

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

35TH AHRQ ANNIVERSARY Today's Research, Tomorrow's Healthcare

Pre-Application Technical Assistance Webinar

RFA-HS-24-003, Notice of Funding Opportunity (NOFO)

Implementing and Evaluating Patient-Centered Clinical Decision Support Strategies in Real-World Settings (U18)

August 1, 2024 | 1-2p EDT

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Agenda

- AHRQ Staff
- Background and Award information
- NOFO Requirements & Review Criteria
- Frequently asked questions
- Final comments

AHRQ Staff

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BACKGROUND & AWARD INFORMATION

Agency for Healthcare Research and Quality (AHRQ)

- **AHRQ's Mission:**
  - To produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within HHS and with other partners to make sure that the evidence is understood and used.

- **AHRQ's Digital Healthcare Research (DHR) Program:**
  - DHR's mission, within the Center for Evidence and Practice and Improvement, is to determine how the various components of the ever-evolving digital health care ecosystem can best come together to positively affect health care delivery and create value for patients and their families.

  - http://digital.ahrq.gov

Clinical Decision Support in Legislation at AHRQ

Since 2016, DHR's Initiative has been based on patient-centered outcomes research and ACA legislative requirements (Sec 6301).

- (b) INCORPORATION OF RESEARCH FINDINGS – The Office [AHRQ], in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on **clinical decision support** *to promote the timely incorporation of research findings* disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

- (c) FEEDBACK – The Office shall establish a *process to receive feedback* from physicians, health care providers, **patients**, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

- Re-authorized in 2019 for 10 years.

AHRQ PCOR CDS Initiative

<u>Two Basic Goals</u>: (1) To advance evidence into practice through CDS, and (2) to make CDS more shareable, standards-based, and publicly available.

Source: http://cds.ahrq.gov

AHRQ PCOR CDS Initiative (continued)

Two Basic Goals: (1) To advance evidence into practice through CDS, and (2) to make CDS more shareable, standards-based, and publicly available.

Full List of PCOR CDS Resources: https://cds.ahrq.gov/about

Clinical Decision Support and PC CDS

- **Clinical decision support (CDS)** refers to digital tools that are used to help inform patient care.
- CDS can take many forms, such as order sets, recommendations about needed care like screening tests, dashboards that can provide summary information, and alerts that need attention from care team members.
- **Patient-centered clinical decision support (PC CDS),** in contrast to traditional clinician-facing CDS, is CDS that focuses on the patient, or their caregiver, and facilitates their active involvement in healthcare decision-making with their clinicians.
  - AHRQ defines PC CDS as CDS that significantly incorporates patient-centered factors related to knowledge, data, delivery and use. You can learn more about this definition at the weblink here, also referenced in the NOFO: https://cdsic.ahrq.gov/cdsic/patient-centered-clinical-cds-infographic

CDS Innovation Collaborative (CDSiC)

The CDSiC is an AHRQ-funded collaborative that integrates diverse perspectives to produce resources and evidence to advance the field of patient-centered clinical decision support (PC CDS).

This project began in September 2021 and is currently finalizing this year's resources. It has produced dozens of resources on PC CDS so far.

- The CDSiC aims to support advancement of PC CDS by:
  - Creating a **learning community to share and advance the knowledge, resources, and methods** for developing, implementing, using, measuring and evaluating high-quality PC CDS.
  - **Promoting the practice and adoption of high-quality PC CDS** that considers patient/caregiver preferences & goals, clinician workflows, and shared-decision making values.
  - **Advancing standards-based CDS that can be shared and scaled** across the US health care ecosystem and result in measurable improvements in processes, experiences, and outcomes.

CDSiC Overview: Three Unique Centers

CDSiC Operations Center

Operational oversight that flows throughout CDSiC and strategic direction from Steering Committee

CDSiC Stakeholder Community & Outreach Center

Thought leadership from four Workgroups that informs the Steering Committee and Innovation Center

CDSiC Innovation Center

Two cores that will develop and execute innovative projects

Purpose of RFA

- The purpose of this Notice of Funding Opportunity (NOFO), Request for Applications (RFA) is to conduct research on patient-centered clinical decision support (PC CDS), a nascent area within the larger field of CDS.

- Through the AHRQ-funded Patient Centered Outcomes Research (PCOR) CDS Initiative and the CDS Innovation Collaborative specifically, PC CDS resources are now publicly available for interested researchers to further build upon, develop, and test, in real-world settings.

RFA Key Dates

Milestone	Date
RFA Posted	July 10, 2024
Earliest Submission	July 10, 2024
Letter of Intent Due**	August 12, 2024
Application Due	**September 12, 2024***
Estimated Award	February 2025

This RFA is a one-time call for applications.

*Applications are due by 5:00 PM local time of applicant organization
**Letter of intent is not required, not binding, and not entered into review of subsequent application

Award Information

Mechanism	U18: Cooperative Agreement, with substantial AHRQ programmatic involvement and participation in the CDSiC*
Funds available	$6,000,000
Number of awards (anticipated)	Up to 6
Total costs (direct and indirect)	Up to $500,000 in a year Up to $1,000,000 for the entire project
Project duration	Not to exceed 2 years

*Substantial involvement means that, after award, AHRQ scientific or program staff will assist, guide, coordinate, or participate in project activities. See Cooperative Agreement Terms and Conditions of Award in RFA.

OVERVIEW OF RFA REQUIREMENTS

Eleven (11) "Must" Requirements (1-2)

- First, you must utilize one or more of the products from the CDSiC or more broadly from the overall PCOR CDS Initiative, available on the project websites: **cdsic.ahrq.gov**, and (**cds.ahrq.gov**)
  - The full list of PCOR CDS projects (including links to CDSiC resources) is available at https://cds.ahrq.gov/about

- IF CDSiC products are used, applicants must identify if any other frameworks are also being used to evaluate the performance of their PC CDS (e.g., RE-AIM or other)

Eleven (11) “Must” Requirements (3-5)

- Apply the definition of patient-centered CDS (available here: https://cdsic.ahrq.gov/cdsic/patient-centered-clinical-cds-infographic) and describe the degree to which each of the 4 elements are incorporated into your patient-centered CDS tool: ***knowledge, patient data, delivery, and use***
- Apply an equity lens, consistent with AHRQ's PCOR Strategic Framework
- Apply at least 1 of the 4 priorities from AHRQ's PCOR Strategic Framework

Eleven (11) "Must" Requirements (6-9)

- Include meaningful and substantial **participation from patients** and/or patient representatives in the co-design, implementation, and evaluation of their research, to also be reflected in the proposed budget
- Fully describe your **research ecosystem**
- IF you are developing or extending a digital tool, be **mobile friendly** to be more accessible to a broader population (for example, a patient-facing portal, website, etc.)
- IF your research or tool will be incorporated into an EHR system, the facility must have a mature, functioning EHR system (e.g., the facility is not planning any significant system upgrade or migration). Otherwise, an alternative means to test and evaluate the selected CDS product can be described

Eleven (11) "Must" Requirements (10-11)

- IF your research strategy intends to modify an existing clinical workflow that is currently clinician-focused, to become a patient-centric or patient-facing approach, then the strategy must include an evaluation component to characterize the performance of the PC CDS tool versus the previous clinician-facing workflow
- IF your proposed project plans to promote implementation of shared decision making (SDM), it should align with AHRQ's definition of SDM (available here: https://www.ahrq.gov/sdm/about/index.html) and include at least one validated measure of SDM in its evaluation

Other Elements to consider incorporating

- Clinical Quality Language (CQL)
- HL7 standards
- FHIR data standards
- Value sets from common clinical terminologies
- Use of open-source tools developed through AHRQ's Multiple Chronic Conditions Electronic Care Plan project to improve interoperability of data for people living with MCCs

U18 Cooperative Agreement Requirements for PI

The PD(s)/PI(s) must participate in regularly scheduled (e.g., monthly) teleconferences with the AHRQ program official and/or other AHRQ personnel as appropriate.	As part of the Cooperative Agreement, PIs will be required to be an **active stakeholder in AHRQ's CDS Innovation Collaborative (CDSiC), a separately funded learning collaborative. **Active participation means that PIs may, based on expertise and interest, be a workgroup member or a key informant on specific issues or products, may present to various committees including the steering or planning committees, or co-author on products, manuscripts, and posters. Applicants must indicate a **commitment** to participate in these activities as well as collaborate with other recipients.	The PD(s)/PI(s) must attend the annual conference of the CDSiC, which is held in the Washington, DC area.

"Active Stakeholder RE: CDSiC, continued"

- Your role in the CDSiC does not need to be determined in advance in order to submit an application.
  - *Do not contact the CDSiC leadership to discuss future roles at this time.*
- Cooperative activities are intended to strengthen individual projects and at the same time generate collaboration across the projects.
- By being an active participant in the CDSiC, recipients will have the benefit of additional input, feedback, and expertise from a diverse array of stakeholders, and will themselves be a source of cutting-edge knowledge and thought leadership as the CDSiC continues to develop PC CDS resources in future years.

- *<u>NOTE:</u> The CDSiC will not be available to provide free, ongoing technical assistance for your independent research.*

Eligibility for U18

Higher Education Institutions
- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for AHRQ support as Public or Private Institutions of Higher Education:
- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education
- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Refer to RFA section III: Eligibility Information

For-Profit Organizations
- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments
- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments
- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other
- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Application Requirements

- All required sections, including page limitations, must be followed as noted in **Section IV of the NOFO**: "Application and Submission Information."
- All PD/PIs must devote a minimum of 20% annual full-time effort (i.e., at least 8 hours per week) in each year of the project
- For institutions/organization proposing multiple PDs/PIs, regardless of the number of PDs/PIs proposed, each PD/PI must devote a minimum of 10% annual full-time effort (i.e., at least 4 hours per week) in each year of the project
- Budget:
  - Attendance/travel to the CDSiC annual meeting
  - Study budgets should provide appropriate levels of funding ***for patients, families, and caregivers commensurate with the roles and the level of effort they will provide to the research***, if applicable

Required Performance Measures

Measure Domain	Timeline	Measure
Applying PC CDS	By end of Year 2	Assess the level of patient centeredness by applying the definition of patient-centered CDS
		Identify how much each of the 4 definition elements are incorporated into your tool
Outcomes	By end of Year 2	Success in implementing the planned CDS within the environment
		If applicable, when modifying an existing workflow, the details should be captured in an evaluation
Impact	By end of Year 2	Degree of direct patient involvement or feedback
		Overall usefulness of the PC CDS tool; generalizability

Letters of Support

- In some situations, it may be appropriate for applicants to include letters of support from:
  - Personnel who have agreed to participate in and collaborate as part of the proposed project (e.g., IT leadership at a participating site).
  - A patient group or patient advocacy organization that endorses the research.

  - *A clinical site collaborator (since fully described research should ideally include a facility with a mature, functioning EHR system), or where there is otherwise a justification for an alternative means to test and evaluate the selected CDS product.*

APPLICATION REVIEW PROCESS

Review Criteria

- **Administrative criteria**
  - Upon receipt, applications will be evaluated for completeness and responsiveness.
  - Incomplete and/or non-responsive applications or applications not following instructions given in this NOFO will not be reviewed.

- **Merit review criteria**
  - Scored review criteria
  - Additional review criteria

Overall Impact Score

- Reviewers will provide an overall impact score to reflect their assessment of the likelihood that the project will:
  - Successfully build and deploy a patient-centered clinical decision support tool in a real-world healthcare setting, while incorporating AHRQ PCOR CDS resources
  - Be able to successfully complete the research within the given timeframe and funded amount, while also being generalizable to the PC CDS field

Scored Review Criteria

- **Significance**
- **Investigator(s)**
- **Innovation**
- **Approach**
- **Environment**
- An application does not need to be strong in all categories to be judged likely to have major impact. For example, a project that by its nature is not innovative may be essential to the field of PC CDS by showcasing specific user scenarios, unique perspectives, or incorporating data sources in a unique way.
- **Note:** Items in red text in the following slides align with the "must requirements."

Scored Review Criteria: Significance

- Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- How will the project increase our knowledge regarding best practices for using PC CDS in real-world settings?

Scored Review Criteria: Investigator(s)

- Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
- If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
- Does the team have specific expertise and a track record in clinical decision support, health IT, testing, implementation, and evaluation?
- Does the project have sufficient participation from patients and/or patient representatives to be considered meaningful and substantial with respect to CDS co-design, implementation, and evaluation?
- Does the PD/PI devote a minimum of 20% annual full-time effort (i.e., at least 8 hours per week) in each year of the project? For institutions/organization proposing multiple PDs/PIs, regardless of the number of PDs/PIs proposed, does each PD/PI devote a minimum of 10% annual full-time effort (i.e., at least 4 hours per week) in each year of the project?
- Are the proposed levels of effort for all key personnel appropriate for carrying out the project successfully?

Scored Review Criteria: Innovation

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

- If the research strategy intends to modify an existing clinician-focused clinical workflow to become a patient-centric or patient-facing approach, does the strategy include an evaluation component to characterize the performance of the PC CDS tool versus the previous clinician-facing workflow?

- If the proposed project plans to promote implementation of SDM, does it align with AHRQ's definition of SDM (available here: https://www.ahrq.gov/sdm/about/index.html) and include at least one validated measure of SDM in its evaluation?

Scored Review Criteria: Approach (general)

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?
- Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?
- Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

Scored Review Criteria: Approach (specific #1)

- Has the applicant used one or more products from the CDSiC, or the PCOR CDS Initiative (applicants should identify the specific product used)?
- If CDSiC products are used, has the applicant identified if any other frameworks are being used to evaluate the performance of their PC CDS (e.g., RE-AIM or other)?
- Has the applicant applied the definition of PC CDS and described the degree to which each of the 4 elements of the PC CDS definition are incorporated into the PC CDS tool (e.g. knowledge, patient data, delivery, or use)?
- Has the applicant been consistent with AHRQ's PCOR Strategic Framework by applying an equity lens to the research plan and the framework overall?

Scored Review Criteria: Approach (specific #2)

- Has the applicant applied at least 1 of the 4 elements from AHRQ's PCOR Strategic Framework?
  - *These elements include: (1) High quality safe care that is aligned with national priorities; (2) Prevention and improved care of patients with chronic conditions including multiple chronic conditions; (3) Primary care transformation; (4) Patient, family provider, and community experience of care that enhances trust in the healthcare system.*
- Has the applicant included meaningful and substantial participation from patients and/or patient representatives in the co-design, implementation, and evaluation of their research, to also be reflected in the proposed budget?
- If the applicant is developing or extending a digital tool, have they employed a mobile-friendly approach to be more accessible to a broader population (for example, a patient-facing portal, website, etc.)?

Scored Review Criteria: Environment

- Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

- Have the applicants fully described their research ecosystem?
- If the research or tool will be incorporated into an EHR system, has the applicant shown that their facility has a mature, functioning EHR system (e.g., the facility is not planning any significant system upgrade or migration)?
  - Otherwise, have they provided an alternative means to test and evaluate the selected CDS product?

Additional Review Criteria

- Data Management Plan
- Protections for human subjects
- Inclusion of priority populations
- Degree of responsiveness
- Budget and period of support

FREQUENTLY ASKED QUESTIONS

Responses to Questions Received

We will now review the questions received by Friday 7/26/2024.

While we will be unable to provide an answer to new questions during the webinar today, we will post an FAQ document on AHRQ's Notice of Funding Opportunities Page here: https://www.ahrq.gov/funding/fund-opps/index.html

If you have any new questions, please submit them in the Q+A section of the Zoom window or submit them to clinicaldecisionsupport@ahrq.hhs.gov.

Data Management Plans

Q: Can you clarify the Data Management Plan requirements?

A: Data Management Plans (DMPs) are required for all applications

- DMPs should describe what data will be generated (e.g. for evaluation activities) and how the recipient will manage, store, and disseminate data generated. Review the RFA DMP section and the "AHRQ Data Management Plan Policy" for additional details.

- DMPs do not count toward page limits.

Letters of Support Question

Q: Are letters of support required from all senior/key personnel and other significant contributors?

A: Provide letters of support from partnering organizations or clinicians, where possible, including IT site personnel who would support implementation of your PC CDS concept.

- The letters' text should demonstrate their specific commitment and summarize any agreements in place to support the proposed project.

Budget Caps/Limits

Q: May we request an exception to the budget limits in the RFA?

A: No. AHRQ will not consider requests above the funding limits described in the RFA ($500,000 total costs in any given year and $1,000,000 for the entire project period).

- Please note that budget limits are for **total costs** (direct + indirect).

Q&A – AHRQ Collaboration

Q: Our research team has not yet collaborated with the AHRQ CDS Initiative and does not have prior experience with the tools or resources. Will that make us less competitive in the application process?

A: All applications will first be reviewed to see if each meets all administrative criteria. If accepted, those applications will continue to review by the study section and evaluated fairly in the areas of Significance, Investigators, Innovation, Approach and Environment. While the RFA does require use of a PCOR CDS resource/tool, there is no requirement that an applicant must have interacted with AHRQ previously or been part of a past project.

Q&A - Partnerships

Q: As we have only recently had access to the NOFO, we have not yet figured out exactly who we can partner with to support local IT staff at our partner clinic locations in using AHRQ tools (e.g., the CDS Authoring Tool) to create interoperable platforms and applications for EHR integration. Do you have suggestions for how we could identify potential partners, in a relatively short time frame,who might be interested in working with us on this?

A: There are multiple resources for finding potential partners. Those interested in partnering with community health centers, for example, may wish to visit HRSA's Health Center Controlled Networks webpage (https://bphc.hrsa.gov/technical-assistance/strategic-partnerships/health-center-controlled-networks). You may also want to look through our posted CDSiC products for any topics that are relevant to your proposed research and review the list of workgroup members as a potential resource. For example, in this CDSiC product addressing PC CDS workflows and lifeflows (here: https://cdsic.ahrq.gov/cdsic/workflow-lifeflow) workgroup members listed on page ii may be a resource. Additionally, CDSiC members and stakeholders listed here may also point out some additional resources.

Q&A – Informal Feedback

Q: We are mindful of keeping the project feasible given the short timeframe (2 years). Can we share with you a brief abstract or description of our preliminary aims?

A: We'd welcome the opportunity to provide non-binding, informal feedback on your concept to advise on its appropriateness for this particular RFA. However, we cannot provide feedback on the quality of approach or other aspects that are the purview of AHRQ's peer review study sections. Feel free to send us a 1 pager with your aims, background and high-level approach to clincialdecisionsupport@ahrq.hhs.gov.

Q&A – Additional Feedback

Q: Can we set up a time with you to discuss specific questions?

A: Please send your questions in writing so that we can address appropriately. This also helps us ensure consistency in our answers, as we respond to many inquiries. For questions that we receive repeatedly, we plan to add to the list of FAQs that will be posted on AHRQ's Notice of Funding Opportunities webpage. Please visit this page frequently for any updates. We may have already addressed your question.

Q&A – Potential Conflicts

Q: If a current paid member of the CDSiC team is asked to partner with another group (unaffiliated with CDSiC) can they apply? How would this change if they have a prominent role on CDSiC for e.g., workgroup co-lead?

A: There is no restriction in participating in multiple research efforts supported by AHRQ. However, the key question is whether there is clear scientific overlap when comparing aims and project objectives. For example, if a CDSiC steering committee member is working on a new product being developed by the CDSiC in that current year (perhaps in looking at patient-clinician workflows), but wishes to submit an application to the RFA that leverages a product the CDSiC created in a prior year around artificial intelligence used to develop a patient-centered lung cancer screening tool, these activities are most likely distinct and separate and having a defined role in the CDSiC would not preclude him or her from applying.

Likewise, if that same person was asked to partner with another group, being listed as a Co-investigator with dedicated hours listed on the application budget would help clarify that the two efforts are separate.

Q&A - Timeline

Q: Will there be another opportunity to submit to this funding announcement in the future?

A: This is a one-time funding opportunity. Please refer to all applicable deadlines.

Final Comments

- Important Due Dates:
  - Letter of Intent: **August 12, 2024** (we encourage you to submit one if you are considering applying)
  - Application Submission: **September 12, 2024, 5pm local time of applicant organization**

- Please email additional questions:
  - Scientific/research questions: clinicaldecisionsupport@ahrq.hhs.gov
  - Peer review questions: DSR@ahrq.hhs.gov
  - Financial/grants management questions: Janene.Dyson@ahrq.hhs.gov

- This presentation will be posted on the AHRQ website at Notice of Funding Opportunities | Agency for Healthcare Research and Quality (ahrq.gov)
  - An FAQ document will also be posted and updated.

- Refer to the RFA as the final source of guidance

THANK YOU!

CLINICALDECISIONSUPPORT@AHRQ.HHS.GOV