



Title	Summary of evidence: Use of overalls - "protective overalls" for health care in the emergency services, ICU and hospitalizations in the medical field.
Identification code	04132020BGJAIHCG
Requesting area	COVID-191. Keralty Public Health Crisis Committee
Name	COVID-191. Keralty Public Health Crisis Committee
Answer date	13 04 2020
Update date	21 04 2020

### Questions:

Does the use of Protective Overalls safeguard the safety of health teams in Intensive Care settings?

**Search Terms:** COVID 19, Coronavirus, N95, Elements of Personal Protection, PPE, coverall, critical care.

**Types of study:** Recommendations of scientific societies and national and international health reference organizations, systematic literature reviews (RSL), meta-analyzes, clinical trials and other primary studies.

**Data Sources**: Directed search on the websites of scientific societies: The Emergency Nurses Association, Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), The National Institute for Occupational Safety and Health (NIOSH), Ministère des Solidarités et de la Santé (France), Robert Koch Institute (Germany), European Center for Disease Prevention and Control, Institute for Health Care Improvement (IHI), The American Academy of Family Physicians, Colombian Association of Critical Medicine and Care Intensive, Public Health (United Kingdom), Society of Critical Care Medicine. Colombian Association of Infectious Diseases Guide / Ministry of Social Protection Colombia, Pubmed, Google Scholar.

### **Background information:**

As part of the previous review carried out by the IGEC, on the use of personal protection elements for health care in emergency services in the medical and dental field, this document is generated with emphasis on the use of protective overalls or "coverall" in intensive care units (ICU).

The Ebola outbreak that occurred in West Africa in 2014 provided valuable lessons regarding emergency preparedness, the use of personal protective equipment and classification processes, particularly there is an emphasis on the need for training, practice, competition and observation in the donning and doffing personal protective equipment (PPE) (workers must have received adequate training and demonstrate that they understand and are competent to put on and take off PPE and the staff is supervised by a field manager ensuring that the donning protocol and withdrawal has been applied correctly. If an individual is unable or unwilling to follow the protocol, he should not be considered fit to perform in that area).

The Ebola virus enters by contact of blood or fluids of a contaminated person through injured skin or uncovered membranes, so the health team must be completely covered and the recommended suit





used is the protective suit. They also emphasize the importance of the frequency of cleaning floors and work surfaces.

SARS-VOC-2 is transmitted by direct contact and drops. Aerial transmission can occur during aerosol-generating and supportive procedures (e.g., orotracheal intubation, non-invasive ventilation). Standard precautions should always be used for all healthcare workers in patient care and contact and airborne precautions should be implemented.

The precautionary principle or precautionary principle is a concept that supports the adoption of protective measures in the face of well-founded suspicions that the SARS-CoV-2 virus creates a serious risk to public health, but without definitive scientific evidence. on the transmission modes and virulence of the SARS-CoV-2. This principle applies and should be considered in relation to the use of the maximum possible protection for health equipment.

Although the use of PPE is the most visible control measure to prevent the spread of infection, it is the last and weakest in the hierarchy of infection prevention and control measures. Administrative and engineering measures can limit workers' exposure to SARS-Cov2 and are therefore considered of greater importance. In the absence of effective administrative and engineering control measures, PPE has limited benefits. Among the administrative and engineering measures, it is worth highlighting:

Engineering measures in the ICU

- Well ventilated areas to accommodate patients with suspected or diagnosed COVID -19. For natural ventilation, the following minimum hourly average of ventilation rates to be provided is:
- 160 l/s / patient (average hourly ventilation rate) for air-insulated caution rooms (with a minimum of 80 l/s / patient) (for further renovation);
- 60 I/s/patient for general rooms and outpatient departments; and
- 2.5 I / s / m3 for corridors and other transitory spaces without a fixed number of patients; however, when patient care is performed in hallways during emergencies or other situations, the same ventilation requirement for air isolation rooms or general rooms will apply.

An air isolation room is a room with> 12 air changes per hour (ACH) (for example, equivalent to>  $80 \, \text{I}$  / s for a  $4 \times 2 \times 3$  m3 room) and must have controlled air flow direction , and can be used to contain airborne infections

Natural ventilation can be used in air isolation rooms. In rooms where air-generating procedures are performed, other protection measures are added, but there are no studies showing that mechanical ventilation reduces the risk of transmission.

- Separate areas for respiratory patients
- Guarantee the space between patients of at least 1 meter,
- Implement glass or plastic windows in the admissions or presentation areas.

Other protection measures:

- Strengthen telemedicine channels and increase telephone solutions
- Postpone elective surgical procedures or non-urgent procedures
- Cohort patients with confirmed diagnosis of COVID-19 and without coinfections in shared rooms





- Appoint teams dedicated to the care of only patients with COVID-19, which allows to extend the use of PPE and try to do the activities in a single admission, for example, take signs when administering the medication.
- Exclude personnel not directly involved in patient care from patient care areas
- Restrict visits (in number and time) of patients diagnosed or suspected with COVID to those strictly necessary. Provide information on which PPE is necessary
- Shorten the hospitalization time of stable patients with COVID 19
- The use of N95 or elastomeric respirators or PAPRs should be prioritized for health professionals with the highest risk exposures and for those responsible for procedures that generate aerosols.

## **Definitions**

Gowns	Coveralls
Provide discontinuous protection for the entire body (does not cover the neck or face, has an opening in the back and covers only up to the calf)	They provide 360-degree protection because they are designed to cover the entire body, including the back and lower legs, and sometimes the head and feet as well.
Easy to put on and, in particular, to take off	Greater difficulty to withdraw. This implies an increased risk of contamination
Its use is more familiar to healthcare workers, the more likely it is to be used and disposed of correctly.	Healthcare workers must receive placement and removal training. In case of use for Ebola there should be a person supervising the donning and removing of the suit
Source: CDC 2020.	The level of heat stress generated by the additional layer of clothing is lower for gowns than for Protective Overalls for several reasons, including openings in the gown design and the total area covered by the fabric.

Source: CDC 2020.





There are no clinical studies comparing the efficacy of gowns versus protective overalls in the prevention of COVID 19; The use of one type of clothing or another to protect health workers from skin exposures should be selected according to the danger of infection, material, design, durability, comfort and functionality.

A Cochrane review was found on the use of PPE to prevent highly infectious diseases due to contamination of body fluids in health personnel. Almost all of the findings are based on one or two small simulated exposure studies (which makes the evidence indirect, since we don't know how much this represents exposure to the virus in real life). Thus, the certainty of the evidence was considered low or very low. Included in this review, there is a study of 50 subjects who found less contamination (determined by a fluorescent marker) with the use of a powered air purifying respirator (PAPR) with a diving suit attached to a coverall, compared wearing a gown, N95 respirator, goggles, face shield and gloves, but without PAPR. However, there was greater noncompliance with the recommendations to wear the coverall with PAPR. The review also found that coveralls are more difficult to remove (have a higher proportion of compliance errors) than the other set of items; Coveralls take longer to withdraw, with an average withdrawal time greater than 10 minutes. This review also found that consistent use of PPE is more important than type of PPE. Therefore, the authors concluded that wearing a long gown together with other protective elements may present the best balance between the protection provided during use and the risks of PPE removal.

Some statements from relevant national and international organizations are mentioned below:

The European Center for Disease Prevention and Control, reviewing in March 2020 the prevention and control of infections in relation to COVID-19, does not mention the use of protective overalls when referring to PPE. A review on the treatment of these patients in intensive care published in April 2020 by Phua et al. From the Asian Group of Clinical Studies in Critical Care, in their section on infection prevention, also makes no mention of protective overalls or neck protection.

Nor do they mention the matter: the American Association of Critical Care Nurses, Intitute for Health Improvement, Society of Critical Care Medicine. The Guidelines of the Colombian Association of Infectious Diseases and the Ministry of Social Protection in Colombia do not mention protection monkeys in their section on PPE either.

In its latest version (of April 2020) of recommendations on the use of PPE, the World Health Organization states that double-gloved coveralls, or hoods or head and neck covers that were used in the management of Ebola patients, they are NOT required for the care of patients with COVID-19.

The Centers for Disease Control of the United States recommends as a strategy against conventional capacity the use of non-sterile disposable long-sleeved gowns for the management of patients with suspected or confirmed COVID in March 2020. Among the strategies for contingency capacity, it recommends, among other measures: cancel non-urgent procedures that require the use of gowns, change the isolation gowns to those that are reusable, and consider the use of "coveralls" (as a way to replace the eventual shortage of disposable long-sleeved gowns). In case of considering the protective overalls, the collaborators should receive training and practice in their use before making their clinical use.

In the document of Guide for the critical care of serious adult patients with coronavirus (COVID-19) in the Americas of the PAHO it is established that "For health workers in contact with patients with COVID-19 who perform procedures that generate aerosols in the ICU or are in a unit where these procedures are performed without adequate ventilation or independent negative pressure system, it is





recommended to use fitted respirators (N-95, FFP2 or equivalent), rather than surgical masks, in addition to other personal protective equipment (gloves, gown and eye protection such as face shields or safety glasses). "Regarding gowns, they establish that gowns are recommended to be "single use, fluid resistant, disposable, length to mid-calf to cover the upper part of the boots, preferably light colors to better detect possible contamination, thumb / finger loops or elastic cuff to anchor sleeves in place. Option 1: Resistant to fluid penetration: EN 13795 high performance, or AAMI PB70 level 3 or higher, or equivalent. Option 2: penetration-resistant blood-borne pathogens: AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent." The protective suit complies with these PAHO regulations.

Slightly more clearly, in its April 2020 release, Public Health of England recommends disposable liquidresistant coveralls as an alternative to anti-flow long-sleeved gowns for aerosol-generating procedures or when working in acute areas of increased risk, such as the intensive care unit, the emergency resuscitation area, areas where non-invasive ventilation or CPAP is used, operating rooms where aerosols are generated, and endoscopic procedure units. They emphasize the need for personnel to be trained in the safe removal of protective overalls.

# In table 1, the recommendations of different organizations regarding the use of overalls and neck or head protectors are attached:

Table 1. Summary of recommendations for the use of coveralls, coveralls, hoods or neck covers as part of the protection elements in different organizations and countries for patient care in emergencies, triage and ICU in pandemic due to SARS-CoV-2 (COVID-19 disease)

Institute / Organization	Long- sleeved gown	Anti-fluid apron	Coveralls	Neck covers	OBSERVATIONS
Colombian Association of Critical Care	YES	YES	YES	YES	Recommends the use of protective overalls and a disposable gown on top to perform aerosol-generating procedures, based on units lacking a negative pressure system
Society of Critical Care Medicine	YES	NO	NO	NO	No mention is made regarding protective overalls, anti-fluid long-sleeved gowns are assumed
Center for Disease Control	YES	YES	YES	No	Suggests consider protective overalls when there is a shortage of an anti-





					fluid long-sleeved gown Does not mention neck covers
World Health Organization (WHO)	YES	YES	NO	NO	Does not recommend the use of protective overalls or head or neck covers
Panamerican Health Organization (PAHO)	YES	YES	YES	YES	Recommends the use of protective overalls implicitly in areas of exposure or high risk
Ministère des Solidarités et de la Santé (Francia)	YES	YES	NO	NO	No mention of protective overalls or neck covers
Robert Koch Institute (Germany)	YES	YES	YES	YES	The use of Overalls is according to the criteria for each health institution.
European Centre for Disease Prevention and Control	YES	YES	NO	NO	No mention of protective overalls or neck protectors
Institute for Healthcare Improvement (IHI)	YES	YES	NO	NO	No mention of protective overalls or neck protectors
The American Academy of Family Physicians (AAFP)	YES	YES	YES	YES	The AAFP strongly supports the use of PPE for family physicians, based on their clinical judgment.
Public Health (United Kingdom)					Recommends protective overalls as an alternative to anti-flow long- sleeved gowns for procedures that
NHS & Salud Pública UK	YES	YES	YES	YES	generate aerosols or





				when working in acute areas of higher risk
Consenso IETS-ACIN (Ministerio de Salud / IETS / Asociación Colombiana de Infectología)	YES	NO	NO	

## GRAPHICAL EVIDENCE OF THE USE OF EPP

The photographic record of some hospitals in the world in which the use or not of the mentioned protective overalls is evidenced is attached:

Evidence of gown wear:



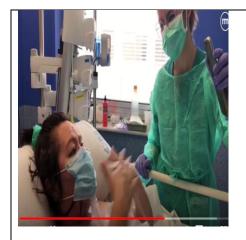
Freiburg University Hospital in Germany<a href="https://www.youtube.com/watch?v=amksmwdxTuM">https://www.youtube.com/watch?v=amksmwdxTuM</a>



Reina Sofía Hospital of Córdoba -42 ICUhttps://www.diariocordoba.com/noticia s/cordobalocal/coronavirus-cordoba-uci-reina-sofia-disena-medidas-atender-pacientes-mas-graves-covid-19\_1362556.html







Hospital October 12<sup>th</sup>
<a href="https://www.youtube.com/watch?ti">https://www.youtube.com/watch?ti</a>
<a href="mailto:me\_continue=87&v=1cYr0NMi5m0">me\_continue=87&v=1cYr0NMi5m0</a>
<a href="mailto:kfeature=emb\_logo">kfeature=emb\_logo</a>



Prague, Czech Republic. https://www.businessinsider.com/coronavirus-nyc-more-than-doubled-its-icu-capacity-in-weeks-2020-4



is inside intensive care at University College Hospital in London https://www.bbc.com/news/av/healt h-52190961/coronavirus-inside-anicu-fighting-covid-19



San Carlos clinical hospital in Madridhttps://www.youtube.com/watch?v=vBITCIFOdDE

Evidence of the use of overalls for protection:







South Korean ICU https://www.bbc.com/news/av/world-asia-52046339/coronavirus-inside-a-covid-19-intensive-care-unit



Vall d'Hebron – 56 UCI https://www.lavanguardia.com/vida/20200 408/48389995507/entramos-uci-vallhebron-coronavirus-cada-hora-intubarpaciente-covid-19-pandemia-video-seolv.html



Jn paciente con Covid-19 es atendido en la UCI del hospita Barcelona)

Hospital Germans de Trias i Pujol Badalona- Barcelona <a href="https://www.20minutos.es/noticia/4221154/0/dostercios-fallecidos-europa-coronavirus-hombres/">https://www.20minutos.es/noticia/4221154/0/dostercios-fallecidos-europa-coronavirus-hombres/</a>





### **RECOMMENDATIONS**

- 1. For the prevention and control of SARS CoV2 infection, administrative and engineering measures should take precedence as well as hand washing and surface cleaning measures; the use of PPE is considered complementary.
- Protective coverall is suggested as an alternative in the event of a shortage of anti-flow longsleeved gowns for procedures that generate aerosols when working in acute areas of higher risk (such as intensive care unit, emergency resuscitation area, areas where uses non-invasive ventilation or CPAP, operating rooms where aerosols are generated, and endoscopic procedure units).
- 3. For the correct implementation of the use of protective overalls, specific training, designated areas and accompaniment for supervision and instructions are recommended to guarantee their placement and removal without risk of contamination; in addition to establishing protocols for its reuse and disposal. The technical characteristics of antifluid fabrics are important to guarantee biosecurity, in the annex to this summary of evidence are the applicable standards and conclusions to guide the acquisition process from a technical-scientific point of view.

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# Annex Technical Specifications of Antifluid Fabrics for gowns

To determine what specifications antifluid fabrics require, an identification of the hazard and risks of exposure should be made initially.

According to CDC1 the movement of a microorganism through protective clothing materials depends on several factors:

- Physical and chemical properties of the fabric: includes factors such as pore size thickness and repellency.
  - Shape, size and other characteristics of microorganisms: includes factors such as morphology, motility and adaptation to environmental extremes.
- Carrier Characteristics: Includes factors such as surface tension, volume, and viscosity.
  - External factors: includes factors such as physical, chemical and thermal stresses.

However, it is very important to note that the WHO currently reports that respiratory infections can be transmitted through respiratory droplets, which have a diameter of 5 to 10 micrometers ( $\mu$ m), and also through droplet nuclei, whose diameter is less than 5  $\mu$ m. According to the available data, the COVID-19 virus is transmitted mainly between people through contact and respiratory droplets. Transmission through droplets occurs by close contact (less than one meter) of a person with respiratory symptoms (for example, cough or sneeze), or through fomites in the immediate environment of an infected person. Therefore, the COVID-19 virus can be spread by direct contact with an infected person and indirectly, by contact with surfaces in their immediate environment or with objects that they have used (for example, a stethoscope or a thermometer). 2 Droplet transmission is different from airborne transmission, as the latter takes place through droplet nuclei that contain microbes.

The droplet nuclei, which are less than 5  $\mu$ m in diameter, can remain in the air for long periods and reach people who are more than a meter away. Airborne transmission of the COVID-19 virus may be possible in specific circumstances and locations where procedures are performed or treatments that can generate aerosols are administered (for example, endotracheal intubation, bronchoscopy, open





aspiration, administration of a drug by nebulization, manual ventilation before intubation, turning the patient to the prone position, disconnecting the patient from a ventilator, non-invasive ventilation with positive pressure, tracheostomy and cardiopulmonary resuscitation).

Taking into account the above mentioned, the relevance of the different standards proposed for protective gowns can be determined. Although there are several regulations listed below, some of them refer to the external penetration of liquids, including in several cases viruses through blood but not by droplets that must be taken into account in the case of SARS CoV-2 and that would have a higher surface tension to blood therefore a lower risk of penetration.

Table 1. Commonly used test methods to determine the effectiveness of the gown barrier and overalls

Test	Challenge	Determinati	Interpretation of results
		on	
AATCC 42 Impact penetration	Water	It determines the ability of a material to resist the penetration of water under the impact of spraying. Lower results (grams of weight gain	Lower results (grams of weight gain on blotting paper) mean material more resistant to water penetration
		on blotting paper) mean material more resistant to water penetration	
AATCC 127 hydrostatic Pressure	Water	a material to resist the penetration of water under constant contact with increasing pressure	Higher hydrostatic pressure results (in cm or inches of water column) mean material more resistant to water penetration
IN 20811 hydrostatic Pressure	Water	the ability of a material to	Higher hydrostatic pressure results (in cm or inches of water column) mean material more resistant to water penetration





		penetration of water under constant contact with increasing pressure	
EN ISO 22612 Resistance to microbial penetration: dry	Contaminated Powder ( <i>Bacillus Subtilis</i> )	the ability of	Lower Colony Forming Units (CFU) means material more resistant to dry microbial penetration
IN ISO 22610 Resistance to microbial penetration: wet	Suspension of Staphyl ococcus aureus	determines the resistance of a tissue to the	
Synthetic blood penetration test to ASTM F1670	Subrogated Blood	the ability of a material to resist the penetration of synthetic blood in constant contact	"Pass" means the material is resistant to synthetic blood penetration at a pressure of 2 psi (13.8 kPa)
Synthetic blood penetration test ISO 16603	. •	the ability of a material to resist the penetration	Material that passes this test at a higher-pressure level (kPa) is considered more resistant to synthetic blood penetration at the specified pressure level (pressure range: 0 kPa to 20 kPa)
Viral penetration test ASTM F1671		blood in	"Pass" means the material is resistant to viral penetration at a pressure of 2 psi (13.8 kPa)





	the ability of a material to resist the penetration of a microorganis m under constant contact.	
Viral penetration test IS O 16604	determines the ability of a material to	The material that passes this test at a higher-pressure level (kPa) is considered more resistant to viral penetration at the specified pressure level (pressure range: 0 kPa to 20 kPa)

Likewise, the World Health Organization establishes in the "List of priority medical devices in the context of COVID -19", the following essential requirements for medical protection gowns:

- Single use, disposable. Fluid resistant.
- Length: up to mid-calf (covering the top of the boots).
- Light colors (to better detect possible contamination. With thumb holes or elastic on the sleeve s.
- Compliance with EU PPE Regulation 2016/425 and EU MDD Directive 93/42 / EEC; o FDA Class I or II MD or equivalent; or EN 13795; or AAMI PB70 or its equivalent.

ANSI / AAMI PB70 and EN 13795 are used for gowns and EN 14126 and NFPA 1999 are used for coveralls. However, there are several differences between the ANSI / AAMI PB70 and EN 13795 surgical gown ratings, because test methods and performance requirements cannot be directly compared; similarly, it is difficult for overalls to directly compare test methods and performance specifications.

In the United States,	A	ANSI		/		AAMI
PB70 establishes a classifi	cation system for	protective	suits (including	surgical o	gowns and iso	lation go
wns) that are used in healt	hcare facilities bas	sed on the	ir liquid barrier p	erforman	ice.	Page
break	Table	2.	ANSI	/	AAMI	PB
70:12 classification of the b	parrier performand	e of surgion	cal gowns, other	protectiv	e clothing, sur	gical dr
apes, and drapery accesso	ories	_				

Table 2. ANSI / AAMI PB 70:12 classification of the barrier performance of surgical gowns, other protective clothing, surgical drapes, and drapery accessories1





Leve I	Proove	Liquid Challenge	Result	Barrier Expected effectivity
	AATCC 42 Penetrati on Impact		4.5 g	Minimum resistency to water (certain resistency to water spraying)
2		Water	1.0 g	Low resistency to water (water spray resistance and some resistance to water penetration under constant contact with increasing pressure
	AATTCC 127 Hydrostat ic Pressure		20m	
	AATCC 42 Penetrati on Impact	Water	1.0g	Moderate resistance to water (resistant to water spray and some resistance to water penetration in constant contact with increasing pressure)
	AATTCC 127 Hydrostat ic Pressure		50m	
		Blood	Without penetration to 2 psi (13.8 K pa)	Blood penetration resistance and virus (2 psi)
	Viral penetrati on test ASTM F1671 (for surgical and isolation gowns)	Bacteriopha ge Phi-X 174	Without penetration to 2 psi (13.8 K pa)	





## Salto de página

On the other hand, EN 13795 evaluates main aspects such as:

Characteristic	Testing	Unit	Performance	Standar	High		
	Method				Performance		
			Critical Area	Less	Critical Area	Less	
			of product	Critical	of product	Critical	
				area		area	
Liquid Penetration Resistency	In 0811	cmHO	20	10	100	10	
Microbiane Penetration resistency	In ISO	UFC	N/A	300	N/A	300	
Dry	22612						
Microbiane Penetration resistency:	In ISO	Yo	2.8	N/A	6.0	N/A	
Wet	22610						
Powder challenge concentration							ı
test conditions and 30 minutes of							ı
vibrating time 6.0 for the purposes							
of this European standard means:							
without penetration. 6.0 that is the							
reachable and maximum rate							

In any case,

a review recently presented by Cochrane, indicates that compliance with European Standards or ISO, for clothing and fabrics used in protective suits and virus permeability, are useful to technically determine protection sufficiently against highly infectious diseases.

. However, the risk of contamination depends on more than just these technical factors.

In simulation studies, contamination occurred in almost all forms of intervention and control.

To choose between PPE types, there is very little certainty and evidence, based on single exposure si mulation studies1. On the other hand, in Colombia there are no mandatory technical standards to demonstrate the permeability of the fabrics used in protective go wns, additionally non-

sterile gowns are not considered medical devices and therefore do not require sanitary registration. In conclusion, the necessary fluid resistance characteristics of the fabrics used in protective gowns for SARS-CoV-2 will depend on the danger and risks of exposure.

In this sense, it is understood its contagion through respiratory droplets that occurs by close contact (I ess than one meter) of a person with respiratory symptoms (for example, cough or sneeze), or through fomites in the immediate environment of an infected person. Therefore, the virus protection standards that are based on the permeability with artificial blood, would not correspond to the surface tension, having a greater similarity to the fulfillment of water permeability requirements. This agrees with the recommendations of the WHO, in the sense of indicating the Standard EN 13795; or AAMI PB70 or its equivalent, as a desirable standard and the degree of penetration, depending on the related hazards. Finally, it is clear that the risk of contamination will depend on other factors, rather than on these technical aspects.



