REAGAN-UDALL FOUNDATION for the Food and Drug Administration

# Best Practices in Clinical Practice Guideline Development

## Roundtable Meeting Summary

October 2025

REAGAN-UDALL FOUNDATION FOR THE FDA

## ABOUT THE REAGAN-UDALL FOUNDATION FOR THE FDA

The Reagan-Udall Foundation for the FDA (Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

This activity is one part of a multi-part Foundation project related to substance use disorder. The multi-part project is supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of an overall award of $2,470,442 of federal funds (100% of the project). The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by FDA, HHS, or the U.S. Government. For more information, please visit FDA.gov.

As the funders of specific guidelines, FDA had no decision-making role in designing and conducting the systematic reviews, data collection, analysis, and interpretation of the data or approval privilege on the recommendation and good practice statements. As requested, the FDA provided nonbinding feedback and technical support to the respective guideline panels and methodological teams.

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# Introduction

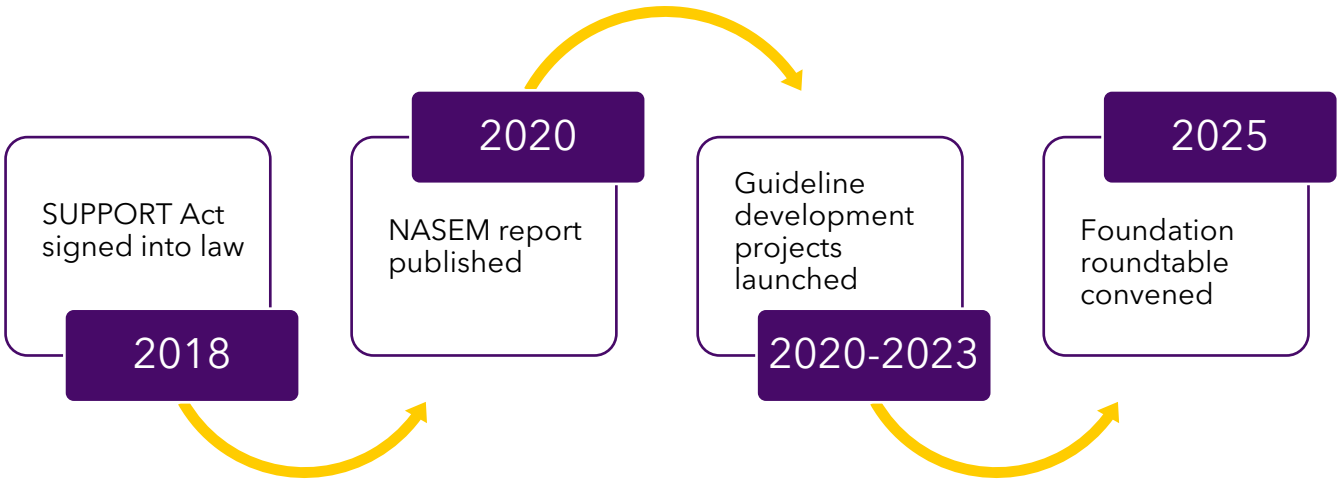
On June 4, 2025, the Reagan-Udall Foundation for the Food and Drug Administration (Foundation), in collaboration with the U.S. Food and Drug Administration (FDA), convened a one-day, in-person roundtable in Washington, DC to explore shared challenges and strategies in the development of clinical practice guidelines (CPGs) involving controlled substances. The event brought together FDA-funded development teams, federal partners and others with expertise in guideline development and implementation, and Foundation staff.

Structured as a collaborative working session, the roundtable featured a mix of plenary discussions and breakout groups focused on addressing evidence limitations, stakeholder engagement, communication strategies, implementation, and evaluation. It also provided space to reflect on the complexity of developing guidelines in priority therapeutic areas where evidence may be limited and unintended consequences are a concern. This report summarizes cross-cutting themes, insights, and lessons that emerged from discussions.

# Background

The overdose crisis remains an evolving and urgent public health challenge. As part of a broader effort to promote safe prescribing, the FDA has taken a pragmatic, evidence-based approach to expanding access to effective interventions and improving clinical decision-making. Ensuring the availability of evidence-based, indication-specific prescribing information for opioid analgesic products has long been a key component of that strategy.

**Figure 1: Timeline for FDA-Supported Guideline Development**



The FDA guidelines development initiative was established in partial fulfillment of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, passed by Congress in 2018.[1] The legislation directed FDA to develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain, in therapeutic areas where such guidelines did not already exist. In response, FDA commissioned the National Academies of Sciences, Engineering, and Medicine (NASEM) to convene a panel of outside experts to (1) identify priority areas for guideline development, (2) recommend a framework for evaluating CPGs, and (3) develop a future research agenda to support guideline advancement.[2]

Building on the NASEM recommendations, FDA launched a cooperative agreement program to fund external organizations, including academic institutions and professional societies, to develop, disseminate, and evaluate guidelines in high-need clinical areas. Each awardee retained autonomy over guideline scope and methods while coordinating with FDA for transparency and alignment. Initial projects, launched between 2020 and 2023, focused on acute dental pain, postpartum pain, lower back pain, and pain following laparoscopic abdominal surgery. In 2022, a project was initiated to develop a benzodiazepine tapering guideline, based on insights raised during the 2021 Duke-Margolis Public Workshop on the safe use of benzodiazepines and informed by extensive stakeholder engagement.[3]

Although these five guidelines vary in scope, target audience, and methodological approach, they share a common goal: to provide actionable, evidence-informed tools that support clinical decision-making, without imposing unnecessary restrictions or reinforcing stigma. This initiative reflects FDA's broader commitment to fostering thoughtful, collaborative processes that improve prescribing practices for controlled substances and reduce the risk of unintended harms. More information on each project can be found on the FDA webpage on guideline development and in Appendix A of this report.

To build on this work, the Foundation convened a one-day, in-person roundtable on June 4, 2025, in Washington, DC. The roundtable agenda can be found in Appendix B. The event brought together representatives from each of the five development teams, FDA staff, federal partners, and Foundation colleagues to reflect on shared challenges, exchange lessons learned, and explore opportunities to strengthen current and future guideline efforts. This report summarizes the key insights that emerged during the day's discussion.

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[1] "(a) GUIDELINES.—The Commissioner of Food and Drugs shall develop evidence-based opioid analgesic prescribing guidelines for the indication-specific treatment of acute pain only for the relevant therapeutic areas where such guidelines do not exist." Substance Use–Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, Pub L No. 115-271, 132 Stat 3934 (2018). https://www.congress.gov/115/statute/STATUTE-132/STATUTE-132-Pg3894.pdf.

[2] National Academies of Sciences, Engineering, and Medicine. Framing Opioid Prescribing Guidelines for Acute Pain: Developing the Evidence. Washington, DC: The National Academies Press; 2020. DOI: https://doi.org/10.17226/25555.

[3] Duke-Margolis Institute for Health Policy. Safe Use of Benzodiazepines: Clinical, Regulatory, and Public Health Perspectives. Public Workshop. July 12, 2021. https://healthpolicy.duke.edu/events/safe-use-benzodiazepines-clinical-regulatory-and-public-health-perspectives.

# Cross-Cutting Themes and Insights

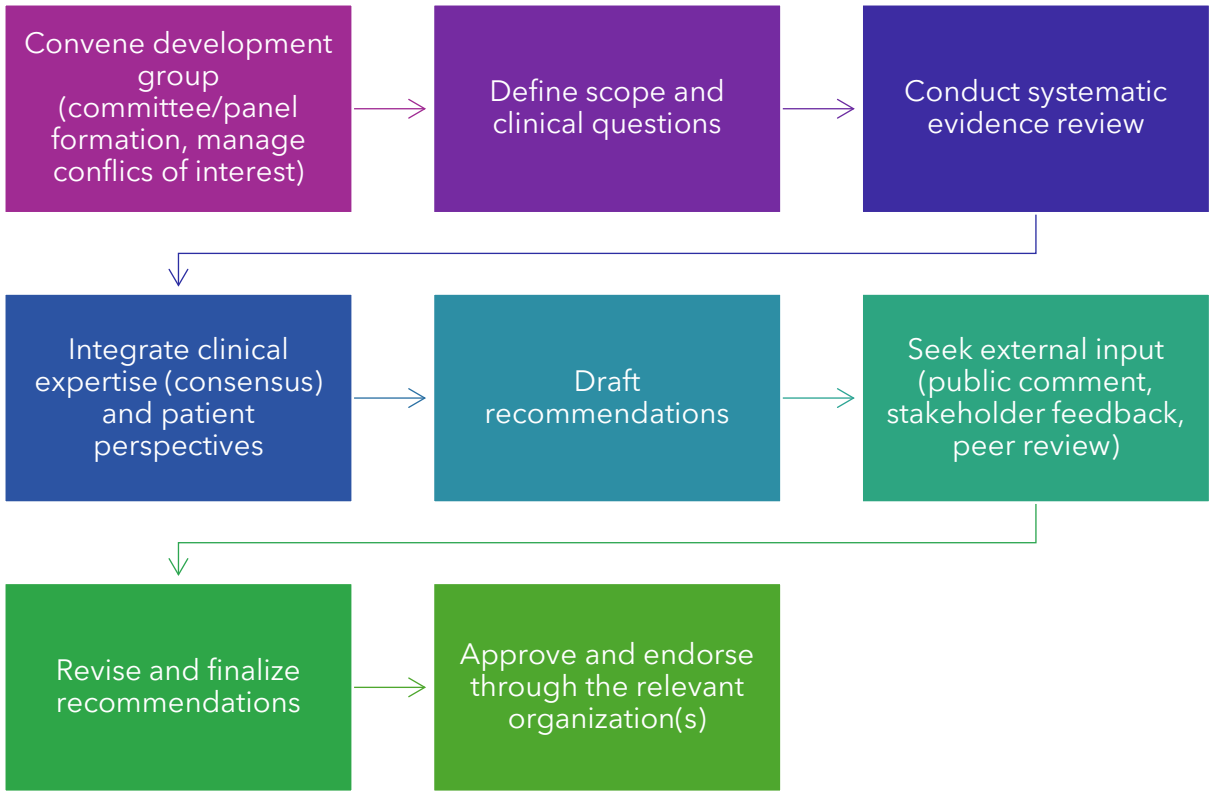
## Addressing Evidence Limitations

### Rationale

CPGs play a critical role in ensuring safe and consistent care for conditions that may utilize controlled substances for treatment. In areas such as acute pain management, perioperative care, and the treatment of substance use disorders, guidelines provide an essential foundation for clinical decision-making. They can help promote evidence-informed prescribing, reduce unwarranted variations in care, and offer reassurance to clinicians navigating complex therapeutic choices. The availability of CPGs is especially important for providers considering use of controlled substances given the potential unintended consequences, such as misuse or overdose.

Throughout the course of the roundtable, participants highlighted the complexity of developing rigorous, clinically useful guidelines when the evidence base is limited, unclear, or still evolving. Participants cited persistent gaps in critical areas such as tapering regimens, care for specific patient subgroups, and long-term outcomes of pharmacologic and non-pharmacologic interventions. These limitations challenge the ability to generate recommendations that are both methodologically sound and relevant to frontline practice. While each of the CPG development teams chose different specific strategies, many of the teams followed a similar process, summarized in Figure 2.

**Figure 2: General CPG Development Process Map**



## Literature Review and Challenges

Most groups used structured, transparent processes for reviewing the literature and grading the strength of recommendations. Participants referenced a range of methodological standards and tools, including the GRADE[4] approach, the Evidence to Decision (EtD) framework,[5] and guidance from the Agency for Healthcare Research and Quality (AHRQ),[6] Cochrane,[7] and NASEM.[8] These frameworks were adapted to reflect available evidence and the clinical realities of prescribing controlled substances and pain management. Evidence identification and reviews are often the most time- and labor-intensive components of CPG development processes.

In addition to these processes, guideline teams emphasized the importance of clinical expertise in interpreting and applying the evidence to practice. Expert input was used both to translate research findings into recommendations that are practical and usable in real-world care, and, where needed, to address gaps in the literature. Several participants discussed the need for minimum thresholds or standards for evidence inclusion, for example, what types of studies, how many studies, or what size of study population should be considered sufficient to support a given recommendation. Participants discussed the challenges associated with setting thresholds for including evidence in recommendations, especially when evidence was limited.

Suggested strategies for improving consistency included using checklists or flowcharts to guide decision-making about which evidence to include and how to weigh or characterize it. [9] Transparency was seen as equally important. Participants worked to document what was excluded from the review and why, helping to clarify the rationale behind each recommendation.

## Leveraging Clinical Expertise

To address these challenges, development teams used structured consensus methodologies, such as modified Delphi processes (e.g., RAND/UCLA),[10] in parallel with formal literature reviews. These approaches allowed teams to formulate recommendations in areas where empirical evidence was sparse or conflicting. Participants were careful to distinguish between recommendations based on direct evidence versus those based primarily on expert consensus.

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[4] Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650):924-926. doi:10.1136/bmj.39489.470347.AD.
[5] Alonso-Coello P, Schünemann HJ, Moberg J, et al. GRADE Evidence to Decision (EtD) frameworks: a systematic and transparent approach to making well informed healthcare choices. 1: Introduction. *BMJ*. 2016;353:i2016. Published 2016 Jun 28. doi:10.1136/bmj.i2016.
[6] Agency for Healthcare Research and Quality. (2014). Methods Guide for Effectiveness and Comparative Effectiveness Reviews (AHRQ Publication No. 10(14)-EHC063-EF). Rockville, MD: AHRQ. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-methods-guide_overview.pdf.
[7] Higgins JPT, Thomas J, Chandler J, et al. (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.5 (updated August 2024). Cochrane, 2024. Available from www.cochrane.org/handbook.
[8] Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical Practice Guidelines We Can Trust. Graham R, Mancher M, Miller Wolman D, Greenfield S, Steinberg E, editors. Washington (DC): National Academies Press (US); 2011. PMID: 24983061.
[9] Schünemann HJ, Wojtek Wiercioch, Itziar Etxeandia, et al. Akl CMAJ Feb. 2014, 186 (3) E123-E142; DOI: 10.1503/cmaj.131237.
[10] Fitch K, Bernstein SJ, Aguilar MD, et al. The RAND/UCLA Appropriateness Method User's Manual. Santa Monica, CA: RAND Corporation, 2001. https://www.rand.org/pubs/monograph_reports/MR1269.html.

Participants also emphasized the importance of transparency when consensus was not achieved. Some methodologies required consensus before a recommendation could be advanced, while others documented the lack of agreement and were explicit about the remaining uncertainty. Making both the basis for consensus decisions and the boundaries of unresolved debate clear to end users was seen as essential for maintaining credibility and guiding appropriate interpretation of the guidelines.

Participants acknowledged the tension between methodological rigor and practical utility. While strict adherence to evidence grading criteria can enhance the rigor and trustworthiness of guidelines, it may exclude clinically relevant insights, particularly in under-researched areas. In the absence of evidence from randomized control trials, findings from observational studies and qualitative research may help inform recommendations. Conversely, more flexible approaches can risk introducing recommendations that need to be corrected or updated. One risk to making recommendations based on expert opinion rather than high-quality research is that once guidelines are available, it can be challenging to encourage shifts in practice based on new evidence. Striking a balance between needing guidelines to inform practice and ensuring the long-term utility of guidelines was a priority among all the development teams.

### Informing Future Research

In addition to bridging gaps in the existing literature, many teams viewed the guideline development process as a valuable opportunity to formally identify priority research questions. By highlighting unresolved issues and areas of insufficient data, participants hoped to help shape future investigations and strengthen the evidence base for guideline updates.

Another area flagged for future attention was the evaluation of guideline uptake and impact. Participants emphasized the need for research not only on clinical outcomes but also on implementation strategies, dissemination effectiveness, and unintended consequences of guideline use. Strengthening this evidence base would provide important feedback loops to improve the relevance and utility of future guideline iterations.

## Stakeholder Engagement

Meaningful engagement of patients, clinicians, and other stakeholders was a core component of each guideline development effort. Most teams involved a broad range of perspectives, including primary care providers, specialists, pharmacists, professional societies, and people with lived experience. Engagement formats varied and included advisory board meetings, key informant interviews, listening sessions, and formal public comment periods. While some interactions were one-time consultations, many participants emphasized the value of early and sustained engagement in building the relevance, legitimacy, and eventual uptake of the guidelines. There are also platforms that enable panel deliberations to be conducted virtually.[11] Advisory boards were a common mechanism for sustained engagement to gather clinical expertise to inform recommendations, particularly when evidence was limited. Participants noted the importance of each participant understanding why they were invited to the process

[11] Dawson T, Pahlke S, Carrasco-Labra A, Polk D. Patient Values and Preferences for Managing Acute Dental Pain Elicited through Online Deliberation. JDR Clin Trans Res. 2024 Apr;9(2):104-113. doi: 10.1177/23800844231174398. Epub 2023 Aug 4. PMID: 37542374; PMCID: PMC10871022.

and what perspective organizers hope they will contribute. Preparation by facilitators was emphasized as critical to guiding discussion and managing power dynamics, especially when participants represented different areas of expertise and had various levels of experience and seniority. Clear communication at the outset about the expected time commitment and type of involvement was also identified as a useful way to support recruitment and sustain participation throughout the process.

Participants noted that stakeholder input often brought valuable context to the evidence base, highlighting real-world challenges, information gaps, or unintended effects that may not be captured in clinical studies. Several participants used this input to refine both content and presentation of information. External feedback helped clarify language, adjust framing, and tailor resources for specific audiences. At the same time, participants acknowledged that feedback could be difficult to reconcile, particularly when stakeholders' experiences or values conflicted with one another or with the available evidence.

To manage expectations and maintain trust with stakeholders, several teams developed strategies for communicating with stakeholders throughout the process. Teams explained what materials would be provided before meetings, what channels of communication would be used, what timelines for feedback would be used, and how their input would be used to inform guidelines. Some shared summaries of feedback themes or responses to public comments; others were more cautious, noting the risk of overpromising responsiveness in situations where not all feedback could be incorporated. Participants noted the particular importance of communicating how patient representatives in advisory panels were expected to contribute, both in clarifying how engagement will influence recommendations and in outlining how often and how much input stakeholders can expect to provide.

Some teams also adopted novel strategies to understand the broader environment. A few monitored social media informally to identify emerging concerns, track misinformation, or gain insight into how patients and clinicians were talking about particular topics in real time. This approach, while exploratory, helped developers stay attuned to shifting narratives and public sentiment.

## Leveraging Partnerships

Partnerships were widely recognized as essential to both the development and dissemination of effective clinical guidelines. Participants emphasized the value of engaging a variety of

### FEDERAL PARTNERS IN GUIDELINE DEVELOPMENT

Federal partners who develop guidelines noted the unique considerations within the government setting. While FDA has supported external organizations to develop guidelines through cooperative agreements, other agencies such as the Centers for Disease Control and Prevention (CDC) and the Veterans Health Administration (VHA) directly oversee their own development processes. These efforts are subject to additional requirements that shape how projects are carried out by influencing the collection of stakeholder input, the level of documentation required, and the timeline for review and release. Federal partners have mechanisms such as Federal Register Notices and other public comment opportunities to gather feedback from the public. For CPG implementation, agencies such as VHA or Department of War have unique levers for impact. They can embed guideline recommendations into health system policies and clinical workflows, increasing adherence and consistency across large patient populations.

partners, including hospital systems, universities, professional societies, patient advocacy groups, and federal and state government agencies. These partnerships can help expand reach, strengthen credibility, and ensure practical relevance. At the same time, teams noted the importance of understanding the distinct motivations, structures, and constraints that shape how each type of partner contributes to guideline efforts.

**Table 1: Potential Opportunities and Challenges Associated with Various Partners**

| Partner | Opportunities | Challenges |
|---|---|---|
| Hospital Systems | Can help drive implementation and uptake | May require alignment with internal workflows, electronic health records, or continuing education programs |
| Universities | May provide access to subject-matter expertise and methodological support | May have limited capacity for outreach |
| Professional Societies | Often viewed as trusted voices within clinical communities and may serve as powerful dissemination partners | Endorsement processes and messaging priorities may not align with guideline content or timelines |
| Advocacy Groups | Can provide insights from patients and caregivers | Expectations for the purpose and content of guidelines might not be aligned with developers |
| Federal and State Government Agencies | Can bring additional visibility and influence | Often operate on longer review cycles or with stricter protocols for public communication |

Some teams partnered with patient advocacy groups and professional societies to help inform the CPG development process as well as leverage established communication channels and large social media followings in the dissemination phase. Professional societies and patient groups are natural platforms for health professionals, patients, and caregivers to seek information about treatment options and recommendations. These collaborations helped amplify messaging and reach specific target audiences but were not always straightforward to coordinate with. Participants noted that leveraging organizational resources (such as marketing teams, digital platforms, or distribution networks) often requires prior relationships, formal agreements, or staff bandwidth that can be difficult to secure within project timelines. Beyond initial development and dissemination, partnerships with professional societies can help support ongoing review and updates for CPGs.

## PAYERS AND GUIDELINE IMPLEMENTATION

Payers, while not involved directly in the guideline development process, are often influential downstream stakeholders; several participants emphasized the importance of anticipating how recommendations may be interpreted or operationalized by health plans and benefit managers. For example, a recommendation intended to inform clinical judgment could be used as a justification to limit coverage or access for patients.

Participants identified closer engagement with payers during the development process as an opportunity for the future. They noted that while it might not be appropriate to have payers contribute to the recommendations, it would be insightful to understand how they might use the recommendations before they are finalized in case there are opportunities for clarification. Such interactions may help promote alignment between guideline intent and implementation in payer decisions.

Participants highlighted the role of partnerships in shaping content and sustaining engagement over time. Organizations with strong networks can help with recruitment for listening sessions or advisory boards, collect late-stage feedback through public comment, and potentially provide support for future guideline updates or related initiatives.

The topic of endorsement emerged as a particular area of interest and uncertainty. Participants described a range of endorsement models, from formal co-branding and joint publication to more informal acknowledgment or inclusion on a partner's website. Clarifying what endorsement entails, both in perception and in practice, was seen as important for setting expectations upfront and maximizing the potential of the partnership. Overall, participants agreed that cultivating trusted partnerships both within and beyond traditional academic settings was critical for ensuring that the guidelines reach the audiences they were designed to serve.

## TAILORING CONTENT

Developers discussed strategies for clarifying which recommendations apply broadly and which should be adapted for specific subgroups. Given the diversity of patients and clinical circumstances involved in pain management and benzodiazepine tapering, developers discussed strategies for identifying and prioritizing subpopulations for tailored guidance. In some cases, developers chose to focus on a core "general population" while noting areas where individualized clinical judgment or further evidence would be needed to guide care for other groups.

One recurring challenge was deciding whether to include specific numerical thresholds in recommendations, such as doses, pill counts, or days of treatment. While quantitative guidance can provide clarity and consistency, developers acknowledged that overly prescriptive figures can have unintended consequences. Fixed limits have historically been used by insurers and health systems to restrict access or deny coverage, regardless of clinical context. Several developers emphasized the need to frame numbers as flexible, evidence-informed reference points rather than strict caps. Participants identified closer engagement with payers during the development process as an opportunity for the future. They noted that while it might not be appropriate to have payers contribute to the recommendations, it would be insightful to understand how they might use the recommendations before they are finalized in case there are opportunities for clarification. Such interactions may help promote alignment between guideline intent and implementation in payer decisions.

## Implementation and Real-World Integration

In addition to methodological rigor, participants emphasized the importance of designing guidelines that are usable in real-world settings. Developing a strong, evidence-informed product is only part of the equation. Translating that guidance into practice requires deliberate implementation strategies, sustained partnerships, and context-specific adaptation.

Participants emphasized the importance of tailoring implementation strategies to the specific settings and systems in which guidelines will be used. While not all projects focused on the same audiences, there was a shared recognition that different environments may require different approaches. These may include adapting content for clinical workflows, aligning with organizational priorities, or identifying key champions to facilitate uptake. Participants noted that successful implementation often hinges on understanding who will be using the guidelines and what support or adjustments may be needed to integrate them effectively.

Teams also highlighted opportunities to align guidelines with licensing and training requirements. This included referencing connections to licensing board priorities, continuing education requirements, and curricular needs for training programs and building partnerships to review learning modules for alignment. A few participants explored whether their guidelines could inform or be reflected in performance measures, though others warned that this would require careful alignment and extra caution to ensure measures did not impede clinical judgment.

Several participants emphasized the value of using structured implementation science frameworks to guide this work. For example, the EPIS framework[12] (Exploration, Preparation, Implementation, Sustainment) provides a phased approach to identifying contextual factors at different stages of the process that influence adoption, such as leadership buy-in, workflow alignment, and stakeholder engagement.

Some participants discussed the value of integrating guideline content into electronic health records (EHRs) to support decision-making at the point of care. While technically and logistically challenging, these approaches can help bridge the gap between written guidelines and routine clinical action. One group described using the EBMonFHIR[13] standard to structure recommendations in a machine-readable format, allowing for digital implementation across systems. These strategies were seen as important for ensuring guidelines are accessible and usable in real-time clinical settings. In one example, CDC developed electronic clinical decision support tools to support the integration of prescribing recommendations into EHR systems.[14] EHR integration was noted as a potential mechanism for monitoring implementation and utilization of recommendations as well.

Participants stressed the importance of articulating how guidelines should and should not be used, particularly in the context of insurance coverage, performance measures, and regulatory oversight. Participants emphasized that guidelines are designed to support clinical decision-

[12] Aarons GA, Hurlburt M, Horwitz SM. Advancing a conceptual model of evidence-based practice implementation in public service sectors. *Adm Policy Ment Health*. 2011;38(1):4-23. doi:10.1007/s10488-010-0327-7.
[13] HL7 International. Evidence-Based Medicine Implementation Guide. HL7 FHIR Implementation Guide. https://build.fhir.org/ig/HL7/ebm/index.html. Published 2024.
[14] Electronic Clinical Decision Support Tools: Opioid Prescribing. U.S. Centers for Disease Control and Prevention. Published May 8, 2024. Accessed October 3, 2025. https://www.cdc.gov/overdose-prevention/hcp/ehr/index.html.

making, not to restrict them. CPGs can be used as tools to facilitate patient education and shared decision-making between a provider and patient formulating a treatment plan. Several participants discussed the need to anticipate how payers or institutions might use guideline content to shape access to care and the importance of framing recommendations carefully to avoid misuse.[15]

Some teams engaged in early field testing or piloting of draft recommendations and decision support tools to improve usability before formal release. These efforts helped surface real-world challenges and refine language, structure, or delivery formats to better fit the needs of end users. Participants noted that involving future implementers, especially those working in primary care or other high-volume settings, early in the process was essential for surfacing usability issues and identifying unintended friction points.

To support clinical implementation, many teams included practical tools and resources alongside their core recommendations. These included sample patient scripts, example order sets, tapering templates, and decision support prompts that could be adapted for use in EHRs or continuing education platforms. Participants viewed these tools as a way to bridge the gap between written guidance and everyday clinical practice. Identifying ways to insert guidelines into clinical workflow is an emerging application of artificial intelligence (AI).

Several participants noted that implementation success depends not only on content but also on design. Guideline documents must be accessible, intuitive, and easy to navigate, as it would be used by time-pressed clinicians. Teams discussed ways to "make the right thing the easiest thing," including the use of visual aids, summary tables, pocket guides, sample clinical orders, and companion resources that streamline adoption at the point of care.

Participants highlighted the value of developing guidelines that adhere to standardized templates and formats. When guidelines follow a consistent order and structure, end users (e.g., clinicians) know where to find key information quickly, and organizations can more readily integrate recommendations into clinical workflows and training programs. Standardization can also reduce confusion across specialties, improve comparability between guidelines, and strengthen trust in the documents as reliable clinical tools.

Participants spoke about the importance of moving from the idea of a static, one-time publication to a more dynamic model, where guidelines are treated as evolving tools that can be updated, integrated, and embedded into workflows. One team shared an example of developing a "living guideline," updated in real time as new evidence becomes available.[16] While such approaches require significant investment and coordination, they represent an important opportunity to bridge the gap between "guideline as product" and "guideline as practice."

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[15] From the SUPPORT Act: (e) STATEMENT TO ACCOMPANY GUIDELINES AND RECOMMENDATIONS-
The Commissioner of Food and Drugs shall ensure that opioid analgesic prescribing guidelines and other recommendations developed under this section are accompanied by a clear statement that such guidelines or recommendations, as applicable—
(1) are intended to help inform clinical decision making by prescribers and patients; and
(2) are not intended to be used for the purposes of restricting, limiting, delaying, or denying coverage for, or access to, a prescription issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

[16] Living Guidelines Handbook V1.0. Australian Living Evidence Consortium, 2022.

### WHAT ARE LIVING GUIDELINES?[17, 18]

Living guidelines are CPGs that are continually updated to reflect new, high-quality evidence as it emerges. This dynamic model ensures that recommendations remain current and responsive to changes in the evidence base—especially critical in areas like pain management, tapering, or substance use, where knowledge is evolving and clinical decisions carry high stakes. This approach offers particular advantages in high-uncertainty settings where clinicians and patients need timely, trustworthy guidance that can adapt to the pace of discovery.

Living guidelines rely on living systematic reviews (LSRs) which are ongoing evidence syntheses that incorporate new research in real time. When new findings have the potential to change a recommendation, guideline panels reconvene promptly to review and revise the guideline. This cycle of constant evidence surveillance, appraisal, and update allows living guidelines to reduce the lag between research and practice while preserving methodological rigor.

Key components include the following:

- **Continuous evidence surveillance**, often supported by LSRs
- **Predefined update triggers,** based on the significance of new findings
- **Rapid guideline development processes**, with agile review and approval workflows
- **Collaborative infrastructure**, including standing panels and methodological teams
- **Clear communication**, so users can distinguish between updated and unchanged recommendations

At the same time, developers have cautioned that living guidelines pose significant challenges. Questions remain about when and how to include unpublished studies and broader types of evidence, and how to securely share data given copyright restrictions. Frequent updates also pose difficulties, as reimbursement and procurement systems are not designed for continual pricing changes. Multi-stakeholder engagement is further complicated by the need to coordinate across groups with differing priorities and to manage commercially sensitive information. Linking new evidence to reimbursement introduces its own obstacles, since pricing negotiations can be lengthy and frameworks must allow for both increases and decreases, including potential de-adoption of ineffective technologies. Finally, system capacity is a recurring concern, as fixed reimbursement schedules, regulatory barriers, and limited methodological expertise can all slow the timely inclusion of emerging evidence.[19]

## Communication and Dissemination

Participants highlighted the critical role of communication in shaping how clinical guidelines are understood, received, and ultimately applied. In areas involving controlled substances, where public attention is high and clinical nuance is essential, language choices take on heightened importance. Participants emphasized the need to use clear, accessible, and non-stigmatizing language to describe patient experiences, treatment goals, and risk considerations. Framing recommendations with care was seen as especially important to avoid triggering fear, reinforcing stigma, or contributing to misapplication.

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[17] Australian Living Evidence Consortium. *Living Guidelines Handbook: Version 1.0*. Melbourne, Australia: Australian Living Evidence Consortium; 2022. Accessed August 11, 2025. https://static1.squarespace.com/static/5c1aeebd9f87705cde7498f1/t/6350e029ddf0742f9c65d4fc/1666244654438/Living+Guidelines+Handbook+V1.0.pdf.

[18] El Mikati IK, Khabsa J, Harb T, et al; Living Guidelines Group. A framework for the development of living practice guidelines in health care. *Ann Intern Med*. 2022;175(8):1154-1160. doi:10.7326/M22-0514.

[19] Cheyne S, Chakraborty S, Lewis S, Campbell S, Turner T, Norris S. What could health technology assessment learn from living clinical practice guidelines? *Front Pharmacol*. 2023;14:1234414. doi:10.3389/fphar.2023.1234414.

To reach a wide range of audiences, including clinicians, patients, policymakers, and the public, teams employed a variety of dissemination strategies. These included traditional academic publications, webinars, accredited continuing education modules, and conference presentations, as well as pocket cards, bedside tools, microlearning videos, podcasts, and translated materials. Several teams co-developed dissemination products with end users to ensure that tone, format, and messaging aligned with audience needs. Others explored earned media opportunities or informal outreach to help raise awareness.

One strategy that resonated with participants was the use of short videos and podcast episodes to introduce guideline topics in a more conversational, narrative-driven way. Rather than leading with directives, these formats allowed key issues to emerge "organically," creating space for curiosity and reflection. Participants noted that this approach helped reduce defensiveness and made the content more approachable, especially for clinicians navigating sensitive or controversial areas of practice.

Despite these creative efforts, many participants noted that a lack of infrastructure and sustained funding posed significant barriers to dissemination and implementation. While most teams produced core materials for initial publication, few had the capacity to develop tailored resources, maintain ongoing outreach, or evaluate impact over time. Several participants voiced concern that without additional support, even well-developed guidelines risk remaining underused.

The online environment presents another set of challenges. Participants acknowledged the risk of misinterpretation or oversimplification once guideline content is shared publicly. Nuanced recommendations can be reduced to headlines or oversimplified takeaways. This has the potential to undermine their intent, particularly in areas involving individualized care or benefit-risk tradeoffs. Teams discussed the need to proactively shape messaging, anticipate points of confusion, and engage trusted messengers who can contextualize the guidance in real-world conversations.

Some participants also noted the potential for emerging technologies, such as AI, to play a role in dissemination and clinical decision support in the future. While not a current focus, these tools may present opportunities to integrate guidelines more seamlessly into care workflows.

## Evaluating Uptake and Impact

Participants acknowledged that evaluating the uptake and impact of clinical guidelines remains a challenging and resource-intensive endeavor. While each FDA-funded project incorporated some evaluation component, there was broad agreement that deeper, long-term assessment of behavioral and clinical outcomes is difficult to achieve within the typical constraints of guideline development efforts.

Throughout the conversation, participants identified limitations of commonly used evaluation metrics. Participants noted that indicators such as changes in prescribing volume may be easy to track but do not necessarily reflect clinical appropriateness or alignment with guideline recommendations. While data from EHRs may be able to provide near real-time data on whether CPGs are followed, they will not necessarily capture when shared decision making was undertaken and the patient chose to disregard the guideline. These proxy measures may be misleading or insufficient to capture the nuanced goals of the guidelines. Participants

emphasized that evaluating implementation to understand whether and how guidelines are being used may be more feasible in the near term than assessing long-term impact on health outcomes. Although projects aimed to promote consistent, evidence-informed care, the capacity to measure whether they lead to better patient outcomes was limited. In some cases, participants expressed a desire to do more but acknowledged that time, staffing, and funding were barriers to comprehensive evaluation activities.

### Opportunities for Coordination

The roundtable also surfaced enthusiasm for greater coordination among CPG development teams. While each project had a distinct clinical focus and set of deliverables, several participants noted meaningful overlap in areas such as target audience, dissemination strategies, or implementation challenges. Participants expressed interest in sharing tools and templates, aligning messaging, and identifying opportunities to develop common resources that could reduce duplication and promote consistency across guidelines.

There was also strong support for continued convenings like this roundtable. Many participants said that this was the first time they had the opportunity to gather in person for extended discussion and learn from other CGP developer teams, and found exchange of experiences and lessons learned both validating and practical. Looking ahead, attendees expressed interest in creating more structured opportunities for peer learning, shared problem-solving, and ongoing collaboration. This is particularly significant as projects move into later stages of dissemination, adoption, and evaluation.

## Conclusion and Call to Action

Throughout the roundtable, participants returned to the shared motivation that drives this work: the urgent need to develop guidelines to support safe, effective, and compassionate care in areas where clinical guidance is lacking or inconsistent. In the context of the ongoing overdose crisis, evidence-informed CPGs remain an essential tool for promoting better outcomes and reducing harm. This is particularly true in areas where the evidence base is limited or still emerging. In such cases, guidelines serve not only to inform clinical decision-making, but also to reduce variation in practice, provide reassurance to clinicians, and signal where additional research and support are needed.

Participants also noted that new guidelines and recommendations should be contextualized for end users relative to existing guidelines, knowledge, and practices. This is especially important where there is overlap in clinical domains (e.g., across related conditions, procedures, or care pathways) and professionals may consult CPGs from different disciplines. Ultimately, the goal is not to create rigid rules that impede patient access and individualized care but to offer meaningful guidance that helps clinicians navigate complex treatment decisions while centering patient needs and safety.

As projects move from development to dissemination and evaluation, participants emphasized the need for ongoing investment that extends beyond creating guidelines, and into understanding impact and unintended consequences as well as maintaining them over time. Developers are more likely to maximize impact if there are adequate resources for broad

dissemination, real-world implementation, and iterative updates. Concretely, this includes resourcing dissemination plans (e.g., clinician education, point-of-care tools, EHR order sets), establishing feedback loops to monitor adoption and unintended effects (including equity impacts), and budgeting for scheduled updates or a living-guidelines cadence where appropriate.

Finally, participants emphasized the benefit of developing shared tools and minimum standards to guide future efforts of guideline development. Common approaches to evidence review, stakeholder engagement, and dissemination planning can strengthen alignment across CPG development efforts while preserving the flexibility needed for different contexts. Some participants pointed to the value of treating guideline development as part of a broader ecosystem, where documents are designed to align in format and terminology. This approach can make it easier for related guidelines to be read side by side and to be used by a variety of health professionals from different specialties. Practical suggestions included developing a common template with consistent formatting, sections, terminology, and tools. While complete convergence for guideline development may not be feasible, greater standardization in the presentation and intended use of CPGs was seen as a practical step toward optimizing development resources, addressing time and energy constraints for health professionals, and enhancing utility across settings.

# Appendix A: FDA-Supported Clinical Practice Guidelines for Drugs with Abuse Potential

Below is a list of FDA-supported clinical practice guidelines related to drugs with abuse potential. The most current and complete version of this list is available on FDA's website.

**Dental Pain Guideline (funded in 2020)**

Building on its leadership in opioid-sparing dental care, Pitt Dental Medicine, in partnership with the American Dental Association and the Pittsburgh VA Hospital, received FDA funding to develop evidence-based clinical practice guidelines for managing acute dental pain. The project aims to formalize opioid-alternative strategies, disseminate the guidelines, and evaluate their adoption in practice. By promoting safe and effective pain relief while reducing reliance on opioids, the initiative seeks to establish a standard of care that improves patient outcomes and reduces the risk of opioid misuse. You can find more information on the University of Pittsburgh's website. See below for the published guidelines on the pharmacologic management of acute dental pain in adolescents through older adults and in children:

- Carrasco-Labra A, Polk DE, Urquhart O, et al. Evidence-based clinical practice guideline for the pharmacologic management of acute dental pain in adolescents, adults, and older adults: A report from the American Dental Association Science and Research Institute, the University of Pittsburgh, and the University of Pennsylvania. J Am Dent Assoc. 2024;155(2):102-117.e9. doi:10.1016/j.adaj.2023.10.009.
- Carrasco-Labra A, Polk DE, Urquhart O, et al. Evidence-based clinical practice guideline for the pharmacologic management of acute dental pain in children: A report from the American Dental Association Science and Research Institute, the University of Pittsburgh School of Dental Medicine, and the Center for Integrative Global Oral Health at the University of Pennsylvania. J Am Dent Assoc. 2023;154(9):814-825.e2. doi:10.1016/j.adaj.2023.06.014.

**Benzodiazepine Tapering Guideline (funded in 2022)**

Developed by the American Society of Addiction Medicine (ASAM), the benzodiazepine tapering guideline offers evidence-informed and consensus-based strategies to help clinicians decide when tapering may be appropriate and how to approach it safely. It focuses on adult patients who use benzodiazepines regularly and may be at risk for physical dependence – an expected outcome of use that differs from benzodiazepine use disorder. The guideline also includes considerations for patients with co-occurring substance use disorders and specifies that it is not intended for clinicians working in palliative or end-of-life care.

See below for the published guideline from the American Society of Addiction Medicine on safe tapering of benzodiazepines:

- Brunner E, Chen CA, Klein T, et al. Joint Clinical Practice Guideline on Benzodiazepine Tapering: Considerations When Risks Outweigh Benefits. *J Gen Intern Med*. Published online June 17, 2025. doi:10.1007/s11606-025-09499-2.

**Postoperative Obstetric Pain Guideline (funded in 2022)**

The University of Michigan was awarded a grant to develop a guideline that will serve as a standard of care for the management of postoperative pain in obstetric and postpartum patients. For all surgical procedures in obstetric patients, ensuring adequate pain management while balancing the special considerations on the amount and timing of opioid dosing is needed to ensure patient safety.

**Laparoscopic Abdominal Surgeries Pain Guideline (funded in 2023)**

The University of Minnesota and the University of California, San Francisco are working on a project to address the overprescription of opioids following abdominal laparoscopic surgery—a common procedure for which comprehensive, evidence-based pain management guidelines do not currently exist. Overprescribing opioids increases the risk of misuse and overdose, fueling the broader public health crisis of opioid-related deaths. Recognized as a high-priority need by NASEM, the initiative seeks to create, implement, and evaluate guidelines that minimize opioid use while ensuring effective pain control before, during, and after surgery. More information on their work can be found on the University of Minnesota's website.

**Lower Back Pain Guideline (funded in 2023)**

Oregon Health & Science University, Aggregate Analytics, Inc., and the American Academy of Pain Management received a grant to develop a clinical guideline establishing a standard of care for managing acute low back pain. By standardizing care and incorporating both pharmacologic and nonpharmacologic treatment options, the guideline aims to improve patient outcomes and lower the risk of prolonged opioid use.

# Appendix B: Roundtable Agenda

## Best Practices in Clinical Practice Guideline Development Roundtable

**1333 New Hampshire Ave NW, Rooftop, Washington, DC 20036**
**June 4, 2025 from 9am – 4:30pm ET**

Meeting Description: The Reagan-Udall Foundation for the FDA, in collaboration with U.S. Food and Drug Administration, is hosting a one-day, invitation-only roundtable to bring together organizations developing clinical practice guidelines related to controlled substances. In recent years, the Agency has funded five guideline development projects that aim to address critical knowledge gaps and support appropriate prescribing. The meeting will connect guideline developers and federal partners to share best practices for clinical guideline development, dissemination, and evaluation.

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| **9:45 am** | Welcome and FDA Remarks |
| **10 am** | Overview of FDA-Funded Clinical Practice Guidelines |
| **11:10 am** | Breakout 1 – Collecting Feedback through Partnerships and Collaboration |
| **12:30 pm** | Lunch |
| **1:30 pm** | Breakout 2 – Communication and Dissemination Strategies |
| **2:45 pm** | Break |
| **3 pm** | Evaluating Uptake and Impact: Lessons Learned |
| **4:10 pm** | Final Reflections |
| **4:30 pm** | Adjourn |

# Appendix C: Resources for Guideline Development

**Clinical Guideline Standards**


- American Academy of Family Physicians. ***Clinical Practice Guideline Manual.*** American Academy of Family Physicians; 2017. Accessed September 12, 2025. https://www.aafp.org/family-physician/patient-care/clinical-recommendations/cpg-manual.html
- Carande-Kulis V, Elder RW, Koffman DM. ***Standards Required for the Development of CDC Evidence-Based Guidelines.*** *MMWR Suppl.* 2022;71(Suppl-1):1–6. doi:10.15585/mmwr.su7101a1. https://www.cdc.gov/mmwr/volumes/71/su/su7101a1.htm
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- Guidelines International Network. ***Resources.*** Accessed October 3, 2025. https://g-i-n.net/get-involved/resources
- Schünemann H, Wiercioch W, Etxeandia I, et al. ***Guideline Development Checklist: A Tool to Support the Development of Evidence-Based Guidelines.*** The GRADE Working Group, McMaster University, and Guidelines International Network; 2014. Accessed September 12, 2025. https://macgrade.mcmaster.ca/resources/gin-mcmaster-guideline-development-checklist/gin-mcmaster-guideline-development-checklist/
- U.S. Advisory Committee on Immunization Practices (ACIP). ***Handbook for Developing Evidence-Based Recommendations: Formulating Questions, Conducting the Systematic Review, and Assessing the Certainty of the Evidence Using GRADE (Grading of Recommendations Assessment, Development and Evaluation).*** Updated April 22, 2024. Centers for Disease Control and Prevention; 2024. Accessed September 12, 2025. https://www.cdc.gov/vaccines/acip/recs/grade/downloads/ACIP-GRADE-Handbook_4-22-24.pdf
- U.S. Department of Veterans Affairs. ***VA/DoD Clinical Practice Guideline Program: Policies and Guidance.*** U.S. Department of Veterans Affairs; 2025. Accessed September 12, 2025. https://www.healthquality.va.gov/policy/index.asp
- U.S. Preventive Services Task Force. ***Procedure Manual.*** Updated 2018. U.S. Preventive Services Task Force; 2018. Accessed September 12, 2025. https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/standards-guideline-dev%20%281%29.pdf
- World Health Organization. ***WHO Handbook for Guideline Development.*** 2nd ed. World Health Organization; 2014. Accessed September 12, 2025. https://iris.who.int/bitstream/handle/10665/145714/9789241548960_eng.pdf?sequence=1


**Frameworks and Tools for Reviewing Evidence**


- Agency for Healthcare Research and Quality. ***Methods Guide for Effectiveness and Comparative Effectiveness Reviews (AHRQ).*** Publication No. 10[14]-EHC063-EF. Rockville, MD: AHRQ; 2014. Accessed September 12, 2025. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/cer-methods-guide_overview.pdf

- Alonso-Coello P, Schünemann HJ, Moberg J, et al. ***GRADE Evidence to Decision (EtD) Frameworks: A Systematic and Transparent Approach to Making Well-Informed Healthcare Choices. 1: Introduction.*** *BMJ.* 2016;353:i2016. doi:10.1136/bmj.i2016. https://www.bmj.com/content/353/bmj.i2016
- Fitch K, Bernstein SJ, Aguilar MD, et al. ***The RAND/UCLA Appropriateness Method User's Manual.*** Santa Monica, CA: RAND Corporation; 2001. Accessed September 12, 2025. https://www.rand.org/pubs/monograph_reports/MR1269.html
- Guyatt GH, Oxman AD, Vist GE, et al. ***GRADE: An Emerging Consensus on Rating Quality of Evidence and Strength of Recommendations.*** *BMJ.* 2008;336(7650):924–926. doi:10.1136/bmj.39489.470347.AD. https://www.bmj.com/content/336/7650/924
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- Montes M, Wargo J, Jones-Jang SM, et al. ***Evaluating Video-Based Science Communications Practices: A Systematic Review.*** *JCOM.* 2025;24(3):V01. doi:10.22323/2.24030901. https://doi.org/10.22323/2.24030901

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