CDC/ATSDR Formative Research and Tool Development

OMB# 0920-1154

SUPPORTING STATEMENT: PART A

Evaluating Content and Usability of CDC's Clinical Heat Guidance

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health is requesting approval for a new GenIC under OMB Control No. 0920-1154, entitled "Evaluating CDC's Clinical Heat Guidance", to evaluate the effectiveness of its heat guidance used by clinicians at nationwide health centers, also known as Community Health Centers (CHCs) or Federally Qualified Health Centers (FQHCs). Health centers (referred to in this document as CHCs) are local clinics that provide affordable health care to individuals and communities, including medical, dental, mental health, and other health care. To improve customer service to CHCs, CDC plans to obtain content and usability feedback on heat guidance materials used during the 2024 heat season to inform revisions and improvements to the materials for re-release in Spring 2025. Evaluation of CDC's first-ever clinical heat guidance is needed to ensure that the most effective, audience-informed messages are available to help clinicians and other health clinic staff reduce the impact of heat on the health of the CHC patient population and on the American public.

Rising ambient temperatures have increasingly threatened the public's health, especially during summer months. Summer 2024 was the hottest period ever recorded in the United States since temperatures began being measured in the 1880s (1). Each year, thousands of preventable deaths occur because of heat. Heat can harm anyone's physical and mental health (2). However, certain populations are disproportionately affected by extreme heat (3), including older persons, children, pregnant women, people with chronic medical or behavioral health conditions, and those without adequate access to cooling resources.

Heat contributes to a wide range of adverse health impacts, including worse pregnancy outcomes; greater need for emergency medical treatment; hospitalizations for cardiovascular and respiratory disease, asthma, kidney disease, and behavioral health issues; a higher prevalence of an array of infectious diseases; and injuries, including injuries at work (4). Where people live and what they do for a living can shape how much heat they are exposed to. Individuals living in "heat islands"—urban areas with limited greenspace and extensive pavement—may endure temperatures >10 degrees Fahrenheit higher compared to surrounding areas. Extended time outdoors paired with high levels of physical exertion further amplifies risk, affecting outdoor workers (including farmworkers, construction workers, and military personnel), outdoor athletes, and those who are unhoused. These risks also extend to rural communities, where outdoor work is prevalent and cooling resources may be scarcer.

Public health heat resilience planning has not traditionally engaged the healthcare delivery system, a system well positioned to help protect those most at risk from heat because of age, underlying health, or social determinants of health. In addition, clear and simple guidance has not been widely available for clinicians, patients, and the general public to enable planning ahead for heat protection *before* the start of the heat season, with no clinical guidance materials previously available from US Health and Human Services.

In response to this public health need, in April 2024, CDC released first-ever heat-related clinical guidance to help clinicians counsel patients on preventing health harms from heat for individuals at increased risk from heat, such as children with asthma, pregnant women, and adults with cardiovascular disease, and for the general public. This is a CDC Director's Priority under the category of Readiness and Response.

Three types of materials were created, including 1) background heat and health information for clinicians, 2) guidance materials for clinicians focused on populations at increased risk for health harms from heat, and 3) informational tools and heat action plans for patients and the general public. The intended audience for this guidance is clinicians practicing at CHCs across the US, in partnership with their patients. Secondary audiences include non-clinician CHC staff - such as community health workers (CHWs), patient educators, health and safety team members, patient navigators, and/or call center staff - who may also be sharing CDC's clinical heat guidance with CHC patients. This document uses the terms physician and clinician interchangeably when referring to medically trained and licensed individuals who deliver medical care to patients and who may be counseling their patients on heat prevention.

Clinical guidance from CDC utilized in healthcare delivery settings is critical to ensuring effective and consistent care across the nation (5). Consensus from evidence-based research on what improves patient outcomes informs such guidance. When physicians adhere to clinical guidance, studies have shown improvements in patient outcomes (6). Further, combining use of guidance with other interventions is found to improve health outcomes most effectively for patients (7). By encouraging physician adherence to recommended guidance, variability in care across practitioners can be reduced, ensuring that patients will have consistent care across the nation (8).

A.2 Purpose and Use of the Information Collection

CDC will collect data through a cooperative agreement recipient, the National Center for Farmworker Health (NCFH), who will be working in subcontract with the National Association of Community Health Centers (NACHC), via a survey administered to the universe of 1,496 CHCs. This includes all Health Center Program awardees and look-alikes funded through the Health Resources and Services Administration (HRSA). NCFH and NACHC will administer a 37-question CDC and NCFH-designed survey to clinicians and non-clinicians at CHCs for content and usability testing of CDC's Clinical Heat Guidance. This evaluation will use qualitative and quantitative data collection methods to assess the design and use of CDC's web-based heat guidance materials. Additionally, the survey will gather audience knowledge, attitudes, and beliefs (KABs), perceptions of campaign asset products, and clinic and clinician specialty characteristics. NCFH/CDC will deploy the electronic survey over a three-week period to capture responses about CDC's heat and health guidance.

The survey will be offered in both English and Spanish, with respondents selecting their preferred language in which to complete the survey (**see Attachment 10, draft Spanish language survey instrument**). Estimates suggest that up to almost 80% of CHC health care providers, both clinicians and non-clinician providers, speak Spanish, and some conduct patient conversations entirely in Spanish (15). While CHC health care providers are proficient in

English, some may prefer Spanish as their primary language in which to respond to the survey. In an effort to respond to this preference and thereby to potentially increase survey response rates, the survey will be offered in both languages. The attached draft Spanish language instrument will be finalized by NCFH and ready for use upon OMB approval, with any necessary updates made as a result of OMB review.

The purpose of this data collection is to:

1. Assess how and to what extent CHCs have used CDC's new clinical heat guidance.
2. Assess the content and usability of the clinical heat guidance in supporting CHC efforts to reduce the impact of heat on their patients' health.
3. Identify barriers, facilitators, and areas of need and support for CHCs in using CDC's new clinical heat guidance.

The information collected will be used to:

1. Gain an understanding of the perceived effectiveness and utility of CDC's clinical heat guidance.
2. Support the development and improvement of future clinical heat guidance materials and products.

The survey instrument **(Attachment 1)** will contain Likert-scale, binary, and open-ended questions. Items were developed from the utilization-focused evaluation theory. Each question is created with the intention of producing actionable findings that are relevant to the implementation of the Heat and Health Initiative (5). See table below.

Domain	**Measures**	**Response Types**
Knowledge, Attitudes and Behaviors related to Perception of Health Risks from Exposure to Heat	Items related to knowledge (e.g., HeatRisk forecast tool is available to determine impact of specific heat levels on health), attitudes (e.g., concerns raised by patients related to hot weather and their health), and behaviors (e.g. I talk to my patients about heat and their health)	Binary (Yes/No), Multi-Response Drop-down
Knowledge, Attitudes, and Behaviors related to CDC's Clinical Heat Guidance released April 2024	Items related to knowledge (e.g. clinical heat guidance is available for physicians and healthcare providers), attitudes (e.g. clinical heat guidance can help physicians and non-physician clinic staff protect patients from heat-related illness), and behaviors (e.g. I use CDC's clinical heat guidance to protect my patients from heat-related illness)	Binary (yes/no), Multi-response drop-down, Likert
Clinician Perceptions of	Items related to clinician perceptions of clinical heat guidance: usability in a clinical	Binary (yes/no), Multi-response

CDC's clinical heat guidance	setting, familiarity with the materials, navigability (i.e. website accessibility), likability (i.e., general perception of favorability), barriers to use, settings/populations to be included in the future, and clarity of guidance/resources	drop-down, Likert, Open-ended
Demographic	Clinic information/location, Name of CHC, clinic staff role, clinician specialty, patient population information	Multi-response drop-down, Open-ended

A.3 Use of Improved Information Technology and Burden Reduction

To reduce burden, technology will be used to collect data using an online survey. Questions will be kept to a minimum required for the intended use of the data with programmed skip patterns to allow respondents to answer only pertinent questions.

A.4 Efforts to Identify Duplication and Use of Similar Information

There are no other known federal generic collections that duplicate the project included in this request. CDC's Clinical Heat Guidance is a new resource, and no other federal agency has a similar guidance or resources. Therefore, there is no similar data available.

A.5 Impact on Small Businesses or Other Small Entities

This project does not have an impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data.

A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This information collection request does not require publication of a 60-day notice in the Federal Register.

CDC consulted with several outside experts to provide input into the development of the heat guidance as listed in the table below.

Exhibit A.8.1. Outside Consultation

Name	Organizational Unit
Elise LaFlamme MD, Associate Program Director, Surgical OB-Gyn	Greater Lawrence Community Health Center
Ellen Hey, Family Nurse Practitioner	Fingerlakes Community Health Center
Kelly Jones MD, Family Practitioner, Clinic CMO	Kedren Community Health Center
Eugene Nor MD, Family Medicine, Clinic CMO	Robeson Community Health Center
Eric Henley, MD MPH, recently retired CMO	Lifelong Medical Community Health Center
Lisa Lynn Vendeland, DO, MA, Director of Obstetrics, Gynecology and Women's Services	Advance Community Health Center
Sherrill Brown, MD, Medical Director	Altamed Health Services
Carol Gambrill DO, Family Practitioner	Hope Clinic Community Health Center
Mitchell Grayson MD	American Academy of Allergy, Asthma, and Immunology and American College of Allergy, Asthma, and Immunology
Michelle Jones MD	American College of Obstetrics and Gynecology
Megan McReynolds MD	Society for Maternal-Fetal Medicine (SMFM)
Sarah Boudova MD	SMFM Committee on Infectious Diseases and Emerging Threats
Alan Woolf	PEHSU program R1
Rose Goldman	PEHSU program R1
Shalini Shah	PEHSU program R1
Melissa Haupman	PEHSU program R1
Gredia Huerta-Montanez	PEHSU program R2
Perry Sheffield	PEHSU program R2
Becca Philipsborn MD	PEHSU program R4
Marya Zlatnik MD	PEHSU program R9
Aparna Bole, MD MPH	HHS Office of Climate Change and Health Equity
Jim McCrae MD	Health Services Research Administration
Michael Warren	Health Services Research Administration
Wayne Cascio MD	Environmental Protection

	Agency

A.9 Explanation of Any Payment or Gift to Respondents

All respondents will receive a $30 Visa eGift Card following completion of the survey.

Evidence from the past decade has consistently demonstrated that financial incentives are an effective strategy in boosting physician and non-physician clinic staff response rates to surveys. When surveying physician (and other clinicians) and non-physician clinic staff, there are multiple barriers, including time constraints, heavy workload, and oversampling the population, leading to survey fatigue. Financial incentive has been found to offset perceived time burden to make participation more appealing. Clinicians facing demanding workloads are more likely to respond to surveys if provided with a direct and tangible benefit (9). In a study by Cho et al. (2013), study authors reviewed various methods to enhance survey responses by healthcare professionals (10). Similar studies have been conducted and found that even a modest financial incentive significantly improved response rate. One review paper found that financial incentive increased the likelihood of healthcare provider response compared with surveys with no incentives and concluded that financial incentives were among the most effective motivators (11). Other research suggests that nonmonetary incentives are more effective than no incentive, with monetary incentive having a bigger effect in the clinician population (12). This underscores that financial remuneration can offset barriers to survey participation and increase survey response rates by physicians and non-physician health care staff.

A.10 Assurance of Privacy Provided to Respondents

This submission has been reviewed by the CDC Chief Privacy Officer, who has determined that the Privacy Act does not apply (**Attachment 8)**. Survey participants will receive a $30 Visa eGift Card following completion of the survey if they provide their email address. Only email address of the Survey participants (clinicians and non-clinician staff at community health centers) will be collected (**Attachments 1 and 12, English and Spanish versions**). A Federal Risk and Authorization Management Program (FedRAMP) authorized secure tool will be used to collect and store the PII (email addresses). All survey responses will be destroyed three years after completion of the project. No identifiable information describing individual respondents will be included in the analyzed data and aggregate reports. CDC will identify, screen, and recruit potential participants through the cooperative agreement recipients NCFH and NACHC. Staff will be required to sign a privacy agreement prior to the start of the project. On the opening page of the survey, participants will receive information regarding privacy and confidentiality along with a valid OMB number and contact information in case participants have questions about their rights as a participant. Data will be kept private to the extent allowed by law.

A.11 INSTITUTIONAL REVIEW BOARD (IRB) AND JUSTIFICATION FOR SENSITIVE QUESTIONS

Institutional Review Board (IRB)

This project is being undertaken as public health practice and to improve customer service to the heat guidance end users, healthcare professionals who care for patients at CHCs nationwide. No information will be collected that are of personal or sensitive nature. This data collection is not research involving human subjects. Therefore IRB approval is not required (**Attachment 9**).

Justification for Sensitive Questions

There is minimal risk that questions related to use of heat guidance by CHC healthcare professionals during normal patient interactions may make respondents feel uncomfortable or cause some emotional discomfort. It is necessary to get feedback around these topics, as best practices show that to develop effective communications and/or guidance materials, they must be based on audience data (13). The respondent consent statement includes a statement informing participants that they may choose not to answer a particular question if they wish and/or end the session at any time without penalty.

A.12 Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 250 hours (Exhibit A.12.1).

The survey is estimated to take 15 minutes to complete. Timing is based on previous experience conducting research through online survey panels for message testing to determine the overall burden per respondent and based on several survey pilot tests by members of this project team. It is possible that among respondents, up to two-thirds might be unfamiliar with the CDC heat guidance, allowing them to skip portions of the survey. For those respondents, the survey will is estimated to take 8-10 minutes to complete.

A maximum of 1000 survey responses will be collected from a total of 1,496 CHCs nationwide. Of those, it is estimated that 75% of surveys will be completed by physicians and 25% by non-physician staff at CHCs.

Exhibit A.12.1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden (in hours)
Physicians	Survey	750	1	15/60	187.5

Non-physicians	Survey	250	1	15/60	62.5
Totals	-	1,000	-	-	250

According to the U.S. Department of Labor (DOL) December 2023 (the most up-to-date non-provisional data) National Occupational Employment and Wage Estimates, the average hourly wage for physicians is $113.46 or for non-physician health care providers/CHC staff is $57.69 (14). The total annualized burden cost is estimated at $24,879.38 per year. Nonusers will spend less time completing the survey, and therefore reduce cost. Costs calculated here reflect the maximum burden and costs.

Exhibit A.12.2 Estimated Annualized Burden Costs

Type of Respondent	Number of Respondents	Average Burden per Respondent (hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physicians	750	15/60	187.5	$113.46	$21,273.75
Non-physicians	250	15/60	62.5	$57.69	$3,605.63
Totals	1,000	-	250	-	$24,879.38

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There will be no direct costs to the respondents other than their time to participate in the information collection.

A.14 Annualized Cost to the Federal Government

The total annualized cost to the government is estimated to be $185,611.10 (Exhibit A.14.1). This cost includes salaried labor for contractor staff and other direct costs associated with planning and execution of the collection.

Exhibit A.14.1. Estimated Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct cost to the federal government		
CDC oversight of contractor and project	CDC Project Officer (25%)	$29,875.25
	CDC Co-Principal Investigator (5%)	$5,735.85
Subtotal, Direct Costs to the Government		*$35,611.10*
Labor hours and other direct costs	Design, implementation, recruitment, data collection, analysis, reporting and incentives	*$150,00.00*
Total cost to the government		$ *185,611,10.*

A.15 Explanation for Program Changes or Adjustments

No change in burden is requested, as this is a new information collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Data will be tabulated, and a report will be developed outlining the findings from this formative research. The project team will use Qualtrics, MS Excel, and SPSS data analysis tools to visualize and explore trends among the data. To compare findings across groups or among demographic factors, the team will analyze the data using crosstabs for selected variables of interest. Results of this analysis will be used in reports, other dissemination activities, and to inform materials and message development. All findings will be used internally by the CDC to make recommendations to improve communications products and strategies. The project time schedule is provided below.

Exhibit A.16.1. Project Time Schedule

Activity	Due Date
Recruitment	Within 1 week of OMB approval
Data Collection	Within 1 week of OMB approval
Analyze Data and Report	2 months after OMB approval

A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate

OMB Expiration Date will be displayed on necessary materials and documents.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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