ANTIMICROBIAL RESISTANCE SURVEILLANCE TASK FORCE, YEAR 2

Report and Recommendations for Antimicrobial Resistance Surveillance in the United States

September 2018
Federal Funding Statement

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Surveillance for antimicrobial resistance is complex and poses tremendous challenges. There are many pathogens to track, many resistance mechanisms and profiles of epidemiological and clinical importance, many groups of stakeholders (e.g., clinicians, clinical and public health epidemiologists, infection prevention and control professionals, clinical and public health laboratorians, and information technology (IT) professionals), and many IT systems sharing detailed data. An effective surveillance network must meet daunting challenges and requirements. Testing technology and information are sophisticated and rapidly advancing. The need for actionable data requires real-time data sharing. It needs to be well-resourced and able to integrate with and build on existing public health and clinical systems, including those for disease reporting/notification, isolate submission, and facility-based monitoring. The network needs to be clear on roles and communications across the public health and clinical sectors, as well as draw on existing data where possible to avoid undue burden. It should use technologies that are automated and standardized to the extent possible. It must be capable of tracking both existing and emerging pathogens and resistance mechanisms, including those arising in other countries.

In recognition of the need for comprehensive systematic antimicrobial resistance (AR) surveillance planning, Council of State and Territorial Epidemiologists (CSTE) adopted Position Statement 13-SI-01, which led to the establishment of the Antimicrobial Resistance Surveillance Task Force (ARSTF) by the CSTE, the Centers for Disease Control and Prevention (CDC), and the Association of Public Health Laboratories (APHL). Last year, the 35-member Task Force consisting of clinical, epidemiology, laboratory, and informatics representatives developed a vision, strategic profile, and strategic map to guide planning. This year, the ARSTF formed workgroups to complete a comprehensive assessment and develop recommendations. These recommendations aim to exploit opportunities, fill gaps, and overcome barriers to build a national AR surveillance network capable of producing surveillance data that can meet the needs of AR prevention. The assessment consisted of consultations among Task Force members, a review of the literature and existing planning and technical assistance documents, surveys of stakeholders, and interviews of subject matter experts. The recommendations to achieve the vision of the Task Force were developed in response to the assessment findings.

These recommendations are the core of this report. In summary, this report recommends:

**Terminology/Data Standards, Use of Standardized Codes**

- Identify/create Logical Observation Identifiers Names and Codes (LOINC) codes for all relevant tests and Systematized Nomenclature of Medicine (SNOMED) codes for pathogens and corresponding test results for all AR pathogens and Antimicrobial Sensitivity Testing (AST), and a process for timely establishment of these codes.
- Develop processes for ensuring that LOINC/SNOMED codes are available for non-proprietary tests. Encourage Clinical & Laboratory Standards Institute (CLSI) or Food and Drug Administration (FDA) to require manufacturers to recommend a standard three-letter antibiotic codes when submitting new compounds for review.
- CLSI or FDA should also submit a request to the Regenstrief Institute for the creation of relevant LOINC codes for new compounds under review. A standardized approach for submitting for LOINC codes for new/emergent pathogens should be developed.
- Support efforts to routinely include standard codes in package inserts for proprietary tests (e.g. SHIELD).
- Routinely include LOINC/SNOMED code recommendations in laboratory guidance documents (e.g. CLSI).

**Breakpoints**
- Encourage the adoption of the President’s Advisory Council – Combatting Antibiotic Resistant Bacteria (PAC-CARB) recommendation that the use of the most up-to-date breakpoints be a Clinical Laboratory Improvement Act (CLIA) requirement.

**Data Suppression**
- Gather more information on why susceptibility data are suppressed, how data suppression may be helpful or harmful to encourage appropriate antimicrobial usage, and implications for clinical and public health interventions. Gather a list of expert rules from instrument manufacturers. Evaluate how those rules would impact public health surveillance data. This evaluation should include assessment of the impact of data suppression on public health reporting of AR resistant pathogens, in antibiograms for antimicrobial stewardship (AMS). Assess the effect of data suppression rules on the availability and usefulness of resistance data on the data currently reported via the National Healthcare Safety Network (NHSN) antimicrobial use and resistance (AUR) module.
- Develop guidance for laboratories on how to approach de-suppression of data for public health purposes (e.g. CLSI M39). Include recommendations on how to apply suppression rules for public health surveillance to de-suppress appropriately.

**AR Electronic Laboratory Reporting (ELR)**
- Establish and disseminate best practices in ELR for AR by revisiting the guidance document created by the CSTE AR/ELR Working group in 2017 for CRE, (“Best Practices for Surveillance of Antimicrobial Resistance via Electronic Laboratory Reporting Recommendations from the CSTE AR/ELR Working Group, June 2017”), and broadening its scope to include the other pathogens and/or AR mechanisms that should be reported through ELR.
- Of those laboratories that submit via ELR, all should submit reportable AR laboratory findings to public health via ELR, with messages transmitted conforming to nationally accepted standards, and validated in content and structure for accuracy and completeness when sent or received. Laboratories that are not currently reporting via ELR are encouraged to do so, especially as electronic reporting of AR is a compelling reason to develop this capacity.
- ELR for laboratory results obtained through the AR Lab Network data should be submitted to public health agencies using HL7 messages routed through APHL Informatics Messaging Services (AIMS).

**Nationally Notifiable Disease Surveillance System Carbapenemase Producing-CRE Message Mapping Guide**
- Finalize and implement the Message Mapping Guide (MMG) for Nationally Notifiable Disease Surveillance System (NNDSS) Carbapenemase Producing Carbapenem-Resistant Enterobacteriacea (CP-CRE) and include the ARSTF MMG workgroup in this CDC process.

**Linking Laboratory and Epidemiological Data**
- Publish guidelines for creating and maintaining linkages between laboratory findings and case findings for both state/local and CDC programmatic needs.
**NHSN, Informatics to Track AR Among Healthcare Facilities**
- Healthcare facilities should use the NHSN AUR module (the AR Option in particular) and jurisdictions should consider using the AR Option as a component of their public health reporting system.
- Develop surveillance infrastructure (registries, similar to the XDRO registry in Illinois) to rapidly identify patients that are infected or colonized with certain AR pathogens so that appropriate infection control measures can be taken upon admission and when transferred between facilities.

**Sustainability of AR Surveillance and the Work of the Task Force**
- Create and implement a plan to integrate AR surveillance planning into ongoing processes and organizations.

**Surveillance Scope**
- Develop a policy for surveillance of colonization with multidrug resistant organisms (MDRO)/AR that can be used to inform CSTE Position Statements for standardized surveillance.
- Develop guidance for development of statewide/jurisdictional anti-ARograms for use by States and large cities.

**Cross-cutting Recommendations**
- Crosscutting recommendation F (Leverage Public Health-Clinical partnership and policy) will be addressed in the coming years through the “Sustainability of AR surveillance and the work of the Task Force” topic area.
- Cross cutting recommendation G (Incorporate New Technology) will be addressed in the “Terminology/data standards Use of Standardized Codes” topic area.

**Next Steps**
During the third year the Task Force will advocate for and foster implementation of the recommendations. Individuals or groups of members of the Task Force will be assigned to facilitate each of the recommendations. These champions for the recommendations will have linkages to the lead and stakeholder organizations (e.g., membership in the organization, a staffing role, etc.). They will advocate for implementation of the recommendation with the lead organization(s) and with stakeholders. They will then report on progress in implementation of the benchmarks to the Task Force at regular intervals.

As the Task Force advocates for implementation of the recommendations, it will engage in sustainability planning for when it concludes at the end of year three of its work (June 2019).
BACKGROUND AND WORK SUMMARY

Genesis of the Report

This report is a product of the ARSTF. The ARSTF was formed in response to the CSTE position statement 13-SI-01, "Recommendations for strengthening public health surveillance of antimicrobial resistance in the United States." The position statement was created because strains of bacterial, mycobacterial, and fungal pathogenic microorganisms have become alarmingly resistant to available antimicrobial agents for treatment of life-threatening infections, and those resistant strains are spreading. Moreover, new mechanisms conferring resistance are developing and spreading among pathogenic microorganisms. This problem has progressed to the point that clinicians are encountering infections caused by pathogens that are resistant to most, and sometimes all, available therapeutic agents. This trend shows no sign of slacking, raising the specter of a return to the pre-antibiotic era, which would mean that now common and life-saving and quality-of-life treatments, including common surgeries such as hip and knee replacement, could become dangerous or impossible to perform. This increase in resistance is being driven by the over-use and incorrect use of antimicrobial therapeutic agents among humans and for non-human animals. Once resistance develops in strains or species of microorganisms, these genetically coded resistance mechanisms can be transferred to other strains and species of microorganisms and spread. Because of this there is an increasing need to prevent the misuse of antimicrobial agents as well as the transmission of resistant pathogens. Fortunately, prevention methods such as infection control practices and antimicrobial stewardship (AMS) can slow and even potentially reverse the prevalence of antimicrobial resistance. Prevention efforts are highly dependent upon accurate knowledge of where and when antimicrobial resistance occurs. This problem is commonly found in acute care hospitals; however, it is also a significant problem across the spectrum of healthcare, and in the community, where it includes foodborne infections, gonorrhea, and tuberculosis.

As the CSTE Position Statement states, "Surveillance for antimicrobial resistance provides vital data on the emergence and spread of resistant pathogens. Early detection of resistance at the local and state level is important for understanding the factors responsible for emergence and preventing spread. We must identify and track antimicrobial resistance before we are fully able to construct control and prevention strategies. A standardized and comprehensive national network is needed; otherwise safety can only be assured in a few locations. Without a comprehensive antimicrobial resistance surveillance network in the United States, patient and consumer safety cannot be assured. Preservation of the usefulness of antimicrobial agents requires a multi-pronged and comprehensive approach that includes judicious use, the support of new agent research, innovative new treatment options, healthcare quality improvement, program evaluation and surveillance." The work of the Task Force, including these recommendations, are a contribution to the surveillance component. Other groups and initiatives address the other factors mentioned.

The position statement was written because current surveillance is inadequate in scope or timeliness to meet the challenges presented by the dynamic and complicated problem of antimicrobial resistance. The Position Statement notes that, "New solutions are needed that build upon the strengths of existing infrastructure and provide more timely, comprehensive, and broadly applicable data about current and emerging antimicrobial resistance problems. Improved laboratory diagnostic tests and additional training for laboratories on detection
of resistant pathogens are high priorities. Evaluation and dissemination of effective surveillance programs are imperative. Actions that strengthen public health surveillance of antimicrobial resistance should complement efforts aimed at improving clinical decision making about antimicrobial use and clinical performance benchmarking. A comprehensive surveillance strategy should provide timely, accurate, and standardized data in the following four categories:

1. **Early detection of new antimicrobial resistance**
2. **Monitoring the spread of antimicrobial resistance over time**
3. **Measuring the burden of infection, identifying at-risk populations, and evaluating interventions**
4. **Microbiological characterization of resistant pathogens”**

Clearly, we cannot conquer antimicrobial resistance merely through accelerated development of antimicrobial drugs. The selective pressure of injudicious antimicrobial use acting on these organisms that have very short generation times creates resistance quickly and easily outpaces our capacity to develop new antimicrobial drugs and classes of antimicrobials capable of treating highly resistant organisms. While we understand that judicious use of antimicrobials is a key factor in prevention, continued use of antimicrobials is vital for healthcare. Rather than a general interdiction of antimicrobials, specifically focused interventions to guide judicious use and to evaluate the effect of AR prevention intervention are needed. To accomplish this, a surveillance network to inform all stakeholders with accurate, complete, timely, and relevant actionable data is required – but AR provides challenges. Many stakeholders must participate in the development, maintenance and use of AR surveillance. These stakeholders come from different disciplines, including clinical healthcare, clinical and public health laboratory, informatics, healthcare-based infection control and epidemiology, and public health epidemiology. All these stakeholders have different roles and responsibilities for clinical care or public health, various constraints and need for data, and various capacities to generate and use data. In addition to this challenge, a timely surveillance network requires use of sophisticated and highly integrated informatics technology and software to transmit test results and other relevant data. Further complicating the situation, the resistance mechanisms, laboratory technology, and informatics solutions are each rapidly changing.

The Position Statement offers a solution to strengthen public health surveillance of antimicrobial resistance: "Strengthening public health surveillance of antimicrobial resistance will require a concerted effort by CDC, CSTE, and individual state and local health departments coupled with active participation by other organizations that have major roles in delivering or using those data for analysis and action. Strategic objectives for this effort include:

1. **better defining and coordinating the responsibilities of surveillance systems at all jurisdictional levels for early detection and ongoing monitoring of antimicrobial resistance problems,**

2. **establishing strategies and rules for safeguarding against suppression of antimicrobial susceptibility test results when those results are delivered from Laboratory Information Systems (LIMS) to public health surveillance systems,**

3. **assuring that Electronic Laboratory Reporting (ELR) serves the dual-purpose needs of communicable disease and antimicrobial resistance reporting at the local, state, and national levels,**

4. **enabling antimicrobial resistance surveillance systems to take full advantage of a shared technical infrastructure on the sending side for microbiology results reporting while preserving and enhancing their capacity to meet additional jurisdictional- or program-specific needs that go beyond ELR messages,**
(5) identifying and coordinating a response to the challenges and opportunities that multiple antimicrobial resistance surveillance systems face because of changes in diagnostic microbiology technology and practices,

(6) taking full advantage of public-private partnerships and policy levers that can be applied to further streamline and standardize the delivery of antimicrobial resistance data to public health surveillance systems, and

(7) recommending models for communicating antimicrobial resistance data to healthcare practitioners, policymakers, and the public in actionable forms to promote and inform antimicrobial resistance prevention programs...

“...A successful response to the challenges and opportunities that multiple antimicrobial resistance surveillance systems are encountering will yield benefits for analysis and action at all jurisdictional levels and across all categorical disease programs. More timely detection of new problems, more comprehensive coverage of temporal and geographic trends, and improved capacity to measure public health burden and characterize the microbiology of resistant pathogens are achievable through a concerted effort. No single system can meet all needs, but a singularly well-organized initiative will help assure that scarce resources are focused on crosscutting priorities and support systems that are optimally integrated and operating as efficiently and effectively as possible.

“...Achieving these strategic objectives and others needed to strengthen public health surveillance of antimicrobial resistance calls for a national initiative that is catalyzed and coordinated by CDC and CSTE.”

CDC agreed to support a three-year project in which CDC, CSTE, and other stakeholders form an Antimicrobial Resistance Surveillance Task Force to plan and implement solutions needed to strengthen surveillance and to develop partnerships around actionable recommendations to achieve the goals of the Position Statement.

**Structure of the Task Force**

The Task force is co-sponsored by three organizations: CDC, CSTE, and the APHL. Its 35 members represent individuals from the four main groups of stakeholders that are involved in AR surveillance and there is a special interest group of non-Task Force members who are on the contact list for documents and information (see Acknowledgements):

<table>
<thead>
<tr>
<th>Clinicians</th>
<th>Laboratorians</th>
<th>Informaticists</th>
<th>Public Health Epidemiologists</th>
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</thead>
<tbody>
<tr>
<td>- Prescribers</td>
<td>- Clinical (facility-based, reference)</td>
<td>- Information Technology staff in healthcare facilities</td>
<td>- Federal (CDC)</td>
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<tr>
<td>- Pharmacists</td>
<td>- Public health</td>
<td>- Public health-based IT professionals</td>
<td>- State</td>
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<td>- Infection prevention and control professionals</td>
<td>- Vendors</td>
<td>- Vendors</td>
<td>- Local</td>
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<td>- Standards setting orgs</td>
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Background 7
The Task Force is led by three co-chairs, each representing one of the sponsoring organizations, and three staff from CSTE or APHL to lead and facilitate the work of the Task Force.

**Vision Statement**

During the first year of its work, the Task Force adopted the following vision statement that embodies the founding position statement, and guides the continuing work, and hopefully the legacy, of the Task Force:

A comprehensive national public health antimicrobial resistance surveillance system (network), coordinated at the federal, state and local levels, ensures that surveillance data play a key role in preventing and reducing resistance. This well-resourced system (network):

- Integrates and expands multiple related and foundational surveillance systems including those for disease reporting/notification, isolate submission, and facility-based reporting using NHSN
- Uses technologies that are automated and standardized to the extent possible to generate accurate, timely, accessible, and useful data that enable public health institutional interventions to be taken
- Reflects role clarity and communication across the public health and clinical sectors to assure optimal efficacy
- Ensures that data collection, reporting, and analytical requirements draw on existing data where possible and avoid undue burden on facilities’ stakeholders
- Builds in flexibility so that the system (network) can respond to existing and emerging global pathogens, including allowing for data comparison with other countries

**Work of the ARSTF to Date**

As noted above, the Task Force has a (slightly more than) three-year lifespan.

**Year 1** (January 2016 – January 2017) – The Task Force was formed, recruited members, and developed planning capacity. Important products from the first year have been incorporated into this report: a policy paper on “Surveillance Design Principles,” a survey of state and local health department capacity for CRE surveillance, and a white paper on the roles and responsibilities of key stakeholders (e.g., clinicians, laboratorians, and public health professionals) in AR surveillance.

**Year 2** (March 2017 - June 2018) – The Task Force developed a vision statement strategic map and profile, a detailed strategic planning assessment informed and facilitated by prioritized strategic planning objectives, and recommendations based on the assessment. The Task Force also finalized recommendations on AR surveillance roles and responsibilities of local, state, and federal public health agencies.

**Year 3** (July 2018 – June 2019) [Pending] The Task Force will apply tactical planning to implement strategic priority recommendations. It will also develop and implement a succession plan to ensure that stakeholders assimilate the recommendations into their work that will continue after the ARSTF concludes.
Surveillance design principles

During the first year of its work, the Task Force developed Surveillance Design Principles (see Appendix) to both guide its work, and to serve as a resource for future planning. This Design Principles document is based on CSTE Position Statement 13-SI-01 and on the CDC-CSTE “Blueprint for Public Health Surveillance in the 20th Century.” There are eight principles that apply to AR surveillance:

1. Methods should be ethical (and by corollary unobtrusive)
2. The roles and responsible of federal, state, and local public agencies should be available and clear
3. Case and data definitions should be aligned and harmonized
4. Electronic reporting should be standardized
5. The Nationally Notifiable Disease Surveillance System (NNDSS) and National Healthcare Safety Network (NHSN) should be complementary, not duplicative
6. Data should be available for surveillance, infection control, and AMS (e.g., de-suppress Antimicrobial Susceptibility Testing-AST)
7. Culture Independent Diagnostic Testing (CIDT) will impact the availability of AR data
8. Additional resources will be necessary

Strategic Objectives, ARSTF Year 2

The Task Force is a planning organization, and its core work is developed around a Strategic Map with planning objectives to achieve the Task Force’s Vision. The Strategic Map (page 10) consists of five domains (foundational components, enhanced lab capacity, improved surveillance data, strengthened analysis and use of surveillance data, and secure resources/govern/sustain the network). Each domain includes several objectives. Two cross-cutting objectives (leverage partnerships and policy and incorporate new technologies) apply to all the domains. The Strategic Map is further described in the Strategic Profile.

Prioritization Process

After reviewing the Position Statement and other foundational documents, the full Task Force met in March 2017 in Atlanta for two days to develop a strategic plan for the Task Force’s work in years two and three. Task Force members completed an environmental scan through facilitated discussion, and brainstormed the vision, strategic domains, and objectives. Through a weighted voting process they prioritized objectives, identifying two governance priority objectives for the Core workgroup, and seven other priority objectives that fit into two tracks of work. The two tracks of work were assigned to one of two workgroups: Public Health Informatics Tools for Epidemiology, and Laboratory Data to Public Health. One of the priority objectives (A-5) was assigned to both tracks of work and both workgroups. Before beginning the assessment, the workgroups finalized the priority objectives ( modifying them somewhat from the version in the original strategic map).
National Antimicrobial Resistance Surveillance Strategic Map: 2017-2020

Strengthen Antimicrobial Resistance Surveillance in the United States

A. Provide Foundational Components for Surveillance
   1. Encourage Appropriate Use of Diagnostic Testing/Culturing
   2. Provide Timely Delivery of Guidance to Detect and Respond to Novel/Emerging AR Threats
   3. Promote Standards for Cumulative Antibiotics at the Facility, Regional and National Levels
   4. Provide Antimicrobial Resistance Surveillance Workforce Development Curriculum
   5. Increase Public Health, Lab and Clinical Informatics and Bioinformatics Capacity
   6. Establish Roles, Responsibilities and Priorities of Public Health and the Clinical Sector

B. Enhance the Capacity and Use of Laboratory Diagnostics for Surveillance
   1. Ensure Clinical Labs Have Access to Up-to-Date, FDA-Approved, Reimbursable Tests for Antimicrobial Resistance
   2. Sustain Antimicrobial Resistance Work in Public Health Labs and Expand Where Needed
   3. Provide Technical Education about Antimicrobial Resistance Testing
   4. Enable Capture of Data Using Standardized Vocabulary Codes for New Tests and Other AR Data
   5. Implement a Strategy to Extract Supported Antimicrobial Susceptibility Test Results

C. Improve Quality and Availability of Surveillance Data
   1. Evaluate, Enhance & Promote Existing Systems, Processes & Tools
   2. Leverage Shared Technical Infrastructure and Services
   3. Increase Automation across the Surveillance Continuum
   4. Establish and Align Standards for Data Collection, Transmission and Provisioning
   5. Maintain Epi, Lab and Clinical Information Systems with Appropriate Vocabulary and Code Sets

D. Strengthen the Analysis and Use of Surveillance Data for Action
   1. Improve and Automate Detection of Emerging Resistance
   2. Integrate Epi, Lab and Clinical Data
   3. Improve and Automate Outbreak/Cluster Detection
   4. Build AR Situational Awareness at the Facility, Community and Regional Levels
   5. Integrate Lab, Epi and Antimicrobial Use Data for Human, Animal and Environmental Health

E. Secure Resources and Legal and Policy Supports to Implement, Govern, and Sustain the System
   1. Establish and Implement a Governance Structure
   2. Align with CARB and Successor Objectives
   3. Nurture Strategic Partnerships
   4. Support Stakeholders in Navigating the Regulatory Environment
   5. Provide Timely Communication and Evaluation to Stakeholders

F. Leverage Public Health-Clinical Partnerships and Policy

G. Incorporate New Technology (e.g., Advanced Molecular Detection) and Epidemiological Analytic Methods
Priority Objectives

These are listed here by workgroup assignment. Under each objective, there are several bulleted action items or directions for use during assessment, recommendation development, and recommendation implementation tracking and follow-up.

Laboratory Data to Public Health Workgroup

Objective B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data.

- Define data that are needed.
- Assess how standardized the codes are currently and how mapping to codes is conducted.
- Make recommendations on implementation of standardized codes.
- List principles for standardization to apply to new tests.

Objective B-5: Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response.

- Define “data suppression” and “cascading suppression” for AR.
- Assess the prevalence and patterns of suppression, where suppression occurs in laboratory or health care systems, support for and barriers to de-suppression in the clinical and laboratory communities.
- Make recommendations on how de-suppression could be accomplished.

Objective C-4: Establish and align standards for data collection, transmission and provisioning. Fundamental question: Where is the data collection, referred to here, happening?

- Is this an area for the development of recommendations regarding electronic data transfer from labs to public health?
- How many states currently have capacity to receive to ELR? Most states. However, whether they can use that data and receive susceptibility data is another question.
- Suggestion: look carefully at ELR message and determine if it includes all the desired data elements. If not, now is the time to provide input on adding those elements.
- Another avenue to consider: implications for HL7 messages, barriers associated with that format.

Objective A-5: Increase public health, lab and clinical informatics capacity.

- Enhance laboratory IT, informatics capacity to generate, store, analyze, and transfer large and complex data sets capable of AR surveillance. These data sets should be readily modifiable to address changes in pathogens under surveillance, information on resistance, and in testing technology.
- Define what “capacity” means vis-à-vis AR.
- Assess current capacity in these areas.
- Make recommendations for increase, with priorities.
- Identify actions to increase capacity with current resources and estimates of additional resources for increase in capacity.

Note: The original strategic objectives include “bioinformatics.” However, this was tabled pending other more general planning work underway in this area (not just restricted to AR) that would be best completed before addressing AR issues.
Public Health Informatics Tools for Epidemiology Workgroup

**Objective C-1:** Evaluate, enhance and promote existing systems, processes and tools.

Conduct an assessment to:

- Assess and describe the current structure of AR surveillance.
- Identify and describe gaps.
- Identify model systems.
- Identify opportunities for interoperability among existing systems (also A-5).
- Produce a data flow diagram with annotation reflecting current systems and processes that a variety of stakeholders can understand.

**Objective D-2:** Integrate epi, lab and clinical data.

- Assess what epidemiology, laboratory, and clinical data are available and need to be integrated to have an effective AR surveillance network:
  - Assess current levels of integration and identify model programs.
  - Make recommendations for national integration “expectations, standards” (also A-5).
- Create a vision of what integration and standardization would look like – including a data flow diagram with annotation reflecting recommended systems and processes that a variety of stakeholders can understand (also A-5). Also include One Health in the vision for integration.

**Objective C-2:** Leverage shared technical infrastructure and services.

- Based on C-1 and D-2, identify the work that will be required to enable leveraging.
- Specify leveraging opportunities. In particular, identify opportunities and work needed to leverage opportunities with Laboratory Information System (LIS) and Electronic Health Records (E.H.R.) vendors.
- Assess what work will be needed to make the leveraging happen.
- Engage and collaborate with vendors.
- Make recommendations for leveraging with priorities (also A-5).

**Objective A-5:** Increase public health, lab and clinical informatics capacity.

- Prior objectives (as noted) will address various aspects of A-5.
- Identify actions to increase capacity with current resources.
- Consider performing estimates of additional resources for increase in capacity.

**Core Workgroup**

**Objective E-1:** Establish and implement a governance structure.

**Objective A-6:** Establish roles, responsibilities, and priorities of public health and the clinical sector.
Extent to Which Addressing the Priority Strategic Objectives Addresses the Remaining Objectives in the Strategic Map

The nine objectives prioritized for action are a fraction of the 28 objectives in the Strategic Map. However, as shown in the analysis below, the priority objectives address remaining objectives, in whole or in part.

**Priority Objective B-4:** Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data. Non-priority objectives addressed in whole or part by this priority objective:

- C1: Evaluate, enhance and promote existing systems, processes and tools
- C3: Increase automation across the surveillance continuum
- C5: Maintain epi, lab, and clinical information systems with appropriate vocabulary and code sets
- C6: Ensure sufficient data to track resistance patterns across settings and organisms
- D1: Improve and automate detection of emerging resistance
- D3: Improve and automate outbreak/cluster detection

**Priority Objective B-5:** Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response. Non-priority objectives addressed in whole or part by this priority objective:

- C6: Ensure sufficient data to track resistance patterns across settings and organisms
- D1: Improve and automate detection of emerging resistance
- D3: Improve and automate outbreak/cluster detection

**Priority Objective C-4:** Establish and align standards for data collection, transmission, and provisioning. Non-priority objectives addressed in whole or part by this priority objective:

- A3: Promote standards for cumulative antibiogram at the facility, regional, and national levels
- B3: Provide technical education about antimicrobial resistance testing
- C1: Evaluate, enhance, and promote existing systems, processes and tools
- C3: Increase automation across the surveillance continuum
- C5: Maintain epi, lab, and clinical information systems with appropriate vocabulary and code sets
- D1: Improve and automate detection of emerging resistance
- D3: Improve and automate outbreak/cluster detection
- D5: Integrate lab, epi, and antimicrobial use data for human, animal, and environmental health

**Priority Objective C-1:** Evaluate, enhance, and promote existing systems, processes and tools. Non-priority objectives addressed in whole or part by this priority objective:

- A4: Provide antimicrobial resistance surveillance workforce development curriculum
- C3: Increase automation across the surveillance continuum
- D1: Improve and automate detection of emerging resistance
- D3: Improve and automate outbreak/cluster detection
- D5: Integrate lab, epi, and antimicrobial use data for human, animal, and environmental health
**Priority Objective D-2:** Integrate epi, lab and clinical data. Non-priority objectives addressed in whole or part by this priority objective:

- A3: Promote standards for cumulative antibiograms at the facility, regional, and national levels
- C1: Evaluate, enhance and promote existing systems, processes, and tools
- C3: Increase automation across the surveillance continuum
- C5: Maintain epi, lab, and clinical information systems with appropriate vocabulary and code sets
- D4: Build AR situational awareness at the facility, community, and regional levels
- D5: Integrate lab, epi, and antimicrobial use data for human, animal, and environmental health
- D6: Communicate results and suggested actions

**Priority Objective C-2:** Leverage shared technical infrastructure and services. Non-priority objectives addressed in whole or part by this priority objective:

- C1: Evaluate, enhance and promote existing systems, processes and tools
- C5: Maintain epi, lab, and clinical information systems with appropriate vocabulary and code sets
- E3: Nurture strategic partnerships
- E4: Support stakeholder in navigate the regulatory environment
- E5: Provide timely communication and evaluation to stakeholders

**Priority Objective A-5:** Increase public health, lab and clinical informatics capacity. Non-priority objectives addressed in whole or part by this priority objective:

- A4: Provide antimicrobial resistance surveillance workforce development curriculum
- B1: Ensure clinical labs have access to up-to-date FDA-approved reimbursable tests for antimicrobial resistance
- B2: Sustain antimicrobial resistance work in public health labs and expand where needed
- C3: Increase automation across the surveillance continuum
- D5: Integrate lab, epi, and antimicrobial use data for human, animal, and environmental health
- E3: Nurture strategic partnerships
- E4: Support stakeholders in navigating the regulatory environment

**Priority Objective E1:** Establish and implement a governance structure (for the Task Force). No other objectives addressed by this priority objective.

**Priority Objective A-6:** Establish roles, responsibilities, and priorities of public health and the clinical sector. Non-priority objectives addressed in whole or part by this priority objective:

- A1: Encourage appropriate use of diagnostic testing/culturing
- A2: Provide timely delivery of guidance to detect and respond to novel/emerging AR threats
Crosscutting Objective F: Clinical-Public Health Partnerships, Crosscutting Objective G: New technology

By their very nature, these strategic objectives both address all five domains and all the objective listed under each domain.

This analysis shows that recommendations developed to address the priority objectives also address the non-priority objectives to a significant degree. Also, in several instances priority objectives re-enforce and support each other. As the Task Force continues into the next, more tactical, implementation phase of its work, a repeated and more detailed coverage analysis would be worthwhile.

ARSTF Planning Activities

CP-CRE MMG Workgroup

In June 2017, CSTE approved Position Statement 17-ID-04: “Public Health Reporting and National Notification of Carbapenemase Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) for E. coli, Klebsiella spp. and Enterobacter spp.” which called for making CP-CRE nationally notifiable. CP-CRE is a particularly worrisome form of AR because the genes conferring high-level resistance against carbapenems via a carbapenemase enzyme that destroys the antibiotic are found on a plasmid that can be easily transferred to other bacterial strains and species. CSTE adopted making CP-CRE nationally notifiable, thereby directing all states and territories to transfer reports on CP-CRE cases to CDC. Transmission of nationally notifiable disease (NND) data to CDC is facilitated by the development of a message mapping guide (MMG), which specifies the information (data elements) that should be reported to CDC and how. The ARSTF convened the CP-CRE sub-Workgroup, an ad hoc sub-workgroup in the Informatics Workgroup, to collaborate with CDC on recommendations for the data elements that should be collected for CP-CRE reporting notifications from states and territories to CDC. These recommendations were submitted by the CP-CRE sub-workgroup to CDC in December 2017 and are being used to help CDC prepare the MMG. The MMG is anticipated to be available for pilot-testing by January 2019. This sub-workgroup’s work demonstrated the usefulness of the collaboration between stakeholders fostered by the ARSTF to create a surveillance resource that embodies the Vision and Design Principles.

Roles and Responsibilities of Local, State, and Federal Agencies in Public Health

During its first year, the Task Force began work on a document that outlines “Roles and Responsibilities of Public Health Agencies for Surveillance of Antimicrobial Resistance,” published mid-2017. The document is in the form of a table with guidance in three domains: 1) collection of AR data; 2) analysis, interpretation, and use of surveillance data; and 3) gaps. Each domain is presented in a table. The first two domains identify actions and guidance for each level of public health (local, state, federal), while the Gaps table specifies the “Gap,” recommended “Response,” “Responsible Entity or Entities,” and describes “Incentives for Action.”

“Collection” makes seven recommendations, including providing criteria for reporting and managing a national registry of local and state AR reporting requirements for situational awareness and facilitation of reporting; technical assistance and infrastructure at federal and state levels to support clinical providers, laboratories, and public health programs that must participate in a coordinated surveillance network; and that both infrastructure and technical assistance are needed to promote dissemination of the data.
“Analysis, interpretation, use” makes 11 recommendations, including cluster detection and intervention, tracking of spread of AR, and the scope of data to be collected to measure impact, risk and inform prevention and inform research.

“Gaps” identifies gaps and issues to address and also makes 11 recommendations, including the suppression of laboratory data that is important for surveillance, resource needs, better alerting and timeliness of data for action, standardization and technical challenges, the need to understand what data are most relevant for tracking and action, better capacity to analyze and use the data, better system and network status awareness and evaluation, and linkage to One Health for surveillance and action.

Assessment

From July 2017-June 2018 the Task Force engaged in an assessment of the status of AR surveillance, identifying gaps and opportunities that can be exploited to advance AR surveillance. This assessment was designed to gather background information specifically related to the strategic objectives prioritized by the Task Force to guide recommendations. Each of the two main Task Force workgroups (Laboratory and Informatics) planned and carried out an assessment and analyzed the data. The Lab Workgroup used a network survey methodology, and the Informatics Workgroup used focus groups.

Summary of the Assessment Findings

The assessment found that much AR surveillance and many initiatives to strengthen surveillance are already underway. It is however, vitally important to link the various data systems employed in AR surveillance together, and progress still needs to be made in that direction. Communication across clinical, lab, IT/informatics, public health exists, but can be further strengthened. Timeliness of testing and communication of test results have improved significantly within public health due to initiatives, such as National Antibiotic Resistance Monitoring System (NARMS) and Antibiotic Resistance Lab Network (ARLN), that are doing AR testing. More collaborative planning and communication between the various stakeholders and vendors of informatics services and manufacturers of (lab equipment, IT) could be very beneficial. We can exploit existing infrastructure (e.g., electronic case reporting (eCR) and Reportable Condition Knowledge Management System (RCMKS); CLIA, ARLN, CDC Laboratories; APHL Informatics Messaging Services (AIMS) platform; NHSN AUR module; RCKMS - both to build collaborations and to build initiatives and infrastructure to address gaps. Situational awareness is not shared effectively across AR surveillance. A map of the available systems and stakeholders and activities already involved in AR testing and surveillance is needed. The ARSTF developed a Data Flow Diagram (DFD) to meet this need (see Appendix), which will be very helpful in future planning.

Incorporating AR data into the ELR messages sent from clinical and public health laboratories to public health epidemiology programs is a key factor in systematic and integrated AR surveillance. While the proportion of reportable laboratory findings sent to public health using ELR has increased over time, there still are gaps, especially among smaller clinical laboratories that are not able to report electronically, or where reporting is not complete. During the assessment, it was noted that the capacity of state health department informatics to process ELR varies and that some are not ready to receive or consume AR reporting through ELR.

There still appears to be a significant number of laboratories who do not use the current CLSI breakpoints, despite FDA actions to facilitate rapid and consistent uptake.

In reporting of Antimicrobial Susceptibility Test (AST) data, significant proportion of laboratories send only an interpretation (e.g., “R” resistant, “S” susceptible) and not quantitative data (e.g., Minimum Inhibitory
Concentration - MIC). This makes it difficult to compare data across reporters, especially when breakpoints are not consistent or up-to-date.

A significant amount of AST data is suppressed; the ARSTF assessment suggests that 1/3 of test results have some of the AST results suppressed and that approximately half of suppression is done by the testing equipment and half by the Laboratory Information System (LIS). The assessment suggests that valuable surveillance information is lost when antimicrobial resistance findings are suppressed but acknowledges that suppression may be implemented to support antimicrobial stewardship to prevent the provision of results that are of questionable reliability or usefulness. However, in general, better access to suppressed data could be very helpful to both infection control professionals as well as epidemiologists for tracking emerging resistance. A particular type of suppression, “cascading” was identified during the assessment. Cascading can entail the suppression of susceptibility testing against other antibiotics in the same class when resistance to one antibiotic in that class has been demonstrated. Another is the suppression of data on susceptibility against newer-generation antibiotics when an isolate demonstrates sensitivity to “first choice” antibiotics. More assessment and study of these complex issues with import for clinicians and public health AR programs could clarify these issues and should be pursued.

Laboratorians and clinicians need clear instructions to help them implement standardized coding systems (e.g., SNOMED, LOINC) effectively and consistently. The individual responsible for applying codes varies by laboratory.
General Premise

These recommendations are presented in a format designed to foster implementation and tracking. The Task Force is not intended as a permanent organization, nor does it have authority over or responsibility for clinical care, laboratory testing, or public health surveillance. However, it can facilitate partnerships among a variety of agencies, organizations, and collaboratives that do have those authorities and infrastructure. For each recommendation, presented below, partners and stakeholders are identified. Where beneficial, additional context is given in a narrative section.

Note: These recommendations also indicate proposed benchmarks and timeframes. The benchmarks listed are ambitious, even ideal outcomes. The lead organizations and stakeholders will be best suited to redefine the benchmarks and timelines as work progresses. The recommendations will be updated to reflect this.

Topic: Terminology/data Standards Use of Standardized Codes

**Recommendation 1:** Identify/create LOINC codes for all relevant tests and SNOMED codes for pathogens and corresponding test results for all AR pathogens and AST, and a process for timely establishment of these codes.

**Type of recommendation:** standardization

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** HL7, Regenstrief Institute (LOINC), National Library of Medicine (SNOMED), APHL, Joint Public Health Informatics Taskforce (JPHIT), Laboratory Information Management System (LIMS) vendors, state lab and clinical lab directors, CDC

**Lead organization/consortium/person:** APHL

**Timeframe/key benchmark(s):** Regenstrief Institute (LOINC) and NLM (SNOMED) develop and adopt processes by July 2019

**ARSTF Workgroup:** Lab, Informatics

**Narrative:** New test methods become available and new resistance mechanisms emerge. LOINC codes for these new tests and corresponding SNOMED codes for the findings are needed in a coordinated manner to capture findings in a standard way as soon as the new tests are available. The Task Force’s assessment shows the importance of identifying and using the appropriate codes and for making sure they are correctly utilized and applied, both for new and for existing tests and resistance mechanisms.
**Sub-Recommendation 1A:** Develop processes for ensuring that LOINC/SNOMED codes are available for non-proprietary tests.

**Type of recommendation:** standardization, communication

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** HL7, Regenstrief Institute (LOINC), International Health Terminology Standards Organization (IHTSDO) & National Library of Medicine (SNOMED), APHL, JPHIT, LIMS vendors, state lab and clinical lab directors, CDC

**Lead organization/consortium/person:** APHL

**Timeframe/key benchmark(s):** Regenstrief Institute and NLM develop and adopt processes by July 2019

**ARSTF Workgroup:** Lab, Informatics

**Narrative:** Non-proprietary tests are often developed and/or implemented through the public health laboratories. There is no standard process currently to ensure that standardized LOINC and SNOMED codes are requested of Regenstrief Institute and NLM who assign the codes when non-proprietary tests are adopted. As a result, non-standard coding by laboratories using the new test is common, especially soon after the test is rolled out. A recommended process to ensure that standard codes are available when these nonproprietary tests are disseminated will ensure better standardization of data. Also, the proper codes, once developed, need to be assigned appropriately by the labs, etc. There is need for extensive education and training to ensure this proper assignment.

**Sub-Recommendation 1B:** Encourage CLSI or FDA to require manufacturers to recommend a standard three-letter antibiotic code when submitting new compounds for review. CLSI or FDA should also submit a request to the Regenstrief Institute for the creation of relevant LOINC codes for new compounds under review.

**Type of recommendation:** standardization

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** FDA, CLSI, HL7, Regenstrief Institute, National Library of Medicine, APHL, JPHIT, pharmaceutical companies, diagnostics manufacturers

**Lead organization/consortium/person:** FDA and CLSI

**Timeframe/key benchmark(s):** July 2019

**ARSTF Workgroup:** Lab

**Narrative:** Submitting recommended codes early in the process of review by FDA/CLSI will facilitate more rapid availability of the appropriate codes, which will avoid a gap when codes are not available when the equipment is beginning to be used, leading to lack of standardization and difficulties in determining data trends.
**Sub-Recommendation 1C:** Develop a standardized approach for submitting for LOINC codes for new/emergent pathogens.

**Type of recommendation:** standardization

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** Regenstrief Institute, APHL, CDC, Lab instrument manufacturers, LIMS vendors, state lab and clinical lab directors, state AR programs, WHONET

**Lead organization/consortium/person:** Regenstrief Institute

**Timeframe/key benchmark(s):** Standard procedure developed by July 2019

**Narrative:** The Regenstrief Institute assigns LOINC codes for pathogens. Currently, there is no standard approach for assigning LOINC codes to new/emerging pathogens of interest to AR. Whomever applies for the LOINC code can do so in a manner that may not align with other existing pathogen codes. To ensure consistency or an agreed upon process that is well publicized for applying in accordance with Regenstrief protocols should be developed and disseminated.

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**Sub-Recommendation 1D:** Support efforts to routinely include standard codes in package inserts for proprietary tests (e.g. SHIELD)

**Type of recommendation:** standardization, communication

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** FDA, HL7, Regenstrief Institute (LOINC), National Library of Medicine (SNOMED CT), APHL, JPHIT, LIMS vendors, state lab and clinical lab directors

**Lead organization/consortium/person:** FDA

**Timeframe/key benchmark(s):** FDA begins to routinely include standard codes in package inserts by July 2019

**ARSTF Workgroup:** Lab, Informatics

**Narrative:** SHIELD is a multi-agency/stakeholder group, led by FDA, to support the development, adoption, harmonization, and implementation of semantic interoperability standards and structured communication formats for lab test data. The FDA has awareness over package inserts. The Task Force could address this issue with FDA via SHIELD consultations.
**Sub-Recommendation 1E:** Routinely include LOINC/SNOMED code recommendations in laboratory guidance documents (e.g. CLSI).

**Type of recommendation:** standardization, communication

**Priority Strategic objective(s) to which it relates:** B-4: Enable or improve capture of data using standardized vocabulary codes for new tests and other antimicrobial resistance data

**Stakeholders:** CLSI, CDC, HL7, Regenstrief (LOINC), National Library of Medicine, APHL, JPHIT, LIMS vendors, state lab and clinical lab directors

**Lead organization/consortium/person:** CLSI

**ARSTF Workgroup:** Lab

**Timeframe/key benchmark(s):** Obtain a commitment to include this recommendation by July 2019, CLSI includes SNOMED/LOINC recommendations in its 2020 guidance.

**Narrative:** CLSI has several committees or working groups that make recommendations and publish guidelines for laboratory practice, including recommendations on both testing and reporting of test results. These guidelines are developed by subject matter experts (SMEs), are authoritative, and are regularly updated. Including proper code recommendations within these guidelines would provide standardization and rapidly disseminate and foster adoption by clinical as well as public health laboratories.

**Topic: Breakpoints**

**Recommendation 1:** Encourage the adoption of the President’s Advisory Council – Combatting Antibiotic Resistant Bacteria (PAC-CARB) recommendation that use of most up to date breakpoints becomes a CLIA requirement.

**Type of recommendation:** standardization

**Priority Strategic objective(s) to which it relates:** C-1: Evaluate, enhance and promote existing systems, processes and tools

**Stakeholders:** CMS, APHL, LIMS vendors, state lab and clinical lab directors, state AR programs, IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), STMA (Susceptibility Testing Manufacturers Association)

**Lead organization/consortium/person:** CMS

**Timeframe/key benchmark(s):** Updated breakpoints become CLIA requirement by July 2019

**ARSTF Workgroup:** Lab
**Narrative:** Though this recommendation has been widely known for the past 3 years, and CLSI had updated breakpoints at that time, FDA now has adopted the new breakpoints, and equipment manufacturers are able to implement them as well. However, an estimated 30-40% of clinical laboratories still use the old breakpoints. Standardized and widely used up-to-date breakpoints are fundamental to the quality of the data, and effective and coordinated action based on the data. Therefore, a CLIA requirement is needed.

**Topic: Data Suppression**

**Recommendation 1:** Gather more information on the reasons surrounding data suppression of susceptibility data, including why those data are suppressed, circumstances in which data suppression may be helpful or harmful to encourage appropriate antimicrobial usage, and implications for clinical and public health interventions.

**Type of recommendation:** assessment and planning

**Priority Strategic objective(s) to which it relates:** B-5: Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response

**Stakeholders:** APHL, CDC (NHSN), Lab instrument manufacturers, LIMS vendors, state lab and clinical lab directors, state AR programs, WHONET

**Lead organization/consortium/person:** AR test machine manufacturers (e.g., Vitek, Microscan), NHSN, CDC Emerging Infections Program (EIP)

**Timeframe/key benchmark(s):** Fall 2018-Spring 2019

**ARSTF Workgroup:** Lab

**Sub-Recommendation 1A:** Gather list of expert rules from instrument manufacturers. Evaluate how those rules would impact public health surveillance data. This evaluation should include assessment of the impact of data suppression on public health reporting of AR resistant pathogens in antibiograms for AMS.

**Type of recommendation:** assessment and planning

**Priority Strategic objective(s) to which it relates:** B-5: Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response

**Stakeholders:** APHL, CDC (NHSN), Lab instrument manufacturers, LIMS vendors, state lab and clinical lab directors, state AR programs, WHONET

**Lead organization/consortium/person:** AR test machine manufacturers (e.g., Vitek, Microscan), NHSN, CDC Emerging Infections Program (EIP)

**Timeframe/key benchmark(s):** List of expert rules October 2018, WHONET analysis January 2019 NHSN pilot July 2019

**ARSTF Workgroup:** Lab
**Narrative:** Manufacturers should be encouraged to ensure that all AST data are sent from the machines performing the testing to the LIS employed by the laboratories. This often requires the involvement of the IT support personnel serving the laboratories to address who should be able to access the de-suppressed data; however, not having the data accessible can impede public health and infection control personnel from getting critical information for action to investigate and respond with appropriate infection control actions.

**Sub-Recommendation 1B:** Assess the effect of data suppression rules on the availability and usefulness of resistance data on the data currently reported via the NHSN AUR module.

**Type of recommendation:** assessment and planning

**Priority Strategic objective(s) to which it relates:** B-5: Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response

**Stakeholders:** APHL, CDC (NHSN), Lab instrument manufacturers, LIMS vendors, state lab and clinical lab directors, state AR programs, WHONET

**Lead organization/consortium/person:** AR test machine manufacturers (e.g., Vitek, Microscan), NHSN, CDC Emerging Infections Program (EIP)

**Timeframe/key benchmark(s):** List of expert rules October 2018, WHONET analysis January 2019 NHSN pilot July 2019

**ARSTF Workgroup:** Lab

**Narrative:** NHSN already receives (presumably suppressed) comprehensive AST data from facility laboratories participating in the AUR modules. A look-back project would access de-suppressed data, evaluate the degree of suppression and assess the public health and AMS implications of that suppression on what is reported in NHSN. The Emerging Infections Program (EIP) has begun to study this issue using data from the EIP MuGSI project. This study could be continued and extended to address questions raised by the pilot MuGSI project in this area.

**Recommendation 2:** Develop guidance for laboratories on how to approach de-suppression of data for public health purposes (e.g., CLSI M39). Include guidance on how to apply rules that allow for appropriate de-suppression of data for public health surveillance.

**Type of recommendation:** standardization

**Priority Strategic objective(s) to which it relates:** B5: Implement a strategy to extract suppressed antimicrobial susceptibility test results that are critical to public health surveillance and response.

**Stakeholders:** APHL, CLSI, Lab instrument manufacturers, LIMS vendors, state lab and clinical lab directors, state AR programs

**Lead organization/consortium/person:** CLSI

**Timeframe/key benchmark(s):** CLSI M39 recommendations developed by July 2019
**Narrative:** Guidance depends on intended use. For public health reporting purposes, it would be possible for the vendor to maximize rules. For full reporting to the LIS, and role-based suppression rules, the assistance of the healthcare facility IT department would be needed.

**Topic name:** AR Electronic Laboratory Reporting (ELR)

**Recommendation 1:** Establish and disseminate best practices in ELR for AR by revisiting the guidance document created by the CSTE AR/ELR Working group in 2017 for CRE, (“Best Practices for Surveillance of Antimicrobial Resistance via Electronic Laboratory Reporting Recommendations from the CSTE AR/ELR Working Group, June 2017”), and broadening its scope to include the other pathogens and AR mechanisms that should be reported through ELR.

**Type of recommendation:** communication, infrastructure building, standardization

**Priority Strategic objective(s) to which it relates:** C-1: Evaluate, enhance and promote existing systems, processes and tools; A-5: Increase public health, lab and clinical informatics capacity

**Stakeholders:** CDC, CSTE, APHL, vendors, state lab and clinical lab directors

**Lead organization/consortium/person:** CSTE

**Timeframe/key benchmark(s):** Guidance would be revised and distributed by July 2019.

**ARSTF Workgroup:** Informatics

**Narrative:** The “Best Practices” document offers operational guidance to state and territory health departments engaged in AR surveillance, fostering consistency and helping make best practices accessible and achievable for all states and territories. CSTE should be asked to review the current document, assess best practices called for in that document, identify best practices that have been developed since the document was published, and revise and disseminate a revised document.

**Recommendation 2:** All laboratories that submit reportable lab findings to public health via ELR should submit reportable AR laboratory findings via ELR, with messages conforming to nationally accepted standards, validated for accuracy and completeness of content and structure when sent or received. Laboratories that are not current reporting via ELR are encouraged to do so, especially as electronic reporting of AR is a compelling reason to develop this capacity.

**Type of recommendation:** communication, infrastructure building, standardization

**Priority Strategic objective(s) to which it relates:** C-1 Evaluate, enhance and promote existing systems, processes and tools; A5: Increase public health, lab and clinical informatics capacity

**Lead organization/consortium/person:** CDC (ELC)

**Timeframe/key benchmark(s):** A timeframe will be proposed after recommendations from the ARSTF are disseminated. Benchmarks and timeframe will be determined after additional planning.

**ARSTF Workgroup:** Informatics
**Narrative:** Continued and expanded resources provided to public health agencies through CDC’s Epidemiology and Laboratory Capacity Cooperative Agreement (ELC) would be helpful in achieving this recommendation. While this recommendation is focused only on AR reporting from laboratories currently reporting via ELR, all laboratories should be working toward submitting electronically, consistent with the CDC ELR metrics. To foster this, ELC should require that states strive to obtain ELR from all laboratories.

**Recommendation 3:** ELR for laboratory results obtained through the AR Lab Network data should be submitted to public health agencies using HL7 messages routed through AIMS.

**Type of recommendation:** communication, data access

**Priority Strategic objective(s) to which it relates:** C-1: Evaluate, enhance and promote existing systems, processes and tools

**Stakeholders:** CDC, CSTE, APHL, state lab and clinical lab directors, state AR coordinators

**Lead organization/consortium/person:** CDC (ARLN) and APHL

**Timeframe/key benchmark(s):** July 2019.

**ARSTF Workgroup:** Informatics

**Narrative:** Public health laboratories are currently submitting AR Lab Network laboratory results to AIMS. These data should be utilized to populate a standard HL7 ELR message based on standards recommended by CSTE.

**Topic:** NNDSS CP-CRE MMG

**Recommendation 1:** Finalize and implement the MMG for NNDSS CP-CRE and include the ARSTF MMG workgroup in this CDC process.

**Type of recommendation:** communication, standardization, alignment

**Priority Strategic objective(s) to which it relates:** A-5: Increase public health, lab and clinical informatics capacity

**Stakeholders:** APHL, CDC, CSTE, ARSTF

**Lead organization/consortium/person:** CDC

**ARSTF Workgroup:** Informatics

**Timeframe/key benchmark(s):** MMG finished December 2018 and used by state for reporting January 2019.

**Narrative:** As described earlier, an ad hoc sub-workgroup of the Task Force consulted with CDC staff and submitted recommendations on the data elements that should be collected for national reporting of CP-CRE. These recommendations are being considered by CDC, and to maximize the quality and usefulness of the final product, the Task Force should continue to be engaged during CDC’s deliberations and finalization of the MMG.
### Topic: Linking Laboratory and Epidemiological Data

**Recommendation 1:** Publish guidelines on how to create and maintain linkages between laboratory findings and case findings for state, local and CDC programmatic needs.

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<tr>
<th>Type of recommendation</th>
<th>Communication, standardization, alignment</th>
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<tbody>
<tr>
<td>Priority Strategic objective(s) to which it relates</td>
<td>D-2: Integrate epi, lab and clinical data</td>
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<tr>
<td>Stakeholders</td>
<td>APHL, CDC, CSTE, ARSTF</td>
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<td>Lead organization/consortium/person</td>
<td>CDC</td>
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<td>Timeframe/key benchmark(s)</td>
<td>Publish guidance by July 2019</td>
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<td>ARSTF Workgroup</td>
<td>Informatics</td>
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<tr>
<td>Narrative</td>
<td>The Epi Case ID and Accession Number are important linking identifiers. The state public health accession number may be a useful standard identifier that can be used by clinical labs, state and local public health labs, and CDC to link their data.</td>
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### Topic: NHSN, Informatics to Track AR Among Healthcare Facilities

**Recommendation 1:** Healthcare facilities should use the NHSN AUR module (the AR Option in particular) and states should consider using the AR Option as a component of their public health reporting.

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<th>Type of recommendation</th>
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<tr>
<td>Priority Strategic objective(s) to which it relates</td>
<td>C-1: Evaluate, enhance and promote existing systems, processes and tools; D-2: Integrate epi, lab and clinical data</td>
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<tr>
<td>Stakeholders</td>
<td>CDC, APHL, CSTE, healthcare facilities (IT, pharmacists), public health epidemiologists</td>
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<td>Lead organization/consortium/person</td>
<td>CMS, CDC, CSTE</td>
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<tr>
<td>Timeframe/key benchmark(s)</td>
<td>Report on degree of implementation of the JPHIT NHSN AUR module policy by July 2019</td>
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<td>ARSTF Workgroup</td>
<td>Informatics</td>
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<td>Narrative</td>
<td>The AUR module has two Options, AU and AR. AUR uptake by healthcare facilities has been slow. The AR Option, being newer, is less than the AU Option in uptake. SHEPheRD grants, ELC, or meaningful use (MU) funds might be used to incentivize and disseminate AUR use in states. The role of CMS would be to promote the use of AR though incentives, such as value-based purchasing. The CDC could also incentivize increase use through ELC funding opportunities. CSTE’s role can be to encourage states to use the AUR module, the AR Option, as a vehicle for AR public health reporting, in addition to other routes (such as AR through ELR reporting of reportable conditions). According to the PAC-CARB, more work needs to be done on risk stratification with the AUR module before it could be accepted by the National Quality Forum (NQF), and mandated by CMS; therefore, this effort should be explored and</td>
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pursued. JPHIT has detailed recommendations on the promotion of use of the NHSN AUR module that can be used for detailed planning and follow-up to implement this recommendation.

**Recommendation 2:** Develop surveillance infrastructure (registries, similar to the XDRO registry in Illinois) to rapidly identify patients that are infected or colonized with certain AR pathogens so that appropriate infection control measures can be taken upon admission and when transferred between facilities.

**Type of recommendation:** communication, standardization, alignment

**Priority Strategic objective(s) to which it relates:** D-2: Integrate epi, lab and clinical data

**Stakeholders:** APHL, CDC, CSTE, ARSTF

**Lead organization/consortium/person:** CDC

**Timeframe/key benchmark(s):** Publish guidance by July 2019

**ARSTF Workgroup:** Informatics

**Narrative:** Registries like the XDRO can alert clinicians with permission to access to the registry about known MDROs in patients that are being admitted to healthcare facilities. The data are useful surveillance information for health department epidemiologists as well.

**Topic:** Sustainability of AR Surveillance and the Work of the Task Force

**Recommendation 1:** Create a plan and implement it to integrate AR surveillance planning into ongoing processes and organizations.

**Type of recommendation:** planning

**Priority Strategic objective(s) to which it relates:** F (Crosscutting)

**Stakeholders:** CDC, APHL, CSTE, ARTF members, clinicians, laboratorians, public health epidemiologists

**Lead organization/consortium/person:** CDC, APHL, CSTE

**ARSTF Workgroup:** Core

**Timeframe/key benchmark(s):** Plan by December 2018, implementation complete by July 2019

**Narrative:** This Task Force has a three-year timeline, with the expect sunsetting of the Task Force in July 2019. Through follow-up on the recommendations on their part, the Task Force can establish a presence in ongoing organizations and ensure the work of the Task Force continues and its mission is sustained. During the Spring of 2019, before the Task Force sunsets, members should cycle back to the strategic map and add more objectives to the distributed portfolio.
**Topic: Surveillance Scope**

**Recommendation 1:** Develop a policy for surveillance of colonization with MDRO/AR that can be used to inform a CSTE Position Statement for standardized surveillance of MDRO colonization.

*Type of recommendation:* Standardization, communication, planning

*Priority Strategic objective(s) to which it relates:* C-4: Establish and align standards for data collection, transmission and provisioning.

*Stakeholders:* CSTE, state epidemiologists, public health epidemiologists

*Lead organization:* CSTE

*ARSTF Workgroup:* Lab, Informatics

*Timeframe:* By November 2018 submit draft policy brief to CSTE Board for January 2019 Board approval

**Recommendation 2:** Develop guidance for development of statewide/jurisdictional antibiograms for use by States and large cities.

*Type of recommendation:* Standardization, infrastructure

*Stakeholders:* CLSI, CSTE, state and local public health laboratories and epidemiologists, clinical laboratories, infection control professionals, prescribers

*ARSTF Workgroup:* Informatics

*Lead organization:* CSTE/CLSI

*Timeframe:* By June 2019 complete an assessment of antibiogram use and prepare updated guidelines, policy statement or whitepaper (and possibly a Toolkit) of jurisdiction-wide antibiograms.

*Narrative:* The development of antibiograms in state-jurisdictions and regions within the jurisdiction would complement local facility and health system antibiograms, as well as serve as a model, standard (including if called for by regulation), and guidance for facilities and prescribers. Antibiograms guide empirical choice and raise the profile of judicious antibiotic use; however, many facilities have not developed these, or have not done so appropriately. Therefore, the strategy is to develop a CLSI position statement or policy addressing the development of antibiograms, which could lead to a template for states. A toolkit could possibly include recommendations for what should be in the antibiogram, how to create and maintain the template, model examples, and suggestions on use and prevention to foster AMS using the antibiogram.

**Cross-cutting Recommendations**

**Crosscutting Recommendation F** (Leverage Public Health-Clinical partnership and policy) will be addressed in the coming years through the “Sustainability of AR surveillance and the work of the Task Force” topic area. **Crosscutting Recommendation G** (Incorporate New Technology) will be addressed in the “Terminology/data standards, Use of Standardized Codes” topic area.
Planning for Year 3

During its third year the Antimicrobial Resistance Surveillance Task Force will advocate for and foster the implementation of these recommendations. The Task Force will modify its structure to reflect this strategy. Rather than two broad-based Workgroups, Task Force members will be asked to shepherd specific recommendations. These “recommendation champions” will be selected for their expertise and organizational roles/linkages to the lead and stakeholder organizations listed in the recommendations.

Task Force members will advocate with the lead organization and stakeholders for implementation of the recommendation, work to revise the benchmarks and timelines for each recommendation and engage with stakeholders to operationalize the recommendations. They will report to the Task Force at regular intervals (monthly or quarterly) on progress. In early 2019, The Task Force will assess the impact of progress on the non-priority objectives. These recommendations will likely evolve as they are implemented. Sequentially, the Task Force will update them in this document as needed, using a versioning progress to identify and organize updates.

The Task Force will report on progress to stakeholders as we progress throughout the year via the Task Force’s email distribution list and the CSTE website. Implementation of the recommendations will favor sustainable strategies to ensure continued impact after the Task Force sunsets at the conclusion of Year 3.

Federal Funding Statement

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This document is the product of the exceptional efforts over the past two years of many hard working, dedicated participants generously sharing their expertise, including:

- Members of the Task Force
- Members of the Task Force workgroups: Lab, Informatics, CP-CRE, and in particular, Core Group
- Co-chairs and staff of the Task Force and other APHL, CSTE, and CDC staff who supported the work of the Task Force
- Members of the Task Force interest list
- Participants in the assessment and focus groups
- Participants in lectures, discussions, and roundtables
- CSTE Executive Board and Surveillance/Informatics (SI) Steering Committee
- The creators of the CSTE Position statement that lead to the formation of the Task Force and that has guide it work
- Gus Birkhead, Chair of the Task Force during its first year

**Full Task Force Membership**

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We gratefully acknowledge and thank them for their efforts without which this report and recommendation could not be written.
RESOURCES

The below resources are referenced throughout the report:

2. Task Force member list (referenced in previous section)
3. Surveillance Design Principles (Appendix)
4. Strategic Profile
5. Roles and Responsibilities
6. Data Flow Diagram (Appendix)
7. Assessment materials (please contact CSTE staff for access)
Surveillance System Design Principles as Applied to Antimicrobial Surveillance

**Principle 1.** The methods for public health surveillance at each governmental level should be based on the ethical purposes for which the data are being collected. Corollary: Public health surveillance at each governmental level should collect only data necessary to meet the purposes of decision making and action. This principle and its corollary are based on minimizing the burden on data reporters and on public health agency staffs alike, and have both a pragmatic and ethical basis. A possible counterpoint to these precepts in the 21st century is that access to ‘big data’ may make it more efficient to collect large amounts of available data and extract the limited data needed for surveillance. The Taskforce can examine this approach, but it seems likely that most data necessary for ARS currently are not present or easily extractable from big data systems such as electronic health records (EHRs) by public health agencies. Specifically designed ARS systems such as NHSN and reportable disease surveillance systems likely will be the primary sources of ARS data in the near future. This in no way diminishes CSTE’s or CDC’s commitment to continue to work with states, clinicians and others to access EHR data for public health surveillance purposes. Accordingly, the Taskforce will work with partner efforts in electronic case reporting (RWJ, CDC, ASTHO), clinical decision support (ONC), and various CDC surveillance strategy initiatives.

**Principle 2.** The roles and responsibilities of federal, state, and local public health agencies in ARS should be based on the purposes for surveillance at each level. To the extent possible, these efforts should be complementary, not duplicative, and should not place an undue burden on those providing data for surveillance purposes.

**Principle 3.** All ARS systems should use the same case definitions and other data definitions to the extent possible. This will assure the comparability of facility-based, enterprise-based, and population-based surveillance data.

**Principle 4.** Electronic reporting of ARS data to local and state health departments should be based on prevailing standards for such reporting, for example, HL7 standards.

**Principle 5.** To the extent that laboratory reporting is done electronically, the systems for electronic laboratory reporting (ELR) to the National Notifiable Disease Surveillance System and to the National Healthcare Safety Network should be complementary and not duplicative.

**Principle 6.** All clinical laboratory results, in general, and AR data in particular, generated by clinical laboratories should be available for public health surveillance, infection control, and antibiotic stewardship. This includes not only phenotypic and genomic test results, but also antimicrobial susceptibility testing results that currently may be forwarded from antimicrobial sensitivity test (AST) instruments or laboratory information systems (LIMs) for a variety of reasons, using electronic laboratory reporting systems and capacity.
Principle 7. Recent changes in clinical laboratory practices such as increased use of culture independent methods will result in AR data being less available. Such changes in practices will also impact surveillance for antimicrobial resistance in programs directed at the prevention and control of tuberculosis, STDs, and foodborne diseases.

Principle 8. Additional resources, based on the surveillance goals and data needs are necessary for robust ARS systems at the state and local level.

1 Note: many of these principles are based on the 1996 blueprint for public health surveillance and the 2013 “blueprint version 2.0” that still guide CSTE’s stewardship of the list of nationally notifiable diseases (3, 4).
2 https://www.cdc.gov/surveillance/

AR Data Flow Diagrams

The following charts summarize the specimen collection and data flow for some of the importance programs, processes, and participants providing data for AR surveillance uses. The charts are by no means comprehensive; however we think they are representative of data generated and significant participants. While the below charts represent the latest iteration, it is clear that interpretations of existing flows are literally innumerable. As such, data flows may be updated periodically and will be noted by new version numbers.
**AR INTEGRATED DATA FLOW PROCESS CHART V15**

**Clinical Lab**
- **Provider/Facility**
  - **Send Specimen**
  - **Obtain Specimen**
    - **ELR**
    - **Analyze and Report**
      - **Evaluate and Respond**
      - **Obtain Isolate**
      - **Send Specimen**
  - **Public Health Case Report**
  - **Currently paper form downloaded from internet. Moving to electronic case reporting.**

**PH Lab**
- (Also part of ARLN Network)
  - **Analyze and Report**
  - **Obtain Isolate**
  - **Send Specimen**

**PH Agency/Dept**
  - **Evaluate and Respond**
  - **Send Specimen**
  - **Report**

**ARLN Regional**
  - **Send Specimen**
  - **Report**
  - **Case Notification**
  - **Transform Transport Route**

**AIMS**
  - **Send Specimen**
  - **Report**
  - **Case Notification**
  - **Transform Transport Route**

**CDC Programs**
  - **Report out to Various CDC Programs**
  - **NNDSS**
  - **CDC LAB Analyze and Report**
    - **CDC PROGRAMS**
      - **TB STD(GIST) Strep Candida Foodnet Pulsenet MuGSI CBI NARMS HAIPS ESBL CRE/CRPA**
      - **other**
  - **CDA Report**

**NHSN**
  - **Reports to CMS on behalf of some facilities for MU reporting.**

**CMS**
  - (not CDC but Federal HHS)

---

* ELR is gold standard for reporting. However, not all jurisdictions/lab are currently ELR capable. Paper, and non-standardized ELR are also widely used in current practice.

** CDA is standard for AU/AR reporting. However, NHSN also uses portal based manual entry in addition to CDA for several modules.

Based on data use agreements, some health departments receive NHSN data summaries which are used in surveillance.

NHSN reports to CMS on behalf of some facilities for MU reporting.
ELR is the gold standard for laboratory reporting to public health and is becoming more widely adopted. We are aware that many jurisdictions and labs are not fully ELR capable as defined by MU. Non-standards based ELR and paper based reporting are still widely used in many jurisdictions.
AR (NHSN) DATA FLOW PROCESS CHART V15

PT Encounter - Obtain Specimen

Analyze and Report

Send Specimen

Obtain Isolate

Send Specimen

Facilities can view and analyze their own data. NHSN provides reports regarding predictive values for benchmarking. Other data sharing based on agreements.

Red lines represent data flow.

Gray lines represent specimen flow.

CDA** Report
CDA is Standard for AU/AR reporting. In addition to CDA, NHSN also uses portal based manual entry for several modules.

Evaluate and Respond

NHSN Data may be shared with State and/or Local PHD’s depending on data sharing agreements.

Facilities can view and analyze their own data. NHSN provides reports regarding predictive values for benchmarking. Other data sharing based on agreements.

NHSN reports to CMS as a “specialized registry” under MU.

CMS

[TECHNICALLY AN HHS FUNCTION OUTSIDE OF CDC]

NHSN
AR CASE NOTIFICATION DATA FLOW V15 – CASES, NOT LAB DATA. NOT STRICTLY NNDSS

Provider/Facility

Clinical Lab

PH Lab

PH Agency/Dept

ARLN Regional

AIMS

CDC Programs

PT Encounter - Obtain Specimen

Analyze and Report

Obtain isolate

Evaluate and Respond

Send Specimen

Obtain Isolate

Analyze and Report

Send Specimen

Case Notification

NNDSS

Report to Various CDC Programs

CDC PROGRAMS
Red lines represent data flow.
Gray lines represent specimen flow.
Green lines represent occasional additional testing and dashed green lines represent associated reporting.
NOTE: PHL could send panresistant specimens directly to CDC and CDC will report back to the submitter.
NOTE 2: ARLN does not control clinical laboratory recruitment. The stages are shown here for informational purposes only.
PT Encounter - Obtain Specimen

Send Specimen

Evaluate and Respond

Analyze and Report

Transform Transport Route

Monthly Summary Report

DHQP

Red lines represent data flow.

Gray lines represent specimen flow.

Green lines represent occasional specimen and data flows.

Dotted lines represent future data flows. Some early adopting participants are currently using or adopting these flows.
The public health case report is the process by which state and local health departments obtain data on the occurrence and severity of occurrence of infectious pathogens which are required to be reported within that jurisdiction.

In most cases today, a specimen is obtained from a patient and analyzed by a clinical or public health laboratory. The result is reported to the provider who initiates the public health case report by submitting a form to the health department. In some jurisdictions, this process is tightly coupled to electronic laboratory reporting.

* While ELR is the Gold Standard for public health reporting of laboratory results, we are aware that many jurisdictions/labs are not fully ELR capable as defined in MU. Non-standards based ELR and paper based reporting are still widely used.
Provider obtains a specimen and submits to laboratory or in some cases makes a presumptive diagnosis. A positive match to the national Reportable Conditions Trigger Code Table (integrated into EMR) initiates an eICR to the AIMS platform which is processed through the Reportable Conditions Knowledge Management System (RCKMS) to determine if the condition is reportable in that jurisdiction. Reportability Response is returned to the provider explaining whether or not the condition is reportable. If it is reportable, an Initial Case Report and a Reportability Response is also sent to the Jurisdiction to initiate action.

Electronic case reporting coordinated project with CSELS, Digital Bridge, PHII and others. EMR participants include EPIC, CERNER, ALLSCRIPTS, MEDITECH, eClinical Works.

Pilot Jurisdictions include MA, UT, KS, NY, NYC, Houston, CA, MI

LEGEND
Gray lines represent specimen flow
Red lines represent data flow
Purple dotted line represents future state data flow
Green boxes and lines indicate call out
PT Encounter and Clinical Diagnostics

Obtain specimen for Whole Genome Sequencing

Evaluate and Respond

Isolate Obtained From Specimen
Analyze Using Standardized WGS Methods and Report

Red lines represent pulsenet data flow.
Purple lines represent NARMS data flow
Red dashed lines represent pulsenet specimen flow.
Purple dashed lines represent NARMS specimen flow to CDC NARMS lab based on sampling scheme

STATE FOOD AND AG LABS/Genome Trackr
FDA CVM-CFSAN Lab Retail Meats
USDA FSIS Animal Slaughter Cecal Sampling
NCBI
NLM
STATE FOOD AND AG LABS/Genome Trackr
Genome Trackr
NARMS
Standardized Fields, Data Types Forms
PulseNet National Databases

AR PULSENET NARMS COMBINED DATA FLOW PROCESS CHART V15E
Clinical Lab Provider/Facility
PH Lab (Also part of ARLN Network)
PH Agency/Dept
ARLN Regional
AIMS
CDC Programs
FDA CVM-CFSAN Lab Retail Meats
USDA FSIS Animal Slaughter Cecal Sampling