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Remote Laboratory Management: Respiratory Virus Diagnostics

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Abstract:

An uptick in recent pandemics (Ebola, Zika, MERS, influenza, etc.) underlines the need for a more 'nimble,' coordinated response that addresses a multitude of issues ranging from transportation, access, facilities, equipment, and communication to provider training. To address this need, we have developed an innovative, scalable, logistics-enhanced, mobile, laboratory facility for emergencies and epidemics in resource-constrained global settings. Utilizing a background in clinical operations as an academic medical center, we designed a rapidly-deployable, modular BSL-2 and BSL-3 facility with user-friendly software for tracking and management of drugs and supplies in remote regions during epidemics and outbreaks. Here, we present our intermodal, mobile, expandable shipping-container laboratory units. The design of the laboratory facilitates off-grid usage by minimizing power consumption and allowing alternate water sources. The unit's information communication technology (ICT) platform provides (i) user-friendly tablet-based documentation, (ii) enhanced tracking of patients and supplies, and (iii) integrated communication onsite with built-in telehealth capabilities. To ensure quality in remote environments, we have developed a checklist for a basic laboratory workflow and a protocol for respiratory viral diagnosis using reverse-transcription polymerase chain reaction (RT-PCR). As described, this innovative and comprehensive approach allows for the provision of

laboratory capability in resource-limited global environments.

Keywords: Laboratory Management, Respiratory Virus Diagnostics.

Introduction

Rapid diagnostics is a critical instrument in timely viral infection control, especially if early symptomatology is indistinguishable to a variety of infection diseases. uncovered the need for rapidly-deployable, laboratory facilities that address a multitude of issues from transportation, access, facilities, equipment, and communication (Connelly, 2015).

The assurance of quality laboratory results depends on a commitment to assess all aspects of the entirety diagnostic testing process. Here, we present a checklist for the BSL-2 and BSL-3 laboratory workflow, and a protocol for rapid respiratory virus diagnostic test. The proposed diagnosis of viral diseases relies on the detection of viral RNA or DNA in specimen (nasal wash, blood, stool, and urine, etc.) through real-time reverse-transcription polymerase chain reaction (RT-PCR). The ability to rapidly estimate viral loads in a specimen makes PCR an efficient tool for viral disease screening

The goal of this work is to validate a novel modular and rapidly-deployable laboratory facility and provide a training guide for laboratory personnel working in remote, low-resource environments during an epidemic, natural disaster or other emergency relief situation. Here, we present a protocol for respiratory influenza diagnosis in this innovative, portable laboratory(Wölfel, R., et al. 2015).

Checklist for personal protection and basic laboratory workflow:

Before preparing to enter the installed laboratory unit, ensure that all BSL-2 or BSL-3 safety requirements are accounted for: dressing with proper personnel protective equipment (PPE), washing hands, wearing gloves, and decontaminating any

workspaces that are to be used (Gaglani, M., et al., 2016).

Follow the checklist in contains safety requirements for personal protection during tests run in the lab BSL-2 and the BSL-3 module (the assembled glove box room – negative pressure and PCR room – positive pressure (Fauci, 2016).

Decontaminate all work space and supplies in the laboratory. If planning to use sodium hypochlorite solution (0.5%), also known as liquid bleach, to decontaminate the workspace and supplies, also use 70% ethanol to clean all areas exposed to bleach, as bleach can mix with other chemicals in the workspace to create toxic fumes. Dispose all bleach products into their own designated waste bin.

Before beginning to work in the laboratory unit, become familiar with its arrangement and layout. Strict rules apply for processing samples in the glove box (GB) room. The GB room is negative pressure! To operate a glove box, check the manufacturer's instruction. Multiple sources provide detailed tutorials on glove box operation (Gaglani, M., et al., 2013).

NOTE: The purpose of this assay is to extract and purify ribonucleic acid (RNA) or deoxyribonucleic acid (DNA), if present, from specimens. The extracted RNA/DNA will be tested by a real-time RT-PCR to detect the presence or absence of targeted viral pathogens – influenza (INF).

Rapid influenza virus diagnostics by RT-PCR in a BSL-2 laboratory facility:

As sample swabs are taken from patients, transport them to the laboratory facility from the field or clinic. Transfer samples via the pass-through window; this window cannot be opened from both sides.

In the pass-through window, spray tubes containing samples with bleach for 1 min followed by 70%

ethanol and wipe dry in order to provide adequate decontamination before they enter the laboratory unit. Following the submersion, the lab technician inside the unit will open the pass-through window and collect the samples from the bleach container to be registered. Usually, the person passing the sample and the person extracting the sample are not the same (Wölfel, R., et al., 2015).

Recommendations:

The remote laboratory facility described above is logistically-oriented, expandable, rapidly deployable, multifunctional, and based on human-centered design concepts that have been geared to protect laboratory personnel and workspace efficiency. The detailed protocol for quick laboratory set-up and safe respiratory virus isolation and diagnosis was developed and presented.

The goal of this study is to demonstrate that the proposed BSL-2 and BSL-3 mobile laboratory facilities provide an adequate environment allowing respiratory virus diagnostic tests with representative results identical to tests performed in high-quality stationary laboratories. The laboratory facilities are designed to comply with the test requirements given in Occupational Health and Safety (OHS) recommendationslaboratories.

In accordance with laboratory standard operating procedures, PPE (lab coats, protective shoes, gloves, advanced mask, protective eyewear,.) appropriate for BSL-2 practice is required. For BSL-3 practice, the PCR laboratory module of negative pressure is equipped with a certified glove box. The laboratory units are upgraded by external pass-through windows to protect personnel at the step of sample receiving. The registration process can be simplified with previously developed tablet-based application . Other acceptable applications that run on a laptop can be used as well.

Conclusion:

A rapidly-deployable, off-grid laboratory has been designed and built for remote, resource-constrained global settings. The features and critical aspects of the logistically-enhanced, expandable, multifunctional laboratory modules are explored. A checklist for a basic laboratory workflow and a protocol for a respiratory viral diagnostic test are developed and presented.

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