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Italian Society of Interventional Cardiology (GISE) position paper for Cath lab-specific preparedness recommendations for healthcare providers in case of suspected, probable or confirmed cases of COVID-19

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Abstract

COVID-19 pandemic raised the issue to guarantee the proper level of care to patients with acute cardiovascular diseases and concomitant suspected or confirmed COVID-19 and, in the meantime safety and protection of healthcare providers. The aim of this position paper is to provide standards to healthcare facilities and healthcare providers on infection prevention and control measures during the management of suspected and confirmed cases of 2019-nCoV infection accessing in cath-lab. The document represents the view of the Italian Society of Interventional Cardiology (GISE), and it is based on recommendations from the main World and European Health Organizations (WHO, and ECDC) as well as from the Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI).

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KEYWORDS

new coronavirus, SARS Cov-2, transmission, prevention, infections, healthcare protection

With the spread of deadly SARS-Cov-2 (2019-nCoV) infection worldwide, it is essential to be prepared to manage suspected, probable or confirmed cases of coronavirus disease 2019 (COVID-19) patients, who need nondeferrable invasive procedures in cath lab.¹⁻³ SARS-Cov-2 has the same stability on aerosol and surface of SARS-Cov-1.⁴ but the rate of transmission is higher.⁵ This seems related to the higher viral load in upper respiratory tract, and the potential for persons infected with SARS Cov-2 to transmit the virus while asymptomatic.^{6,7} It has been shown that on Diamond Princess cruise ship, 17.9% of these passengers were asymptomatic carriers of COVID-19.8 Others found that the proportion of pre-symptomatic transmission was 48-62% for Singapore and Tianjin respectively.⁹ Most secondary cases of virus transmission of SARS-CoV-2 appear to be occurring in community settings rather than healthcare settings. Notwithstanding, the healthcare setting is also vulnerable to the introduction and spread of SARS-CoV-2, and its environmental stability contributes to transmission of the virus in healthcare settings. To this regard, it has been reported that 41% of COVID transmission in Wuhan were hospital related.¹⁰

It is then fundamental to guarantee a proper protection of healthcare workers (HCWs) for their own health, to minimize the risk of spreading the infection to other health care providers and patients, and finally to guarantee the proper level of care in cath lab in case of suspected or confirmed COVID-19 patients.¹¹⁻¹³

This position paper summarizes the view of the Italian Society of Interventional Cardiology (GISE), on the base of World Health Organization (WHO), European Centre for Disease Prevention and Control (ECDC) and Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Care (SIAARTI) recommendations.¹⁴⁻²⁴

The aim is to provide standards to healthcare facilities and healthcare providers on infection prevention and control measures during the management of suspected and confirmed cases of 2019-nCoV infection accessing in cath-lab. These guidelines can be extended and adapted to other operating rooms.

The definition of suspected COVID-19 patients is continuously changing depending on epidemiological factors, so it is recommended to refer in turn to WHO updates (https://www.who.int/emergencies/ diseases/novel-coronavirus-2019).

1 | GENERAL MANAGEMENT OF CATH LAB

1.1 | Daily checklist in cath lab

If the hospital has multiple cath-labs/operating rooms, it is suggested to identify dedicated lab for the treatment of suspected or confirmed COVID-19 patients, if needed. Only clinical staff who have been trained and is therefore considered to be competent in the use of personal protective equipment (PPE) should be allowed to access the cath lab in case of suspected or confirmed COVID-19 patients.

Due to the spread of infection worldwide and the risk of supply shortages of PPE, it is recommended to have a dedicated registry of all the available PPE in cath lab.

It is suggested to do a daily check to verify the presence of an adequate number of PPE including:

- Surgical mask
- Respirator N95 or FFP2 standard and FFP3, or equivalent.
- Long-sleeved water-resistant gown
- Sterile standard gown
- Gloves
- Hair covers
- Eye protection (goggles or face shield, better if disposable)
- Apron (for aerosol-generating procedures such as intubation)
- Shoe covers due to the risk of splash from organic material or chemicals.

1.2 | Daily checklist of crash cart

It is advised to alert the anesthesiologist beforehand to consider the opportunity of elective intubation before patient arrival in cath lab. In any case, the crash cart must contain:

- Heat and moisture exchanger (HME) filters to be placed on any interface (mask, circuit, endotracheal tube, supraglottic devices, introducer/exchange pipes)
- 2. Laryngoscope
- 3. Masks
- 4. Circuits
- 5. Endotracheal tubes
- 6. Supraglottic devices
- 7. Introducer/exchange pipes
- 8. Aspirator (closed system)
- 9. Anti-fogging system
- 10. Any potential useful drugs already prepared and double checked
- 11. Clamp, if necessary to disconnect the patient from the ventilator.

2 | PROCEDURES FOR WEARING ("DONNING") AND SAFE REMOVAL ("DOFFING") OF PPE

It is strongly suggested to print these instructions (Supplemental Appendix S1) and keep them available in the lab together with PPE.

Donning/doffing maneuvers should be performed with proper supervision by a trained observer who reads the correct sequence in the order to verify the correct execution and minimize the risk of accidental contamination (see Supplemental Movies 1 and 2 for tutorial on correct donning and doffing of PPE).

Clinical staff should be routinely trained on the correct use of PPE to be prepared for emergency situations.

2.1 | Donning of PPE before entering Cath lab

All HCWs involved in the procedure must wear proper PPE before patient's arrival in cath lab in a safe noncontaminated environment. The sequence is:

- 1. Remove any personal items
- 2. Put on the lead apron
- 3. Put on a first disposable gown
- 4. Gather the necessary PPE and check for their integrity
- 5. Perform hand hygiene with alcohol hand gel/rub
- Put on the proper disposable respirator N95 or FFP2 standard (FFP3 available for anesthesiologist and nurse helping on airways maneuvers)
- 7. Put on hair cover
- 8. Put on shoe covers
- Put on googles and/or face shield avoiding any interference with the respirator
- 10. Perform hand hygiene
- 11. Put on the first pair of gloves
- Put on a gown (sterile or not according to your role in cath lab) not using the inside tie
- 13. Put on a second pair of gloves (over cuff), sterile if needed.

2.2 | Doffing of PPE

A safe doffing area should be identified in each cath lab, in particular if no anteroom or exists. If no anteroom is available, doffing of PPE could be done inside the lab, at the end of procedure and when the patient has been transferred away.

Only facial respirator must be removed outside the contaminated area.

- Avoid any contact with your face, hair and eyes before of completing the entire doffing process.
- 2. Place any disposable PPE in the clinical waste bin.
- Do not fill the clinical waste bin more than ³/₄ in order to be able to close it safely without squeezing contaminated materials to avoid aerosolization.
- 4. Reprocess the not-disposable PPE.
- 5. Follow the sequence.

Inside the operating room:

- a. Wait until patient is out of the room; close the door.
- b. Perform hand hygiene over the gloves.
- c. Peel off gown and gloves together and roll inside, slowly and carefully, avoiding aerosolization.
- d. If gloves are removed separately, touch only the external part (use glove-in-glove or beak technique).
- e. Perform hand hygiene (over the internal gloves).
- f. Remove face shield and/or googles avoiding contact with face and eyes and dispose them safely or put in a separate container for reprocessing.
- g. Perform hand hygiene (over the internal gloves).
- h. Remove hair cover and dispone it safely.
- i. Remove shoe covers and dispone them safely.
- j. Perform hand hygiene (over the internal gloves).
- k. Remove internal gloves and dispose them safely.
- I. Perform hand hygiene.
- m. Step out of the operating room and immediately close the door.

Outside the operating room:

- n. Put on another pair of gloves.
- o. Remove facial respirator without touching the front side of the respirator.
- p. Remove the disposable gown and the gloves.
- q. Remove lead apron.
- r. Perform hand hygiene with soap and water and alcohol gel/rub.

3 | WHAT TO DO BEFORE THE ARRIVAL IN CATH-LAB OF A SUSPECTED OR CONFIRMED COVID-19 PATIENT

- 1. Notify the area receiving the patient of any necessary precautions as early as possible before the patient's arrival.
- 2. Ensure maximal coordination to avoid steadying in waiting areas.
- Get all other patients in cath lab away from the path the COVID patient will have to take.
- Identify the staff that will be in contact with the patient avoiding unnecessary exposure of other members in order to reduce the risk of contamination and wasting of PPE.
- 5. Assign roles to each staff member.
- Briefing with the (few) member of the dedicated staff, identify a buddy who is designated to read the instructions and supervised the correct sequence of donning and doffing.
- Pre-warning of the anesthesiologist to evaluate the opportunity of elective intubation, recommended before patient's arrival in the lab; otherwise, the anesthesiologist stays outside the room with proper PPE.
- 8. All useful material for interventional cardiology must be stored inside the lab (for instance a full-size series of catheters, balloon-catheters

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and stents), avoiding entry and exit of the staff members during procedure.

- 9. Any useful drugs have to be prepared in advance.
- 10. Supervised donning PPE for all the member of the staff (it is suggested to have at least one physician and one nurse sterile and one nurse and one technician nonsterile).
- 11. Only when all is prepared, accept the patient in cath lab.
- 12. If in spontaneous breathing, the patient must wear a surgical mask before entry the lab.

4 | PERIPROCEDURAL MANAGEMENT OF SUSPECTED OR CONFIRMED COVID-19 PATIENTS IN CATH-LAB

- 1. Keep the door closed for the whole duration of procedure.
- 2. PPE-protected (but nonsterile) member staff put the patient on the operating table.
- Avoid entry and exit from the room of the staff for bringing material (everything necessary should be planned in advance and stored inside).
- 4. Nonsterile staff members moving into the operating room during the procedure should minimize any contact with the surfaces. Before any contact (for example before opening a tray), he should change the external gloves (or put on another pair of cleaned gloves).
- 5. Keep the procedure as simple as possible (only culprit lesion revascularization).

5 | POST-PROCEDURAL REQUIREMENTS WHEN A SUSPECTED OR CONFIRMED COVID-19 PATIENT LEAVES THE CATH-LAB

- 1. Keep the door closed.
- Supervised doffing as previously described; if no anteroom is available, doffing of PPE could be done inside the room, at the end of procedure and when the patient has been transferred away. Only facial respirator must be removed outside the contaminated area.
- Dispose of all waste according to protocols (do not squeeze contaminated material into the container).
- 4. Treat used tissues in accordance with standard procedures.
- 5. Get out of the operating room and keep the door closed for at least an hour prior to performing a terminal clean (in particular for a neutral pressure room).
- Reuseable equipments have to be decontaminated according to the manufacturer's instructions (i.e., lead apron).
- 7. Notification of any new confirmed case.
- A record of all staff providing care for suspected or confirmed 2019-nCoV cases must be maintained.
- 9. If at any point a member of the staff feels as he/she has been exposed to the pathogen, follow facility protocols.

10. Staff who have been provided care to confirmed 2019-nCoV cases, should be vigilant for fever and any respiratory symptoms in the 14 days following the last exposure to a confirmed case, and follow internal protocols.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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REFERENCES

- Roffi M, Patrono C, Collet J-P, et al. 2015 ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: task force for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J. 2016;37:267-315.
- FGP W, Shah PB, Aronow HD, et al. American College of Cardiology's (ACC) Interventional Council and the Society of Cardiovascular Angiography and Intervention (SCAI)Catheterization laboratory considerations during the coronavirus (COVID-19) pandemic: from ACC's interventional council and SCAI. J AM Coll Cardiol. 2020. https://doi.org/10. 1016/j.jacc.2020.03.021. [Epub ahead of print].
- Romaguera R, Cruz-González I, Ojeda S, et al. Consensus document of the interventional cardiology and heart rhythm associations of the Spanish Society of Cardiology on the management of invasive cardiac procedure rooms during the COVID-19 coronavirus outbreak. REC Interv Cardiol. 2020. https://doi.org/10.24875/RECICE.M20000116. [Epub ahead of print].
- van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. N Engl J Med. 2020. https://doi.org/10.1056/NEJMc2004973. [Epub ahead of print].
- Meo SA, Alhowikan AM, Al-Khlaiwi T, et al. Novel coronavirus 2019-nCoV: prevalence, biological and clinical characteristics comparison with SARS-CoV and MERS-CoV. Eur Rev Med Pharmacol Sci. 2020;24:2012-2019.
- Bai Y, Yao L, Wei T, et al. Presumed asymptomatic carrier transmission of COVID-19. JAMA. 2020. https://doi.org/10.1001/jama.2020. 2565. [Epub ahead of print].
- Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. N Engl J Med. 2020;382(12): 1177-1179. https://doi.org/10.1056/NEJMc2001737
- Mizumoto K, Kagaya K, Zarebski A, Chowell G. Estimating the asymptomatic proportion of coronavirus disease 2019 (COVID-19) cases on board the diamond princess cruise ship, Yokohama, Japan, 2020. Euro Surveill. 2020;25(10):2000180. https://doi.org/10.2807/1560-7917. ES.2020.25.10.2000180
- Ganyani T, Kremer C, Chen D, Torneri A, Faes C, Wallinga J, Hens N. Estimating the generation interval for COVID-19 based on symptom onset data. https://doi.org/10.1101/2020030520031815.
- Wang D, Hu B, Hu C, et al. Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus-infected pneumonia in Wuhan, China. JAMA. 2020. https://doi.org/10.1001/jama.2020.1585. [Epub ahead of print].

- Wong J, Goh QY, Tan Z, et al. Preparing for a COVID-19 pandemic: a review of operating room outbreak response measures in a large tertiary hospital in Singapore. Can J Anaesth. 2020. https://doi.org/10. 1007/s12630-020-01620-9. [Epub ahead of print].
- Huh S. How to train the health personnel for protecting themselves from novel coronavirus (COVID-19) infection during their patient or suspected case care. J Educ Eval Health Prof. 2020;17:10.
- Zeng J, Huang J, Pan L. How to balance acute myocardial infarction and COVID-19: the protocols from Sichuan provincial People's hospital. Intensive Care Med. 2020. https://doi.org/10.1007/s00134-020-05993-9. [Epub ahead of print].
- 14. Coronavirus disease (COVID-19) outbreak: rights, roles and responsibilities of health workers, including key considerations for occupational safety and health. World Health Organization 2020. WHO reference number: WHO/2019-nCov/HCW_advice/2020.2. Available from: https://www.who.int/publications-detail/coronavirus-disease-(covid-19)-outbreak-rights-roles-and-responsibilities-of-health-workersincluding-key-considerations-for-occupational-safety-and-health.
- 15. World Health Organization 2020. Critical preparedness, readiness and response actions for COVID-19. WHO reference number: WHO/2019-nCoV/Community_Actions/2020.3. Available from: https://www.who.int/publications-detail/critical-preparedness-readinessand-response-actions-for-covid-19
- World Health Organization 2020. Infection prevention and control during health care when novel coronavirus (nCoV) infection is suspected. Interim Guidance Geneva 2020. WHO reference number: WHO/2019-nCoV/IPC/2020.3. Available from: https://www.who. int/publications-detail/infection-prevention-and-control-duringhealth-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125.
- 17. World Health Organization 2020. Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19). Interim guidance February 27, 2020. Available from: https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE_use-2020.1-eng.pdf.
- World Health Organization 2020. Advice on the use of masks in the community, during home care and in health care settings in the context of the novel coronavirus (2019-nCoV) outbreak. Interim guidance January 29, 2020. WHO reference number: WHO/2019nCoV/IPC_Masks/2020.2. Available from: https://www.who.int/ publications-detail/advice-on-the-use-of-masks-in-the-communityduring-home-care-and-in-healthcare-settings-in-the-context-of-thenovel-coronavirus-(2019-ncov)-outbreak.
- 19. European Centre for Disease Control and Prevention. Interim infection prevention and control recommendations for patients with confirmed

coronavirus disease 2019 (COVID-19) or persons under investigation for COVID-19 in healthcare settings. [updated 21 Febraury 2020]. Available from: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/ infection-control.html.

- European Centre for Disease Prevention and Control (ECDC). Safe use of personal protective equipment in the treatment of infectious diseases of high consequence Stockholm: ECDC; 2014. Available from: https://www.ecdc.europa.eu/sites/default/files/media/en/ publications/Publications/safe-use-of-ppe.pdf.
- European Centre for Disease Prevention and Control (ECDC). Interim U.S. guidance for risk assessment and public health management of healthcare personnel with potential exposure in a healthcare setting to patients with coronavirus disease (COVID-19). Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-riskassesment-hcp.html.
- SIAARTI COVID-19. Procedura Area Critica. Available from: http:// www.siaarti.it/SiteAssets/News/COVID19%20%20documenti%20 SIAARTI/SIAARTI%20-%20Covid19%20%20Percorso%20Area%20 Critica.pdf.
- SIAARTI COVID-19. Controllo Delle Vie Aeree. Available from: http://www.siaarti.it/SiteAssets/News/COVID19%20%20documenti %20SIAARTI/SIAARTI%20-%20Covid19%20%20Controllo%20vie% 20aeree.pdf.
- SIAARTI COVID-19. Gestione del Paziente Critico Affetto da Coronavirus: Raccomandazioni per la Gestione Locale Available from: http:// www.siaarti.it/SiteAssets/News/COVID19%20%20documenti% 20SIAARTI/SIAARTI%20%20Covid19%20%20Gestione%20del% 20paziente%20critico%20affetto%20da%20coronavirus%20-% 20Raccomandazioni%20per%20la%20gestione%20locale.pdf.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: Tarantini G, Fraccaro C, Chieffo A, et al. Italian Society of Interventional Cardiology (GISE) position paper for Cath lab-specific preparedness recommendations for healthcare providers in case of suspected, probable or confirmed cases of COVID-19. *Catheter Cardiovasc Interv.* 2020; 1–5. https://doi.org/10.1002/ccd.28888