommendations and</td>
<td></td>
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<tr>
<td>6 and previous phases and</td>
<td>in development.</td>
<td>SUBJ SMEs</td>
<td>computable guidelines</td>
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<tr>
<td>computable CPG design</td>
<td>b. Informaticians and</td>
<td>INFO SMEs</td>
<td>design.</td>
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<tr>
<td>meeting with SME's and</td>
<td>implementors present</td>
<td>IMPL SMEs</td>
<td>Approved decision</td>
<td></td>
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<tr>
<td>relevant stakeholders.</td>
<td>case presentation,</td>
<td>Other external SMEs, to include patient</td>
<td>trees, flow diagrams,</td>
<td>L2 ARTIFACT done</td>
</tr>
<tr>
<td></td>
<td>user stories, use cases,</td>
<td>patient representative and end-</td>
<td>other artifacts</td>
<td>The L2 product may be</td>
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<td></td>
<td>use case diagram, decision trees, flowcharts, workflow diagrams, proposed terminology, data elements, and other work products.</td>
<td>users (clinical and patients).</td>
<td></td>
<td>the main deliverable</td>
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<tr>
<td>Activities (What to do)</td>
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<td>Responsible entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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| c. Implementors facilitate feedback on work products from clinicians (end-users) and decision support (EHR/CDS) developers. | INFO SMEs IMPL SMEs | for the informatics team if the overall team lacks resources/access to developers (software engineers). | CPG expression (L3) created. Design documentation detailing each workflow. Analysis of existing resources is performed and a determination made on which artifacts need to be created vs. reused. Artifacts are in a publishable state with appropriate documentation for clinical usage implementation. | A multi-layered framework for disseminating knowledge for computer-based decision support.  
Artifacts defined as part of the CDC Opioid Prescribing Guideline Implementation Guide.  
Profiles defined as part of the CDC Opioid Prescribing Guideline Implementation Guide.  
Terminology defined as part of the CDC Opioid Prescribing Guideline Implementation Guide.  
HL7 FHIR Representing Knowledge Artifacts.  
MagicApp. |
<p>| d. Team members refine their work products based on the review and design work. | &quot; | &quot; | &quot; | &quot; |
| 5. Design and build computable CPG artifacts as indicated by prioritization activities, if available resources allow. | a. Develop CPG expression (L3) building on flow diagrams, decision trees, and other work products. Use standards-based interoperable languages where feasible (e.g., CQL, BPM+). | &quot; | &quot; | &quot; |
| | b. Create data elements. Identify existing profiles, value sets, libraries, groups, and rules and those that have parameters; build new elements as needed. Build profiles, value sets, libraries, groups, rules, and logic. | &quot; | &quot; | &quot; |
| | c. Identify comprehensive test cases and testing resources (e.g., sandboxes) required to evaluate computable CPG artifacts. Test cases may include case features, recommendations and logic. | &quot; | &quot; | &quot; |</p>
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
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<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.</strong> Test the computable CPG artifacts.</td>
<td>a. Set up test environment to include appropriate patient-level test data.</td>
<td>INFO SMEs</td>
<td>Documents of test scenarios that cover the computerized recs.</td>
<td>Test Data Defined as part of the CDC Opioid Prescribing Guideline Implementation Guide</td>
</tr>
<tr>
<td></td>
<td>b. Implement test scenarios.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>c. Verify that the computable guideline performs as expected. Validate entire CPG end to end. Use test cases to assure that the computable artifacts provide outputs consistent with the written guidelines.</td>
<td>Guideline authors INFO SMEs</td>
<td></td>
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</tr>
<tr>
<td><strong>7.</strong> Determine what health information technology (HIT) and informatics resources are needed to support computable CPG implementation.</td>
<td>a. Specify needed IT resources and standards to retrieve and implement the computable CPG artifacts in a test system. e.g., FHIR release 4, Value Set Authority Center (VSAC) at <a href="https://vsac.nlm.nih.gov/">https://vsac.nlm.nih.gov/</a>.</td>
<td>INFO SMEs IMPL SMEs</td>
<td></td>
<td>HL7 FHIR Clinical Guidelines CDS Connect Authoring Tool CDS Connect Repository</td>
</tr>
</tbody>
</table>
### Future State Tables – Phase 7: Draft the Guideline Text/Manuscript

Finalize computable CPG artifacts; create documentation

<table>
<thead>
<tr>
<th><strong>[7] Activities</strong> (What to do)</th>
<th><strong>Tasks</strong> (How to do it)</th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools</strong> (Examples)</th>
</tr>
</thead>
</table>
| **1.** Review the defined process by which draft text will be written. (Phase 5, activity 5) | a. Review process for drafting text through organization’s oversight committee for all guidelines. Tailor to each guideline based on factors (e.g., guideline type, rapidity).  
  
b. Finalize plan for timeline, roles, & responsibilities. Determine the following:  
  • Author order, including first author, and finalize journal or other publication venue.  
  • Who will write each section?  
  • Recent major citations that may support guideline text.  
  • Who will monitor and loop back new research advances of critical evidence to the writing group?  
  • Who will give feedback on draft?  
  • Whether to mention emerging areas of research in guideline text under specific recommendations (e.g., important and highly visible findings nearing publication) and/or in a separate section on future research needs. | Guideline staff  
Oversight committee  
Guideline writing group/panel | Tailored process for writing draft text |

Examples of published guidelines from a variety of organizations that represent the different approaches to guideline construction and writing from following resources:  
CDC Guidelines & Recommendations  
WHO Handbook  
Scottish Intercollegiate Guidelines Network (SIGN)  
National Institute for Health and Care Excellence (NICE)  
Australian National Health and Medical Research Council (NHMRC)  
NIH Clinical Practice Guidelines  
USPSTF Procedure Manual  
IOM: Clinical Guidelines
<table>
<thead>
<tr>
<th>Activities (What to do)</th>
<th>Tasks (How to do it)</th>
<th>*Responsible entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
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</table>
| • Whether formal copyediting will occur at this step of the process.  
• Whether there are defined criteria that must be met (e.g., voting, verbal concurrence) before draft is moved on to next step of the development process. | a. Remind participants of expectations as the writing proceeds. for example:  
• Aim for succinct text.  
• Use clear and grammatically correct language with a minimum of jargon.  
• Use visual graphics, e.g., bullet points, tables, flow-charts, algorithms.  
• Distinguish fact from opinion and cite factual statements  
• Reference/link with other related guideline recommendations.  
• Avoid scope creep and focus text on the recommendations and their rationale rather than peripherally related content.  
• If indirectly related content needs to be mentioned, give a short conclusion with few key citations. | Oversight committee  
Guideline staff  
Guideline writing group/panel | | List of expectations for writing group members |
<table>
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</table>
| 3. Develop content to supplement recommendations of the guideline | a. As per agreed upon outline and guideline format, include content: rationale/need for the guideline, guideline scope, methods including literature search strategy, names and affiliations of oversight committee, workgroups, conflict of interest statements, discussion of benefits and harms, patient values and preferences that support the recommendations, supporting references and/or evidence tables; future research needs, plans to update, abbreviations & glossary of terms, appendices (e.g., detailed tables of evidence with associated text). | Guideline staff, Oversight committee, Guideline writing group/panel SUBJ SMEs INFO SMEs COMM SMEs IMPL SMEs Partners | Outline and content of key section headings and subheadings | Examples of published guidelines from organizations that represent the different approaches to guideline construction and writing:  
WHO Handbook  
SIGN  
NICE  
Australia’s National Health and Medical Research Council (NHMRC)  
Evidence to Decision Framework  
Epistemonikos |
| 4. Write supporting guideline text (i.e. text other than recommendations) | a. Draft content according to outline and other requirements of journal or other publication venue.  
b. Begin writing before all recommendations are written. Use an iterative approach to writing, | Guideline staff, Guideline SUBJ SMEs COMM SMEs | First draft of text |
<table>
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<tbody>
<tr>
<td><strong>5. Conduct quality assessment of the guideline</strong></td>
<td>a. Use an appraisal instrument to conduct quality assessment to check if guideline meets established quality standards and reporting criteria.</td>
<td>Guideline development group EVAL SME/Group</td>
<td>Completion of quality assessment</td>
<td>AGREE II Tool Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise, 2014</td>
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<td>b. Add any needed supporting citations.</td>
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<td><strong>6. Finalize computable CPG artifacts (L3) and documentation, to include drafts of user needs, use cases, and other informatics design artifacts.</strong></td>
<td>a. Finalize CPG expressions (L3) and definitional knowledge assets (e.g., declarative or models).</td>
<td>INFO SME IMPL SME</td>
<td>Finalized L3</td>
<td>A multi-layered framework for disseminating knowledge for computer-based decision support</td>
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<td>b. Identify expected common derivatives (e.g., eCQM, eCase reports, CDS) desired by guideline development group, other key stakeholder incl end-user/ consumer reps.</td>
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<td>CDS Connect</td>
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<td>c. Identify requirements related to making resources findable on digital platforms, (e.g., tagging specific sections based on content-based terminologies and ontologies.)</td>
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<td>HL7 FHIR Representing Knowledge Artifacts</td>
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<td>d. Develop documentation.</td>
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<td><strong>7. Prepare computable CPG artifacts and documentation for online repositories.</strong></td>
<td>a. Finalize artifacts to include use cases, use case diagrams, decision trees, flowcharts, workflow diagrams,</td>
<td>Guideline staff, guideline writing group/panel</td>
<td>Supplemental material</td>
<td>Opioid Prescribing Recommendation #5: Lowest Effective Dose</td>
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<td>proposed data elements, and other informatics design artifacts to make available online when the guideline is published.</td>
<td></td>
<td>COMM SMEs INFO SMEs IMPL SMEs</td>
<td></td>
<td>Github CDS Connect Repository Value Set Authority Center</td>
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<td>b. Prepare final repositories and libraries for concepts, data elements (profiles, terminologies, value sets, libraries, groups, rules, and logic representations/expressions). Include test cases and testing results.</td>
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<td>c. Finalize and document necessary tags, structured terminology elements, and other content related to informatics requirements associated with guideline text.</td>
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<td>d. Ensure communications and publication teams are aware of any items that will be published.</td>
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| 8. Obtain feedback on text and incorporate any necessary edits or copyedits. | a. Determine how to obtain and consolidate feedback from co-authors, oversight committee, external SMEs, and organizational authorities.  
  b. Use an iterative approach with writing/editing, and structuring of text among guideline co-authors, informaticians, and implementors. | Guideline staff  
 Guideline writing group/panel  
 INFO SME  
 IMPL SME | Finalized draft of manuscript text, including recommendations, tables, flowcharts, algorithms, figures | Relevant style manuals, e.g., *The Elements of Style, Fourth Edition*, by William Strunk Jr. and E.B. White  
 *Lessons in Clarity and Grace* by Joseph M. Williams and Gregory M. Colomb.  
 Manual for Writers of Research Papers, Theses, and Dissertations by K. Turabian |
| 9. Obtain approval (if required by policy) to move to next step. | a. Approach depends on organizational policies, as defined in earlier steps. | Guideline writing group/panel | Approval obtained (if required) | |
| 10. Update evaluation plan for the guideline.  
  Note: Review evaluation plan prior to release of guideline. | a. Update evaluation plan including logic model components:  
  • Evaluation SMART objectives, target audience, time frame and frequency, methods, measures such as clinical quality performance measures, expected outcomes, resources needed:  
  • WHAT is the theoretical framework for the evaluation?  
  • WHEN will the evaluation begin?  
  • WHAT will be evaluated?  
  • WHO is responsible?  
  • WHAT type of evaluation? | EVAL Team  
 Guideline Lead | Updated evaluation plan  
 List of evaluation questions and methods to operationalize evaluation objectives. Evaluation tools identified or developed | See Phase 4, Activity 7 for evaluation resources. |
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<tr>
<td>11. Ensure COMM plan is shared/agreed upon by all relevant parties, and revise COMM plan based on other’s input.</td>
<td>a. Hold meeting to ensure guideline and other leads agree with COMM plan.</td>
<td>COMM lead</td>
<td>Updated COMM plan</td>
<td>Communication SOPs: A Checklist for Effective Communication and Dissemination (Appendix C)</td>
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<td>b. Coordinate with the organizations’ relevant staff, e.g., communication, media, and policy staff about:</td>
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<td>• HOW will evaluation be conducted?</td>
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<td>• WHEN will guideline be evaluated (3 months, 6 months, 1 year?)</td>
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<td>• HOW will evaluation be funded? In-house or contracted?</td>
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<td>• WHAT measurement tools and databases?</td>
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<td>• HOW will results be used when updating the guideline?</td>
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<td>b. Brainstorm and prioritize draft evaluation questions and appropriate methods to answer them. Methods can be qualitative, quantitative, mixed methods, naturalistic inquiry, and research design, e.g., pre-post, experimental, time series.</td>
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<td>c. Choose/develop the evaluation instruments and methods, e.g., surveys, focus groups, interviews, usability testing.</td>
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| • Clearance & Timing of release  
• Coordination of messages and messengers  
• Plans for controversial topics  
• Who will lead COMM plan  
• Design, format, and branding  
• Metrics- measure reach & impact | | | | |
| 12. Develop communication products | a. Develop communication products – quick guides, mobile apps, pocket cards for different audiences (e.g., consumers, providers). Ensure appropriate design, logos, branding. Pilot test some products, if feasible. Determine how to shorten process. | COMM SME IMPL SME INFO SME | Priority communication products developed | The Science of Science Communication A Research Agenda | National Academies Risk Communication | FDA The CDC Clear Communication Index |
### Future State Tables - Phase 8: Finalize Manuscript for Internal, External & Peer Review/ Public Comment

Validate CPG and create derivatives (measures and interventions)

<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
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<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
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</thead>
<tbody>
<tr>
<td>1. Finalize the draft written guideline and derivative products for formal review.</td>
<td><strong>Full Guideline Draft</strong>&lt;br&gt;a. Apply the agreed upon or a standardized format for the guideline, with structure, headings, and content.&lt;br&gt;b. Edit the full draft.</td>
<td>Technical writer editor&lt;br&gt;IMPL SME&lt;br&gt;INFO SME&lt;br&gt;COMM SME&lt;br&gt;Oversight Group&lt;br&gt;Technical writer-editor</td>
<td>Completed full guideline draft</td>
<td>GIN-McMaster Guideline Development Reporting Checklist&lt;br&gt;Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise, 2013&lt;br&gt;Guidelines and Recommendations: A CDC Primer, 2012&lt;br&gt;WHO Handbook, 2012&lt;br&gt;COGS Checklist, 2003&lt;br&gt;NICE&lt;br&gt;SIGN</td>
</tr>
<tr>
<td><strong>Derivative products</strong>&lt;br&gt;a. Finalize draft computable CPG design artifacts, computational assets, and resources allowing event condition action (ECA) rules, metrics.&lt;br&gt;b. Finalize draft of other products – quick guides, mobile apps, pocket cards. Ensure appropriate design, logos, and branding. Pilot some products, if feasible. Determine how to shorten that process.</td>
<td>COMM SME&lt;br&gt;IMPL SME&lt;br&gt;INFO SME</td>
<td>Completed review of priority derivative products</td>
<td>A multi-layered framework for disseminating knowledge for computer-based decision support&lt;br&gt;CPG-on-FHIR L2 checklist&lt;br&gt;CPG-on-FHIR L3 checklist&lt;br&gt;Peer review&lt;br&gt;Public comment&lt;br&gt;Standards balloting: HL7</td>
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<tr>
<td>What to do (sequence of events)</td>
<td>How to do (activities)</td>
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| 2. Conduct internal review.    | a. Conduct a review of the final draft of the guideline and derivative products to assigned members of the guideline workgroup, allowing sufficient opportunity for feedback, editing and revisions. Collect feedback using a written format.  
   b. Seek approval from all members of the guideline development group for the final document(s) before internal and external reviews.  
   c. Initiate organizational (i.e. internal) review as per organizational policies.  
   d. Incorporate feedback and responses into document and produce next draft (manuscript & derivative products). | Guideline Workgroup Lead  
INFO SME  
IMPL SME  
COMM SME | Review completed | SharePoint, and other software specific to organizations  
**Federal peer review policies and practices, 2020**  
**Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development.** |
3. Conduct external review, and revise recommendations and derivative products as needed.

<table>
<thead>
<tr>
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| 3. Conduct external review, and revise recommendations and derivative products as needed. | a. Decide on the method(s) for engaging external review of the final document(s), including manuscript & derivative products:  
- Invited SMEs (individuals and organizations)  
- Cross-post links for the written and computable guideline  
- Public comments, when appropriate. | Guideline lead INFO SMEs COMM SMEs | Updated guideline document | Engagement with Public Stakeholders and Partners  
Stakeholder Analysis and Risk Assessment Log (Appendix B)  
Stakeholder Analysis Log  
COI forms  
Review comment forms  
British Columbia, External Review of Guidelines |
|                                | b. Incorporate feedback and responses into document; produce next draft. | Section authors Writer-editor INFO SME IMPL SME " | Summary of software options and potential reviewers | Designing a Community-engaged Health Informatics Platform  
Does a Community-Engaged Health Informatics Platform Facilitate Resource Connectivity? An Evaluation Framework  
Intersection of Health Informatics Tools and Community Engagement in Health-Related Research to Reduce Health Inequities: Scoping Review |
<p>|                                | c. Make alterations to the guideline recommendations &amp; products, if needed. | &quot; | &quot; | &quot; |</p>
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<tr>
<td>4. Release computable CPG and derivatives (based on written guideline) for comment by users.</td>
<td>a. If resources are available, invite additional feedback by user groups, partner organizations, and industry. (not intended to be used in clinics) by including cross-posted links to the computable content with a link to the written guideline draft.</td>
<td>INFO SME IMPL SME</td>
<td>Feedback on CPG</td>
<td>CDS Connect Repository</td>
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<tr>
<td>5. Ensure transparency and documentation.</td>
<td>a. Document the internal and external peer review process. b. Document the selection and enrollment of consumers and stakeholders. c. If applicable, publish comments and the guideline dev. group responses.</td>
<td>Project Chair or Manager</td>
<td>Documentation of internal and external peer review process</td>
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<tr>
<td>6. Revise and finalize the draft.</td>
<td>a. Writer-editor performs final editing. b. Guideline workgroup reviews and signs off.</td>
<td>Writer-Editor Workgroup leads</td>
<td>Finalized copy of guidelines</td>
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<tr>
<td>7. Conduct organizational review of manuscript and approval (if required by organization).</td>
<td>a. Submit the draft and derivative products to organizational clearance mechanism for review and approval (e.g. federal/HHS - may need Asst. Sec. for Public Affairs (ASPA) clearance).</td>
<td>Guideline lead</td>
<td>Cleared and approved final copy of guidelines and derivative products.</td>
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<tr>
<td><strong>What to do</strong> (sequence of events)</td>
<td><strong>How to do</strong> (activities)</td>
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<td><strong>Resources and tools (Examples)</strong></td>
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| 8. Ensure all COMM products/messages/social media are approved and are easily accessible, and address different audience needs and risks. Revisit stakeholder analysis. (Appendix B) | a. Ensure products meet audience needs, preferences, and reading level.  
b. Revisit stakeholder analysis to identify COMM channels that will best reach stakeholders, e.g., mass media vs. specialty channels, health information technology (HIT) and topic domain clinical decision support influencers. | COMM Lead | Cleared communication plan | The CDC Clear Communication Index |
| 9. Assess potential media interest, statements/and outreach. | a. Determine if a press release and clearance among contributing organizations is needed.  
b. Identify partners who are trusted sources to share embargoed COMM plan.  
c. Identify and ensure prep for spokespersons for key messages/webinars, etc. | COMM Lead | Determination of media interest, and a plan to overcome potential controversy |
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<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
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| 10. Conduct environmental scan prior to release. | a. Prior to release, conduct an environmental scan to assess issues surrounding guidelines. Assess risk communication. For example: is there an outbreak for a specific pathogen related guideline; a new policy from a regulatory agency; or a congressional testimony or new data being released related to guideline?  
b. Plan for controversy, confusion and need for clear communication.  
c. Archive outdated guideline and replace with updated guideline. For example, AIDS INFO and CHEST guidelines insert a message saying this guideline is the updated version.  
d. Determine if there are old/outdated guidelines, products, CDS, training material, policies that need to be withdrawn or archived or labeled before or parallel to the release of new guidelines. Be clear about what’s been updated if the guideline is an update. | COMM Lead | Completed environmental scan | Crisis and Emergency Risk Communication (CERC) |
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<td>11. Submit manuscript and other products for publication.</td>
<td>a. Send final approved draft and products for publication.</td>
<td>Guideline lead, Workgroup leads, COMM SME</td>
<td>Published copy of manuscript, slide presentation of guideline &amp; other products</td>
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<td></td>
<td>What to do (sequence of events)</td>
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<tr>
<td>1.</td>
<td>Ensure all dissemination approaches, platforms, and content are ready to be used, e.g., website, links.</td>
<td>a. Assess and prepare for dissemination strategies on different platforms; develop clear communication detailed timeline for publication &amp; dissemination.</td>
<td>COMM SME Web team</td>
<td>Final distribution plan</td>
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<td>b. Coordinate dissemination modalities with web team(s).</td>
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<td>Dissemination sites are ready for product distribution</td>
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<td>c. Finalize plans for printing, posting in guideline repositories among stakeholders (e.g., partners, advocates, researchers.) Determine which finalized materials will be used, posted on web and digital platforms, e.g., CDS Connect. Determine if visualization is needed to ensure documents are accessible to those with disabilities.</td>
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<td>2.</td>
<td>Coordinate with journal and partners’ communication team.</td>
<td>a. Share and coordinate delivery of promotional materials, e.g., seminars, webinars for continuing education, blogs, editorials, implementation guides, fact sheets.</td>
<td>COMM SME Chair or Guideline Lead</td>
<td>Rollout directed by communications plan and coordinated by journal and other authors’ organizations (if it applies)</td>
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<td>3.</td>
<td>Prep and coordinate with people who will be speaking</td>
<td>a. Finalize talking points, media statement, FAQs, emails and notifications to</td>
<td>COMM SME Agency Directors</td>
<td>Prepping and coordinating completed</td>
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### What to do (sequence of events)

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<tr>
<th>How to do (activities)</th>
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<td>about the written and computable guidelines (e.g., author, organizational leaders).</td>
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<td>partners, and other public-facing messages.</td>
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<td>b. Conduct practice sessions to role play and prepare for anticipated questions and responses to the media.</td>
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<tr>
<td>a. Prepare spokespersons, messages, webinars, etc. Ensure dissemination modalities, e.g., key partners, media, are ready for guideline and product distribution.</td>
<td>COMM SME EVAL Lead Chair or Guideline lead</td>
<td>Communication plan launched</td>
<td>A Framework for Disseminating Evidence-Based Health Promotion Practices</td>
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<td>b. Start formal implementation, communication, and dissemination activities, e.g., release guideline and products.</td>
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<td>4. Launch communication and timed-release plan when manuscript is published and derivative products are approved for release.</td>
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<td>5. Track activities and evaluate launch of communication plan to determine if a successful release.</td>
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<tr>
<td>a. Measure success of dissemination using current industry standards, techniques, and metrics, e.g., number of paid and earned media placements, engagement of stakeholders, size of reach to intended audiences.</td>
<td>COMM/Web Team</td>
<td>Documented results of website and social media metrics, media articles, syndicated content from partners.</td>
<td>Altmetric Scopus ORCID iCite</td>
</tr>
</tbody>
</table>
# Future State Tables - Phase 10: Implement Guideline

Incorporate computable CPG into clinical decision support (CDS) systems and tools.

Note: This table focuses on CDS implementation at local levels. Activities will vary with various levels of formality based on urgency of implementation and available resources. Optional activities are suggested when work focuses on health provider facing CDS. Patient-facing tools are outside the scope of these tables.

<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
<th>*Responsible Entity, Others involved</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Prioritize, select, and promote guideline recommendations to implement.</td>
<td>a. Conduct care gap analysis between guideline recommendation and local practice, if feasible. Assess potential beneficial impact at the local level. (optional)</td>
<td>CDS Committee-Leadership Team IMPL CDS Team</td>
<td>Completion of local prioritization plan</td>
<td>Developing a checklist for guideline implementation planning, 2015</td>
</tr>
<tr>
<td></td>
<td>b. Conduct local feasibility assessment (what stakeholders are impacted and how guidelines fit and are harmonized with existing information systems, such as CDS workflow &amp; requirements). (optional)</td>
<td>“</td>
<td>“</td>
<td>CPG-on-FHIR L4 Checklist</td>
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<tr>
<td></td>
<td>c. Make decision which guidelines/CDS to implement. Provide analysis to the implementation team to inform project.</td>
<td>“</td>
<td>“</td>
<td>Guidelines into Decision Support (GLIDES)</td>
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<tr>
<td></td>
<td>d. Develop project scope statement and evaluation strategy, including baseline assessment, and implementation and evaluation strategy. (may be informal)</td>
<td>“</td>
<td>“</td>
<td>Implementing Clinical Decision Support Systems</td>
</tr>
<tr>
<td></td>
<td>e. Communicate decision to implement.</td>
<td>“</td>
<td>“</td>
<td>Factors influencing the implementation of clinical guidelines for health care professionals: A systematic meta-review</td>
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<td></td>
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<td></td>
<td>The effectiveness of clinical guideline implementation strategies – A synthesis of systematic review findings</td>
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<td></td>
<td>Successes and failures in the implementation of evidence-based guidelines for clinical practice</td>
</tr>
<tr>
<td>What to do (sequence of events)</td>
<td>How to do (activities)</td>
<td>*Responsible Entity, Others involved</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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</tbody>
</table>
| 2. Analyze local workflow and context. | a. Assess current local workflow including degree of provider burden associated with the proposed CDS.  
   b. Engage stakeholders about proposed CDS implementation. | Clinical INFO SMEs  
   IMPL CDS Team  
   Medical/nursing Leads  
   Clinicians (End Users)  
   “ | Completed evaluation of local workflow | CPG-on-FHIR L4 Checklist  
   GUIDES Checklist  
   Improving Outcomes with Clinical Decision Support: An Implementer’s Guide (Chapter 6)  
   AHRQ Digital Healthcare Research - Workflow Assessment for Health IT Toolkit  
   Workflow Process Mapping for Electronic Health Record (EHR) Implementation |
| 3. Conduct feasibility Assessment (Technical) | a. Assess feasibility of implementing the CDS within local clinical information systems, e.g., EHR, lab systems, pharmacy systems in terms of structured data, CDS triggers, and actions envisioned.  
   b. Assess feasibility for measuring the effectiveness of CDS using local EHR and analytic capabilities. | Clinical INFO team  
   CDS IMPL team  
   IT  
   EHR SME  
   “ | Completed feasibility assessment | Improving Outcomes with Clinical Decision Support: An Implementer’s Guide (Chapter 5) |
| 4. Design local clinical implementation. | a. Map workflow, including end user perspectives. Use real- | Clinical INFO Team,  
   Localized workflow is mapped | | User stories as lightweight requirements for agile clinical |
<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
<th>*Responsible Entity, Others involved</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
</table>
| (e.g., Localization of new workflow, any L3 to L4 adjustments) | world recent use cases to validate designs; locate records/data that inform these use cases.  
b. Design IT artifacts/features within local system architecture.  
c. Formalize an approach to measuring impact and outcomes, including metrics that can improve clinical practice and patient care. (optional)  
d. Determine how data needed for measurement will be captured locally from EHR and other sources e.g., define what population and other conditions are in denominator. (optional)  
e. Start to develop training (localize) and make clinicians aware of any workflow changes.  
f. If needed, repeat above for multiple EHRs in the local environment. (optional) | CDS IMPL team (internal & external) IT End users | Local IT artifacts are designed.  
Local measurement approach is designed | decision support development  
See references in 10.2 and 10.3  
BPM+ Health  
CDS Connect |
<table>
<thead>
<tr>
<th><strong>[10]</strong> What to do (sequence of events)</th>
<th><strong>How to do (activities)</strong></th>
<th>*<strong>Responsible Entity, Others involved</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
</table>
| 5. Conduct mid-progress review and launch planning. | a. Review design before build and testing.  
   b. Plan launch, e.g., go-live staffing (optional) | Clinical INFO Team,  
   CDS IMPL team (internal & external)  
   Clinical end users | | |
| 6. Build and test L4 artifacts and features in EHR. | a. Build and unit test L4 artifacts or features using real-world use cases, such as:  
   • Value sets, logic records, rules  
   • Order sets, alerts  
   • Web services, e.g., CDS HOOKS, SMART-on-FHIR apps, or local implementation of clinical quality language (CQL)  
   • Dashboards and patient summary views.  
   b. Consider synthetic testing with sandboxes using simulated patients or EHRs, if available.  
   c. Conduct a build review.  
   d. Demo to clinical stakeholders and build consensus among practitioners. (optional) | Clinical INFO  
   CDS IMPL team (including IT staff Vendor) | L4 artifacts built and unit tested | CDC Opioid Prescribing Support Implementation Guide  
   Profiles defined as part of the CDC Opioid Prescribing Guideline Implementation Guide  
   Terminology defined as part of the CDC Opioid Prescribing Guideline Implementation Guide |
<p>| 7. Test clinical information systems and decision support. | a. Write localized test scripts and conduct integrated system testing. Use real-world recent | CDS IMPL Team QA testers | Clinical validation completed | See resources in activity #6 above |</p>
<table>
<thead>
<tr>
<th><strong>What to do</strong> (sequence of events)</th>
<th><strong>How to do</strong> (activities)</th>
<th>*<strong>Responsible Entity, Others involved</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Use cases &amp; records/data to test systems. Test local system and connectivity to outside resources (e.g., APIs).</td>
<td>use cases &amp; records/data to test systems. Test local system and connectivity to outside resources (e.g., APIs).</td>
<td>End users (clinicians and/or patients)</td>
<td></td>
<td>Best practices for preventing malfunctions in rule-based clinical decision support alerts and reminders: Results of a Delphi study</td>
</tr>
<tr>
<td>b. Conduct clinical validation through user acceptance testing, workflow validation, and usability testing, if appropriate. For example: Test with real patients, non-visible to clinicians; test in production by small number of clinicians; pilot in a small subset of clinical settings and provide feedback.</td>
<td>Conduct clinical validation through user acceptance testing, workflow validation, and usability testing, if appropriate. For example: Test with real patients, non-visible to clinicians; test in production by small number of clinicians; pilot in a small subset of clinical settings and provide feedback.</td>
<td>CDS IMPL Team</td>
<td></td>
<td>The Design of Decisions: Matching clinical decision support recommendations to Nielsen’s design heuristics</td>
</tr>
<tr>
<td>c. Revise clinical information systems and decision support as needed, based on testing and user feedback.</td>
<td>Revise clinical information systems and decision support as needed, based on testing and user feedback.</td>
<td>CDS IMPL Team</td>
<td></td>
<td>Electronic Health Record (EHR) System Testing Plan</td>
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<td></td>
<td>Testing electronic health records in the &quot;production&quot; environment</td>
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<td>Heuristic Evaluations and Expert Reviews</td>
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<td>HHS Policies and Standards</td>
</tr>
<tr>
<td>8. Update policy &amp; procedures, as needed; educate and train end users how to use guidelines in clinical decision support, using the most appropriate methods.</td>
<td>a. Update organizational policies and procedures, as needed.</td>
<td>CDS IMPL SME Trainers</td>
<td>Completed training</td>
<td>What is clinical decision support (CDS)?</td>
</tr>
<tr>
<td></td>
<td>b. Update education with local systems final interface design, i.e., screenshots.</td>
<td>INFO SME</td>
<td></td>
<td>Clinical Decision Support Software</td>
</tr>
<tr>
<td><strong>What to do</strong> (sequence of events)</td>
<td><strong>How to do</strong> (activities)</td>
<td><strong>Responsible Entity, Others involved</strong></td>
<td><strong>Success Indicators</strong></td>
<td><strong>Resources and tools</strong> (Examples)</td>
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<td>c. Decide who to train, &amp; how to best deliver training; tailor to local training channels.</td>
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<td>d. Train end users on how to use guidelines in CDS.</td>
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<td><strong>9. Deploy clinical decision support using the most appropriate methods.</strong></td>
<td>a. Determine date to deploy new CDS, based on operational readiness.</td>
<td>IT Change management team CDS IMPL TEAM</td>
<td>Completed deployment</td>
<td>Improving Outcomes with Clinical Decision Support: An Implementer’s Guide (Chapter 8) GUIDES Checklist CPG-on-FHIR L2, L3, and L4 checklists</td>
</tr>
<tr>
<td></td>
<td>b. Update and execute go-live staffing plan for release of clinical decision support for clinicians.</td>
<td>Clinical INFO staff and trainers (assist end-users)</td>
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<td></td>
<td>c. Migrate artifacts from development to testing to production.</td>
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<td></td>
<td>d. Test with real patients, non-visible to clinicians. (silently). (optional)</td>
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<td></td>
<td>e. Test in production by small number of clinicians (optional)</td>
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<td></td>
<td>f. Pilot in a small subset of clinical settings and provide feedback. (optional)</td>
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<tr>
<td><strong>What to do</strong> (sequence of events)</td>
<td><strong>How to do</strong> (activities)</td>
<td><strong>Responsible Entity, Others involved</strong></td>
<td><strong>Success Indicators</strong></td>
<td><strong>Resources and tools (Examples)</strong></td>
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<td>10. Use clinic decision support in clinics.</td>
<td>a. Use system as designed.</td>
<td>Clinicians</td>
<td>System implementation and feedback to users.</td>
<td>Clinical decision support alert malfunctions: analysis and empirically derived taxonomy.</td>
</tr>
<tr>
<td></td>
<td>b. Assess end user interactions with clinical decision support, e.g., observations or data on usage patterns. Identify variations across users.</td>
<td>CDS INFO team INFO SME Trainers Clinicians &amp; patients</td>
<td>“”</td>
<td>“”</td>
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<tr>
<td></td>
<td>c. Users provide feedback (subjective and real time). Assist users as needed.</td>
<td>“”</td>
<td>“”</td>
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<tr>
<td>11. Assess and refine the CDS.</td>
<td>a. Conduct quantitative assessment per measurement strategy.</td>
<td>CDS IMPL Team INFO Team Data Analytics Team Quality Improvement Team</td>
<td>Completed evaluation and refinement of artifact</td>
<td>Change-point detection method for clinical decision support system rule monitoring The Effect of Passive Choice and Active Choice Interventions in the EHR to Cardiologists on Statin Prescribing: A Cluster Randomized Clinical Trial Recommendations for Clinical Decision Support Deployment: Synthesis of a Roundtable of Medical Directors of Information Systems</td>
</tr>
<tr>
<td><strong>What to do</strong> (sequence of events)</td>
<td><strong>How to do</strong> (activities)</td>
<td><strong>Responsible Entity, Others involved</strong></td>
<td><strong>Success Indicators</strong></td>
<td><strong>Resources and tools (Examples)</strong></td>
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<td>12. Provide feedback to guideline developer and implementor on the computable CPG.</td>
<td>a. Report feedback from end-users and other relevant data sources.</td>
<td>IMPL SME</td>
<td>Summary of feedback</td>
<td></td>
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</tbody>
</table>
## Future State Tables – Phase 11: Evaluate Guideline Outcomes and Impact

<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
</tr>
</thead>
</table>
| 1. Tailor and finalize evaluation plan and questions to context of local implementation, such as a regional health care system, hospital network, or individual clinics. | a. Finalize evaluation questions. Guideline implementation evaluation is dependent on program and stakeholder priorities and feasibility of conducting the evaluation per resources. The plan should be flexible and adaptive. Adaptive means to target questions to local implementation.  
   b. Adapt and finalize methods for collecting, analyzing, and sharing data/findings via feedback loops to the guideline developers.  
   c. Reconsider environmental context. | EVAL Team  
   Guideline Lead | Final evaluation plan finalized, including questions and methods | See resources in Phase 4, activity 7. |
| 2. Implement the evaluation plan at the time the guideline is released, and in conjunction with the communication plan. | a. Launch evaluation plan  
   Collect, summarize, and document the first wave of results, e.g., hits on the written document; downloads of CDS code, solicited and unsolicited user feedback. Evaluation implementation process issues, awareness and knowledge improvements, if feasible. (short-term or proximal evaluation) | EVAL Team  
   INFO SME  
   IMPL SME  
   Partners  
   COMM SME  
   A convenient sample of clinicians/practitioners | Evaluation plan implemented and feedback documented  
   Evaluation results are summarized and provided to guideline workgroup and oversight committee. | **Trends in guideline implementation: a scoping systematic review.**  
**Factors influencing the implementation of clinical guidelines for health care professionals: A systematic meta-review.**  
**The effectiveness of clinical guideline implementation strategies – A synthesis of systematic review findings** |
<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators (Examples)</th>
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</thead>
<tbody>
<tr>
<td>c.</td>
<td>Present results to guideline authors, oversight committee, and partners.</td>
<td>EVAL Team</td>
<td>Recommendations documented for updating guideline</td>
</tr>
<tr>
<td>d.</td>
<td>Collect, summarize, and document the second wave of results, e.g., behavioral and policy changes, feedback if feasible (intermediate evaluation).</td>
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<tr>
<td>e.</td>
<td>Present results to guideline authors, oversight committee and partners.</td>
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<td>f.</td>
<td>Collect, summarize, and document the third wave of results, e.g., feedback, health outcome improvements, if feasible (distal evaluation).</td>
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<td>g.</td>
<td>Present results to guideline authors, oversight committee, and partners.</td>
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<td>h.</td>
<td>Submit feedback and suggestions for guideline update for phase 12 – guideline update, based on results, new evidence, other criteria, e.g., a guideline can be updated because of evaluation outcomes or changing parameter estimates.</td>
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</table>

**Resources and tools**

- Facilitating the Use of Evidence in Practice: Evaluating and Adapting Clinical Practice Guidelines for Local Use by Health Care Organizations.
- Successes and failures in the implementation of evidence-based guidelines for clinical practice.
- Translating guidelines into practice: A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines.
- Conceptual frameworks and empirical approaches used to assess the impact of health research: an overview of reviews.
- Measuring the Use of NICE Guidance.
### Future State Tables - Step 12: Update Guideline

<table>
<thead>
<tr>
<th><strong>What to do</strong> (sequence of events)</th>
<th><strong>How to do</strong> (activities)</th>
<th><strong>Responsibility, Expertise Needed</strong></th>
<th><strong>Success Indicators</strong></th>
<th><strong>Resources and tools (Examples)</strong></th>
</tr>
</thead>
</table>
| 1. Create management or operational plan for updating the written and computable guidelines. See cycle diagram. | a. Create/define criteria for updating guidelines, (who, what, when-time frame, how) including the types of updates and their scope, to determine if an update is needed.  

b. Determine the methods, scope, type of updates, and prioritization needed to update the quality of evidence for a specific recommendation(s) in a guideline.  

c. Define and establish resources to create a system that supports continuous and timely feedback and updating of the written and computable guideline, according to established criteria. Sub-steps include detailing project management plans, staffing and reporting structure, infrastructure required (cloud computing) software procurement, and associated costs, etc.). | Guideline Lead/SMEs  
INFO SMEs  
IMPL SMEs | Operational plan |  
NICE CRITERIA  
Grohl R, Improving the quality of medical care... JAMA 2001  
Developing clinical practice guidelines: reviewing, reporting, and publishing guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development.  
The validity of recommendations from clinical guidelines: a survival analysis. |
<table>
<thead>
<tr>
<th>What to do (sequence of events)</th>
<th>How to do (activities)</th>
<th>Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
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</thead>
</table>
| 2. Use on-line resources, e.g., standardized registries and repositories to hold, share, and receive feedback on guideline data, content, and digitized components. | a. Create or use existing electronic (on-line) and other feedback mechanisms.  
b. Develop specifications to create, manage, and maintain documentation of technical and informatics knowledge associated with the guideline. | INFO SME  
IMPL SME  
IT  
Guideline Lead/SMEs | Completed infrastructure that guideline developers can use efficiently. | Federal Register  
ONC Project Tracking System |
| 3. Update systematic reviews as needed to keep them current and relevant. Consider living systematic reviews. | a. Review time frame on how frequently new evidence is sought and screened.  
b. Continuous expert/surveillance teams (example, living systematic review (LSR) Team and guideline sub-workgroup) connected to each knowledge/information byte (recommendation or research question) conduct continual, active monitoring of the evidence (i.e., daily, monthly, quarterly searches- as per resources) and subsequent updating of recommendation.  
c. Update systematic review with new evidence. Consider whether PICO questions should be added or revised.  
d. Where applicable, and if feasible, explore the use of new technologies which utilize human and machine effort, | Content SMEs  
Guideline SME  
INFO SMEs  
IMPL SMEs | Systematic reviews updated | Living systematic review: 1. Introduction—the why, what, when, and how  
AHRQ Systematic Review Data Repository  
KDIGO Guideline Updating  
Online guideline authoring tools Crowdsourcing (e.g., Cochrane Crowd)  
Task-sharing platforms (e.g., TaskExchange)  
Database aggregators (e.g., HDAS, epistemonikos.org)  
Automatic retrieval of full-text papers (e.g., CrossRef)  
Covidence  
GRADEPro  
Machine-learning information-extraction systems (e.g., RobotReviewer, ExaCT, Dr. Evidence) |
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<tr>
<th>What to do</th>
<th>How to do (activities)</th>
<th>*Responsible Entity, Expertise Needed</th>
<th>Success Indicators</th>
<th>Resources and tools (Examples)</th>
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<tr>
<td>(sequence of events)</td>
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<tr>
<td></td>
<td>such as artificial intelligence (AI), text mining, machine learning, and crowd sourcing.</td>
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<tr>
<td>4. Reaffirm, update, retire the current guideline recommendation(s) or develop new guideline recommendation(s) if needed, according to the criteria established in the operational plan for updating recommendations. (see step 1)</td>
<td>a. Periodically review feedback, literature evidence, and evaluation results against the criteria in the operational plan to determine whether to update or develop new recommendations.</td>
<td>SUBJ SME, COMM SME, EVAL SMEs</td>
<td>Determination of what to do with guideline recommendations</td>
<td>Linkage of existing structured data sources (e.g., clinical trials registries). Automated structured data extraction tools for PDFs. (e.g., ContentMine, Graph2Data) Assessing risks of bias (e.g., RobotReviewer)</td>
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<td>b. Develop process to reaffirm recommendation(s) not to update.</td>
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<td></td>
<td>c. Label, remove, replace, or archive all outdated guideline recommendation(s) and derivative products.</td>
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<tr>
<td>5. Update related CPG artifacts, (e.g., CDS tools, eCQMs) as needed, based on updated recommendations.</td>
<td>a. Review updated recommendations and any other factors, such as local clinical systems feedback, other new evidence that may affect CPG artifacts, e.g., changes to value sets or terminologies, software updates for CDS, eCQMs.</td>
<td>INFO SME, Content SMEs, Guideline SMEs, COMM SMEs</td>
<td>Updated CPG artifact(s), as needed.</td>
<td>Principles of Guidelines-Driven PPM Informatics Github CDS Connect Repository</td>
</tr>
<tr>
<td></td>
<td>b. Update CPG artifacts and associated code repositories, systems, policies, and training, as needed.</td>
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<tr>
<td>What to do (sequence of events)</td>
<td>How to do (activities)</td>
<td>*Responsible Entity, Expertise Needed</td>
<td>Success Indicators</td>
<td>Resources and tools (Examples)</td>
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<tr>
<td>c. Label, remove, replace or archive all outdated CPG artifacts.</td>
<td>(6.) Monitor the landscape for changes such as new drugs, coding schemes, adverse events that would require modification of semi-structured, structure, and executable recommendations (L2-L4).</td>
<td>&quot;</td>
<td>Assigned Guideline, SUBJ and INFO SME, per operational plan. May vary by organization.</td>
<td><a href="https://www.nlm.nih.gov/news/NLM_VSAC_Intensional_Definition_Functionality.html">https://www.nlm.nih.gov/news/NLM_VSAC_Intensional_Definition_Functionality.html</a> Note: Use of Intensional Value Sets can obviate the need for monitoring.</td>
</tr>
<tr>
<td>a. Describe the items that need to be monitored that require updating the CPG artifacts but may not change the recommendation, e.g., FDA requirements, new drugs and therapies, adverse events, SNOMED, generic changes in coding, e.g., ICD, CPT. For example, a new beta blocker is approved for use so the code for the beta blocker name would be added to the CDS, but the recommendation would remain to use beta blockers.</td>
<td>(7.) Communicate updated or new recommendations and CPG artifacts and evaluate communication products.</td>
<td>COMM SME EVAL SME</td>
<td>Communication strategy and evaluation completed</td>
<td>[The Science of Science Communication A Research Agenda</td>
</tr>
</tbody>
</table>
Overview of Integrated Process for Developing Written and Computable Guidelines

Appendix A

Guideline Development Decision Tool

The Guideline Development Decision Tool (GDDT) consists of questions in three steps. Step 1 helps you determine whether a proposed guideline is needed. Step 2 helps you determine whether your organization should develop the proposed guideline. Step 3 helps you determine whether to develop a computable version of a proposed clinical practice guideline. Information is provided under each question to help you answer those questions. Since guideline development can take many years and consume many resources, we encourage guideline developers to answer each question in their order before developing a guideline, and to justify their answers in the boxes provided. Respondents can attach a document, link, citation, or highlighted section as rationale. For a more informative process, we recommend that more than one guideline developer respond to the questions.

Step 1. Answer all four questions under “Step 1.” If you have answered all questions without any “reconsider” responses, a strong case exists for developing the proposed guideline.

Step 2. Answer all questions under “Step 2.” If you have answered all questions without any “reconsider” responses, a strong case exists for your organization to be involved in developing the proposed guideline.

Step 3. Answer all questions under “Step 3.” If you have answered all questions without any “reconsider” responses, a strong case exists to develop a computable clinical practice guideline (CCPG).

Once completed, bring all information to leadership for a decision to proceed with the guideline development process. We recognize that this tool will be used for multiple and diverse public health guidelines, so not every question will be equally relevant. Although the primary use of the information is to inform decision making, it may also be useful for providing background information in the guideline manuscript.

This tool was adapted from the original CDC Guideline Development Decision Tool. Atlanta, GA: US Department of Health and Human Services, CDC https://stacks.cdc.gov/view/cdc/81404
GUIDELINE DEVELOPMENT DECISION TOOL

Step 1: Determine whether to develop the guideline at all, regardless of whether your organization develops it?

1.1 PUBLIC HEALTH BURDEN OR OTHER JUSTIFICATION
Will the guidelines focus on a current or potential public health burden, gap in clinical care, or other important need?

For example, the guideline could focus on a current or potential public health burden, clinical gaps in care, an emerging public health hazard, important public health methods, best practices, safety guidelines, lab practices, surveillance reports, or meaningfully reduce the gap between current and optimal practice in clinical care.

☐ If “Yes,” briefly describe the justification for the guideline. Type description here

☐ If “No,” reconsider whether the proposed guideline should be developed.

1.2. SIMILAR GUIDELINES
Are there current, credible, and relevant guidelines that make the proposed guideline entirely duplicative?

For example, an existing guideline on the same topic would not be entirely duplicative if the plan was to adopt or update the guideline based on current evidence.

☐ If “Yes,” reconsider whether the proposed guideline should be developed.

☐ If “No,” describe differences between existing and proposed guideline. Type description here

1.3 EVIDENCE
Does an evidence base exist on which to develop these guidelines?

Potential sources of evidence to consider beyond direct and indirect research findings include epidemiological data, case reports, EHR data, and practice-based evidence from subject-matter experts?

☐ If “Yes,” briefly describe available evidence and literature sources. Type description here

☐ If “No,” reconsider whether the proposed guideline should be developed.

1.4 ASSESSMENT OF STAKEHOLDER INTERESTS
Have your intended audience or other stakeholders expressed a need for a new or updated guideline on the topic?

Audience need could be communicated through meetings, focus groups, conferences, surveys, public hearings, or requests for information.

☐ If “Yes,” briefly describe audience feedback. Type description here

☐ If “No,” reconsider whether the proposed guideline should be developed.

Considerations for 1.1
1. Critical or potential burden or hazard can be expressed in various metrics, such as prevalence of mortality, morbidity, injury, disability, quality of life years (QALYs), disability adjusted life years (DALYs).

2. Gaps can be reflected in deficiencies in knowledge, clinician or patient awareness or adherence, progress in a particular public health area such as preventing, detecting, or treating a condition, reducing health disparities, or meeting health objectives.

Considerations for 1.2
3. Potential sources of guidelines include the Centers for Disease Control and Prevention (CDC), the National Institute for Health and Care Excellence (NICE), the U.S. Preventive Services Task Force (USPSTF), the Community Preventive Services Task Force (CPSTF), and other government agencies and professional organizations.

Considerations for 1.3
1. A preliminary scanning of the literature can be helpful to determine whether published evidence is available to support the proposed guidelines.

Considerations for 1.4
2. An assessment of stakeholder and end user needs can inform decisions on whether to produce a new or updated guideline, what questions should be prioritized, and what communication and dissemination strategies may be needed to foster uptake. Consider additional stakeholder engagement if needs of key stakeholders is not clear. For example, opinions can be collected from internal and external champions, subject-matter experts, and partners interested in collaboration.
Step 1 Results: If you have reached this point without any “reconsiders” to the four questions, a strong case exists for guideline development. Go to Step 2.

GUIDELINE DEVELOPMENT DECISION TOOL

Step 2: Should your organization develop the proposed guideline?

2.1 PRIMARY RESPONSIBILITY
Does your organization have primary responsibility (or is it mandated by legislation, policy, or other directives) to lead development of this guideline?

☐ If “Yes,” briefly describe how the proposed guideline aligns with your organization’s mission and goals.

☐ If “No,” reconsider whether your organization should develop the proposed guideline.

2.2 PARTNERSHIPS
Is it appropriate for your organization to partner with another organization to develop the proposed guideline?

☐ If “Yes,” briefly describe the organization and the proposed approach for collaboration.

☐ If “No,” explain why it is not appropriate or feasible for your organization to partner with another organization to develop the proposed guideline.

2.3 RESOURCES and TIME:
Are there adequate resources and time available to develop the proposed guideline?

Resources for guideline development include staff and manager time as well as financial resources for meetings, scientific and logistical support, and publishing. Guideline developers can construct a work plan for guideline development to determine timeline and resources needed.

☐ If “Yes,” briefly describe resources and time necessary to carry out these activities.

☐ If “No,” reconsider whether your organization should be involved in developing the proposed guideline.

Considerations for 2.1
• The topic aligns with my organization’s mission.
• My organization has recognized expertise or responsibility for the topic.
• My organization is mandated to take the lead on this guideline.
• If my organization doesn’t develop the guideline, it may not be developed.

Considerations for 2.2
1. A partnership could increase support and reach of the proposed guideline, inspire creative ideas, solutions, and greater potential for guideline use, or provide an opportunity to reduce staffing and financial burden. On the contrary, it may not be appropriate to partner with another organization due to anticipated challenges, e.g., lengthening time, less control over the process.

Considerations for 2.3
1. Guideline development can take a substantial amount of time. Determining whether adequate time is available and ensuring that stakeholders are comfortable with that timeline is important before embarking on a guideline development project. Consider adding partnerships or reducing the guideline scope or adopting a modular approach (i.e., one research question at a time) to make it more feasible to develop the proposed guideline.

2. Adequate consideration also needs to be given to planning guideline dissemination, communication/translation, and evaluation. To maximize guideline use, consider staff availability and resources for distributing guideline through multiple channels (e.g., manuscripts, emails, webinars, websites, presentation, conferences, social media), communication or translating the guideline into easy-to-use formats (e.g., charts, videos, briefs, web applications, electronic protocols), and evaluating the guideline.
Step 2 Results: If you have reached this point without any “reconsiders” to the three questions, a strong case exists for your organization to be involved in developing the proposed guideline. Proceed to Step 3, if your organization is considering whether to develop a computable guideline.

GUIDELINE DEVELOPMENT DECISION TOOL

Step 3: Determine whether to develop a computable clinical practice guideline (CCPG)

3.1 STAKEHOLDER AND ENDUSER NEEDS ASSESSMENT
Do stakeholders report a desire for CCPGs based on their current views of CCPG capabilities and lessons learned? AND Do end users report that a CCPG will be more easily accessible, implementable, and adhered to compared to a written guideline?

☐ If “Yes,” briefly describe assessment results. Type description here

☐ If “No,” reconsider whether your organization should develop a CCPG.

3.2 EVIDENCE REVIEW
Does the literature provide any information on advantages, cost-effectiveness, or acceptability of CCPGs for this topic or related topics? AND Do open-source computable components exist that could be reused in this proposed CCPG, (e.g., value sets, logical models and resources for FHIR profiles, algorithms, libraries)?

☐ If “Yes,” briefly describe evidence review and available open-source computable components. Type description here

☐ If “No,” reconsider whether your organization should develop a CCPG.

3.3 FEASIBILITY AND PRIORITY ASSESSMENT
Is it logistically feasible for the organization to develop the CCPG? For example, do the data elements exist in EHR? Will CCPG development benefit the organization or advance its mission, e.g., improve health outcomes? Will CCPG be expected to accelerate implementation and adoption of the guideline recommendations? Are resources available for developing, piloting, and publishing a CCPG? Are resources available for maintaining a CCPG?

☐ If “Yes,” to most questions, briefly describe assessment results. Type description here

☐ If “No,” reconsider whether your organization should develop a CCPG.

Considerations for 3.1 and 3.2
The following information may be collected:
• End user desired capabilities
• End user defined benefits and harms
• Existing facilitators (e.g., resources)
• Current barriers and challenges in accessing, accepting, implementing, adapting, and adopting CCPGs
• Effect on patient outcomes and costs
• Impact on clinical workflows

Considerations for 3.3
Assess expert opinion, and conduct SWOT, PESTLE, CDC example of PESTLE, and industry analysis.

The following resource and industry information may be collected from experts:
1. Development feasibility and costs, e.g., computable components needed if already exist that could be reused. Complete the “At a Glance” Implementation L4 Checklist
2. Current IT technological resources and gaps
3. Fixed and recurring costs
4. Staffing and training resources and needs
5. Business strategies used by other groups

Information may be collected from
• Champions—internal and external who may collaborate
• Internal and external groups who are developing or who have developed similar tools
• Potential partnerships with internal and external groups
• Resources: See L2, L3, and L4 checklists
Step 3 Results: If you have reached this point without any “reconsiders” to the three questions, a strong case exists for your organization to develop a computable clinical practice guideline. Bring results to leadership for a decision to proceed with the guideline development process.

Appendix B
Stakeholder Communication Analysis

Who has information, expertise, or experience that could meaningfully support this project?

Whose support is needed to improve the chances of a successful outcome?

☐ Who could inhibit our success?
☐ Who serves as our champion in the organization?
☐ Who can help communicate how the project integrates with larger enterprise goals?
☐ Who is paying for the project?
☐ Who will work with us to implement the project, from our team, other internal teams or external organizations? Who might endorse the guideline?
☐ Who will receive the deliverables or benefits from the results?
☐ Who needs to know about our project outcomes/deliverables as it will impact their work?
☐ Who will have to change the most?
Appendix C
Communication Standard Operating Procedures: A Checklist for Effective Communication and Dissemination

A stepwise approach to advancing Clinical Practice Guidelines

Before guideline is submitted to journal
☐ Determine guideline scope
☐ Consider what supporting products need to be created
☐ Identify external target audiences
☐ Draft communication plan
☐ Plan for visual elements to support guidelines
☐ Determine editorial and media strategy

Once guideline submitted to journal
☐ Plan for plain language messages
☐ Draft questions for FAQs
☐ Draft teaching PowerPoint
☐ Draft messaging and communications products
☐ Draft release/announcement to target audience(s)
☐ Draft web content pieces
☐ Work with creative experts on visual/multimedia products
☐ Work with web designers to plan web strategy
☐ Work with media relations to develop release plan

Once guideline approved by journal
☐ Determine release date and build timeline leading up to release
☐ Develop a visual summary of recommendations
☐ Clear draft communication products
☐ Alert communication, web, and social media teams of pending guidelines
☐ Write editorials
☐ Identify upcoming meetings or webinars to present guidelines

Two weeks from release
☐ Finalize communication and web content pieces

One week from release
☐ Submit final documents/content to web team
☐ Review and test outgoing messages for email distribution
☐ Review and approve content on webpage
☐ Alert relevant staff to upcoming release
**Day/Week of release**
- Final verification of all web and media content
- Send and confirm email messages, web, social media, and other time-sensitive messaging
- Compile media results report
- Update guidelines web page(s)
- Send announcements to relevant newsletters and other channels
- Send editorials

**When article is in print**
- Post guideline to relevant websites, publications, and clearinghouses