

ASST PAPA GIOVANNI XXIII, BERGAMO: A NEW ORGANIZATIONAL MICROBIOLOGY AND VIROLOGY LABORATORY STRUCTURE TO FACE THE HEALTH EMERGENCY FROM THE SARS-COV-2 OUTBREAK

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KEYWORDS: Covid-19, Sars-cov-2 molecular diagnosis, reorganization

ABSTRACT

On January 12, 2020, the World Health Organization (WHO) declared Covid-19 an emergency of international interest. The first documented case in the "Pope John XXIII" Hospital in Bergamo was identified on Friday, February 21, 2020.

The ASST Pope John XXIII of Bergamo was among the very first Hospital Companies to implement a series of organizational remodelling to quickly face the health emergency from the Sars-Cov-2 outbreak.

In this context, we will describe the role and organizational changes adopted by the Complex Operating Unit (UOC) Microbiology and Virology.

Laboratory diagnostics can effectively help counteract this and other (future) viral outbreaks.

Molecular diagnostics is the only method currently recommended for the identification of infectious cases.

The gold-standard method for identifying the virus is Real-time PCR (RT-PCR) according to both the protocol of the Charité University Hospital in Berlin and the American CDC (Center for Disease Control and Prevention).

Biological samples of the lower respiratory tract (sputum, endotracheal aspirate, or broncho-alveolar washing) or alternatively upper respiratory tract samples are preferred for the execution of a swab for each nostril and a swab for each side of the oropharyngeal cavity.

The need to adopt a new organizational structure also concerned the UOC Microbiology and Virology, which was quickly called upon to cope with the health emergency by making its contribution through molecular research of the Sars-Cov-2 virus. We will illustrate the salient phases of the reorganization that led to the execution of over 1000 molecular swabs per day and the implementation of a service in H24.

Properly managing human resources in the 24 hours was essential for the proper functioning of the laboratory itself and to deal with the ongoing health emergency. In this even evolving and uncertain context, it was difficult to adopt predefined strategies, but the right involvement, the self-denial of the staff and the strong team spirit have made it possible to achieve excellent performance and quality results.

INTRODUCTION

The ASST "Papa Giovanni XXIII" of Bergamo is part of the Regional Health Lombardy System, aimed to answer the health needs of the population, through the provision of healthcare including diagnosis services, treatment and rehabilitation to the person, ensuring the Essential Levels of Care (LEA) and any additional level provided by the Region. The hospital, in force since December 2012, has 36 operating theatres, 238 outpatient clinics, 1,036 accredited beds and a helipad. The seven towers house the inpatient and outpatient departments, while a central plate is hosting all the diagnostic and treatment services, from operating rooms to intensive care, from laboratories to the emergency department (1).

Bergamo and its surroundings, of over 1.1 million inhabitants, was one of the first Italian provinces severely affected by the Covid-19 emergency with 14,177 cases as of 23 June 2020. In early December

2019, the new virus named Covid-19 was identified as the causative agent of the first pneumonia cases in Wuhan, the capital of the Hubei region in China (2). On January 12, 2020, the World Health Organisation (WHO) declared Covid-19 an emergency of international interest. A few months later, on March 11, the WHO reclassified the Covid-19 outbreak as a global pandemic.

The first case in Italy was identified in the province of Lodi, Lombardy, northern Italy. The first case in our hospital was identified on a Friday, February 21, 2020 (3).

OBJECTIVE

The ASST Papa Giovanni XXIII of Bergamo was one of the first hospitals that implemented a series of organizational remodeling to quickly face the health emergency caused by the Sars-Cov-2 outbreak. Reorganization by means intra- and extra-

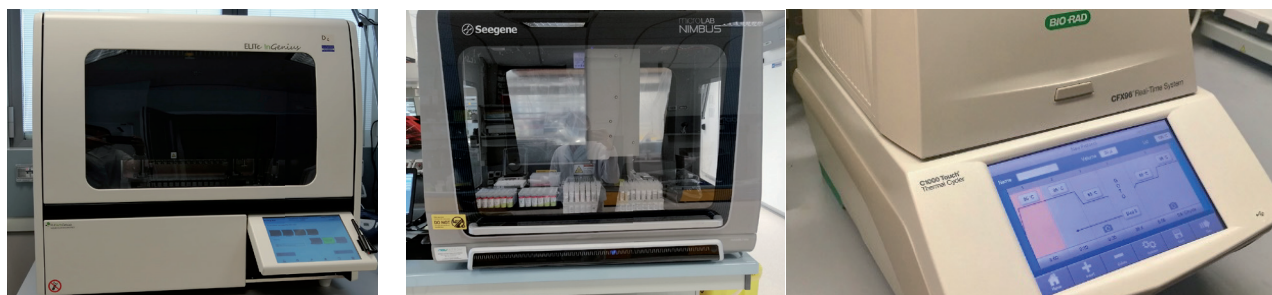


Fig. 1a - Instrumentation Elite Ingenius – Elitechgroup. **Fig. 1b** - Instrumentation Nimbus - Seegene (on the left) / CFX96 –Biorad (on the right).

departmental mobility projects affected all sectors and disciplines: individual operators temporarily changed their operating unit in order to deal with the current pandemic demand.

In this context, we describe the role and organizational changes adopted by the Complex Operating Unit (UOC) Microbiology and Virology of the ASST Papa Giovanni XXIII in Bergamo to cope with the pressure arising from the necessity to have a quickly Covid-19 diagnosis. In particular, in the Microbiology and Virology laboratory, which became one of the first regional reference laboratories in Italy involved in the front line of this emergency, the reverse transcription-polymerase chain reaction test (RT-PCR), based on the identification of viral RNA, has been directly implemented, following the WHO guidance in terms of diagnostic strategies (4).

■ MATERIAL AND METHODS

Laboratory diagnostic can effectively contribute to fight this pandemic and any other (future) viral outbreaks; strong evidence has proven that laboratory testing are critical to improve care and/or preserving people's well-being (5).

The identification of Sars-Cov-2 as a causative agent (6) (7), has rapidly promoted the development of virological and serological diagnostic tests. Molecular diagnostics is currently the only recommended method to identify infected people. The gold-standard method for virus identification is the Real-time PCR (RT-PCR) according to both the protocol of the University Hospital of the Charité in Berlin and the American CDC (Center for Disease Control and Prevention) (8) (9). For this test, biological samples are collected from the lower respiratory tract (sputum, endotracheal aspirate or bronchoalveolar lavage) or alternatively from the upper respiratory tract by swabbing each nostril and each side of the oropharyngeal cavity (10). The obtained material can provide a reliable and rapid diagnosis for patients who develop Covid-19. Therefore, amplification of viral RNA with RT-PCR is the gold-standard test to confirm the actual infection (11), however, the large demand due to worldwide virus outbreak has highlighted the limitations of this type of diagnosis. This technique takes long time (3-4 hours) to give an outcome, 15-20% false negatives depend on to the way the biological sample is taken and finally it requires expensive equipment and trained staff.

In order to achieve the objective of high analytical frequency and to meet the numerous demands of more than 1000 processable swabs per day, the following technologies were used in the early phase:



Fig. 12 - Instrumentation Panther (Hologic)

4 Elite Ingenius instruments / Elitechgroup company (Fig.1.a) and a Nimbus extractor - Seegene / Arrow Diagnostics coupled to its CFX96 / Biorad amplifier (Fig.1.b).

At later stage, the Panther equipment from Hologic (Fig.2) was added to these technologies. Thanks to the several donations, the ASST "Papa Giovanni XXIII" acquired - on "rental" basis - this analyser, which, when fully operational, reaching a productivity of over 600 swabs per day using a technology of continuous sample loading.

■ DISCUSSION

The first Covid-19 case in our hospital was diagnosed on Friday, 21 February 2020. As of Saturday, 22 February 2020, half of the infectious disease unit (24 beds) of the ASST Papa Giovanni XXIII in Bergamo was dedicated to Covid-19 patients. On February 23, it became clear that this was not sufficient and on Friday 28 of February all 48 beds of the infectious disease unit were saturated with Covid-19 positive patients. As consequence, a new 48-bed Covid unit was prepared every 48 hours. Several medical and surgical units were dismantled until March 10, and a total amount of 240 beds entirely dedicated to Covid patients.

The increased pressure prompted the hospital management to quickly discharge or transfer non-Covid patients towards other hospital wards outside the Lombardy region. More than 35% of the medical staff (around 400 doctors of all disciplines), together

with over 900 nurses, were recruited and trained to be fully dedicated to the newly established Covid-19 units. The rapid spread of the infection led to a progressive increase in the number of patients in the hospital emergency room and the concomitant necessity for a rapid diagnosis. The molecular biology tests were used to fast diagnosis of Sars-Cov-2.

In this context, all the Operating Units were forced to seek more flexible and dynamic organizations to efficiently manage their human resources. To this scope, the Microbiology and Virology Complex Operating Unit, requested to implement molecular research about the Sars-Cov-2 virus, adopted a new organizational structure.

The meeting with all managerial, technical and administrative staff was the first step. On February 25, the Microbiology and Virology unit began to introduce the first strategies in order to become one of the first regional center performing molecular diagnosis of Sars-Cov-2. Since the first meeting, it immediately emerged that the virology group needed to be enlarged. Until then, it was consisting of 6.75 Full Time Equivalents (FTEs) and it was shared with the Simple Departmental Operating Unit (UOSD) Biobank and Advanced Biotechnologies.

On February 29, the virology group was reinforced by three units for a total of 9.75 FTE:

- 6.75 FTE – already existing virology staff;
- one Biomedical Laboratory Technician (TSLB) from the bacteriology laboratory;
- one TSLB coming from pathological anatomy with previous experience in molecular biology;
- a new TSLB.

The staff one-day trained (February 29, 2020), was able to manage part of the Sars-Cov-2 virologic diagnostics on Nimbus/CFX 96 instrumentation (Seegene/Arrow Diagnostics) and rapidly acquired to support the Elite Ingenius instrumentation (Elitechgroup), used to increase the capacity for processing swabs.

Later on, 4th of March 2020, Lombardy Region authorized the Microbiology and Virology laboratory of ASST Papa Giovanni XXIII in Bergamo to carry out Sars-Cov-2 molecular diagnosis, after an assessment of the instrumental, technical and training requirements. For the first five following days, the duty was open from 7 a.m. to 7 p.m. Once the supplies and staff training were optimized, the processing swabs activity was extended until the midnight. From March 09 till April 26, 2020, the virologic diagnostics department worked from 7 a.m. to midnight, 7 days a week, with a shift schedule of 6 working days x 6 hours per day, with the following time slots: 7 a.m. to 1 p.m., 1 p.m. to 7 p.m., 6 p.m. to midnight.

The growing pressure, linked to the considerable number of daily swabs to be handled (on average 600- 700 per day with peaks of 950), led the technical coordinator to change the former organization. Additional support of human resources were used to provide 24-hour service. They came from the laboratory of the Bergamo Health Protection Agency (ATS - 2 FTE TSLB) and pathological anatomy staff (a further 2 FTE TSLB). The new resources allowed to strength the pre-analytical phase (1 FTE) and to manage virologic diagnostics, processing an average

of about 1000 swabs in 24 hours with a shift schedule structured as follows: Morning-Afternoon-Night-Rest Period (M-P-N-S-R) with double presence (2 TSLB on duty).

From the emergency status of March/April 2020, we gradually moved on to a management routine phase that involved the return to ATS of the two TSLB people (from 11 May 2020) and the return of the pathological anatomy staff (3 TSLB, from 20 June 2020). The 5 TSLBs human resources that highly supported the Microbiology and Virology unit were gradually replaced by temporary/self-employed technical staff, who is currently work 24 hours a day, with the aim of processing swabs on the various analytical guidelines that to date have been increasingly optimized and consolidated. This was accompanied by the acquisition of the Panther instrumentation (Hologic), an analyzer with continuous samples loading and a maximum daily processing capacity of around 600 swabs (in routine since September 2020).

Once the emergency phase was over, further challenges involved the Microbiology and Virology Unit. Serological diagnostics and the beginning of everyday activities in the serology/bacteriology department have imposed further organizational changes, driving a re-organization of Laboratory of Medicine Services (SMeL).

The management of serological tests was organized by involving the SMeL 2 Clinical Chemistry Analysis unit, equipped with highly automated analyzers to allow the preanalytical samples handling. In addition, an automatic check-in and centrifugation of samples was implemented. Previously, this operation were carried out manually by the technical personnel of microbiology laboratory with a considerable waste of human resources.

■ CONCLUSIONS

The laboratory tests results play a decisive role in “clinical thinking”, in “decision making” and in therapeutic drug monitoring (12) (13) (14) (15) (16).

Over the past few years, there were a progressive reduction in the economic resources allocated to healthcare, as consequence, a decrease in personnel availability and the necessity to optimize the staff.

Laboratories asked to maintain or increase productivity and quality of services with a growing demand for workforce reduction. Hence, an appropriate management of 24-hour staff were essential for smooth running of the laboratory.

During the last decades, technology made ‘leaps and bounds’; more skills and more ‘elasticity’ are required of technical staff (17). Technologies helped laboratories to improve quality and speed. The new technologies are able to report results in a very short time frame with a very narrow and controlled margin of error and in addition the patient/client/user gets more reliable and safer data.

In the context of general guidelines issued by the regions and of human resources (18), the organizational models of in vitro diagnostic services may be different. The Italian situation presents a great variety of solutions about work organization and work shifts, distinct from region to region, but also between diverse health authorities in the same territory. The differences have been acquired from historical traditions or from contingent situations such

as trade union negotiations, staff shortages, technical manager's preferences, etc. These have led to the adoption of different models (not always optimal), as well as to the use of disparate terminologies.

Nowadays, coping and managing changes is often a complex and stressful process that can generate different emotions in individuals, ranging from support to resistance. Change is a delicate process that has to be carefully prepared in order to be an opportunity of real growth (19). The greatest barrier to this process is the human factor. In effect every type of re-organization affects organizational balances, working methods, skills, behaviors and relationships, mostly like in health emergency contexts.

A correct management of change can prevent, or at least constrain, the impact of negative forces by creating the right synergy between the need to change and the actual organization's capacity for that change. Being receptive to switch determines the company's

ability to survive and to develop with respect to its environment. But for a change to be successful, those who lead it, have to be aware of the central role of people involved in that process. Furthermore, the leaders have to understand and interpret negative reactions, and have to engage the staff to explain them the choices even the more complicates.

The delicate task turned out to be listening to doubts and perplexities. The possible difficulties were promptly detected, and the staff adequately informed on the various stages of the change. Individuals and the group must have a precise role and finally it is necessary to plan in detail the process of managing the growing pressures linked to an ever-changing scenario. In such an uncertain environment it was difficult to adopt predefined strategies. However, the right involvement, self-sacrifice of the staff and a strong team spirit have made possible the achievement of excellent performance and quality results.

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