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Research Article

Rapid Deployment and Application Exploration of the Mobile Shelter Laboratories under the Outbreak of COVID-19 Epidemic

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ABSTRACT

Since the end of 2019, the COVID-19 epidemic has swept the world. With the widespread spread of the COVID-19 and the continuous emergence of mutated strains, the situation for the prevention and control of the COVID-19 epidemic remains severe. On May 21, 2021, Guangzhou City, Guangdong Province notified the discovery of a new locally confirmed case. Guangzhou became the first city in mainland China to compete with the delta mutant strain. As a local hospital with strong nucleic acid detection capabilities, Sun Yat-sen University Sun Yat-sen Memorial Hospital took the lead in launching the construction and deployment of the Mobile Shelter Laboratories and large-scale screening work in Foshan and Zhanjiang, Guangdong Province. Through summarizing "practical" experience, observation and comparison data analysis, we use real data to verify a feasible solution for rapid expansion of detection capabilities in a short period of time. We hope that these experiences will have certain reference value for other countries or regions, especially the underdeveloped areas of medical and health care.

Keywords: COVID-19; Mobile shelter laboratories; Vaccine; Nucleic acid amplification testing

INTRODUCTION

The ongoing outbreak of Coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has become a public health emergency of international concern [1]. To this day, there are still constant reports of new coronavirus variants [2]. Among them, Guangzhou has become the first city in China to confront the delta variants. On May 21, 2021, Guangzhou first reported infections of the new coronavirus delta variants. The local spread caused by the mutant strain has spread to the entire Guangdong Province, including Foshan, Zhanjiang, Dongguan and other places. As of now (July 5, 2021, there were no local new additions for the previous 14 consecutive days), a total of 192 cases have been reported (Figure 1).

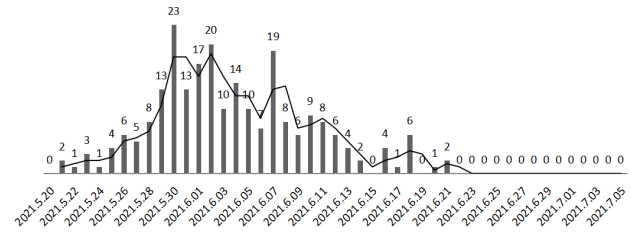

Figure 1: From the first report of a local infection of the Delta variant in mainland China on May 21 to the total number of cases in Guangdong Province at the end of this round of the epidemic. Note: (▬) number of new cases.

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In order to achieve early detection and early isolation, and timely prevent the spread of virus, the improvement of COVID-19 nucleic acid detection capacity of medical and health institutions has become an important part in the epidemic prevention and control. Due to the limitation of construction, some existing laboratories in China cannot improve the abilities for nucleic acid detection through reconstruction and expansion in a short time. Therefore, the Mobile nucleic acid detection Shelter Laboratory (MSL) will prove to be an effective means of solving the dilemma. With the features of portability, long service life and strong environmental adaptability, MSL can quickly move and deploy to the epidemic area to carry out detection at the first time. It can effectively shorten the reporting time by reduce the sample turnaround time. While reducing the risk of communication, MSL can meet the emergency needs of large-scale testing in the short term. In view of this situation, Sun Yat-Sen Memorial Hospital first dispatched a MSL and a team of clinical laboratory technicians to participate in actual battle against the epidemic. In this report, we record the concept and development of shelter laboratory during the outbreak of COVID-19 in Guangdong China. We describe the main features and basic functions of MSL, and discuss the key issues of its success. We consider the application of this concept in other countries as part of the public health response of COVID-19 especially in underdeveloped areas with insufficient nucleic acid testing capabilities.

MATERIALS AND METHODS

The Mobile Shelter Laboratories (MSL) development status study

MSL is a mobile laboratory which is convenient to move and can carry out nucleic acid detection quickly and flexibly. It is composed of rigid integrated box, equipment and support system. Temperature and humidity control system, negative pressure ventilation system, power supply system, water supply and drainage system, information system and other related supporting facilities provide guarantee for the detection environment, which can meet the needs of clinical sample detection or scientific experiment activities [3]. The design of MSL conforms to the relevant national industry standards [4]. It has the characteristics of flexible design, short construction period, low cost, strong mobility and good maintainability. Mobile lab started late in China. But due to the outbreak of COVID-19 and the importance of bio-safety, the mobile lab has entered a rapid development period in China. By learning from the advanced experience of foreign mobile laboratory construction and management, the management of China's mobile laboratory began to move towards scientization, standardization and legalization [5].

The Mobile Shelter Laboratories (MSL) site selection and installation requirements study

The location of MSL should follow the principle of minimal impact on environment, high safety, and be close to the nucleic acid collection center, so as to shorten the transportation time. Make sure there is good ventilation and small flow of people around the shelter. Under the condition of flat site, MSL only needs to carry out box hoisting and placement, with water supply and electricity docking. In addition, around the mobile laboratory box, medical waste storage area, material storage area, staff rest area, etc. should be arranged at the same time. The layout method is as follows (Figure 2).

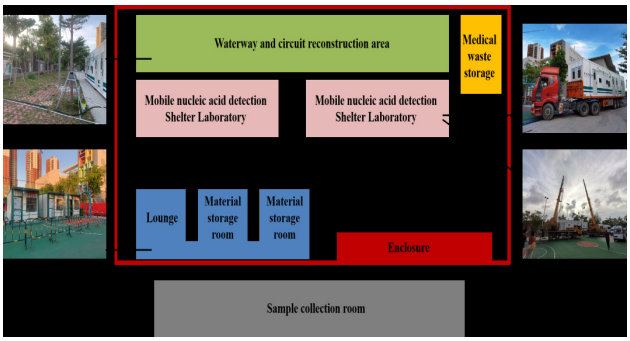

Figure 2: Site selection and layout of the Mobile Shelter Laboratory.

The internal structure of the Mobile Shelter Laboratory (MSL)

We use a containerized mobile laboratory. Compared with a gas film laboratory, the biggest advantage of a containerized laboratory is that it can be used repeatedly, the built-in equipment can be integrated, no installation, and it can be vehicle-mounted, stop and go. The specific layout of the Mobile Shelter Laboratory used this time is as follows (Figure 3), including reagent preparation area, sample processing area, amplification analysis room and data analysis room, as well as air-conditioning room to control the fresh air system and autoclaving chamber to ensure biological safety. The entire container is 13.716 meters long, 2.438 meters wide, and 2.896 meters high.

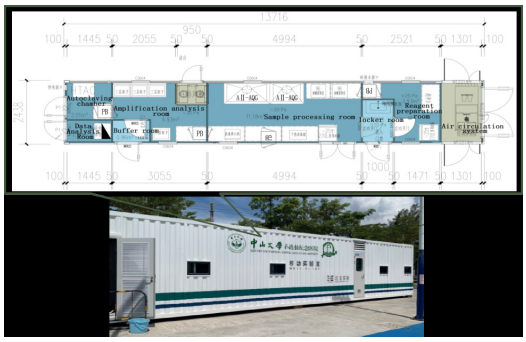

Figure 3: The internal structure of the Mobile Shelter Laboratory.

Operation management of the Mobile Shelter Laboratory (MSL)

In order to ensure the efficient, safe and high-quality operation of the Mobile Shelter Laboratory, laboratory personnel shall be trained strictly before taking up their posts. Laboratory personnel of the MSL shall hold the post certificate of technical personnel of clinical gene amplification laboratory and the certificate of nucleic acid detection of new coronet, pass the biosafety protection training, and meet the requirements of "Administrative Measures for Clinical Gene Amplification Laboratory of Medical Institutions" [6] before they can start their work. The shifts should be flexibly adjusted according to the sample size and sample arrival time, and personnel should be scheduled reasonably. In the case of large-scale testing, a 24-hour three-shift system can be used, with one shift every 8 hours. Hardware conditions meet the "Medical Biosafety Laboratory Building Technical Standards" [7], "General Criteria for Pathogenic Microorganism Laboratory Biosafety" [8] and "General Requirements for Laboratory Biosafety" [9], and the negative pressure, temperature and humidity control and cleanliness level of the laboratory all meet the corresponding standards.

Quality control and management

Quality control and management before being used for clinical specimen testing, the laboratory shall perform necessary performance verification for the detection system consisting of extraction reagents, extractors, amplification reagents, and thermal cyclers. Performance indicators include but are not limited to precision (at least repeatability) and the lowest detection limit. It is recommended to use highly sensitive reagents (detection limit ≤ 500 copies/mL). Each batch of testing has at least 1 weak positive quality control product (third-party quality control product, usually 1.5-3 times the detection limit) and 3 negative control products (physiological saline). The negative control should be opened and placed on the extractor or operating table overnight for environmental pollution assessment. The quality control products are randomly placed in clinical specimens and participate in the whole process from extraction to amplification. However, when testing COVID-19 specimens on a large scale in the shelter laboratory, in accordance with relevant regulations, each batch of testing could randomly conduct weak positive and negative indoor quality control [10]. In large-scale population screening, due to the extremely low population prevalence (<0.1%), once a positive result appears, another one or two more sensitive nucleic acid detection reagents that amplify different regions are used on the original sample for the positive sample. Recheck the test, and only if the check is positive, it can be reported [11]. Those that do not meet the quality control requirements shall not carry out nucleic acid testing [12].

Establishment and implementation of biosafety related management systems The laboratory should be equipped with biosafety guarantee equipment, including type A2 biological safety cabinet, vertical pressure steam sterilizer, circulating air disinfection machine, mobile ultraviolet disinfection lamp, accident handling box, sample transfer box, medical waste bins, etc., and equipped with adequate personal protective equipment, hand sanitizer, and hand-cleaning paper box, etc., and requires staff to strictly implement the biosafety management system, operating procedures and standard precautions, and correctly put on and take off personal protective equipment to ensure safety [13]. The sample transfer box needs to be wiped or sprayed with 0.2% chlorine disinfectant or 75% alcohol before and after use. After the experiment in each area, use a chlorine-containing disinfectant with an effective chlorine content of 0.2% (required to be prepared on-the-spot) to disinfect the countertops, floors and other places for at least 30 minutes. When spills occur in the laboratory, use a chlorine disinfectant with a concentration of 0.55% (5500 mg/L) to deal with it [14].

RESULTS

Research results of the control and deployment of the speed limit link in the actual work of the Mobile Shelter Laboratory (MSL)

The main speed-limiting link of large-scale screening in the internal workflow of the MSL comes from the allocation of personnel and the preparation of the number of equipment. If you want to make a breakthrough in detection capabilities, you must allocate reasonably and optimize the workflow. Limited by the space environment of the MSL, 3 nucleic acid extractors (SWIFT96, DAAN GENE™ CHINA) can be placed in the sample preparation room, and 6-9 nucleic acid amplifiers (96 panels) or double the number of 48-panel equipment can be placed in the amplification area. The working time of every two extraction instruments corresponds to the working time of a thermal cycler. Each thermal cycler works for 2 hours at a time and works 10 times a day. The daily detection volume of a mobile shelter laboratory is 5000~8000 specimens. The sample preparation area requires 4 staff members, 1 reagent preparation area and 1 amplification area each, with 6 persons per shift, and 3 shifts can be set up throughout the day to work in shifts. The specific correspondence is shown in Table 1.

Table 1: Correspondence between the Mobile Shelter Laboratory staff, equipment, and maximum daily detection volume.

Staff	Nucleic acid extractor	Thermal cycler	Maximum detection volume
6 people/shift	3*96T Instruments or 2*96T instruments+ 1*32T instruments	6~9*96T Instruments or 12~18*48T Instruments	5000~8000 tubes/day

The results of nucleic acid detection capability amplification

Take our testing site in Zhanjiang as an example. There are 15 local laboratories with COVID-19 testing capabilities, with testing capabilities ranging from 500 to 3000 tubes per day. The testing capacity of the Mobile Shelter Laboratory is equivalent to a large Class A hospital (the highest rating of Chinese hospitals) is twice, and compared with Class A hospitals, the Mobile Shelter Laboratories are more flexible and can be flexibly deployed near the sample collection place.

DISCUSSION

In terms of biosafety, the MSL's access channels which we set out this time needs to be improved. There are some design flaws, such as: there is no internal corridor, only a buffer room in the sample preparation area, resulting in the entrance and exit not meeting in the clean area. The water supply and drainage system cannot meet the same requirements of large medical institutions. Since the MSL are not hospitals after all, their construction requirements cannot meet the requirements of hospitals, especially infectious disease hospitals. Therefore, large-scale renovations cannot be achieved in a short time, such as water supply pipelines are not separated in clean areas and contaminated areas; drainage pipes are not set up in districts; drain traps for sewer pipes lack effective "water seals" due to long-term idleness [15]. Due to the tight time and heavy tasks, we can continue to improve the biosafety while putting into use, such as optimize the environment according to local conditions, configure sufficient disinfection facilities and equipment, alleviate the risk of biosafety caused by insufficient hardware, and strengthen the training of different staff members on the knowledge of COVID-19 infection. In addition, we have continuously improved our awareness of biosafety, set up full-time biosafety control positions, reduced the risk of infection, ensured the health and life safety of all staff, and successfully completed the epidemic prevention and control tasks.

At the same time the psychological counseling of the staff in the shelter laboratory is also an issue that cannot be ignored. Some researchers pointed out that the medical and nursing work in the shelter is huge, and the physiological pressure is also doubled: 1 to 10 days after entering the cabin, the initial excitement turns to anxious state, fear, helplessness, adjustment disorder, panic disorder, etc. In the middle stage of cabin entry (11-25 days), various degrees of sleep disturbance, obsessive-compulsiveness,

sense of uselessness, somatization, empathic fatigue, job burnout, and acute stress disorder may occur. In the late stage of cabin entry (26-40 days), there may be varying degrees of missing psychology, prolonged grief disorder, depressive disorder, post-traumatic stress disorder, and suicidal ideation. Therefore, it is necessary to reasonably rotate the shelter staff and increase psychological guidance and intervention measures (talking, acceptance, support, relaxation training, etc.) [16].

The speed-limiting link that affects the large-scale screening work of the Mobile Shelter Laboratory includes field weather conditions, personnel arrangements, the proficiency of staff cooperation, the concentration of sample collection and delivery, the technical level of the sampling personnel, and the layout of the laboratory experimental equipment, especially the number of nucleic acid extractors and thermal cyclers, etc. In terms of personnel management and deployment, according to emergency detection needs, personnel can be transferred in stages and batches to flexibly respond to emergencies. Establish effective communication channels with equipment and reagent manufacturers to ensure that equipment engineers and technical support personnel of each manufacturer can arrive within the agreed time. If necessary, arrange equipment engineers and technical support personnel to be stationed on site. Make overall arrangements according to the corresponding relationship between personnel and machine configuration and production capacity. In short, the deployment principle of the Mobile Shelter Laboratory is to complete the construction or transformation in the shortest time and at the lowest cost, respond to emergent medical rescue tasks, and follow the safety principles to ensure the quality of the situation, complete the inspection work, even if it is just a temporary medical testing organization.

CONCLUSION

Due to construction conditions, some laboratories cannot improve their nucleic acid detection capabilities through reconstruction and expansion in a short period of time. Because of its portability, long service life, and strong environmental adaptability, the Mobile Shelter Laboratory can be quickly moved and deployed to the epidemic area for testing in the first time. It can effectively shorten the reporting time by reducing the sample turnaround time, and can meet the emergency needs of large-scale testing in the short term. We use real data to verify the feasible plan for rapid expansion of detection capabilities in a short period of time. We hope that these experiences will be of reference value for other countries or regions, especially those with underdeveloped medical and health care.

AUTHOR CONTRIBUTIONS

YL, RD and CHD designed the study. XLC, XFZ, WSG revised the manuscript. All authors participated in the practice summary work of the Mobile Shelter Laboratory, contributed to drafting the manuscript and approved the final version of the manuscript.

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