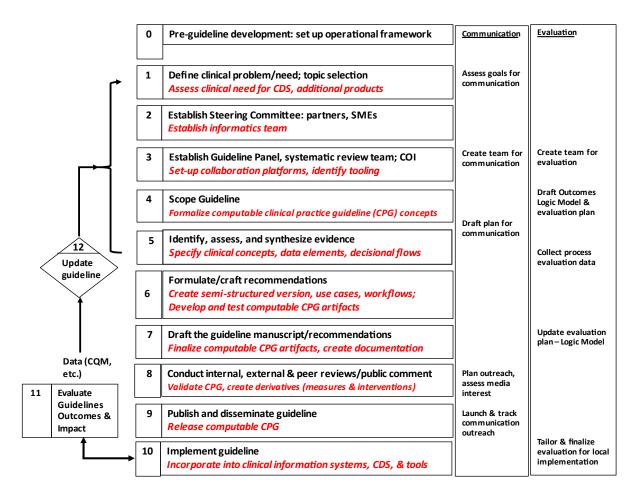
Integrated Process Model Tables. These tables correspond to the manuscript "An Integrated Process for Co-Developing and Implementing Written and Computable Clinical Practice Guidelines" published in the American Journal of Medical Quality (citation)

Figure 1: Overview of Integrated Process for Developing Written and Computable Guidelines Note: red italicized font represents informatic activities



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

[0] Activities (What to do)	Tasks (How to do it)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Identify functional and operational (including informatics and information technology) needs and requirements and limitations for developing written and computable guidelines in the organization. 	b. Review experience in the field and identify	Organizational management INFO SME IMPL SME	Requirement list	
	d. Brainstorm on processes, people, and place.	w		
 Assess current resources and capacity for guideline development in the organization. 	development.	Organizational Management "	A needs assessment of the organizational capability for computable guideline development	

[0] Activities (What to do)	Tasks (How to do it)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Develop organizational 	 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. a. Develop framework for project organization, 	EVAL SME Organizational	Established process,	Decision Tool
framework for developing a written and computable guideline.	 planning, and control for integrating informatics standards and protocols in guideline development. b. Establish management committee for decision-making to specify technologies, systems, staff, and materials that the organization can maintain or contract out. c. Identify education, training and support, plus incentives to help staff adapt to the new ways of operating. d. Establish standard operating procedures (SOPs) for implementing the operational framework in organizations. e. Revise general standard operating procedures (SOPs) for guideline development to include computable guideline development processes and rules (guideline methodology, software, language, 	leadership and Management Guidelines Lead INFO Lead **	framework, & procedures for • computable guidelines model • informatics framework • management of process	(Appendix A) Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action

[0] Activities (What to do)	Tasks (How to do it)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	the strength of the guideline recommendations (based on the evidence) consistent with computable guidelines (e.g., logical, computer interpretable format).			
	f. 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.	w		
	g. 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.	n		

Future State Tables -Phase1: Define Clinical Problem /Assess Clinical Need / Select Topic Assess Clinical Need for the Computable CPG/ Additional Products

[1] Activities	Tasks	*Responsible entity,	Success Indicators	Resources and tools
(What to do)	(How to do it)	Expertise Needed		(Examples)
 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. Process for management and evaluation of aggregated patient data + implementation Summary of guideline requests from stakeholders.	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
 Prioritize topics (if there	 a. Establish process for prioritizing topics –	Guideline office/ lead	Criteria to identify and	NICE process for
is more than one	aligned to end-user need or organization		prioritize key clinical	selecting & prioritizing
proposed topic).	priorities.		topics	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 	Topic SME EVAL SME INFO SME	Completion of Decision Tool (Appendix A)	USPSTF Procedure Manual Decision Tool (Appendix A)

[1] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
computable version of the guideline.	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.			
	 c. Assess topic for implementation, feasibility, and support. 	w		
 Obtain leadership approval of topic and funding. 	 a. In-house – as per organizational protocols (no standard process), obtain leadership approval of topic and assure funding is available internally and with partners. 	Organizational leaders	Topic and funding approval	

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

[2, 3] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Convene an oversight committee/group, determine goals, roles, and responsibilities, and assess conflict of interest. 	 a. Select multidisciplinary members from organizational leadership and broad stakeholder representation, which will vary across different organizations. b. Establish: Goals, composition, and charge of an oversight committee Members' roles & responsibilities. 	Guideline lead	Established protocols and criteria for oversight committee membership, management, selection of chair and members, roles and responsibilities of SMEs (SUBJ, INFO, EVAL,	Managing conflicts of interest in the development of health guidelines. (NIH) Jan. 11, 2021 GIN-McMaster Guideline Development Checklist- Conflict of Interest Disclosing Competing Interests in CDC
	c. Assess & manage conflict of interest.d. Establish informatics team, including knowledge engineer (KE) SMEs, and informatics technical SMEs.	Guideline Lead Guideline Lead INFO SME	COMM, IMPL SMEs)	Guidelines, Oct. 2015 The vexing problem of guidelines and conflict of interest: a potential solution. 2010. <u>A Quality-Driven</u> Approach for Translating
	 Ensure at least one communication, evaluation, and implementation SMEs are on oversight committee to inform stakeholders of guideline creation or update and timeline. 	COMM lead EVAL Lead IMPL SME		Evidence into Action
 Establish project management plan, including time frame and 	a. Develop project management plan for integrating informatics standards and	Oversight Committee representing: SUBJ SME	Buy-in on process & procedures for:	Agile development tools, <i>e.g., <u>kanban</u>, <u>scrum</u></i>

<mark>[2, 3]</mark> Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
milestones, for specific guideline topic.	 protocols to develop computable CPGs. b. Choose collaboration mechanisms and processes to share knowledge, e.g., SharePoint, Microsoft Teams, Confluence, DropBox, Google Docs. 	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
	c. Establish code repositories, e.g., Github.	INFO SME		CDS Connect Repository MagicApp Introduction to living guidelines and recommendations
 Establish an evaluation team. 	 a. Determine the types of evaluation to be conducted (e.g., process, product, outcome). 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. 		Evaluation team formed	
	c. Determine roles and responsibilities of members of the evaluation team.	EVAL Team including IMPL SME	Roles and responsibilities listed	

[<mark>2, 3]</mark> Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Establish guideline workgroup(s). 	 a. Identify the need and types of multidisciplinary workgroups, e.g., main guideline workgroup, external reviewer's group, evidence review group. b. Ensure that informatician has experience in guideline development, or provide them 	Oversight Committee	Protocols and criteria for selecting chair and members, member type (SUBJ, INFO, EVAL, COMM etc.), and their roles & responsibilities Criteria for incorporating	National Academies of Sciences- Standards for Systematic Reviews Cochrane Handbook A Quality-Driven Approach for Translating Evidence into Action
	with guideline training, as needed.		informatics in systematic reviews (living evidence profile)	
	 c. Define goals, composition, and charge of the guideline workgroup(s). 	Oversight Committee	Criteria for if/when to include HCO members for assessment of implementation feasibility in guideline development	
	d. Identify and select members and obtain and manage COI.	Oversight Committee		
	 Establish criteria for if/when to include health care organization (HCO) for implementation issues. 	Oversight Committee		
 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	Protocols/criteria to identify partners and types of partnerships, communication, and roles and responsibilities of partners.	
	b. Establish partner/collaborator rules of management and communication.	w		

<mark>[2, 3]</mark> Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 Conduct educational training session(s) for all workgroup leads and team on how the integrated process will work. 	w		
 Conduct kickoff meeting with relevant stakeholders. 	 a. Hold kickoff meeting to assess communication needs, issues, risks, intended audience, and to understand science/ underpinnings of guidelines. b. Obtain agreement of external communication standards, protocol, clearance, and identify communication workgroup members. 	Oversight Committee COMM SMEs	Kickoff meeting accomplished Description of communication standards and protocols, and communication workgroup members	Stakeholder Communication Analysis (Appendix B)
7. Develop communication plan and estimated timeline of activities to do before, during, and after release of guideline, including a plan for tracking results.	 a. Consider steps to inform communication/dissemination plan for guideline, e.g., focus groups, surveys, community forums, listening sessions. b. Facilitate information sharing between communication and guideline workgroups. 	COMM Lead	Draft communication plan	Communication SOPs: A Checklist for Effective Communication and Dissemination (Appendix C) Developing Effective Communication Products A Framework for Disseminating Evidence- Based Health Promotion Practices Strategies for disseminating recommendations or guidelines to patients: a systematic review

[2, 3] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Set-up collaborative platforms and tools. 	 Decide on collaboration platforms for information sharing and tools for producing computable guidelines CPG artifacts. 	Guideline Lead INFO Lead	Collaborative platform established	

Future State Tables - Phase 4: Scope Guideline Identify Computable Clinical Practice Guideline (CPG) Concepts

[4] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Convene scoping group and ensure familiarity with guideline development procedures of the sponsoring organization. 	 a. Select multidisciplinary membership for scoping group – consider including subject SME, guideline methodologist, guideline lead, INFO SME, IMPL SME, systematic reviewer, health economist, and selected stakeholders. 	Subgroup of the oversight committee that focuses on scope	Established methods and criteria for membership	IOM: Clinical Guidelines Cochrane Handbook GIN-McMaster Guideline Development Checklist Guidelines and Recommendations: A CDC Primer, 2012 NICE Process WHO Handbook
				Canadian Guide to Clinical Preventive Health Care
 Get input for the scope of the guideline. 	a. Conduct targeted outreach with stakeholders to get input on scope.b. Identify key studies to support scope and future planning.	Evidence Review Group	Input on PICO or PICOTS for guideline scope: P – population I – intervention C – comparator group O – outcomes	GRADE equity guidelines 2: considering health equity in GRADE guideline development: equity extension of the guideline development checklist, 2017 How to Write a Research
	 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. 	COMM SME	T – timing S – setting	Question Using the PICOTS Framework to Strengthen Evidence Gathered in Clinical Trials—Guidance from the AHRQ's Evidence-based Practice Centers Program

[4] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
3. Develop draft scope	 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. 	Scoping Group	Draft scope developed	<u>NICE Scoping</u> <u>checklist</u> <u>AGREE-II Tool</u>
	 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 	w	Structured PICO or PICOTS and key research questions	
	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	
 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

<pre>[4] Activities (What to do)</pre>	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
pathway for the proposed research questions and intervention(s) in PICO.	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.			
5. Consult with INFO SME to inform and refine scope.	 a. Convene internal and external consultations, if needed, to provide feedback on proposed scope. 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. 	Scoping Group Stakeholders IMPL SME Oversight Committee INFO SME	Summary of feedback Refined scope, and draft framework, terminology, and use cases. Use cases cover the scope of recommendations to be digitized.	
 Finalize guideline scope after consultation with oversight committee and partners. 	 a. Oversight Committee (and guideline partner organizations, if relevant) review and approve all drafts. b. Use scope to determine guideline type (new, interim, update, adaptation etc.). 	Oversight Committee Partners INFO SME	Final scope as reflected in PICO or PICOTS and logic model	
7. Develop a logic model and evaluation plan.	a. Develop the logic model in collaboration with oversight committee to produce a shared purpose, transparency through the implementation process, and a	EVAL Team Guideline Team	Draft evaluation plan	Logic Models: CDC Approach to Evaluation CDC: A Framework for Program Evaluation

[4] Activities	Tasks	*Responsible entity,	Success Indicators	Resources and tools
(What to do)	(How to do it)	Expertise Needed		(Examples)
	common understanding of the intended			Indicators: CDC Approach
	evaluation outcomes. A logic model is a			to Evaluation
	graphic road map that presents the			CDC Division for Heart
	shared relationships among the			<u>CDC Division for Heart</u> Disease and Stroke
	resources, activities, outputs, outcomes,			Prevention Evaluation
	and impact for your proposed guideline.			<u>Plan</u>
	(1) <u>A statement of the intervention;</u>			Framework for Program
	(2) Inputs or program resources: needed			Evaluation in Public
	for guideline intervention and evaluation,			Health: A Checklist of
	e.g., staff, budget, partners;			Steps and Standards
	(3) Activities: What we do to produce			Western Michigan
	desired guideline outcomes, based on			University: Evaluation
	theory, evidence, or best practice;			<u>Checklists</u>
	(4) <u>Outputs:</u> The direct tangible results			Checklist of Key
	of activities, e.g., health care			Considerations for
	professionals trained in use of			Development of Program Logic Models
	computable guidelines;			Logic Models
	(5) Short-term/Proximal Outcomes:			<u>A science impact</u>
	The immediate effects of the guideline.			framework to measure
	e.g., reach, awareness or knowledge			impact beyond journal metrics
	and, satisfaction with guidelines among			
	intended audience;			An organizing framework
	(6) Intermediate Outcomes:			for translation in public health: The knowledge to
	The behavior, normative, and policy			action framework
	changes, e.g., health systems in place to			
	implement computable guidelines;			Developing Your
	clinicians using computable guidelines.			Evaluation Plans: A Critical Component of
	(7) Long-term/Distal Outcomes:			Public Health Program
	the desired health outcomes of the			Infrastructure.

[4] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 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 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. c. Draft a detailed evaluation plan for assessing the guideline process, products, and outcomes. 			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.
8. Update draft of communications plan.	a. Update first draft of communication plan.	COMM SME	Updated draft of communication plan	The new P Process: Steps in Strategic Communication A Framework for Disseminating Evidence- Based Health Promotion Practices

[4] Activities (What to do)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
			Strategies for disseminating recommendations or guidelines to patients: a systematic review

Future State Tables - Phase 5: Identify, Assess, and Synthesize Evidence Represent CPG Artifacts: Logic Representations/ Expressions

[5] Activities	Tasks	*Responsible entity,	Success Indicators	Resources and tools
(What to do)	(How to do it)	Expertise Needed		(Examples)
 Select evidence review methods and infrastructure most appropriate for the guideline under development. 	reviews, (living or dynamic updating, digitized).	Evidence Review Group	Evidence review methods and rationale selected Overarching lead describes responsibilities for each group (SUBJ, INFO, IMPL, COMM, EVAL)	Systematic Reviews: the process: Guides/ManualsG-I-N. Guideline process - useful tools, 2015National Academies of Sciences- Standards for Systematic ReviewsCoursera Course (free): Introduction to Systematic Reviews and Meta-AnalysisCochrane Community: Living Systematic Reviews Living systematic reviews: 4. Living guideline recommendations, 2017.Living systematic review: 1. Introduction—the why, what, when, and howDevelopment of Rapid Guidelines: GIN-McMasterSystematic review automation technologies PRISMA 2015 Prisma Flow Diagram GeneratorBrown Center for Evidence Synthesis in Health

[5] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
				The Global Evidence Mapping Initiative Design and implementation of Metta, a metasearch engine for biomedical literature retrieval intended for systematic reviewers.
 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. 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 	Evidence Review Group Guideline development group	Determination of final PICO or PICOTS questions, sources for information, and metrics	GRADE Evidence-to-Decision Framework
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

[5] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 Identify search parameters (database, years, language, MeSH terms, etc.) Determine number of reviewers Conduct a systematic review to search for and gather evidence per research question(s). Types of evidence can include: Current systematic and living reviews Other similar guidelines Primary studies and reports (published and grey literature) Patient level data (pulled from real-time analysis of data in EHRs, etc.) Modeling (may be appropriate for certain types of questions) Expert opinion (may be relevant for emergency situations and questions with limited data). c. Screen articles at the abstract and full text level and evaluate quality of screening process. 	N.		RevManOVID ScopusMcMaster Health Information Research Unit: Evidence- Based Health InformaticsGuide to Community Preventive Services/Task Force on Community Preventive ServicesEvidence Ecosystem concept and advances in evidence synthesis and dissemination - CochraneWhen and how to update systematic reviews: consensus and checklist, Developing WHO rapid advice guidelines in the setting of a public health emergencyThe System for the Unified Management, Assessment and Review of Information (SUMARI)Machine-learning information-extraction systems (e.g., RobotReviewer, ExaCT)
	 d. Abstract relevant study information (i.e., demographic, interventions, effect sizes, key findings) into 	N		, <u>, , , , , , , , , , , , , , , , , , </u>

Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
tables. a. Evaluate and rate the quality of	Evidence Review Group	Individual study	AMSTAR quality assessment checklist
 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) 		rating schema established and applied to gathered evidence	The EPC Approach AHRQ GRADE GRADEPro GRADE-CERQual The Cochrane Collaboration-Qualitative Research Appraisal Robins-I
 Other potential blases (e.g., funding source). b. Conduct a meta-analysis, if appropriate. 	w		Cochrane-RevMan) PRISMA and PRISMA-P Prisma Flow Diagram Generator Critical Appraisal Skills Programme (CASP)
 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. 	w		<u>Dr. Evidence</u>
	 (How to do it) tables. a. Evaluate and rate the quality of each individual study using predefined quality appraisal criteria for each element. For example: Study design and quality of execution Internal validity External validity External validity 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 	(How to do it)Expertise Neededtables	(How to do it) Expertise Needed tables. Individual study using pre- defined quality appraisal criteria for each element. For example: Study design and quality of execution Internal validity External validity External validity External validity External validity Other potential biases (e.g., funding source). Conduct a meta-analysis, if appropriate. 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.

[5] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	d. Conduct economic analysis, if appropriate.			
 Synthesize evidence and define a process for writing draft text for manuscript for Phase 7. 	 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. 	Evidence Review Group	Developed evidence tables Established body of evidence rating schema and applied	
	 Evaluate and rate the quality of the body of evidence using pre-defined criteria (for each research question). 	π	to all evidence	
	 c. Develop a process for drafting text for manuscript through organization's oversight committee for all guidelines. 	Guideline Oversight Committee	Established process for writing manuscript text (see Phase 7)	
 Specify computable CPG artifacts. 	 Begin development of CPG artifacts and refine draft concepts, data elements, terminologies (values sets), and logic representations/ expressions. 	INFO SME	Computable CPG artifacts specified.	Overview: <u>FHIR Clinical Guidelines</u> (v1.0.0) (STU 1) <u>Examples of artifacts:</u> <u>FHIR Clinical Guidelines</u> (v1.0.0) (STU 1) (hI7.org)

Future State Tables - Step 6: Formulate (Craft) the Recommendations Create Semi-structured version, use cases, workflows; develop & test computable CPG artifacts

[6] Activities	Tasks	*Responsible entity,	Success Indicators	Resources and tools
(What to do)	(How to do it)	Expertise Needed		(Examples)
 Develop, rate, and prioritize recommendations. 	 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). b. Review the evidence and formulate draft recommendation(s). Decide if any current recommendation should be maintained and cited. c. Describe information in support of the recommendation(s) (e.g., rationale for group decisions, benefit vs. harm considerations, patient values and preferences). d. Rate recommendation strength/class of recommendation (e.g., strong, weak) and direction (e.g., for, against) based on quality/Level of evidence. e. Based on pre-determined steps, finalize draft recommendations 	Guideline multidisciplinary panel including INFO SMEs and IMPL SMEs	Clear, concise, and unambiguous recommendations	Approaches to scoring recommendations (e.g., GRADE, USPSTE).GRADE Evidence to Decision (EtD) FrameworkGRADE ADOLOPMENTBridge-WizBuilding better guidelines with BRIDGE-Wiz, 2012Moving from evidence to developing recommendations in guidelines: article 11 in Integrating and coordinating efforts in COPD guideline development, 2012Guidelines into Decision Support (GLIDES).Developing clinical practice guidelines, 2012IOM: Clinical Guidelines We Can Trust, 2011Reviewing clinical guideline development tools, 2017How "Should" We Write Guideline Recommendations? 2010Clinical Practice Guideline guideline Development Manual, Third

[6] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 (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). 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. 	w.		Edition: A Quality-Driven Approach for Translating Evidence into Action, 2013
 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

] Activities Vhat to do)	Task (Hov	xs w to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
3.	Represent written recommendations (as appropriate) into logical diagrams for use in creating computable guideline.	a.	Based on analysis, translate related/bundled recommendations into algorithmic decision trees, data capture needs, concept maps or decision analyses (if applicable). Create a semi-structured diagram (L2) representing the steps involved in implementing the recommendation at the clinical level. Diagram should incorporate previous analyses to model the work, such as decision trees.	Guideline writing group Guideline office/lead Methodology SMEs INFO SMEs IMPL SMEs Other SMEs	Decision trees and concept maps created Semi-structured diagram (L2) created	Digital Adaptation Kits Opioid Prescribing Recommendation #5: Lowest Effective Dose Computer Interpretable Clinical Guidelines, 2014 Computer-interpretable clinical guidelines: A methodological review, 2013 From clinical practice guidelines to computer- interpretable guidelines. A literature overview, 2010 Modeling a Nursing Guideline with Standard Terminology and Unified Modeling Language for a Nursing Decision Support System: A Case Study
4.	Conduct mid-progress internal review(s) of Phase 6 and previous phases and computable CPG design meeting with SME's and relevant stakeholders.		Guideline developers present recommendations in development. Informaticians and implementors present case presentation, user stories, use cases, use case diagram, decision trees, flowcharts, workflow diagrams, proposed terminology, data elements, and other work products.	Guideline office/lead Methodology SMEs SUBJ SMEs INFO SMEs IMPL SMEs Other external SMEs, to include patient representative and end- users (clinical and patients).	Revised written recommendations and computable guidelines design. Approved decision trees, flow diagrams, other artifacts L2 ARTIFACT done The L2 product may be the main deliverable	

[6] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 c. Implementors facilitate feedback on work products from clinicians (endusers) and decision support (EHR/CDS) developers. d. Team members refine their work products based on the review and design work. 		for the informatics team if the overall team lacks resources/ access to developers (software engineers).	
 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+). 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. c. Identify comprehensive test cases and testing resources (e.g., 	INFO SMES IMPL SMES	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 Supporting the Refinement of Clinical Process Models to Computer-Interpretable Guideline Models, 2016
	sandboxes) required to evaluate computable CPG artifacts. Test cases may include case features, recommendations and logic			HL7 FHIR Representing Knowledge Artifacts MagicApp

[6] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	representations based on patient data; workflows & contexts of use.			
 Test the computable CPG artifacts. 	a. Set up test environment to include appropriate patient-level test data.b. Implement test scenarios.	INFO SMEs	Documents of test scenarios that cover the computerized recs. Test data exists for	Test Data Defined as part of the CDC Opioid Prescribing Guideline Implementation Guide
	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.	Guideline authors INFO SMEs	each scenario; tests reviewed & verified for: -clinical usage -implementation	
 Determine what health information technology (HIT) and informatics resources are needed to support computable CPG implementation. 	 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 <u>https://vsac.nlm.nih.gov/</u>. 	INFO SMEs IMPL SMEs		HL7 FHIR Clinical Guidelines CDS Connect Authoring Tool CDS Connect Repository

Future State Tables – Phase 7: Draft the Guideline Text/Manuscript Finalize computable CPG artifacts; create documentation

[7] Activities	Tasks	*Responsible entity,	Success Indicators	Resources and tools
(What to do)	(How to do it)	Expertise Needed		(Examples)
 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: <u>CDC Guidelines &</u> <u>Recommendations</u> <u>WHO Handbook</u> <u>Scottish Intercollegiate Guidelines Network (SIGN)</u> <u>National Institute for Health and Care Excellence (NICE)</u> <u>Australian National Health and Medical Research Council (NHMRC)</u> <u>NIH Clinical Practice Guidelines</u> <u>USPSTF Procedure Manual</u> <u>IOM: Clinical Guidelines</u>

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 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. 			
 Set specific expectations regarding the text 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	

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 Keep additional citations to a minimum except for the evidence supporting the recommendations. 			
 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).		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
 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.	Guideline staff Guideline SUBJ SMEs COMM SMEs	First draft of text	
	 Begin writing before all recommendations are written. Use an iterative approach to writing, 	w		

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
5. Conduct quality assessment of the guideline	 reviewing, and editing for clarity. b. Add any needed supporting citations. a. Use an appraisal instrument to conduct quality assessment to check if guideline meets established quality standards and reporting criteria. 	" Guideline development group EVAL SME/Group	Completion of quality assessment	AGREE II Tool Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise, 2014
 Finalize computable CPG artifacts (L3) and documentation, to include drafts of user needs, use cases, and other informatics design artifacts. 	 a. Finalize CPG expressions (L3) and definitional knowledge assets (e.g., declarative or models). b. Identify expected common derivatives (e.g., eCQM, eCase reports, CDS) desired by guideline development group, other key stakeholder incl end-user/ consumer reps. c. Identify requirements related to 	INFO SME IMPL SME	Finalized L3	A multi-layered framework for disseminating knowledge for computer-based decision support CPG-on-FHIR (L3, derivatives such as CDS, eCQMs, etc.) CDS Connect HL7 FHIR Representing Knowledge Artifacts
 Prepare computable CPG artifacts and documentation for online repositories. 	 making resources findable on digital platforms, (e.g., tagging specific sections based on content-based terminologies and ontologies.) d. Develop documentation. a. Finalize artifacts to include use cases, use case diagrams, decision trees, flowcharts, workflow diagrams, 	" Guideline staff, guideline writing group/panel	Supplemental material	Opioid Prescribing Recommendation #5: Lowest Effective Dose

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	proposed data elements, and other informatics design artifacts to make available online when the guideline is published.	COMM SMEs INFO SMEs IMPL SMEs		<u>Github</u> <u>CDS Connect Repository</u> <u>Value Set Authority Center</u>
	 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. 	w		
	c. Finalize and document necessary tags, structured terminology elements, and other content related to informatics requirements associated with guideline text.	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		
	 Ensure communications and publication teams are aware of any items that will be published. 	w		

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
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., <i>The Elements of Style, Fourth</i> <i>Edition,</i> by William Strunk Jr. and E.B. White <i>Lessons in Clarity and Grace</i> by Joseph M. Williams and Gregory M. Colomb. Manual for Writers of Research Papers, Theses, and Dissertations by K. Turabian
 Obtain approval (if required by policy) to move to next step. 	 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? 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.

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 HOW will evaluation be conducted? WHEN will guideline be evaluated (3 months, 6 months, 1 year?) HOW will evaluation be funded? In-house or contracted? WHAT measurement tools and databases? HOW will results be used when updating the guideline? 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, 	N		
	 experimental, time series. c. Choose/develop the evaluation instruments and methods, e.g., surveys, focus groups, interviews, usability testing. 	n		
 Ensure COMM plan is shared/agreed upon by all relevant parties, and 	a. Hold meeting to ensure guideline and other leads agree with COMM plan.	COMM lead	Updated COMM plan	Communication SOPs: A Checklist for Effective Communication and Dissemination (Appendix C)
revise COMM plan based on other's input.	 b. Coordinate with the organizations' relevant staff, e.g., communication, media, and policy staff about: 	N.		Developing Communication Products (Quick Check)

[7] Activities (What to do)	Tasks (How to do it)	*Responsible entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 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)

[8]What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Finalize the draft written guideline and derivative products for formal review. 	 Full Guideline Draft a. Apply the agreed upon or a standardized format for the guideline, with structure, headings, and content. b. Edit the full draft. 	Technical writer editor IMPL SME INFO SME COMM SME Oversight Group Technical writer-editor	Completed full guideline draft	GIN-McMaster Guideline Development Reporting ChecklistGuidelines 2.0: systematic development of a comprehensive checklist for a successful quideline enterprise, 2013Guidelines and Recommendations: A CDC Primer, 2012WHO Handbook, 2012 COGS Checklist, 2003NICE SIGN
	 Derivative products a. Finalize draft computable CPG design artifacts, computational assets, and resources allowing event condition action (ECA) rules, metrics. 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. 		Completed review of priority derivative products	A multi-layered framework for disseminating knowledge for computer-based decision support CPG-on-FHIR L2 checklist CPG-on-FHIR L3 checklist Peer review Public comment Standards balloting: HL7

[8]What to do		How to do	*Responsible Entity,	Success Indicators	Resources and tools
(sequence of events)		(activities)	Expertise Needed		(Examples)
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.	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
	b.	Seek approval from all members of the guideline development group for the final document(s) before internal and external reviews.	Guideline lead		guidelines; updating guidelines; and the emerging issues of enhancing guideline implementability and accounting for comorbid conditions in guideline development.
	c.	Initiate organizational (i.e. internal) review as per organizational policies.	Guideline lead Guideline draft authors Technical writer-editor	Updated guideline document after internal review	
	d.	Incorporate feedback and responses into document and produce next draft (manuscript & derivative products).	INFO SME IMPL SME COMM SME		

_	What to do		How to do	*Responsible Entity,	Success Indicators	Resources and tools
_	conduct external review, and revise recommendations and derivative products as needed.	a.	 (activities) 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. 	Expertise Needed Guideline lead INFO SMEs COMM SMEs		(Examples) 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. c.	Incorporate feedback and responses into document; produce next draft. Make alterations to the guideline recommendations & products, if needed.	Section authors Writer-editor INFO SME IMPL SME [*]	Updated guideline document	
		a.	Formatics: Software options (e.g., online review, mobile app reviewer alerts). Access easily searchable database of multidisciplinary potential reviewers.	INFO SME COMM SME	Summary of software options and potential reviewers	Designing a Community- engaged Health Informatics PlatformDoes a Community-Engaged Health Informatics Platform Facilitate Resource Connectivity? An Evaluation FrameworkIntersection of Health Informatics Tools and Community Engagement in Health-Related Research to Reduce Health Inequities: Scoping Review

<mark>[8</mark>	[8]What to do (sequence of events)		ow to do	*Responsible Entity,	Success Indicators	Resources and tools
(s			ctivities)	Expertise Needed		(Examples)
4.	Release computable CPG and derivatives (based on written guideline) for comment by users.	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.	INFO SME IMPL SME	Feedback on CPG	<u>CDS Connect Repository</u>
5.	Ensure transparency and documentation.		Document the internal and external peer review process. Document the selection and enrollment of consumers and stakeholders. If applicable, publish comments and the guideline dev. group responses.	Project Chair or Manager	Documentation of internal and external peer review process	
6.	Revise and finalize the draft.		Writer-editor performs final editing. Guideline workgroup reviews and signs off.	Writer-Editor Workgroup leads	Finalized copy of guidelines	
7.	Conduct organizational review of manuscript and approval (if required by organization).	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).	Guideline lead	Cleared and approved final copy of guidelines and derivative products.	

[8]What to do (sequence of events)		*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 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	

(sequence of events)				
	(activities)	Expertise Needed		(Examples)
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 a surface data data data data data data data dat	COMM Lead	Completed environmental scan	Crisis and Emergency Risk Communication (CERC)
	 need for clear communication. 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. 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 	u	Archived outdated guideline and replace with updated guideline.	

[8]What to do	How to do	*Responsible Entity,	Success Indicators	Resources and tools
(sequence of events)	(activities)	Expertise Needed		(Examples)
11. Submit manuscript and other products for publication.Note: Review evaluation plan prior to release of the guideline.	products for publication.	Guideline lead Workgroup leads COMM SME	Published copy of manuscript, slide presentation of guideline & other products	

Future State Tables – Phase 9: Publish and Disseminate Guideline Release computable CPGs

[9] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 Ensure all dissemination approaches, platforms, and content are ready to be used, e.g., website, links. 	 a. Assess and prepare for dissemination strategies on different platforms; develop clear communication detailed timeline for publication & dissemination. b. Coordinate dissemination modalities with web team(s). 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. 	COMM SME Web team	Final distribution plan Dissemination sites are ready for product distribution	Communication Plan Checklist (Appendix C) Github CDS Connect Repository A Framework for Disseminating Evidence- Based Health Promotion Practices Strategies for disseminating recommendations or guidelines to patients: a systematic review
 Coordinate with journal and partners' communication team. 	 a. Share and coordinate delivery of promotional materials, e.g., seminars, webinars for continuing education, blogs, editorials, implementation guides, fact sheets. 	COMM SME Chair or Guideline Lead	Rollout directed by communications plan and coordinated by journal and other authors' organizations (if it applies)	Communication Plan Checklist (Appendix C)
 Prep and coordinate with people who will be speaking 	 a. Finalize talking points, media statement, FAQs, emails and notifications to 	COMM SME Agency Directors	Prepping and coordinating completed	

_] What to do equence of events)		ow to do ctivities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	about the written and computable guidelines (e.g., author, organizational leaders).	b.	partners, and other public-facing messages. Conduct practice sessions to role play and prepare for anticipated questions and responses to the media.		Messages picked up by media and partners	
4.	Launch communication and timed-release plan when manuscript is published and derivative products are approved for release.		Prepare spokespersons, messages, webinars, etc. Ensure dissemination modalities, e.g., key partners, media, are ready for guideline and product distribution. Start formal implementation, communication, and dissemination activities, e.g., release guideline and products.	COMM SME EVAL Lead Chair or Guideline lead	Communication plan launched	A Framework for Disseminating Evidence- Based Health Promotion Practices
5.	Track activities and evaluate launch of communication plan to determine if a successful release.	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.	COMM/Web Team	Documented results of website and social media metrics, media articles, syndicated content from partners.	Altmetric Scopus ORCID iCite

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.

[10] What to do (sequence of events)		ow to do ctivities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
1. Prioritize, select, and	a.	Conduct care gap analysis between	CDS Committee-	Completion of local	Developing a checklist for
promote guideline		guideline recommendation and local	Leadership Team	prioritization plan	guideline implementation planning, 2015
recommendations to		practice, if feasible. Assess potential	IMPL CDS Team		
implement.		beneficial impact at the local level.			CPG-on-FHIR L4 Checklist
		(optional)			
					Guidelines into Decision Support (GLIDES)
	b.	Conduct local feasibility assessment	w		
		(what stakeholders are impacted and	Medical/nursing leads		Implementing Clinical
		how guidelines fit and are harmonized			Decision Support Systems
		with existing information systems, such			AHRQ CDS Connect Clinical
		as CDS workflow & requirements).			Decision Support
		(optional)			
					Factors influencing the implementation of clinical
	с.	Make decision which guidelines/CDS to	w		guidelines for health care
		implement. Provide analysis to the			professionals: A systematic
		implementation team to inform project.			meta-review
					The effectiveness of clinical
	d.	Develop project scope statement and	w		guideline implementation
		evaluation strategy, including baseline			<u>strategies – A synthesis of</u>
		assessment, and implementation and			systematic review findings
		evaluation strategy. (may be informal)			Successes and failures in the
					implementation of evidence-
	e.	Communicate decision to implement.	w		based guidelines for clinical practice
					practice

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
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

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
(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) 	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
	 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) 	w		
	 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) 	n		

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
 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 	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
	 patients or EHRs, if available. c. Conduct a build review. d. Demo to clinical stakeholders and build consensus among practitioners. (optional) 	" " and end users		
 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

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
	 use cases & records/data to test systems. Test local system and connectivity to outside resources (e.g., APIs). 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. 	End users (clinicians and/or patients)		Best practices for preventing malfunctions in rule-based clinical decision support alerts and reminders: Results of a Delphi study The Design of Decisions: Matching clinical decision support recommendations to Nielsen's design heuristics Electronic Health Record (EHR) System Testing Plan Testing electronic health records in the "production" environment Heuristic Evaluations and Expert Reviews HHS Policies and
	 c. Revise clinical information systems and decision support as needed, based on testing and user feedback. 	CDS IMPL Team		<u>Standards</u>
 Update policy & procedures, as needed; educate and train end users how to use guidelines in clinical decision support, using the most appropriate methods. 	 a. Update organizational policies and procedures, as needed. b. Update education with local systems final interface design, i.e., screenshots. 	CDS IMPL SME Trainers INFO SME [*]	Completed training	What is clinical decision support (CDS)? Clinical Decision Support Software

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
	 c. Decide who to train, & how to best deliver training; tailor to local training channels. d. Train end users on how to use guidelines in CDS. 	" Builders & trainers Clinicians & users		
 Deploy clinical decision support using the most appropriate methods. 	 a. Determine date to deploy new CDS, based on operational readiness. 	IT Change management team CDS IMPL TEAM	Completed deployment	Improving Outcomes with Clinical Decision Support: An Implementer's Guide (Chapter 8)
	 Update and execute go-live staffing plan for release of clinical decision support for clinicians. 	Clinical INFO staff and trainers (assist end- users)		GUIDES Checklist CPG-on-FHIR L2, L3, and L4 checklists
	 c. Migrate artifacts from development to testing to production. 	N		
	 d. Test with real patients, non- visible to clinicians. (silently). (optional) 	N		
	e. Test in production by small number of clinicians (optional)	N		
	 f. Pilot in a small subset of clinical settings and provide feedback. (optional) 	N		

[10] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Others involved	Success Indicators	Resources and tools (Examples)
10. Use clinic decision support in clinics.	a. Use system as designed.b. Assess end user interactions	Clinicians CDS INFO team	System implementation and feedback to users.	Clinical decision support alert malfunctions: analysis and empirically derived taxonomy
	with clinical decision support,	INFO SME		
	e.g., observations or data on	Trainers		
	usage patterns. Identify variations across users.	Clinicians & patients		
	c. Users provide feedback	u		
	(subjective and real time).			
	Assist users as needed.			
11. Assess and refine the CDS.	a. Conduct quantitative	CDS IMPL Team	Completed evaluation	Change-point detection
	assessment per measurement	INFO Team	and refinement of artifact	method for clinical decision support system rule
	strategy.	Data Analytics Team		monitoring
		Quality Improvement		The Effect of Passive Choice
	b. Conduct qualitative assessment	Team		and Active Choice Interventions in the EHR to
	e.g., focus groups; build	w		Cardiologists on Statin Prescribing: A Cluster
	satisfaction surveys into artifacts. (optional)			Randomized Clinical Trial
				Recommendations for Clinical
	c. Report findings to leadership	w		Decision Support
	and quality improvement group.			Deplo0yment: Synthesis of a Roundtable of Medical
				Directors of Information Systems
	d. Optimize CDS tools and update	w		
	local documentation accordingly.			
	e. Repeat the assessment of the			
	refined CDS			

[10] What to do	How to do	*Responsible Entity,	Success Indicators	Resources and tools
(sequence of events)	(activities)	Others involved		(Examples)
 Provide feedback to guideline developer and implementor on the computable CPG. 		IMPL SME	Summary of feedback	

	What to do uence of events)	ow to do ctivities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
pla of sys inc No be	ilor and finalize evaluation an and questions to context local implementation, such a regional health care stem, hospital network, or dividual clinics. Dete: Evaluation plan should reviewed prior to release of e guideline as noted in phase activity 11.	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. Adapt and finalize methods for collecting, analyzing, and sharing data/findings via feedback loops to the guideline developers. Reconsider environmental context.	EVAL Team Guideline Lead	Final evaluation plan finalized, including questions and methods	See resources in Phase 4, activity 7.
at rel	nplement the evaluation plan the time the guideline is leased, and in conjunction th the communication plan.		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 guidelineimplementation: a scopingsystematic review.Factors influencing theimplementation of clinicalguidelines for health careprofessionals: A systematicmeta-review.The effectiveness of clinicalguideline implementationstrategies – A synthesis ofsystematic review findings

Future State Tables – Phase 11: Evaluate Guideline Outcomes and Impact

[11] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 c. Present results to guideline authors, oversight committee, and partners. d. Collect, summarize, and document the second wave of results, e.g., behavioral and policy changes, feedback if feasible (intermediate evaluation). e. Present results to guideline authors, 	EVAL Team	Recommendations documented for updating guideline	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.
	oversight committee and partners.f. Collect, summarize, and document the third wave of results, e.g., feedback, health outcome improvements, if feasible (distal evaluation).	w w		Translating guidelines into practice: A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines.
	 g. Present results to guideline authors, oversight committee, and partners. 	w		Conceptual frameworks and empirical approaches used to assess the impact of health research: an overview of
	 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. 	π.		reviews Measuring the Use of NICE Guidance

[12] What to do	How to do	*Responsible Entity,	Success Indicators	Resources and tools
(sequence of events)	(activities)	Expertise Needed		(Examples)
 Create management or operational plan for updating the written and computable guidelines. See cycle diagram. 	 a. Create/refine 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

Future State Tables - Step 12: Update Guideline

[12] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
 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.	<u>Federal Register</u> <u>ONC Project Tracking</u> <u>System</u>
 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 	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)

[12] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	such as artificial intelligence (AI), text mining, machine learning, and crowd sourcing.			Linkage of existing structured data sources (e.g., clinical trials registries). Automated structured data extraction tools for PDFs. e.g., <u>ContentMine, Graph2Data</u>) Assessing risks of bias (e.g., <u>RobotReviewer</u>)
4. Reaffirm, update, retire the	a. Periodically review feedback, literature	SUBJ SME	Determination of what	NICE Criteria
current guideline	evidence, and evaluation results against	COMM SME	to do with guideline	
recommendation(s) or	the criteria in the operational plan to	EVAL SMEs	recommendations	
develop new guideline	determine whether to update or develop			
recommendation(s) if needed,	new recommendations.			
according to the criteria				
established in the operational	b. Develop process to reaffirm			
plan for updating recommendations.	recommendation(s) not to update.			
(see step 1)	c. Label, remove, replace, or archive all			
	outdated guideline recommendation(s)	w		
	and derivative products.			
5. Update related CPG artifacts,	a. Review updated recommendations and	INFO SME	Updated CPG artifact(s),	Principles of Guidelines-Driven
(e.g., CDS tools, eCQMs) as	any other factors, such as local clinical	Content SMEs	as needed.	PPM Informatics
needed, based on updated	systems feedback, other new evidence	Guideline SMEs		
recommendations.	that may affect CPG artifacts, e.g.,	COMM SMEs		<u>Github</u>
	changes to value sets or terminologies,			
	software updates for CDS, eCQMs.			CDS Connect Repository
	b. Update CPG artifacts and associated	n		
	code repositories, systems, policies, and			
	training, as needed.			

[12] What to do (sequence of events)	How to do (activities)	*Responsible Entity, Expertise Needed	Success Indicators	Resources and tools (Examples)
	 Label, remove, replace or archive all outdated CPG artifacts. 	n		
 Monitor the landscape for changes such as new drugs coding schemes, adverse events that would require modification of semi- structured, structure, and executable recommendatio (L2-L4). 	 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. 	Assigned Guideline, SUBJ and INFO SME, per operational plan. May vary by organization.		https://www.nlm.nih.gov/new s/NLM VSAC Intensional Defi nition Functionality.html Note: Use of Intensional Value Sets can obviate the need for monitoring.
 Communicate updated or n recommendations and CPG artifacts and evaluate communication products. 	 a. Develop communication and dissemination strategy, tactics, and materials to clearly communicate updated recommendation(s) and derivative products. b. Communicate updated recommendations and derivative products to stakeholders. c. Evaluate if communication products were used, usable, & useful to users. 	COMM SME EVAL SME [*]	Communication strategy and evaluation completed	The Science of Science Communication A Research Agenda I National Academies Risk Communication I FDA The CDC Clear Communication Index

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 <u>https://stacks.cdc.gov/view/cdc/81404</u>

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 Considerations for 1.1 Will the guidelines focus on a current or potential public health burden, gap in clinical care, or other important need? 1. Critical or potential burden or hazard can be expressed in various For example, the guideline could focus on a current or potential public health burden, clinical gaps in care, an metrics, such as prevalence of mortality, morbidity, injury, emerging public health hazard, important public health methods, best practices, safety guidelines, lab practices, disability, quality of life years (QALYs), disability adjusted life years surveillance reports, or meaningfully reduce the gap between current and optimal practice in clinical care. (DALYs). If "Yes," briefly describe the justification for the guideline. Type description here 2. Gaps can be reflected in deficiencies in knowledge, clinician or patient awareness or adherence, progress in a particular public If "No," reconsider whether the proposed guideline should be developed. health area such as preventing, detecting, or treating a condition, reducing health disparities, or meeting health objectives. 1.2. SIMILAR GUIDELINES Considerations for 1.2 Are there current, credible, and relevant guidelines that make the proposed guideline entirely duplicative? 3. Potential sources of guidelines include the Centers for Disease For example, an existing guideline on the same topic would not be entirely duplicative if the plan was to adopt or Control and Prevention (CDC), the National Institute for Health update the guideline based on current evidence. and Care Excellence (NICE), the U.S. Preventive Services Task Force (USPSTF), the Community Preventive Services Task Force (CPSTF), If "Yes," reconsider whether the proposed guideline should be developed. and other government agencies and professional organizations. □ If "No," describe differences between existing and proposed guideline. Type description here Considerations for 1.3 1.3 EVIDENCE Does an evidence base exist on which to develop these guidelines? 1. A preliminary scanning of the literature can be helpful to determine whether published evidence is available to support the Potential sources of evidence to consider beyond direct and indirect research findings include proposed guidelines. 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 Considerations for 1.4 Have your intended audience or other stakeholders expressed a need for a new or updated guideline on the topic? 2. An assessment of stakeholder and end user needs can inform decisions on whether to produce a new or updated guideline, Audience need could be communicated through meetings, focus groups, conferences, surveys, public hearings, or what questions should be prioritized, and what communication requests for information. and dissemination strategies may be needed to foster uptake. Consider additional stakeholder engagement if news of key If "Yes," briefly describe audience feedback. Type description here stakeholders is not clear. For example, opinions can be collected from internal and external champions, subject-matter experts, and If "No," reconsider whether the proposed guideline should be developed. partners interacted 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. Type description here
- 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. Type description here
- If "No," explain why it is not appropriate or feasible for your organization to partner with another organization to develop the proposed guideline. Type description here

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. Type description here

□ 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

 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

- 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.
- 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 Considerations for 3.1 and 3.2 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 The following information may be collected: written guideline? • End user desired capabilities ٠ End user defined benefits and harms If "Yes," briefly describe assessment results. Type description here Existing facilitators (e.g., resources) Current barriers and challenges in accessing, accepting, ٠ If "No," reconsider whether your organization should develop a CCPG. implementing, adapting, and adopting CCPGs Effect on patient outcomes and costs 3.2 EVIDENCE REVIEW Impact on clinical workflows Does the literature provide any information on advantages, cost-effectiveness, or acceptability of CCPGs for this topic or Considerations for 3.3 related topics? AND Do open-source computable components exist that could be reused in this proposed CCPG, (e.g., value sets, logical Assess expert opinion, and conduct SWOT, PESTLE, CDC example of models and resources for FHIR profiles, algorithms, libraries)? PESTLE, and industry analysis. If "Yes," briefly describe evidence review and available open-source computable components. The following resource and industry information may be collected Type description here from experts: 1. Development feasibility and costs, e.g., computable If "No," reconsider whether your organization should develop a CCPG. components needed if already exist that could be reused. Complete the "At a Glance" Implementation L4 Checklist 3.3 FEASIBILITY AND PRIORITY ASSESSMENT 2. Current IT technological resources and gaps Is it logistically feasible for the organization to develop the CCPG? For example, do the data elements exist in EHR? 3. Fixed and recurring costs Will CCPG development benefit the organization or advance its mission, e.g., improve health outcomes? Staffing and training resources and needs Will CCPG be expected to accelerate implementation and adoption of the guideline recommendations? 5. Business strategies used by other groups Are resources available for developing, piloting, and publishing a CCPG? Are resources available for maintaining a CCPG? Information may be collected from Champions-internal and external who may collaborate If "Yes," to most questions, briefly describe assessment results. Type description here Internal and external groups who are developing or who have • developed similar tools If "No," reconsider whether your organization should develop a CCPG. 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
- $\hfill\square$ 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