

National Center for Emerging and Zoonotic Infectious Diseases Division of Healthcare Quality Promotion

Modeling Infectious Diseases in Healthcare (MInD Healthcare) to Improve Pathogen Prevention and Healthcare Delivery

Opportunity number: CDC-RFA-CK-25-0018

Contents

	Before you begin	3
@	Step 1: Review the Opportunity	4
	Basic information	<u>5</u>
	Eligibility	Z
	Program description	8
\odot	Step 2: Get Ready to Apply	40
	Get registered	<u>41</u>
	Step 3: Prepare Your Application	<u>42</u>
	Application contents and format	<u>43</u>
Q	Step 4: Learn about Review and Award	49
	Application review	<u>50</u>
	Award notices	<u>58</u>
(Step 5: Submit Your Application	<u>59</u>
	Application submission and deadlines	<u>60</u>
	Application checklist	<u>62</u>
Ŀ	Step 6: Learn What Happens After Award	<u>63</u>
	Post-award requirements and administration	<u>64</u>
<u>(8)</u>	Contacts and Support	<u>69</u>
	Appendix: HAI Modeling Publications	71

Contents 2



Before you begin

If you believe you are a good candidate for this funding opportunity, secure your <u>SAM.gov</u> and <u>Grants.gov</u> registrations now. If you are already registered, make sure your registrations are active and up-to-date.

SAM.gov registration (this can take several weeks)

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier (UEI).

See Step 2: Get Ready to Apply

Grants.gov registration (this can take several days)

You must have an active Grants.gov registration. Doing so requires a Login.gov registration as well.

See Step 2: Get Ready to Apply

Apply by the application due date

Applications are due by 11:59 p.m. Eastern Time on April 18, 2025.



To help you find what you need, this NOFO uses internal links. In Adobe Reader, you can go back to where you were by pressing Alt + Left Arrow (Windows) or Command + Left Arrow (Mac) on your keyboard.

Before you begin 3



Step 1: Review the Opportunity

In this step

Basic information	5
Eligibility	7
Program description	8

Basic information

Centers for Disease Control and Prevention (CDC)

National Center for Emerging and Zoonotic Infectious Diseases

Division of Healthcare Quality Promotion

Supporting and providing workforce development opportunities centered on new models to understand how antimicrobial resistant pathogens spread.

Summary

The purpose of this Notice of Funding Opportunity (NOFO) is to support development of innovative and applied mathematical models and computational tools for:

- Modeling the spread of pathogens in healthcare settings, for example, healthcare-associated infections (HAIs) and antimicrobial resistant organisms (AROs).
- Predicting outbreaks of HAI pathogens and trends in the burden of antimicrobial resistant and susceptible HAIs.
- Assessing the effectiveness of intervention strategies.

This NOFO will increase training and workforce development opportunities about applied public health modeling, including collaboration with public health partners. Models developed by HAI and ARO leaders within the Modeling Infectious Diseases in Healthcare (MInD Healthcare) network could help public health partners make informed decisions and optimize evidence-based prevention strategies to respond to evolving public health needs and emergencies in healthcare settings.



Have questions?
See Contacts and
Support.

Key facts

Opportunity name:
Modeling Infectious
Diseases in Healthcare
(MInD Healthcare) to
Improve Pathogen
Prevention and
Healthcare Delivery

Opportunity number: CDC-RFA-CK-25-0018

Federal assistance listing: 93.084

Key dates

Application deadline: April 18, 2025

Optional letter of intent deadline: February 28, 2025

Expected award date: August 16, 2025

Expected start date: September 1, 2025

Funding details

Type: Cooperative Agreement

Expected total program funding over the performance period: \$16,500,000

to \$19,500,000

Expected total program funding per budget period: \$3,300,000 to

\$3,900,000

Expected awards: 4 to 6

Funding range per applicant per budget period: \$550,000 to \$650,000

Expected average award amount per budget period: \$550,000 to \$650,000

We plan to award projects for five 12-month budget periods, for a five-year period of performance.

The number of awards is subject to available funds and program priorities.

Funding strategy

This NOFO will fund recipients with the necessary capabilities, including subject matter expertise; administrative infrastructure; regional, state, and local partnerships; and management capabilities to make substantial contributions to the activities and outcomes of the logic model. You will be required to respond to the two mandatory strategies outlined in this NOFO.

You must address all of the strategies in the Project Abstract Summary, Project Narrative, Work Plan, and Budget Narrative as described in this NOFO.

You can propose activities that are complementary to, but must not be duplicative of, work funded through any other mechanism or source during the period of performance.

We may deem any strategy that is not funded at the time of a new award "Approved but Unfunded (ABU)." We cannot guarantee funding for all strategies in a budget period. ABU components are subject to availability of funds.

If funded, continuation funds will be based on the availability of funds and agency priorities.

Statutory authority

Public Health Service Act, Section 317(k)(2), [42 USC 247b(k)(2)], as amended.

Eligibility

Who can apply

Eligible applicants

Only these types or organizations may apply:

- State governments
- · County governments
- · City or township governments
- Special district governments
- Public and state-controlled institutions of higher education
- Native American tribal governments (Federally recognized)
- Native American tribal organizations, other than federally recognized tribal governments
- Nonprofits having a 501(c)(3) status, other than institutions of higher education
- · Private institutions of higher education

Other required qualifying factors

Applicant organizations that request funding above the ceiling amount listed in the <u>funding details</u> for this NOFO will be considered non-responsive and will not be passed along for further review.

Cost sharing and matching funds

This program has no cost-sharing requirement or matching funds requirement. If you choose to include cost-sharing funds as a contribution to the award, we won't consider it during review of your application. If you receive an award, voluntary cost-sharing funds will be a requirement of your award and you will need to report on them.

Program description

Background

Overview

Each year, healthcare-associated infections (HAIs) lead to substantial morbidity and mortality. Antimicrobial resistant (AR) pathogens within and outside of healthcare settings, including strains that are resistant to antibiotics used as treatments of last resort, are becoming a significant public health threat. Better understanding of the dynamics of pathogen transmission, within and between U.S. healthcare facilities and in the community, is crucial to informed decision-making and implementation of optimal evidence-based prevention strategies. Early in the coronavirus disease 2019 (COVID-19) pandemic, the importance of transmission of SARS-CoV-2 within nursing homes was recognized and associated with substantial morbidity and mortality.

Pathogen transmission in healthcare settings is complex, often involving multiple human actors (for example, healthcare workers, hospital patients, nursing home residents, visitors) and non-human actors (such as the environment). The most affected groups are people who experience frequent sickness and have immunodeficiencies. Studying transmission processes while accounting for health status of populations can present challenges. Some populations are also placed at an increased risk for experiencing infection, severe illness, and death from pathogens in healthcare settings.

Moreover, a greater understanding of how policies, systems, and environments may influence transmission processes and how intervention effectiveness can be supported across different healthcare settings is needed. Limited resources preclude testing many intervention combinations across all healthcare settings (for example, acute care hospitals, long-term acute care hospitals, nursing homes) or evaluating which combinations are most effective in each setting.

Modeling the transmission of healthcare-associated or antimicrobial-resistant pathogens creates a virtual laboratory to identify and evaluate drivers of disease or pathogen spread and estimate the relative benefits of multiple prevention strategies in a timely and cost-effective manner. Epidemiological modeling provides insights into how HAI pathogens spread through healthcare settings and the community geospatially, temporally, and through patient transfer and social networks.

Modeling can enable a better understanding of the dynamics of pathogen spread and identify which interventions can maximize prevention and control. The latter includes pathogen-specific response strategies and intervention bundles which could be effective across a range of organisms. Epidemiologic modeling can enhance the understanding of findings from previous epidemiologic trials, and aid in the design of future epidemiologic trials. Individual and social behavior contributes greatly to the dynamics of infectious disease emergence and spread, and to public health policy compliance. Modeling can help assess the potential impact of behavioral interventions in different healthcare settings.

This Notice of Funding Opportunity (NOFO) aims to fund innovative and applied transmission modeling activities to expand knowledge and to develop and apply computational tools and mathematical methods to model the spread of healthcare-associated or antimicrobial-resistant pathogens in healthcare and community settings. This includes creating a network of multidisciplinary scientists and public health partners who will conduct computational, statistical, and mathematical work to improve the ability to prepare for, detect, control, and prevent antimicrobial resistant HAI pathogens in the United States. This network will be called the Modeling Infectious Diseases in Healthcare Network (MInD Healthcare Network) and will contribute to generalizable scientific knowledge through dissemination (for example, pre-prints, peer-reviewed studies, scientific presentations) and collaboration between mathematical modelers and public health partners.

Related work

This NOFO builds on work from three prior NOFOs: <u>CK17-001</u>, <u>CK20-003</u>, <u>CK22-008</u>.

- Research Gaps in Patient and Healthcare Personnel Safety
- Biggest Threats and Data: 2019 Antibiotic Resistance Threats Report (CDC)
- National Strategy for Combating Antibiotic Resistant Bacteria
- U.S. Health and Human Services, <u>National Action Plan to Prevent</u> Healthcare-Associated Infections: Roadmap to Elimination

Go to our abbreviated list of HAI modeling publications.

Purpose

For the purposes of this NOFO, "transmission modeling" is defined as statistical, computational, and mathematical methods employed to study the spread of healthcare-associated or antimicrobial-resistant pathogens that account for transmission from infectious to susceptible individuals.

Examples of transmission modeling include but are not limited to computational and mathematical methods to simulate the spread of infectious diseases (for example, compartmental models, agent-based models, network models, machine learning techniques) and statistical methods to quantify pathogen transmissibility (for example, estimate reproduction numbers, describe contacts between people relevant to transmission, conduct phylodynamic analyses).

To appropriately use modeling results, decision-makers must understand the limitations of the data and methods used, the assumptions employed, and how these issues affect the results (through complete model specification of compartmental models or use of the MInD-Healthcare Framework for describing agent-based or individual-based models).

Consequently, critical steps in the modeling process include uncertainty analyses, sensitivity analyses, and model validation, and their clear communication. Such analyses are especially important when there is little or no data to support specific assumptions or parameters.

"Uncertainty analyses" summarize the range of possible outcomes (for example, numbers of cases averted) due to imperfect knowledge about the true model structure (such as natural history of disease, demographics

relevant to transmission and disease, risk factors) and parameter values corresponding to the real world. "Sensitivity analyses" quantify which parameters or aspects of the model structure most influence a model's outcomes.

By identifying influential parameters and structural assumptions, models can be used to support development of research priorities for empiric data collection, thereby improving the value of future modeling analyses. "Model validation" compares model outputs to data not used in the construction of the model to help ensure that the model performs as expected. "Stochastic process" indexes a family of random variables against some other variable or a set of variables.

If funded, you will use existing or simulated datasets to conduct analyses and build computational models relevant to the MInD Healthcare Network goals. Award funding may be used for generating simulations. Any anticipated need for collecting primary data to directly inform model calibration or validation throughout the 5-year period of performance should be outlined in your initial application and should not exceed 25% of the proposed annual budget. Your application should focus on diverse transmission settings relevant to the United States.

Approach

Overview

The following logic model includes the strategies and activities allowed under this NOFO. It also includes the program's expected outcomes. The asterisked outcomes are those we expect you to achieve during the five-year period of performance.

Outcomes are the results that you intend to achieve and usually show the intended direction of change, such as increase or decrease.

Not all outcomes apply to all strategies. The table shows how they apply. You will use these outcomes as a guide for developing performance measures.

Program logic model

The logic model shows the strategies and activities of the program along with the outcomes we expect over time. We will require you to report on the asterisked (*) outcomes as follows.

Table: Strategies and outcomes

Strategies and activities	Short-term outcomes	Intermediate outcomes	Long-term outcomes	
Strategy 1. Conduct modeling activities focused on at least three of the thematic areas incorporating at least two healthcareassociated or antimicrobial resistant pathogens.	 Identification of high priority applied public health activities (for example, thematic areas focused on outbreak response, simulations of epidemiologic studies, surveillance), and relevant research questions.* Identification of influential modeling parameters (for example, determinants of transmission) and assumptions to develop priorities for future data collection.* Determination of groups of people or healthcare settings that have a role in transmission, and/or to whom 	 Improved understanding of the determinants of pathogen transmission and HAI risk, and how this can inform HAI prevention, control, and treatment.* Increased dissemination of findings from modeling activities to inform development of guidance for infection prevention and control, particularly in antimicrobial resistant infections.* Increased availability of and access to modeling code, tools, and resources on commonly available and preferably non-proprietary 	 Reduced morbidity, mortality, and healthcare costs associated with HAI/AR pathogens because of modeling-informed improvements in patient safety. Increased dissemination, citation, translation, and integration of modeling evidence in consensus, evidence-based guidelines or policies for HAI/AR prevention and control. Increased knowledge and prevention gains resulting from this program to reduce the morbidity, mortality, and costs associated with HAI pathogens. 	

Strategies and activities	Short-term outcomes	Intermediate outcomes	Long-term outcomes
	interventions should be prioritized to effectively reduce risk of HAIs.* • Identification of data needs to improve the applicability of modeling studies for improving patient safety practices in healthcare settings.* • Improved epidemiologic study design and application driven by novel modeling methodologies to answer high- priority questions related to transmission, risk factors, and other disease-related topics. • Innovative analytic approaches and translational research to inform HAI and antimicrobial resistance prevention, control, and treatment.* • Meaningful collaboration with academic,	platforms (for example, GitHub), consistent with the federal government source code policy.* • Improved design of surveillance systems and interpretation of surveillance data. • Documentation of lessons learned from failures of innovative analytic approaches and translational research.* • Effective working relationships with state, tribal, local, or territorial (STLT), federal, or international public health organizations, healthcare epidemiologists, and clinical partners to identify modeling topics, strategies, and products that address public health problems, and improve public health problems, and improve public health proton health.	 Improved understanding of the risk factors and mechanisms for transmission of HAI pathogens. Improved prioritization and delivery of specific interventions that are most effective in combating HAIs and/or antimicrobial resistant HAIs.

Strategies and activities	Short-term outcomes	Intermediate outcomes	Long-term outcomes
	governmental, and healthcare practice partners to identify modeling topics, strategies, and products to address ongoing public health needs.		
Strategy 2. Provide training and workforce development opportunities centered on public health modeling, including collaboration and embedding with public health partners.	 Recruitment, development, and retention of graduate student (master's and predoctoral) and postdoctoral public health modelers.* Demonstrated capacity and willingness to develop and maintain continuing collaborations with STLT public health partners and within healthcare settings.* 	 Increased knowledge among early-career modelers of infection prevention and control, particularly in antimicrobial resistant infections. Increased number of early-career modelers with expanded knowledge and capability to develop and apply computational tools and mathematical methods modeling the spread of pathogens in healthcare settings to fill critical gaps in workforce capacity and infrastructure.* Increased collaborations 	 Improved knowledge of public health modeling of HAIs, and antimicrobial resistance within the scientific and public health communities. Sustained HAI and antimicrobial resistance modeling capacity for responding to routine and emerging public health threats.

Strategies and Short-term outcomes activities		Intermediate outcomes	Long-term outcomes
		between professional mathematical modelers across federal and STLT government- funded public health programs, as well as with scientists focused on translational research.* Increased collaborations between professional modelers and academic partners focused on collaborative, translational research that leads to the prevention of HAIs and other adverse health outcomes.	

^{*} Indicates outcomes you are required to report on.

Strategies and activities

This section elaborates on the strategies and activities described in the logic model and provides details on how you are expected to implement the NOFO.

Proposed activities will be required to address the two strategies outlined within this NOFO.

- Strategy 1: You should use the following lists of thematic areas and pathogens of interest to construct your proposed workplans of non-research and research activities. Full workplans should include at least three or more of the following outlined thematic areas and at least two or more of the following identified pathogens. You should include a summary table highlighting selected thematic area(s) and pathogens(s) for each proposed activity.
- Strategy 2: Clearly identify how you will incorporate workforce development and training activities for junior and early-career modeling professionals throughout proposed non-research and research activities in Strategy 1. For this NOFO, junior and early-career modeling professionals include graduate students (master's and predoctoral) and postdoctoral researchers.

Strategy 1: HAI modeling activities

Strategy 1 objectives are to develop and/or apply computational, statistical, and/or mathematical transmission modeling methods focused on **three or more of the thematic areas** to improve the understanding of major determinants of transmission and/or prevention of **two or more healthcare-associated or antimicrobial-resistant pathogens**.

The following lists are organized alphabetically and do not reflect any specific ranking or importance.

Choose **two or more** pathogens with substantial burden and/or clinical significance. This includes, but is not limited to:

- Candida auris: An emerging fungus first identified in 2009 in Japan that presents a serious global health threat. C. auris often does not respond to commonly used antifungal drugs, making infections difficult to treat. C. auris clinical cases have steadily increased since 2015, growing by 60% in 2020 compared to 2019.
- *Clostridioides difficile*: Responsible for almost half a million infections and estimated to be associated with approximately 12,800 deaths in the United States annually.

- Enterobacterales: Enterobacterales with notable resistance mechanisms, such as extended-spectrum beta-lactamase (ESBL)-producing-Enterobacterales and carbapenem-resistant Enterobacterales (CRE), are of special concern because they can be challenging to treat.
- Nontuberculous mycobacteria (NTM): Mycobacteria other than *M. tuberculosis* complex (the cause of tuberculosis), *M. leprae* complex (the cause of leprosy), and *M. ulcerans* (the cause of Buruli ulcers); the rest of the species are referred to as NTM. Healthcare-associated NTM infections and outbreaks can occur when environmental and infection control factors permit susceptible hosts to be exposed to NTM in the healthcare environment, such as a facility's water system.
- **Resistant** *Acinetobacter* **species:** Outbreaks of *Acinetobacter* infections typically occur in intensive care units and healthcare settings housing very ill patients. *Acinetobacter* infections rarely occur outside of healthcare settings. More than 60% of *Acinetobacter* infections are resistant to at least three classes of antibiotics.
- **Resistant** *Pseudomonas aeruginosa*: Infections with *P. aeruginosa* are caused by strains of bacteria found widely in the environment.
- Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2):
 Responsible for >6,800,000 hospitalizations and >1,180,000 deaths in the
 United States as of March 2024. It has been associated with substantial
 morbidity and mortality in long-term care settings. Activities and analyses
 focused primarily on community-onset SARS-CoV-2 are not sufficient.
- Staphylococcus aureus: S. aureus, including strains with notable resistance mechanisms such as methicillin-resistant S. aureus (MRSA), vancomycin-intermediate S. aureus (VISA), and vancomycin-resistant S. aureus (VRSA), are of special concern because they can be challenging to treat.

Choose **three or more** of the following thematic areas for HAI modeling activities. Clearly indicate selections in the application using the following headings/embedded topics:

Antimicrobial Resistance

Each year in the United States, at least 2.8 million people become infected with bacteria that are resistant to antibiotics. Such cases can cause even greater concern than antimicrobial susceptible infections because effective treatment may be delayed, leading to increased morbidity, mortality, and economic costs. Modeling may contribute to better understanding:

 The evolution, sources, and spread of resistance in microbial populations.

- The dynamics of pathogen spread at the hospital, public health system, and regional levels.
- The patterns of antimicrobial use that have the largest impact on the dissemination of antimicrobial resistant strains.
- The interplay between susceptible and resistant strains.

Modeling can also help evaluate evidence regarding differences in transmission patterns of resistant and susceptible strains, and the effectiveness of interventions to reduce the incidence of antimicrobial resistant infections. This includes: antimicrobial stewardship, rapid testing to identify pathogens and their antimicrobial susceptibility, screening to identify carriers, isolating carriers and/or infected persons, hand hygiene, barrier precautions, vaccination, interventions to reduce the load of organisms colonizing host anatomic sites, such as the skin and gastrointestinal tract (known as "pathogen burden reduction"), and other interventions.

Economic Modeling

Understanding potential changes in disease dynamics, with prevention strategies developed under realistic economic constraints, is vital for designing feasible prevention strategies. Activities may include:

- Estimating the costs and epidemiologic benefits of pathogen-specific or more general response strategies and intervention bundles, which can contribute to decision-making about implementation of prevention strategies.
- Modeling the development and implementation of incentives and penalties from both private and public healthcare payers, which can also provide important policy insights.
- Assessing the burden and cost of intervention strategies and incentive structures, which can aid in their design and implementation. For example:
 - Adverse outcomes related to inappropriate outpatient antibiotic use and the potential impact of improving antibiotic use, which may be useful for strengthening the case for antibiotic stewardship in ambulatory healthcare settings, and
 - Economic analyses for different use cases for transmission-based precautions.

Genomics

Genetic sequences can provide highly detailed information on pathogen relatedness, which can inform transmission inferences when combined with traditional epidemiologic data (for example, demographics, common exposures, dates, locations of patients sampled, healthcare environment sampling, wastewater sampling). Combining these data sources can improve characterization of the spread of pathogens across timescales and multiple geographic levels (for example, within hospitals, across state and other borders). This information can increase our understanding of disease dynamics, including:

- How patient and healthcare worker movement patterns affect disease transmission.
- Patient and environmental factors that affect the risk of transmitting or acquiring HAI and related pathogens.
- The extent of transmission across settings (for example, short-term acute care hospitals, long-term acute care hospitals, nursing homes, wider community) which may not accurately reflect where disease diagnoses occur.
- The role of endogenous versus exogenous flora in healthcare-associated infections and colonization.

Additionally, this information can inform:

- Defining cutoffs for using sequencing analyses to determine which cases are part of an outbreak and are likely associated with a particular transmission pathway.
- Where interventions should be prioritized to interrupt transmission.
- The evolution and emergence of strains of interest (for example, antimicrobial resistant strains, hypervirulent strains), including how such information can be used to better understand and reduce HAI pathogen transmission.
- The fraction of total pathogen transmission that occurs from asymptomatically colonized versus sick individuals.
- The amount of transmission that occurs due to long-lasting environmental contamination (for example, hospital transmission that occurs after an infectious patient has been discharged due to contamination of rooms, sinks, or equipment).
- Calculation of parameters useful for simulations (for example, generation times, serial intervals, reproduction numbers). Read about sequence data from CDC surveillance systems and outbreak investigations.

Healthcare Systems Resilience

Healthcare systems resilience is the cyclical ability of healthcare workers, organizations, or systems to prepare for and prevent expected and unexpected events, absorb and adapt to maintain structure and function during an event, and to recover and review from crises, shocks, or stressors.

Long-term Care Facilities

It is estimated that one to three million serious infections occur every year in nursing homes, skilled nursing facilities, and assisted living facilities. Recent data suggest that prevalence of AR pathogen colonization is high in these settings, and that transmission in such facilities may play an important role in amplifying and sustaining spread of multidrug-resistant organisms (MDROs).

This area focuses on understanding the transmission dynamics within facilities across the post-acute care spectrum, including in long-term acute care hospitals and long-term care facilities (for example, skilled nursing facilities, assisted living facilities, rehabilitation centers). Of particular interest is the role of high-acuity skilled nursing facilities that provide ventilator services in facilitating spread of MDROs, and the role of nursing homes in broader MDRO transmission dynamics across regions.

One Health

Although this announcement focuses on healthcare-associated human disease, animals can act as reservoirs, hosts, and vectors of infectious agents for humans. For example, animals could serve as a source of novel strains of antibiotic-resistant bacteria and other pathogens that often cause HAIs.

Studies of animal populations should focus on issues or modeling approaches directly relevant to the colonization and/or infection of people in the communities surrounding healthcare facilities and those within healthcare facilities. Examples of relevant modeling activities include analyses of genetic data to assess the role of transmission from animals to humans in the emergence of novel strains of HAI pathogens that spread widely among humans.

Outbreak Response

Correctly identifying and characterizing an outbreak is a critical step to public health response. The speed and accuracy of a response (for example, provision of antimicrobials, contact tracing, isolation) may determine whether an outbreak will be contained.

Technological advances in disease detection will continue to provide considerable data, and statistical and modeling methods are needed to

search for, and characterize, signals that reliably identify outbreaks in a timely manner in the presence of highly variable background information. These issues are relevant at many levels of organization, from individual hospitals, to communities, metropolitan areas, and countries.

Additionally, modeling can help refine approaches for limiting the spread of new or rare forms of antibiotic resistance by detecting threats early and with sufficient specificity (for example, regional prevention strategies).

Simulations of Epidemiologic Studies

Healthcare-associated and antimicrobial-resistant pathogens are difficult to study using standard epidemiologic methods. For example, colonization often does not lead to clinical symptoms and therefore is not captured in electronic health records or standard surveillance systems, making it difficult to identify risk factors for transmission or acquisition of HAI pathogens and to design effective public health intervention strategies to reduce their burden.

There can also be strong confounding (for example, case-fatality rates can be biased because very ill people are susceptible to acquiring an HAI pathogen and already have an elevated risk of death) and selection bias (for example, healthier people are discharged from the hospital more quickly than very ill people, thereby reducing their risk of acquiring an HAI pathogen and potentially creating informative censoring; health status could also affect the duration of colonization and/or the risk of progressing to disease; durations of colonization can be both left-censored and right censored).

Simulations can investigate alternative ways to design data collection and/or conduct analyses with goals that include obtaining more reliable estimates of the following:

- Risk factors for colonization and/or infection.
- Understanding the natural history of HAIs, including:
 - Case-fatality rates
 - Incubation periods
 - Generation times
 - Asymptomatically colonized individuals
 - Symptomatic individuals
- Effectiveness of individual-level, facility-level and/or regional interventions.
- Estimating unintended consequences of intervention strategies.
- Attributable proportion of total transmission due to environmental contamination.

- Healthcare worker interactions.
- Direct patient-to-patient contact.
- The ability to identify the appropriate model structure for a pathogen's transmission and accurately estimate relevant model parameter values.

Surveillance

We can improve the effectiveness of public health interventions if we have an accurate understanding of the overall incidence and burden of disease, groups at high risk of infection, primary modes of transmission, and settings in which transmission commonly occurs.

Burden of disease estimates also help in setting public health priorities and gauging progress in the control of nosocomial pathogens. Consequently, accurate and efficient surveillance systems are crucial to combating the spread of HAI pathogens and AR pathogens.

Modeling can help identify efficient strategies for designing or informing public health surveillance and estimating the incidence or prevalence of carriage and the disease burden of established pathogens. The early identification and accurate threat assessment of emerging nosocomial infections, including their transmissibility, case fatality rates, average numbers of transmissions and infections that occur for each clinical case identified, is important.

Transmission Dynamics

Pathogens that cause HAIs, and AR pathogens in particular, can be acquired anywhere healthcare is delivered, such as nursing homes (see <u>Thematic Area: Long-term care facilities</u>) and outpatient settings (for example, clinics, ambulatory surgical centers, end-stage renal disease facilities). Patients may have interactions with other patients, healthcare workers, and the environment that could result in transmission of infectious diseases.

Additionally, AR pathogens may circulate in the community and HAIs may be introduced into the community once a patient leaves the healthcare setting, which complicates prioritizing interventions to reduce pathogen burden. Studying where infection onset occurs may not be the best way to understand where transmission is occurring; there are often long delays between acquisition of a pathogen and detection of colonization or infection, and patients may have accessed healthcare at multiple locations during this period.

Application of infectious disease modeling within and among healthcare facilities and the surrounding community focusing on transmission dynamics

and pathogen burden reduction interventions can contribute to understanding how the movement of healthcare workers and patients, their interactions with the healthcare environment, and their interactions with the surrounding community affect HAI pathogen transmission dynamics and how to most effectively interrupt transmission.

Such modeling activities should provide actionable information to help public health decision-making at the levels of federal, state, or local health departments and within individual facilities.

Strategy 2: Training and workforce development opportunities

The purpose of Strategy 2 is to provide training and workforce development opportunities centered on public health modeling and including collaboration and embedding with public health partners.

This is intended to increase the number of junior and early-career modeling professionals who are trained and experienced in modeling transmission of pathogens in healthcare settings at the local, state, and national levels of applied public health.

- Proposed activities should support the training and professional development of graduate students (master's and predoctoral) and postdoctoral researchers in modeling the spread of pathogens in healthcare settings.
- Your application should include plans for internships or collaborations for early career modelers in at least one of the following settings of applied mathematical modeling: state, tribal, local, territorial (STLT), federal, international public health institutions, hospitals, and long-term care facilities.

Outcomes

This section includes outcomes you are expected to report progress on and achieve within the performance period.

Strategy 1

The anticipated outcomes of the proposed projects for Strategy 1 include the following:

• Identification of high priority applied public health activities (for example, thematic areas focused on outbreak response, simulations of epidemiologic studies, surveillance), and relevant research questions.

- Identification of influential modeling parameters (for example, determinants of transmission) and assumptions to develop priorities for future data collection.
- Determination of groups of people or healthcare settings that have a role in transmission, and/or to whom interventions should be prioritized to effectively reduce risk of HAIs.*
- Identification of data needs to improve the applicability of modeling studies to improving patient safety practices in healthcare settings.
- Innovative analytic approaches and translational research to inform HAI and antimicrobial resistance prevention, control, and treatment.*
- Improved understanding of the determinants of pathogen transmission and HAI risk, and how this can inform HAI prevention, control, and treatment.*
- Increased dissemination of findings from modeling activities to inform development of guidance for infection prevention and control, particularly in antimicrobial resistant infections.*
- Increased availability of and access to modeling code, tools, and resources on commonly available and preferably non-proprietary platforms (for example, GitHub), consistent with the <u>federal government</u> <u>source code policy</u>.*
- Documentation of lessons learned from failures of innovative analytic approaches and translational research.*

Strategy 2

The anticipated outcomes of the proposed projects for Strategy 2 include the following:

- Recruitment, development, and retention of graduate student (master's and predoctoral) and postdoctoral public health modelers.
- Demonstrated capacity and willingness to develop and maintain continuing collaborations with STLT public health partners and within healthcare settings.*
- Increased number of early-career modelers with expanded knowledge and capability to develop and apply computational tools and mathematical methods modeling the spread of pathogens in healthcare settings to fill critical gaps in workforce capacity and infrastructure.*
- Increased collaborations between professional mathematical modelers across federal and STLT government-funded public health programs.*

Organizational capacity

Describe how you will address the organizational capacity requirements. You should have expertise in:

- The dynamics of HAIs, antimicrobial resistance, and/or methodological expertise that is relevant and scientifically appropriate for addressing the prevention of HAIs or related antimicrobial resistance.
- Infectious disease transmission modeling as evidenced by a significant track record of high-quality communication products such as peer reviewed publications.

In addition, you should have the capacity to:

- Define modeling questions, generate hypotheses, conduct literature searches, determine needed data inputs, construct models individually and in collaboration with other recipients, disseminate findings, and evaluate the impact of their work.
- Access sufficient institutional support, equipment and other physical resources, and computational resources to perform the planned transmission modeling activities.
- Work effectively with STLT, federal, or international public health organizations; healthcare epidemiology; and clinical partners to identify modeling topics, strategies, and products that are of most use to them in efforts to address public health problems and to contribute to improvements in public health practice and population health.
- Collaborate effectively with STLT, federal public health partners during public health emergencies.

You must provide attachments that support this section, including:

- Letters of support: Attach letters from relevant STLT, federal, or international public health organizations, healthcare epidemiology, and clinical partners supporting your organization's successful collaborative work. Examples of content for letters of support include:
 - Description of successful past and/or current collaborative work that includes length, type, and results.
 - Plans for future active collaboration, including suggested roles and responsibilities of partners, in the design of projects and activities to maximize the use of model findings to improve the practice of healthcare epidemiology and clinical practice.

· Resumes and job descriptions

- Personnel: Curriculum vitae for key personnel should be provided in a file named "Resumes and job descriptions" and this file should be uploaded to www.grants.gov with the application. Collectively these key personnel should have clear and demonstrated experience and expertise that covers the range of proposed activities outlined within the Strategies and Activities section.
- Describe your organization's capacity to staff projects with substantial leadership effort from key personnel. You should also describe your capacity to accomplish potential tasks outlined within the <u>Collaborations</u> section.

· Organization chart

 Management: You must demonstrate sufficient project management structure and experience to achieve the project outcomes, including having appropriate policies and procedures in place. This includes program and staffing management, financial reporting systems, communication, and technological and data systems required to implement activities in an effective and expedited manner.

Collaborations

Recipients of this NOFO will be organized into a network with principal investigators from each recipient institution acting as network representatives. Network representatives will collaborate to serve in a technical advisory role to other individual investigators and/or teams, as needed. A well-developed and collaborative network is integral to the program's success but will **not** serve as an advisory committee to CDC.

Participation in the MInD Healthcare Network includes active participation in conference calls, webinars, in-person meetings (recipient meetings, special projects meetings, ad hoc meetings), site visits, and collaborative modeling exercises to facilitate multicenter collaboration and the achievement of the NOFO's aims.

You should describe the following:

- Plans, including suggested roles and responsibilities, for collaboration with healthcare systems and with public health entities, including STLT, other federal, and international public health institutions.
- Extent of previously successful, existing, and/or future plans for collaboration with the public health institutions noted.

- Plans, including suggested roles and responsibilities, for active collaboration with clinical and healthcare epidemiology experts (for example, Prevention EpiCenters Program, Emerging Infections Program Healthcare-Associated Infections-Community Interface Activity) in the design of projects and activities to maximize the likelihood that model findings will be used to improve the practice of healthcare epidemiology and clinical practice. In the event of a public health emergency, the MInD Healthcare Network may collaborate to respond by using computational, statistical, and/or mathematical transmission modeling methods.
- Previous successful collaborations among academic institutions to conduct computational, statistical, and mathematical work to improve the ability to prepare for, detect, control, and prevent the growing problem of antimicrobial resistant HAI pathogens in the United States.
- Capacity and willingness to collaborate with other selected MInD Healthcare recipients upon award.
- Plans for recipients to participate in at least one collaborative project
 with at least one other funded recipient. Evaluation plans will be tailored
 after recipients are selected and refined in yearly workplan development,
 as needed.

Data, monitoring, and evaluation

Required performance measures

Following are the draft performance measures you will need to report on after award. We will likely refine the required measures for this program. If so, we will work with you and finalize them before we require you to submit any data.

Process measures for strategies and activities

Strategy 1: Conduct HAI modeling activities focused on at least three of the thematic areas incorporating at least two healthcare-associated infection pathogens, particularly those causing antimicrobial-resistant infections.

- Develop a summary table highlighting relevant thematic area(s) and HAI pathogen(s) for each proposed activity.
- Complete <u>methodological descriptions for agent-based or individual-based models</u> developed and detailed, reproducible descriptions of other models and tools developed.

- Plan to use existing or simulated datasets, as well as real-time information, to conduct analyses and build computational models relevant to the goals of the MInD Healthcare Network.
- Completed agreements and protocols such as memoranda of understanding, data use agreements, Institutional Review Board (IRB) protocols.
- Plan to develop, disseminate, and evaluate potential impact(s) of model code, findings, and communication products for internal and/or external use.
 - Examples of communication products include publications, presentations, scientific posters, issue briefs, summaries, customized analytical tools, reports, and visualizations.
 - Example of communication products developed for internal use by MInD Healthcare funded recipients: Documentation of lessons learned from successful and unsuccessful research and nonresearch efforts to inform future activities.
 - Example of communication products developed for external use by federal, STLT, and/or international public health partners: Informing clinicians, public health officials, and/or policymakers to effectively rank and prioritize the delivery of specific interventions that are effective in combating HAIs and antimicrobial resistance and/or the development of new data collection studies that will gather data that are critical to effectively identifying the burden of disease, risk factors for transmission, and/or intervening effectively to eliminate HAIs.
- Plan to ensure active participation within the MInD Healthcare Network as outlined in the <u>Collaborations</u> section.

Strategy 2: Provide training and workforce development opportunities centered on public health modeling, including collaboration and embedding with public health partners.

- Plan for recruitment, professional development, and retention of graduate students (master's and predoctoral) and postdoctoral public health modelers.
- Plans for the principal investigator / mentor to consult with and integrate early career modelers into research projects proposed in Strategy 1, including an adequate level of effort to support early career modelers.
- Plans to engage early career modelers with a team of highly qualified, senior modelers and exposure to other relevant HAI modeling projects.

- Plan for internships or embedding of early career modelers in at least one of the following settings of applied mathematical modeling: STLT, federal, and international public health institutions.
- Proposed efforts to strengthen collaborations or networks with public health organizations (for example, health departments) and stakeholders to promote organizational HAI/infectious diseases (ID) workforce development priorities.

Outcome Measures: Short-term outcomes

- Identification of high priority applied public health activities (for example, thematic areas focused on outbreak response, simulations of epidemiologic studies, surveillance), and relevant research questions.
 - Number and description of high priority activities focused on applied public health.
- Identification of influential modeling parameters (for example, determinants of transmission) and assumptions to develop priorities for future data collection.
 - Number and description of modeling methods developed and activities conducted that improve understanding of major determinants of HAI pathogen transmission.
 - Number and descriptions of new or existing data sources identified and used to conduct modeling activities.
- Determination of groups of people or healthcare settings that have a role in transmission, and/or to whom interventions should be prioritized to effectively reduce risk of HAIs.*
 - Number and description of mathematical methods and activities conducted that focus on improving understanding of HAI prevention, transmission, control, and treatment.
- Identification of data needs to improve the applicability of modeling studies for improving patient safety practices in healthcare settings.*
 - Descriptions of identified data gaps in conducting modeling activities, including time frame, geography, variables, base population, etc.
 - Description of products and mechanisms to facilitate identification of and collaboration to address data needs unique to improving patient safety practices in healthcare settings.
- Innovative analytic approaches and translational research to inform HAI and antimicrobial resistance prevention, control, and treatment.*

- Number and description of mathematical methods and activities conducted that constitute novel modeling approaches.
- Number and descriptions of communication products and data visualizations developed to translate the novel approached into applied public health practice.
- Recruitment, development, and retention of graduate student (master's and predoctoral) and postdoctoral public health modelers.
 - Number, role, and degree-seeking program for graduate students or completed degree background for post-doctoral modelers, etc.) of early career modelers recruited to be involved in carrying out MInD Healthcare activities.
 - Number and description of professional development opportunities provided to early career modelers.
- Demonstrated capacity and willingness to develop and maintain continuing collaborations with STLT public health partners and within healthcare settings.*
 - Number and description of current and future collaborative efforts with public health partners and within healthcare settings.
 Descriptions should include suggested roles and responsibilities between collaborating partners and the applicant.
 - Completed agreements and protocols such as memoranda of understanding, data use agreements, and IRB protocols.

Outcome Measures: Intermediate outcomes

- Improved understanding of the determinants of pathogen transmission and HAI risk, and how this can inform HAI prevention, control, and treatment.*
 - Number and description of presentations, abstracts, publications, and/or other scientific dissemination avenues for describing determinants of pathogen transmission and HAI risk and informed preventions, control, and treatment strategies.
 - Development of complex models that build off, explore, and advance understanding of HAI pathogen transmission.
- Increased dissemination of findings from modeling activities to inform development of guidance for infection prevention and control, particularly in antimicrobial resistant infections.*
 - Number and descriptions of communication products and data visualizations appropriate for federal or STLT public health officials.

Descriptions should include 1) what products were used by federal or STLT public health officials and how; and 2) lessons learned from efforts to communicate model findings to decision makers; and 3) current or future plans to evaluate potential impact of findings and communication products for internal or external use.

- Number and description of completed in-person or online presentations or posters for conferences and meetings.
- Increased availability of and access to modeling code, tools, and resources on commonly available and preferably non-proprietary platforms (for example, GitHub), consistent with the <u>federal government</u> <u>source code policy</u>.
 - Number, functional description, and location of developed code, tools, and resources. Descriptions should also include potential frequency of updates and revisions and accessibility of the platforms used for dissemination of modeling code, tools, and/or resources, preferably publicly access.
 - Number and description of STLT public health partners using developed code, tools, and/or resources. Descriptions should include what/how products were used by federal or STLT public health officials and 2) current and/or future plans to evaluate potential impact(s) of model code and communication products for internal and/or external use.
 - Documentation of standard operating procedures and/or other narratives (for example, success stories, case studies, etc.) for promising practices in code/tool/data sharing.
- Documentation of lessons learned from failures of innovative analytic approaches and translational research.*
 - Documentation of "successes," "failures," and "lessons learned" from all stages of the modeling, research, and/or translational processes.
 - Recommendations for areas of improvement and encouraging innovative analytic approaches.
- Increased number of early-career modelerse with expanded knowledge and capability to develop and apply computational tools and mathematical methods modeling the spread of pathogens in healthcare settings to fill critical gaps in workforce capacity and infrastructure.*
 - Number, role, and responsibilities of early career modelers (for example, degree-seeking program for graduate students or completed degree background for post-doctoral modelers, etc.)

involved in carrying out MInD Healthcare activities for 6 months or longer.

- Documentation of early career modelers' exposure to and inclusion within collaborative MInD Healthcare Network projects with other modelers in effort to develop advanced analytic and critical decisionmaking skills.
- Increased collaborations between professional mathematical modelers across federal and STLT government-funded public health programs.*
 - Number and description of collaborative efforts with public health partners, including internships or other forms of embedding early career modelers within STLTs. Descriptions should include 1) what collaborative activities were initiated, roles and responsibilities of collaborating partners, and the status of activities (for example, initiated but not completed; ongoing; completed); 2) lessons learned from challenges faced in collaborating; 3) current and/or future plans to evaluate potential impact(s) of collaborative activities; and 4) plans to share stories of successful collaborative activities.
 - Completed agreements and protocols such as memoranda of understanding, data use agreements, and/or IRB protocols for collaborative activities.

Evaluation and performance measurement plan

You must provide an evaluation and performance measurement plan. Use the measures required under the CDC strategy.

Include the following elements.

Methods

Describe:

- How you will:
 - Collect the performance measures.
 - Respond to the evaluation questions.
 - Use evaluation findings for continuous program quality improvement.
 - Incorporate evaluation and performance measurement into planning, implementation, and reporting of project activities.

- How key program partners will participate in the evaluation and performance measurement process.
- How you will share evaluation findings with communities and stakeholders.

Data management

For all public health data you plan to collect, describe:

- The data you plan to collect and their available data sources.
- The feasibility of collecting appropriate evaluation and performance data.
- A data management plan (DMP) that includes:
 - The data you will collect or generate.
 - If there are reasons why you cannot share data collected or generated under this award with CDC. These could include legal, regulatory, policy, or technical concerns.
 - Who can access data and how you will protect it.
 - Data standards that ensure released data have documentation that describes collection methods, what the data represent, and data limitations.
 - Archival and long-term data preservation plans.
 - How you will update the DMP as new information is available over the life of the project. You will provide updates to the DMP in annual reports. For more information about CDC's policy on the DMP, see <u>Data Management and Access Requirement</u> at CDC's website.
- Other relevant data information, such as performance measures you propose.

For a definition of "public health data" and other key information, see <u>Data Management and Access</u>.

Evaluation activities

You must take on specific evaluation activities. Describe:

- The type of evaluations, such as process, outcome, or both.
- Key evaluation questions addressed by these evaluations.
- · Other information such as measures and data sources.

An initial draft of your Evaluation and Performance Measurement Plan, including the DMP, should be submitted with your application. You must submit a more detailed plan within the first six months of the award. See Reporting.

Work plan

You must provide a detailed work plan for the first budget period (12 months) and a high-level work plan for subsequent years. The work plan should address staff roles, functions, and time allocation. This should include the identification of staff providing all areas of expertise referred to under the Strategies and Activities section and their respective time allocations. In addition, you should outline the level of effort provided by key personnel on projects.

Post-award, the proposed work plan and activities may be adjusted within the scope and terms of this NOFO in collaboration with CDC to ensure compliance with applicable grant regulations and policies, to avoid duplicative work within the network and to prioritize the highest priority efforts to address the objectives of this NOFO.

Table: Sample format

Activities to be implemented	Progress or process measures From Data, Monitoring, and Evaluation section	Relevant period of performance outcomes From Outcomes section	Responsible position or party	Completion date
Strategy 1:				
1.				
2.				
3.				
Strategy 2:				
1.				
2.				
3.				

Paperwork Reduction Act

Any activities involving information collection from 10 or more individuals or organizations may require you to follow the Paperwork Reduction Act (PRA). This requires review and approval by the White House Office of Management

and Budget. For further information about CDC's requirements under PRA see <u>CDC Paperwork Reduction Act Compliance</u>. Collections include items like surveys and questionnaires.

Funding policies and limitations

General guidance

- Your budget is arranged in eight categories: salaries and wages, fringe benefits, travel, equipment, supplies, contractual, other (includes consultant costs) and indirect costs.
- You may use funds only for reasonable program purposes consistent
 with the award, its terms and conditions, and federal laws and
 regulations that apply to the award. Questions about this determination
 should be posed to the grants management specialist.
- Generally, you may not use funds to purchase furniture or equipment.
 Clearly identify and justify any such proposed spending in the budget.
- Your budget should include funding for peer-reviewed publications resulting from this cooperative agreement in compliance with the updated CDC Public Access Policy. For more information, see the Copyright Interests Provision and Public Access to CDC-Funded Publications [2024].
- Any anticipated need for primary data collection to directly inform model calibration or validation throughout the 5-year period of performance should be outlined in the initial application and should not exceed 25% of the proposed annual budget.
- Applications should focus on transmission settings relevant to the United States.

Research-Related Policies and Restrictions

Under this NOFO, we allow research activities. If you intend to conduct research activities, you must say so in your application. When you conduct research activities, you must follow all applicable laws, regulations, and policy requirements. Be sure to address the CDC research and human subjects protection requirements throughout this NOFO. See the Strategies and Activities section for more details.

 You must not include activities that overlap with simultaneously funded research under other awards. We do not allow scientific, budgetary, or percent effort overlap.

- We do not allow certain grants or recipients to use expanded authorities.
 Additionally, we may override one or more expanded authority with a
 special term or condition of the award. The Notice of Award (NoA) will let
 you know what expanded authorities you may use. We may do this by
 reference to the HHS Grants Policy Statement or through specific award
 terms and conditions. Therefore, you must review the NoA to determine
 how expanded authorities apply to you.
- We will restrict research funds involving human subjects until the
 appropriate assurances and IRB approvals are in place. After award, you
 will need to submit copies of all current local IRB approval letters and
 local IRB approved protocols (and CDC IRB approval letters, if applicable)
 to your Scientific Program Officer or Project Office to lift the restrictions.
 If multiple collaborating institutions are involved, include your single IRB
 Plan in the human subjects section of the project narrative:
 - Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114(b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the IRB of record.
 - Indicate that all engaged institutions or participating sites will agree to rely on the proposed IRB and that any institutions or sites added after award will rely on the IRB.
 - Briefly describe how you or your collaborating partners will handle communication between institutions and the IRB.
 - Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization or reliance agreement that will clarify the roles and responsibilities of the IRB and participating sites.
 - Indicate which institution or entity will maintain records of the authorization or reliance agreements and of the communication plan.
 - Do not include the authorization or reliance agreements or the communication plans documents in your application. You'll need to submit these documents after you've been approved for funding.
 We'll provide additional guidance after we make awards.
 - If you anticipate research involving human subjects but cannot describe the study at the time of application, include information about how the study will comply with the single IRB requirement prior to initiating any multi-site study in the delayed onset study justification.

- We will restrict funds relating to the conduct of activities involving vertebrate animals until the appropriate assurances and Institutional Animal Care and Use Committee (IACUC) approvals are in place. You will need to submit copies of all current local IACUC approval letters and local IACUC approved protocols to lift restrictions after you receive funding.
- Certain projects will require that you obtain review and approval of collections from the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). These projects may include those that:
 - Involve collecting information, identical record keeping, or reporting from 10 or more people.
 - Are funded by a cooperative agreement.
 - Constitute a burden of time, effort, or resources expended to collect or disclose the information.
- If your project involves life sciences research, you must follow the policy for "Dual Use Research of Concern" (DURC). If applicable, you will have several responsibilities. See the requirements at Science Safety Security, <u>Dual Use Research of Concern</u>. Non-compliance with this policy may result in:
 - Suspension, restriction, or termination of federal funding under this award.
 - Loss of future funding opportunities and of federal funds for other life sciences research at the institution.
 - Other potential penalties under applicable laws and regulations.
- You must include a Data Management Plan (DMP) in your application. See <u>CDC AR-25</u> for more information. We may impose funding restrictions if the evaluation of your application determines the Data Management Plan is incomplete and does not conform to CDC requirements.
- Per the <u>Bayh-Dole Act</u> (the <u>Patent and Trademark Law Amendments Act</u>), all businesses and nonprofits (including universities) can retain ownership of the inventions made under federally funded research.

Unallowable costs

You may not use funds for:

- Clinical care except as allowed by law.
- Pre-award costs unless CDC gives you prior written approval.
- Other than for normal and recognized executive-legislative relationships:
 - Publicity or propaganda purposes, including preparing, distributing, or using any material designed to support or defeat the enactment of legislation before any legislative body.
 - The salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or executive order proposed or pending before any legislative body.
- See <u>Anti-Lobbying Restrictions for CDC Granteess</u>.
- Primary data collection activities exceeding the allowed 25% of your annual proposed budget.

Indirect costs

Indirect costs are those for a common or joint purpose across more than one project and that cannot be easily separated by project.

There are two methods to calculate indirect costs:

Method 1 — **Approved rate.** You currently have an indirect cost rate approved by your cognizant federal agency.

Justification: Provide a summary of the rate. Enclose a copy of the current approved rate agreement in the Attachments.

Method 2 — *De minimis* rate. Per 45 CFR 75.414(f), if you have never received a negotiated indirect cost rate, you may elect to charge a *de minimis* rate. If you are awaiting approval of an indirect cost proposal, you may also use the *de minimis* rate. If you choose this method, costs included in the indirect cost pool must not be charged as direct costs.

This rate is 15% of modified total direct costs (MTDC). See <u>2 CFR 200.1</u> for the definition of MTDC. You can use this rate indefinitely.

Other indirect cost policies

- As described in 45 CFR 75.403(d), you must consistently charge items as either indirect or direct costs and may not double charge.
- Indirect costs may include the cost of collecting, managing, sharing, and preserving data.

National public health priorities and strategies

This NOFO supports the following public health priorities and strategies:

- U.S. actions and events:
 - U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria



Step 2: Get Ready to Apply

In this step

Get registered

<u>41</u>

Get registered

While you can review the requirements and get started on developing your application before your registrations are complete, you must be registered in both SAM.gov and Grants.gov to apply.

SAM.gov

You must have an active account with SAM.gov. This includes having a Unique Entity Identifier. SAM.gov registration can take several weeks. Begin that process today.

To register, go to <u>SAM.gov Entity Registration</u> and click Get Started. From the same page, you can also select the Entity Registration Checklist for the information you will need to register.

Grants.gov

You must also have an active account with <u>Grants.gov</u>. You can see step-by-step instructions at the Grants.gov <u>Quick Start Guide for Applicants</u>.

Find the application package

The application package has all the forms you need to apply. You can find it online. Go to <u>Grants Search at Grants.gov</u> and search for opportunity number CDC-RFA-CK-25-0018.

If you can't use Grants.gov to download application materials or have other technical difficulties, including issues with application submission, <u>contact</u> <u>Grants.gov</u> for assistance.

To get updates on changes to this NOFO, select **Subscribe** from the View Grant Opportunity page for this NOFO on Grants.gov.

Need help? See Contacts and Support.

Help applying

For help related to the application process and tips for preparing your application see <u>How to Apply</u> on our website.

For other questions, see Contacts and Support.

1. Review 2. Get Ready

3. Prepare

4. Learn

5. Submit



Step 3: Prepare Your Application

In this step

Application contents and format

<u>43</u>

Application contents and format

Applications include two main elements. This section includes guidance on each. Make sure you include each of the following:

Table: Application contents

Element	Submission form
Project Abstract	Use the Project Abstract Summary form.
Project Narrative	Use the Project Narrative Attachment form.
Budget Narrative Justification	Use the Budget Narrative Attachment form.
Attachments	Insert each in the Other Attachments form.
Other Required Forms	Upload using each standard form.

We will provide instructions on document formats in the following sections. If you don't provide the required documents, your application is incomplete. See <u>initial review</u> to understand how this affects your application.

Required format for project abstract, project narrative, and budget narrative

Font: Calibri

Format: PDF

Size: 12-point font

Footnotes and text in graphics may be 10-point.

Spacing: Single-spaced

Margins: 1-inch

Include page numbers

Project abstract

Page limit: 1

File name: Project Abstract Summary

Provide a self-contained summary of your proposed project, including the purpose and outcomes. Do not include any proprietary or confidential information. We use this information when we receive public information requests about funded projects.

Project narrative

Page limit: 15

File name: Project Narrative

Your project narrative must use the exact headings, subheadings, and order as follows. See <u>Merit Review Criteria</u> to understand how reviewers will evaluate your project narrative.

Background

Describe the problem you plan to address. Be specific to your population and geographic area.

See Program Description, Background.

Approach

Strategies and activities

Describe how you will implement the proposed strategies and activities to achieve performance outcomes. Explain whether they are:

- Existing evidence-based strategies
- Other strategies, with a reference to where you describe how you will evaluate them in your <u>Evaluation and Performance Measurement Plan</u>

See Program Description, Strategies and Activities.

Outcomes

Using the logic model in <u>Program Description</u>, <u>Approach</u>, identify outcomes you expect to achieve or progress on by the end of the performance period.

Evaluation and performance measurement plan

You must provide an evaluation and performance measurement plan. This plan describes how you will fulfill the requirements in <u>Program Description</u>, <u>Data</u>, <u>Evaluation</u>, and <u>Performance Measurement</u>.

Work plan

Include a work plan using the requirements in <u>Program Description</u>, <u>Work Plan</u>.

Organizational capacity

Describe how you will address the organizational capacity requirements in Program Description, Organizational Capacity.

You must provide attachments that support this section, including:

- Letters of Support
- · Resumes and Job Descriptions
- Citations of peer-reviewed publications
- Organizational Chart

Collaborations

Describe how you will collaborate with programs and organizations, either internal or external to CDC. Explain how you will address the Collaboration requirements in <u>Program Description</u>, <u>Collaborations</u>.

Budget narrative

Page limit: None

File name: Budget Narrative

The budget narrative supports the information you provide in Standard Form 424-A. See <u>Other Required Forms</u>.

HHS now uses the definitions for <u>equipment</u> and <u>supplies</u> in 2 CFR 200.1. The new definitions change the threshold for equipment to the lesser of the recipient's capitalization level or \$10,000 and the threshold for supplies to below that amount.

As you develop your budget, consider if the costs are reasonable and consistent with your project's purpose and activities. CDC will review and must approve costs prior to award.

For guidance to complete a detailed budget narrative, see <u>CDC Budget</u> <u>Preparation Guidelines</u> on the CDC Application Resources webpage. Following this guidance will also facilitate our review and approval of your budget request if we select your application for award.

The budget narrative must explain and justify the costs in your budget. Provide the basis you used to calculate costs. It must follow this format:

- · Salaries and wages
- · Fringe benefits
- · Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total direct costs (total of all items)
- Total indirect costs

See Funding Policies and Limitations for policies you must follow.

Attachments

You will upload attachments in Grants.gov using the Other Attachments Form. When adding the attachments to the form, you can upload PDF, Word, or Excel formats.

Table of contents

Provide a detailed table of contents for your entire submission that includes all the documents in the application and headings in the "Project Narrative" section. There is no page limit.

File name: Table of contents

Indirect cost agreement

If you include indirect costs in your budget using an approved rate, include a copy of your current agreement approved by your cognizant agency for indirect costs. If you use the *de minimis* rate, you do not need to submit this attachment.

File name: Indirect cost agreement

Resumes and job descriptions

For key personnel, attach resumes for positions that are filled. If a position isn't filled, attach the job description with qualifications and plans to hire.

File name: Resumes and job descriptions

Citations of peer-reviewed publications

For key personnel, attach citations of peer-reviewed publications to show evidence of technical expertise required to successfully accomplish proposed activities in the NOFO.

File name: Citations of peer-reviewed publications

Organizational chart

Provide an organizational chart that describes your structure. Include any relevant information to help understand how parts of your structure apply to your proposed project.

File name: Organizational chart

Letters of support

Attach letters from relevant STLT, federal, or international public health organizations, healthcare epidemiology, and clinical partners supporting your organization's successful collaborative work.

Examples of content for letters of support include:

- Description including length, type, and results of successful past or current collaborative work.
- Plans for future active collaboration, including suggested roles and responsibilities of partners, in the design of projects and activities to maximize the likelihood that model findings will be used to improve the practice of healthcare epidemiology and clinical practice.

File name: Letter of support (if you upload each letter separately, add the organization name)

Report on overlap

You must provide this attachment only if you have submitted a similar request for a grant, cooperative agreement, or contract to another funding source in the same fiscal year and it may result in any of the following types of overlap:

Programmatic

- · They are substantially the same project, or
- A specific objective and the project design for accomplishing it are the same or closely related

Budgetary

• You request duplicate or equivalent budget items that already are provided by another source or requested in the other submission.

Commitment

• Given all current and potential funding sources, an individual's time commitment exceeds 100 percent, which is not allowed.

We will discuss the overlap with you and resolve the issue before award.

File name: Report on overlap

Other required forms

You will need to complete some other forms. Upload the following forms at Grants.gov. You can find them in the NOFO <u>application package</u> or review them and their instructions at <u>Grants.gov Forms</u>.

Table: Required standard forms

Forms	Submission requirement
Application for Federal Assistance (SF-424)	With application
Budget Information for Non-Construction Programs (SF-424A)	With application
Disclosure of Lobbying Activities (SF-LLL)	If applicable. With the application or before award



Step 4: Learn about Review and Award

In this step

Application review 50

Award notices 58

Application review

Initial review

We review each application to make sure it meets responsiveness requirements. These are the basic requirements you must meet to move forward in the competition. We won't consider an application that:

- Is from an organization that doesn't meet eligibility criteria. See requirements in <u>Eligibility</u>.
- Is submitted after the deadline.
- Request funding above the ceiling amount listed in <u>Funding Details</u>.

We will not review any project narratives that exceeds the page limit of 15 pages.

Merit review

A panel reviews all applications that pass the initial review. The members use the following criteria.

Table: Criteria and total points

Criterion	Total number of points = 100
1. Background and approach	40 points
2. Organizational capacity	40 points
3. Evaluation and performance measurement	20 points
4. Budget	Not scored

Criteria

Background and approach (Maximum points: 40)

Ensure that responses are consistent with the Program Description requirement sections shown in the following table.

Table: Background and approach criteria

Consistent with:
Background
Strategies and activities, Work plan Approach, logic model
Strategies and activities Approach, logic model

Evaluate the extent to which the applicant describes:	Consistent with:
document lessons learned from successes and failures of innovative analytic approaches and using findings to inform public health practice. (5 points)	
Plans to incorporate workforce development and training activities for graduate students (master's and predoctoral) and postdoctoral public health modelers, including: • Incorporating early career modelers within collaborative non-research and research MInD Healthcare Network projects in Strategy 1 and connecting them with other modelers in effort	Strategies and activities Approach, logic model
to develop advanced analytic and critical decision-making skills throughout proposed activities. (4 points) Collaborative efforts with STLT public health partners, including but not limited to internships or other forms of	
 embedment of early career modelers. (4 points) Identifying professional development opportunities, including 	
presentation of findings resulting from the proposed projects at meetings and conferences. (3 points)	
Plans to share mathematical modeling approaches, assumptions, inputs, data and compare results with collaborators within the MInD Healthcare Network. (2 points)	

Organizational capacity (Maximum points: 40)

Ensure that responses are consistent with the Program Description section Organizational Capacity generally, including any subsection or required attachment shown in the following table.

Table: Organizational capacity criteria

Evaluate the extent to which the applicant:	Consistent with:
Provides evidence of technical expertise in the dynamics of HAIs, antimicrobial resistance, and/or methodological expertise that is relevant and scientifically appropriate for addressing the prevention of HAIs or related antimicrobial resistance, including evidence of prior collaborations. (10 points) • Experience could be demonstrated through citations of peerreviewed publications in addition to CVs/resumes of key personnel (for example, principal investigator or project director and other leaders, program staff, technical staff, and consultants).	Resumes and Job Descriptions
Provides evidence of relevant technical expertise and capacity to define modeling questions, generate hypotheses, conduct literature searches, determine needed data inputs, construct models individually and in collaboration with other recipients, disseminate findings, and evaluate the impact of their work. (10 points) • Experience could be demonstrated through citations of peerreviewed publications in addition to CVs/resumes of key personnel (for example, principal investigator or project director and other leaders, program staff, technical staff, and consultants).	Organizational Capacity, Resumes and Job Descriptions
Describes relevant project management, administrative expertise, and capacity of key and supporting personnel to successfully develop, implement, monitor, and evaluate a federally funded cooperative agreement. Provides an organizational chart that supports the structure and that clearly defines staff roles. (3 points)	Resumes and Job Descriptions Organization Chart
Describes sufficient access to institutional support, equipment, and computational resources to perform the planned transmission modeling activities. (1 point)	Organizational Capacity

Evaluate the extent to which the applicant:	Consistent with:
Provides evidence of past collaborations with key academic, public health, and healthcare partners to conduct computational, statistical, and mathematical work to improve the ability to prepare for, detect, control, and prevent the growing problem of HAI/AR pathogens in the United States. Descriptions of past collaborations should include length, type, and results of collaborative activities. (5 points)	Resumes and Job Descriptions Organization Chart Collaborations
Outlines plans, including suggested roles and responsibilities, for active collaboration with healthcare systems and with public health entities, including STLT, other federal, and international public health institutions to identify modeling topics, strategies, and products that are of most use to them in efforts to address public health problems and to contribute to improvements in public health practice and population health. (5 points) • Letters of support describing collaborations with public health entities where products are limited to internal audiences will be accepted.	Collaborations Letters of Support
Outlines plans, including suggested roles and responsibilities, for active collaboration with clinical and healthcare epidemiology experts (for example, Prevention EpiCenters Program, Emerging Infections Program Healthcare-Associated Infections - Community Interface, etc.) in the design of projects and activities to maximize the likelihood that model findings will be used to improve the practice of healthcare epidemiology and clinical practice. (5 points) • Letters of support from proposed clinical and healthcare epidemiology experts should be included.	Collaborations Letters of Support
Describes both capacity and willingness to collaborate with at least one other funded MInD Healthcare Network recipient in at least one collaborative project upon award. (1 point)	Collaborations

Evaluation and performance measurement (Maximum points: 20)

Ensure that responses are consistent with the Program Description's Data, Evaluation, and Performance Measurement section generally, including any subsection shown in the following table.

Table: Evaluation and performance measurement criteria

Evaluate the extent to which the applicant describes:	Consistent with:
Their ability to collect the data needed for evaluation and performance measurement. (2 points)	Methods
Clear monitoring and evaluation procedures of how they will incorporate evaluation and performance measurement into planning, implementation, and reporting of project activities. (2 points)	Methods
How they will report and use performance measurement and evaluation findings to demonstrate outcomes and for continuous program quality improvement. (2 points)	Methods
Appropriate participation in the evaluation and performance measurement planning process by key partners involved in the design of projects and activities to maximize the likelihood that model findings will be used to improve the practice of healthcare epidemiology and clinical practice. (2 points)	Methods
How they will share evaluation findings from modeling activities to inform development of guidance for infection prevention and control, particularly in antimicrobial resistant infections with focus communities and stakeholders. (5 points)	Methods
Their available data sources and feasibility of collecting appropriate evaluation and performance data. Their plan to increase availability of and access to modeling code, tools, and resources on commonly available and preferably non-proprietary platforms (for example, GitHub), consistent with the federal government source code policy. (3 points)	Data Management
A data management plan that includes data, access, standards, long-term and archiving plans, collection methods, data limitations. Includes how they will update the plan throughout an award. (2 points)	Data Management
The type of evaluations, such as process, outcome, or both and the key evaluation questions, data sources, and measures. Includes how evaluation and performance measurement will contribute to developing an evidence base for programs that lack a strong effectiveness evidence base. (2 points)	Methods

Budget (not scored)

The panel will review but not score the budget and will assess whether the budget aligns with stated objectives, planned program required, and optional strategies and related activities.

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research. Reviewers will assess if the proposed use of funds is an efficient and effective way to implement the strategies and activities and attain the period of performance outcomes.

Risk review

Before making an award, we review the risk that you will not prudently manage federal funds. We need to make sure you've handled any past federal awards well and demonstrated sound business practices. We use SAM.gov Responsibility / Qualification to check this history for all awards likely to be over \$250,000. We also check Exclusions.

You can comment on your organization's information in SAM.gov. We'll consider your comments before making a decision about your level of risk.

We may ask for additional information prior to award based on the results of the risk review.

If we find a significant risk, we may choose not to fund your application or to place specific conditions on the award.

For more details, see 45 CFR 75.205.

Selection process

We may:

- Fund application out of the rank order developed in merit review.
- Fund applications in whole or in part.
- Fund applications at a lower amount than requested.
- Decide not to allow a prime recipient to subaward if they may not be able to monitor and manage subrecipients properly.
- Choose to fund no applications under this NOFO.

Our ability to make awards depends on available appropriations.

Phase 3 Review

When making funding decisions, we consider merit review results. These are key in making decisions, but are not the only factor. We may fund applications out of rank order to address the program priorities and funding preferences listed below. We will provide justification for any decision to fund out of ranked order of scores.

We may fund out of rank order:

- To ensure a range of thematic areas, HAI pathogens, and range of
 interventions across transmission settings will be covered by recipients
 when the NOFO allows applicants to select from a menu of activities to
 implement. Funding recommendations may consider eliminating
 redundant lines of research and non-research activities in the program
 portfolio as a whole. For example, preference may be given to unique
 model structures or model elements that would ensure a variety of
 approaches across the research network when there are multiple models
 utilizing the same broad methodological approaches.
- To ensure inclusion of various research and non-research activities, including:
 - Reaching populations who are experiencing the greatest risk of HAIs, including, but not limited to, pediatrics, persons admitted to hospitals or long-term care facilities, and persons receiving care in ambulatory settings.
 - To ensure maximum geographic coverage of dataset(s) proposed, both in the U.S. and overseas, to maximize generalizability of the results. (Greatest diversity will be achieved by the selection of recipients in both the U.S. and overseas, with applications focusing on transmission settings relevant to the U.S.) Geographic coverage will be defined in the U.S. by using Census regions and divisions.

Award notices

If you are successful, we will email a Notice of Award (NoA) to your authorized official.

We will email you or write you a letter if your application is disqualified or unsuccessful.

The NoA is the only official award document. The NoA tells you about the amount of the award, important dates, and the terms and conditions you need to follow. Until you receive the NoA, you don't have permission to start work.

Once you draw down funds, you have accepted all terms and conditions of the award.

If you want to know more about NoA contents, go to <u>Understanding Your</u> Notice of Award at CDC's website.



Step 5: Submit Your Application

In this step

Application submission and deadlines 60
Application checklist 62

Application submission and deadlines

See Find the Application Package to make sure you have everything you need.

You must obtain a Unique Entity Identifier (UEI) number associated with your organization's physical location. Some organizations may have multiple UEI numbers. Use the UEI number associated with the location of the organization receiving the federal funds.

Make sure you are current with SAM.gov and UEI requirements. See <u>Get registered</u>.

You will have to maintain your registration throughout the life of any award.

Deadlines

Optional letter of intent

Due on February 28, 2025.

Application

Due on April 18, 2025 at 11:59 p.m. ET.

Grants.gov creates a date and time record when it receives the application. If you submit the same application more than once, we will accept the last ontime submission.

The grants management officer may extend an application due date based on emergency situations such as documented natural disasters or a verifiable widespread disruption of electric or mail service.

Submission methods

Grants.gov

You must submit your application through Grants.gov. See Get registered.

For instructions on how to submit in Grants.gov, see the <u>Quick Start Guide for Applicants</u>. Make sure your application passes the Grants.gov validation checks. Do not encrypt, zip, or password-protect any files.

See Contacts and Support if you need help.

Other submissions

Intergovernmental review

This NOFO is not subject to Executive Order 12372, Intergovernmental Review of Federal Programs. No action is needed.

Optional letter of intent

We ask that you let us know if you plan to apply for this opportunity. We do this to plan for the number of reviewers we will need to evaluate applications. You do not have to submit a letter of intent to apply.

Please email the notice to Nga Vuong at ypg2@cdc.gov.

In your email, include:

- The funding opportunity number and title.
- · Your organization's name and address.
- A contact name, phone number, and email address.

See the deadline for letters of intent.

Mandatory disclosure

You must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, 45 CFR 75.113.

Send written disclosures to both:

- CDC at Kathy Raible, kcr8@cdc.gov
- The Office of Inspector General at grantdisclosures@oig.hhs.gov

Application checklist

Make sure that you have everything you need to apply:

Component	How to upload	Page limit
☐ <u>Project Abstract</u>	Use the Project Abstract Summary Form.	1 page
☐ Project Narrative	Use the Project Narrative Attachment form.	15 pages
☐ Budget Narrative	Use the Budget Narrative Attachment form.	None
Attachments (7 total)	Insert each in a single Other Attachments form.	
☐ 1. Table of contents		None
☐ 2. Indirect costs agreement		None
☐ 3. Resumes and job descriptions		None
4. Citations of peer-reviewed publications		None
☐ 5. Organization chart		None
☐ 6. Letters of support		None
☐ 7. Report on overlap		None
Other required forms (3 total)	Upload using each required form.	
☐ Application for Federal Assistance (SF-424)		No
☐ Budget Information for Non- Construction Programs (SF-424A)		No
☐ Disclosure of Lobbying Activities (SF-LLL) (if applicable)		No

1. Review

2. Get Ready

3. Prepare

4. Learn

5. Submit

6. Award

Contacts



Step 6: Learn What Happens After Award

In this step

Post-award requirements and administration 64

Post-award requirements and administration

We adopt by reference all materials included in the links within this NOFO.

Administrative and national policy requirements

There are important rules you need to read and know if you get an award. You must follow:

- All terms and conditions in the Notice of Award. The NoA includes the requirements of this NOFO.
- The rules listed in 45 CFR part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, or any superseding regulations. Effective October 1, 2024, HHS adopted the following superseding provisions:
 - 2 CFR 200.1, Definitions, Modified Total Direct Cost.
 - 2 CFR 200.1, Definitions, Equipment.
 - 2 CFR 200.1, Definitions, Supplies.
 - 2 CFR 200.313(e), Equipment, Disposition.
 - 2 CFR 200.314(a), Supplies.
 - 2 CFR 200.320, Methods of procurement to be followed.
 - 2 CFR 200.333, Fixed amount subawards.
 - 2 CFR 200.344, Closeout.
 - 2 CFR 200.414(f), Indirect (F&A) costs.
 - 2 CFR 200.501, Audit requirements.
- The HHS <u>Grants Policy Statement</u> (GPS). This document has policies relevant to your award. If there are any exceptions to the GPS, they'll be listed in your Notice of Award.
- All federal statutes and regulations relevant to federal financial assistance, including the cited authority in this award, the funding authority used for this award, and those highlighted in the HHS Administrative and National Policy Requirements.
- The following <u>CDC's Additional Requirements</u> (AR) apply to this NOFO's awards: 1, 2, 11, 16, 22, 25, 27, 31, 33, 36, 37.

- Please note for this NOFO, CDC-RFA-CK-25-0018, research activities are allowable and will be subject to all applicable laws, regulations, and policy requirements. Note the research and human subjects protection requirements inserted throughout this NOFO. All instructions pertaining to research should be addressed and followed as indicated in this NOFO. Please refer to the <u>Strategies and Activities</u> for more details.
- Funds relating to the conduct of research involving human subjects will be restricted until the appropriate assurances and Institutional Review Board (IRB) approvals are in place. Copies of all current local IRB approval letters and local IRB approved protocols (and CDC IRB approval letters, if applicable) will be required to lift restrictions. If multiple collaborating institutions will be involved, please include in the human subjects section of the Project Narrative your single IRB Plan:
 - Describe how you will comply with the single IRB review requirement under the Revised Common Rule at 45 CFR 46.114 (b) (cooperative research). If available, provide the name of the IRB that you anticipate will serve as the IRB of record.
 - Indicate that all identified engaged institutions or participating sites will agree to rely on the proposed IRB and that any institutions or sites added after award will rely on the IRB.
 - Briefly describe how communication between institutions and the IRB will be handled.
 - Indicate that all engaged institutions or participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the IRB and participating sites.
 - Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
 - Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.
- If you anticipate research involving human subjects but cannot describe
 the study at the time of application, include information regarding how
 the study will comply with the single Institutional Review Board (IRB)
 requirement prior to initiating any multi-site study in the delayed onset
 study justification.

Reporting

If you are successful, you will have to submit financial and performance reports. These include:

Table: Financial and performance reports

Report	Description	When
Recipient Evaluation and Performance Measurement Plan	 Builds on the plan in the application. Includes measures and targets. Shows how data are collected and used (data management plan). 	6 months into award.
Mid-Year Progress Report	 Includes performance measures, successes, challenges. Includes how CDC could help overcome challenges. 	6 months into each budget period.
Annual Performance Report	 Serves as yearly continuation application. Includes performance measures, successes, challenges. Updates work plan. Includes how CDC could help overcome challenges. Includes budget for the next 12-month budget period. 	No later than 120 days before the end of each budget period.
Federal Financial Report	 Includes funds authorized and disbursed during the budget period. Indicates exact balance of unobligated funds and other financial information. 	90 days after the end of each budget period.

Report	Description	When
Data on Performance Measures	 Includes information similar to the Annual Performance Report. 	CDC will only require this report if it needs more frequent reporting than in the Annual Performance Report.
Final Performance Report	 Includes information similar to the Annual Performance Report. 	120 days after the end of the period of performance.
Final Financial Report	 Includes information in Federal Financial Report. 	120 days after the end of the period of performance.

To learn more about these reporting requirements, see Reporting on the CDC website.

CDC award monitoring

Monitoring activities include:

- Routine and ongoing communication between CDC and recipients.
- · Site visits.
- Recipient reporting, including work plans, performance reporting, and financial reporting.

We expect to include the following in post-award monitoring:

- Tracking recipient progress in achieving the outcomes.
- Ensuring the adequacy of your systems to hold information and generate data reports.
- Creating an environment that fosters integrity in performance and results.

We may also include the following activities:

- · Ensuring that work plans are feasible based on the budget.
- Ensuring that work plans are consistent with award intent.
- Ensuring that you are performing at a level to achieve outcomes on time.
- Working with you to adjust your work plan based on outcome achievement, evaluation results, and changing budgets.
- Monitoring programmatic and financial performance measures to ensure satisfactory performance levels.

 Other activities that assist CDC staff to identify, notify, and manage risk, including high-risk recipients.

We can take corrective action if your performance is poor. We can also take corrective action if you have failed to materially comply with the terms and conditions of award. We may withhold, suspend, or terminate the award. The regulatory procedures are specified at 45 CFR 75.371.

CDC's role

Our partnership is essential to the success of the MInD Healthcare cooperative agreement. Close collaboration and a willingness to work together with us to ensure these goals are met is critical.

Our staff and subject matter experts across CDC will review applications to ensure activities are in scope and are not duplicative of those funded by other grants and cooperative agreements.

To ensure MInD Healthcare recipients achieve the purpose of this award, we will conduct the following activities in addition to what was outlined above in CDC award monitoring:

- Provide ongoing guidance, consultation, programmatic support, training, and technical assistance related to:
 - Mathematical modeling of HAIs and AROs in healthcare settings.
 - Activities outlined in this funding opportunity.
- Facilitate opportunities to collaborate with other CDC subject matter experts and/or with peers within the MInD Healthcare Network.
- Convene either an in-person and/or virtual annual program meeting with MInD Healthcare Network recipients.



Contacts and Support

In this step

Agency contacts	<u>70</u>
Grants.gov	70
SAM.gov	70
Reference websites	70

Agency contacts

Program

Nga Vuong

ypg2@cdc.gov 970-494-6682

Grants management

Kathy Raible

kcr8@cdc.gov 470-316-8061

Grants.gov

Grants.gov provides 24/7 support. You can call 800-518-4726 or email support@grants.gov. Hold on to your ticket number.

SAM.gov

If you need help, you can call 866-606-8220 or live chat with the <u>Federal Service Desk</u>.

Reference websites

- U.S. Department of Health and Human Services (HHS)
- Grants Dictionary of Terms
- CDC Grants: How to Apply
- CDC Grants: Already Have a CDC Grant?
- Grants.gov Accessibility Information
- · Code of Federal Regulations (CFR)
- United States Code (U.S.C.)

Contacts and Support 70

Appendix: HAI Modeling Publications

- 1. Agnew E, Davies KA, Viprey VF, et al. Impact of testing on Clostridioides difficile infection in hospitals across Europe: a mathematical model. *Clin Microbiol Infect*. 2023;29(6):796.e1-796.e6. doi:10.1016/j.cmi.2023.02.004.
- 2. Austin DJ and Anderson RM. Studies of antibiotic resistance within the patient, hospitals and the community using simple mathematical models. *Philos Trans R Soc Lond B BiolSci.* 1999 Apr 29;354(1384):721-38.
- 3. Beams A, Keegan LT, Adler FR, Samore MH, Khader K, Toth DJA. Are Staphylococcus aureus Carrier Types Evidence of Population Heterogeneity?. *Am J Epidemiol*. 2023;192(3):455-466. doi:10.1093/aje/kwac201.
- 4. Campbell F, Cori A, Ferguson N, and Jombart T. Bayesian inference of transmission chains using timing of symptoms, pathogen genomes and contact data. *PLoS Comput Biol.* 2019 Mar 29;15(3): e1006930.
- 5. Campbell F, Strang C, Ferguson N, Cori A, and Jombart T. When are pathogen genome sequences informative of transmission events? *PLoS Pathog.* 2018 Feb 8;14(2):e1006885.
- 6. Chang HH, Dordel J, Donker T, Worby CJ, Feil EJ, *et al.* Identifying the effect of patient sharing on between-hospital genetic differentiation of methicillin-resistant Staphylococcus aureus. Genome Med 2016 Feb 13;8(1):18.
- 7. Cincotta SE, Walters MS, Ham DC, et al. Regional impact of multidrugresistant organism prevention bundles implemented by facility type: A modeling study. *Infect Control Hosp Epidemiol*. Published online February 28, 2024. doi:10.1017/ice.2023.278.
- 8. Donker T, Wallinga J, and Grundmann H. Patient referral patterns and the spread of hospital-acquired infections through national health care networks. *PLoS Comput Biol.* 2010 Mar 19;6(3): e1000715.
- 9. Eyre DW, Davies KA, Davis G, Fawley WN, Dingle KE, *et al.* Two distinct patterns of *Clostridium difficile* diversity across Europe indicating contrasting routes of spread. *Clin Infect Dis.* 2018 Sep 14;67(7):1035-1044.
- 10. Gowler CD, Slayton RB, Reddy SC, O'Hagan JJ. Improving mathematical modeling of interventions to prevent healthcare-associated infections by

- interrupting transmission or pathogens: How common modeling assumptions about colonized individuals impact intervention effectiveness estimates. *PLoS One*. 2022;17(2):e0264344. Published 2022 Feb 28. doi:10.1371/journal.pone.0264344.
- 11. Khader K, Thomas A, Huskins WC, Leecaster M, Zhang Y, *et al.* A Dynamic Transmission Model to Evaluate the Effectiveness of Infection Control Strategies. *Open Forum Infect Dis.* 2017 Feb 10;4(1):ofw247.
- 12. Lee BY, Bartsch SM, Hayden MK, Welling J, DePasse JV, *et al.* How Introducing a Registry With Automated Alerts for Carbapenem-resistant Enterobacteriaceae (CRE) May Help Control CRE Spread in a Region. *Clin Infect Dis.* 2019 May 9.
- 13. Love J, Keegan LT, Angulo FJ, McLaughlin JM, Shea KM, *et al.* Continued need for non-pharmaceutical interventions after COVID-19 vaccination in long-term-care facilities. *Sci Rep.* 2021 Sep 10;11(1):18093.
- 14. Paul P, Slayton RB, Kallen AJ, Walters MS, Jernigan JA. Modeling regional transmission and containment of a healthcare-associated multidrugresistant organism. *Clin Infect Dis.* 2019 Mar 28.
- 15. Richard DM, Lipsitch M. What's next: using infectious disease mathematical modelling to address health disparities. Int J Epidemiol. 2024 Feb 1;53(1):dyad180. doi: 10.1093/ije/dyad180. PMID: 38145617; PMCID: PMC10859128.
- 16. Sewell DK, Simmering JE, Justice S, Pemmaraju SV, Segre AM, Polgreen PM. Estimating the Attributable Disease Burden and Effects of Interhospital Patient Sharing on *Clostridium difficile* Infections. *Infect Control Hosp Epidemiol*. 2019 Jun;40(6):656-661.
- 17. Slayton RB, O'Hagan JJ, Barnes S, Rhea S, Hilscer R, *et al.* Modeling Infectious Diseases in Healthcare Network (MInD-Healthcare) Framework for Describing and Reporting Multidrug-resistant Organism and Healthcare-Associated Infections Agent-based Modeling Methods. *Clin Infect Dis.* 2020 Nov 1;71(9):2527-2532.
- 18. Slayton RB, Scott RD, Baggs J, Lessa FC, McDonald LC, and Jernigan JA. The cost-benefit of federal investment in preventing *Clostridium difficile* infections through the use of a multifaceted infection control and antimicrobial stewardship program. *Infect Control Hosp Epidemiol.* 2015 Jun;36(6):681-7.
- 19. Smith DL, Dushoff J, Perencevich EN, Harris AD, and Levin SA. Persistent colonization and the spread of antibiotic resistance in nosocomial pathogens: resistance is a regional problem. *Proc Natl Acad Sci U S A*. 2004 Mar 9;101(10):3709-14.

- 20. Smith DL, Levin SA, and Laxminarayan R. Strategic interactions in multi-institutional epidemics of antibiotic resistance. *Proc Natl Acad Sci USA*. 2005 Feb 22;102(8):3153-8.
- 21. Tedijanto C, Olesen SW, Grad YH, Lipsitch M. Estimating the proportion of bystander selection for antibiotic resistance among potentially pathogenic bacterial flora. *ProcNatlAcad Sci USA*. 2018 Dec 18;115(51): e11988-e11995.
- 22. Thomas A, Khader K, Redd A, Leecaster M, Zhang Y, *et al.* Extended models for nosocomial infection: parameter estimation and model selection. *Math Med Biol.* 2018 Mar 16;35(suppl_1):29-49.
- 23. Toth DJA and Khader K. Efficient SARS-CoV-2 surveillance strategies to prevent deadly outbreaks in vulnerable populations. *BMC Med.* 2021 Jan 22;19(1):25.
- 24. Toth DJA, Khader K, Slayton RB, Kallen AJ, Gundlapalli AV, *et al.* The potential for interventions in a long-term acute care hospital to reduce transmission of carbapenem-resistant enterobacteriaceae in affiliated healthcare facilities. *Clin Infect Dis.* 2017 Aug 15;65(4):581-587.
- 25. Van Kleef E, Luangasanatip N, Bonten MJ, and Cooper BS. Why sensitive bacteria are resistant to hospital infection control. *Wellcome Open Res.* 2017 Mar 10; 2:16.