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A SWIFT RISK ANALYSIS FOR COVID-19 TESTING FACILITIES USING RAPID TESTS

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Keywords: *biosafety, risk assessment, SWIFT, SARS-CoV-2, COVID-19, POCT, rapid tests.*

Introduction. *COVID-19 is an infectious disease of International Concern, due to the widespread geographic impact and high transmissibility, causing severe illnesses. Many testing facilities were set-up for monitoring the spread of the SARS-CoV-2 virus, at the early days of the coronavirus pandemic. From Biosafety aspect this study investigates a reliable risk assessment method to identify and mitigate the risks of COVID-19 testing facilities using Rapid diagnostic tests (POCT), in order to protect the staff, the people who got tested, the community and the environment.*

Material and methods. *Many techniques have been used so far for performing a risk assessment. In the present study, SWIFT analysis suitable for biosafety facilities and for risks of different magnitude, was used for identifying threats and hazards and to calculate the risks for COVID-19 testing facilities.* ***Results.*** *Our analysis showed several initial and potential risks, which could lead to unwanted exposure or release of the SARS-CoV-2, and/or unwanted infection of staff and patients. With minor adjustments of the testing facility, by creating standard operating procedures and awareness of the potential risks, most of the identified risks could be mitigated.*

Conclusions*. Our study demonstrated that when setting up a COVID-19 testing facility, a proper risk assessment should be part of the process, in order to ensure the safety of staff, patients, and the environment. Additionally, we proposed a number of multiple mitigation measures and recommendations, with the goal to reduce the risks during the rapid testing diagnostic procedure.*

Cuvinte cheie: *biosecuritate, evaluarea riscurilor, SWIFT, SARS-CoV-2, COVID-19, POCT, teste rapide.*

ANALIZA RISCURILOR SWIFT PENTRU INSTALAȚIILE DE TESTARE COVID-19 CU UTILIZAREA TESTELOR RAPIDE

Introducere. *COVID-19 este o boală infecțioasă cu un impact geografic larg răspândit și transmisibilitate ridicată, care poate provoacă boli grave. Încă de la debutul pandemiei de COVID-19 au fost înființate multe stații de testare pentru monitorizarea răspândirii virusului SARS-CoV-2. Din punct de vedere al biosecurității acest studiu investighează o metodă de evaluare a riscurilor în vederea identificării și atenuării riscurilor stațiilor de testare COVID-19, care utilizează teste de diagnosticare rapidă (POCT) pentru a proteja personalul, pacienții, comunitatea și mediul.*

Material și metode. *În prezentul studiu au fost aplicate diferite tehnici pentru realizarea unei evaluări a riscurilor. A fost utilizată analiza SWIFT pentru instalațiile de biosecuritate și pentru riscuri de diferită amploare pentru identificarea amenințărilor și pericolelor, și pentru a calcula riscurile pentru stațiile de testare COVID-19.* ***Rezultate.*** *Analiza noastră a identificat mai multe riscuri inițiale și potențiale, care ar putea duce la expunerea sau eliberarea nedorită a SARS-CoV-2 și/sau la infectarea nedorită a personalului și a pacienților. Cu ajustări minore ale stațiilor de testare, prin crearea de proceduri standard de operare și conștientizarea riscurilor potențiale, majoritatea riscurilor identificate ar putea fi atenuate.*

Concluzii. *Prezentul studiu a demonstrat că atunci când se înființează o unitate de testare COVID-19, o evaluare adecvată a riscurilor ar trebui să facă parte din proces pentru a asigura siguranța personalului, a pacienților și a mediului. În plus, am propus o serie de măsuri și recomandări multiple de atenuare cu scopul de a reduce riscurile în timpul procedurii de diagnosticare a testării rapide.*

INTRODUCTION

Emerging and re-emerging infectious diseases represent a substantial threat to public health and should be considered as a high-risk situation for humans, animals and the environment. In 2020 coronavirus disease (COVID-19) was first identified in the city of Wuhan, Hubei, China. COVID-19 is an infectious disease caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (1), which is a newly discovered β-coronavirus, with an enveloped positive-sense single-stranded RNA 30 kilobase genome and it is highly pathogenic (2). Then on 30 January 2020 the World Health Organization (WHO) designated this outbreak as a Public Health Emergency of International Concern and on 11 March 2020 a pandemic, due to its widespread geographic impact, affecting a large proportion of the world's population (3, 4) and its high transmissibility, multiple mutations and severe illnesses.

COVID-19 is spread from human to human by breathing in droplets that contain the SARS-CoV-2 virus (e.g. from the nose or/and the mouth, and when an infected person usually coughs or strongly exhales), or from a direct contact of droplets by touching contaminated surfaces and then touching eyes, nose, or mouth (5), or during specific laboratory procedures that could produce aerosols, droplets and splashes. The infection has been estimated to have a mean incubation period of 6.4 days, ranging from 2.1 to 11.1 days and the virus can survive for up to 72 hours or more out of the body on various surfaces (6, 7), depending on temperature, humidity and viral load. Its infectious dose is under investigation.

To contain COVID-19, it has become vital to quickly discover and isolate cases. In order to fulfil the growing need for diagnostic services, many kinds of testing facilities were set-up for monitoring the spread of the virus during the early days of the COVID-19 pandemic. The facilities were located in hospitals, health centres, but also in non-healthcare facilities. From Biosafety aspect, the main question for most of them is, whether during the analytical procedures, the staff, the people who got tested, the community and the environment are protected.

Therefore, in the present study a Structured What-if Technique (SWIFT), was used for identifying, evaluating and mitigating the possible risks, with the goal to provide a set of recommendations, aligned with national and international guidelines, which could help minimize the risks while working in these testing facilities.

Risks and Risk Assessment

Risk is an inescapable aspect of everyday life, and every complex program is no exception (8). "Risk is a combination of the likelihood of an incident occurring and the severity of the consequences (harm) if that incident were to occur" (9).

Organizations of all types and sizes face a variety of hazards that may jeopardize their ability to achieve their goals, and therefore these risks must be managed. Risk management is a continuous process for the detection, review, evaluation and monitoring of risk control, and financial resources to minimize various effects of losses (10).

To control related risks when handling biological agents, toxins and materials in the laboratories and facilities, a Biorisk management system is needed. Risk assessment is the fundamental process of the Laboratory Biorisk Management system and help to determine and mitigate laboratory risks to an acceptable or manageable level. According to ISO 31010 Risk assessment attempts to answer what can happen and why, the consequences, the probability and the factors that reduce the probability of the risk (11).

An approach for managing biological risks and preventing Laboratory Acquired Infections (LAIs) is the hierarchy of controls, which indicates that when facing hazards there is an optimal order to minimize the risks and ensure that staff is safe. This approach has the following 5 steps (fig. 1) to manage risks (12):

1. Elimination (Not performing the tests)
2. Substitution (Replacing the organism by a less harmful one).
3. Engineering controls (Facility design, ventilation, containment, equipment).
4. Administrative controls (Standard Operating Procedures, Good Microbiological Practices).
5. Personal Protective Equipment (PPE: Gloves, face masks, goggles, laboratory coats).

In a laboratory the mitigation of risks is mainly to prevent laboratory acquired infections (LAIs) when biological materials are used. It is therefore necessary for laboratories to identify and control these risks, in order to avoid LAIs, diseases and to protect the laboratory staff and thereby the community from biological agents and possible harmful patient samples, and also to improve the overall safety and quality within the laboratory setting.

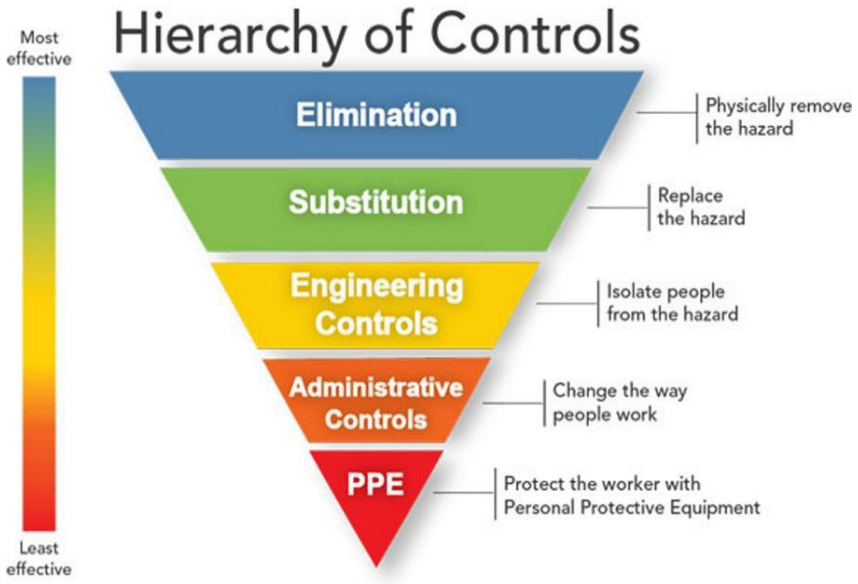

Figure 1. Hierarchy of controls (Centers for Disease Control and Prevention, 2015) (12).

For mitigating risks for staff of the COVID-19 testing facility a similar approach could be used. The mitigation measures start at the engineering controls. Elimination and substitution are not suitable for this, due to obvious reason, it is need to test for the disease.

Risk assessment techniques

There are numerous different techniques for performing a risk assessment, such as: Hazard and Operability Studies (HAZOP), The Structured What-if Technique (SWIFT) and Failure Mode and Effects Analysis (FMEA). FMEA is often used in the pharmaceutical industry, while SWIFT is mainly used in biosafety facilities and HAZOP is used for individual equipment. All of the mentioned techniques result in a qualitative and not quantitative risk.

SWIFT is a risk-identification technique that makes use of structured brainstorming, facilitates discussions by utilizing pre-created guidewords and headings (e.g., timing, amount, etc.) in conjunction with participant-generated prompts (which frequently begin with the phrases "What if..." or "How could..."), to examine risks and hazards at the system or subsystem level (13). SWIFT is a high-level Process Hazard Analysis (PHA) technique that assist the team in examining alternative scenarios, their associated consequences, causes and effects. It distinguishes from the hazard operability studies (HAZOP) method, which is similar but identifies hazards through a thorough examination of low-level processes, subcomponents of equipment (14).

For our study we have used the SWIFT method, because it is usually faster than the HAZOP method due to its emphasis on high-level processes and can be completed in less than a third of the time required for a HAZOP-based approach, which is a significant benefit (14, 15).

The *purpose of the research* is to show that the SWIFT risk assessment method is an easy-to-use method, to identify and mitigate the risks of COVID-19 testing facilities using Rapid diagnostic tests (POCT), in order to protect the staff, the people who got tested, the community and the environment.

MATERIAL AND METHODS

Description of the testing facility

For the SWIFT risk assessment, a fictitious COVID-19 testing facility that used on many locations has been evaluated. The facility had the fol-

lowing layout and design, depicted in Figure 2. In the lay-out the various movements of people, testing material (clean and contaminated) and waste are depicted.

COVID-19 rapid test

Rapid detection of SARS-CoV-2 is critical for limiting the transmission of COVID-19 in the community. Although reverse transcriptase polymerase chain reaction (RT-PCR) is the gold standard for COVID-19 diagnosis (16), RT-PCR assays require specific instruments and expertise, while many countries may face a lack of RT-PCR reagents. In contrast point-of-care testing (POCT, diagnostic tests performed at or near the site of specimen collection), is simple to execute and to interpret without the use of specialized equipment, is less expensive, significantly reduce the turnaround times (17), and could provide testing to communities and groups that are underserved, thus enabling rapid response to emerging outbreaks (18).

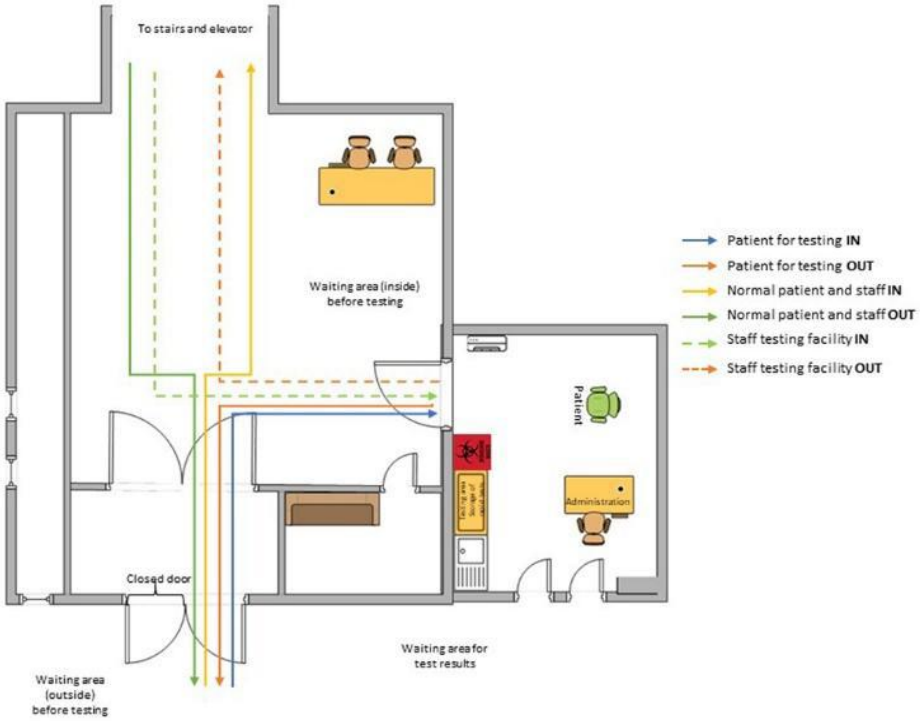

Figure 2. Testing facility design.

Rapid tests used in the testing facilities do have similar procedures and as an example, for monitoring the spread of COVID-19 we have used the Panbio™ COVID-19 Ag Rapid Test (fig. 3), from Abbott Diagnostic GmbH, Germany. It is an in vitro diagnostic indirect flow immune-chromatographic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal specimens. The test line on the strip is coated with specific antibodies to SARS-CoV-2 and once the virus is captured, conjugate antibody can react with antigen on the surface of SARS-CoV-2 that has been captured and produces a visible line in the test line area. The test is intended to assist in the diagnosis of SARS-CoV-2 infection in persons who fulfil the COVID-19 clinical and/or epidemiological criteria (19).

For running the test steps involve collection of a specimen by a swab from the potentially infected individual's nasal cavity (step 2 in fig. 3), swirling the specimen in an open tube with a liquid buffer. Then the swab tip should be mixed with the buffer fluid inside the extraction tube, pushing it into the tube's wall at least five times, and squeeze out the swab with the fingers (step 3 in fig. 3) (20). It has been known that the buffer supplied in the rapid test does not inactivate the virus (21), thus all these handlings during the rapid test procedure raise the probability of an aerosol formation containing SARS-CoV-2, thereby posing the risk of exposure for the staff and for contamination of surfaces in the testing facility.

According to international guidelines, procedures with high likelihood to generate aerosols or droplets should be performed in a primary containment device such as a well maintained and validated BSC or using additional precautionary measures to provide a barrier between the specimen and health care professionals (22).

For POCT testing that is conducted outside of a clinical laboratory, biological safety cabinets are not available. Therefore, a risk assessment should be contacted, with the consideration on how the rapid test procedure could be safely performed outside a biosafety cabinet (22), using the standard precautionary measures for biosafety protection in the lab. The manufacturer of the rapid test and CDC also advise a risk assessment (23, 24).

We have used the SWIFT method as a risk as sessment method, because this method is best suited, where the risks are of different magnitude. A list of what-if questions with the potential hazard were prepared by the authors, based on the above described facility (Appendix I), but also on working procedures and the features of the rapid test itself. During the discussions in the execution of the SWIFT analysis, the consequence of the potential hazard, the mitigation measures that were already in place and the available SOPs, were scored using the tables for likelihood and severity of the hazard, giving the initial risk. This initial risk was then used for determining the significance of the risk and if additional mitigation measures were needed. The complete overview, advantages and stages of the SWIFT technique can be found in Appendixes I, II and III.

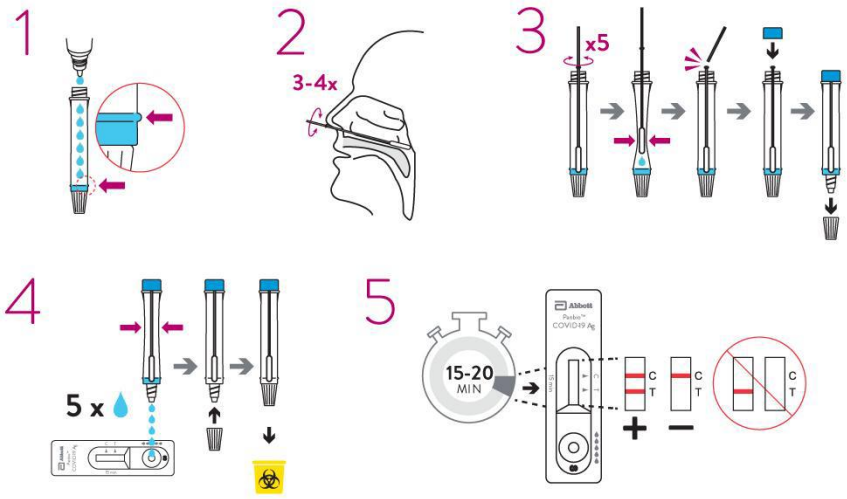

Figure 3. Panbio™ COVID-19 Ag Rapid Test (ABBOTT Product Sheet).

RESULTS

During that SWIFT risk assessment several initial and potential risks were identified, where the original lay-out of the testing facility and the mitigation measures were not sufficient to reduce risk for staff, the people who were tested, or the general public not involved in the COVID-19 testing. These were:

1. Flow of patients and staff
2. No proper ventilation in the waiting area and testing room
3. No PPEs are worn when entering the testing room by staff
4. No proper decontamination of horizontal surfaces
5. No separation between clean material and the testing area
6. Not safe handling of Waste
7. Lack of SOPs for important procedures

All identified potential risks could lead to unwanted exposure or release of the SARS-CoV-2, and/or unwanted infection of staff and patients of the health center in which we positioned the fictious, but very common testing location. With minor adjustments of the testing facility, by creating standard operating procedures and awareness of the potential risks among the staff, most of the identified risks could be mitigated:

1. As shown in figure 2 the flow of patients that enter the health center and the patients that are going to the testing facility are not separate. They use the same door for entering in or exiting the facility. Furthermore, the flow of health center staff crosses that of patients going to the testing center. The risk of these crossing flows is that the patients going to the testing facility are coming within 1.5 m of staff and patients that come to the health center for different reasons than testing. This may lead to infection of staff or these patients, although all people entering the health center are requested to wear a surgical mask, so transfer of the virus is then considered low. However, it is better to separate flows from patients going to the testing facility from other flows. Even when face masks are worn, they could be not of the right specifications or may not worn properly, increasing the risk of transferring infections.

   Recommendation
   To mitigate this potential risk, it is advised to separate the different flows of people. This can be achieved by creating a separated entrance AND exit for patients entering the health center and patients going to the testing facility. Alternatively, both doors of the entrance should be open and a barrier in the middle of the wider entrance could be placed. One lane can be used by patients going to the testing facility (right lane) and the left lane by other patients of the health center. Additionally, there should be a check on the facial mask and how it is worn before people enter the health center, thus it should cover both mouth AND nose.

2. People that go to the testing facility or come from the testing facility have to wait to be tested or for the result of the test. This waiting can be inside or outside. When waiting inside the people will block the entrance of the testing facility and staff and new people for testing will have to go past the waiting people. This is not acceptable, although everybody wears a face mask. Furthermore, in the waiting area there is hardly any ventilation. As it is known, a proper ventilation can prevent the transfer of SARS-CoV-2 between people in the same space. Also, social distancing will become an issue in a small space, because the flow of regular patients into the health center should not be blocked, leaving only a small area as a waiting area for the testing facility.

   Recommendation
   It is recommended to let people wait outside the health center, for several reasons. There is no blockage of the flow of patients and staff, ventilation outside is not an issue and social distancing can be practiced easily. The prerequisite is that people do not block the entrance of the health center and wait aside the entrance at least 1.5 m distance of the normal people flow into and out the health center.

   If people are waiting outside the building, they should not wait in front of the open windows of the facility. Also, a certain distance should be kept, so that people can come to the open window to hear the result, without crossing with other people who are waiting.

3. Staff that enter the testing room are not always wearing the proper PPE, such as a FFP2 respiratory protection. They enter during a shift change, to collect samples or to ask for the result of a test. As already described above, the risk of creating aerosols during testing is significant. Because of this entering without the proper respiratory protection can be a risk.

   Recommendation
   To mitigate this risk, it is recommended to put on PPE, especially respiratory protection, before entering the testing room, but also before crossing patient flows that are going to the testing facility. A separate space should be created where staff that going to take samples and perform the tests can don the PPE. This should be in the vicinity of the testing room. Other staff should always wear an FFP2 before going to the facility. A face shield can be put on in the facility itself and that is only mandatory for staff taking the swap and performing the test. The preferred option is that only staff involved in the testing is allowed in the room and others are not. This reduces traffic and opening the door of a potentially contaminated room.

4. During testing aerosols and small droplets will be generated. As already described above PPE should be worn when in the testing room. These aerosols and small droplets will finally settle on horizontal surfaces, making them a possible secondary source of infection when are touched and no proper hygiene practices are followed. To minimize the risk of spreading SARS-CoV-2 via the surfaces, a regular disinfection of the room should be performed. Also cleaning and disinfecting of some surfaces in between patients is necessary, such as surfaces patients can touch, the chair while seating and standing up. During the SWIFT analysis it became clear that there was no SOPs for the cleaning and disinfection of the testing room.

   Recommendations
   Some areas of the testing facility must be disinfected in between patients, such as the chairs. A complete cleaning and disinfection of the entire room must be performed at least once a day. To organize this, an SOP should be written and put in place. A staff member should be made responsible for the cleaning, disinfecting and oversee this. Furthermore, there should be a proper instruction and training of the cleaners.
   It is also recommended to disinfect the working area with an appropriate disinfectant following each batch of testing. Also, this disinfection step must be described in an SOP and a staff member should be made responsible for this.

5. Another issue found during the SWIFT risk assessment was that there is no clear separation between the clean materials in the room and the space where the rapid test is executed. Risk is that the clean material can get unwantedly contaminated. If these "clean" materials will be used or leave the room at the end of the day, they are not treated as potentially contaminated and are handled as no risk material, this could lead to unwanted exposure of staff.

   Recommendation
   It is recommended to separate dirty electronical devises (e.g. phones, computer keyboards, paper) that may be touched with gloved hands, from those that are clean and can be touched without wearing gloves. Alternatively, all objects in the room must be treated as potentially infectious and be cleaned and disinfected on a daily basis, in the same procedure with all parts of the room. Keep in mind that using potentially contaminated phones the source of an infection is brought to the face, which is a potential cause of transferring an infection. It is better not to use phones within the testing facility, at all.
   It is also advised to make a clear separation between clean material, such as clean PPE and unused rapid tests and the area where the test are performed. This can be solved using separate tables or a plexiglass screen between the clean and dirty areas.

6. All the waste that is created in the testing procedure should be treated as potentially infectious. All specimens, used tubes with the dispensing nozzle closed, used tests, and other possibly contaminated materials should be disposed of in a proper biohazardous waste container. During the SWIFT assessment it was observed that disposing these materials in the testing room was correct. However, the biohazardous waste bags could sometimes be transported out of the testing room not properly closed and without using gloves. The biohazardous waste bag was not disinfected before leaving the room and therefore potentially contaminated on the outside surface. Touching it with bare hands can be a source of transmission of SARS-CoV-2 from the bag to the staff, if they are not aware of this. When an unproperly closed bag is transported from the testing room to the waste collection area, poses a risk of spreading when the bag drops and material falls out. This might pose a larger risk, if the location of the incident is not properly treated and disinfected.

   Recommendation
   It is recommended to make an SOP that addresses all the above findings for waste handling. Furthermore, people who handle the waste should be properly trained and someone from staff should be made responsible for the waste management in the health center. Improper waste handling in the health center can also pose a risk for the staff of the company who collect the

waste from the health center, if the bags are not disinfected and/or not properly closed. Unwanted exposure can occur of the staff of the waste handler involved.

7. It is clear from the above, that one of the main findings of the SWIFT assessment, is the lack of SOPs for important processes of the testing facility, which are important for safety of the staff, patients and the environment.

   Recommendations
   It is recommended to write an SOP containing all procedures that have to be performed in the testing facility. The following subjects must be incorporated in this SOP:

   - The testing procedure as described by the manufacturer of the rapid test (include biosafety and quality issues of the test)
   - Standard precautionary measures
   - Donning and Doffing of PPEs while entering and exiting the testing room
   - Regular Cleaning and disinfection of the testing room and of the objects inside
   - Cleaning and disinfection of a spill of infectious biological materials
   - Collecting and handling of biohazardous waste

DISCUSSIONS

Our goal was to show that the SWIFT technique can be easily applied on small facilities such as a CoVID-19 testing facilities in which POCT tests are performed. Using the SWIFT technique we identified 7 points of improvement to increase the safety for staff, patients and the environment. Our study also shows that with some minor adjustments these identified risks could be easily mitigated and that the recommendations lead to a reduction of the hazards identified. Furthermore our study shows that it is very important to have SOPs in place and provide training. Having SOPs and train the procedures described in the SOPs, also greatly reduces the risks of this COVID testing facility. This is not only a recommendation for the investigated testing facility, but for every diagnostic lab in general.
Finally having SOPs and perform training, besides the reduction of the risks, the quality of the tests will improve.

CONCLUSIONS

Our study showed that when setting up a testing facility, a proper risk assessment should be part of the process and that with introducing of some extra mitigation measures and procedures, the testing facility could be safe for all categories of people involved in the process of such a facility. We recommend performing the following steps before starting an operation of the facility, so it becomes a safe environment for staff, additional staff members and the patients:

1. **Conduct a local risk assessment.** Identify and mitigate potential risks to an acceptable level. This will also help in a proper design of the facility, including flow of patients, staff etc., but will also clarify any occupational health issues of the testing procedure.
2. **Follow Standard Precautionary measures.** These standard measures include: hand hygiene and the use of the proper Personal protective equipment (PPE), cleaning, disinfection, good microbiological practices and proper waste management.
3. **Training.** Train all staff involved in the processes within the testing facility, in the procedures described in the internal SOPs. Also, people should be trained in the emergency/incident response plan of the facility.
4. **Carefully dispose of biohazard waste.** A waste management procedure should be included in the SOP, together with training procedures for spills.
5. **Regularly clean and disinfect.** Utilize an approved disinfectant according to the manufacturer's guidelines, which include adequate dilution, contact time, and safe handling.
6. **POCT should take place in a secure area.** Also, the use of plexiglass barriers and face shields can really help minimize splashes and exposure to droplets and aerosols.
7. **Quality.** Follow all of the manufacturer's instructions for performing the test in the exact order specified. Train staff in performing the rapid test, including proper sample storage and handling.

Beside biosafety issues, also issues with the quality of the testing procedures are crucial and must be taking into account, when training and creating awareness of all staff members. Quality and biosafety are interrelated subjects, therefore these quality issues can be incorporated into the training of the biosafety issues of the testing facility, because some are closely related.

We recommend performing a PDCA cycle to identify risks in diagnostic laboratories and to reduce the risks for the workers, but also to improve the quality of the diagnostic testing in these laboratories.

CONFLICT OF INTERESTS

All authors declare that they have no conflicts of interest.

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There is no financial interest to report.

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Appendix I

SWIFT analysis of CoVID-19 Testing unit

Risk description					Initial assessment			Implement risk extra control measures			
Ref. no.	Activity / Operation	Potential Hazard	Consequence	Control measures already in place	Likelihood	Severity	Initial risk	Proposed Mitigation measures	Likelihood	Severity	Residual risk
A1	Waiting room	Not enough space for social distancing	Unwanted close contacts with possible CoVID-19 patients	Patients wait outside. People wear face masks	2	2	4				
A2	Waiting room	Patients wear a face mask not properly	Unwanted exposure risks by possible CoVID-19 patients	Oversight on wearing mask and if it worn properly. Patients are requested to wait outside the building	2	2	4				
A3	Waiting room	Not enough space to hang coats	Coats will mix and can transfer SARS-COV-2 from possible CoVID-19 patients	Coats are worn the whole time. No need of coats storage	1	1	1				
A4	Waiting room	Personnel has to go through the waiting room to the test unit	Unwanted contacts with possible CoVID-19 patients by the personnel not wearing PPE	Oversight on wearing mask and if it worn properly. Patients are requested to wait outside the building	2	5	10	Personnel only enter waiting room wearing proper PPE	1	5	5
A5	Waiting room	Ventilation is insufficient in the waiting room	Build-up of virus in the waiting room. More possibilities for transfer of the virus	Patients are requested to wait outside the building	10	2	20	Front door and other doors/windows should be opened during working hours to increase ventilation	1	5	5
A6	Waiting room	Chairs in the waiting room would not disinfected regularly	CoVID-19 can survive for longer periods of time on surfaces. Unwanted exposure risks and release into the environment	No chairs needed. Patients are requested to wait outside the building	1	5	5				
Ref. no.	Activity / Operation	Potential Hazard	Consequence	Control measures already in place	Likelihood	Severity	Initial risk	Proposed Mitigation measures	Likelihood	Severity	Residual risk
B1	Entering the unit	No PPE are worn by the personnel	Contamination risk of the personnel	PPE are in the room and the personnel is dressed up in the room	10	5	50	Don your PPE outside the testing room. Or only don in a clean room	1	5	5
B2	Entering the unit	No proper PPE are worn by the personnel	Contamination risk of the personnel	FFP2 mask are not available or there is not a proper education to properly wear them	10	5	50	Create awareness and education on the use of PPE and provide only FFP2 masks	1	5	5
B3	Entering the unit	Unit is entered by unauthorized personnel	Contamination risk of people and personnel		6	5	30	Signs and SOP for only authorised personnel and patients to enter the unit	2	5	5
B4	Entering the unit	Unit is entered when swaps are taken from patient	Possible risk of spreading outside the unit	Door is not locked and there are no signs on it	6	5	30	Put a sign on the door. Make people aware of the risk entering without PPE	2	5	10
B5	Entering the unit	Unit is entered when handlings with patient material are performed	Possible risk of spreading outside the unit	Door is not locked and there are no signs on it	6	5	30	Put a sign on the door. Make people aware of the risk entering without PPE	2	5	10
B6	Entering the unit	Patient can spread SARS-CoV-2 within the testing unit	The testing unit can become contaminated at places that are not properly cleaned and disinfected	There is oversight on wearing a mask and if its worn properly. There is a strict flow of patients inside the testing unit and personnel is wearing PPE	10	1	10	Potential risk can be lowered by regular cleaning and disinfection	2	1	2

Ref. no.	Activity/Operation	Potential Hazard	Consequence	Control measures already in place	Likelihood	Severity	Initial risk	Proposed Mitigation measures	Likelihood	Severity	Residual risk
C1	Layout of the room	Flooring is not intact or damaged	No proper decontamination is possible. Unwanted contact and spreading possible. Possible release into the environment	Flooring is not intact	10	5	50	Make an SOP to indicate the damaged spots of the flooring and give extra attention on the spots. Training to the cleaning personnel	3	5	15
C2	Layout of the room	Floor is not cleared before decontamination	No proper decontamination is possible. Unwanted contact and spreading possible. Possible release into the environment	Flooring cannot be disinfected completely	10	5	50	Make an SOP to clear the floor from objects before cleaning	3	5	15
C3	Layout of the room	Surfaces cannot be decontaminated (for example the chairs)	No proper decontamination is possible. Unwanted contact and spreading possible	People could come in contact with contaminated surfaces	10	2	20	Change the chair for plastic or metallic. Or a Paper covering that is replaced after each patient. Hand hygiene of patients before they leave	1	5	5
C4	Layout of the room	Surfaces are not resistant to disinfectants	Damage to surfaces could cause no proper decontamination. Unwanted contact and spreading possible	The surfaces are not damaged	1	3	3	Extra advice: Check SOP for details on cleaning and disinfection			
C5	Layout of the room	There is no separated IN and OUT in the room	Crossing lines of people and personnel. Unwanted contact and spreading possible	People will wear PPE and wait outside	10	2	20	Make separate flows for incoming and outgoing people (social distancing)	2	2	4
C6	Layout of the room	Mechanical ventilation is insufficient in the room	Build-up of virus in the waiting room. More possibilities for transfer of the virus	No ventilation	10	2	20	Look for possibilities to use the windows for ventilation. Waiting peoples outside should be at a distance from the window	2	2	4
C7	Layout of the room	Separation between clean and dirty is not possible in the room	Clean material can be contaminated by the dirty material. Unwanted contact and spreading possible. Possible release into the environment		10	4	40	Create zones and SOPs to prevent cross contamination	3	5	15

Ref. no.	Activity/Operation	Potential Hazard	Consequence	Control measures already in place	Likelihood	Severity	Initial risk	Proposed Mitigation measures	Likelihood	Severity	Residual risk
D1	Working in the unit	Door is opened when a procedure is taking place	Possible risk of spreading outside the unit	This is possible: Door is not locked and there is no sign on the door	6	5	30	Put a sign on the door. Make people aware of the risk entering without PPE	2	5	10
D2	Working in the unit	No disposables in the room	Unwanted extra traffic from an to the room. Unwanted spreading outside the room possible	Never happens	6	1	6	Make SOP for asking to supply materials	1	1	1
D3	Working in the unit	Move reagents between different floors after testing	Unwanted extra traffic of material from the unit. Unwanted spreading outside the room possible	Spreading SARS-CoV-2 via the sample kit	6	5	30	Decontaminated kit before transport or leave the kit in the testing room	1	5	5
D4	Working in the unit	No biological waste container in the room	Waste can't be properly stored. Unwanted spreading in and/or outside the room possible	Yellow needle containers for waste remain in the unit till disposed of in Red box for incineration. PPE are disposed of directly in a Red box	6	1	6	Create awareness and perform trainings. Create an SOP	1	1	1
D5	Working in the unit	Contaminated waste is not collected as biohazardous waste	Unwanted spreading in and/or outside the room possible. Possible release into the environment	Never happens	3	5	15				
D6	Working in the unit	Potentially contaminated waste is not defined in the SOP	Possible wrongly disposed biohazardous materials. Unwanted spreading in and/or outside the room possible. Possible release into the environment	There is no SOP for the unit, but there is a law that has to be followed	3	5	15	Create awareness for waste collection. Training is needed. Create a SOP	1	1	1
D7	Working in the unit	Small spill of medium with swap or aerosol formation	Unwanted spreading in and/or outside the room possible	PPE is worn by the personnel. No spill kit or SOP for disinfection	6	5	30	Create awareness. Training is needed. Create a SOP for disinfection. Separate the various areas	2	5	10
D8	Working in the unit	No spill kit in the room	Unwanted extra traffic from an to the room	No spill kit available. No SOP for distinction after spill	6	5	30	Prepare an spill kit and a disinfection SOP	2	5	10
D9	Working in the unit	Aerosol are formed during washing swap	Risk for the personnel. Unwanted spreading in and/or outside the room possible	PPE is worn by the personnel. No spill SOP for disinfection	6	5	30	Create awareness. Training is needed. Create a SOP for disinfection. Separate the various areas	2	5	10
D10	Working in the unit	Patient sneezes during procedure	Risk for the personnel. Unwanted spreading in and/or outside the room possible	PPE is worn by the personnel. No SOP for disinfection	6	5	30	Create awareness. Training is needed. Create a SOP for disinfection. Separate the various areas	2	5	10
D11	Working in the unit	A glove is thorn during the procedure	Risk for the personnel. Unwanted contamination of personnel possible	Gloves will be replaced. No SOP for this	1	2	2				
D12	Working in the unit	FFP2 masks flips of face	Risk for the personnel. Unwanted contamination of personnel possible	FFP2 masks are worn. No fit test performed. Event probably	4	5	20	Perform fittest. Try to purchase better quality of masks. Reserve better quality masks for the unit	2	5	10
D13	Working in the unit	FFP2 mask doesn't fit properly	Risk for the personnel. Unwanted contamination of personnel possible	FFP2 masks are worn. No fit test performed. Event probably	4	5	20	Perform fittest. Try to purchase better quality of masks. Reserve better quality masks for the unit	2	5	10
D14	Working in the unit	Tubes are not properly marked	Mixen-up clean and potential hazardous material. Quality issue		2	5	10	Mixen up samples is possible. Make SOP for marking	1	1	1
D15	Working in the unit	Final cleaning is performed by house keeping	House keeping personnel can be exposed to biohazardous materials	No mitigation methods	10	5	50	Create awareness. Training is needed. Create a SOP	2	5	10

Ref. no.	Activity/Operation	Potential Hazard	Consequence	Control measures already in place	Likelihood	Severity	Initial risk	Proposed Mitigation measures	Likelihood	Severity	Residual risk
E1	Exiting the unit	PPE cannot be doffed in a separate room	Personnel must doff in the CoVID-19 unit. Risk for contamination of personnel during doffing	No specific SOP for this present. General pictures from donning and doffing in the room	10	5	50	Create awareness. Training is needed. Create a SOP	2	5	10
E2	Exiting the unit	Personnel forgot to doff the PPE	Unwanted spreading outside the room possible. Possible release into environment		3	5	15	Create awareness. Training is needed. Create a SOP	2	5	10
E3	Exiting the unit	Waste container is not closed when exporting from the unit	Unwanted spreading outside the room		5	5	25	Create waste SOP. Only transport closed boxes	2	5	10
E4	Exiting the unit	Not properly closed waste container falls in public area and waste spills out	Unwanted spreading outside the room		6	5	30	Create waste SOP. Only transport closed boxes	2	5	10
E5	Exiting the unit	Waste container is not disinfected before exporting	Unwanted spreading outside the room. Risk for waste transporter	Boxes are transported with gloves on. Transporting company staff should also wear gloves. No SOP for mandatory gloves for transporting	5	5	25	Create waste SOP. Only transport boxes with gloves on. Or disinfect by spray and wipe (best option)	2	5	10
E6	Exiting the unit	Sample tubes are not tightly closed and/or decontaminated before exporting	Risk of a spill and unwanted spreading outside the room	Test is performed in the unit itself. No transport of used tubes	1	5	5				

Likelihood

Score	Classification	Probability	Frequency	Examples		
10	Very high	>10%	Many times per shift	Contamination of a patient	Contamination of personel	Risk for qualty issues
9	Very high	<10%	Many times per day	Contamination of a patient	Contamination of personel	Risk for qualty issues
8	High	<5%	Many times per week	Contamination of a patient	Contamination of personel	Risk for qualty issues
7	High	<2%	Few times per week	Contamination of a patient	Contamination of personel	Risk for qualty issues
6	Moderate	<1%	Once per week	Contamination of a patient	Contamination of personel	Risk for qualty issues
5	Moderate	<0.50%	Few per month	Contamination of a patient	Contamination of personel	Risk for qualty issues
4	Moderate	<0.25%	Few per quarter	Contamination of a patient	Contamination of personel	Risk for qualty issues
3	Low	<0.10%	Once per month	Contamination of a patient	Contamination of personel	Risk for qualty issues
2	Very low	<0.010%	One per quarter	Contamination of a patient	Contamination of personel	Risk for qualty issues
1	Remote	<0.001%	Onze per semester	Contamination of a patient	Contamination of personel	Risk for qualty issues

Severity

10	Catastrofic			Death of patient	Death of personel	Test results are wrong resulting in >5 deaths of others
9	Critical			ICU admission of patient, with ventilator	ICU admission of personel with ventilator	Test results are wrong resulting in ,5 deaths of others
8	Critical			ICU admission of patient	ICU admission of personel	Test result are wrong, resulting in >5 secondary contaminations
7	Very important			Hospital admission of patient >10 days	Hospital admission of personel >10 days	Test results are wrong, resulting in <5 secondary contaminations
6	Very important			Hospital admission of patient <10 days	Hospital admission of personel <10 days	Test results are wrong, resulting in <1 secondary contaminations
5	Important			Patient gets ill with long lasting side effects; no hospital admission	Personel gets ill with long lasting side effects; no hospital admission	Test results are wrong resulting in no treatment
4	Important			Patient gets ill with some short term effects; no hospital admission	Personel gets ill with some short term effects; no hospital admission	Test results are wrong resulting in wrong treatment
3	Important			Patient gets ill fully recovers; no hospital admission	Personel gets ill fully recovers, no hospital admission	Test results are wrong resulting in postponed treatment
2	Secondary			Patient becomes contaminated	Personel gets contaminated	Test result were wrong, but detected in due time
1	Secondary			No harm to patient	No harm to personel	Test result were wrong, but immeditely detected in due time

Scoring table

	Severity									
Likelihood	1	2	3	4	5	6	7	8	9	10
10										
9										
8										
7										
6										
5										
4										
3										
2										
1										

Color	Risk	Action required
Red	Extreme risk	Immediate
Orange	High risk	High priority
Yellow	Manageble risk	A s soon as possible
Green	Minor or low risk	Continuous improvement

Appendix II

SWIFT technique advantages and disadvantages

Advantages

The technique is efficient because it generally avoids lengthy discussions of areas where hazards are well understood or where prior analysis has shown no hazards are known to exist.
It is very flexible, and applicable to any type of installation, operation or process, at any stage of the lifecycle.
It is quick, because it avoids repetitive consideration of deviations.
It uses the experience of operating staff as part of the team.
If the subject matter experts are not available for the SWIFT session their questions can be gathered in advance and included in the checklist.
The checklists used are robust as the questions asked intuitively to cover historical incidents that have happened in the past

Disadvantages

Adequate preparation of a checklist in advance is critical to achieve completeness.
Its benefit depends on the experience of the leader and the knowledge of the team.
SWIFT relies exclusively on the knowledge of the participants to identify potential problems. If the team fails to ask important questions, the analysis is likely to overlook potentially important weaknesses.
Reviewing a what-if analysis to detect oversights is difficult because there is no formal structure against which to audit.
Most what-if reviews produce only qualitative results; they give no quantitative estimates of risk-related characteristics. This simplistic approach offers great value for minimal investment, but it can answer more complicated risk-related questions only if some degree of quantification is added (for example using Risk Matrices)
Acquisition Safety and Environmental Management System ASEMS, SWIFT, https://www.asems.mod.uk/toolkit/swift

Appendix III

SWIFT technique stages

Stage 1 (preparation): Analyzing the current situation in connection with relevant regulations and procedures. Specific questions based on stage 1 will be attempted to be answered by team professionals.
Stage 2 (review): Presenting the problem and asking relevant questions to identify risks and establish corrective actions.
Stage 3 (documentation): Report of the SWIFT method and determine the dangers and their consequences.
Orymowska J., SOBKOWICZ P. (2017). Hazard identification methods. Scientific Journal of Silesian University of Technology. Series Transport. 95. 145-158. DOI: 10.20858/sjsutst.2017.95.14.