SYSTEMATIC REVIEW

Impact of Clinician Personal Protective Equipment on Medical Device Use During Public Health Emergency: A Review

LT Hanniebey D. Wiyor, PhD; LCDR James C. Coburn, MS; Karen L. Siegel, MS

ABSTRACT

The aim of this systematic review is to evaluate the impact of personal protective equipment (PPE) on medical device use during public health emergency responses. We conducted a systematic literature search of peer-reviewed journals in PubMed, Web of Science, and EBSCO databases. Twenty-nine of 92 articles published between 1984 and 2015 met the inclusion criteria for the review. Although many medical device use impacts were reported, they predominantly fell into 3 categories: airway management, drug administration, and diagnostics and monitoring. Chemical, biological, radiological, and nuclear (CBRN)-PPE increased completion times for emergency clinical procedures by as much as 130% and first attempt failure rates by 35% (anesthetist) versus 55% (non-anesthetist). Effects of CBRN-PPE use depend on device, CBRN-PPE level, and clinician experience and training. Continuous clinical training of responders in CBRN-PPE and device modifications can improve safety and effectiveness of medical device use during public health emergency response.

Key Words: medical device, emergency response, public health, personal protective equipment, CBRN

Emergency medical responders are skilled at assessing and treating patients in high-stress and time-critical situations. However, many emergency situations fall outside of even their normal operations. Chemical, biological, radiological, and nuclear (CBRN) exposure can come from a variety of man-made and natural disasters. The most common include terror attacks, industrial accidents, earthquakes, extreme weather, and infectious diseases (H1N1 and H5N1 influenza), severe acute respiratory syndrome (SARS), cholera, Ebola hemorrhagic fever, enterovirus-71 [EV71]). Personal protective equipment (PPE) for disaster workers came to the forefront after the 1995 Sarin gas attack in a Tokyo subway by a religious cult. Health-care professionals became casualties in that incident because they lacked proper CBRN-PPE.[1,2] Similarly, the 2014 Ebola virus disease outbreak in West Africa (Sierra Leone, Guinea, Nigeria, and Liberia) killed more than 200 doctors, nurses, and healthcare workers due to lack of access to proper protective gear and training.[3] There has been a resurgence of interest in the topic due to these and other recent events. Many disease outbreaks and disasters may require PPE but no existing device can detect all possible CBRN agents[4] or communicable diseases. Wearing CBRN-PPE is one of many safety precautions that can ensure that healthcare responders and receivers do not become victims.

There are 2 primary CBRN-PPE classification systems in the United States from the Occupational Safety and Health Administration (OSHA) / Environmental Protection Agency (EPA) and the National Fire Protection Association Standards (NFPA). These 2 systems use 4 categories of protection: OSHA/EPA Levels A-D and NFPA Class 1-4. In both instances, the level of protection increases with decreasing number or letter, meaning Level A and Class 1 are the most protective.[5,6] Level C or greater PPE are recommended in a CBRN-contaminated zone. Briefly, Level A comprises a fully encapsulated and chemically resistant suit, gloves, boots, and self-contained breathing apparatus (SCBA); Level B uses a nonencapsulated chemically resistant suit, boots, gloves, and SCBA; Level C also uses a nonencapsulated suit with air filter apparatus and butyl gloves; Level D includes coveralls, chemical resistant gloves and boots, head protection, face shield, and mask. In contrast, the U.S. military designates mission oriented protective posture (MOPP) gear, in which higher numbers denote greater protection. MOPP 1-3 fall in between OSHA Levels D and C.[7] MOPP 4 is equivalent to OSHA Level C, and it may be modified to include either a powered air purifying respirator or SCBA to make it equivalent to OSHA Level B.[8]

Other PPE classification systems also exist for different occupational hazards. Typical clinical PPE used for the tasks described in this article do not conform to the OSHA classification system. Standard PPE used in clinical and hospital settings are rated for their ability to prevent or reduce the risk of disease transmission both from the patient to the user and vice versa. They are also rated to be used in controlled environments, such as a clinic or operating room. In the event of emergency medical response in field or austere conditions, or in any response to a CBRN event, U.S. personnel should refer to the OSHA or NFPA PPE standards. Outside of the United States, the European[9] and British[10] standards have been adopted for CBRN-PPE with similar protection levels to the United States.

Many general and specialized PPE selection guides exist and are beyond the scope of this article. For example, OSHA publishes 1 for CBRN responders and hospital-based first receivers.[11] In general, OSHA Level A protection is worn when the highest level of respiratory, skin, eye, and mucous membrane protections is needed. Level B protection is selected for respiratory protection, but a lesser level of skin and eye protection is needed. Level C protection is selected when the type of airborne substance is known, and the criteria for using air-purifying respirators are met. Level D protection is primarily a work uniform and is used for nuisance contamination. For radiation, chemical, and/or biological hazards referred to as "combined hazard" event or unknown contaminant, Level A PPE ensemble is recommended for first responders. Furthermore, for radiological incidents where PPE can be effective, Level C PPE often provides adequate protection for first responders.[12] Generally, PPE Level B or C offers adequate protection for biological or chemical hazards. However, higher levels of PPE are recommended for unknown or specific high-level hazards.[12]

A national survey of U.S.[13] and Canadian[14] EMS providers showed that more than half have received training in CBRN response. However, CBRN-PPE use poses numerous physiological, psychological, and biomechanical effects,[7,8] impacting medical device use safety and effectiveness.[15] The physiological and psychological stress associated with the use of CBRN-PPE can reduce working capability by as much as 30%.[16] Training in mass casualty and pandemic response as well as adherence to recommended guidelines[5,6,17] has been shown to improve performance. The purpose of this study was to systematically review literature examining the impact of CBRN-PPE on the efficiency (time) and accuracy (error rate) of medical device use during simulated and actual emergency medical responses. We believe our study is the first systematic literature review of CBRN-PPE effects on medical device use during emergency response.

METHODS

Data Sources and Search Strategy

We conducted a systematic literature search of publications describing PPE use with medical devices in PubMed, Web of Science, and EBSCO using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses framework.[18] We included publications in English from January 1984 through February 2015. A combination of keywords within the title or abstract were used, including: impact (effect, issues, human factors, or ergonomic issues), personal protective equipment or PPE (chemical protective suit, chemical protective ensembles, mission oriented protective posture or MOPP, anti-chemical protective gear, chemical protective clothing, hazardous materials or HAZMAT suits), medical device (devices, medical instrument, medical equipment, armamentarium, airway management medical devices, diagnostic and/or monitoring medical devices), and public health emergency (public health disaster, public health crisis, mass casualty events, pre-hospital, chemical, biological, radiological, nuclear, or explosive or CBRNE).

Inclusion and Exclusion Criteria

To be included in the present review, articles had to satisfy the following criteria: (1) published in peer-reviewed journal, book, or commission report; (2) contained both PPE and at least 1 medical device; (3) included at least 1 emergency medical procedure or task; and (4) included subjective and/or objective assessment based on the interactions pertaining to the device use with the PPE. The abstracts were screened for inclusion criteria, and uncertainties about inclusion were referred for a second opinion. The selected articles were then reviewed. The focus for the review was to identify each study's PPE, medical device(s), use environment, tasks, impacts, and limitations. We also extracted other identifying information to assist in categorization. The first author's corresponding address was used to identify each paper's affiliated country. Furthermore, we used the study participants' background and journal title to classify a study as either civilian or military. Study participants were evaluated on task performance using normalized criteria based on each study's dependent variables. This provides a window into the interactions between medical devices, the intended users, and the use environment. Some objective task performance variables were error rates, task completion times, percentage of task completion, accuracy, safety, and success rates. Subjective response variables were ease-of-use (the ability of user to readily and successfully use a product/tool to perform a task), comfort, and task difficulty.

Articles were excluded for the following reasons: abstract only (in conference proceeding), non-clinical task, quality (durability or reliability) and safety or use compliance of PPE, and inapplicable PPE (eg, night vision googles). Inclusion and exclusion discrepancies were unanimously resolved by the authors. The characteristics of the studies meeting inclusion criteria are summarized in Tables 1, 2, and 3.[15,19–46]

RESULTS

We retrieved 92 titles from all sources (Figure 1). Of these, 29 studies published between 1984 and September 2015 were identified for review based on the predefined inclusion and exclusion criteria (Figure A). While the studies were

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Table 1

Summary of Study Characteristics, Findings, and Limitations on the Impact on CBRN-PPEs on Drug Delivery Medical Device Use

				Impact and Findings
Author(s)	**PPE Description**	**Medical device**	**Participants (*n*) & Task**	**Drug and Fluid Delivery**
Castle et al. (2010)[19]	UK NHS CBRNE-PPE Level C	Syringes: Aurum (A) & Minijet (MJ); Ampoules: glass (GA) & Plastic (PA)	Nurses (28) and paramedics (52) draw up drug using the four different techniques	• Gloves reduced finger mobility by decreasing dexterity and accuracy • 63.8% longer completion time in CBRN-PPE • A or MJ were rated as the safest and easy to use techniques
Berkenstadt et al. (1999) [34]	UK NHS CBRNE –PPE Level C and Level D (control)	IV Infusion set, Tourniquet, 18-gauge Venflon cannula	60 military emergency medical technicians performed IV cannulation in field on healthy soldiers	• CBRN-PPE prolonged task completion times and decreased success rates • Time for task completion was 303s for control and 351s for CBRN-PPE • Success rate was 56% for CBRN-PPE
Borron et al. (2011) [35]	CBRN PPE Levels A,B,C and D	EZ-IO® Infusion System	18 medical professionals performed IO placement on anesthetized goats	• Task completion times in Level B were longer than other levels • First responders and receivers placed IO lines successfully in 100% and 91% of cases, respectively.
Ben-Abraham et al. (2003)[29]	CBRN-PPE Level C	Bone Injection Gun (BIG)	20 inexperienced emergency care physicians performed IO emergency access using uncooked turkey femurs	• Increased completion times and reduced success rate occurred with protective gear • Success rate was greater than or equal to 80% with full CBRN-PPE
Lamhaut et al. (2010)[45]	CBRN-PPE Level C	EZ-IO® Vidacar infusion system and IV Infusion system	25 pre-hospital emergency professionals performed vascular access procedures with each system	• The time to establish IO procedures was significantly shorter than that for IV procedures under both no CBRN and CBRN conditions • Under No-CBRN-PPE conditions, the time to establish IO infusion was shorter than the equivalent IV time • Under CBRN-PPE conditions, the time for IO infusion was shorter than for IV infusion
King et al.(1984)[37]	CBRN-PPE Level C and standard clothes	Hypodermic needles, tourniquets, and IV-IS	6 military medical specialists performed 8 basic medical tasks	• Task completion time and number of errors were significantly impacted by MOPP- 4 (CBRN PPE –Level C). • The highest number of errors were observed involving IV infusion system in CBRN-PPE Level C
Brinker et al.(2012) [20]	CBRN-PPE Level-C	EZ-IO and IV Infusion	15 paramedics carried out IV and IO procedures	• The CBRN-PPE did not have impact on treatment times
Suyama et al.(2007)[15]	CBRN-PPE Level C	EZ-IO® and IV infusion systems	22 EMTs performed antecubital IV and anterior tibial IO	• Reduced hand and finger dexterity caused significant differences between IO and IV

Summary of responses published between 1984 and February 2015 in English-language peer-reviewed journals.

TABLE 2

Summary of Study Characteristics, Findings, and Limitations on the Impact on CBRN-PPEs on Airway Management Medical Device Use

Author(s)	PPE Description	Medical Device	Participants (*n*) & Task	Impact and Findings: Airway Management
Burns Jr, et al. (2010)[36]	CBRN-PPE Level C and standard uniform	King LT supralaryngeal airway and endotracheal tube (ETT)	47 fire medics with 1-20 years of service performed emergency airway management procedures	•CBRN-PPE use significantly increased the time to successful placement of ETT but not King LT
Flaishon et al. (2004)[32]	CBRN-PPE Level C	LMA, cuffed ETT and pulse oximeter (PO)	15 anesthetists with 2-5 years residency performed intubation procedures	•The CBRN-PPE significantly impacted speed and success rates in performing LMA and ETT procedures
Shin et al.(2013)[46]	CBRN-PPE Level C	Pentax-Airwayscope Macintosh laryngoscope	31 experienced doctors performed tracheal intubations on an advanced life support simulator	• CBRN-PPE significantly increased the time required to complete ETT in both devices
Castle et al. (2010)[42]	UK NHS CBRN-PPE Level C	ETT with either the Thomas Tube Holder TM or cotton tape	Anesthetist (15), physician (29), and paramedic (23). performed ETT	• Task completion was faster and easier with Thomas Tube Holder. • Time to apply the Thomas Tube Holder was 29.02s compared to 58s for the tape and clinicians rated it easier to use
Wedmore et al. (2003) [38]	CBRN-PPE Level C	Intubating (iLMA): Fastrach, ETT, bag-valve-mask apparatus (BVM), and Miller laryngoscope (ML)	16 physicians performed endotracheal intubation using manikin head	• ML had a success rate of 78% significantly less than the 100% success rate with iLMA • Intubation using the iLMA was significantly faster than ML
Greenland et al. (2007) [39]	CBRN-PPE Level C and standard uniform	Laryngoscope, ETT, iLMA, Fastrach, fiberoptic bronchoscope	Consultant (4) and trainee (14) anesthetists, performed tracheal intubation	• CBRN-PPE increased task difficulty particularly fibreoptic intubation using a fiber-optic bronchoscope • 67 % of subjects rated CBRN-PPE as the main contributing factors to task difficulty
Goldick et al. (2002) [33] Goldick et al. (2002) [33]	CBRN-PPE Level C	LMA and cuffed ETT	Anesthetists (20) and non-anesthetists (20) performed airway management procedures	• CBRN-PPE negatively impacted speed and success rates for ETT • Failed intubation occurred 35% (anesthetist) vs. 55% (non-anesthetist)
Ben-Abraham et al. (2004)[30]	CBRN-PPE Level C	LMA and 7.5 mm cuffed ETT	Anesthetists (10) and non-anesthetists (10) performed airway management procedures	• Slower task completion times and high failure rates were observed in ETT with non-anesthetists in full anti-chemical protective gear
Castle et al. (2011)[25]	CBRN-PPE Level C	Cuffed ETT and laryngoscope	48 final year paramedic students performed intubation procedures on manikins	• CBRN-PPE had a negative impact on intubation performance (success rate and speed)
Castle et al..(2010)[43]	CBRN-PPE Level C	Laryngoscope and ETT	Anesthetists (15), physicians (29), and paramedics (23) performed airway management procedures	• CBRN-PPE and patient position significantly affected successful skill completion times • Intubation on the floor took significantly longer task performance (45.9 s slower) with 9.33 % failure rates
Coates et al. (2000)[26]	TST -Sweden chemical protection suit with a respirator	BVM, ETT, and Guedel oropharyngeal airway (GOA)	10 doctors and 10 nurses performed airway management, ETTi, and defibrillation	• Difficulties were observed during tasks that required a high degree of fine movement and tactile feedback • The main difficulty was in sensing the effectiveness of the BVM seal around the face. Nurses ratings for tasks difficulty using BVM was doubled than physicians mean ratings. Less difficulty ratings for intubation with ETT than GOA
Castle(2010) [24]	CBRN-PPE Level A	Supraglottic airway devices as listed above	Anesthetic (12) physician (16) pre-hospital care doctor (7) performed airway management procedures	• The overall ratings for devices ease of use was 64% • Familiarity with device-LMA (32%); I-gel (32%), PLMA (24%), intubating LMA (24%)
Castle et al. (2011) [22]	UK NHS CBRNE-PPE Level C	7 Supraglottic airway devices	58 paramedics inserted each supraglottic airway device	• CBRN-PPE impacted insertion time and ease of insertions • The slowest insertion time was 65s observed with Combitube^{TM} • The I-gel was the fastest at 19s in and the ease of ratings of 94%
Ben-Abraham et al. (2008) [31]	CBRN-PPE Level C	Cuffed oropharyngeal airway (COPA)	12 anesthetists with 2-5 years of residency, placed COPA in 24 anesthetized patients	• Time for COPA correct placement and fixation of the devices was almost doubled when anesthetists were wearing protective gear

Summary of responses published between 1984 and February 2015 in English-language peer-reviewed journals.

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TABLE 3

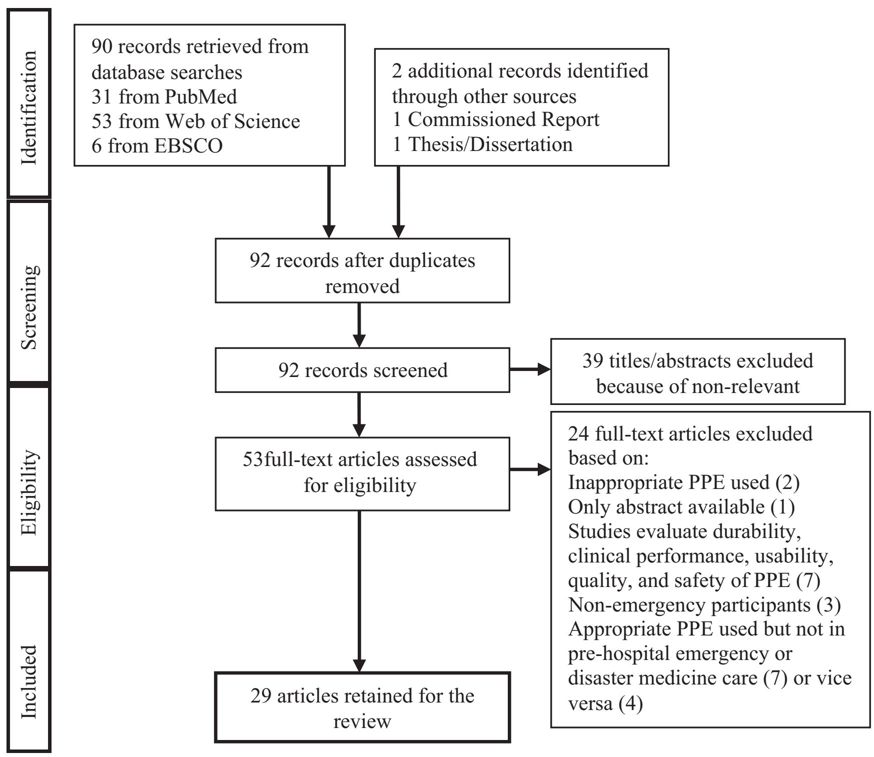
Summary of Studies Evaluating Both Drug Delivery and Airway Management Medical Device Use

				Impact and Findings	
Author(s)	**PPE Description**	**Medical device**	**Participants (*n*) & Task**	**Drug and Fluid Delivery**	**Airway Management**
Castle et al. (2009) [23]	UK NHS CBRNE-PPE Level C	Endotracheal tube (ETT) laryngeal mask airway (LMA), IV, and IO cannula	Pre-hospital physicians (29), resuscitation officers (20), and anesthetists (15) performed airway management, IV, and IO	• IO cannulation was 90 s faster than IV.12% of IV cannulation were unsuccessful in first attempts	• LMA placement was 45 s faster than ETT • 8% of intubation and were unsuccessful in first attempts
Udayasiri et al. (2007)[40]	CBRN-PPE Level C	Needle thoracostomy, GOA, IV cannula, and MJ	18 clinicians performed airway management, IV cannulation, and administered antidote	• CBRN-PPE use increased time to successful completion of resuscitation skills where fine motor skills are required, namely administration of epinephrine subcutaneously and IV cannulation	• CBRN-PPE used did not impair resuscitation skills requiring gross motor skills for tracheal intubation procedure
Schumacher et al. (2013)[28]	Air-purifying respirators (APR) and powered air-purifying respirator-hoods (PAPR-hood)	BVM, GO airway, EZ-IO laryngoscope, and IV-IS	16 paramedics performed emergency pediatric life support (EPLS) inside an ambulance for task	• Respiratory devices increased cardiopulmonary resuscitation time and impacted the overall task completion time; significant differences were found in: time IO cannulation for PAR vs. PAPR-hood	• Significant differences were found in: time to lung inflation using an for PAR vs. PAPR-hood • The most time-consuming task carried out was the implementation of successful endotracheal intubation (87-92 s)
MacDonald et al. (2006) [44]	CBRN-PPE Level C PPE	Laryngoscope, ETT, 10 ml syringe and stylet (ETTi), IV-IS	16 Paramedics performed four resuscitative tasks	• CBRN-PPE use increased time to successful completion of resuscitation skills where fine motor skills are required, namely administration of epinephrine subcutaneously and IV cannulation	• CBRN-PPE impaired resuscitation skills involving bag and mask ventilation
Garner et al. (2004)[44]	CBRN-PPE Levels A-D	GO airway, LMA, 10 mL syringe, a bougie, BVM, laryngoscope	Paramedics (11) and physicians (5) performed airway procedures, antidote administration, and cannula insertion	• There was a significant difference in time taken to perform procedures in differing levels of personal protective equipment involving the use of 10 mL syringe A significantly greater time to complete procedures was observed in CBRN-PPE Level A as compared with Levels C and D	• There was a significant difference in time taken to perform procedures in differing levels of personal protective equipment in airway management skills and associated equipment • Significant differences were found in: time to lung inflation using an endotracheal tube
Schumacher et al. (2008)[27]	CBRN-PPE PPE Level C: binocular mask & panoramic visor	GOA, ETT, defibrillator, IV cannula, laryngoscope	22 Anesthetists performed monitoring, airway management, and drug administration	• Longer treatment times for binocular respirator. • Participants preferred the panoramic visor in terms of visual orientation but rated the binocular mask as more comfortable; the fastest time as achieved in IV access and drug administration	• Longer treatment times for binocular respirator. The most time-consuming task was tracheal intubation (taking panoramic visor (43s) and binocular visor (45 s), but there were no failed attempts
Brinker et al. (2007) [21]	Binocular and panoramic visor	BVM, GO airway, ETT, laryngoscope, and IV/IO	14 UK paramedics performed management of the airway and monitoring, ETTi, IV for atropine, & defibrillation	• Respiratory protection devices had a negligible effect on treatment times. There was no significant difference in treatment times between the groups wearing respiratory protection and the controls. Generally, IO access administration was 3 s faster than IV access administration	• Respiratory protection devices had a negligible effect on treatment times. There was no significant difference in treatment times between the groups wearing respiratory protection and the controls*

Summary of responses published between 1984 and February 2015 in English-language peer-reviewed journals.

FIGURE 1

PRISMA[18] Flowchart Showing the Review Process for Studies That Assessed the Impact of CBRN-PPE on Medical Device Use, 1984 -2015.



performed all over the world, the United Kingdom (10),[19–28] Israel (6),[29–34] and the United States (5)[15,35–38,52–54],published the majority of the studies. Australia (3),[39–41] South Africa (2),[42,43] Canada (1),[44] France (1),[45] and South Korea (1)[46] published the rest. Only 3 (10%) of the studies were performed by military organizations. All the studies selected for inclusion took place in a setting that mimicked realistic situations, involving trained healthcare responders with an average of 1 to 15 years of relevant clinical experience using medical devices for emergency responses. The September 11 and 18, 2001, terrorist and anthrax attacks marked a sharp increase in CBRN preparedness research, as denoted by a subsequent increase in publications (Figure 2). Studies of medical device use with CBRN-PPE primarily focused on 2 main areas: drug administration and airway management. Diagnostics and monitoring, although less often evaluated, also factors into PPE use and training decisions and was included in this discussion.

Taxonomy of PPE Impact on Device Use

Impact on the Administration of Fluids and Drugs

Intravenous (IV) and intraosseous (IO) drug administration were the most reported procedures. Task completion times were reported to be approximately 1.2-2.5 times longer at first attempt when participant performed a task involving IO or IV cannulation in CBRN-PPE Level C or greater conditions. In addition to increased task completion times, the most often reported difficulty associated with additional PPE was reduced dexterity for fine motor tasks. In total, 11 studies reported on the impact of PPE on drug administration. Each study reported significant negative impacts on task completion times. Seven studies assessed IO[15,23,29–31,35,45], infusion, 6 evaluated IV[15,20,21,23,34,44], drug administration, and 3 studies included subcutaneous drug administration.[19,42,44], Many of the reviewed studies showed that peripheral IV catheter insertion is often difficult, resulting in more frequent failures (12% compared with 3% of IO), with an average increase in completion time of 90 s compared with IO.[20,23,34,45] Berkenstadt et al.[34] reported 56% IV placement failure rates in real patients. A 2009 study by Castle et al.[23] showed that the mean task completion times at first attempt for 64 prehospital clinicians in surgical attire verses CBRN-PPE Level C doubled in the IO cannulation and tripled for IV cannulation tasks.

Impact on Airway Management

Twenty-two studies assessed the impact of CBRN-PPE on airway management tasks. Most studies reported that CBRN-PPE

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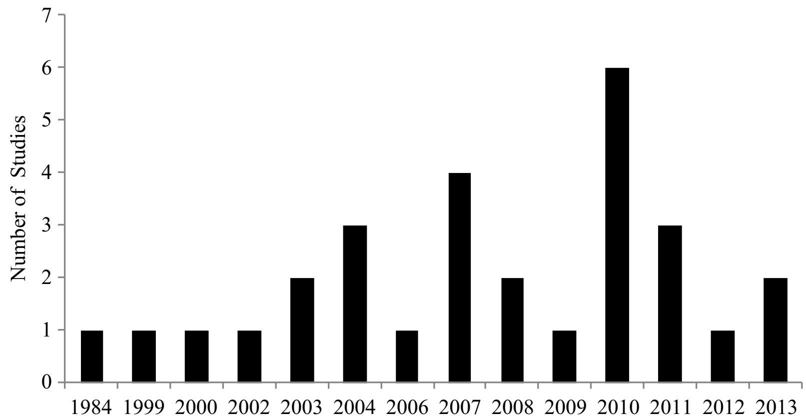
FIGURE 2

Number of Studies Carried out in 7 Countries From 1984 to 2015.



significantly degraded airway management task performance. CBRN-PPE prolonged the time to successfully complete airway management tasks and increased failure rates regardless of specialization and task experience (time-on-task). Significant task performance degradation was observed when a high level of the CBRN-PPE was used. Twenty studies used Level C CBRN-PPE, 1 study used all the CBRN-PPE Levels (A-B-C-D)[44], and 1 used Level B[48] to assessed task performance. On the average, compared to with performance in their standard uniform, participants took about approximately 78.6 secondss and 75.6 seconds s longer to successfully complete intubation task in Level- C and Level- D conditions,[27,45] respectively. Again, manual dexterity played a role in decreased performance. CBRN gloves impeded both gross and fine hand movements.

Castle[24] reported that 64% of participants chose 1 of the studied airway devices to use while in CBRN-PPE, primarily based on its ease-of-use or insertion speed. The reviewed studies generally reported approximately 8-12% failure rates and doubled task completion times of airway management procedures when participants were wearing CBRN-PPE at first attempts.[25,28,33,38,39] However, 1 study reported that second attempts reduced task completion times and failure rates compared with the first attempts (eg, 9.33% to 4%).[43] This is still greater than the average failure rate without CBRN-PPE. Castle et al.[25] evaluated the effect of responders' positioning on intubation performance (ie, task successfully completed) and found that in standard uniform, performance was similar in all 4 positions, but variable in CBRN-PPE: trolley (100%), sitting (88.8%), kneeling (81.2%), and laying (62.5%). Responder experience also affected task performance. Goldik et al.[33]reported that the first attempts of both anesthetists and non-anesthetists failed at the significant rate of 35% and 55%, respectively for endotracheal intubation.

Diagnostic and Monitoring Interaction Impact

Two studies [21,27], investigated diagnostic and monitoring device use while wearing CBRN-PPE. Devices such as pulse oximeters, automated external defibrillators (AEDs), and patient monitors took a longer time to use successfully by participants in CBRN-PPE. Both Brinker et al. and Schumacher et al. determined that there was very little difference in the time required to perform diagnostic tasks with either the binocular or panoramic visor respirators compared with a control.[21,27]

DISCUSSION

The year 1984 was selected as the initial year for this review because of increased awareness of CBRN safety due to 2 major CBRN events that year. The largest bioterrorism attack in the United States was carried out in Dalles, Oregon, United States, where terrorists sickened 751 people with salmonella spread through restaurant salad bars. In the same year, a gas leak at a Union Carbide pesticide plant in Bhopal, India, caused one of the worst chemical disasters in modern history.[47,48] However, only 1 article in 1984 met this review's inclusion criteria. Additional articles published during this time were not included, because they assessed elements of PPE effectiveness, responder fatigue, and training for a variety of applications that did not involve the use of medical devices.

The attack of September 11, 2001 followed by the London Underground bombings of July 7, 2005 focused national attention on nations' and international preparedness and responses for attacks. In a show of national resilience, nations increased their spending on preparedness and response to public health emergencies. In 2007, the United States alone invested 5 billion dollars into public health emergency preparedness.[41] After the September 11th attacks, European member countries also increased their spending on security and public safety.

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Spending averaged between 1.0% and 2.5% of national gross domestic product and this increased (at European Union [EU] level) by 163% for fiscal framework from 2007-2013[49] There was a corresponding increase in mass casualty preparedness and response research publications during this time. With recent world events and the Ebola outbreak in West Africa, even more attention has been brought to PPE for healthcare providers and emergency responders. The Centers for Disease Control and Prevention has also updated its Guidance on Personal Protective Equipment to include new donning and doffing instructions to decrease the chance of infection during the transition from contaminated to safe areas.[50]

Administration of Fluids and Drugs

Vascular access techniques require fine hand and finger motor skills[19,29,34,43] and a firm, strong grip,[51,52] which are often difficult to achieve in CBRN-PPE. While visual field occlusion had some effect on performance, the CBRN-PPE that had the most impact on these activities were the gloves. Bulky, thick gloves with liners provide greater user protection but reduce fine finger motor movements and finger grip strengths. Coupled with the small sizes and designs of IV device components, this can compromise clinical task performances. Manual or semi-IO techniques and devices (eg, battery-powered IO-insertion devices) can reduce failure rates and completion time compared with procedures done with standard IV.[15,30,35,45] Handheld semi-automatic devices can provide good grip strength mostly unaffected by user dexterity, but they are more specialized.

Overall, these studies support the conclusion that IO access is easier and faster to achieve than IV access with minimal skill and practice when using CBRN-PPE. These data would not likely be sufficient to support switching standard emergency response techniques from IV to IO. In contrast to IV delivery, fluid delivery through an IO port (depending on the type and location) can be extremely painful to the patient. Manufacturers often recommend using a local anesthetic before delivering IO fluids. This tradeoff may be outweighed when using CBRN-PPE. However, a recent review of IO access techniques across several use cases and disaster scenarios by Burgert[53] found that emergency response organizations might improve overall responses by generally adopting IO techniques.

Airway Management

Airway management techniques also require dexterity and tactile sensation to be performed effectively. Adequate oxygenation and sufficient ventilation are crucial when delivering emergency care during mass casualty incidents. The safety and efficacy of the devices in this category depends on complex controls and user experience, which is characterized by time on task and tacit knowledge. Increased frequency of training may be the best method to optimize airway management performance procedures in CBRN environments. Furthermore, airway management devices provide little or no visual information and audio feedback. In an instance where the oral cavity is obstructed due to secretion or vomitus (a common occurrence), insertion may be further hindered due to the CBRN-PPE. Greenland et al.[39] found that improving visual feedback with a bronchoscopic eyepiece or attached camera/video screen mitigated significant differences in task completion times and failure rates between CBRN-PPE and standard uniforms.

Diagnostics and Monitoring

Wearing CBRN-PPE may cause a short delay in diagnosis, but when coupled with the additional factors described here, it can have a subsequent impact on downstream treatment. Diagnostic and monitoring devices often include screens and audio feedback for menu-driven and user-prompted operation. Input interfaces include keypads, touchscreens, keyboards, etc. CBRN-PPE can reduce the user-experienced fidelity and functionality of these interfaces. Mask lenses reduce peripheral vision (tunnel vision) and fogging and high internal reflection of face piece may impair device user's ability to read device interfaces in real-world conditions. From a visual perspective, anti-glare coatings on screen surfaces, newer high brightness /contrast displays, and attention-getting visual alarms can also increase the usability of standard medical devices without modification to the original device. Attachment straps for devices and styli are invaluable when multitasking with limited tactile feedback in the fast-paced emergency response environment.

As with the other activities, large CBRN gloves make it very difficult for users to interact with many standard diagnostic and monitoring devices such as defibrillators, pulse oximeters, or electrocardiographs. Styli are often used to activate touchscreens with gloves, but they can also have dexterity drawbacks. Mitigating strategies that can be designed into the devices include larger push buttons, push buttons with high relief, adequate separation between buttons, and lower activation force.

Overall Lessons

During prehospital or disaster emergency conditions, there is a risk of prolonged completion times and increased failure rates for both airway management and drug administration procedures. Estimates place the rate at which a responder can treat victims of a disaster at 12 min per patient[17]; longer dwell times on 1 patient reduces the next victim's probability of survival. The impact of CBRN-PPE on the efficiency (time) and accuracy (error rate) may reduce treatment rate and thereby reduce overall survival from a mass casualty disaster. The physiologic effects of CBRN-PPE are well understood.[63–66] Training in full equipment includes work-rest cycles, additional hydration, and physiologic monitoring. However, the effects of CBRN-PPE on medical procedure completion are less frequently assessed. Across the reviewed studies, the success rate of disaster emergency medical procedures was significantly impacted

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by the users' CBRN-PPE. Clinical procedures ranged from gross motor tasks such as chest compressions, defibrillation, and fine motor skill tasks such as venous access and intubation.

Collectively, these studies support the firm conclusion that a user's CBRN-PPE can have a substantial detrimental effect on clinical task performance due to deterioration of tactile and visual input. CBRN-PPE butyl gloves (range: 7-14 mil thickness) reduce both fine (finger) and gross (hand) motor movements and tactile sensation, which are vital skills for airway management and cardiovascular access. Thus, the ease-of-use of these devices is primarily dictated by the minimum dexterity needed to operate them effectively. Purchasing or 3D printing accessory devices may reduce the dexterity needed to operate a device and, therefore, increase its usability. 3D printing has become inexpensive and relatively easy to do for groups of all sizes. It also allows people and groups to design assistive strategies that allow people with reduced mobility to use standard devices. Assistive devices are often used for patients with mobility deficits [54–57] but may also be useful to responders using displays and diagnostics with reduced mobility. Overlays to mask areas of touchscreens that should not be activated or larger buttons that cover a control surface and actuate the smaller buttons below are easy to make with 3D printing. While many clinicians are not experts in creating these kinds of assistive devices, hospitals, universities, and community centers often have facilities that can design and create 3D printed parts and adaptations.

Proper selection of CBRN gloves can also increase user dexterity and reduce the impact on clinical performance. Teixeira et al.[58] in 1990 and Scanlan et al.[59] in 2004 both reviewed a selection of CBRN gloves, identifying user preferences for fitted, seamless, single layer gloves among participants. Improvements in polymers are increasing the dexterity in CBRN-PPE but consistent training will always be an important factor in making any system work.[60–63] Likewise, PPE selection guides offer suggestions based on user activities and experience.

Limitations

Every effort was made to provide a comprehensive review of the available literature through the use of a systematic literature search strategy and abstraction processes. The included studies covered recruited subjects from several medical specialties with varied years of experience, giving this review broad applicability. However, this review has several limitations. Only articles published in English were reported and sample sizes varied among the studies. A handful of studies reported small sample sizes without statistical justification, whereas other studies did not perform statistical analyses. Furthermore, variability in the experimentation regarding test bed models and simulated environment may have had an impact on device use, limiting the ability to compare across studies. The studies used different test bed models: 23 (79%) studies used mannequin, 4 (14%) human, and 3 (7%) animal. Each test bed model has some level of realism in physiological response. Additionally, these experiments did not attempt to replicate the chaotic conditions that characterize mass casualty events and, hence, the level of urgency and stress felt by the participants was likely reduced. Despite the numerous device use impacts by the CBRN-PPEs during public health emergencies, it was possible to conduct the review and develop a taxonomy of device use impacts.

CONCLUSION

We believe this is the first comprehensive review to examine the impact of CBRN-PPE on device use during emergency response. Despite the limitations on available research and/or published literature, our findings suggest that CBRN-PPE use by first responders can significantly delay task completion times and increases failure rates in pre-hospital emergency clinical procedures. The simplest strategy to mitigate the impact of CBRN-PPE on medical device use is to increase training and practice in CBRN environments. Long-term, development of ruggedized hardware and design modifications to medical devices and accessories may improve the usability, safety, and efficacy of medical devices during public health emergency response.

Practicing in CBRNE-PPE should place the intended device users in real settings or represented simulated use environments so that tasks performance experiences can be obtained and thoroughly evaluated. Measurable parameters include use difficulties, use hesitations, confusion, close calls, and failures. User feedback interactions can also be gained using neutrally worded open-ended questions regarding impact of the CBRN-PPE on the overall device use experience, the most challenging user tasks, and instances of all task failures, difficulties, and hesitations The data/information should be used to inform and support the design of device-user interface including but not limited to component, buttons, data trends, size, color, screen size, display. The testing data should also be used to design new training materials or revise existing training materials.

Additionally, we recommend device developers and designers appropriately apply human factors principles, particularly the analysis and evaluation of use-related risk, to identify the weaknesses and strengths associated with device users, device use environments, and device user interfaces. This process will ensure that medical device use during emergency response is not vulnerable to potentially harmful use errors that could lead to patient/user work-related injuries, sub-optimal use, such as delay in therapy or diagnosis. Finally, we conclude that more research collaborations between device manufacturing companies and government regulatory agencies are needed to determine user interface specifications, CBRN-PPE material characterizations and specifications to optimize the efficacy of device use during emergency response.

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About the Authors

Office of Device Evaluation, Center for Device and Radiological Health, U.S. Food and Drug Administration, Maryland (Dr Wiyor, Mr Coburn); Human-Device Interaction Lab, Division of Biomedical Physics, Office of Science and Engineering Laboratories, Center for Device and Radiological Health, U.S. Food and Drug Administration, Maryland (Mr Coburn) and Office of Research and Development, Department of Veterans Affairs, Washington DC (Ms Siegel)

Correspondence and reprint requests to LT Hanniebey D. Wiyor, PhD, United States Food and Drug Administration, White Oak Campus, 10903 New Hampshire Avenue, CDRH Building 66, Room 2563, Silver Spring, MD 20993 (e-mail: hanniebey.wiyor@fda.hhs.gov).

Conflicts of Interest

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References

1. Nakajima T, Sato S, Morita H, Yanagisawa N. Sarin poisoning of a rescue team in the Matsumoto sarin incident in Japan. *Occup Environ Med.* 1997;54(10):697-701.
2. Suzuki T, Morita H, Ono K, et al. Sarin poisoning in Tokyo subway. *Lancet.* 1995;345(8955):980-981.
3. Diamond D. Ebola has killed more than 200 doctors, nurses, and other healthcare workers since June. 2015. https://www.forbes.com/sites/dandiamond/2014/10/15/ebola-has-already-killed-more-than-200-doctors-nurses-and-other-healthcare-workers/#6a85fb03640e. Accessed June 14, 2014.
4. Ramesh AC, Kumar S. Triage, monitoring, and treatment of mass casualty events involving chemical, biological, radiological, or nuclear agents. *J Pharm Bioallied Sci.* 2010;2(3):239-247.
5. Gershon RR, Vandelinde N, Magda LA, et al. Evaluation of a pandemic preparedness training intervention for emergency medical services personnel. *Prehosp Disaster Med.* 2009;24(6):508-511.
6. Scott JA, Miller GT, Issenberg SB, et al. Skill improvement during emergency response to terrorism training. *Prehosp Emerg Care.* 2006; 10(4):507-514.
7. Tavares W. Impact of terrorist attacks on hospitals. *J Emerg Nurs.* 2018;44(2):188-190.
8. McIsaac JH. *Hospital Preparation for Bioterror: A Medical and Biomedical Systems Approach.* Amsterdam: Elsevier; 2010.
9. National Standards Authority of Ireland. SR CWA 16106 : 2010: PPE for chemical, biological, radiological and nuclear (CBRN) hazards. https://infostore.saiglobal.com/en-us/Standards/SR-CWA-16106-2010-874408_SAIG_NSAI_NSAI_2078872/2010. Accessed June 9, 2019.
10. British Standard Institute. BS 8467:2006 Protective clothing. Personal protective ensembles for use against chemical, biological, radiological and nuclear (CBRN) agents. Categorization, performance requirements and test methods. https://shop.bsigroup.com/ProductDetail/?pid=000000000030127794. Accessed June 9, 2019.
11. Occupational Safety and Health Administration (OSAH). OSHA best practices for hospital-based first receivers of victims from mass casualty incidents involving the release of hazardous substances. https://www.osha.gov/dts/osta/bestpractices/html/hospital_firstreceivers.html. Accessed June 9, 2019.
12. Goldfrank L, Manning FJ. *Preparing for Terrorism: Tools for Evaluating the Metropolitan Medical Response System Program.* Washington, DC: National Academies Press; 2002.
13. Reilly MJ, Markenson D, DiMaggio C. Comfort level of emergency medical service providers in responding to weapons of mass destruction events: Impact of training and equipment. *Prehosp Disaster Med.* 2007;22(4):297-303.
14. Kollek D, Welsford M, Wanger K. Chemical, biological, radiological and nuclear preparedness training for emergency medical services providers. *Can J Emerg Med.* 2009;11(4):337-342.
15. Suyama J, Knutsen CC, Northington WE, et al. IO versus IV access while wearing personal protective equipment in a HazMat scenario. *Prehosp Emerg Care.* 2007;11(4):467-472.
16. Krueger GP. Psychological and performance effects of chemical-biological protective clothing and equipment. *Mil Med.* 2001;166(Suppl 2):41-43.
17. Hsu EB, Jenckes MW, Catlett CL, et al. Effectiveness of hospital staff mass-casualty incident training methods: A systematic literature review. *Prehosp Disaster Med.* 2004;19(3):191-199.
18. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. *PLoS Med.* 2009;6(7):e1000100.
19. Castle N, Bowen J, Spencer N. Does wearing CBRN-PPE adversely affect the ability for clinicians to accurately, safely, and speedily draw up drugs? *Clin Toxicol.* 2010;48(6):522-527.
20. Brinker A, Gray S, Michel S, et al. Vascular access skills during cardiopulmonary resuscitation in hazardous environments: 13AP2-4. *Eur J Anaesthesiol (EJA).* 2012;29:191-192.
21. Brinker A, Gray SA, Schumacher J. Influence of air-purifying respirators on the simulated first response emergency treatment of CBRN victims. *Resuscitation.* 2007;74(2):310-316.
22. Castle N, Pillay Y, Spencer N. Insertion of six different supraglottic airway devices whilst wearing chemical, biological, radiation, nuclear-personal protective equipment: A manikin study. *Anaesthesia.* 2011;66(11):983-988.
23. Castle N, Owen R, Hann M, et al. Impact of chemical, biological, radiation, and nuclear personal protective equipment on the performance of low-and high-dexterity airway and vascular access skills. *Resuscitation.* 2009;80(11):1290-1295.
24. Castle N. Care after chemical, biological, radiation or nuclear events. *Emerg Nurse.* 2010;18(7):26-36.
25. Castle N, Pillay Y, Spencer N. What is the optimal position of an intubator wearing CBRN-PPE when intubating on the floor: A manikin study. *Resuscitation.* 2011;82(5):588-592.
26. Coates MJ, Jundi AS, James MR. Chemical protective clothing; a study into the ability of staff to perform lifesaving procedures. *J Accid Emerg Med.* 2000;17(2):115-118.
27. Schumacher J, Runte J, Brinker A, et al. Respiratory protection during high-fidelity simulated resuscitation of casualties contaminated with chemical warfare agents. *Anaesthesia.* 2008;63(6):593-598.
28. Schumacher J, Gray SA, Michel S, et al. Respiratory protection during simulated emergency pediatric life support: A randomized, controlled, crossover study. *Prehosp Disaster Med.* 2013;28(01):33-38.
29. Ben-Abraham R, Gur I, Vater Y, et al. Intraosseous emergency access by physicians wearing full protective gear. *Acad Emerg Med.* 2003;10(12): 1407-1410.
30. Ben-Abraham R, Weinbroum AA. Laryngeal mask airway control versus endotracheal intubation by medical personnel wearing protective gear. *Am J Emerg Med.* 2004;22(1):24-26.
31. Ben-Abraham R, Flaishon R, Sotman A, et al. Cuffed oropharyngeal airway (COPA) placement is delayed by wearing antichemical protective gear. *Emerg Med J.* 2008;25(12):847-850.
32. Flaishon R, Sotman A, Ben-Abraham R, et al. Antichemical protective gear prolongs time to successful airway management: A randomized, crossover study in humans. *Anesthesiology.* 2004;100(2):260-266.

33. Goldik Z, Bornstein J, Eden A, et al. Airway management by physicians wearing anti-chemical warfare gear: Comparison between laryngeal mask airway and endotracheal intubation. *Eur J Anaesthesiol*. 2002; 19(03):166-169.
34. Berkenstadt H, Arad M, Nahtomi O, et al. The effect of a chemical protective ensemble on intravenous line insertion by emergency medical technicians. *Mil Med*. 1999;164(10):737-739.
35. Borron SW, Arias JC, Bauer CR, et al. Intraosseous line placement for antidote injection by first responders and receivers wearing personal protective equipment. *Am J Emerg Med*. 2011;29(4):373-381.
36. Burns JB Jr, Branson R, Barnes SL, et al. Emergency airway placement by EMS providers: Comparison between the King LT supralaryngeal airway and endotracheal intubation. *Prehosp Disaster Med*. 2010;25(1):92-95.
37. King JM, Frelin AJ. Impact of the chemical protective ensemble on the performance of basic medical tasks. *Mil Med*. 1984;149(9):496.
38. Wedmore IS, Talbo T, Cuenca PJ. Intubating laryngeal mask airway versus laryngoscopy and endotracheal intubation in the nuclear, biological, and chemical environment. *Mil Med*. 2003;168(11):876-879.
39. Greenland K, Tsui D, Goodyear P, et al. Personal protection equipment for biological hazards: Does it affect tracheal intubation performance? *Resuscitation*. 2007;74(1):119-126.
40. Udayasiri R, Knott J, McD Taylor D, et al. Emergency department staff can effectively resuscitate in level C personal protective equipment. *Emerg Med Australas*. 2007;19(2):113-121.
41. Garner A, Laurence H, Lee A. Practicality of performing medical procedures in chemical protective ensembles. *Emerg Med*. 2004;16(2):108-113.
42. Castle N, Owen R, Clark S, et al. Comparison of techniques for securing the endotracheal tube while wearing chemical, biological radiological or nuclear protection: A manikin study. *Prehosp Disaster Med*. 2010; 25(6):589-594.
43. Castle N, Owen R, Clarke S, et al. Does position of the patient adversely affect successful intubation whilst wearing CBRN-PPE? *Resuscitation*. 2010;81(9):1166-1171.
44. MacDonald RD, LeBlanc V, McArthur B, et al. Performance of resuscitation skills by paramedic personnel in chemical protective suits. *Prehosp Emerg Care*. 2006;10(2):254-259
45. Lamhaut L, Dagron C, Apriotesei R, et al. Comparison of intravenous and intraosseous access by pre-hospital medical emergency personnel with and without CBRN protective equipment. *Resuscitation*. 2010;81(1):65-68.
46. Shin DH, Choi PC, Na JU, et al. Utility of the Pentax-AWS in performing tracheal intubation while wearing chemical, biological, radiation and nuclear personal protective equipment: A randomised crossover trial using a manikin. *Emerg Med J*. 2013;30(7):527-531.
47. Tucker JB. Historical trends related to bioterrorism: An empirical analysis. *Emerg Infect Dis*. 1999;5(4):498.
48. Bowonder B, Linstone HA. Notes on the Bhopal accident: Risk analysis and multiple perspectives. *Technol Forecast Soc Change*. 1987;32(2):183-202.
49. European Paliament. Directorate-general for internal policies, Policies Department C: Citizens' Rights and Constitutional Affairs. http://www.europarl.europa.eu/RegData/etudes/note/join/2011/453181/IPOL-LIBE_NT%282011%29453181_EN.pdf. 2011. Accessed January 13, 2015.
50. Center for Disease Control and Prevention. Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing). http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html. Vol 20152014. Accessed June 9, 2019.
51. Willms K, Wells R, Carnahan H. Glove attributes and their contribution to force decrement and increased effort in power grip. *Hum Factors*. 2009;51(6):797–812.
52. Hur P, Motawar B, Seo NJ. Hand breakaway strength model—Effects of glove use and handle shapes on a person's hand strength to hold onto handles to prevent fall from elevation. *J Biomech*. 2012;45(6):958-964.
53. Burgert JM. Intraosseous vascular access in disasters and mass casualty events: A review of the literature. *Am J Disaster Med*. 2016;11(3):149-166.
54. Northington WE, Suyama J, Goss FL, et al. Physiological responses during graded treadmill exercise in chemical-resistant personal protective equipment. *Prehosp Emerg Care*. 2007;11(4):394-398.
55. Blacker SD, Carter JM, Wilkinson DM, et al. Physiological responses of police officers during job simulations wearing chemical, biological, radiological and nuclear personal protective equipment. *Ergonomics*. 2013;56(1):137-147.
56. Hostler D, Bednez JC, Kerin S, et al. Comparison of rehydration regimens for rehabilitation of firefighters performing heavy exercise in thermal protective clothing: A report from the Fireground Rehab Evaluation (FIRE) trial. *Prehosp Emerg Care*. 2010;14(2):194-201.
57. Hanson M. Development of a draft British standard: The assessment of heat strain for workers wearing personal protective equipment. *Ann Occup Hyg*. 1999;43(5):309-319.
58. Teixeira RA, Bensel CK. *The Effects of Chemical Protective Gloves and Glove Liners on Manual Dexterity*. Natick, MA: Army Natick Research Development and Engineering Center; 1990.
59. Scanlan S, Roberts W, McCallum R, et al. *A dexterity and tactility evaluation of the Australian Nuclear Biological Chemical (NBC) glove*. Fairbairn, Camberra: Defence Science and Technology Organisation Victoria (Australia) Platform; 2004.
60. Magalhães MJ, de Magalhães ST, Revett K, et al. Chemical, Biological, Radiological and Nuclear (CBRN) protective clothing–A review. In: Proceedings of the International Conference on Global Security, Safety, and Sustainability. ICGS3 2017: ***Global Security, Safety and Sustainability - The Security Challenges of the Connected World***, London, UK, January 18-20, 2017, pp 331-341.
61. Gorji M, Bagherzadeh R, Fashandi H. *Electrospun nanofibers in protective clothing. Electrospun Nanofibers*. Amsterdam: Elsevier; 2017:571-598.
62. Chen P-Y, Zhang M, Liu M, et al. Ultrastretchable graphene-based molecular barriers for chemical protection, detection, and actuation. *ACS Nano*. 2017;12(1):234-244.
63. Moseman J. Are these the right gloves? Solubility & maximum protection. *Prof Saf*. 2016;61(04):40-47.