

National and State Level Validation Efforts



Third Plenary

Co-Chairs:

Rani Jeeva, MPH, CPH

Lisa McGiffert

9:00 AM – 10:15 AM





Key Question Addressed

5. What can and should be done to improve, extend, and sustain efforts at the local, state, and national levels to validate facility-specific HAI data that are collected, analyzed, and publicly reported?



Validation: Consumer Perspective

Lisa McGiffert
Consumers Union



CMS Validation of Hospital Inpatient HAI Measures



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Quality Improvement Group

Office of Clinical Standards and Quality

Centers for Medicare and Medicaid Services





Outline

- Inpatient Quality Reporting Program
 - Overview
 - HAI-related requirements
- Validation Activities
 - Objectives
 - Current methods and timeline
 - Proposed methods
 - Gaps and future plans





Hospital Inpatient Quality Reporting (IQR) Program

- Mandated by law since 2003
- Provides hospitals with financial incentive to report on quality of care delivery
- Provides consumers with data to make informed decisions about their care
- Data used for CMS Hospital Value-Based Purchasing
- Applies to hospitals paid under the inpatient prospective payment system
- Includes 72 quality measures in several domains
 - Clinical Processes of Care* -- Patient experience
 - Healthcare-Associated Infections (HAI)* -- Structural Measures
 - Mortality and Readmissions -- Cost Efficiency

*Validated through medical records abstraction





Statutory Requirement – Hospital IQR Validation

- The Affordable Care Act modified Section 1886(b)(3)(B)(viii)(XI) of the Social Security Act to mandate Hospital IQR program validation
 - *“The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.”*





Measures Validated in Hospital IQR program

- Process of Care: AMI, Heart Failure, Pneumonia, Surgical Care Improvement Project, Emergency Department Throughput, Immunization measures
- Healthcare Associated Infection measures





Overview of CMS Hospital IQR Validation Process

- CMS randomly selects hospitals annually (currently 800) from eligible hospital list
- CMS selects targeted hospitals (e.g., hospitals failing previous annual validation)
- CMS selects medical records randomly from selected hospitals (up to 18 per quarter per hospital)
- CMS mails letter requiring hospitals to copy and return medical records to contractor
- Hospital submits medical record copies
- CMS contractor independently abstracts medical records
- CMS contractor adjudicates mismatches
- CMS computes validation score at the measure level





HAI Measures Timelines

Measure	Discharge dates reported	Discharge dates validated	Notes
Central line-associated bloodstream infection (CLABSI)	Beginning January 2011	Beginning January 2012	ICU locations only
Catheter-associated urinary tract infection (CAUTI)	Beginning January 2012	Proposed October 2012	ICU locations only
Surgical site infection (SSI)	Beginning January 2012	Proposed October 2012	Colon surgery and abdominal hysterectomy only
MRSA bacteremia, C. difficile, Healthcare personnel vaccination	Beginning January 2013	Not yet proposed	



CLABSI Validation (As finalized August 2011)

Objectives

- Within each hospital:
 - Estimate reliability of IQR reporting for all chart-abstracted metrics
 - Ensure it meets a minimal level of reliability (75%)
- Across all hospitals as an aggregate:
 - Evaluate predictive power of validation for ICU patients





CLABSI Validation Timeline

Discharges

- 1Q 2012
- 2Q 2012
- 3Q 2012

- First Results

Validation activities

- August-December 2012
- November-March 2013
- February- May 2013

- Summer/Fall 2013





CLABSI Validation Operations

- 800 randomly sampled hospitals
- Each sampled hospital, each quarter (Q1-Q3 2012)
 - Positive blood culture list for all ICU patients
 - Annotated to identify patients with central lines
- CMS Validation Support Contractor will
 - Check for presence of all basic qualifiers:
 - ICU patient
 - Bloodstream infection (positive blood culture results) - Isolate is:
 - ✓ A likely pathogen found at least once
 - ✓ Common skin commensal (CSC) found in two or more positive blood cultures drawn on separate occasions
 - Central line
 - Review and remove duplicates to identify candidate CLABSIs (unique patient episodes of care)
 - Random sample of 3 candidate CLABSIs





CLABSI Validation Sample Size

- 800 hospitals randomly sampled
- 3 candidate CLABSIs per hospital per quarter
- Total
 - 7,200 candidate CLABSIs





CLABSI Validation

- CMS Clinical Data Abstraction Center (CDAC) Contractor
 - Requests copies of records from hospitals
 - Hospital sends CDAC copies of requested charts
 - Abstracts hospital
 - For candidate events, determines if any CLABSI events occurred
 - For other records, identifies any candidate CLABSIs and determines if any CLABSI events occurred
- Validation Support Contractor
 - Provides CDC with information for all candidate events
 - Checks to see if candidate events were reported to NHSN
 - Reviews/adjudicates mismatches between hospital and CDAC
 - Scores each case as 1/1 for matches; 0/1 for mismatches





IQR and NHSN: Alignment Challenges

NHSN = infection events  IQR=hospital admissions

- Multiple events may occur during one admission
- IQR only selects events occurring in discharge quarter
- IQR does not validate central line days





Proposed Changes for Next Year Candidate Cases

- Hospitals identify candidate CLABSIs, CAUTIs and SSIs
- Candidate CLABSI: proposed same definition
- Candidate CAUTI
 - similar to candidate CLABSI
 - positive urine culture lists for ICU patients
- Candidate SSI:
 - Identified for Medicare beneficiaries from claims for index and readmissions within 30 day to same hospitals





Proposed Changes for Next Year Sample Size and Scoring

- 400-600 hospitals annually
- Random sample of 12 candidate HAIs per hospital per quarter
- Separate score for HAIs and clinical process of care measures
- Charts sampled for clinical process of care will not be abstracted/scored for CLABSI





How to Find and Comment on Proposals

Read and comment on the rule online
at <http://www.regulations.gov>. Search for "CMS-2012-0052-0001"

The screenshot shows the homepage of regulations.gov. At the top, there is a navigation bar with links for Home, Help, Resources, and Feedback and Questions. Below this is a search bar with a magnifying glass icon and buttons for Search, Browse, and Learn. The main heading is "Let Your Voice Be Heard" in red. Below the heading is a paragraph explaining the site's purpose: "Regulations.gov is your source for U.S. government regulations and related documents. Here you can find, read and comment on documents. Share your knowledge and make your voice count." Below this is a search box with the text "SEARCH for: Rules, Comments, Adjudications or Supporting Documents:" and a "Search" button. To the right of the search box is a link for "Advanced Search". Below the search box are three columns of information: "Coming Soon... My Recent Searches" with a magnifying glass icon and the text "A Quick & New Way to Search"; "Regulations With Comments Due Soon" with a list of counts for different time periods (Today, Next 3 Days, Next 7 Days, Next 15 Days, Next 30 Days, Next 90 Days); and "Newly Posted Regulations" with a list of counts for different time periods (Today, Last 3 Days, Last 7 Days, Last 15 Days, Last 30 Days, Last 90 Days). On the right side of the page, there is a section titled "Are you new to the site?" with a list of links: "How do I find a rule?", "How do I submit a comment?", "How do I find my comment?", and "Do my comments make a difference?". Below this are three more sections: "Regulations.gov Re-launch", "President's Executive Order", and "Visit our new Facebook page!". At the bottom right, there is a section titled "Join in the exchange with TRI" with a photo of a dam and the text "Learn about the potential TRI Chemical Expansion and give us your feedback.".

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Future Challenges

- New measures (MRSA, CDI)
- SSI readmissions for other than Medicare patients and to hospitals other than index hospital
- Submission through electronic health records, including device days





Questions not Related to Proposals?

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CDC Support for Valid HAI Data and Lessons Learned from State Validation

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HAI Data Validation is Important

- Concerns about uneven data quality
 - Always important, now more than ever
- Need for training on all levels
- Validation findings help guide training
- Credible data are vital for prevention, public reporting, and incentivizing improvements in clinical performance





CDC Supports Valid NHSN Data

- User Support Team
- Training
 - Web-based (www.cdc.gov/nhsn/training.html)
 - CDC-hosted and professional meeting venues
 - State validation work
- Refining NHSN
 - Business rules reduce opportunities for data entry error
 - Built-in analyses explore data quality
 - Consultation with partners to modify NHSN methods and definitions





2009 ARRA* Grants to States

- Few states received resources with their state reporting mandates
- CDC administered ARRA grants
 - CDC-funded PHAs to support state programs
 - All states: one position to develop and implement HAI prevention plan, advisory group
 - 31 states: money for surveillance (+/- validation)
 - 27 states: prevention collaboratives
- ARRA funding provided short-term validation resources to many states

* American Recovery and Reinvestment Act





States as Validation Laboratories

- States created innovative approaches and tools
- Central Line-Associated Bloodstream Infection (CLABSI):
 - Structure of sampling frame
 - Numerator sampling approaches
 - (Targeted, Lot Quality Assurance, Probability)
 - Checklists
 - Denominator methods surveys
 - Risk-factor (location mapping) investigations
- Surgical Site Infection (SSI):
 - Data linkage to enrich sampling frame (procedures) for SSI
 - In house and post-discharge case-finding surveys
 - Risk-factor audits in access database





Lessons Learned from State Validation

- ❑ Under-reporting is common (but not universal)
 - CLABSI Sensitivity as low as 48%
- ❑ Over-reporting is rare
 - CLABSI Specificity at least 90%
- ❑ Therefore, validation has to look for what's missing
- ❑ This is harder than validating what's reported





Lessons Learned from State Validation

- ❑ **Sampling frame design may be important for efficiency**
 - SSI validation with un-enriched sampling frame (surgical procedures) changes reporting in only 1-2% of charts
 - SSI validation with enriched sampling frame (surgical procedures linked to high-risk ICD-9-CM discharge codes) changes reporting in 13 to 40% of charts
 - Error rate varies by procedure, and was particularly high for colon procedures

<http://www.scstatehouse.gov/reports/dhec/2011HIDAAnnualReport.pdf>
<http://nhicep.org/Attachments/NHICEP%20Update%2003-20-2012.pdf>
Haley VB, et al. ICHE 2012 33(6):565-571.





Lessons Learned from State Validation

- ❑ Reporting can improve with validation and training
 - Serial annual CLABSI audits in NY 2007-2009*
 - Adult and pediatric ICU agreement from 92% to 94%
 - NICU agreement from 89% to 95%

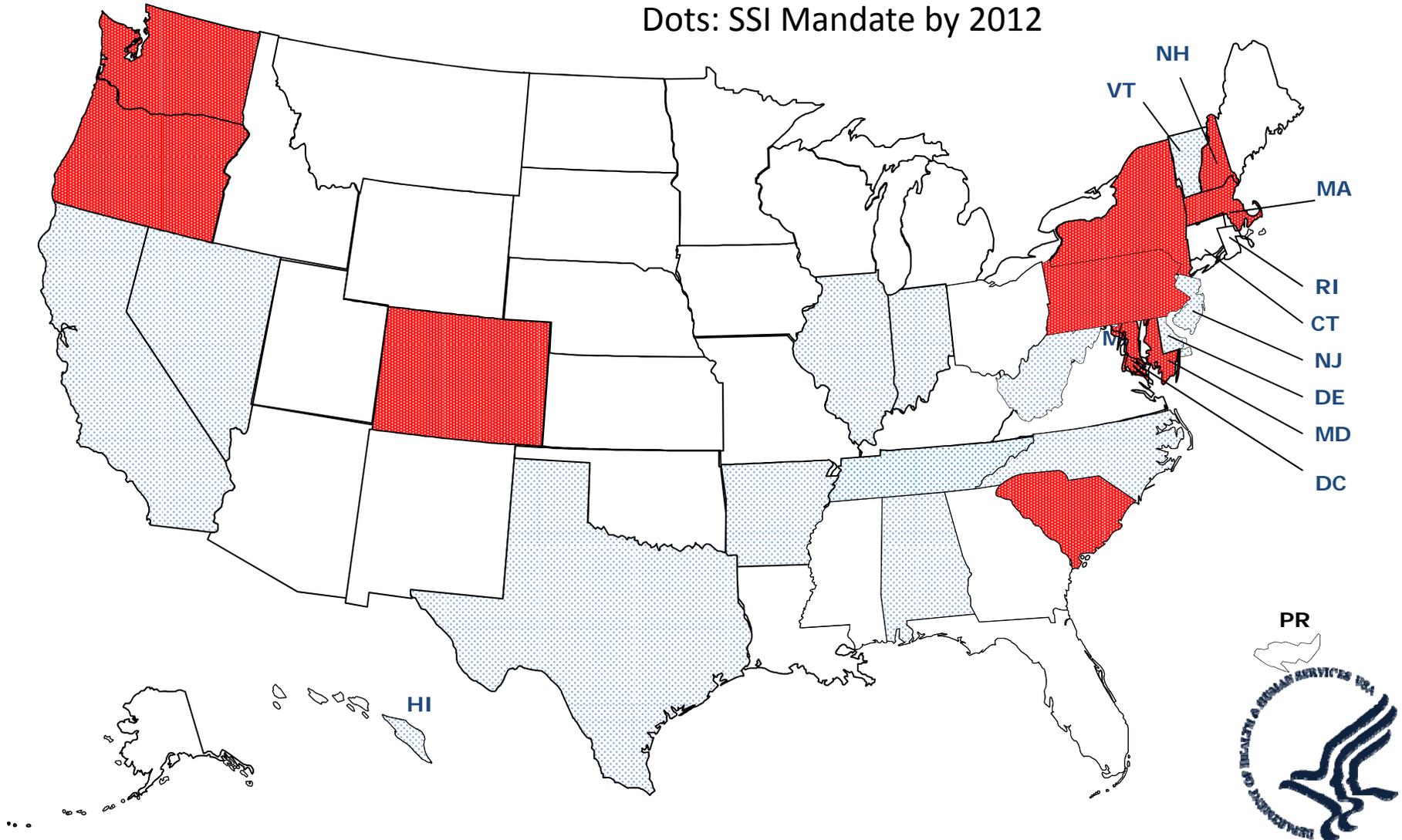
- ❑ Validation must be ongoing
 - Every year there is turnover in the healthcare workforce
 - Those who track HAIs
 - Those who must prevent HAIs
 - Every year a new cohort of patients is at risk





SSI Ever (Externally) Validated, as of 2012

Dots: SSI Mandate by 2012





CDC Validation Guidance and Toolkit

- ❑ Developed by adaptation of state protocols and tools, and study of survey methodologies
- ❑ To be vetted with states at Council of State and Territorial Epidemiologists (CSTE) Meeting, June 2-7
- ❑ Goals
 - Share resources, tools, and lessons learned
 - Outline strategic options for
 - Efficient data quality improvement
 - Periodic comprehensive review
 - Seek consensus on elements of national standards
- ❑ Plan to share after state input
- ❑ Ever-green document





CDC Support for CMS Validation

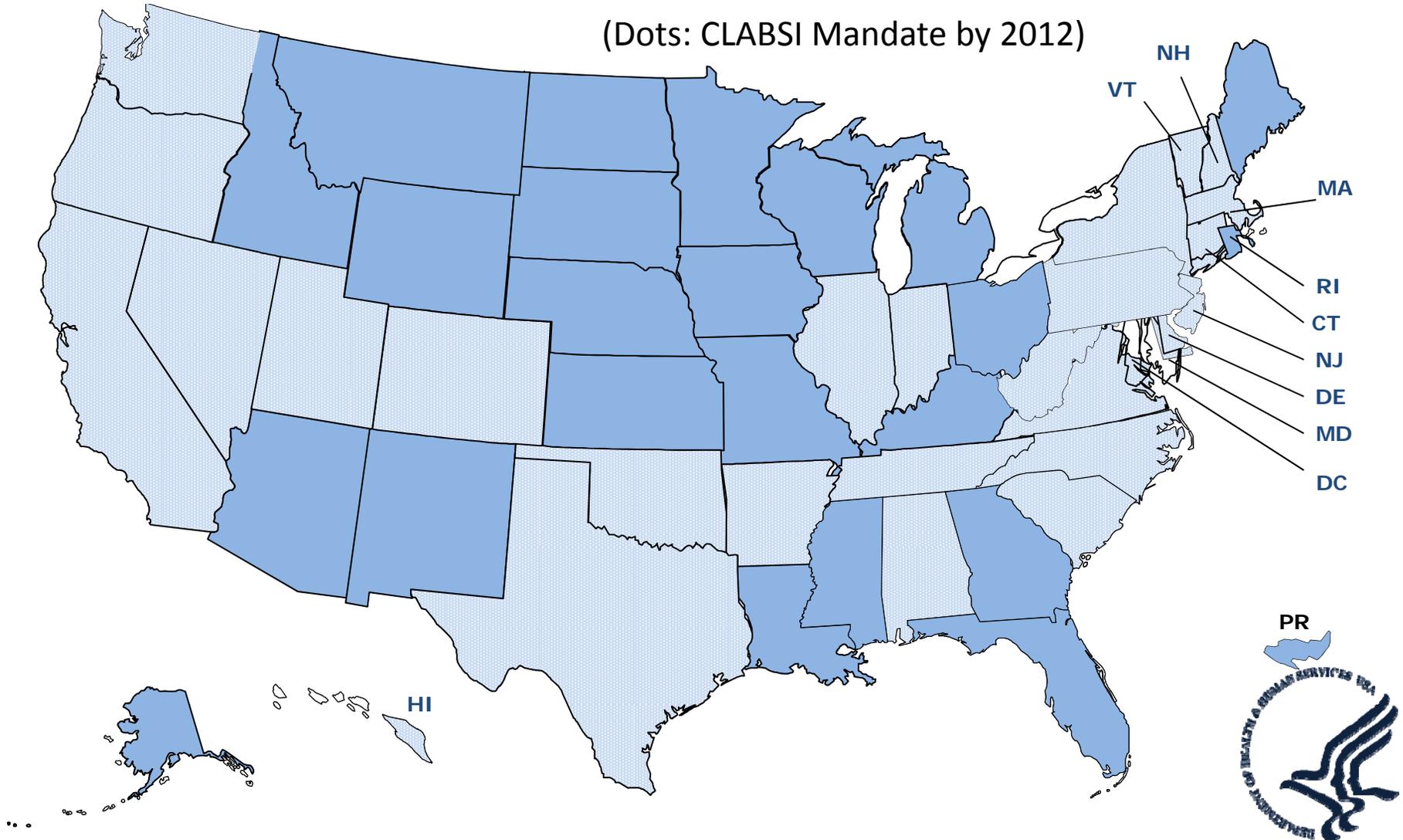
- Integrates existing CMS validation program and NHSN definitions
 - Borrows many aspects of state validation





CMS CLABSI Validation 2012 and After

(Dots: CLABSI Mandate by 2012)





State and CMS Validation are Complementary, but Not the Same

	State	CMS
Approach	Differs state-by-state	Nationwide probability sample
Constrained by	Statute (access to data), and resources	Statute (scope), resources, and existing infrastructure
Validates	Cases; denominator methods; risk adjustment variables	Cases
Sampling	Hospitals, locations, pathogens often targeted; sample varies	All IPPS hospitals, at least every 4 years; small sample each facility
Primary goals	Improve surveillance practice; train reporters; optimize data quality, all levels	assure compliance; validate accuracy of metric; motivate internal improvement





Vision for the Future

- ❑ **Ongoing validation is essential**
- ❑ **CDC, CMS, and states have a great beginning, with complementary approaches**
 - Need to continue and expand validation
 - Hope for integrated requirements and infrastructure
 - Continue to benefit from state innovations
 - Need to identify state validation resources
 - Continue to work toward nationwide participation
 - Periodic comprehensive look at facility level surveillance



State Level Validation: Results and Lessons Learned from California



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Slides Not Available

Questions & Answers



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