

ASPE REPORT

Developing and Piloting a Federal Evaluation Approach for Complex Cross-Agency Initiatives: The Overdose Prevention Test Case

Final Report Summary

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Introduction

The Foundations of Evidence Based Policy Making Act of 2018 (Evidence Act) was established to advance evidence-building in the federal governmentⁱ and mandated new approaches to the federal government's evidence-building activities, including both building new evidence as well as using existing evidence in novel ways and contexts. Guidance from the Office of Management and Budget (OMB) encourages federal evaluators to build on activities already underway and, in some cases, requires coordination of these activities in new ways. As the lead for implementing this mandate of the Evidence Act within the US Department of Health and Human Services (HHS), the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is tasked with developing resources to support and expand evidence building activities across the Department.

HHS is a large, decentralized agency with 13 Operating Divisions and 10 Staff Divisions (Op/Staff Divs) that conduct a broad array of activities and provide a wide set of programs and services. While high quality evidence is generated for many individual programs, there is a need to better understand how these programs and activities, when taken together, enhance the health and well-being of people and communities. To address this need ASPE engaged staff from across the Department to develop and test an approach for evaluating initiatives that involve multiple divisions, address the needs of a diversity of communities, and include varied approaches. This work also tested a process for identifying HHS-wide initiatives that are sufficiently coherent, about which there are adequate data regarding their performance, and which are central enough to the HHS Mission to warrant such an evaluation. For evaluations conducted at the agency level rather than at the level of specific programs or activities, it can be difficult to identify a manageable number of measurable outcomes or impacts. To help define the desired outcomes and impacts and create a realistic focus for the evaluation, the team relied on a synthesis of evaluation literature and empirical analysis of evaluation reports conducted by Teasdale (2021) that identified 11 evaluation domains. These domains, described in detail later in this report, were used as a framework for describing the aspects, dimensions, or characteristics against which a cross HHS intervention could potentially be assessed.

Building upon this framework and relying on widely accepted evaluation standards¹, ASPE created an approach involving five characteristics of initiatives suitable for cross-HHS evaluation and five steps for conducting a comprehensive and systematic cross-HHS evaluation. This systematic approach to identifying initiatives and carrying out evaluative activities that might be applied to heterogenous projects across the HHS enterprise was designed to generate usable information and to help determine what initiatives and part of initiatives are and are not working as intended and achieving intended

¹ American Evaluation Association Competencies & Standards available at https://www.eval.org/About/Competencies-Standards and OMB M-20-12; Step 4 Implementation of the Foundations for Evidence-Based Policymaking Act of 2018: Program Evaluation Standards and Practices available at https://www.whitehouse.gov/wp-content/uploads/2020/03/M-20-12.pdfs

outcomes. It was also developed to help to answer questions regarding why, for whom, and under what circumstances an initiative is successful. As is widely known, it is always preferrable to plan evaluation at the beginning of an initiative, but this is not always possible. The Federal Evaluation Approach for Complex Cross-Agency Initiatives, developed by HHS, is a framework by which evaluation of complex initiatives might done primarily retrospectively, though the building blocks of this approach are broadly applicable and may be adapted for prospective cross-initiative planning. This report describes how ASPE established and tested this framework so that it might serve as a template for evaluating cross-HHS initiatives now and in the future.

Characteristics for Initiative Selection

The characteristics of HHS topics suitable for cross-HHS evaluation include alignment with HHS priorities, maturity, cross-HHS representation, clear problem statement, and information availability. These characteristics are elaborated below and in Appendix A. The systematic application of these characteristics aids in the determination of whether i an evaluation is justified, feasible, and likely to provide useful information. It also helps to ensure that evaluation results will be relevant to HHS leadership.

Selection Characteristic 1: Alignment with HHS Priorities

How central is the initiative to current administration and Secretarial priorities. Example questions which may demonstrate this characteristic are:

- Is this focus of the initiative an established, current administration priority?
- Is it highly relevant to the HHS mission?
- Is it aligned with administration/HHS aims and interconnected problems (e.g., priority populations and systems)?

Information to answer these questions can be found in Presidential executive orders, State of the Union addresses, Healthy People objectives, messages from the HHS Secretary, HHS budgetary documents as well as HHS evaluation, evidence building, and strategic plans.

Selection Characteristic 2: Maturity

The second assessment characteristic assesses how well-developed HHS' approach to addressing the topic is. Example questions which may demonstrate this characteristic are:

- How long has the topic been an HHS priority?
- How long has there been a concerted effort to address the topic?
- Are there fully operational programs and policies in place that address the topic?

These questions help to determine how much work has been done in a topic area and how much data may be available for review. Answering these questions might be done by assessing how long HHS has been funding or directly conducting activities related to a topic. Funding information is available in HHS Op/Staff Divisions' budget justifications and from sites such as Grants.gov. It is also important to confirm

that activities related to the topic have been conducted over a long enough time period that evidence of demonstrated results is available.

Selection Characteristic 3: Cross-HHS representation

The third assessment characteristic is the degree to which multiple parts of HHS are funding or conducting activities to address the topic. Example questions which may demonstrate this characteristic are:

- How many HHS Op/Staff Divisions are conducting or funding activities in support of the initiative?
- How many funding streams are supporting relevant activities?

These questions help determine the reach of a topic or area across the HHS enterprise and can be answered by assessing the number of HHS Op/Staff Divisions involved in relevant activities; engagement of multiple departments and offices within involved HHS Op/Staff Divisions; and the number of relevant programs/initiatives per HHS Op/Staff Division. In addition to reviewing HHS Op/Staff Divisions' budget documents, relevant data sources may include HHS Op/Staff Division websites, press releases, and publications.

Selection Characteristic 4: Clear Problem Statement

The fourth assessment characteristic is the existence of a well-defined problem statement and quantifiable objectives. Example questions which may demonstrate this characteristic are:

- Is there a clearly articulated problem or issue to be resolved?
- Is it feasible to measure progress towards issue resolution?
- Are there a manageable number of goals and outcome areas that make sense within a common framework across HHS Op/Staff Divisions?
- Are the proposed strategies for achieving desired outcomes/impacts easily identified?
- Is there a defined set of activities addressing the problem?

These questions can be answered by assessing consistency of the terminology and constructs related to the problem or issue across HHS Op/Staff Divisions and over time, the clarity of initiative's aims, the existence of well-defined and measurable objectives, and whether there is a logic model(s) to describe the initiative or sub-parts of the initiative. It may also be helpful to identify a related agency priority goal, or an agency strategic objective that provides common language and focus.

Selection Characteristic 5: Information Availability

The fifth assessment characteristic is the availability of sufficient, high-quality documentation of the implementation of the initiative and its effect on people, communities, and/or organizations. Example questions which may demonstrate this characteristic are:

- Are high-quality reliable and valid data (e.g., performance data, evaluation findings) available across identified activities?
- Do the data focus on both process (outputs) and results (outcomes)?
- Are data available from a range of sources (e.g., staff, service recipients, federal statistics, scholarly literature, professional standards/guidelines)?
- Are the data readily available?
- Are data collected for relevant indicators with sufficient frequency and completeness?

These questions can be answered by reviewing program reports, policy analyses, performance data, evaluation, and other research reports, and by conducting interviews with key program staff.

Using the five characteristics outlined here, appropriate initiatives can be identified for the cross-HHS evaluation framework, thus allowing for greater understanding of the evidence-building actions occurring around any given enterprise level initiative. The next section of this report describes the process of conducting a cross-HHS evaluation.

Steps For Conducting a Cross-HHS Evaluation

Once a cross-cutting initiative has been identified, there are five steps for conducting a comprehensive and systematic cross-HHS evaluation (Table 1). These steps are intended to serve as a guide to approaching evaluative activities across any initiative. Each step is described in more detail in the following sections. In some sections, additional information is provided using examples from a pilot application of the framework to HHS' overdose prevention efforts using the structure of the current the HHS Overdose Prevention Strategy².

Table 1: Five steps of cross-HHS evaluation			
Step 1	Define the HHS initiative ³ to be evaluated	, The scope of the HHS initiative should be specified for the purpose of the cross-agency evaluation. Defining the initiative includes specifying the timeframe, focus area(s), approach or methods, and expected results that will be the focus of the evaluation.	

² The Overdose Prevention Strategy was selected for this pilot because of its centrality to the HHS mission as demonstrated through the inclusion of overdose prevention-related goals in multiple HHS Strategic Plans and its prominence in agency performance reporting, funding, research, and policy development. It was determined to be evaluable based on the clarity of the goals of the HHS Overdose Prevention Strategy and the identification of measurable objectives within specific HHS programs.

³ For this report, we use the term *initiative* broadly to include any department-wide activity or measure taken or to be taken by HHS.

Table 1: Five steps of cross-HHS evaluation				
Step 2	Identify and group activities ⁴ that support the broad initiative	List and categorize all department-wide activities related to the initiative. Activities may include programs, policies, regulations, interventions, research, and other agency efforts that support the broad initiative defined in Step 1.		
Step 3	Classify categories of results across initiative activities	Collect and categorize information on the intended results of each activity listed in Step 2.		
Step 4	Document the actual progress towards each activity's stated goals and objectives (e.g., evidence that it is achieving its goals or meeting its objectives)	Collect information on activity-level accomplishments from sources such as evaluation reports, performance measurement data, survey results, grantee reports, or interviews with key staff.		
Step 5	Select and apply the evaluation domains	Conduct a systematic review of the available evidence to assess the degree to which the intended results of each activity (Step 3) were achieved (Step 4) and contribute to meeting the overall goal or sub goals of the broad initiative. While the findings will be at the individual activity level, it is important to compile the information to assess the larger impact at both the overall initiative level as well as by the categories defined in Step 2 using explicit and reproducible methods.		

Step 1: Define the HHS initiative to be evaluated

Cross-HHS evaluation requires applying evaluative standards consistently across many activities. Therefore, a clear definition of the scope and breadth of the broader initiative is critical to help evaluators understand the initiative and set up clear evaluation parameters.

• Timeframe: Having a specific timeframe helps evaluators: 1) build a database of activities within clear start and end dates, 2) apply a consistent timeframe to database and literature searches.

⁴ For this report, we use the term *activity* broadly to include policies, regulations, programs, interventions, and any other coordinated activities – which are directly or indirectly funded, in whole or in part, by HHS.

- Sample Question: Was there are any notable change in approach or legislation relevant to the initiative?
- Example: For HHS Overdose Prevention Strategy, the Comprehensive Addiction and Recovery Act (CARA) was chosen as the starting point to evaluate the HHS Overdose Prevention S evaluation based on the input of subject matter experts that it was the first major federal addiction act passed in 40 years.
- Focus Area(s): Identifying the primary goals of the initiative helps evaluators: 1) know what terms and phrases to use when searching for activities and 2) make sense of the large number of potential activities.
 - Sample Question: Is there a published speech, press release, webpage, or announcement that defines the agency focus for the initiative?
 - Example: The HHS Overdose Prevention Strategy has a website that describes four distinct focus areas: Primary Prevention, Harm Reduction, Evidence-based Treatment, and Recovery Support.
- Approach or Methods: Having a set of defined methods that are being used for the initiative helps evaluators 1) better understand the different ways to approach the overall goal of the initiative, and 2) better construct the database of activities. Such information can also be used in Step 5 when evaluating the initiative's design and alignment.
 - Sample Question: What is the theory of change underlying the initiative and what related standards or best practices are reflected in the activities that make up the initiative?
 - Example: HHS' approach to overdose prevention includes: 1) clinical and supportive services, 2) clinical guidance for providers, 3) primary and translational research, and 4) policy implementation.
- Expected results: Having a set of well-defined outcomes helps evaluators understand what the
 constitutes success for the initiative and identify indications that the desired results have been
 achieved.
 - Sample Question: What has been the desired goal(s) across the entire timeline of the initiative?
 - Example: With regard to overdose prevention although the approaches and terminology have evolved as new research has been conducted, since the passage of CARA HHS has consistently focused on primary prevention, harm reduction, evidence-based treatment, and recovery support.

Step 2: Identify and group activities that support the broad initiative

This step involves creating an inventory of all department-wide activities that support the broad initiative defined in Step 1. Information collection strategies will vary depending on the initiative, but sources of such information might include:

- The websites of HHS and each of its Op/Staff Divisions
- Grants.gov
- Tracking Accountability in Government Grants System (TAGGS)
- Government reports published within the timeframe defined in Step 1
- Interviews with agency staff

- Budget documents published by HHS and each of its Op/Staff Divisions
- Reports to Congress

After the inventory has been established, the evaluators can categorize the activities to guide the crosscutting evaluation. Categorization can be conducted in various ways including by 1) focus areas set forth in the initiative 2) types of approaches taken to address the issue (e.g., direct service, awareness campaigns, training for service providers, foundational or translational research) or 3) initiative goals and subgoals.

Step 2 Box. Identifying activities supporting the HHS Overdose Prevention Strategy

In Step 2, an *Inventory of HHS Overdose Prevention Activities* was developed to provide a comprehensive view of overdose prevention efforts. This inventory served as the main data source for the subsequent assessment of evaluation domains. The inventory was organized by the following 5 approaches taken to address the issue 1) direct service programs, 2) research, 3) clinical guidelines and related resources, 4) policies and regulations, and 5) surveys and statistical systems.

For each funded activity, documentation included:

- o HHS Operating or Staff Division
- Activity name
- Start and end dates/publication date
- Overdose Prevention Strategy strategic priority area addressed
- Focus or description of the activity
- Website addresses

For direct service programs, documentation also included:

- Total federal funding value
- Level of operation (e.g., federal, tribal, state, local)
- Data collected and reporting tools
- Approach (e.g., capacity building, evidence building, education, training, or therapeutic services)
- Number of grantees
- Target population

For research and surveys, documentation also included:

The process for obtaining data

Step 3: Classify categories of results across initiative activities

In Step 3, the intended outcomes of each activity are clearly identified and organized into broad categories.

Information about expected outcomes may be found in program descriptions, statements of work (SOW), notices of funding opportunities (NOFOs), program guidance documents, authorizing legislation,

and other documents that describe the goals and purposes of each activity.

Step 3 Box. Classifying categories of results related to the HHS Overdose Prevention Strategy

	Program Types	Direct interventions supported by grants and awards
	Capacity Building	Programs focused on strengthening systems for surveillance or service delivery
	Evidence Building	Programs focused on research to develop new therapies and clinical guidance or identify best practices
	Payment Reform	Programs focused on changing reimbursement structures to incentivize high-quality care
8/-	Public Awareness/Education	Programs focused on communication and outreach to spread awareness and knowledge
[ĀĒ] AAA	Training	Programs focused on training health care workers and researchers to increase workforce capacity
9	Therapies	Programs focused on improving and delivering clinical treatment
	Clinical Guidance	Resources for providers on best practices
	Research and Reports	Statistical briefs, environmental scans, and journal articles
= -×	Public Policies	Official rules issued by HHS agencies regarding medical practices, certification, and consumer protection

Step 4: Document the actual progress towards each activity's stated goals and objectives

Step 4 involves examining information on the actual results of each activity. Information about the results achieved by the activities is typically found in progress reports, reports to congress, performance reports, and evaluation reports. Interviews with key program staff can also inform this process.

Step 4 Box. Documenting the actual outputs and outcomes of each program

Questions used in interviews with key staff to help identify activity results:

- How are (initiative/your agency's initiatives)' goals and objectives aligned with the Overdose
 Prevention Strategy's goals and objectives? [FOR PROGRAMS THAT PREDATE THE HHS OVERDOSE
 PREVENTION STRATEGY: Have the initiative goals and objectives changed with the specific
 implementation of the HHS Overdose Prevention Strategy?] (Alignment)
- How do you measure success in (initiative/your agency's initiatives)? To date, what has been the
 effectiveness of (initiative/your agency's initiatives)? (Effectiveness)
- Have there been unintended consequences/outcomes of (initiative/your agency's initiatives)? If so, please describe. (Unintended Consequences)
- Was an external evaluation conducted of [INSERT NAME OF ACTIVITY] or is an independent evaluation underway?

Step 5: Select and apply the evaluation domains

Step 5 involves two parts. The first is to determine which of the evaluation domains are relevant based on the level of available information and their relationship to the overall goals of the initiative defined in Step 1. The second is to determine the extent to which both the initiative focus areas as well as the overall initiative itself meet the definition of each domain using a scale, such as high, medium, or low. It can also be helpful, especially for initiatives to which this approach is applied retroactivity, to have a scale category for use when the information available about progress towards each activity's stated goals and objectives is insufficient to assess the results.

Selecting the applicable evaluation domains:

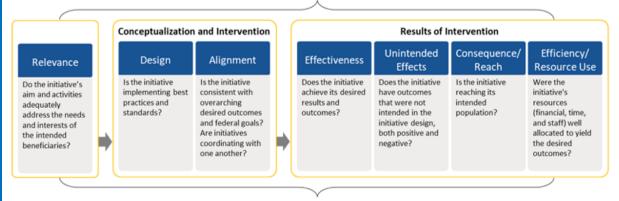
Starting with the list of evaluation domains shown in Table 2, evaluators should determine, based on the available information gathered in Steps 1-4 for which domains there is enough information to assess whether or not the initiative was successful. Beginning with these 11 domains, evaluators should examine the relevance of each criterion to their specific information needs. Step 5 Box (below) describes the results of this process when applied to the HHS Overdose Prevention Strategy.

Table 2: 11 Evaluation Domains			
#	Domain	Description	
1	Relevance	Aims and activities are consistent with the needs, requirements, culture, interests, or circumstances of the intended beneficiaries. Activities can be easily mapped to the HHS mission, Strategic Plan or stated initiative objectives.	plementation of
2	Design	Activities and implementation are consistent with relevant theoretical principles, best practices, standards, and/or laws and/or implementation is timely.	in and in
3	Alignment	There is coherence across activities, activity groupings (Step 2) and categories of results (Step 3). Initiative is consistent and coordinated with larger initiatives, related interventions, aims of federal and other partners, and/or interconnected problems.	Domains that address the conceptualization and implementation of an initiative (process)
4	Replicability	Components, activities, or the underlying model or principles can be duplicated or adapted to another context.	nat addre
5	Experience	Activities are delivered in a way that facilitates constructive and culturally responsive interaction and that promotes consistent and systematic fair, just, and impartial treatment of all individuals.	Domains th
6	Effectiveness	Initiative achieves desired results, outcomes, or objectives both individually and when examined as a group.	(6
7	Unintended Effects	Initiative is associated with unintended positive consequences and/or the absence of negative consequences.	ults (outcomes)
8	Consequence /Reach	Initiative yields significant benefits to intended beneficiaries and other relevant populations and/or reaches a significant number of its intended target (i.e., people or locations).	itive results (
9	Equity	Opportunities, experiences, benefits, and results are fair and just, with particular consideration of populations who have historically been disproportionately affected.	address Initia
10	Efficiency/ Resource Use	Funding, personnel, and materials are used economically; funding, personnel, and materials are sufficient to implement the initiative; and/or initiative yields an appropriate level of benefit relative to the funds, personnel, and materials required.	Domains that address Initiative res
11	Sustainability	Initiative has long-term benefits, and/or activities have been institutionalized.	

Step 5 Box. Applying the Evaluation Domains to the HHS Overdose Prevention Strategy

Based on qualitative analysis of the information in the Inventory of HHS Overdose Prevention Activities and other sources, nine of the 11 evaluation domains were applicable: Relevance, Design, Alignment, Effectiveness, Unintended Effects, Consequence/Reach, Equity, Efficiency/Resource Use, and Sustainability.

Equity: How well does the initiative address the needs of all affected populations?



Sustainability: Can an initiative continue after the initial funding period?

Has the initiative been incorporated into standard practice?

From the *Conceptualization and Implementation* (Process) category, three evaluation domains were appropriate for evaluation of the HHS Overdose Prevention Strategy: 1) Relevance, 2) Design, and 3) Alignment. The category – and the three domains – is intended to address how the effort was created and delivered. It can be evaluated on its own or in relation to the *Initiative Results* (Outcomes) category.

The domains of Replicability and Experience were excluded because they were either relatively less relevant to the initiative (e.g., the level of replicability was not the core evaluation question for this project) or unavailable due to lack of easily accessible data (e.g., data required to measure the experience domain needs comprehensive and detailed data collection methods such as community outreach).

From the *Intervention Results* (Outcomes) Category, all six domains were applicable: 6) Effectiveness, 7) Unintended Effects, 8) Consequence/Reach, 9) Equity, 10) Efficiency/Resource Use, and 11) Sustainability. These domains are intended to assess whether the initiative achieved the desired results and if the initiative had any positive or negative influence on the intended population.

How Well Did the Evaluation Domains Work as a Framework for a Cross-HHS Evaluation?

Applying the evaluation domains to the HHS Overdose Prevention Strategy involved an intensive review of publicly available evidence, the methods of which are presented below. The remainder of this section explains the decision-making process used to determine the relevance of each of the evaluation domains for this test case. A detailed table outlining the research questions, analytic methods, and the data sources used to inform each evaluation domain can be found in **Appendix B**.

Relevance

An initiative is considered relevant if its aims and activities address the needs and interests of the intended beneficiaries. To identify key public health needs related to the overdose crisis and understand best practices to address overdose, a general search was performed on HHS websites to gather statistics about trends in overdose. A literature review of peer-reviewed systematic reviews and meta-analyses focused on one or more domains of the HHS Overdose Prevention Strategy. PubMed and Cochrane Review were used to locate systematic reviews published from January 1, 2016 to July 15, 2022 in the United States with one of the following phrases:

- 1. "Primary prevention" AND Overdose;
- 2. "Evidence-based treatment" AND Overdose;
- 3. "Harm reduction" AND Overdose: or
- 4. "Recovery support" AND Overdose.

After completing the searches, a structured abstract review was performed to determine whether the article provides empirical data or expert recommendations on preventing overdoses or overdose deaths. Three reviewers first reviewed three sample abstracts together to ensure interrater reliability, then split the abstracts to review and identify relevant articles. Selected articles were then split among the reviewers, who reviewed the articles in their entirety and summarized key findings.

Searches of the websites of the American Medical Association (AMA) and American Society of Addiction Medicine (ASAM), National Harm Reduction Coalition, and Community Anti-Drug Coalitions of America (CADCA) were conducted for position papers that discuss their priorities for overdose prevention programs, policies, and research, and summarized key findings. These organizations were prioritized to understand the clinical and advocate perspectives.

Design

Evaluation of an initiative's design considers whether it is implementing best practices and standards. The same literature review conducted to evaluate relevance also yielded information for design. An additional literature review was conducted, using the process described under relevance, adding the terms "evidence" OR "best practice." Articles, clinical guidance, and collated recommendations v,v,vi were then reviewed. Interventions identified as best practices are included in Exhibit 6.

Exhibit 6: List of Evidence-Based Interventions for Overdose Prevention

Targeted Naloxone Distribution

Medication Assisted Treatment (MAT)

Academic Detailing (structured visits to health care providers to provide training on responsible prescribing)

Eliminating Prior Authorization Requirements for MAT

Screening for Fentanyl in Routine Clinical Toxicology Testing

911 Good Samaritan Laws

Naloxone Distribution in Treatment Centers and Criminal Justice Settings

MAT in Criminal Justice Settings and Upon Release

Initiating Buprenorphine-based MAT in Emergency Departments

Syringe Service Programs (SSPs)

Naloxone Distribution in Emergency Departments

Naloxone Access Laws

Opioid Use Disorder (OUD) Treatment Training

Guideline for Prescribing Opioids for Chronic Pain

Person-centered medication management

Extended Telehealth Flexibilities for Prescribing Buprenorphine for OUD

Supervised Dosing with a Long-Acting Opioid Medication

Finally, the extent to which HHS overdose prevention activities incorporated best practices using information from the Inventory of HHS Overdose Prevention Activities on the approach and focus of activities was assessed.

Alignment

Alignment considers whether an initiative is consistent and coordinated with, in this case, the HHS Overdose Prevention Strategy. Alignment was evaluated using a two-pronged approach, a document review, and key informant interviews. First a document review was conducted of the HHS Overdose Prevention Strategy to identify priorities for overdose prevention programs, and the Inventory of HHS Overdose Prevention Activities to identify the focus areas of activities. Interviews with HHS staff involved with key initiatives to gauge their perspectives on the alignment across HHS overdose prevention activities were conducted using an interview guide with a core set of questions that also allowed interviewers to probe and add customized questions as relevant (see **Appendix C**). To recruit participants, directors of major HHS overdose prevention activities were identified and contacted via email with contractor support. Interviews lasted between 30 and 45 minutes. The contractor's senior researcher led each interview, supported by a mid-level staff taking notes. Interviews were recorded and transcribed with the permission of participants. Notes and transcripts were used to conduct thematic qualitative analysis.

Effectiveness

An initiative is considered effective if it achieves its desired results, outcomes, or objectives. VIII To understand the desired results interview respondents were asked how they measure success in their programs, and how they perceived the effectiveness of their activities on overdose prevention. The Inventory of HHS Overdose Prevention Activities was also reviewed, and the objectives laid out by the respective activities. Agency websites and PubMed were additionally searched, using the name of the program in quotations, to find reports or articles on the performance and outcomes of programs

focused on overdose prevention. Searches focused on published evidence demonstrating that programs are reducing non-fatal overdoses or overdose deaths.

Unintended Effects

Unintended effects are outcomes that are not planned in an initiative's design or implementation, whether positive or negative. This question was explored through interviews as described under alignment. Although relevant to the goals of the initiative that was evaluated, few HHS staff reported positive (e.g., more interest from small companies to develop alternative pain therapies) or negative (e.g., social media backlash to a communication campaign) unintended consequences. As more data become available for and rigorous evaluations are conducted of overdose prevention programs, these evaluations can also explore any unintended consequences of activities.

Consequence/Reach

Consequence, which the team considered as reach (i.e., level of service coverage), is an indicator of whether an initiative is reaching the populations with the most need of the services provided.* This criterion was addressed through interviews as described under alignment.

Equity

Equity is a measure of the degree to which opportunities, experiences, benefits, and results are fair and just, with particular consideration to populations who have historically been underserved or disproportionately affected by the problem or issue that the initiative was designed to address. Health equity is a key principle of the HHS Overdose Prevention Strategy and HHS broadly. *i To explore the extent to which HHS overdose prevention activities are reaching all persons, including the ways in which different populations are uniquely affected, the Inventory of HHS Overdose Prevention Activities was reviewed to determine whether HHS programs are available to all affected populations and geographies. Through the interviews with HHS staff described under alignment, the team further explored how HHS Op/Staff Divisions are addressing health equity in their programs.

Efficiency/Resource Use

Resource use, which the team considered as efficiency, measures whether the funding, time, and effort to implement an initiative yield the desired outcomes. Xii While the team's ability to quantitatively assess efficiency was limited due to lack of public data, HHS' total investment in overdose prevention initiatives was summed up based on information from the Inventory of HHS Overdose Prevention Activities. Additionally, the question of how HHS staff define efficiency and return on investment (ROI) for programs was explored through the interviews with HHS staff as explained under alignment to learn program staff perspectives on whether HHS overdose programs are efficient and offering value for the investments.

Sustainability

Sustainability, which the team also framed as institutionalization, is an indicator of whether an initiative can be carried out after the initial funding period, or the extent to which it is incorporated into standard

practice (e.g., institutionalized). XIII While the team was unable to assess the long-term sustainability of HHS activities given the limited time frame of the analysis, the extent to which HHS overdose prevention activities were codified into permanent programs, regulations, or public policies was explored. This was done relying on the Inventory of HHS Overdose Prevention Activities and interviews with HHS staff about their perceptions of the sustainability and institutionalization of the activities, programs, or projects that they oversaw.

Discussion

The cross-HHS evaluation framework was created to assess the combined effect of a range of activities, programs, and projects focused on a common overarching goal. While this framework can be applied to smaller or less complicated initiatives, its greatest value comes in providing an approach for the evaluation of complex, multi-facetted initiatives. Specifically, findings from the application of this approach to the HHS Overdose Prevention Strategy (**Appendix D**) show the approach to be a promising one for producing evidence needed to understand and improve HHS' ability to achieve its broad goals and objectives.

However, like most evaluative work, measurement is best when considered at the start of an initiative. A limitation of this pilot was that the framework was developed and applied retroactively to an ongoing initiative and this accounts, at least in part, for the disparity of results across a heterogenous effort. ASPE sees the evaluation domains outlined here as a solid foundation which can be planned into when they are being designed. This pilot identified a generalized need to:

- Increase the capacity of grant programs to:
 - o Develop standardized measures (where possible) to allow for aggregation, and
 - Collect intermediate and long-term outcome data tied to specific programs.
- Improve availability of high-quality program administrative data especially related to recipient demographics; and
- Improve models for predicting need and risk to improve our ability to measure Consequence/Reach.

Next steps for this work are to apply this evaluative approach to other cross-HHS program areas with the goal of further refining the evaluation domains for broader use. In doing this we can continue to test the suitability of this approach, the evaluation domains, and the framework for other areas of work and continue to refine our methods for large, comparable but distinct efforts addressing needs around HHS.

Appendix A: Matrix of Initiative Selection Characteristics

Criteria	Question(s)	Metrics	
Alignment with HHS Priorities	Is this topic an established, current Administration priority? Is it aligned with Administration/HHS aims and interconnected problems (e.g., priority populations and systems)?	Representation in HHS evaluation plans and strategic plans, executive orders, HP2030 objectives, performance measures, messages from the Health Secretary, and/or budgetary documents; # priority populations covered; # or size of grants issued; Addresses interconnected problems (e.g., inequity)	
Maturity	How long has the topic been an HHS priority and how long has there been a concerted effort to address the topic? Are there operational programs and policies that address the topic?	Length of time initiative/portfolio underway and fully implemented – target at least 3-5 years to allow time for the realization and documentation of results.	
Cross-HHS representation	Is initiative/portfolio represented across HHS agencies?	# Divisions involved (must be at least half of Op/Divs); engagement of multiple departments and divisions within involved agencies; # relevant programs/initiatives per agency – prioritize initiatives/portfolios that engage majority of HHS Divisions	
Clear problem statement	Is there a clearly articulated problem or issue to be resolved and is progress measurable? Are the long-term HHS impact and target outcomes clearly identified and are the proposed approaches towards achieving these clearly defined? Are there a manageable number of goals and outcome areas that make sense within a framework that can be applied across agencies?	Well-defined and measurable outcomes for HHS approach; Clear implementation plan and/or logic model(s) connected to outcomes; Number of goals and outcome areas reasonable in context of evaluation planning; Identified project(s) with clear aims directly related to the problem	
Information availability	Quality and availability of aggregate reports (e.g., annual reports, progress reports, commissioned studies, process or outcome evaluation reports) to draw on for purposes of evaluation. Do we know if high-quality reliable and valid data (e.g., performance data, evaluation findings) are available across relevant activities? Is data collected for relevant indicators with sufficient frequency and completeness?	Sufficient documentation available to assess initiative/portfolio. If reviews or evaluations have been carried out, are the reports available and instruments available? Sufficient data available to assess initiative/portfolio. Are there readily identifiable and accessible data related to the relevant programs and policies under the portfolio/initiative and are those data reliably collected and valid? Are there performance measurement data available? Are there sufficient, high-quality data across the portfolio/initiative to capture the main predictors and targeted outcomes for evaluation purposes? Are there identifiable challenges to accessing data?	

Appendix B: Research Questions and Analytic Approaches: Overdose Prevention Strategy Test Case

Evaluation Questions, Approaches, and Data Sources				
Research Question	Analytic Method	Data Source		
Relevance				
What are the key public health needs in addressing the overdose crisis?	Literature Review	Peer Reviewed Literature: PubMed, Google Scholar, Cochrane Review		
	Environmental Scan, Document Review	HHS agency websites, strategic plans and reports of federal agencies related to overdose prevention, position papers of the American Medical Association (AMA) and American Society of Addiction Medicine (ASAM)drug and overdose prevention advocacy groups (e.g., National Harm Reduction Coalition and Community Anti-Drug Coalition)		
To what extent are HHS' Overdose Prevention activities designed to address these needs?	Environmental Scan, Document Review	Inventory of HHS Overdose Prevention Activities		
Design				
What are best practices for overdose prevention?	Literature Review	Peer Reviewed Literature: PubMed, Google Scholar, Cochrane Review, clinical guidelines (AMA and ASAM)		
Do projects reflect the theoretical principles, standards, and best practices?	Environmental Scan, Document Review	Inventory of HHS Overdose Prevention Activities		
Alignment				
To what extent are an initiative's goals and objectives	Environmental Scan, Document Review	Inventory of HHS Overdose Prevention Activities		
aligned with the Overdose Prevention Strategy's goals and objectives?	Qualitative Analysis	Interviews with HHS staff		
Effectiveness				
Is there evidence that HHS initiatives are reducing non-fatal overdoses or overdose deaths?	Environmental Scan, Literature Review	Evaluation reports, Inventory of HHS Overdose Prevention Activities		

Evaluation Questions, Approaches, and Data Sources				
Research Question	Analytic Method	Data Source		
Do HHS staff perceive HHS Overdose Prevention Initiatives as being effective?	Qualitative Analysis	Interviews with HHS staff		
To what extent are HHS reports and surveys informing public health research and policy analysis?	Environmental Scan, Literature Review	PubMed, Google Scholar, agency websites		
Unintended Effects				
To what extent are initiatives realizing outcomes that are not anticipated based on an initiative's design or implementation?	Qualitative Analysis	Interviews with HHS staff		
Consequences/Reach				
To what degree is an initiative reaching the populations in need of the services provided?	Qualitative Analysis	Interviews with HHS staff		
Efficiency				
What are HHS' total investments in Overdose Prevention Initiatives?	Environmental Scan, Document Review	Inventory of HHS Overdose Prevention Activities		
Is there evidence of return on investment (ROI) for HHS Overdose Prevention Initiatives?				
How do HHS officials define ROI? What is the perceived ROI for HHS Overdose Prevention Initiatives?	Qualitative Analysis	Interviews with HHS staff		
Equity				
Is there evidence of differential effects of HHS Overdose Prevention Initiatives by key subgroups of interest (based on answers to previous questions)?	Is there evidence of differential effects of HHS Overdose Prevention Initiatives by key subgroups of interest (based on answers to previous questions)?	Is there evidence of differential effects of HHS Overdose Prevention Initiatives by key subgroups of interest (based on answers to previous questions)?		
To what extent are HHS Overdose Prevention Initiatives available to populations and geographical areas that have been underserved (based on answers to previous questions)?	To what extent are HHS Overdose Prevention Initiatives available to populations and geographical areas that	To what extent are HHS Overdose Prevention Initiatives available to populations and geographical areas that have been underserved (based on answers to previous questions)?		

Evaluation Questions, Approaches, and Data Sources				
Research Question	Analytic Method	Data Source		
	have been underserved (based on answers to previous questions)?			
How are HHS agencies addressing equity within their programs?	How are HHS agencies addressing equity within their programs?	How are HHS agencies addressing equity within their programs?		
Sustainability and Institutionalization				
Are HHS Overdose Prevention Initiatives codified into permanent programs, regulations, or public policies?	Environmental Scan, Document Review	Inventory of HHS Overdose Prevention Activities, agency websites, congress.gov, National Council of State Legislatures (NCSL) legislative databases, Harvard Catalyst's Policy Atlas		

Appendix C: Interview Discussion Guide: Overdose Prevention Example

Introduction	Welcome. Thank you for taking the time to participate in today's interview. My name is [INTERVIEWER'S NAME]. I will be leading this discussion today, and I'm joined by my colleague [NOTETAKER'S NAME] who will be taking notes while we talk.
Consent	Before we begin the discussion, I want to review our informed consent statement. It explains the purposes of the project and why we are conducting this interview. It also explains your rights as a participant in this project.
	First, a little background on the project:
	NORC at the University of Chicago is a non-profit research organization, working with the Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the U.S. Department of Health and Human Services. ASPE advises the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science; and provides advice and analysis on economic policy. For this project, ASPE has contracted with NORC to develop a comprehensive plan for documenting HHS evidence-building activities and evaluating cross HHS initiatives. This will involve informing HHS' approach to tracking progress towards and updating it Evidence-Building Plan as well as developing and testing a model for cross HHS evaluation.
	Our team is currently piloting the model by conducting a cross-HHS assessment of Overdose Prevention work since the passage of the Comprehensive Addiction and Recovery Act in 2015, with the goal of looking across HHS at the varied activities conducted on this topic to get a broad picture of HHS's role and focus. As part of this pilot, we are conducting interviews with agency leads to take a deeper look at select, relevant programs and initiatives to understand their specifi goals and how well you feel they are achieving these goals.
	We expect that the interview will last less than 60 minutes. With your permission, we would like to record the interview to ensure that our notes are complete. We are the only people who will be able to access recordings, and we will destroy the recordings once analysis is complete in the next few months.
	I also want to make you aware of the benefits and risks of participating:
	There are no known risks to you for participating. Your participation in the interview is completely voluntary. Also, you can choose to skip any questions. You can stop participating at any time, and there are no consequences for you if you want to stop. If you would like to stop the discussion or recording at any point, just let me know.
	As in any study, there is a risk of possible loss of privacy. NORC is committed to keeping your personal information private. We plan to highlight key themes and other feedback provided by you and other interview participants in a summary report to ASPE. This report will include a list of the agencies and organizations who participated in interviews, but we do not plan to use information such as your name. If we do, we will obtain your express consent before sharing.
	Do you have any questions at this time?
	[ANSWER QUESTIONS]
	[OBTAIN VERBAL CONSENT TO PARTICIPATE & RECORD]:
	Do you voluntarily agree to participate in this study?
	Do we have your permission to record the interview?

[START RECORDING]

General Questions

• Are you familiar with the framework of the HHS Overdose Prevention Strategy? (If yes, proceed to next question.)

The HHS Overdose Prevention Strategy was released in October 2021 and was the culmination of the effort of an interagency workgroup of experts in overdose prevention and substance use disorders (SUDs) to summarize evidence and best practices. The four priority areas are: primary prevention, harm reduction, evidence-based treatment, and recovery support.

- How is (initiative/your agency's initiatives)' goals and objectives aligned with the Overdose
 Prevention Strategy's goals and objectives? [FOR PROGRAMS THAT PREDATE THE HHS OVERDOSE
 PREVENTION STRATEGY: Has the initiative goals and objectives changed with the specific
 implementation of the HHS Overdose Prevention Strategy?] (Alignment)
- Which priority or priorities are (initiative/your agency's initiatives) focused on?
- Are projects aims and activities consistent with the needs, requirements, culture, interests, or circumstances of the intended beneficiaries and the research community? Do you feel you are reaching the intended beneficiaries? (Relevance and Consequence/Reach)
- To what extent are you incorporating evidence-based practices in (program/your agency's programs). (Design)
- How is your agency addressing equity within (initiative/your agency's initiatives)? (Equity)
- How do you measure success in (initiative/your agency's initiatives)? To date, what has been the effectiveness of (initiative/your agency's initiatives)? (Effectiveness)
- Have there been unintended consequences/outcomes of (initiative/your agency's initiatives)? If so, please describe. (Unintended Consequences)
- How do you define efficiency in (initiative/your agency's initiatives)? What is your perception of the efficiency of (initiative/your agency's initiatives)? (Resource Use)
- How do you define return on investment?
- How is this work coordinated with work in other parts of HHS? Other Federal agencies? Other non-federal organizations
- Does (your program/your agency's program grant) have any requirements, expectations, or deliverables related to sustainability? (Sustainability)

Questions on Data and Evaluation Capacity (Excluding NCHS and OASH)

- Generally speaking, what data do grantees collect for (initiative/your agency's initiatives)? How is that data reported? How is it used? How is it shared with others (e.g., made public, provided to researchers)?
- How, if at all, are program performance data (e.g., [INSERT PERFORMANCE METRICS SYSTEM, i.e., GPRA-required data collected via SPARS FOR SAMHSA]) made available to the public?

- If not publicly available, can members of the public request/obtain these data for research purposes?
- In not publicly available, how if at all does [INSERT NAME OF AGENCY] make program performance data available within and across HHS agencies?
- Was an external evaluation conducted of [INSERT NAME OF INITIATIVE] or is an independent evaluation underway?
- If the evaluation report is not publicly available, how were/are/will evaluation results shared within and across HHS agencies and the public?

Participant-specific questions:

AHRQ, NCHS, and SAMHSA

- How are you leveraging your databases/surveys to inform programs and policies on overdose prevention? Which database(s)/survey(s) do you think can contribute most to research on overdose prevention?
- To the extent that you know, how are your statistical briefs/surveys are being used in research on overdose prevention? Can you share an example or two of the use of your briefs or surveys in research or practice? Are there additional ways that you would like this information to be used?
- What are some improvements that can be made in how overdoses are measured and reported?
- Are there additional data that HHS could or should be collecting and publishing that would advance work on overdose prevention?
- How are overdose measures being incorporated into initiatives across HHS agencies?

Appendix D: Applying the Evaluative Domains to the HHS Overdose Prevention Strategy

The <u>evaluators retrospectively applied</u> the nine relevant domains to the HHS Overdose Prevention Strategy and its four program areas and rated each priority area as *high*, *mixed*, *low*, or *unable to assess* based on the analysis of the inventory of HHS Overdose Prevention Initiatives and interviews with HHS staff.

#	Domains	Primary Prevention	Harm Reduction	Evidence-Based Treatment	Recovery Support
1	Relevance	High	High	High	High
2	Design	High	High	High	Unable to Assess
3	Alignment	High	High	High	High
4	Effectiveness	Mixed	Mixed	Mixed	Unable to Assess
5	Unintended Effects	Unable to Assess	Unable to Assess	Unable to Assess	Unable to Assess
6	Consequence	Unable to Assess	Unable to Assess	Low	Unable to Assess
7	Equity	Mixed	Mixed	Mixed	Unable to Assess
8	Efficiency	Unable to Assess	Unable to Assess	Unable to Assess	Unable to Assess
9	Sustainability	Mixed	Mixed	Mixed	Unable to Assess

When the nine domains were applied to the HHS Overdose Prevention Strategy and its four program areas, the evaluators were able to find evidence of 1) Relevance, 2) Design, and 3) Alignment for three of the HHS Overdose Strategy strategic priority areas: Primary Prevention, Harm Reduction, and Evidence-Based Treatment. For these three HHS Overdose Prevention Strategy areas, the evidence was mixed for 4) Effectiveness, 7) Equity, and 9) Sustainability. The team was not able to assess 8) Efficiency or 5) Unintended Effects for all four Overdose Prevention strategic priority areas. Recovery Support proved to be a challenging area to evaluate as the evaluators were only able to address 1) Relevance and 3) Alignment, but not any of the other domains.

References

¹ H.R.4174 - 115th Congress (2017-2018): Foundations for Evidence-Based Policymaking Act of 2018. (2019, January 14). Retrieved August 21, 2022, from https://www.congress.gov/bill/115th-congress/house-bill/4174

- ^{iv} Carroll, J.J., Green, T.C., and R.K. Noonan (2018). *Evidence-Based Strategies for Preventing Opioid Overdose: What's Working in the United States*. Centers for Disease Control and Prevention (CDC). Retrieved August 21, 2022, from https://www.cdc.gov/drugoverdose/pdf/pubs/2018-evidence-based-strategies.pdf
- Smith, T.M. (2021). 8 keys to end the nation's drug-overdose epidemic. American Medical Association (AMA). Published April 30, 2021. Retrieved August 21, 2022, from https://www.ama-assn.org/delivering-care/overdose-epidemic/8-keys-end-nation-s-drug-overdose-epidemic
- vi Public Policy Statements | American Society for Addiction Medicine (ASAM) (n.d.). Retrieved August 21, 2022 from https://www.asam.org/advocacy/public-policy-statements.
- vii Teasdale, Rebecca M. (2021). Evaluative criteria: an integrated model of domains and sources. *American Journal of Evaluation*, *42*(3), 354-376. Retrieved August 21, 2022, from https://journals.sagepub.com/doi/abs/10.1177/1098214020955226

- xi Overdose Prevention Strategy. (n.d.). Retrieved August 19, 2022, from http://www.hhs.gov/overdose-prevention/primary-prevention
- xii Teasdale, Rebecca M. (2021). Evaluative criteria: an integrated model of domains and sources. *American Journal of Evaluation*, *42*(3), 354-376. Retrieved August 21, 2022, from https://journals.sagepub.com/doi/abs/10.1177/1098214020955226

ii Ibid

iii Ibid

viii Ihid

ix Ibid

x Ibid

xiii Ibid