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Original Research

Measuring laboratory-based influenza surveillance capacity: development of the '*International Influenza Laboratory Capacity Review*' Tool

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ABSTRACT

Objectives: The 2005 International Health Regulations (IHR 2005) emphasized the importance of laboratory capacity to detect emerging diseases including novel influenza viruses. To support IHR 2005 requirements and the need to enhance influenza laboratory surveillance capacity, the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) Influenza Division developed the International Influenza Laboratory Capacity Review (Tool).

Study design: Data from 37 assessments were reviewed and analyzed to verify that the quantitative analysis results accurately depicted a laboratory's capacity and capabilities.

Methods: Subject matter experts in influenza and laboratory practice used an iterative approach to develop the Tool incorporating feedback and lessons learnt through piloting and implementation. To systematically analyze assessment data, a quantitative framework for analysis was added to the Tool.

Results: The review indicated that changes in scores consistently reflected enhanced or decreased capacity. The review process also validated the utility of adding a quantitative analysis component to the assessments and the benefit of establishing a baseline from which to compare future assessments in a standardized way.

Conclusions: Use of the Tool has provided APHL, CDC and each assessed laboratory with a standardized analysis of the laboratory's capacity. The information generated is used to improve laboratory systems for laboratory testing and enhance influenza surveillance globally. We describe the development of the Tool and lessons learnt.

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Introduction

As a part of the World Health Organization (WHO) Global Influenza Surveillance and Response System (GISRS), National Influenza Centers (NICs) have monitored influenza for over 60 years.[1] An integral part of the influenza surveillance system, NICs detect, report and submit seasonal and emerging influenza viruses to WHO Collaborating Centers for antigenic and genetic characterization. These data are crucial for determining the Northern and Southern Hemisphere influenza vaccine composition each year.[2] Since 1952, WHO has recognized 141 laboratories as NICs spanning 111 member countries.[1]

Under articles five and thirteen of the 2005 WHO International Health Regulations (IHR 2005), countries are required to 'develop, strengthen and maintain… the capacity to detect, assess, notify and report events' such as 'public health risks… and emergencies of international concern'.[3] To support WHO GISRS requirements and improve NIC capabilities to conduct influenza surveillance, the Centers for Disease Control and Prevention (CDC) Influenza Division supports epidemiology and laboratory capacity building in over 40 countries through the use of cooperative agreements.

While it is recognized that quality laboratory testing is important for guiding public health decisions and policies[1,2,4,5] there is, from a global perspective, limited information on methods for measuring laboratory capacity including measuring the impact of improving laboratory-based influenza surveillance over time. Although WHO established terms of reference for NIC participation,[1] standardized processes to assess ongoing quality of influenza laboratories and fulfilment of these terms is limited.

In response to the need for standardized capacity measurement methods and to assist cooperative agreement and partner countries to build laboratory capacity, the Association of Public Health Laboratories (APHL), the CDC Influenza Division and US public health laboratory (PHL) influenza subject matter experts (SMEs) developed the *International Influenza Laboratory Capacity Review* (Tool). Through a series of questions, focussing on specific categories of influenza laboratory functions and practices, the Tool assists SMEs to assess laboratory capacity of national influenza laboratories. Capacity in this context refers to a laboratory's capability to test respiratory specimens for influenza utilizing standard methodologies, biosafety procedures, and quality assurance and quality control methods and using the resulting data to contribute to national and international influenza surveillance.

CDC and APHL collaborate to offer voluntary laboratory capacity assessments for CDC cooperative agreement and partner countries. Using the Tool, data are collected in a standardized manner. The assessment feedback assists national influenza laboratories to establish, improve and/or maintain influenza testing capabilities using internationally accepted biosafety and quality control practices. It also helps laboratories to attain or maintain NIC designation thereby building and enhancing global influenza surveillance capacity.

Following introduction and initial two year use of the Tool, improvements were made and a process to apply a quantitative framework for analysis to key assessment components was developed. This allows for a more systematic comparison of data from individual laboratories over time. This paper details the development of the Tool and the subsequent process to quantitatively analyze data collected from laboratory assessments to characterize capacity across different regions and globally.

Methods

Developing the International Influenza Laboratory Capacity Review

In 2009 representatives from PHLs and CDC, with expertise in influenza laboratory methods and surveillance and familiarity with WHO GISRIS influenza guidelines and laboratory standards, created the Tool to assist in assessing international laboratories' capacity for testing influenza specimens and quality laboratory practices. As agreed upon by the SMEs, through group discussion and majority consensus, the Tool was developed to represent the essential laboratory functions and practices of WHO NICs. The Tool was organized into nine sections (general laboratory, virology laboratory, molecular biology laboratory, influenza testing, laboratory safety and biosafety, training, specimen handling, collection and reporting, and quality assurance) and within each section a series of questions prompts the assessor to evaluate laboratory practice, identify strengths and develop recommendations for improvement. Created in Microsoft Excel, the modular design allows each section to be administered independently and by different assessors. To test the Tool and gain feedback on its usability and content, two pilot assessments were conducted during 2009 in Europe and South America. Utilizing the feedback from the pilot assessments, individual questions were edited for clarity and the Tool was finalized.

Tool revision and quantitative framework development

Assessors, influenza SMEs selected based on their education, expertise, and previous work experience with influenza laboratory diagnostics, completed thirty-seven assessments between 2009 and 2011. Feedback was solicited from the SMEs and it was revised to increase its usability and prepare it for the development of a quantitative framework. Individual questions were edited for clarity, new questions were added to address gaps and questions were reorganized into different categories to better reflect typical laboratory operations. The modular design was retained; however, the sections were updated and reordered to reflect the changes (e.g. the influenza specimen testing section was eliminated because those questions were moved into other sections).

As part of the revision process, the Tool was compared to the *WHO Europe National Influenza Centre Laboratory Assessment Tool* (NIC-LAT),[6] which was developed and piloted a year after the 2009 APHL-CDC Tool. While there is considerable overlap, the tools serve different functions; the NIC-LAT is used as a