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Implementation of NGS in Public Health Laboratories: A Quality Systems Approach

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Overview

- Background
- Purpose of Project
- Next Steps
- Feedback Requested!



Next Generation Sequencing (NGS) Guidance

Next Generation Sequencing Implementation Guide



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Appendix 2: What to Expect When Implementing Whole Genome Sequencing for PulseNet

Background

In 2013, PulseNet, the National Molecular Subtyping Network for Foodborne Disease Surveillance, began a pilot project to conduct real-time surveillance of all Listeriosis cases in the United States using whole genome sequencing (WGS) technology. This study and others have demonstrated the utility and feasibility of next generation sequencing technology for timely surveillance and outbreak detection of *Listeria monocytogenes* and other foodborne pathogens. (References)

The PulseNet USA network has implemented a gene-by-gene based approach, whole genome multi-locus sequence typing (wgMLST), as the primary method used to analyze whole genome sequence data for cluster detection. This method has several advantages over SNP and kmer based analytical methods in that it allows for: 1) standardization enabling comparison of data generated in different laboratories; 2) provides definitive naming scheme of sequence types for tracking subtypes over time; 3) method is computationally more amendable to program standardization and analytic automation; 4) simple and faster analysis requiring no substantial bioinformatics skills; 5) similar or better discriminatory power and epidemiological concordance compared to PFGE for cluster detection and outbreak investigations.

In addition to pathogen subtyping, WGS may replace most traditional reference testing by consolidating various workflow practices used by public health laboratories (PHLs). Antimicrobial susceptibility, serotype and other virulence markers can be predicted from the sequence data.

This document is intended to assist PHLs with the implementation of WGS for PulseNet. It is projected that whole genome sequencing will be implemented in PulseNet laboratories using a tiered approach through 2018. This guide will be a useful resource for bench level laboratorians, managers and laboratory directors by providing information to assist PHLs with the set up and implementation of WGS within the PulseNet network.

References

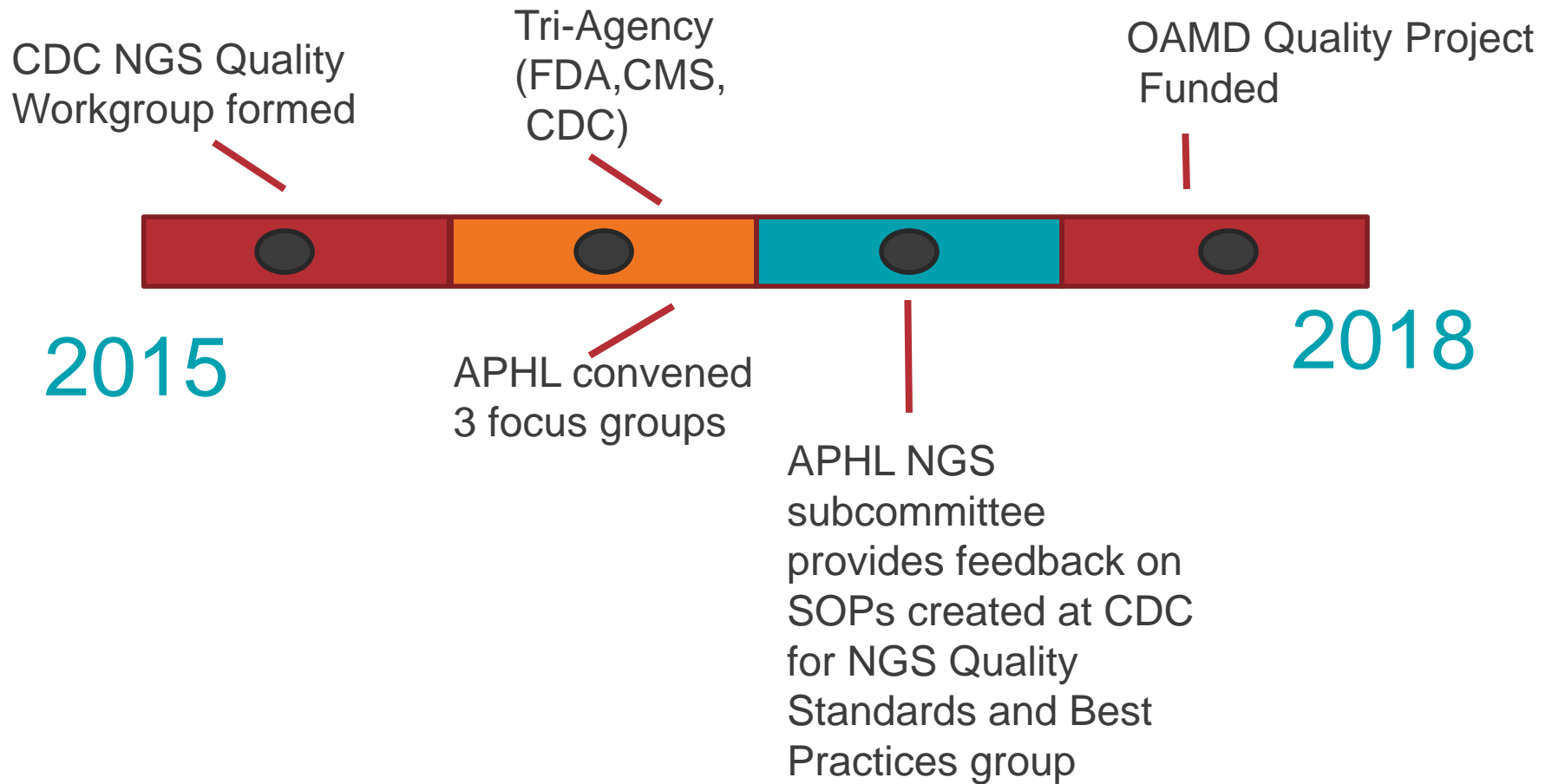
1. Use of Whole Genome Sequencing and Patient Interviews To Link a Case of Sporadic Listeriosis to Consumption of Prepackaged Lettuce. JFP, V 79, No5, 2016, p806-809
2. Implementation of Nationwide Real-time Whole-genome Sequencing to Enhance Listeriosis Outbreak Detection and Investigation. CID, 2016, Aug

Chapter 1. Before implementation of WGS for PulseNet, what do I need to do?

1.1 Requirements for Laboratory Instrumentation/Equipment/Reagents

The PulseNet Standard Operating Procedure, PNL32, provides specific requirements for the laboratory instrumentation, equipment, reagents and supplies for performing WGS using the standardized PulseNet protocol. All references to PulseNet Standard Operating Procedures (SOPs) in this document can be found on the PulseNet SharePoint Site in the Library of PulseNet Documents under QA/QC Manual.

Quality Efforts to Date



OAMD NGS Quality Project

APHL CDC (CSELS)



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Purpose:

- To provide public health laboratories with tools and resources for implementing NGS into current public health laboratory practice.
 - Quality Management Systems approach
 - Ability to meet regulatory requirements (CLIA/CAP) for diagnostic purposes



Impact

- Using Quality System Essentials (QSEs) as a framework ensures
 - High quality data is generated by laboratories
 - Reliable data needed
 - National disease surveillance programs
 - Diagnostic/reference laboratory testing
 - Public health actions!

Laboratory
Quality
Management
System

Handbook



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Next Steps

- Develop Coordinating NGS quality Workgroup (CDC, APHL committees)
- Conduct baseline survey Needs Assessment
- Create web-page to access all guidance documents

WE WANT TO HEAR FROM YOU!!

Questions??

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