CDC Guideline Development Decision Tool

To strengthen the process for developing CDC guidelines, the Office of the Associate Director for Science (OADS), Office of Science Quality (OSQ), Guidelines and Recommendations Activity has developed the *CDC Guideline Development* ***Decision*** *Tool* (GDDT).

CDC bases the development of documents like this tool on the World Health Organization (WHO) definition of guidelines:

> *"A guideline is a document that contains recommendations about health interventions, whether they be clinical, public health, or policy interventions. A recommendation provides information about what policy makers, health care providers, or patients should do. It implies a choice between different interventions that have an impact on health and that have ramifications for the use of resources."*

The GDDT consists of two steps, each containing 5 questions. Step 1 will help you determine whether *the proposed guideline is needed.* Step 2 will help you determine whether *CDC is the most appropriate organization to lead the development of the proposed guideline.* Figures 1 and 2 are flow diagrams that summarize this 2-step process. Since guideline development can take many years and consume many resources, make sure you can answer these questions before starting the process.

We encourage guideline developers to answer the questions in order. There are no wrong or right answers. Developers should give reasons for "Yes" responses and may attach a document, link, citation, or highlighted section as rationale. For a more informative process, we recommend that more than one developer respond to the questions. We recognize that this tool will be used for multiple and diverse public health guidelines, so not every question will be relevant. However, the information may be useful background information for a manuscript where the guideline is published. The Guidelines and Recommendations Activity has other resources[1] to assist developers in answering these questions. Please see the *Decision Diagram for Guideline Development*, a companion piece to the GDDT, located at the end of this document.

You may contact the Guidelines and Recommendation Activity Team located in the OADS, Office of Science Quality for a consultation at any stage of the guideline development process.
For more information about the Guidelines and Recommendations Activity, resources and tools, and training visit the Office of the Associate Director for Science Guidelines and Recommendations Activity site.

Vilma Carande-Kulis, PhD, MS vcarande-kulis@cdc.gov, 404-639-4691

Dyann Matson Koffman, DrPH, MPH, CHES dmatsonkoffman@cdc.gov, 404-639-4783

Step 1: Determine whether the guidelines should be developed at all, regardless of whether CDC or an external party develops them.

QUESTION	YES	NO
1. Will the guidelines address a current or potential public health burden, or an emerging public health hazard? *Current or potential burden or hazard can be expressed in more than one unit measure such as prevalence of mortality, morbidity, injury, disability, quality of life years (QALYs), Disability Adjusted Life Year (DALYs).* **a. If "Yes," briefly describe and proceed to question 2.** *Type description here.* **b. If "No," is there another justification for developing the guidelines?** *Non-disease specific guidelines may include public health methods, best practices guidelines, safety guidelines, surveillance reports, or laboratory practices and procedures.* **If "Yes," briefly describe and proceed to question 2.** *Type description here.* ***If "No," stop and reconsider whether to develop the proposed guidelines.***		

QUESTION	YES	NO
2. Is there a void in current knowledge or practice that justifies the development of guidelines? *Is there a lack of knowledge, adherence, or progress in a particular public health area? Are there gaps in preventing, detecting or treating a condition, or in meeting public health objectives?* **a. If "Yes," briefly describe and proceed to question 3.** *Type description here.* **b. If "No," *stop and reconsider whether to develop the proposed guidelines.***		
3. Do other guidelines on this topic exist? *Have guidelines on the topic been published in the past 5 years in places such as the National Guideline Clearinghouse (NGC), Cochrane Collaboration, The National Institute for Health and Care Excellence (NICE), The U.S. Preventive Services Task Force (USPSTF), and the Community Preventive Services Task Force (CPSTF)? Do those guidelines have a similar purpose and scope as the proposed guidelines?* **a. If "Yes," are existing guidelines deficient in content, evidence, quality, or another way?** **If "Yes," describe those deficiencies and proceed to question 4.** *Type description here.* **If "No," the current published guidelines are not deficient, then *stop and reconsider whether to develop the proposed guidelines.*** **b. If "No," briefly describe where you looked for information before determining that guidelines do not exist on this topic. Proceed to question 4.** *Examples of sources are CDC publications, the National Guideline Clearinghouse, and recommendations from the U.S. Preventive Services Task Force or the Community Preventive Services Task Force.* *Type description here.*		

QUESTION	YES	NO
4. Does a literature base exist on which to develop these guidelines? *This step is not proposed as a formal systematic review but rather a preliminary scanning of the literature to determine whether published evidence is available to support the proposed guidelines.* **a. If "Yes," briefly describe journal articles or literature sources and proceed to question 5.** *Type description here.* **b. If "No," is expert opinion or another data source available, or can be made available, for the development of the guidelines?** *Other data sources may include epidemiological data, reports from animal studies, indirect research findings, case reports, etc.* **If "Yes," describe briefly and proceed to question 5.** *Type description here.* **If "No," *stop and reconsider whether to develop the proposed guidelines***		
5. Have you determined from your intended audience or other stakeholders a need for new or updated guidelines on the topic? *Intended audience could communicate the need for this guideline through different channels, such as conferences, focus groups, surveys, public hearings, or requests for information.* **a. If "Yes," briefly describe. Proceed to results below.** *Type description here.* **b. If "No," *stop and reconsider whether to develop the proposed guidelines.***		
STEP 1 RESULTS: IF YOU HAVE REACHED THIS POINT WITH NO "STOPs" ALONG THE PATH, A STRONG CASE EXISTS FOR DEVELOPING THE GUIDELINE		

Step 2: Is CDC the best choice to lead the development of the proposed guidelines?

QUESTION	Yes	No
1. Does CDC have primary responsibility (or is CDC mandated by legislation, policy, or other directives) to lead development of these guidelines? *CDC is the only subject matter expert in the country; CDC is mandated to take the lead on this guideline; the topic aligns with CDC's mission; or if CDC doesn't develop the guideline, the guidelines may not be developed at all.* **a. If "Yes," briefly describe. Include how the proposed guideline aligns with the CDC Centers, Institutes, and Offices (CIO) mission and goals. Proceed to question 3.** *Type description here.* **b. If "No," proceed to question 2.**		
2. If CDC is not responsible for leading the development effort, is it appropriate for CDC to partner with another organization to lead the development of the guidelines? (Consider reviewing *CDC's Guiding Principles for Public-Private Partnerships: A Tool to Support Engagement to Achieve Public Health Goals*) **a. If "Yes," briefly describe the organization and proceed to question 3.** *Type description here.* **b. If "No," *stop and reconsider whether CDC should be involved in developing the proposed guideline.***		

QUESTION	Yes	No
3. Are CDC resources available to develop the proposed guidelines? *Resources for guideline development may include staff and manager time, and financial support for development and publishing. Guideline developers can construct a work plan and timeline for guideline development to determine time and resources needed.* **a. If "Yes," briefly describe the resources available and proceed to question 4.** *Type description here.* **b. If "No," are partners available who can provide the resources?** **If "Yes," briefly describe partners, potential resource contributions, and proceed to question 4** *Type description here.* **If "No," *stop and reconsider whether CDC should lead the development of the proposed guidelines.***		
4. Is adequate time available to develop the guideline? *The development of guidelines may take from one to five years. Determining whether the time is available before embarking in guideline development is important to the completion of the project.* **a. If "Yes," briefly describe time needed and proceed to question 5.** *Type description here.* **b. If "No," *stop and reconsider whether CDC should lead the development of the guidelines.***		

QUESTION	Yes	No
5. Is CDC able to publish, translate, distribute, and evaluate the guideline? *To maximize use of the guideline, consider staff availability and resources for converting or translating the guideline into easy-to-use formats (e.g., charts, videos, briefs, Web applications, electronic protocols) and distributing it through multiple channels (e.g., manuscripts, e-mails, webinars, websites, presentations, conferences, social media). Also plan to evaluate the guideline. (See Guideline Follow-up Activities Checklist.)* **a. If "yes," briefly describe capacity (e.g., staff, funds) needed to carry out these activities** *Type description here.* **b. If "No," are partners available to provide these resources?** **If "Yes," briefly describe partners and potential resource contributions. Proceed to question STEP 2 results:** *Type description here.* **If "No," *stop and reconsider whether CDC should lead the development of the proposed guidelines.***		
STEP 2 RESULTS: IF YOU HAVE REACHED THIS POINT WITH NO "STOPs" ALONG THE PATH, A STRONG CASE EXISTS FOR CDC TO LEAD THE DEVELOPMENT OF THE GUIDELINE.		

References:

1. World Health Organization (WHO) handbook for guideline development. 2nd Edition. Guidelines as Topic – standards. 2.Review. 3.Meta-Analysis. 4.Peer Review. 5.Evidence-Based Medicine. 6.World Health Organization. I.World Health Organization. ISBN 978 92 4 154896 0 (NLM classification: WA 39).
2. Guidelines and Recommendations: A CDC Primer. CDC Guidelines and Recommendations Work Group. Version 1.0CDC Primer.
3. Thacker SB, Stroup DF, Carande-Kulis V, Marks JS, Roy K, Gerberding JL. Measuring the public's health. Public Health Rep. 2006 Jan-Feb;121(1):14-22.
4. Health, United States, 2011. CDC National Center for Health Statistics.

Figure 1: Decision Diagram for Guideline Development, Step 1

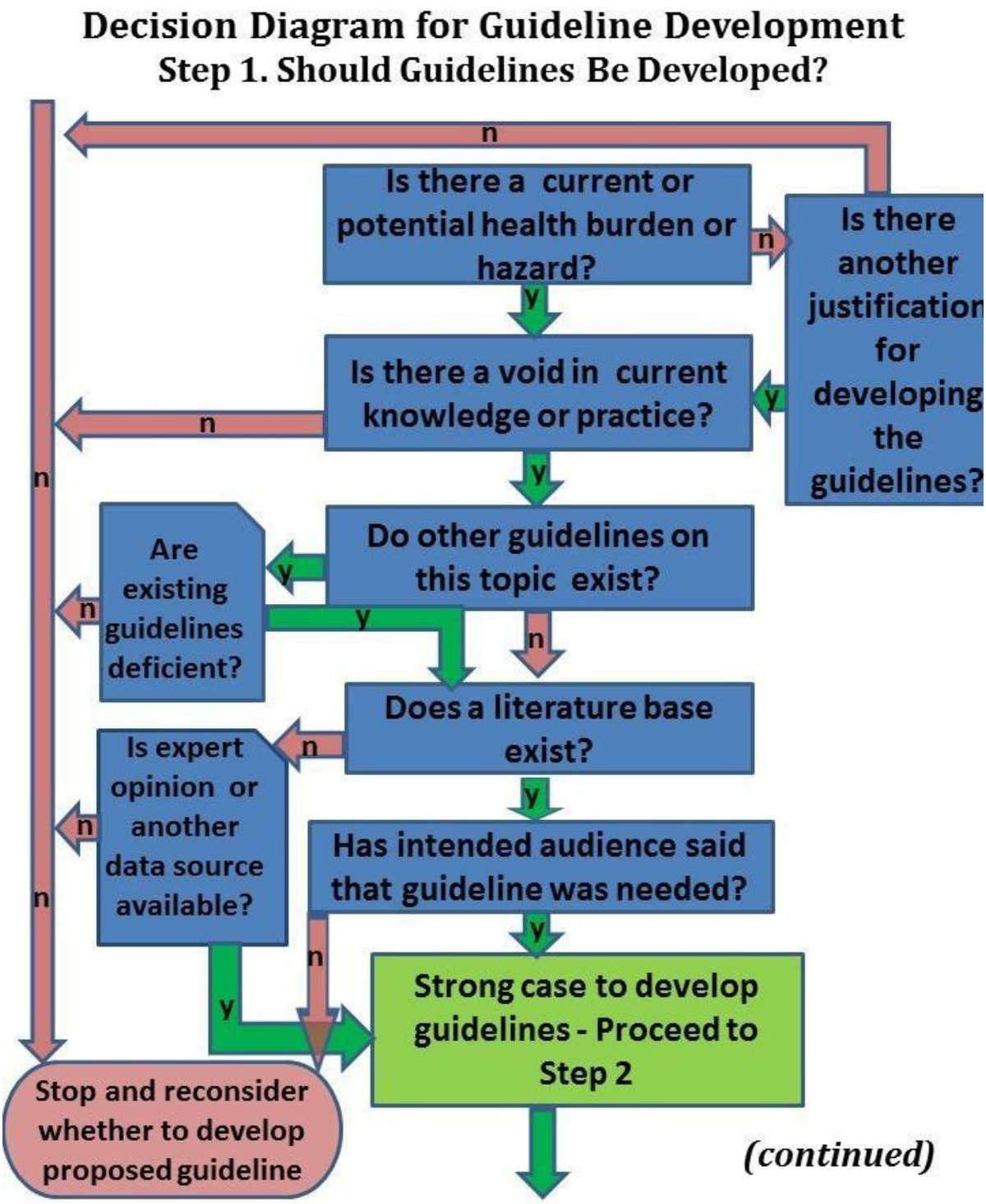

Figure 2: Decision Diagram for Guideline Development, Step 2