Validation of Developed Hazmat Suit as Personal Protective Equipment for Medical Workers

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ABSTRACT
In regard to the existing COVID-19 pandemic, adequate personal protective equipment (PPE) is required, one of which is a hazmat suit. This study aimed to produce a validated hazmat suit for medical personnel. This research and development (R&D) used Thiagarajan's theory consisting of four stages along with the needs analysis. The design stage included designing the initial design of the hazmat suit. The development stage covered design implementation and expert validation. The dissemination stage comprised dissemination through the socialization of the use of PPE for volunteers of Kampung Wani Jogo Suroboyo to deal with covid-19 at Lidah Kulon sub-district, Lakarsantri, Surabaya. The results showed that the present study produced four prototypes of hazmat suits named hazmat prototype 1, hazmat prototype 2, hazmat prototype 3, and hazmat prototype 4 along with the used materials, colors, details, sizes, and cloth cares. Kappa's inter-rater reliability index has resulted at 1.0 in an excellent agreement category. This meant that the products assessed for their design, materials, sewing technique, size, usability, comfort, safety, appearance/look, and color combinations had met the requirements as fashionable PPE.

Keywords: *Covid-19, PPE, hazmat suit, validation*

1. INTRODUCTION

The COVID-19 virus was first discovered in Wuhan, China, at the end of December 2019. The virus spreads rapidly and has spread to other regions in China and to several countries including Indonesia. This has led several countries abroad to implement policies to impose lockdowns to prevent the spread of the Coronavirus.

Coronavirus is a collection of viruses that can infect the respiratory system. In most cases, this virus causes only mild respiratory infections such as flu. However, this virus can also cause severe respiratory infections such as lung infections (pneumonia), Middle-East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). However, it was later discovered that the coronavirus was also transmitted from human to human through various ways namely: (1) accidentally inhaling saliva splashes from a sneeze or cough of a COVID-19 patient, (2) holding the mouth or nose without washing hands first after touching objects that are splashed by the saliva of a COVID-19 patient, and (3) close contact with a COVID-19 patient, for example touching or shaking hands. One of the people who are most vulnerable to contracting COVID-19 is medical personnel who treat patients exposed to the virus. Under WHO protocol, medical personnel who treat patients exposed to COVID-19 must use certain equipment. Some types of PPE that are commonly used are masks, eye protection, face shields, medical gowns, medical gloves, headgear, and protective shoes. According to [1], one of the personal protective equipment (PPE) needed during the coronavirus pandemic is the hazmat suit. PPE is a major requirement for medical personnel when handling patients infected with the COVID-19 virus.

The Coronavirus that causes COVID-19 is highly contagious. Therefore, the use of personal protective equipment (PPE) needs to be done to control and prevent Coronavirus infection. PPE is very important to be used by people who often meet COVID-19 patients, for example, medical personnel in hospitals. Personal protective equipment (PPE) is a set of equipment that serves to protect users from certain health hazards or disorders, such as viral or bacterial infections. When used properly, PPE can prevent the entry of viruses or

bacteria into the body through the mouth, nose, eyes, or skin. One of the groups most at risk of contracting infectious diseases, including COVID-19, is medical staff, whether doctors, nurses, or other medical personnel who are in frequent contact with COVID-19 patients. Therefore, medical personnel who frequently come into contact with COVID-19 patients need to use PPE according to standards so that they are protected from Coronavirus infection.

The selection of PPE to prevent Coronavirus infection cannot be done arbitrarily. According to the technical instructions for the use of PPE issued by the Directorate General of Health Services (2020) some criteria must be met in selecting the ideal PPE to prevent and protect the body from exposure to the Coronavirus, namely: (1) can protect against specific hazards (splashes, direct or indirect contact), (2) light and does not restrict movement or cause discomfort, (3) flexible, both reuse (reusable) and dispossible (single use), (4) do not create an additional danger to the user, (5) not easily damaged, (6) meets the PPE standards that have been set, and (7) maintenance and care are easy. Several types of PPE are commonly used by medical personnel in dealing with ODP (people under monitoring), PDP (patients under surveillance), suspect patients (suspected positive), or have been proven positive for COVID-19, one of which is the hazmat suit.

A hazmat suit is an abbreviation of 'hazardous material suit' which means dangerous material because this clothing is protective from hazardous materials so the design is very closed [2]. Quoted from the technical instructions for the use of PPE issued by the Directorate General of Health Services, hazmat clothes can be made of polyester or polyester cotton with designs that cover the entire body including the head, back, and legs [3]. The Hazmat suit is claimed to be able to protect the body from potential exposure to any virus including the coronavirus so that it can protect medical personnel from hazardous materials or substances, such as the coronavirus which can spread through droplets or saliva from infected patients [4].

As one of the personal protective equipment, hazmat clothing has several levels and most of them are designed to be waterproof to ensure that substances or agents do not touch the wearer. Hazmat suits can be grouped according to level based on how much protection they provide, namely level A to level D hazmat suits [5]. Level A hazmat suits are designed to provide a high level of protection against gas vapors, mists, and particles. This outfit is fully shaped by incorporating an SCBA breathing apparatus and a two-way radio used within the garment. Level B is designed by combining splash-protective, chemical-resistant clothing with gloves and boots that can provide level A protection against liquids but are not airtight.

The Hazmat suit level C has the same materials as the previous outfit but still allows for the addition of other respiratory protective equipment such as an air-purifying respirator. These garments are commonly used when decontaminating a patient or victim. While the Hazmat suit level D is not good at protecting the body from exposure to chemicals, it requires separate face protection for this level. Therefore, the hazmat suit is made using certain materials. Especially for making hazmat suits, other types of materials used generally also tend to be different from everyday materials and can be adapted to the needs of the wearer [6-7]. With this in mind, it is necessary to develop validated PPE for medical personnel. That is, having aspects or indicators following the requirements of a PPE hazmat suit.

There are specifications for Hazmat Test Methods according to WHO and CDC as quoted from the Standard Recommendations for the Use of PPE for handling Covid-19 issued by the Covid-19 Handling Task Force, namely: infectious agents (EN 14126), standard protective clothing for emergency conditions (NFPA 1999), penetration of fluids (AATCC 42), hydrostatic pressure (AATCC 127), penetration of blood (ASTM F1670), penetration of blood-borne pathogens (ASTM F1671), penetration of blood and body fluids (ISO 16603), resistance to bacteria and viruses (ISO 16604) [8]. The purpose of this study was to produce PPE (hazmat suit) according to the design and validation.

2. METHODS

This study was development research that aimed to produce validated PPE for medical personnel in dealing with the corona pandemic. This development research used the model from [9] covering define, design, develop, and disseminate. The flow of the Thiagarajan development model can be described in Figure 1.

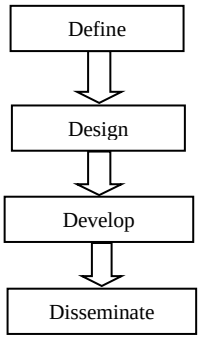

Figure. 1. Thiagarajan's Development Research Model

The procedure for developing Personal Protective Equipment (PPE) for medical personnel in the context of controlling the coronavirus as shown in Figure 1 could be explained as follows.

2.1. Define Stage

This stage showed a preliminary study in the form of a needs analysis consisting of what was meant by PPE and the materials used (availability, type, price, quantity, and time). The types of PPE used by medical professionals were analyzed to determine which level of PPE would be developed, designed, and assessed through expert validation. Thus, this stage was important for the selection of the type of PPE and the materials to be used.

2.2. Design Storage

His stage aimed to design the initial design of PPE. The material used was spun bound gradation 65 with the characteristics of a waterproof, washable, and hazmat wear pack model. In addition, various sizes of PPE were also designed. Figure 2 and Figure 3 show the PPE jumpsuit coverall, which had parts of the headgear, front zipper, wrist and leg wrinkles, and water repellent.

Figure. 2. Coverall Jump Suit PPE

Figure. 3. Standardized PPE Design Size

2.3. Develop Stage

At this stage, the implementation of the design and validation test was undertaken. The implementation of the design was done by making several PPE designs with consistent all sizes. The manufacture of PPE was carried out at the Clothing Design Lab, PKK Department, Faculty of Engineering, Unesa. From the three product variants, product validation tests were carried out by experts, namely doctors and nurses. The validation results were then used for product improvement so that a validated product was produced.

There were four hazmat prototypes developed, namely the hazmat prototype 1, hazmat prototype 2, hazmat prototype 3, and hazmat prototype 4. The four hazmat prototypes were made of the same material. The difference was from the color and additional color combinations. The prototype of the hazmat suit can be seen in Figure 4.

Figure. 4. Hazmat Prototypes

2.4. Discriminant Stage

This stage was the distribution stage of PPE products that had been developed, through socialization and providing hazmat assistance to the community. In other words, PPE products produced were eligible for use because they had been developed through research.

2.5. Data Collection Technique and Instruments

To answer the problem formulation, data were necessary. The data were obtained from the validation of PPE from the validator. Thus the instrument used to collect data is a validation sheet. For the validation results to have sufficient validity, several validators are needed to validate. As validators, it is planned to consist of two doctors and two nurses who have sufficient experience. Thus the research instrument uses a validation sheet and data collection techniques using direct observation.

2.6. Data Analysis Technique

Data analysis in this study used descriptive statistical analysis, namely describing the response data of health workers to the existing PPE. To analyze product ratings by experts or raters, Kappa's inter-rater reliability index was used [10]. Reliability involving raters was called an inter-rater agreement or inter-rater reliability. The inter-rater reliability that was tested for consistency was the rater. So the position of the item was replaced with the position of the person (rater). The category of inter-rater reliability index from Kappa was as follows: < 0.40 poor agreement, 0.40 < < 0.75 good, and > 0.75 excellent agreement [11]. If the order of subject scores of raters A and B was almost the same, then both raters had a high agreement.

3. RESULT AND DISCUSSION

Validation of the Development of COVID-19 Hazmat Suit Personal Protective Equipment for Medical Personnel using Inter-Rater Reliability. Inter-rater reliability was used to see the consistency of measurements between different times. This reliability was also known as inter-rater agreement or inter-rater reliability. The inter-rater reliability tested for consistency was the rater. So the position of the item is replaced with the position of the person (rater). In other words, inter-rater reliability looked at the consistency or agreement of inter-raters. Inter-rater reliability was indicated by the Kappa inter-rater reliability index. If the reliability index was high, it meant that the inter-raters had a high agreement on the item.

The rater for the developed product was carried out by two experts (doctors), the first validator and second Aspects assessed from the developed hazmat clothing products were wearability, safety, comfort, appearance/look, and color combinations. The choice of the validator. rater rating used a Likert scale with four choices, namely very good (VG), good (G), fair (F), and less good (LG). Figure 5 shows the first validator was conducting an assessment of the product being developed.

Figure. 5 Product Assessment by First Validator

The product assessment matrix was set out in a table as shown in Table 1 and Table 2. Notes were given in the remarks column that there should be no holes in the hazmat. The data were then analyzed together with other raters to obtain the Kappa coefficient index.

Table 1. Assessment Matrix From First Validator

No.	Aspects	VG	G	F	LG	Notes
1	Usability	V				
2	Safety		V			There should be no holes in the hazmat
3	Comfort	V				
4	Look	V				
5	Color combination	V				

Table 2. Assessment Matrix From Second Validator

No.	Aspects	VG	G	F	LG	Notes
1	Usability	V				
2	Safety		V			Tested by the Ministry of Health
3	Comfort	V				
4	Look	V				
5	Color combination	V				

The results of the analysis calculation using SPSS obtained the Kappa coefficient index of (κ) = 1.0. According to [11] the Kappa value categories were <0.4 poor agreement, 0.40 <κ<0.75 good, and >0.75 excellent agreement. Thus the Kappa coefficient index was high, this indicated that both raters had the same inter-rater agreement on the hazmat clothing products assessed or observed. However, there were notes from two raters or appraisers. The first validator gave a note that there should be no holes in the hazmat shirt, while the second validator noted that the developed hazmat clothing products needed to be tested at the Ministry of Health.

From the results of the assessment or observation of two experts with a Kappa index > 1.0 in the excellent agreement category, it can be said that the product being assessed: (1) Design, using unusual colors with contrasting combinations to reduce the scary impression of PPE, with different colors. Psychologically bright colors can encourage fatigued health workers. In addition, the white color on the hazmat can cause and increase feelings of anxiety and tension in patients [12-13] (2) the material uses waterproof material from polyurethane and polyester when used, the material gives a cold and not hot feeling like PPE that doctors have never seen before wearing it. The quality of the material is good in terms of thickness and smooth texture. It is hoped that it can provide comfort for health workers when worn. According to BNPB this material meets the standards of ASTM 16604 and has been recommended by the American Chemical Society (ACS) [14-17]. The combination of fabric with polyester with a snug fit can hold 80-99% of aerosol particles up to 10 nm in size. The results of the study used an aerosol particle chamber measuring 10 nm–

6µm. By referring to the material safety data sheet, this polyester material is safe and has no potential to cause skin, eye, or respiratory irritation [18-19]. So that this combination material meets the hydrophobic requirements, is resistant to liquid penetration, and is breathable [2, 20-21], (3) sewing techniques, all seams are made 0.5 cm wide then to prevent holes due to needle puncture, all seams are closed with seam steal tape so that security is maintained when wearing PPE, (4) the size, the size used is all-size standard so that it can be used by people of different body sizes. On the back of the waist, rubber sutures are given to adjust the size of the wearer's body, (5) wearability, when used by a model and tested by doctors, PPE is easy to put on and take off, (6) comfort, looseness on the body, arms, legs are quite good The pegs are also comfortable when used for sitting and activities. According to [2], states that comfort to users, namely, ease of movement, flexibility when providing care to patients, and does not cause stress, heat, and dehydration. PPE material must have the ability to circulate or breathable skin. (7) Security and the design are made to cover the whole body, all seams are given a seam steal tape to prevent holes in the stitches, but it needs to be tested at the Ministry of Health.

Notes on the assessment of two doctors are very important for discussing the results of research on the resulting product. First, the hazmat shirt product must not have holes in it, the holes in the hazmat shirt will cause the entry of the Covid-19 virus if it is used by health workers when handling Covid-19 patients. Therefore, it is necessary to be careful when producing hazmat clothes.

The second validator noted that the developed hazmat clothing products need to be tested with the Ministry of Health. This note is needed before the hazmat clothing products are thrown into the market or used. The product needs to be tested, one of the required test parameters is the measurement of the resistance of the fabric to liquid penetration (water impact) using the American Association of Textile Chemists and Colorists Testing Method (ATCC-TM) 42:2017 test method. The purpose of the test method is to measure the resistance of the fabric to water penetration, for the scope of fabrics that have or have not been given special enhancement substances such as water repellent.

Product testing can be carried out on fibers, yarns, fabrics, color fastness, identification of dyes, analysis of auxiliary substances, analysis of water and waste, and content of substances in materials [22-25]. Test methods that can be carried out are based on Standard National Indonesia (SNI), International Organization of Standardization (ISO), American Society for Testing and Materials (ASTM), BS, America Association of Textile Chemists and Colorists (AATCC) standards, and other standards [26-29]. Thus the product being developed still needs to be carried out with the test so that the hazmat clothes produced as Personal Protective Equipment (PPE) can meet the standards of the World Health Organization (WHO).

4. CONCLUSION

This study has produced four prototypes of hazmat suits, which are named hazmat prototype 1, hazmat prototype 2, hazmat prototype 3, and hazmat prototype 4. The Kappa inter-rater reliability index was obtained at 1.0 in the excellent agreement category. Thus, the product that is assessed from the aspect of design, material, sewing technique, size, usability, comfort, safety, appearance/look, and color combination has met the requirements as fashionable PPE.

Although the Kappa coefficient index is high, this does not yet indicate that the developed product can be mass-produced. There is still the next stage, namely product testing through Industrial R&D. Test methods can be carried out based on SNI, ISO, ASTM, BS, AATCC standards, and other standards. Through these tests, it is hoped that hazmat suits can be produced as Personal Protective Equipment (PPE) that meet the standards of the World Health Organization (WHO).

ACKNOWLEDGMENTS

The title "ACKNOWLEDGMENTS" should be in all caps and should be placed above the references. The references should be consistent within the article and follow the same style. List all the references with full details.

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