Catheterization & Cardiovascular Interventions





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

Journal:	Catheterization and Cardiovascular Interventions
Manuscript ID	Draft
Wiley - Manuscript type:	Core Curriculum
Keywords:	CATH - Catheterization, Diagnostic, HCP - Health Care Policy, ACS - ACS/NSTEMI

SCHOLARONE™ Manuscripts 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

Authors:

Giuseppe Tarantini, MD, PhD, FESC¹, Chiara Fraccaro, MD, PhD¹, Alaide Chieffo, MD², Alfredo Marchese, MD³, Fabio Felice Tarantino, MD⁴, Stefano Rigattieri, MD, PhD⁵, Ugo Limbruno, MD⁶, Ciro Mauro, MD⁷, Alessio La Manna, MD⁸, Battistina Castiglioni, MD⁹, Matteo Longoni, TSRM², Sergio Berti, MD¹⁰, Francesco Greco, MD¹¹, Giuseppe Musumeci, MD¹², Giovanni Esposito, MD¹³ on behalf of GISE

Affiliations:

- 1. Department of Cardiac, Thoracic, Vascular Sciences, University of Padua, Padua, Italy
- 2. Interventional Cardiology Unit, IRCCS San Raffaele Hospital, Milan, Italy
- 3. Santa Maria Hospital, GVM Care & Research, Bari, Italy
- 4. Cath Lab Unit, Cardiovascular Dept., Morgagni Hospital, Vecchiazzano-Forlì, Italy
- 5. Division of Cardiology, Sant'Andrea University Hospital, Rome, Italy
- Dipartimento Cardio-neuro-vascolare, Azienda USL Toscana Sud-est, Ospedale di Grosseto, Grosseto, Italy
- 7. A.O.R.N. A. Cardarelli, Napoli, Italy
- 8. Division of Cardiology CAST, Policlinico Hospital, Catania, Italy
- 9. Ospedale di Circolo e Fondazione Macchi, Varese, Italy
- 10. Fondazione Toscana G. Monasterio Ospedale del Cuore G. Pasquinucci, Massa, Italy
- 11. Division of Cardiology, Ospedale Civile SS Annunziata, Cosenza, Italy
- Interventional Cardiology Unit, Azienda Ospedaliera Ordine Mauriziano di Torino,
 Torino, Italy

13. Department of Advanced Biomedical Sciences, Federico II University of Naples, Naples, Italy

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

Corresponding author:

Giuseppe Tarantini MD, PhD, FESC

Chief of Interventional Cardiology Unit

Dpt of Cardiac, Thoracic and Vascular Science, Padova

Via Giustiniani 2

35128 Padova (Italy)

Phone: +39 049 8211844/8212322

FAX: +39 049 8212309

Mail: giuseppe.tarantini.1@unipd.it

Short title: Management of COVID-19 in cath lab.

Manuscript word count: 3059

Conflict of interest: none of the authors has any conflict of interest to disclose.

Non-structured 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).

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 non-deferrable invasive procedures in cath lab¹⁻³. SARS-Cov-2 has the same stability on aerosol and surface of SARS-Cov-1⁴, but the rate of transmission is higher⁵. 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-19⁸. Others found that the proportion of pre-symptomatic transmission was 48-62% for Singapore and Tianjin respectively⁹. 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 related¹⁰.

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) recommendations¹⁴⁻²⁴.

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 anaesthesiologist beforehand to consider the opportunity of elective intubation before patient arrival in cath lab.

In any case, the crash cart must contain:

- 1. 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 1) and keep them available in the lab together with PPE.

Donning/doffing manoeuvres 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 Movie 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 non-contaminated 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
- 6. Put on the proper disposable respirator N95 or FFP2 standard (FFP3 available for anaesthesiologist and nurse helping on airways manoeuvres)
- 7. Put on hair cover
- 8. Put on shoe covers
- 9. 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
- 12. 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.
- 3. Don't fill the clinical waste bin more than ¾ 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
- 1) 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 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.
 - 3. Get all other patients in cath lab away from the path the COVID patient will have to take.
 - 4. 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.
 - 7. Pre-warning of the anaesthesiologist to evaluate the opportunity of elective intubation, recommended before patient's arrival in the lab; otherwise, the anaesthesiologist 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-catheter 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 non-sterile).
- 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 non-sterile) member staff put the patient on the operating table.
- 3. Avoid entry and exit from the room of the staff for bringing material (everything necessary should be planned in advance and stored inside).
- 4. Non-sterile 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.
- 2. 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.

- 3. 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).
- 6. Re-useable equipment have to be decontaminated according to the manufacturer's instructions (i.e.lead apron).
- 7. Notification of any new confirmed case.
- 8. 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.

References:

1. Roffi M, Patrono C, Collet J-P, Mueller C, Valgimigli M, Andreotti F, Bax J, Borger M, Brotons C, Chew D, Gencer B, Hasenfuss G, Kjeldsen K, Lancellotti P, Landmesser U, Mehilli J, Mukherjee D, Storey R, Windecker S. 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.
- Welt FGP, Shah PB, Aronow HD, Bortnick AE, Henry TD, Sherwood MW, Young MN, Davidson LJ, Kadavath S, Mahmud E, Kirtane AJ, 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.
- 3. Romaguera R, Cruz-González I, Ojeda S, Jiménez-Candil J, Calvo D, García Seara J, Cañadas-Godoy V, Calvo E, Brugaletta S, Sánchez Ledesma S MR. 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;XX:XX–XX.
- 4. van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN, Tamin A, Harcourt JL, Thornburg NJ, Gerber SI, Lloyd-Smith JO, de Wit E, Munster VJ. Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. *N Engl J Med*. 2020:NEJMc2004973.
- 5. Meo SA, Alhowikan AM, Al-Khlaiwi T, Meo IM, Halepoto DM, Iqbal M, Usmani AM, Hajjar W, Ahmed N. Novel coronavirus 2019-nCoV: prevalence, biological and clinical characteristics comparison with SARS-CoV and MERS-CoV. *Eur Rev Med Pharmacol Sci.* 2020;24:2012–9.
- 6. Bai Y, Yao L, Wei T, Tian F, Jin DY, Chen L, Wang M. Presumed Asymptomatic Carrier Transmission of COVID-19. *JAMA J Am Med Assoc*. 2020.
- 7. Zou L, Ruan F, Huang M, Liang L, Huang H, Hong Z, Yu J, Kang M, Song Y, Xia J, Guo Q, Song T, He J, Yen H-L, Peiris M, Wu J. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. *N Engl J Med*. 2020.
- 8. 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. Eurosurveillance. 2020;25.
- 9. 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.

 *Doi:Https://DoiOrg/101101/2020030520031815.
- 10. Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical Characteristics of 138 Hospitalized Patients with 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA J Am Med Assoc*. 2020.
- 11. Wong J, Goh QY, Tan Z, Lie SA, Tay YC, Ng SY, Soh CR. Preparing for a COVID-19 pandemic: a review of operating room outbreak response measures in a large tertiary hospital in Singapore. *Can J Anesth Can d'anesthésie*. 2020.
- 12. 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.
- 13. 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.
- 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-workers-including-key-considerations-for-occupational-safety-and-health
- 15. Critical preparedness, readiness and response actions for COVID-19. World Health Organization 2020. WHO REFERENCE NUMBER: WHO/2019-nCoV/Community_Actions/2020.3. Available from:
 https://www.who.int/publications-detail/critical-preparedness-readiness-and-response-actions-for-covid-19

- 16. 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:
 <a href="https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125</p>
- 17. Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19). Interim guidance 27 February 2020. World Health Organization. Available from: https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE use-2020.1-eng.pdf
- 18. 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 29 January 2020. World Health Organization 2020. WHO REFERENCE NUMBER: WHO/2019-nCoV/IPC_Masks/2020.2. Available from:

 https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-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.
- 20. 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.
- 21. 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-risk-assesment-hcp.html

- 22. SIAARTI COVID-19. Procedura Area Critica. Available from:
 http://www.siaarti.it/SiteAssets/News/COVID19%20%20documenti%20SIAARTI/SI
 AARTI%20-%20Covid19%20%20Percorso%20Area%20Critica.pdf
- 23. SIAARTI COVID-19. Controllo delle vie aeree. Available from:

 http://www.siaarti.it/SiteAssets/News/COVID19%20%20documenti%20SIAARTI/SI

 AARTI%20-%20Covid19%20%20Controllo%20vie%20aeree.pdf
- 24. 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/SI

 AARTI%20%20Covid19%20%20Gestione%20del%20paziente%20critico%20affetto
 %20da%20coronavirus%20-

%20Raccomandazioni%20per%20la%20gestione%20locale.pdf

Legends:

Supplemental Appendix 1. Sequence of donning and doffing of PPE.

Supplemental Movie 1. Video tutorial for correct donning of PPE.

Supplemental Movie 2. Video tutorial for correct doffing of PPE.



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

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

Short title: Management of COVID-19 in cath lab.

Manuscript word count: 3059

Conflict of interest: none of the authors has any conflict of interest to disclose.

Non-structured 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).

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 non-deferrable invasive procedures in cath lab¹⁻³. SARS-Cov-2 has the same stability on aerosol and surface of SARS-Cov-1⁴, but the rate of transmission is higher⁵. 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-19⁸. Others found that the proportion of pre-symptomatic transmission was 48-62% for Singapore and Tianjin respectively⁹. 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 related¹⁰.

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) recommendations¹⁴⁻²⁴.

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 anaesthesiologist beforehand to consider the opportunity of elective intubation before patient arrival in cath lab.

In any case, the crash cart must contain:

- 1. 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 1) and keep them available in the lab together with PPE.

Donning/doffing manoeuvres 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 Movie 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 non-contaminated 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
- 6. Put on the proper disposable respirator N95 or FFP2 standard (FFP3 available for anaesthesiologist and nurse helping on airways manoeuvres)
- 7. Put on hair cover
- 8. Put on shoe covers
- 9. 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
- 12. 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.
- 3. Don't 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
- 1) 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 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.
 - 3. Get all other patients in cath lab away from the path the COVID patient will have to take.
 - 4. 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.
 - 7. Pre-warning of the anaesthesiologist to evaluate the opportunity of elective intubation, recommended before patient's arrival in the lab; otherwise, the anaesthesiologist 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-catheter 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 non-sterile).
- 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 non-sterile) member staff put the patient on the operating table.
- 3. Avoid entry and exit from the room of the staff for bringing material (everything necessary should be planned in advance and stored inside).
- 4. Non-sterile 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.
- 2. 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.

- 3. 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).
- 6. Re-useable equipment have to be decontaminated according to the manufacturer's instructions (i.e.lead apron).
- 7. Notification of any new confirmed case.
- 8. 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.

References:

1. Roffi M, Patrono C, Collet J-P, Mueller C, Valgimigli M, Andreotti F, Bax J, Borger M, Brotons C, Chew D, Gencer B, Hasenfuss G, Kjeldsen K, Lancellotti P, Landmesser U, Mehilli J, Mukherjee D, Storey R, Windecker S. 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.
- Welt FGP, Shah PB, Aronow HD, Bortnick AE, Henry TD, Sherwood MW, Young MN, Davidson LJ, Kadavath S, Mahmud E, Kirtane AJ, 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.
- 3. Romaguera R, Cruz-González I, Ojeda S, Jiménez-Candil J, Calvo D, García Seara J, Cañadas-Godoy V, Calvo E, Brugaletta S, Sánchez Ledesma S MR. 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;XX:XX–XX.
- van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN, Tamin A, Harcourt JL, Thornburg NJ, Gerber SI, Lloyd-Smith JO, de Wit E, Munster VJ. Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1. N Engl J Med. 2020:NEJMc2004973.
- 5. Meo SA, Alhowikan AM, Al-Khlaiwi T, Meo IM, Halepoto DM, Iqbal M, Usmani AM, Hajjar W, Ahmed N. Novel coronavirus 2019-nCoV: prevalence, biological and clinical characteristics comparison with SARS-CoV and MERS-CoV. *Eur Rev Med Pharmacol Sci.* 2020;24:2012–9.
- 6. Bai Y, Yao L, Wei T, Tian F, Jin DY, Chen L, Wang M. Presumed Asymptomatic Carrier Transmission of COVID-19. *JAMA J Am Med Assoc*. 2020.
- 7. Zou L, Ruan F, Huang M, Liang L, Huang H, Hong Z, Yu J, Kang M, Song Y, Xia J, Guo Q, Song T, He J, Yen H-L, Peiris M, Wu J. SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. *N Engl J Med*. 2020.
- 8. 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. Eurosurveillance. 2020;25.
- 9. 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.

 *Doi:Https://DoiOrg/101101/2020030520031815.
- 10. Wang D, Hu B, Hu C, Zhu F, Liu X, Zhang J, Wang B, Xiang H, Cheng Z, Xiong Y, Zhao Y, Li Y, Wang X, Peng Z. Clinical Characteristics of 138 Hospitalized Patients with 2019 Novel Coronavirus-Infected Pneumonia in Wuhan, China. *JAMA J Am Med Assoc*. 2020.
- 11. Wong J, Goh QY, Tan Z, Lie SA, Tay YC, Ng SY, Soh CR. Preparing for a COVID-19 pandemic: a review of operating room outbreak response measures in a large tertiary hospital in Singapore. *Can J Anesth Can d'anesthésie*. 2020.
- 12. 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.
- 13. 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.
- 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-workers-including-key-considerations-for-occupational-safety-and-health
- 15. Critical preparedness, readiness and response actions for COVID-19. World Health Organization 2020. WHO REFERENCE NUMBER: WHO/2019-nCoV/Community_Actions/2020.3. Available from:
 https://www.who.int/publications-detail/critical-preparedness-readiness-and-response-actions-for-covid-19

- 16. 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:
 <a href="https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125</p>
- 17. Rational use of personal protective equipment for coronavirus disease 2019 (COVID-19). Interim guidance 27 February 2020. World Health Organization. Available from: https://apps.who.int/iris/bitstream/handle/10665/331215/WHO-2019-nCov-IPCPPE use-2020.1-eng.pdf
- 18. 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 29 January 2020. World Health Organization 2020. WHO REFERENCE NUMBER: WHO/2019-nCoV/IPC_Masks/2020.2. Available from:

 https://www.who.int/publications-detail/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-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.
- 20. 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.
- 21. 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-risk-assesment-hcp.html
- 22. SIAARTI COVID-19. Procedura Area Critica. Available from:
 http://www.siaarti.it/SiteAssets/News/COVID19%20%20documenti%20SIAARTI/SI
 AARTI%20-%20Covid19%20%20Percorso%20Area%20Critica.pdf
- 23. SIAARTI COVID-19. Controllo delle vie aeree. Available from:

 http://www.siaarti.it/SiteAssets/News/COVID19%20%20documenti%20SIAARTI/SI

 AARTI%20-%20Covid19%20%20Controllo%20vie%20aeree.pdf
- 24. 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/SI

 AARTI%20%20Covid19%20%20Gestione%20del%20paziente%20critico%20affetto
 %20da%20coronavirus%20-

Legends:

Supplemental Appendix 1. Sequence of donning and doffing of PPE.

Supplemental Movie 1. Video tutorial for correct donning of PPE.

Supplemental Movie 2. Video tutorial for correct doffing of PPE.



Supplemental Appendix 1. Sequence of Donning and doffing of PPE.

DONNING PPE SEQUENCE

- 1. Remove any personal item
- 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
- 6. Put on the proper disposable respirator N95 or FFP2 standard (FFP3 available for anaesthesiologist and nurse helping on airways manoeuvres)
- 7. Put on hair cover
- 8. Put on shoe covers
- 9. 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
- 12. 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.

DOFFING PPE SEQUENCE

Inside the operating room (or in the filter zone if available):

- 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
- 1) 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 gloves
- g) Remove lead apron
- r) Perform hand hygiene with soap and water and alcohol gel/rub.