**Longitudinal Program Evaluation of the U.S. Department of Health and Human Services National Action Plan to Prevent Healthcare-Associated Infections: Methods Appendix**

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## Introduction

In this appendix, we describe in more detail the methodologies used in evaluation described in this special issue of *Medical Care*. The evaluation team developed these methodologies in 2010-2011 during the first two years of the evaluation of the Department of Health and Human Services’ (HHS’s) *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination*. The methodologies are intended to inform the Context-Input-Process-Product (CIPP) evaluation model and the HAI prevention system framework described in Kahn et al.1

To conduct the CIPP evaluation, we implemented a multi-level, multi-method strategy. The multiple levels pertain to the various levels of governmental jurisdiction affected by HAIs and potentially affected by the HAI Action Plan, including HAI reduction efforts attempted or conducted by federal agencies, regions, states, and local entities. To capture the rich diversity of interventions spanning these levels, we implemented six key methodologies:

* A **document and** **literature review**, intended to identify and gather internal agency documents and published literature related to the ongoing implementation of the Action Plan and all related Action Plan activities. The team used information from the documents and literature to describe plan implementation activities among HHS working groups and to gauge the extent to which Plan activities had percolated into the published research literature on HAIs, patient safety, and related topics in health services and clinical research.
* A **national** **Program and Project Inventory (PAPI)**, intended to document the breadth and scope of Action Plan programs and projects; characterize the amount and types of collaboration and interaction among activities; and identify gaps, redundancies, and potential areas of complement among activities.
* **National-level internal stakeholder interviews**, intended to document progress on Action Plan goals and timelines, to identify implementation issues, and identify lessons learned for internal stakeholder perspectives at multiple levels, including national, state, and local implementation activities.
* **National-level external stakeholder interviews,** intendedto provide a broad perspective on an array of issues related to the context of the Action Plan’s development and the subsequent inputs associated with its initiation and implementation.
* **Regional activities analysis,** including interviews and document review, intended to examine HHS regional HAI activities and their role in mediating effects of the Action Plan from the Federal to state and local levels.
* **Assessment of data sources**,intended to identify, profile, and analyze the strengths and weaknesses of the HHS data systems available for HAI surveillance, and **longitudinal analyses of HAI rates**, intended to provide a comprehensive understanding of HAI rates in the U.S., and whether and how observed rates differ across the various HHS data systems.

The sections that follow describe the motivation for each of the methodologies and the data collection and analytical methods used as well as any challenges or limitations associated with each method.

## Document and Literature Review

The document and literature review was used to inform the context, input, and process evaluations. For ease of terminology, “document” here refers specifically to the non-peer-reviewed items that were recommended by stakeholders or collected from non-peer-reviewed sources, such as newsletters. “Literature” refers specifically to articles published in peer-reviewed journals. To avoid confusion, these are known collectively as ”Document and Literature Items,” and referred to briefly as “items.”

Documents reviewed included internal agency material (such as HHS workgroup meeting minutes, presentations, and internal reports) and published literature (such as peer-reviewed articles and published agency reports). We used the minutes, presentations, and internal reports to inform the evaluation team’s understanding of how HHS was prioritizing and implementing Action Plan goals and activities. We used peer-reviewed articles and published agency reports to identify how external sources (i.e., peer-reviewed scientific and implementation literature) and sources internal to HHS documented and disseminated HAI materials. The document and literature review informed the evaluation team of relevant HAI-related content and action plan activities. Reviewing and cataloging these materials also allowed the evaluation team to establish an archive of references and a valuable source of contextual information to support other components of the process evaluation.

Once catalogued, the document and literature review served as a repository of information documenting how individuals inside and outside of HHS characterized progress associated with HAI Action Plan activities. Information from the review informed the CIPP evaluation.

### Methods for Conducting Literature Review

The document and literature review identified items from key sources to code for relevance to the system properties and the four system functions for the 3-year window when the evaluation team conducted data gathering and analysis (2010-2012). The evaluation team also conducted an abstraction of Working Group and Steering Committee meeting minutes to identify participants and activities discussed in these key committees. These meeting minute abstractions characterized progress of committee activities over time, and the system functions and system properties addressed by each of those activities.

**Inclusion and Exclusion Criteria.** We included the following items in our document and literature review:

* Items that provide historical context for the Action Plan
* Items that provide information about the development of the Action Plan
* Items related to the implementation of the Action Plan (e.g., Steering Committee and Workgroup meeting minutes, relevant regulation, policy, and legislation)
* Items that resulted from Action Plan-related activities (e.g., tools/toolkits, published reports or evaluations from Agency for Healthcare Research and Quality (AHRQ) grantees or state HAI grantees)

Table 1 shows the sources used in the review.

**Table 1: Sources Used in the Document and Literature Review**

| **Category** | **Sources** |
| --- | --- |
| Committee and working group minutes | Steering Committee and Working Groups minutes, provided by OASH |
| HHS newsletters | * AHRQ newsletters: Consumer Assessment of Healthcare Providers and Systems (CAHPS) Connection; Effective Healthcare Program Update; Evidence-Based Practice Update; Grant Announcements and Funding Opportunities; Medical Errors and Patient Safety Update; National Guideline Clearinghouse (NGC) Updates; National Health Care Quality and Disparities Update; National Quality Measures Clearinghouse (NQMC) Updates; Patient Safety Network Update; Patient Safety and Health Information Technology E-Newsletter; Patient Safety Organizations Update; Quality Information and Improvement Update; Research Training and Education Update
* Assistant Secretary of Health (ASH) HAI email alerts
* Assistant Secretary for Public Affairs
* CDC—Staying Connected for CDC Partners
* CMS Alerts on Medicare, and Regulations and Guidance, Weekly Digest Bulletin
* HHS newsletters on the ARRA
* NIH—Research Matters, Highlights and Headlines
* HHS Daily Digest Bulletin
 |
| Updates | * Office of the Inspector General
* GAO—Reports about Health Care
 |
| Peer-reviewed literature | * Weekly review of PubMed search for HAI-related information, search restricted to publications from September 1, 2010 to June 30, 2012
* Scan of Tables of Contents for *New England Journal of Medicine*, *Annals of Internal Medicine*, and *Journal of the American Medical Association* from September 1, 2010 to June 30, 2012
 |

**Categorizing Documents, Literature, and Meeting Minutes According to the System Framework.** All documents, literature, and meeting minutes identified as relevant and reviewed came from one of three sources: scientific journals, government agencies, or private organizations. All articles came from peer-reviewed, English-language journals, and articles were only included if the setting of the study or discussion included the United States. Internal documents were provided by an HHS agency. The large majority of non-peer-reviewed documents came from government agencies; only a few reports or documents identified as relevant were produced by private organizations (for example, the Association for Professionals in Infection Control and Epidemiology).

The team regularly scanned these sources for items that met the inclusion criteria and relevancy requirements. The team developed coding categories to guide assignment of documents, literature, and meeting minutes to components of the system framework. We based the coding categories for the document and literature review on the HAI Action Plan Evaluation Framework described in Kahn1 in this issue. The review team established a standardized set of definitions (described in Table 2) and a coding system for indicating whether items addressed each of the evaluation framework categories: significantly (A code), moderately (B code), minimally (C code), or not at all (no code).

**Table 2: Definitions and Examples of Coding Categories**

| **Background System Property** | **Definitions for Categories, Examples of Data** |
| --- | --- |
| Policy Context | Defined as legislative action, or description of a situation leading to legislative action. *Example: A change to CMS regulations* |
| National Action Plan Implementation and Progress | Defined as describing Action Plan goals or objectives, strategies for meeting those objectives, and progress toward meeting those objectives. Explicit mention of the Action Plan may merit A, B or C coding depending on information provided.*Example: HHS Steering Committee and Working Group Meeting Minutes coded as A.* |
| Prioritization | Defined as an explicit change in focus, a new direction, or mention of making something a priority.*Examples: Selection of types of infections, targets and metrics, and additional healthcare settings.* |
| Coordination and Alignment | Defined as the coordination of prevention activities across HHS agencies, especially reducing redundancies and inconsistencies between multiple data monitoring systems.(Note: may overlap with Interoperability, within the HAI Data and Monitoring System Function.)  |
| Accountability and Incentives | Defined as a mechanism to reward HAI prevention or punish failure to prevent - usually through payment.*Example: CMS’ ‘Never Events’.* |
| Stakeholder Engagement | Defined as references to, or inclusion of, comments from stakeholders, especially those outside HHS. May include outreach and messaging.(Note: may overlap with Dissemination Mechanisms within the Infrastructure Function). |
| Resources | Defined as money or a service (i.e. technical assistance) being provided by HHS agencies. |
| ***HAI Data and Monitoring*** | ***Definitions for Categories, Examples of Data*** |
| Metrics | Defined as process and outcome measures, measurement definitions, and standards. *Example: Specification of metrics.* |
| Interoperability | Defined as increasing the ability of different HAI data collection and repository systems to exchange data and “talk to each other”, as well as to be used for other purposes. |
| Data collection and validation | Defined as activities related to collecting HAI data (whether through surveillance systems such as NHSN or use of administrative data) and validation of HAI data.(Note: May overlap with ‘Metrics’, also within HAI Data and Monitoring.) |
| Outcomes measurement and monitoring | Defined as activities for using and reporting HAI data for various purposes, including public reporting/transparency, quality/safety improvement efforts, and reimbursement formulas/incentives. |
| ***Knowledge Development*** | ***Definitions for Categories, Examples of Data*** |
| Basic science | Defined as microbiology, pharmaceuticals, ‘lab’ or ‘bench’ science. |
| Epidemiology | Defined as tracking outbreaks, incidence and prevalence rates, and studies on transmission. |
| Infection control interventions | Defined as the development and evaluation of evidence-based prevention practices.(Note: May overlap with HAI Prevention Practice System Function.) |
| Implementation science | Defined as the development evaluative strategies for dissemination and implementation of infection control interventions. |
| ***Infrastructure Development*** | ***Definitions for Categories, Examples of Data*** |
| Regulation and oversight | Defined as specific legislative action related to regulation or oversight.(Note: May overlap with Policy Context and Outcomes measurement and monitoring.) |
| Funding and Payment Systems | Defined as payments or rules about reimbursement to incentivize HAI prevention.(Note: May overlap with the Accountability and Incentives System Property.) |
| Quality/Safety Culture | Defined as interventions to affect attitude or infrastructure changes to support quality and safety.(Note: Behavioral, ‘bedside’ interventions are covered in HAI Prevention Practice and Adoption System Function.) |
| Education and training | Defined as specific efforts that explicitly mention education and training.(Note: General dissemination/outreach efforts are covered in other properties or functions.) |
| Dissemination mechanisms | Defined as tools, repositories, communication, media, collaborative/learning communities, guidelines. |
| Technical assistance and support | Defined as services and non-monetary resources provided by HHS agencies for the implementation of infrastructure to monitor and/or prevent HAIs.*Example: CDC offering technical support for hospitals who wish to initiate NHSN.* |
| ***HAI Prevention Practice Adoption*** | ***Definitions for Categories, Examples of Data*** |
| General/cross-category | Defined as any prevention practice efforts that do not fall into any of the other three prevention practice columns.(Note: This category is mutually exclusive with the other three categories; it is only used if an HAI prevention effort cannot be categorized in one or more of those three columns.) |
| Decision to adopt | Defined as HAI prevention practice ‘knowledge’, ‘persuasion’, and decisions to reject/accept one or more practices. |
| Use of practice  | Defined as HAI prevention practice ‘implementation’ to varying degrees. |
| Sustainability  | Defined as the ‘confirmation’, or decisions to continue or stop using an HAI prevention practice. |

**Review of Peer-Reviewed Literature.** To identify relevant studies in the professional literature, the team ran the following search query through PubMed:

"The New England journal of medicine"[Journal] OR "JAMA: the journal of the American Medical Association"[Journal] OR "Annals of internal medicine"[Journal] OR "American journal of infection control"[Journal] OR "Infection control and hospital epidemiology: the official journal of the Society of Hospital Epidemiologists of America"[Journal] OR "The Journal of hospital infection"[Journal]) AND (healthcare associated infection[All Fields] OR healthcare associated infections[All Fields])

We selected documents from the results if they met the following criteria:

1. Study was conducted in a U.S. setting (in whole or in part) or commented on U.S. policy (in whole or in part).
2. Study was funded by an HHS agency, or (if unable to determine funding) was related to a known HHS activity.
3. Study focused on one or more of the six HAI priority conditions (CAUTI, CLABSI, SSI, VAP, *C. difficile* and MRSA infections).

**Meeting Minutes Abstraction.** We also collected meeting minutes from the Office of the Assistant Secretary of Health (OASH) for the Steering Committee and the Working Groups. The minutes covered ambulatory and long-term-care settings as a supplement to in-hospital HAI settings. For those meeting minutes, we performed an additional level of data abstraction. Complementary to the goals and activities matrix developed by the interview team, this abstraction identified activities in the meeting minutes and tracked the progress of those activities as recorded within minutes. The time period for which we abstracted meeting minutes is July 2008 through June 2011.

By examining a time series of committee meeting minutes and comparing the activities across the various system functions and properties, the team identified progress, as well as barriers and facilitators to progress achieved by committees tasked with implementing the Action Plan.

### Limitations of Document and Literature Review

The document and literature review is not intended to represent the universe of all published literature, internal HHS documents, or published reports. Any conclusions reached from the relative frequency of documents pertaining to each of the system functions and system properties is limited by any bias present in the sample of documents reviewed. Documents might not have been included that cover functions or properties observed with less frequency. However, our methodology, which involved searching literature from major medical journals and including documents identified by agency staff, is more likely to have a positive bias (i.e., more likely to collect only documents that demonstrate progress) than negative bias (i.e., missing the majority of documents or key documents showing progress). A bias toward positive outcomes in publication has been observed in peer-reviewed literature (Olson et al., 20022; Callaham et al., 19983), and the documents that were shared by stakeholders were selected as either being important documentation of activities and their status (i.e. meeting minutes) or updates on HAI prevention efforts (i.e., reports and newsletter items). As mentioned in the results section, the meeting minutes capture only those components of meetings documented in the minutes made available to the evaluation team. These minutes represent time series “snapshots,” providing a unique window into discussions, priorities, participants, and decisions. While meeting minutes serve as working documents intended for Working Group and Steering Committee members, they may omit some of the ”behind the scenes” collaborations or activities that were not reported during meetings.

## Program and Project Inventory (PAPI)

PAPI is a systematic effort to characterize HHS agencies’ HAI-related programs and projects. It was developed by the evaluation team in collaboration with HHS agencies.

While the 2009 and 2012 Action Plans extensively reference a broad set of activities related to HAI reduction, no systematic collection of data characterizing HAI activities across HHS agencies existed at the time we began this evaluation. We developed the National HAI Action Plan PAPI to document the breadth and scope of HHS Action Plan activities conducted by key agencies in HHS. Iteratively working with the agencies, we developed strategies to compile a comprehensive listing of all HAI activities, including both programs and projects. The goal of the inventory was to identify the agencies’ contributions to HAI activities as a method for understanding potential opportunities for coordination and collaboration between agencies and for identifying potential gaps that could be addressed.

The compilation of HAI programs and projects implemented by the Action Plan PAPI provides, for the first time, a cross-agency catalogue of HAI activities. This inventory was designed to achieve the following goals.

* Cataloging and categorizing stand-alone, time-limited projects and ongoing programs related to the Action Plan.
* Capturing the level of effort used to support the programs and projects.
* Measuring the relative effort allocated to specific HAIs included in the Action Plan.
* Measuring the amount of collaboration occurring across HHS as found in the programs and projects, and enabling increased collaboration within HHS.

We also intended the inventory to identify strategic gaps in HHS’s approach to HAIs, and redundancies and potential complementarities that might benefit from additional examination.

### Methods for Developing National HAI AP PAPI

As a first step, the evaluation team worked with the Federal Agency Working Group (FAWG) members from AHRQ, Centers for Disease Prevention and Control (CDC), the Centers for Medicare and Medicaid Services (CMS), the Assistant Secretary for Planning and Evaluation (ASPE), and OASH to explore whether an iterative strategy could identify similarities and differences in the ways HHS agencies define and track HAI programs and projects. With input from these agencies, the evaluation team constructed definitions of programs and projects that would serve as a sampling frame for comprehensively listing each agency’s programs and projects.

We defined relevant programs and projects to be included in the inventory as those that:

* Receive funding by one of the HHS agencies involved in the Action Plan, or by a regional or state agency directly or indirectly supported by one of the HHS agencies.
* Target HAIs (i.e., infections that patients experience while receiving treatment for another condition in some type of health facility).
* Contribute to better understanding of the structure, processes, or outcomes of efforts to improve HAI rates.

Programs are defined as ongoing activities of agencies and may have one overarching objective and goal or one overarching objective with multiple smaller goals. Projects are defined as more time-limited activities with prescribed funding, often having a narrower focus than a program. Programs and projects may be previously or newly funded in relation to the HAI Action Plan, including long-standing activities previously applicable to a broad set of health matters but newly focused on HAIs.

Different agencies had different criteria for deciding which programs and projects were included in the final list of their HAI work, and some projects were not included for one agency that may have been included had they come from another agency. Future iterations of this inventory could include more-standardized criteria so that all agencies could include similar material.

**Data Elements*.*** Once we defined the type of programs and projects that would be included in the inventory, our next step was to develop a pool of potential data elements that would be captured for each of the programs and projects in the inventory. Working iteratively with FAWG agencies, we developed a pool of domains and associated data elements that could structure the data collection activity associated with each inventory program and project. This proved to be challenging because the diversity of agencies’ tracking systems and of the programs and projects we anticipated capturing within the inventory. Where possible, we standardized data elements collected across agencies to support a meaningful aggregated inventory as well as agency-specific inventories. The efforts to standardize data elements were intended to support meaningful comparisons across agencies when appropriate to allow the inventory to serve its stated goals of identifying gaps, redundancies, and potential areas for collaboration. When iterative discussions with agencies proved unlikely to result in a single data element specification across agencies, we chose to emphasize clear specifications for each agency while highlighting unique features associated with each agency’s final data collection strategy.

Table 3 shows the domains and associated variables for which we intended to collect data elements across agencies. These domains and data elements were iteratively discussed with agencies to identify a subset of items that could be comparably collected across agencies.

**Table 3: Domains and Data Elements Associated with the Program and Project Inventory**

|  |
| --- |
| **Domains and Data Elements** |
| **Administrative Information*** Program/Project Name
* HHS agency with oversight
* Primary/Lead organization/agency (if different from oversight agency)
* Brief narrative description/abstract of activity
 |
| **Level of Effort*** Funding (e.g., sources, funding mechanism, funding amount and period of performance
* Funding type (e.g., grant, contract, interagency agreement
* HAI-specific funding? (versus funding for more general purpose, e.g., patient safety)
* ARRA-related funding?
 |
| **Content Focus** * HAI infections/conditions/practices addressed (check all that apply)
* Specific functional areas of HAI prevention addressed (check all that apply)
* Data and monitoring activities (i.e., metrics, system interoperability, surveillance/data collection, data validation, outcomes monitoring)
* Knowledge development/research activities (i.e., basic science, epidemiology, developing practices, evaluating effectiveness of practices, translational/implementation science, HAI outcomes evaluation)
* Infrastructure development activities (i.e., regulation/oversight, funding/payment systems, quality or safety culture, education/training, dissemination mechanisms, technical assistance/support)
* Prevention practice adoption activities (i.e., decisions to adopt, use of practices, sustainability of practices)
 |
| **Coordination/Collaboration*** Other organizations involved (organization/agency name, contact persons)
* For each other organization involved:
* Role(s) in project/program (e.g., joint administration/management of project/program, intervention/practice/tool development, methods technical advising, subject matter technical advising, strategic advising, recruitment of intervention participants, dissemination of results or tools, subcontractor, coordination with other projects/programs
 |
| **Scope of Program/Project*** Types of stakeholders affected/targeted (e.g., patients, healthcare professionals/workers, provider organizations, researchers, policymakers, payers)
* Geographic area of impact
* Healthcare settings affected/targeted
* Metrics used (for research/evaluation or program monitoring)
 |
| **Intended/Expected Impact*** Key goals, objectives, and specific aims
 |

**Agencies Selected to Contribute to PAPI.**Our initial approach to developing the PAPI was focused on FAWG agencies, AHRQ, CDC, CMS, and OASH. Discussions with these agencies resulted in recommendations to also collect data from three other agencies with important HAI programs and projects:

* National Institutes of Health (NIH)
* Federal Drug Administration (FDA)
* Office of the National Coordinator for Healthcare Information Technology (ONCHIT).

Early efforts to initiate data collection with each of these agencies indicated that multiple iterations with each agency would be required to achieve comparable data collection across agencies. For the first national PAPI, the evaluation team limited the data collection effort to five agencies, including the four FAWG agencies and NIH. The FDA and ONCHIT were not involved with initial data collection.

### Structuring Agency-Specific Data Collection Activities

For each agency, we requested a recommendation from the FAWG members for a key contact person to approach about the inventory. As part of our initial contact with each agency representative, we sent background information about the inventory task along with the domains and sample data elements presented above. During our first meeting with each agency representative, we discussed the ways in which the agency conceptualized its own HAI-related programs and projects and explored options for how each agency could populate the inventory. When agencies indicated that their existing data systems could not support the domain or data elements suggested, we explored alternative strategies for representing the agency’s programs and projects in the inventory. We repeated this process until the evaluation team and the agencies were mutually confident that the final PAPI domains and data elements represented a feasible set that could be populated by agencies and that would meaningfully represent the agencies’ HAI programs and projects.

Our final data collection strategy involved two critical steps. First, agencies provided the evaluation team with a listing of all HAI programs and projects in which they were engaged. The evaluation team and individual agencies jointly reviewed the listings for completeness in relation to activities mentioned in the Action Plan and other documents describing the agencies’ activities (e.g., agency websites). The second step involved each agency populating the revised PAPI data collection tool for each listed program and project.

**Collecting PAPI Data.**To characterize its programs and projects, each agency provided the data elements systematically collected by the agency. Data elements were sorted as one of three types:

* Data elements that could be collected comparably across agencies.
* Data elements that could be collected across agencies, but with agency-specific elements that differed in definition and/or content.
* Data elements that could not be provided by each agency.

## National-Level Internal Stakeholder Interviews

The team planned internal stakeholder interviews to supplement the document review and provide a broad perspective on an array of issues related to the Action Plan’s progress in its goals and activities since its initial release in 2009. Consistent with the notion of a formative evaluation, our goal in developing the sampling frame was to create a process that yielded a range of perspectives of the internal stakeholders from federal agencies engaged with the Action Plan. We designed the sampling frame and the interview protocols to capture both mainstream and alternative viewpoints.

### Sampling Frame Development

Internal stakeholders were defined as representatives of federal agencies who participated in the Action Plan Steering Committee and/or Work Groups, or who had important interactions with Action Plan activities. To develop the sampling frame, we first reviewed the sampling frame of internal stakeholders developed in Year 1 for Context and Input Evaluation interviews. These individuals were members of the Steering Committee, Action Plan work groups, and others heavily involved with federal HAI prevention activities. Next, we obtained a full current listing of federal agency members of the Steering Committee and work groups, yielding a master sampling frame of more than 130 individuals. We then consulted with OASH staff to confirm roles of individuals and identify those with higher levels of involvement in both the Action Plan and other prevention activities. We then purposively selected 20 individuals to include a variety of perspectives of federal agencies involved in the Action Plan (AHRQ, Assistant Secretary for Planning and Evaluation [ASPE], CDC, CMS, Indian Health Service [IHS], NIH, OASH, Office of the National Coordinator for Health Information Technology [ONC], Veterans Administration [VA]) as well as from the HHS Steering Committee and all Working Groups (except Outreach and Messaging). Only one person invited for the interviews declined, and this person was replaced by another individual from the master list. The resulting sample represented a 67 percent increase in internal stakeholder respondents from the Year 1 interviews (from n = 12 to n = 20).

### Protocol Development

We initially developed two different protocols, one for Steering Committee members, and one for Work Group members. However, during pilot testing it became apparent that the difference between Steering Committee and Work Group participation was not a major distinction, and that most federal HAI activity including interagency interactions occurred outside the formal Action Plan committee structure. Therefore, we devised one single interview protocol focusing on all HAI prevention activities of participants, with questions asked of all respondents on the types of activities that might take place within, compared to outside the Action Plan committees.

We based interview topics on process evaluation questions developed for the CIPP model, and we also covered the major goals and activities of federal agencies, implementation progress, implementation challenges and facilitators, and future directions. In addition, specific questions on implementation progress, challenges, and opportunities were included for each of the system functions (i.e., HAI Data and Monitoring, Knowledge Development, Infrastructure Development, and Adoption of HAI Prevention Practices) and properties (Prioritization, Coordination and Alignment, Accountability and Incentives, Stakeholder Engagement, and Resources) in our HAI prevention system framework.

The interview leads reviewed protocols internally, and then circulated them to the IMPAQ/RAND team for review and comment before being finalized. Prior to beginning the interview process, the protocols (including the informed consent and confidentiality procedures) were submitted for review and approval to RAND’s Institutional Review Board (IRB), which served as the IRB of record for both RAND and IMPAQ. The protocols were not submitted for OMB clearance, as we only interviewed federal employees and OMB approval is not required.

To personalize the interview protocol for respondents, components of the protocol were enhanced or omitted for particular interviewees. These decisions were made in advance of conducting the interviews. For each system function, some questions were asked of all participants and some specific questions were only asked of individuals within a certain work group. For example, we asked all participants: *What have been the major issues in HAI data and monitoring that agencies and Work Groups in the Action Plan have been or need to be facing?* We asked only Information Systems and Technology (IST) Work Group members additional questions about specific HAI data and monitoring issues. We applied the same methodology to other system function areas and Work Group members.

### Inviting Participants and Conducting Interviews

The IMPAQ/RAND team contacted potential interview participants by email to request an interview and explain the study. The email invitation included a letter in support of the study from Dr. Donald Wright, Deputy Assistant Secretary for Healthcare Quality.

A member of the IMPAQ/RAND team followed up with potential participants by telephone to finalize the interview schedule. Each interview was scheduled for one hour. Given the diverse geographic spread of the interview participants, interviewers, and convenience for the participants, we conducted the interviews by telephone.

The interviews were conducted by two members of the interview team--one lead interviewer and one note-taker to record detailed notes. Each interview began with a brief description of the study and review of Institutional Review Board (IRB) language to obtain informed consent. Upon receiving consent to continue, the interviewer conducted a semi-structured interview using the protocol. Consistent with the semi-structured nature of the interviews, the protocol served as a guide and the interviewer had some flexibility to follow up on interesting discussion points. Not all questions were asked of each participant, although most interviewees were asked a core set of questions for consistency. Following the interview, the notes (generally taken verbatim) were typed and deposited on a password-protected shared workspace. The lead interviewer for each interview reviewed the notes for accuracy and completeness before finalizing them within a week of the interview. The notes were made available for review and analysis by the IMPAQ/RAND team.

### Interview Analysis Methods

The analysis of interview data for the internal stakeholder interviews used a manual coding and extraction procedure consisting of four steps.

First, the interview team developed an initial codebook of research questions and themes. This involved compiling an outline of main research questions based on the conceptual framework for the process evaluation and the interview guide for internal stakeholders, having members of the interview and wider evaluation team review one or two interviews each to identify themes relevant to the process evaluation research questions and/or identify questions not on the initial outline; compiling themes by research question; and prioritizing the questions and themes for systematic coding and extraction of quotes.

Second, the interview team systematically extracted themes across all interviews based on the codebook. Each set of prioritized research questions in the codebook received a two-person team (consisting of a lead and secondary analyst). The lead analyst identified and extracted all portions of text relevant to a particular question and associated themes into a separate document. The secondary analyst reviewed the document file as a validity check to ensure that extracted quotations were relevant and properly matched with themes on the outline and to minimize any idiosyncratic readings of the interview notes. Coding teams were also allowed at this stage to add any new questions and themes that emerged during systematic coding and extraction that did not fit in previous categories in the codebook.

Third, we produced summaries of findings for each set of questions and themes based on the quotations systematically extracted in the previous step. Each two-person team produced a bulleted summary of results and an interpretive “storyline” for each research question and associated themes according to a set of guidelines to identify modal (i.e., most common) themes, clusters of themes, range of themes (including significant “minority” or unique perspectives), and any differences that emerged across types of stakeholders (e.g., agencies that represent particular aspects of HAI prevention, or that have been more vs. less heavily active in the Action Plan). The draft summaries were shared with the full evaluation team for comment for finalizing the results and storylines.

Last, we wrote up and synthesized the results into an integrated summary. The lead person of each two-person team drafted a write-up of the assigned question and associated themes based on the bulleted summary and team feedback in the previous step. After the secondary analyst reviewed the draft summary to ensure that relevant quotations were properly incorporated and minimize idiosyncratic interpretations, the draft write-ups (and bulleted summaries from the previous step) were shared with the full evaluation team for review and discussion of overarching synthesis and storylines (across questions/themes, as well as with the other data sources in the process evaluation). The leads of the interview team then drafted the full results, including an overall summary and synthesis of the interview themes.

## National-Level External Stakeholder Interviews

External stakeholder interviews were planned to supplement the document review and provide a broad perspective on an array of issues related to the Action Plan’s progress in its goals and activities since its initial release in 2009. The focus of the interviews was on the Action Plan and other HAI activities, implementation process, and progress. Consistent with the notion of a formative evaluation, our goal in developing the sampling frame was to create a process that yielded a range of perspectives of external stakeholders outside of federal agencies engaged with the Action Plan. The sampling frame and the interview protocols were designed to capture mainstream and alternative viewpoints.

### Sampling Frame Development

External stakeholders were defined as representative of private organizations or state agencies knowledgeable about, involved in, and/or directly affected by national-level HAI prevention activities. The sampling frame for the external stakeholder interviews was generated by first defining six broad categories of external stakeholders and then using the Year 1 external interview sample, review of participants at HHS stakeholder meetings, suggestions from OASH staff, and snowball sampling based on responses of both the internal stakeholder interviewees and the initial Year 3 external stakeholder respondents. The Year 3 external sample was purposively selected to include a variety of perspectives of external stakeholder groups, including healthcare industry (n = 4), professional associations (n = 9), consumer representatives (n = 3), payer and insurer groups (n = 3), accreditation or improvement organizations (n = 4) and academic/research institutions (n = 2). The Year 3 sampling frame represented a 92 percent increase in external stakeholder respondents from Year 1 (from n = 13 to n = 25). Nine people invited to participate in the external interviews referred us to others in their organization they considered more knowledgeable about the interview topics. Five people declined or did not respond to the invitation and when possible were replaced in the sample by another representative in that organization or by another organization from the same stakeholder group.

### Protocol Development

We based interview topics on process evaluation questions developed for the CIPP model, and covered changes in HAI-related goals and activities, progress and gaps in different areas of HAI prevention, challenges and facilitators for federal agencies and other stakeholders working together to implement HAI prevention practices, and future directions. In addition, specific questions on implementation progress, challenges, and opportunities were included for each of the system functions (i.e., HAI Data and Monitoring, Knowledge Development, Infrastructure Development, and Adoption of HAI Prevention Practices) and properties (Prioritization, Coordination and Alignment, Accountability and Incentives, Stakeholder Engagement, and Resources) in our HAI prevention system framework. To increase the relevancy and quality of information from the interviews, we developed separate interview protocols with specific tailored questions for each of the six stakeholder groups.

Interview leads reviewed the protocols internally and then circulated them to the IMPAQ/RAND team for review and comment before being finalized. Prior to beginning the interview process, the protocols (including the informed consent and confidentiality procedures) were submitted for review and approval to RAND’s Institutional Review Board (IRB), which served as the IRB of record for both RAND and IMPAQ. Given that we did not have more than nine respondents for each stakeholder-specific protocol, the protocols did not require OMB clearance.

### Inviting Participants and Conducting Interviews

The IMPAQ/RAND team contacted potential interview participants by email to request an interview and explain the study. The email invitation included a letter in support of the study from Dr. Donald Wright.

A member of the IMPAQ/RAND team followed up with potential participants by telephone to finalize the interview schedule. Each interview was scheduled for one hour. Given the diverse geographic spread of the interview participants and interviewers, and for the convenience of participants, we conducted the interviews by telephone.

Each interview was conducted by two members of the interview team--one lead interviewer and one note-taker to record detailed notes. Each interview began with a brief description of the study and review of IRB language to obtain informed consent. Upon receiving consent to continue, the interviewer conducted a semi-structured interview using the protocol. Consistent with the semi-structured nature of the interviews, the protocol served as a guide and the interviewer had some flexibility to follow up on interesting discussion points. Given the semi-structured nature of the interviews, not all questions were asked of each participant, although most interviewees were asked a core set of questions for consistency. Following the interview, the notes (generally taken verbatim) were typed and deposited on a password-protected shared workspace. The lead interviewer reviewed the manual notes for accuracy and completeness prior to analysis. Interviews were also audio-recorded (with permission of respondent); audio-recordings confirmed the content of interview notes.

### Interview Analysis Methods

The interview notes were analyzed using qualitative text management software (Atlas.ti) by one investigator and a research assistant who worked as a team to extract themes according to a codebook and code definitions based on the evaluation topics in the interview protocol and the project’s HAI Prevention System framework (i.e., system functions and properties). An initial set of three to five interviews was double-coded by each coder for each set of topics analyzed, with discrepancies resolved and any changes to the codebook or definitions resolved by consensus. The lead investigator also reviewed coding and analysis of the additional interviews on a topic conducted by the research assistant to identify and resolve any discrepancies in application of coding definitions.

## Regional Activities Analysis

Regional activities have the potential to play an enormous role in bridging gaps between national HAI-NAP activities and those that occur on the state and local levels. In May 2010, OASH evaluated 14 proposals and selected six regionally focused projects from among the 14 for a one-year competitive grant award to fund a project related to HAI prevention. OASH, in making its selection, assessed the proposed projects against six criteria: clarity, relevance to the HAI-NAP, internal congruence, impact/collaboration, budget, and clearly delineated timeline. The scoring and selection criteria explicitly rated how well the “goals of the project are aligned with objectives outlined in the National Action Plan.” Four additional projects were selected (from a pool of seven proposals) for Year 2 funding. Subsequently, OASH held the HAI Regional Projects Kick-Off meeting on October 21, 2010.

Our regional activities analysis had two main components: interviews and document reviews.

### Interviews

In July and August 2011, the IMPAQ/RAND staff conducted one‐hour interviews with eight individuals who have in‐depth knowledge of OASH‐funded regional HAI project implementation. In May and June 2012, the team re-interviewed five of those individuals for 30 to 60 minutes each to assess additional progress in the last year. Interviewees include regional project staff, deputy regional health administrators, regional health administrators, and current and former program staff with the Washington, DC OASH. The same IMPAQ/RAND staff member conducted all 13 interviews. The 2011 interviews also included another team member taking notes. The final transcript from each interview combines notes taken by the interviewer and note taker.

### Document Review

Using the system framework developed for the Action Plan, the IMPAQ/RAND team reviewed the interview transcripts as well as the project descriptions and updates provided in the regional progress reports, minutes from regional stakeholder meetings, project quarterly reports, training curricula, and communications to project participants and stakeholders to identify themes and ascertain how the projects fit into the implementation of the Action Plan. In total, the IMPAQ/RAND team included more than 60 documents in its evaluation, all provided by the Health Policy Analyst at the Office of Healthcare Quality within OASH with direct responsibility for the regional projects. The team conducted qualitative analysis on documents using NVivo (version 9.0) software.

## Inventory of Data Systems and Assessment of HAI Rates

The Action Plan evaluation contract included two tasks related to HAI data: the data inventory task and the baseline assessment task. The data inventory task, performed during Year 1 of the contract, identified, profiled, and assessed the strengths and weaknesses of the various HHS data systems that might be used for surveillance of HAIs in acute care hospitals. Part of the motivation for this task is found in the 2008 GAO report4, which noted that HHS maintains several data sources but that none of them were capable of providing a comprehensive understanding of the status of HAIs in the United States, nor were they coordinated to enable the systems to complement one another’s strengths. The Action Plan, another source of motivation, calls for enhanced coordination in many areas, including those related to data and surveillance, and recommends developing a data inventory to help guide interoperability projects.

The baseline assessment, undertaken in Years 2 and 3, is a natural extension of the data inventory work, and required IMPAQ/RAND to develop a compendium of longitudinal HAI rate data from multiple HHS data sources. The baseline assessment integrates information about surveillance specifications and other data source features from the data inventory to explain differences in observed HAI rates across data systems. In addition, the expertise the project team has developed regarding the HAI policy environment is used to interpret the HAI rates.

### Methods for Developing the Data Inventory

Development of the data inventory involved three broad steps: identifying HAIs, data sources, and metrics to include in the inventory; gathering information and populating the inventory; and analyzing the results of our data collection together with those of an environmental scan of the HAI literature related to surveillance.

Drawing upon the solicitation, our technical response, the HHS Action Plan, discussions with the task order officer and the FAWG, and an environmental scan of literature related to HAI surveillance, we identified the HAIs and data systems to include in the inventory. In Phase I, the Action Plan focuses on six infection types: CLABSI, CAUTI, SSI, VAP, MRSA, and *C. difficile*. The inventory was limited to data systems capable of surveilling at least one of these six infections. Using the same sources of information, we created a list of HHS data systems as candidates for inclusion in the inventory. We excluded a number of data systems that were not capable of direct HAI surveillance. For example, the Hospital Survey on Patient Safety Culture contains information on hospital employees’ perceptions of patient safety culture, but does not provide information on HAI rates.

After selecting the infections and data systems to include in the inventory, we again drew on various project documents, HAI studies, and interactions with HHS agencies to choose a set of variables to characterize each data system/HAI/metric observation in the inventory. These variables, organized into several domains, capture information on metrics (e.g., surveillance specifications, numerator, denominator), data sources (e.g., level of aggregation of available data, data accession process, missing data, capacity for estimate generation), and covariates and outcomes (availability of patient demographics, comorbidities, and health outcomes).

The next step in the data inventory development process was the collection of information and population of the inventory. Information for the inventory was collected almost entirely from the documentation for the datasets. These materials included reports produced using the data, data dictionaries, user guides, and data collection protocols/instructions. Conversations with personnel at various HHS agencies provided clarification and further detail.

A report summarizing our findings and providing an analysis of the strengths and weaknesses of each data system accompanied the inventory. This analysis focused on the general differences between administrative data collected for billing purposes and more clinically detailed information contained in data sources based on extraction from patients’ medical records, laboratory results, or direct patient observation. We then separately considered the strengths and drawbacks of each data system. In addition, in preparation for the baseline assessment activities scheduled for Years 2 and 3 of the contract, we recommended data for inclusion in the baseline assessment and developed HAI surveillance definitions to be applied to administrative data. The surveillance protocols were based on our environmental scan as well as input from HHS data experts and our clinical epidemiologist consultant.

### Methods for Developing the Baseline Assessment

Results from the data inventory provided recommendations for measures to be included in the baseline assessment as well as recommendations for administrative data surveillance definitions based on discussions with HHS agency personnel and a scan of the HAI literature. A substantial part of the project team’s baseline assessment activities involved implementing the recommendations derived from the data inventory, which included the compilation, analysis, and presentation of state, regional, and national HAI and prevention process adherence rates for several measures from a number of data systems.

With the exception of publicly available data (e.g., the Hospital Compare database; national rates, and state SIRs for NHSN measures), the compilation of rates required contacting the appropriate HHS agencies and requesting the rates. In some instances (e.g., Connecticut ABCs and MPSMS), agencies provided rates that had already been produced for other purposes. In most cases (Medicare claims, HCUP), however, the evaluation team provided detailed specifications for the measures and worked with agency personnel to develop analysis plans. In addition to ICD-9 code specifications, which evolved through our interactions with agency data experts, the analysis plans provided for stratification of HAI rates by various dimensions such as hospital teaching status, hospital size, patient age, rural vs. urban location, and payer. In requesting the data, the project team tried to obtain rates that would be comparable across data systems and provide the most accurate and valid infection rate information possible. Requesting stratified rates also provided flexibility to compare rates from different systems as directly as possible (e.g., comparing rates for the Medicare payer stratum from HCUP to rates based on Medicare fee-for-service claims).

For each data system, we presented infection rates for each HAI in both graphical and tabular forms at state, regional, and national levels and over time. In addition, we provided cross-data system comparisons over time and analyzed the data to assess the degree of concordance among data sources. We also drew on results from the data inventory and continued interactions with data-holding HHS agencies to shed light on the causes of observed differences in HAI rates across data systems. The national, cross-data system results from the Baseline Assessment Report were summarized in a PowerPoint slide deck and we delivered several presentations to HHS agencies and other stakeholders throughout Year 3 of the evaluation contract. In addition to providing results of our investigations, these presentations also provided an opportunity to learn from the HAI community and to refine our work. The hypotheses generated from discussions taking place during these presentations, and the ensuing additional analyses necessary to investigate the questions, have helped to refine the follow-up data report, *“2012 Compendium of National HAI Rates From Multiple HHS Data Sources”* released separately.5

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