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LABORATORY MANAGEMENT REGARDING THE DIAGNOSIS OF SARS-COV-2 IMPLEMENTATION OF A BIORISK MANAGEMENT SYSTEM

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ABSTRACT

The whole world is currently going through a pandemic, Covid-19, due to a new coronavirus SARS-CoV-2. This pandemic has caused a high number of deaths– by mid-October 2020, 1.073.780 persons (official figures) died from the disease worldwide–and it has overwhelmed international and national health-care systems.

Most countries have succeeded in establishing a legal framework relating to biosafety and biosecurity in terms of laboratory management, but the practical application of emergency biosecurity measures is still lacking. This study will present the model of Morocco's laboratory biorisk-management experience.

In Morocco, the Covid-19 pandemic has resulted in 1 265 301 cases of infection as detected by the health authorities, and in 16 280 deaths until October 19, 2022.This critical situation requires the commitment of all the researchers concerned in order to take appropriate measures to control the pandemic.

Several measures relating to biosafety are part of the national strategy to control the coronavirus disease. However, ***biosecurity measures*** are lacking in this strategy. The resulting increased risk of accidental or deliberate infection and release of SARS-CoV-2, leads us to

put forward the issue of the appropriate measures against bioterrorism, dual use and responsible science. There is a similar situation prevailing in many other countries, and ***there is therefore a need to enhance biosecurity measures***.

This article reviews the existing Moroccan regulation relating to biosafety and biosecurity measures in healthcare in general and in the relevant laboratories. It also focuses on the strategy aimed at the preparedness and reaction against the spread of SARS-CoV-2, in relation with the management of the laboratories performing the test that detects the presence of the virus in patients. On the other hand, we have developed a conceptual framework for the implementation of a biorisk-management system in the laboratories handling pathogens.

Keywords: Biorisk management, biosafety, biosecurity, SARS-CoV-2, Covid-19, qRT PCR

1. INTRODUCTION

Since the detection of SARS-CoV-2 in China and the worldwide spread of the pandemic Covid-19, all countries are struggling to control the disease and are implementing their national plans. Morocco has developed its national monitoring system and reaction plan consisting of strengthening the measures aimed to slowdown or block the circulation of the virus; all skills have been mobilized in several key areas such as national security, health care, border-control services. In his context, when the first imported case occurred in Morocco, three laboratories were involved in the identification of SARS-CoV-2: the Virology laboratories of the National Hygiene Institute in Rabat, the Pasteur Institute in Casablanca and the Mohammed V Military Hospital in Rabat. As the number of infected cases was increasing and as it was necessary to provide a screening coverage on a national scale, several other laboratories across the country had to join forces. According to the health ministry's strategy, other regional laboratories have also been involved in this screening scheme under the supervision of the National Hygiene Institute. Laboratories performing the SARS-CoV-2 test as well as the handling of samples from patients at risk must comply with ***biosafety and biosecurity measures*** while assessing the biological risk to any exposure to the pathogen.

It is the responsibility of all laboratories that work with valuable biological material (VBM) and other valuable laboratory material (VLM) to ***operate safely and securely***. The first step in achieving this operational goal is to assess the safety and security risks present in the laboratory. This is important during both routine work and/or during unexpected conditions **[1]**. The design of a biorisk-management system in these laboratories will give a new vision of laboratory management, thus granting

security not only to the working staff but also to the whole population. There is still much to learn and understand about the Covid-19 and its impact in different contexts. Preparedness, readiness and implementation will continue to be driven by the rapidly accumulating scientific and public health-care knowledge **[2]**.

This article will describe, on the one hand, the national strategy aimed at controlling the spread of SARS CoV-2 and, on the other hand, it will highlight the lack of legislation regarding biosafety and biosecurity at the laboratory level.

2. Epidemiological situation and reactive strategies against Covid-19 in Morocco

Until August 6, 2020, according to the daily information supplied by the health ministry Epidemiology and Disease Control Directorate, a total of 29,644 cases of infected persons have been detected, using the qRT PCR test; 449persons passed away and 20,553have been cured. Since the announcement of the first positive case, the designed strategy against the pandemic has started from contact-case management **(Figure 1)**.

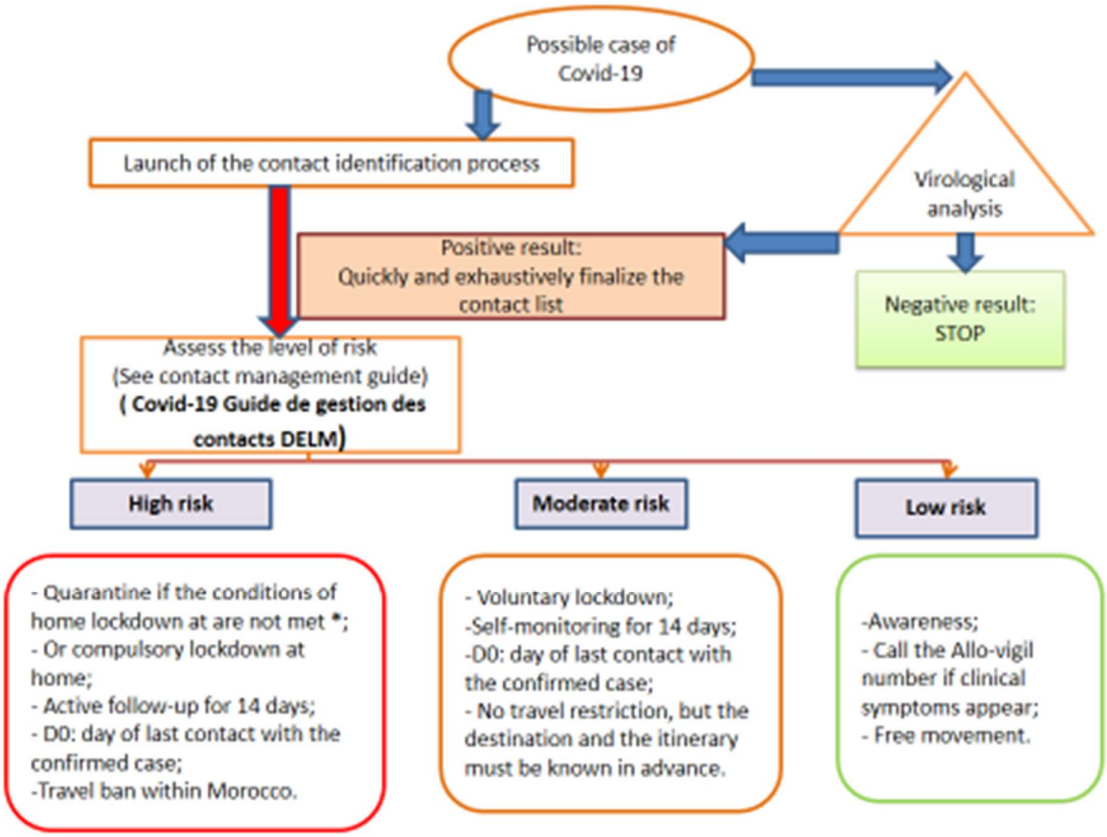

Figure 1: Contact-management algorithm [3]

The Moroccan state has mobilized all of its equipment to react to the coronavirus pandemic and to provide an efficient country wide protecting of its citizens **[4]**. In addition to the economic and social actions carried out to mitigate the impact of the spread of the virus, in terms of healthcare, there have been a strengthening of infrastructure and a supply of health products, including the provision to the laboratories of individual and collective protection equipment, while improving their level of lockdown.

In Morocco, there are four Biosafety-Level 3 laboratories (BSL3), one at the Pasteur Institute in Casablanca, two military laboratories and one at the Royal Gendarmerie in Rabat. Some laboratories are certified (i.e. they comply with specific requirements relating to the regulated standards of products, processes, systems or people; they are recognized by a certification body); others are accredited (their skills to carry out specific activities are recognized by an accreditation body such as AFNOR, COFRAC; they comply therefore with the ISO or other standards); or they are in the process of accreditation. The other laboratories are BSL2 or BSL1. The national network of Health Laboratories is in charge of: the diagnosis and screening of diseases, monitoring and prevention of communicable diseases, as well as of the emergence of pathogens; the contribution to epidemiological work; the awareness and training; the public-health research; and the development and fostering of collaborations and partnerships with other national and international laboratories. Regarding the skills development of laboratory staff, several training courses have been provided in the field of biosafety and biosecurity on the following topics: implementation of a biorisk-management system, risk-assessment tools, microbiological and chemical safety cabinets, transport of infectious material, biological and chemical waste management, planning and reactive strategy to a biological incident. However, these training courses are not taught to all laboratory staff.

Morocco's strategy aims to increase the country's capacity in terms of screening. To that end, the health ministry has provided appropriate training to several regional and provincial public laboratories as well as to university-hospitals' laboratories across the national territory. The objectives are to strengthen the national molecular-diagnostics of SARS-CoV-2 and to broaden the network of Covid-19 laboratories, as well as to include new laboratories from the public and private sector. The requirements for private laboratories to become part of the public-laboratory network have been clearly specified in the prerequisites regarding the implementation of diagnosis

of the coronavirus using qRT-PCR in a private medical –biology–analysis laboratory.

3. Laboratory biosafety measures

Laboratory biosafety includes the set of containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release **[1]**. Laboratories that do not have the biosafety level suitable for the diagnosis of Covid-19 have been supported through the National Hygiene Institute and funding from the health ministry, in terms of technical, hygiene equipment and security, on the one hand, and of improvement of the layout of technical rooms on the other. Some procedures have been developed especially during this pandemic period with regard to the disinfection of premises, equipment and laundry. The recommendations for cleaning and disinfecting medical-treatment areas and common areas are summarized in **Table 1**.

Table 1: Recommendations for cleaning and disinfecting medical-treatment areas and common areas [5]

Premises	Recommendations
Surfaces	- Cleaning with a neutral detergent - Disinfection with a virucidal disinfectant or 12 ° bleach (sodium hypochlorite) diluted to 1/6, or 70% ethanol
Toilets	Disinfection with a virucidal disinfectant or 12 ° bleach (sodium hypochlorite) diluted to 1/6
Laundry and fabrics	Hot cleaning at 60 ° C (at 90 ° C for heavily soiled laundry)with a neutral detergent
Medical equipment	Single use, otherwise disinfection with a virucidal disinfectant or with 12° bleach diluted to 1/6
Personal protective equipment	- Disposable gown, waterproof, long-sleeved - Surgical mask, to be replaced by an FFP2 mask if aerosol-generating treatments are performed - Glasses, gloves and boots
Waste from cleaning and disinfection	To be managed as "Medical Pharmaceutical Waste" of category 1 and 2

In the laboratories performing the test to identify of the coronavirus using the qRT-PCR technique, as major support was given for the technical equipment needed for the test and for some biosafety measures necessary for protecting the staff such as class-2 biosafety cabinets, appropriate and sufficient personal protective equipment, and autoclaves for waste decontamination.

4. Laboratory biosecurity measures

Laboratory biosecurity includes the set of measures aimed at the protection, control and accountability for valuable biological materials and protection of other valuable items (e.g. equipment) within laboratories, in order to prevent their loss, theft, misuse, diversion of, and/or unauthorized access or intentional unauthorized release **[1]**.

Biosecurity approach has still to do, to a large content, with the restriction of access and the affixing of surveillance cameras; there is therefore a lot of work and effort to make in order to strengthen this approach among laboratory staff, and scientific

researchers. ***The lack of regulations in this area*** is a high risk for new laboratories performing tests for the identification of pathogens. Fortunately, in some regulatory texts, certain security measures are specified, such as the destruction of positive pathogen specimens in the presence of a select committee comprising representatives of Civil-protection bodies, the General Directorate of National Security, home ministry and health ministry; the preparation of a report on this destruction, forwarded to the health ministry; and the secured transport of biological samples.

5. Risk analysis of SARS-CoV-2laboratorydiagnosis

In Morocco, the patients at risk are screened, using the nucleic-acid-amplification test qRT-PCR. The nursing staff is trained on the collection of samples (nasopharyngeal and oropharyngeal swab), the storage and transport requirements of the samples, defined as UN 3373 "Biological Substance Category B". Laboratory staff is also trained in the technical analysis and safety procedures. To conduct the risk analysis of SARS-CoV-2 testing is in the purview of each laboratory that performs it, because the facilities are not similar despite the use of the same testing method. Staff's perception and behaviour are also different, the conduct of work and overall organization are specific for each laboratory. In addition to the contacts with surfaces containing the virus for some time, the coronavirus is spread mainly through the close contacts between persons and the respiratory droplets produced when an infected person coughs or sneezes **[6]**. So risk assessment at laboratory level must be carried out with great care, from the collection of samples to their disposal. Should also be taken into account the characteristics of the virus, namely its mode of transmission, its infection dose and its environment stability **[7]**. It is also important to have in mind the location of the laboratory, in a hospital or in an isolated area, as well as the work flow, the separation of handling areas, the availability of safety equipment that can minimize aerosol production, the quantity of appropriate personal and collective protection equipment and standardized operating procedures. To sum up, the analysis of risk of contamination in the laboratory must deal first with the risk assessment, and then with the evaluation of the existing risk-mitigation means in order to be able to determine their criticality.

6. Requirements of biorisk management (standards and regulations)

The biorisk-management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the relevant biosafety and biosecurity risks **[8]**.

The biorisk management approach, includes biosafety, laboratory biosecurity and ethical responsibility. It should derive from an agreement between authorities, the public, and the scientific community, with a view to establishing trust and societal safety and security, while at the same time enabling the progress of science **[9]**. In Morocco, several regulations, directives or guidelines that aim to protect workers in the fields of health and safety, ***are not specifically addressing biorisk management***. Thus the Moroccan guide for the good implementation of analyzes **[10]** gives guidelines concerning the organization of laboratories in terms of quality; and in its last chapter, the health and safety section addresses the instructions for the protection against toxic products, waste management and restriction of access to the laboratories. ***This guide remains unsatisfactory regarding biological risks and biosecurity measures***.

A decree has determined the conditions of using substances or preparations which may affect employees' health or compromise their security, whatever is their chemical or biological origin **[11]**. The decree lays emphasis on biological risk-assessment in its 58th article, whish states that the employer shall determine the nature, duration and conditions of employee's exposure to any activity likely to involve a risk of exposure to biological agents. Also in article 59, the following preventive measures–when the exposure of employees to a dangerous biological agent cannot be avoided–are specified: 1. Limitation to the lowest possible level of the number of employees likely to be exposed. 2. Definition of the work processes and technical control or containment measures aimed at avoiding or minimizing the risk of dissemination of biological agents in the workplace. 3. Implementation of collective protection measures or individual ones, when exposure cannot be avoided by the previous measures. 4. Implementation of appropriate hygienic measures in order to reduce or, if possible, avoid the risk of dissemination of a biological agent outside the workplace. 5. Establishment of action plans that should be implemented when accidents involving pathogenic biological agents occur. 6. Detection, if technically feasible, of the presence, outside the containment area, of pathogenic biological agents, as well as of any breach in the lockdown. 7. Implementation of all safe means to treat–if necessary, after appropriate transformation– wastes (collection, storage, transport and disposal by the staff). These means include, in particular, the use of safe and identifiable containers. 8. Implementation of measures that allow, during laboratory work, the safe handling and transport of pathogenic biological agents. Waste management is

regulated by Moroccan Law 28/00 that gives the guidelines for the proper management of any waste category including hazardous waste. The 37th article of the law specifies the various producers of hazardous wastes and also the persons holding authorizations to treat these wastes. In articles 30 and 35 of the law, it is recommended to keep a register where are recorded the quantities, type, nature and origin of the hazardous waste produced, collected, stored, transported, recovered or disposed of; every year, the administration should receive information on all these measures implemented one year earlier **[12]**.

It should be mentioned that Morocco has signed in 1972 and ratified in 2004 the Convention on the prohibition of the development, production, storage and use of bacteriological (biological) or toxic weapons and their destruction. And following the publication of this convention, the relevant Moroccan legislation has been harmonized.

7. DISCUSSION AND CONCLUSION

Morocco is committed to international collaboration with the United Nations in the fight against terrorism and Chemical, Biological, Radiological and Nuclear (CBRN) risk reduction. It has signed and ratified all international conventions and treaties on the fight and reduction of CBRN risks and threats. It is also involved in the international health network and has been recently evaluated by the WHO. Despite the national existing regulations or guidelines relating to health and safety, ***there is nevertheless a significant lack of biosafety and biosecurity regulations at the level of the laboratory***. The cultural approach to biosafety and biosecurity has started a few years ago, thanks to the training of resource persons at the national level. But this approach to biological risk-management requires advocacy toward decision-makers in order to be properly implemented; it also needs communication between the different sectors. ***It is therefore necessary to develop a biorisk-management policy at national level***, as well as a well-structured action plan, including the development of specific biosafety and biosecurity regulations, thanks to national skills and resources on the one hand, and international cooperation on the other.

In particular and as indicated in the WHO guidelines regarding the implementation of biosafety-and-biosecurity requirements in biomedical laboratories **[13]**, the following seven-step plan should be adopted:

STEP 1: mobilize the national institutions and resources for the development and implementation of a national biosafety and biosecurity policy

STEP 2: conduct a national evaluation and surveys

STEP 3: establish the relevant national institutions and operational mechanisms and develop the best-fitting regulations

STEP 4: strengthen expertise for the implementation of an appropriate regulatory system

STEP 5: implement and enforce regulations

STEP 6: establish national information-exchange networks and international partnerships

STEP 7: review performance and adaptability to the national context and evolving risks.

It should be recognized that despite the work already carried out throughout the world regarding biosecurity legislation, there is still room for improvement with respect to its worldwide application and to the implementation of an efficient biorisk-management system.

Competing interests:

The authors declare that they have no competing interests.

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