1	Intensive care medical procedures are more complicated, more			
2	stressful, and less comfortable with Ebola personal protective			
3	equipment: A simulation study			
4				
5	Guillaume Grillet ^a , Nicolas Marjanovic ^b , Jean-Marc Diverrez ^c , Pierre Tattevin ^{a,*} , Jean-			
6	Marc Tadié ^a , Erwan L'Her ^{c,d}			
7	^a Service des Maladies Infectieuses et de Réanimation Médicale, Hôpital Pontchaillou, rue			
8	Henri Le Guilloux, 35000 Rennes, France			
9	^b Service d'Accueil des Urgences, Hôpital de la Cavale Blanche, 29200 Brest, France			
10	^c Institut de Recherche Technologique B-Com, 25 rue Claude Chappe, 29280 Plouzané,			
11	France			
12	^d Service de Réanimation Médicale, Hôpital de la Cavale Blanche, 29200 Brest, France ;			
13	Centre de Simulation en Santé, Université de Bretagne Occidentale ; LATIM INSERM UMR			
14	1101, Brest, France			
15	Corresponding author: Pierre Tattevin, Service des Maladies Infectieuses et de Réanimation			
16	Médicale, Hôpital Pontchaillou, rue Henri Le Guilloux, 35000 Rennes, France; tel +33			
17	299289564 ; Fax + 33 299282452			
18	<i>E-mail addresses:</i> guillaume.grillet@chu-rennes.fr; nicolas.marjanovic@chu-brest.fr; jean-			
19	marc.diverrez@chu-brest.fr; pierre.tattevin@chu-rennes.fr; jean-marc.tadie@chu-rennes.fr;			
20	erwan.lher@chu-brest.fr			
21	Running Title Impact of Ebola personal protective equipment			
22	Keywords			

- 23 Ebola virus disease; Intensive care; Protective equipment; Stress; Workload; Task
- 24 performance

25 **To the editor**

26 Ebola virus disease (EVD) is a life-threatening condition. Appropriate management of 27 organ failure, hemodynamic instability, and metabolic disorders significantly improves 28 survival. This implies that life-saving procedures are undertaken in case of need, including 29 endotracheal intubation, nasogastric tube placement and central venous catheter (CVC) insertion. The challenge is to provide high quality of care to patients with life-threatening 30 31 EVD, under optimal safety conditions for health care workers, *i.e.* with reinforced personal 32 protective equipment (PPE), ensuring that no exposure to patient blood or any other body fluid occur [1-3]. We assessed the impact of Ebola PPE use on the performance of senior ICU 33 34 physicians during common intensive care unit (ICU) procedures, and on the workload, in a 35 simulation environment.

The study was performed in our simulation department. Thirteen volunteer senior ICU 36 37 physicians performed orotracheal intubation and nasogastric tube placement on a simulation 38 mannequin (Megacode Kelly Sim, LaerdalTM, Stavanger, Norway), and CVC insertion on a 39 dedicated echogeneous task trainer (CAE Healthcare[™], St Laurent, QC, Canada). The use of ultrasound for CVC insertion was left to the discretion of the physician. Each participant had 40 41 to complete all procedures twice, one with standard protection, and one with Ebola PPE, in an 42 order determined by the randomization. The Ebola PPE consisted in a N95 Particulate Filtering Face Respirator, with large protective glasses, surgical hood, fluid resistant 43 44 coveralls, boot covers, and two pairs of gloves, as recommended [4]. All sequences were 45 recorded using an HD video camera. Participants were equipped with a thoracic belt for the monitoring of heart rates and chest wall movements to record upper body tilt (Zephyr 46 BioHarness 3TM, Annapolis, USA). Procedural time was independently assessed by two 47 reviewers, using a video tagging software (StudioCodeTM, Marseille, France). Equipment 48 49 ergonomics were assessed for each participant after the complete course, using a Likert scale

50 asking three questions for each procedure: i) stress during the task (from 1, major stress to 5, 51 no stress); ii) equipment's ease of use (from 1, very difficult to 5, very easy), and iii) comfort 52 (from 1, very uncomfortable to 5, very comfortable). The task workload was assessed using 53 the National Aeronautics and Space Administration Task Load Index (NASA-TLX), a 54 multifaceted tool for perceptual (subjective) workload evaluation [5], based on a weighted average of ratings on six subscales: mental demand, physical demand, temporal demand, 55 56 performance, effort, and frustration. These steps provide a global score from 0 to 100, higher 57 values indicating heavier workload. All tests were performed using Statview 5.0.1 (SAS 58 Institute, Cary, NC, USA). Mann-Whitney and Kruskall Wallis non-parametric tests were 59 used for procedural time analysis and Likert scale comparisons. Physiological parameters 60 comparison used a Laird and Ware regression test with R [6], and the lme4 library [7]. 61 NASA-TLX data were compared using a non-parametric Wilcoxon test. Data are provided as 62 median [interquartile ratio], unless specified otherwise.

Global success rate for the complete procedure course was 100% with standard 63 protection, and 85% with Ebola PPE (p=0.48). Higher degrees of body tilt were measured 64 with Ebola PPE, as compared to standard protection (p < 0.05). In most cases, procedures were 65 66 rated as easier, and more comfortable with standard protection, than with Ebola PPE (Table 1). Median global task load index was higher with Ebola PPE, as compared to standard 67 protection, for orotracheal intubation (44.3 vs. 20.3, p=0.007), and nasogastric placement 68 (38.9 vs. 25.6, p=0.008, Figure 1). For CVC insertion, global task load index was not 69 significantly different for the whole group (58.6 vs. 37.6, p=0.182). However, differences 70 71 were significant for the 7 physicians who performed ultrasound-guided procedures (54.9 72 [34.7-67.1] vs. 29.5 [14.1-50.1], p=0.028), but not for the 6 physicians who didn't use ultrasound (76 [52.9-84.9] vs. 46.3 [36-58.9], p=0.686). Physical demand was higher with 73 Ebola PPE as compared to standard protection for nasogastric tube placement (2.5 [0.9-5.2] 74

3

vs. 0.6 [0.4-0.9], *p*=0.022), and CVC insertion (3.6 [1.8-13.4] vs. 1.2 [0.4-2.5], *p*=0.009), but
nor for orotracheal intubation.

77 Although these findings are not unexpected given the constraints and discomfort of Ebola PPE reported by health care workers, the application of simulation procedures in this 78 79 study provided evidence-based, and quantitative data, on the impact of currently recommended Ebola PPE on these life-saving procedures. This innovative model may be used 80 81 to compare different combinations of Ebola PPE, and select those with lower impact on 82 quality of care and workload, while still ensuring effective protection. Person-to-person transmission of Ebola virus primarily occurs through contact with infected patients' fluids [1-83 3]. During ICU procedures, often performed in emergency, physicians are at risk for 84 contamination [7-9], and the use of a dedicated Ebola PPE is mandatory. All health care 85 providers potentially involved must receive adequate training for correct use of Ebola PPE, 86 87 including safety (i.e. no breaches in protection), and efficacy (i.e. being able to provide appropriate care with maximum ease, dexterity, comfort, and minimal stress) [3,4]. Because 88 the management of patients with EVD is a complex process, simulation plays a major role in 89 the preparation of health care worker to anticipate the difficulties that may arise while taking 90 91 care of patients suspected of, or confirmed with, EVD [10].

Our study has limitations. First, sample size was limited. However, this study was 92 93 performed in a homogeneous group of senior, experienced ICU physicians. Second, the use of 94 manikins, in a simulated environment, is merely a proxy for the actual clinical scenario. However, only simulated conditions enables to perform a standardized, randomized study, 95 96 with prospective collection of an extensive set of data, and extensive post-hoc debriefing. We 97 found that common ICU procedures are more complicated, more stressful, and less 98 comfortable, with Ebola PPE. These necessary protections increase workload, and may be 99 associated with increased risk of severe adverse events, either for the patient (procedure

100	failure, complications), or the physician (Ebola virus transmission). Ebola PPE should be				
101	evaluated by simulation and ergonomics studies as the one reported herein, to optimize the				
102	selection of Ebola PPE that would ensure both the safety of health care workers, and the				
103	quality of care for patients suspected of EVD.				
104					
105	Transparency declaration				
106	All authors: no potential conflict of interest.				
107					
108	Acknowledgment				
109	The authors thank all the physicians from the French Medical Intensive Care Training Team				
110	of Western France, and the dedicated technicians from the simulation department of Brest				
111	University of Medicine, who made this study possible.				
112					
113	Highlights				
114	• This simulation study analyzed the impact of Ebola personal protective equipment (PPE)				
115	on ICU procedures				
116	• Nasogastric tube, central venous catheter, and orotracheal intubation are adversely				
117	affected by Ebola PPE				
118	• This model may be used for the selection of Ebola PPE with limited impact on ICU				
119	procedures				
120					
121					

	ACCEPTED MANUSCRIPT					
122	References					
123 124	1.	Shears P, O'Dempsey TJD. Ebola virus disease in Africa: epidemiology and nosocomial transmission. J Hosp Infect. 2015;90(1):1–9.				
125 126	2.	Cohen J. Infectious diseases. When Ebola protection fails. Science. 2014;346(6205):17–8.				
127 128 129	3.	Rouveix E, Madougou B, Pellissier G, Diaougah H, Saley SM, de Truchis P, et al. Promoting the Safety of Healthcare Workers in Africa: From HIV Pandemic to Ebola Epidemic. Infect Control Hosp Epidemiol. 2015;36(3):361–2.				
130 131 132	4.	WHO WHO updates personal protective equipment guidelines for Ebola response[Internet]. WHO. [cited 2015 Aug 13]. Available from: http://www.who.int/mediacentre/news/releases/2014/ebola-ppe-guidelines/en/				
 133 134 135 136 	5.	Hart SG, Staveland LE. Development of NASA-TLX (Task Load Index): Results of Empirical and Theoretical Research. In: Meshkati PAH and N, editor. Advances in Psychology [Internet]. North-Holland; 1988 [cited 2015 Aug 13]. p. 139–83. Available from: http://www.sciencedirect.com/science/article/pii/S0166411508623869				
137 138	6.	Dean CB, Nielsen JD. Generalized linear mixed models: a review and some extensions. Lifetime Data Anal. 2007;13(4):497–512.				
139 140 141	7.	Zhang H, Lu N, Feng C, Thurston SW, Xia Y, Zhu L, et al. On fitting generalized linear mixed-effects models for binary responses using different statistical packages. Stat Med. 2011;30(20):2562–72.				
142 143 144	8.	Wolf T, Kann G, Becker S, Stephan C, Brodt H-R, de Leuw P, et al. Severe Ebola virus disease with vascular leakage and multiorgan failure: treatment of a patient in intensive care. Lancet. 2015;385(9976):1428-35.				
145 146 147	9.	Markovic-Denic L, Maksimovic N, Marusic V, Vucicevic J, Ostric I, Djuric D. Occupational exposure to blood and body fluids among health-care workers in Serbia. Med Princ Pract Int J Kuwait Univ Health Sci Cent. 2015;24(1):36–41.				
148 149	10.	Gaba DM. Simulation as a critical resource in the response to Ebola virus disease. Simul Healthc J Soc Simul Healthc. 2014;9(6):337–8.				

150

- 151 Figure 1. National Aeronautics and Space Administration Task Load Index (NASA-TLX) for
- 152 orotracheal intubation (1A), nasogastric tube placement (1B), and central venous catheter
- 153 insertion (1C), with Ebola or standard personal protective equipment



156 157 **Table 1.** Comparison of physiological conditions and ergonomics during

 common intensive care medical procedures with Ebola personal protective

 equipment (PPE), and with standard protection

		Standard		
Variables ^a	Ebola PPE	protection	<i>p</i> value	
	(n=13)	(n=13)		
Overall				
Duration, sec	289 [236-440]	167 [139-407]	0.53	
Heart rate, bpm	102 [95-111]	93 (90-104]	0.057	
Upper Body tilt, degrees	14 [12-15]	7 [6-9]	0.044	
Orotracheal Intubation				
Duration, sec ^b	34 [30-46]	35 [24-38]	0.36	
Stress	4 [3-4]	4 [4-5]	0.018	
Ease of use	4 [1.8-4]	5 [4-5]	0.01	
Comfort	3 [1.8-4]	4 [4-5]	0.01	
Nasogastric Tube placement ^b				
Duration, sec	37 [26-61]	30 [22-40]	0.08	
Stress	4 [3-4.5]	4 [4-5]	0.11	
Ease of use	4 [2.5-4]	4 [4-5]	0.12	
Comfort	2.5 [1.5-4]	4 [4-5]	0.008	
Central Venous Catheter				
Duration, sec ^c	199 [123-355]	128 [81-368]	0.79	
Stress	3 [2-3.25]	4[3-5]	0.013	
Ease of use	2 [1.75-3.25]	4 [2-4.25]	0.13	
Comfort	1 [1-2]	4 [3-4]	0.003	

^a values are median [interquartile range]

^b one participant could not complete orotracheal intubation with Ebola PPE, and was excluded for orotracheal intubation duration measurement and nasogastric tube questionnaire (not completed).

^c two participants could not insert central venous catheter with Ebola PPE and were excluded for central venous catheter duration measurement.

Stress, Ease of use and comfort during the procedures are Likert scales from 1 to 5: For Stress during the task, 1 for major stress and 5 no stress; for ease of use, 1 very difficult and 5 very easy; for comfort, 1 very uncomfortable and 5 very comfortable.

158