HHS Action Plan to Prevent Healthcare-Associated Infections:
INFORMATION SYSTEMS AND TECHNOLOGY

I. Introduction

Mounting clinical and public health concerns about healthcare-associated infections (HAIs) compel the healthcare community at large to reexamine the approaches to addressing the prevention of HAIs. Advances in information technology, harmonization of disparate data standards, and capabilities to connect with and integrate multiple data types and sources all create new opportunities for the Department of Health and Human Services (HHS) and other federal agencies to re-think and refine strategies to better focus on improving the national capacity to monitor, measure, and prevent the occurrence of HAIs. HHS and other federal agencies share goals with state agencies, hospitals and other healthcare organizations, healthcare practitioners, accrediting and professional organizations, and the public to take action addressing the prevention of HAIs.

Some such common goals that could be addressed through leveraging advances in state-of-the-art information systems and technology might include:

1) Achieve more rapid and more complete detection of HAIs by increasing capabilities to exploit current and future data sources. Efforts would initially use available laboratory data sources and computer-based detection algorithms, but actively work toward the inclusion of data from the clinical record of care. This will be possible only when standard terms for HAIs are used routinely and when automated, intelligent systems are applied to identify HAI indicators among a constellation of clinical findings within electronic data resources.

2) Increase the rate of dissemination of reporting data to external HAI surveillance activities performed by quality improvement organization and public health monitoring efforts. This will permit rapid detection of patterns and trends for predetermined or ad hoc sets of demographics, thus creating the opportunity to formulate appropriately targeted tactics and execute early prevention and intervention techniques.

3) Provide more comprehensive and timely data to focus prevention efforts and measure their effectiveness at the national level at reducing surgical site infections, central line-associated bloodstream infections, catheter-associated urinary tract infections, ventilator-associated pneumonia, methicillin-resistant *Staphylococcus aureus* infections, and *Clostridium difficile* infections.

4) Make available the HAI data for an entire episode of care, e.g., both surgical process-of-care data recorded at the healthcare facility where the patient had his/her operation as well as surgical site infection data recorded at another

healthcare facility, such as another hospital or a physician's office, when the patient seeks care there.

5) Create an "early warning" mechanism that is context-sensitive to HAI prevention reminders or clinical guidelines, either of which might be triggered automatically by findings or clinical plans or actions that are entered into electronic health record systems, resulting in point-of-care availability of relevant information about patient care practices.

Improvements in national-level HAI data collection, analysis, and reporting are integral to what HHS and other federal agencies seek to accomplish in a broad-based, national HAI prevention effort. The Department recognizes that there are some issues with the current systems, despite notable efforts in this arena by federal agencies.

Previous efforts to pursue integration of federal systems for adverse events reporting have produced mixed results because of the challenges of trying to integrate already-existing data and systems. A proactive strategy to integrate data where it originates, in addition to retrospective integration of different federal systems of reporting, would go beyond addressing data "control and fragmentation" issues in clinical care and begin to capitalize on prevention opportunities in the clinical workflow.

Programs at multiple agencies currently collect and report HAI and HAI-related data in separate systems and databases that function, in effect, as "silos" perpetuating singular and isolated paths of information used for making decisions. In some cases, the lack of an integrated stream of information creates disconnects and results in loss of potentially important information. In other cases, the databases serve such fundamentally different purposes that productive integration efforts may be virtually impossible.

Promoting the linking or sharing of HAI data across systems in a more integrated fashion offers myriad opportunities to yield important benefits for comprehensive analysis and action, provided safeguards are in place to assure that the merged data are used exclusively for authorized public health purposes and are scrupulously protected from unauthorized access. For example, combining patient-level surgical process-of-care data from one system with surgical site infection data from another system, with appropriate protections of personally identifiable health data, could provide new insights into near-term opportunities for prevention and quality-of-care improvement.

In other situations, a longer-term strategy to achieve integration will be needed to enable interoperable data exchanges between separate systems and to leverage the standards-based, electronic record keeping and data sharing that have entered the mainstream of U.S. healthcare. Achieving these longer-term strategies should provide HAI data to multiple agencies with greater efficiency, economy, timeliness, comprehensiveness, and reliability than is currently possible.

II. Establishing the Foundation for HAI Data Integration and Interoperability

Critical precursors to achieving HAI data integration and interoperability within HHS and across federal agencies should include:

- Increased visibility and priority given to the measurement and prevention of HAIs, so agency heads will incorporate this as a key objective and important priority into their respective strategic plans. The proposed goal is the execution of these strategies in an integrated fashion with federal and external partners.

- Careful planning and close coordination across federal agencies towards gradual and intentional implementation of system and process changes that utilize common data, information, and knowledge models. This should be done to support the prevention of HAIs and all quality-of-care initiatives sharing common strategic healthcare improvement goals.

- Close collaboration with private and other public entities that promote, manage, and implement widely adopted healthcare data and technology standards and the Interoperability Standards that have been recognized by the HHS Secretary to ensure that the business case for prevention of HAIs is included in the development and ongoing maintenance of standards, including efforts to harmonize multiple domains of data.

- Proactive participation in large-scale strategies and other federal initiatives, similar to those which have been advanced by the American Health Information Community (AHIC), the Healthcare Information Technology Standards Panel (HITSP), and the HHS Office of the National Coordinator for Health IT (ONC). This will help shape the development and implementation of an HAI Information Architecture that works in conjunction with the Nationwide Health Information Network (NHIN) and the Federal Health Information Sharing Environment (FHISE) initiatives.

To the fullest extent possible, efforts to improve HAI data integration and interoperability should be aligned with the NHIN and FHISE initiatives. The Nationwide Health Information Network is a collective set of health information exchanges (HIEs), including providers and several federal agencies that are working together as the NHIN Cooperative to securely exchange healthcare data.

The purpose of the NHIN is to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. The connection of HIEs is a key step in building a "network of networks," the NHIN. The Federal Health Information Sharing Environment (FHISE) is a framework to help agencies map their business priorities to information-sharing products and identify what interoperable solutions are currently available and in future planning. The FHISE framework will help agencies to sift through the enormous

amount of information available to identify exactly the information, products, and services needed to address problems.

III. Coordination of Efforts: Interagency Working Group

To meet the information technology needs of a national HAI prevention effort, a well-coordinated effort will be required of the Department. Various agencies across HHS house systems and databases containing HAI-related information. These agencies will need to collaborate to find system integration solutions in order to obtain reliable national estimates of HAIs and a more accurate view of the overall issue.

Thoughtful development and successful implementation of specific interagency projects will be essential to improve national-level HAI monitoring and measurement. A coordinated effort will involve enhanced and consistent communication across the Department. This will allow for problems to be approached in a more holistic fashion rather than in its disparate parts.

Programs in existence or development within one or more agencies should be identified and leveraged to aid in the overall prevention strategy. Also, a coordinated effort will potentially reduce duplication of work and enhance the impact of each agency's contribution to the program.

Specifically, the mechanism proposed to accomplish a coordinated effort would be the establishment of an Interagency Working Group. Implementation of this task will serve as the foundation for accomplishing the remaining tasks outlined in the Action Plan. The Interagency Working Group (or "Healthcare-Associated Infections Information Systems and Technology Working Group") should be chartered and will initially be comprised of at least one representative each from the Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and ONC, plus representatives from other agencies as designated. The representatives should have an overarching understanding of their respective agency's HAI-related systems and databases as well as the inter-relationships between these systems. They should also have an in-depth knowledge of gaps in HAI data. Project managers of specific systems within these agencies will serve as technical consultants to the Interagency Working Group. In order to facilitate regular communication, the group will meet monthly.

The Interagency Working Group should focus its attention on specific projects that can be completed with a time horizon of one to two years. The highest priority will be placed on projects that combine data from existing systems to improve capacity at the national level to benchmark progress in reducing HAIs. Near-term efforts to link or share data across systems are likely to require some definitional alignment and data element standardization.

Processes should be established for reconciling differences that would otherwise impede progress in completing high-priority projects. For example, selecting common patient identifiers for use in separate databases may be necessary to link patient-level data that provide a more comprehensive measure of HAIs than is available in any single system.

IV. Work Group Goals, Tasks, and Operational Charter

The goals and tasks for the Interagency Work Group are:

Goal A: Establish definitional alignment and identify standardized data elements that are needed to measure HAIs across HHS agencies and encourage existing federal participation with Standards Development Organizations to ensure that gaps in the available standards are addressed.

Tasks:
1) Develop a comprehensive inventory of existing HAI databases in HHS agencies, including information about data collection, data uses, and data validation.
2) Broker agreement on the terms that need to be defined and the set of data elements that needs to be specified to measure HAIs.
3) Document term definitions, value sets, and data elements included in HAI databases in HHS agencies, specifically those needed to measure HAIs.
4) Establish definitional alignment and data element standardization across HHS agencies, with special emphasis on standardizing healthcare data already available in electronic form.
5) Identify and analyze policy and legal issues and limitations relevant to exchanging data among agencies.

Goal B: Provide guidance to enable integration of HAI data from multiple HHS databases for the purpose of benchmarking progress in reducing HAIs.

Tasks:
1) Reach agreement on what data are needed to benchmark progress.
2) Identify HHS databases that are candidates for integration, with emphasis on the strategic opportunities.
3) Complete a business analysis of the integration opportunities that are identified.

Goal C: Mobilize health information systems to help reinforce appropriate patient safety recommended clinical practices.

Tasks:
1) Compile an inventory of health information system functional components, e.g., clinical decision support. This can be used to reinforce recommended clinical practices.
2) Develop a plan for HHS actions that can help move functional components into wider clinical use at an accelerated pace.

Goal D: Seek strategic opportunities to make varied HHS data systems interoperable to enhance understanding of HAIs.

Tasks:
1) Express strategic opportunities for integration as use cases that describe data flows and what is required to support them.

To accomplish these goals and tasks, the Interagency Working Group should be guided by an operational charter that describes the Working Group's purpose, scope, authority, participants, roles and responsibilities, and stakeholders.

The operational charter should organize the Working Group's efforts around four major objectives:

1) Establish and use an information technology strategy

   a. Develop an overall information technology strategy to support near-term and long-term HAI data integration while safeguarding data from unauthorized access and use.
   b. Make decisions regarding specific projects and the scope and boundaries of projects incorporated within a coordinated strategy.
   c. Establish priorities and provide oversight for interagency system integration projects.

2) Communicate with stakeholders

   a. Formulate a communication strategy to be used both within and external to HHS to ensure the highest degree of understanding of priorities.
   b. Serve as a point of contact for communication to external stakeholders so HHS efforts are coordinated and linked to a broader national coalition.
   c. Provide status reports and updates to the overall HHS Steering Committee.
   d. Identify and serve as a conduit to appropriate points of contact within agencies for data/database information.

3) Maintain accountability for the work effort

   a. Design a set of process measures to monitor progress on achieving goals within the information technology strategy.
   b. Assist related groups (e.g., the Interagency Healthcare-Associated Infections Research Working Group) with the design of a set of measures and a plan to improve the measures over time to monitor the nation's performance on reducing healthcare-associated infections.

4) Minimize reporting burden and maximize information output

    a. Formulate a related strategy to streamline and reduce redundancy in HAI reporting from healthcare facilities to ease the reporting burden on stakeholders, specifically hospitals.

    b. Establish consistent standards and coordinated data collection methodologies for how stakeholders should submit HAI data to various HHS systems.

    c. Develop strategies to ensure that end users (i.e., the institutions and individuals entering the data) have adequate help desk functions available to them and to support end users in a manner that simultaneously reduces their burden and improves the accuracy of data input (e.g., integrated help functions, error-reporting mechanisms, etc.). As part of these strategies, develop tools for user data entry which span a broad range of technical capabilities and work flows.

V. HAI Data and Data Inventory

An inaugural project for the Interagency Working Group would be an inventory of HAI data and database resources to guide preliminary analysis and decision-making for near-term and long-term data integration projects. Specifically, an HAI data inventory will establish the extent of definitional alignment and data element standardization needed to link or share HAI data across agencies. It also will provide operational guidance on the steps needed to achieve integration and semantic interoperability of HAI data from multiple databases. Such an inventory is necessary for and will be used to mobilize health information systems to help reinforce appropriate patient safety recommended clinical practices and to seek strategic opportunities to make varied HHS data systems interoperable to enhance understanding of HAIs.

A comprehensive and consistent set of information about different HAI databases is needed to assess definitions of key concepts across databases, the extent of data element standardization, opportunities to combine data from different HAI databases to provide a unified view for benchmarking purposes, and the prospects for interoperable data communications between HHS systems that can serve to improve understanding of HAIs in terms of risk factors, morbidity, mortality, cost, and prevention. In addition, the inventory should provide the conceptual components of and inform the structural framework for an overarching conceptual model to represent knowledge about HAI.

The information that should be included in the HAI data inventory is broad and complex. It should include data specifications that are already compiled and stored in existing databases and groupings of data based on a set of relationships, and it also will involve access to documents and other information sources that will require special effort to analyze and interpret the metadata. Thus, a well designed and carefully planned project should be done with a commitment of qualified project staff and executive sponsorship

with allocation of sufficient resources and the concerted efforts and resourcefulness of HHS personnel who serve as programmatic stewards for HAI databases.

The HAI data inventory should be a systematic collection of information about HAI-specific and HAI-related data currently collected and housed in different databases maintained by HHS and other federal agencies that provide national-level data about risk factors, morbidity, mortality, cost, or prevention of HAIs. Specific information about each database should be tabulated and the results summarized in a report that is sufficiently comprehensive and detailed to guide assessments and decisions about definitional and data element harmonization across multiple databases and domains, to identify opportunities for data integration, and to determine the level of readiness of the organization hosting the needed HAI data sources to engage in interoperable data exchanges.

The HAI databases to be inventoried should include, but are not necessarily limited to the following:

Agency for Healthcare Research and Quality (AHRQ)
- Healthcare Cost and Utilization Project (HCUP) database, nationwide inpatient sample
- Network of Patient Safety Databases (NPSD)

Centers for Disease Controls and Prevention (CDC)
- Active Bacterial Core surveillance (ABCs) database
- National Healthcare Safety Network (NHSN) database
- National Hospital Discharge Survey (NHDS) database
- Mortality data files

Centers for Medicare and Medicaid Services (CMS)
- Annual Payment Update (APU) database
- Healthcare Cost Report Information System (HCRIS) database
- Medicare Beneficiary Database
- Medicare Patient Safety Monitoring System (MPSMS) database
- Medicare Provider Analysis and Review (MEDPAR) database

Food and Drug Administration (FDA)
- MedWatch
- Manufacturer and User Facility Device Experience (MAUDE) database

Attributes of each database to be inventoried should include, but are not limited to:

- Purpose(s)	- File format
- Reporting incentive(s)	- Documentation
- Geographic coverage	- Privacy protection
- Temporal coverage	- Dissemination
- Data sources	- Access
- Frequency of data collection	- Requirements for use
- Definition of key concepts	- Data Use Agreement
- Data elements	

A detailed plan and timetable should identify all phases, activities, and tasks needed to complete the inventory. It is anticipated that the HAI data inventory would be completed within six months of project kick-off. The objectives of this project should be to deliver a comprehensive and well-characterized inventory of HAI data and source databases in a timely manner. The inventory should be used to help identify near-term and long-term integration projects.

VI. Integrating Sources of Data

Based on the database inventory and deliberations by the Interagency Work Group, decisions should be made about which near-term data integration activities are of the highest priority. These decisions should be guided by the understanding of the original business purposes of the data or data groupings and the metadata information available from the HAI data inventory. Caution should be applied when re-purposing data while also focusing attention on filling the most important gaps in HAI data coverage.

One example of leveraging current capacity would be to provide a means to share data between CMS's Surgical Care Improvement Program (SCIP) and CDC's National Healthcare Safety Network (NHSN); specifically, surgical process-of-care data from SCIP can be combined on the facility and patient levels with surgical site infection data from NHSN. In the current environment, fundamental differences in purpose, data requirements, and methods among some systems reduce the prospects for meaningful data linkage or sharing. For example, combining HAI incidence data collected by hospital infection control professionals with HAI incidence data collected from coded hospital discharge records would have only limited value owing to fundamental methodological differences in case detection. Discrepancies between these two methods of HAI case finding preclude meaningful data mergers: One method involves use of information

beyond what is documented in medical records, while the other uses only the coded discharge abstract of medical records.

A sustained and well-coordinated effort will be needed by AHRQ, CDC, CMS, and other federal agencies to develop and implement a long-term action plan for systems integration. Longer-term opportunities exist to create a formal information architecture supporting HAI prevention. This work should be guided and informed by the FHISE and NHIN and should take full advantage of the healthcare technology and data standards that are entering the mainstream of electronic clinical record keeping and reporting.

Using these standards and interoperability specifications to develop, enhance, or modify federal systems would enable data integration and should connect federal systems to the standards-based electronic health record systems (EHRs) that are rapidly emerging. Thorough and ongoing use of standards-based solutions should be developed to reduce or obviate the need for abstracting clinical observations from healthcare records in order to report HAI data to federal agencies. Ideally, clinical data entries describing HAIs will automatically populate HAI reports generated from EHRs.

While this scenario of electronic HAI reporting remains visionary, HHS and other federal agencies are well positioned strategically to help catalyze and coordinate the technical advances needed to make this vision a reality.

VII. Challenges and Opportunities

The Interagency Working Group will face many challenges in its efforts to create a successful environment for sharing of HAI information among federal agencies.

HAI data owners from a variety of sectors (including state, local, and private) should consider investing in the development and deployment of a common reporting format, as well as the infrastructure needed to share the information nationally. Minimizing HAI data reporting burdens on healthcare facilities is a priority, as is close collaboration with accrediting organizations and healthcare professional organizations. Duplication and other data quality issues must be minimized or eliminated when data are aggregated at the national level. Finally, aggregating data from multiple sources will require agreement on common semantics for the data.

An HAI solution must be requirements driven. An early focus on the data required for specific usages should enable better decisions about information systems and technology. Usage scenarios must be developed for the data. It is anticipated that an informatics solution would be developed in iterative phases. The integration of data from disparate sources might initially target simple collation of data, in which reports would be retrieved from existing HAI databases "as is," and made available through a shared repository.

A subsequent aggregation phase should involve developing common definitions and formats that all HAI databases would use to generate electronic information feeds to the

information sharing environment. An HAI database of the future could be built and maintained using a data model that is harmonized with clinical and administrative domains, maintaining strong linkages to HAI data of interest that are captured by various healthcare systems of origin.

An HAI database of the future should contain metadata and support a standard metadata registry, and would also support a knowledgebase used for developing training, guidance, and adjustments to public health policies with respect to prevention of infections. This future database would ideally capitalize on interoperability between federal systems that enables aggregation and reuse of data from disparate systems, each of which serves a distinct, primary function as well as a secondary purpose in which data are reported to a central system.

VIII. Conclusion

A well-organized and effective Interagency Working Group, informed in its deliberations and decision-making by a systematic inventory of HAI data and databases and a common information model, can complete the fact finding and analytic work needed to refine plans and define resource requirements for integration of HAI data across existing federal systems. Highest priority should be given to near- and long-term integration projects that will yield new capacity to measure national-level progress in HAI prevention.

The Department is strategically positioned to catalyze multi-agency integration efforts and foster close collaboration with other public entities and private sector organizations that have a stake in HAI data or that have lead roles in standard-setting for healthcare data and information technology. To the fullest extent possible, efforts to enhance return on investment in federal sources of HAI data should be aligned with the NHIN and FHISE initiatives. Integrating data from HAI database sources at multiple agencies will require sustained commitment and careful project planning and execution. Successful project outcomes can establish new programmatic collaborations across federal agencies and yield benefits for analysis and action in a broad-based, national effort to prevent HAIs.