State of ELC-funded Biosafety Activities:
Looking Back at Year 1 and to the Future

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Presentation Agenda

- Overview of the ELC and activities for enhancing laboratory biosafety
- Summary of progress and challenges
- Next steps

ELC Purpose

Build and strengthen epidemiologic, laboratory, and information systems capacity in public health departments to:

- Identify and monitor occurrence of known infectious diseases
- Detect new emerging infectious disease threats
- Identify and respond to disease outbreaks
- Develop and evaluate public health interventions

ELC Structure

- Cooperative Agreement between CDC and 50 states, 6 local health departments & 8 territories and affiliates
- Platform that supports multiple infectious diseases simultaneously
- Flexible program for addressing urgent infectious disease needs (e.g. SARS, post-hurricane mosquito abatement, 2009 H1N1 supplement, Recovery Act, Affordable Care Act, **Ebola**, and the Zika virus)
- Non-Research
- Customer Driven

ELC Ebola Supplement for Biosafety

- March 30, 2015 - Funds awarded to 62 grantees - 3 years, $21 million
- Strategy 1: Enhance public health laboratory (PHL) biosafety capacity
  - Hire or designate a PHL biosafety official (BSO),
  - Update biosafety guidelines
  - Conduct risk assessments (RA) and implement risk mitigation strategies
  - Develop and provide training and tools
- Strategy 2: Improve laboratory coordination and outreach
  - Work with clinical laboratory (CL) partners to facilitate their risk assessments and development/implementation of measures to address gaps and mitigate risks

Summary of Progress of Biosafety Project

Biosafety Performance Measures

- ELC grantees provided performance measurement data for CLs in their jurisdictions in May 2015, Oct 2015, and April 2016
- Measures involving PHLs focused on packaging & shipping Category A specimens, BSL-3 competencies, and RA capabilities
- Measures addressed CL capacity for packaging & shipping specimens and RA capabilities, including ETCs and EAHs

Progress Focused on Public Health Laboratories

- 96.8% (60/62) of grantees have hired or designated a BSO as of April 2016
  - 96.6% (56/58) of grantees were funded by ELC for BSO positions and have hired or designated a BSO
- As of April 2016, performance measures from grantees indicated that approximately:
  - 98% (58/59) had conducted RA for EVD in the past year vs. 90% in October 2015
  - 82% (46/56) had sufficient personnel to package and ship Category A specimens vs. 83% in October 2015
  - 82% (42/51) had sufficient personnel with demonstrated competency to work in a BSL-3 laboratory vs. 71% in October 2015
  - 66% (37/56) had policies and/or procedures for conducting RAs vs. 55% in October 2015

Progress Focused on Clinical Laboratories

As of April 2016–

- 32% of the grantees (18/56) reported that 80% of CLs in their jurisdiction had at least two staff members certified in packaging & shipping vs. 33% in October 2015
- 20% (11/56) reported 80% of CLs in their jurisdiction had completed at least one RA vs. 8% in October 2015
- 13% (7/56) reported 80% of CLs had a policy and/or procedure for performing RA vs. 7% in October 2015

Summary of Progress

Public Health Laboratories

- Making progress towards meeting targets
- Focus area for improvement = having a RA policy and/or standard operating procedure (SOP) in place

Clinical Laboratories

- The number of grantees that reported 80% of their CLs had performed a RA increased greatly
- ETC/EAHs are meeting or close to meeting targets for packaging/shipping, performing RAs, and having policies in place for RAs
- Focus area for improvement = Additional outreach for performing RAs and having a RA policy and/or SOP in place

Challenges

- Most grantees have hired BSOs, but there is a continual need for training to bring everyone to a basic level
- Biosafety risk management appears to be a relatively new concept in CLs that will require continued extensive outreach efforts to address
  - Maintaining and enhancing relationships with CLs
- Uncertainty for funding these activities past 2018

NEXT STEPS

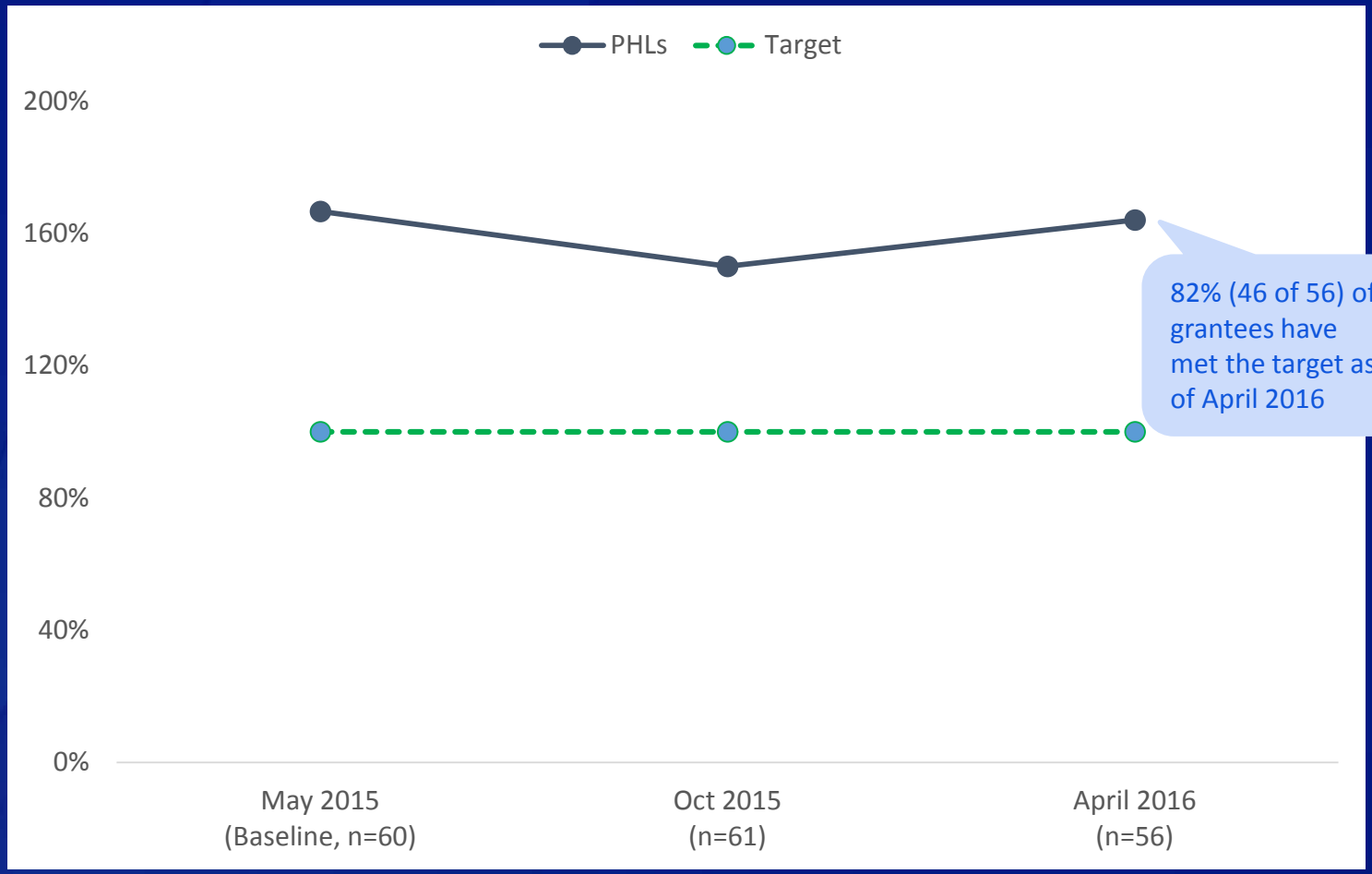
Looking Ahead to 2016/2017

- Year 2 continuation guidance was published in March 2016, applications were due May 2016 and are under review currently
- Continued collaboration with APHL as Technical Resource
- Supplemental awards will go to applicants on August 1
- ELC grantees will continue to work to enhance outreach to their CL partners
- ELC will continue quarterly calls with grantees to discuss progress
- Performance measurement data will be collected in September-October for the period April 1 to September 30, 2016

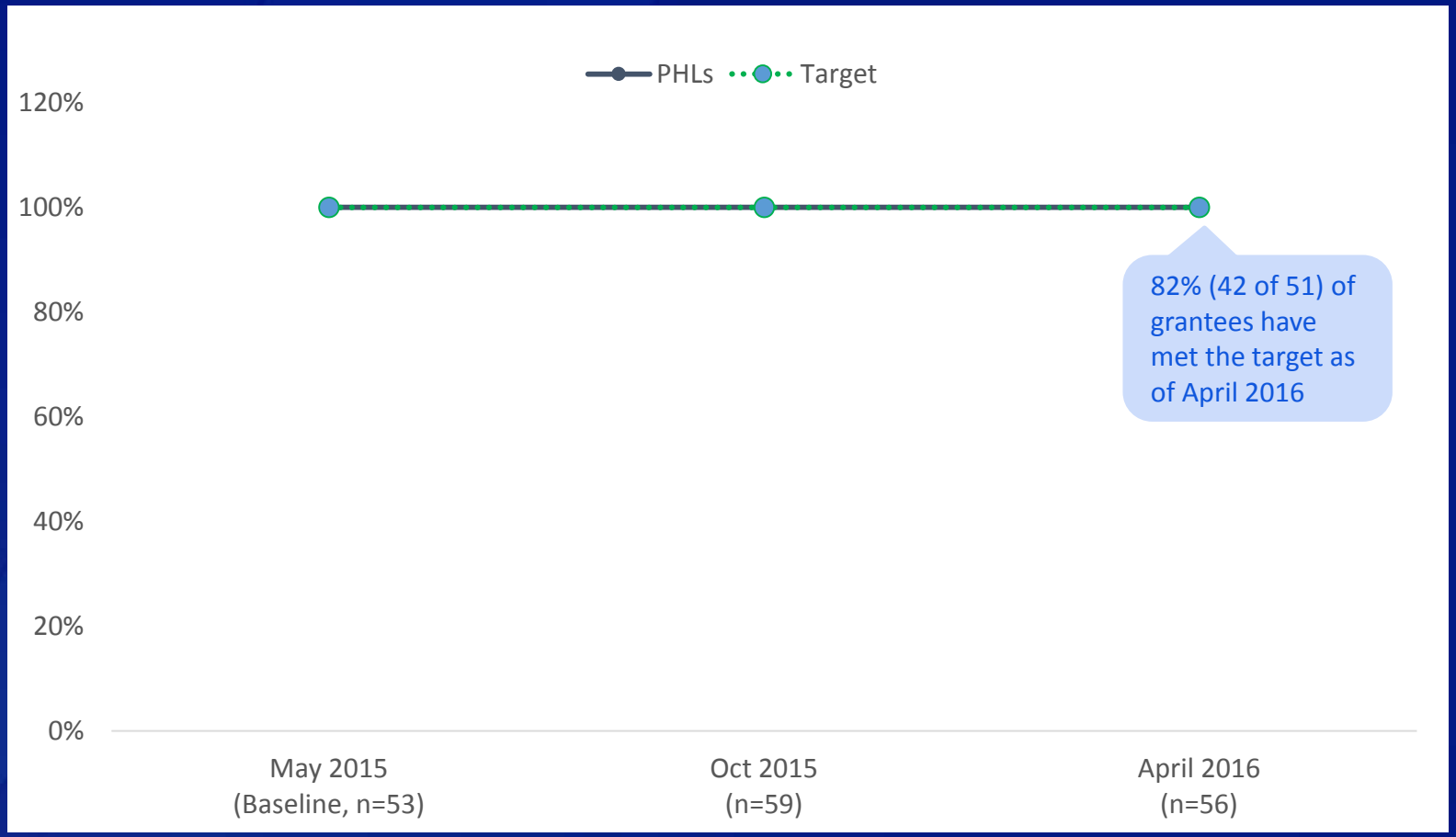
Questions?

Appendix

Median Percentage of Public Health Laboratorians Needed to Package/Ship IATA Division 6.2 Infectious Substances (Category A) Who Are Currently Certified

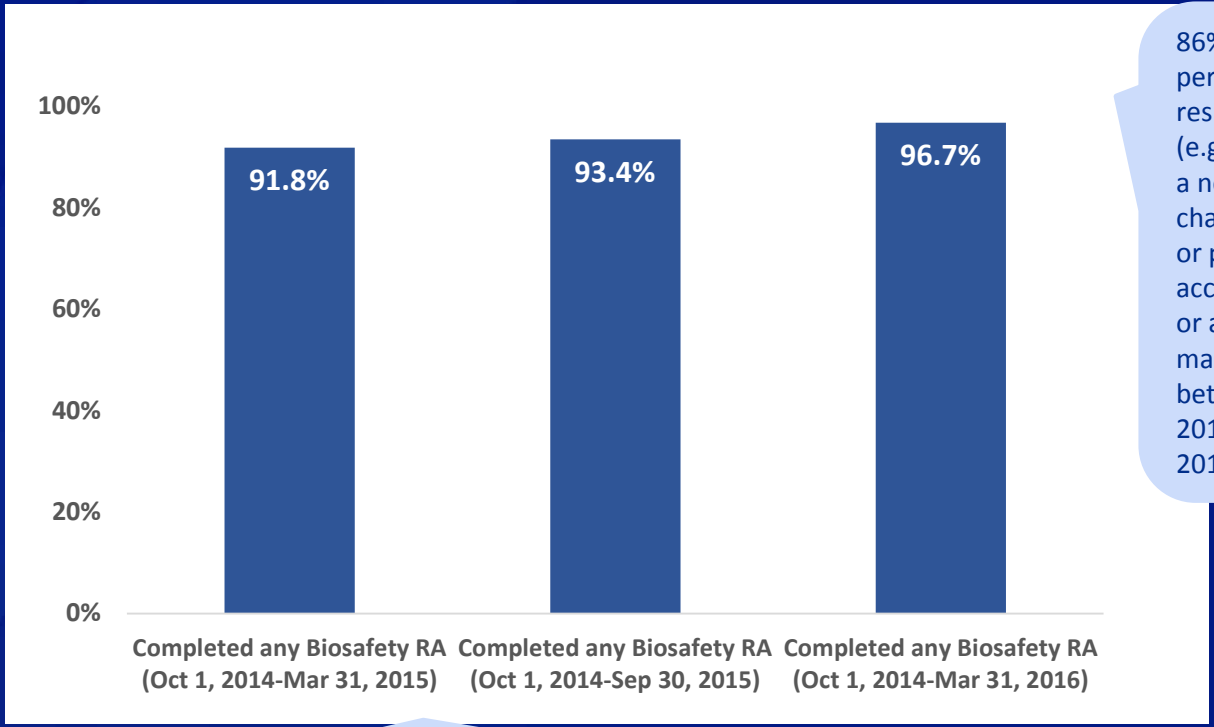


Median Percentage of Public Health Laboratorians Needed to Work in a BSL-3 Who Have Demonstrated Ability to Work in a BSL-3 *



*Measure does not apply to the five jurisdictions without a BSL-3

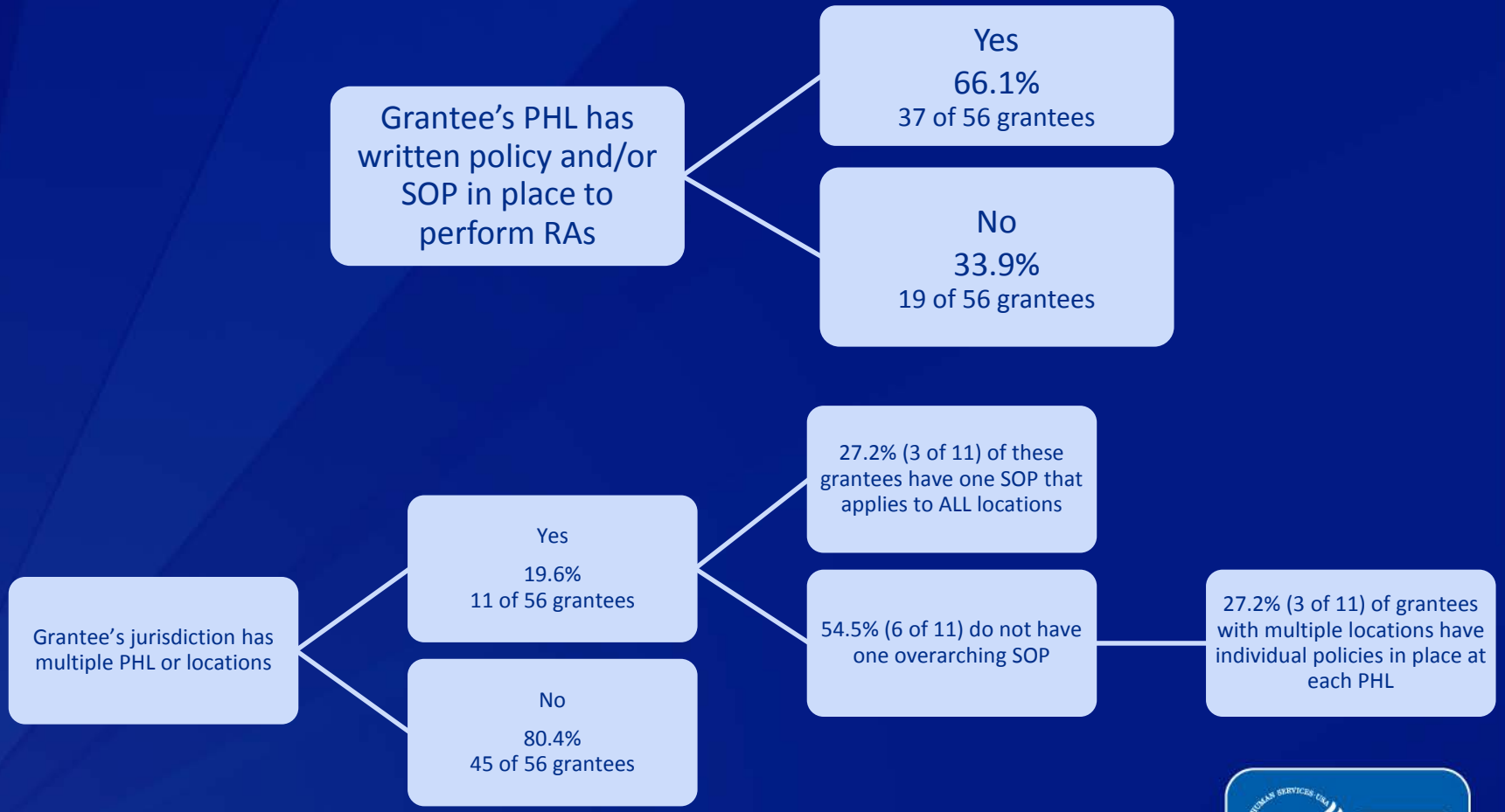
Percentage of PHLs That Completed Biosafety Risk Assessments (RA) (n=61)



86% of grantees performed RAs as a result of some event (e.g. introduction of a new methods, changes in processes or procedures, accidents/incidents, or as part of a management review) between October 1, 2015 and March 31, 2016.

- The percentage of grantees that conducted any biosafety RA increased from 91.8% to 96.7% from May 2015 to April 2016.
- The percentage of grantees that conducted an RA for EVD increased from 90.2% at the time of data collection in May 2015 to 98.3% in April 2016.

Public Health Lab Policies and/or Standard Operating Procedures (SOPs)*



*ELC began collecting Measure B.8 data in October 2015.

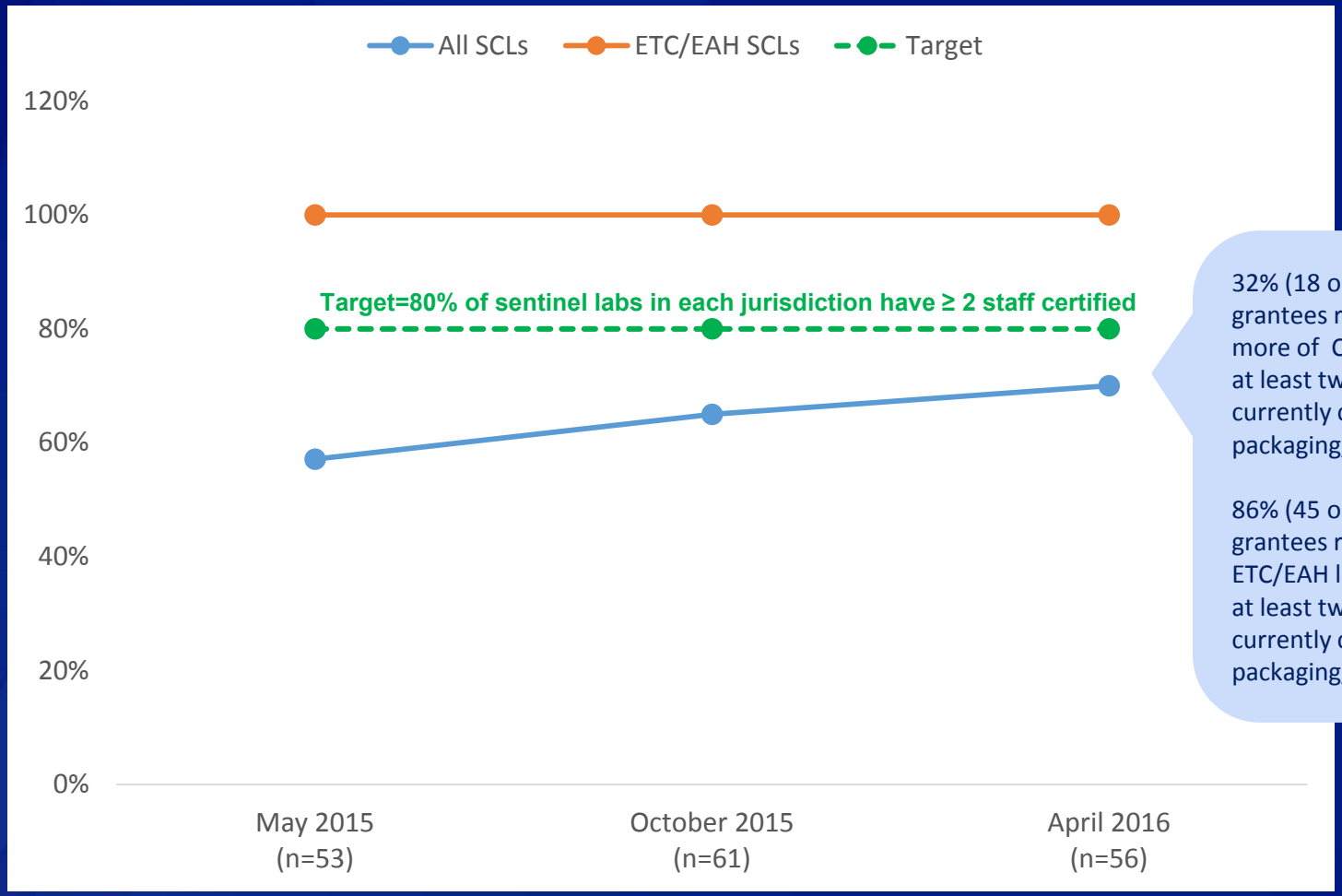
Public Health Lab Measures - In Summary

- **Grantees are making progress towards having sufficient personnel for packaging/shipping infectious agents and working in a BSL-3.**
  - The majority of grantees have met the 3-year target for both measures (100%)
- **The number of RAs has increased overall and for Ebola, specifically**
  - Most of RAs completed for Ebola are for Testing
  - As a result of RAs, over a third of grantees have identified risks since May 2015
  - In the past 6 months, all grantees that identified risks addressed those risks with an improvement plan and most implemented mitigation strategies
- **Two thirds of grantees have a written policy or SOP in place to perform RAs**

Sentinel Clinical Laboratory Measures

Sentinel clinical labs include all labs that test or refer specimens that may contain Ebola virus or other emerging, highly infectious disease pathogens
May include ETC, EAH, and clinical labs in acute care hospitals, critical access hospitals, and urgent care clinics

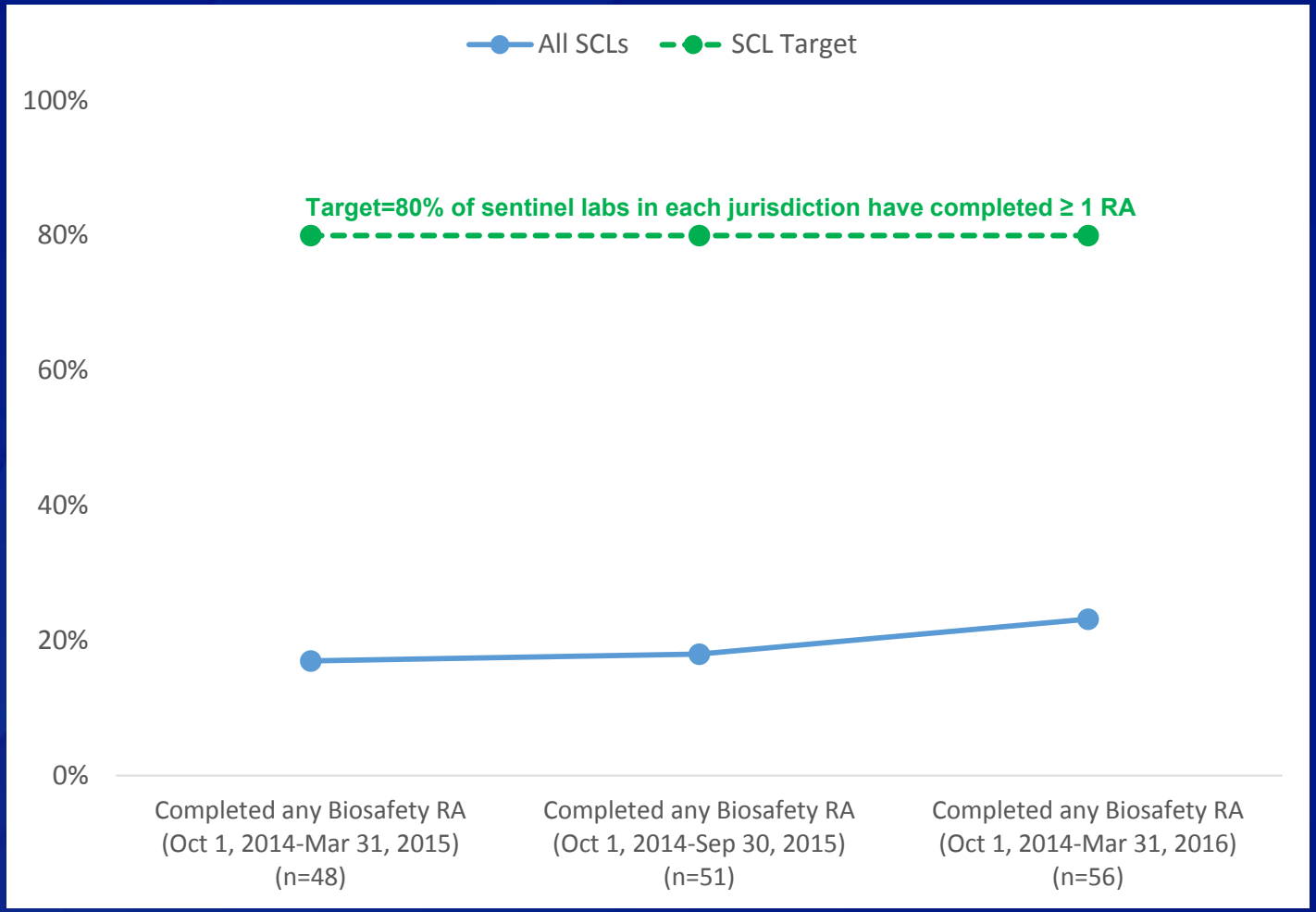
Median Percentage of Clinical Labs in Which at Least Two Staff Members Are Currently Certified in Safe Packaging/Shipping of IATA Division 6.2 Infectious Substances (Category A)



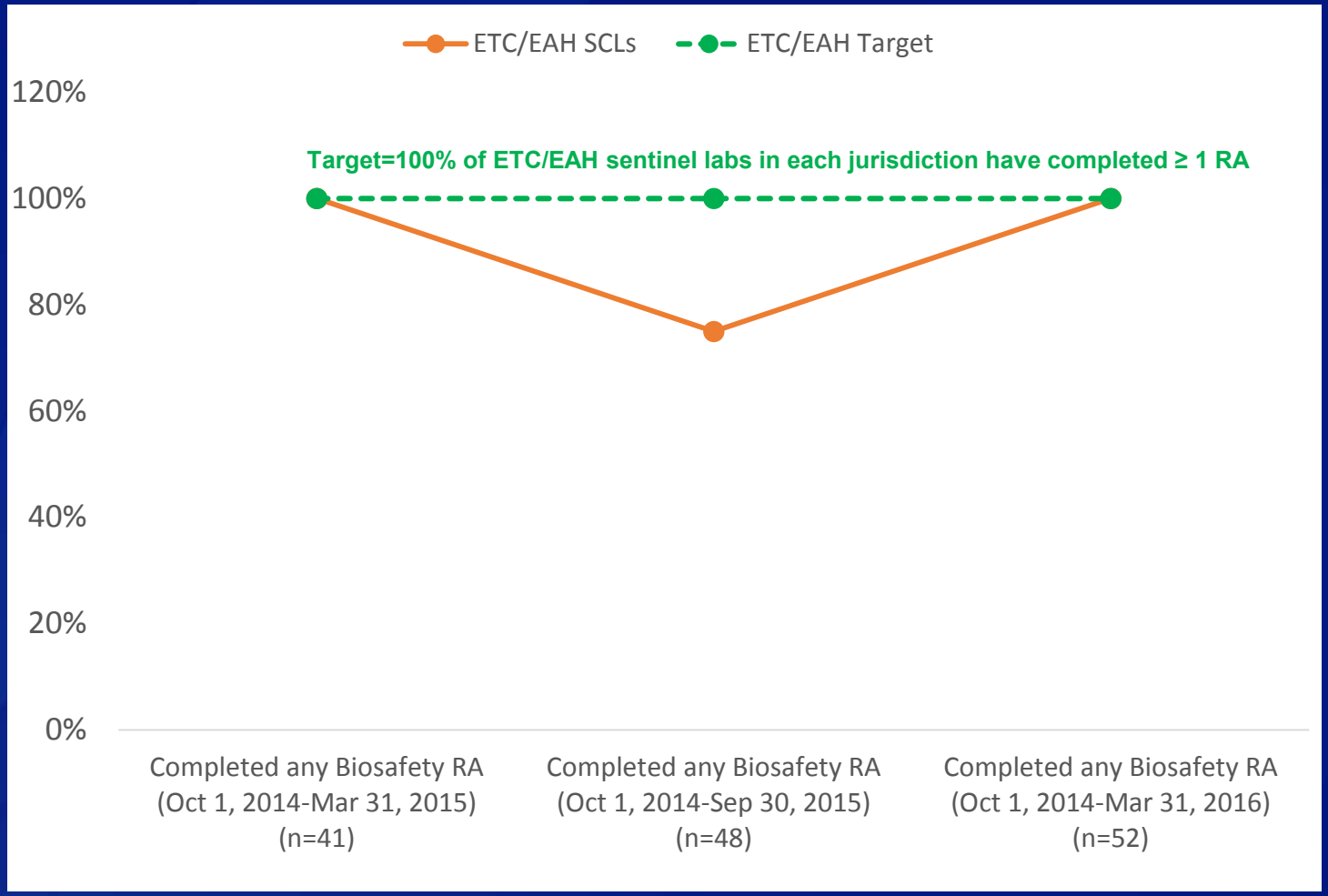
32% (18 out of 56) of grantees reported 80% or more of CLs contacted had at least two staff members currently certified in safe packaging/shipping.

86% (45 out of 52) of grantees reported **all** ETC/EAH labs contacted had at least two staff members currently certified in safe packaging/shipping.

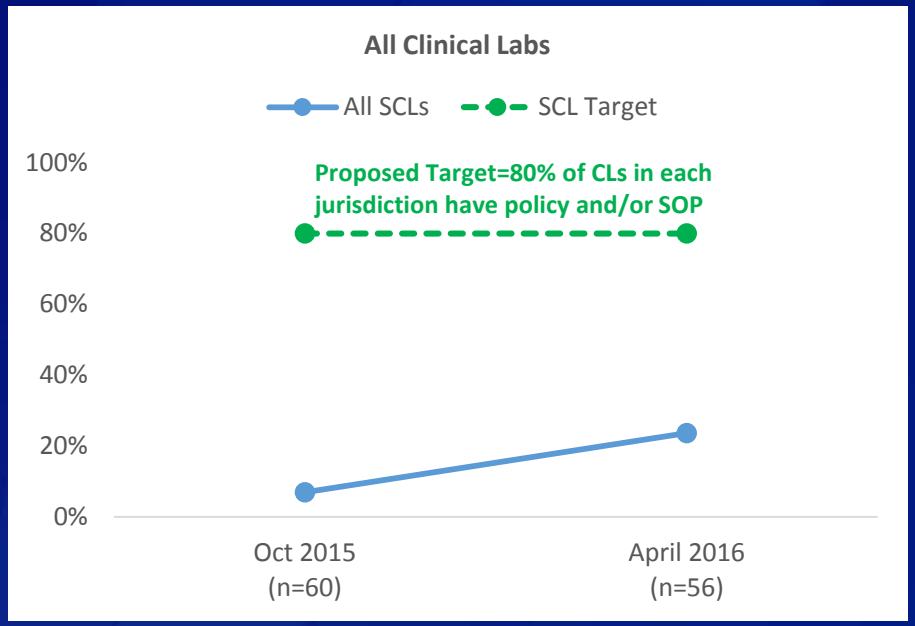
Median Percentage of Clinical Labs That Have Completed at Least One RA for an Identified Infectious Agent

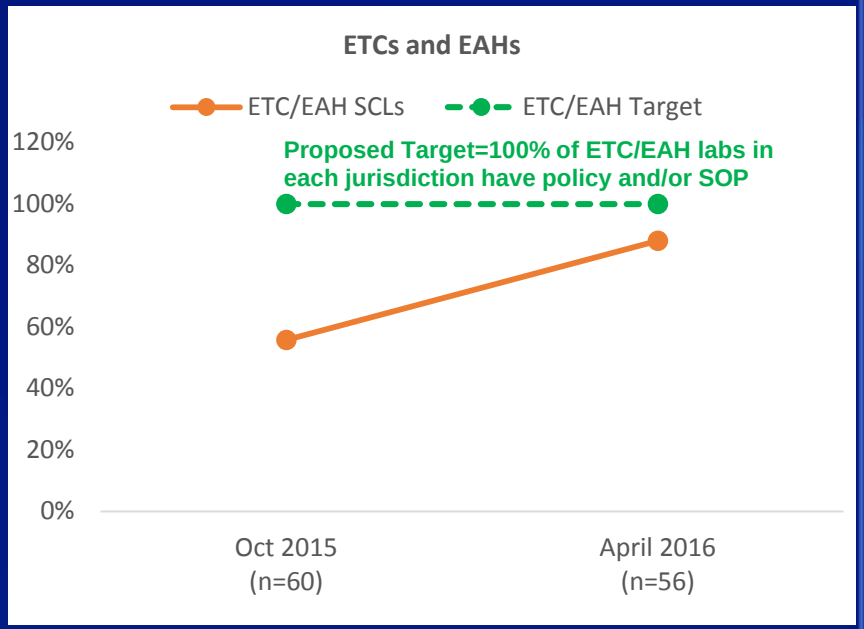


Median Percentage of ETC/EAH Clinical Labs That Have Completed at Least One RA



Median Percentage of Clinical Labs That Have a Written Policy and/or Standard Operating Procedure in Place to Perform RAs





*Measure B.7 is a new measure and has no baseline information.

Clinical Lab Measures - In Summary

- The number of CLs with at least two staff members certified in packaging/shipping infectious agents increased from baseline to April 2016
  - Jurisdictions with CLs that include ETC/EAH are making progress towards 3-year target of 100%
- The number of CLs that have completed an RA has increased, including ETC/EAH
  - Data suggest more outreach is needed overall for performing RAs in the sentinel lab setting
- ETC/EAHs have written policies and/or SOPs in place for RAs in over 80% of jurisdictions
- CL activities are mainly written into Year 2 and 3 of the work plan activities
  - Improvements should be more evident as these activities are implemented