Development of personal protective equipment for the COVID-19 pandemic in Thailand and technical aspects of testing gown materials

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During the coronavirus disease 2019 (COVID-19) pandemic in early 2020, Thailand, like many other countries around the world, experienced a lack of personal protective equipment (PPE) for frontline medical staff. This was not only due to the scarcity of PPE, but also because some of the available PPE did not meet the standard to properly protect frontline medical staff from the virus. During that time, the industrial sector worked closely with academic and governmental sectors to develop and produce appropriate isolation gowns, coveralls and masks.

In mid-March 2020, a polyester fabric-producing factory which is familiar with medical textiles realized that the lack of PPE in Thailand was quite severe. Therefore, the company worked closely with a garment company to develop an isolation gown for medics. Within two months, a reusable isolation gown which passed ANSI/AAMI PB70 Level 2,[1] "Rao Soo" (which means we fight) was successfully developed. The Rao Soo isolation gown can be washed and reused up to 20 times. In addition, it is produced from recycled polyethylene terephthalate water bottles. The Government Pharmaceutical Organization has reported that since May 2020, production capacity has reached more than one million isolation gowns per month.

Because some tasks performed by staff on the medical frontline may cause them to come into contact with fluid containing the virus, a coverall with an infection protection level which can protect the wearer from blood containing the virus has also been developed. The target specification for the coverall gowns was to provide high biohazard performance as well as physical performance. Even though we have never previously produced high-performance fabric for PPE in Thailand, we considered various types of fabric that we were able to produce. There are several spunbonded nonwoven fabric producers in Thailand. Consequently, this type of fabric was chosen to provide the mechanical strength of the fabric. However, spunbonded nonwoven fabric would allow blood and virus particles to penetrate. Therefore, a layer of fabric was needed that was able to withstand both blood and virus particles. First, plastic film is known to withstand the passage of both blood and virus; however, plastic film can be easily torn. In addition, the water vapor transmission of plastic film is quite poor, making it uncomfortable to wear. Fortunately, in Thailand there is also a factory producing breathable plastic film which is used to produce diapers and sanitary napkins. Therefore, they provided the breathable film to be laminated with the spunbonded nonwoven fabric.

While the fabric producers developed a fabric with suitable biohazard and physical performance, the garment factories tried to develop seams which would be able to withstand penetration of the blood and virus. After three months of hard work, a PPE gown that passed ANSI/AAMI PB70 Level 4 was successfully developed. This has been named "Rao Chana" which means, in Thai, "we win".

Overview and definition of PPE: Health-care workers (HCWs) are among the group at highest risk of infection by the spread of infectious diseases such as COVID-19, Ebola virus disease and severe acute respiratory syndrome (SARS).[2,3] When HCWs are the frontline personnel who diagnose and care for the infected patients, the probability of HCWs catching a contagious virus is markedly increased compared to other occupations. Aerosol droplets and transfer of contaminants from hands to mucous membranes are considered major routes of infection for COVID-19.[4] One of the important tools in limiting the transmissibility of the virus to this group of people is by using PPE for the prevention of direct exposure to contaminated fluids from patients' blood and droplets created

by activities such as talking, coughing, and sneezing.[5] In 2004, the Occupational Safety and Health Administration of the U.S. Department of Labor identified the broad meaning of PPE that helps establish and maintain a safe and healthy work environment to be categorized as 1) eye and face protection 2) head protection 3) foot and leg protection 4) hand and arm protection 5) body protection and 6) hearing protection. For HCWs, the importance of PPE in preventing microbial infection highlights the equipment that covers body protection (such as, aprons, gowns or coveralls), respiratory tract protection by masks or respirators, and eye protection by goggles.[3, 6] In this viewpoint, the focus lies on protective clothing for body protection. After gloves, the reported second most frequently-used PPE in the healthcare setting was protective gowns.[7] Appropriate selection of PPE gowns has been suggested in many guidelines.[8-10] The Association for the Advancement of Medical Instrumentation (AAMI) suggested that isolation gowns should be used to prevent the transfer of contaminated fluids within the healthcare environment in high-risk situations of patient isolation.[11] Also, a comparable recommendation on the use of isolation gowns has been produced by The U.S. Food and Drug Administration giving the definition of a PPE gown as "a gown intended to protect healthcare patients and personnel from the transfer of microorganisms, body fluids, and particulate material". The specific definition of PPE gowns includes coverage of the torso including arms and exposed body areas, clothing and garments that create appropriate blockage of the microorganisms and other contagious secretions and excretions.[12]

The U.S. Food and Drug Administration listed the barrier protection levels of gowns and other types of PPE for their levels of protection as follows:[13]

Level 1: Minimal risk, to be used, for example, during basic care, standard isolation, as cover gowns for visitors, or in a standard medical unit;

Level 2: Low risk, to be used, for example, during blood draw, suturing, in the intensive care unit (ICU), or a pathology lab.;

Level 3: Moderate risk, to be used, for example, during arterial blood draw, inserting an intravenous (IV) line, in the emergency room, or for trauma cases;

Level 4: High risk, to be used, for example, during long, fluid-intense procedures, surgery, when pathogen resistance is needed or infectious diseases are suspected (non-airborne).

There are differences in the definitions between isolation gowns and surgical gowns. A surgical gowns' critical zones are defined by the surgical procedures to cover the front of the body from the top of the shoulders to the knees and the arms from the wrist cuff to above the elbow. They are designed to protect both health-care personnel during surgical procedures and the patient from any transmissible matter. While surgical gowns are applicable for any risk level (Levels 1–4), isolation gowns are used when there is a medium to high risk of contamination and a need for larger critical zones. For isolation gowns, critical zones include all areas except bindings, cuffs, and hems that must reach the highest liquid barrier protection level of the performance standards. This protection level applies to all seams as well as the rest of the gown. Moreover, it is recommended that the materials of the isolation gown should cover as much of the body as is appropriate for the intended use. The Centers for Disease Control and Prevention's Guideline for Isolation Precautions suggests that HCWs should wear the isolation gowns during procedures and patient-care activities.[14] In the technical compliance with relevant performance standards options, depending on risks, for isolation gowns to be used with COVID-19, the World Health Organization (WHO) 2020 currently recommends either AAMI PB70 (Level 1–3)[1] and ASTM F3352 (U.S.),[15] EN 13034 - Type PB [6] (stitched gown), with a minimum hydrostatic head of 50 cmH_2O (E.U.),[16] AAMI PB70 Level 4 and ASTM F3352 (U.S.)[1] or ISO 16604 Class 5 (E.U.)[17] for providing viral penetration resistance, or an alternative equivalent set of standards. However, the standard options for surgical gowns are listed by the WHO, 2020 for AAMI PB701 and ASTM F2407 (U.S.),[18] EN 13795 (E.U.),[19] EN 13034 - Type PB [6] (stitched gown), with minimum hydrostatic head of 50 cmH_2O (E.U.), YY/T 0506 (China)[20] or alternative equivalent set of standards, EN 556 (E.U.),[21] if sterile, or alternative equivalent set of standards.[22] Another type of PPE body protection is a coverall, classified only in E.U. standard (EN 13688).[23] A coverall with EN 14126[24] is certified against infective agents. It is designed to protect the entire body, from head to ankle. For the performance tests, a coverall is required to pass fabric, seam and whole garment tests.

Despite the substantial performance of PPE confirmed by standard test methods, the use of such equipment is considered only one of the infection prevention and control measures. HCWs should not rely on PPE as the primary prevention strategy. Without effective administrative and engineering controls, PPE can be inadequate to control the spread of diseases, as described in the WHO's publication 'Infection prevention and control of epidemic- and pandemic-prone acute respiratory infections in health care'.[9] With the extensive use of and demand for PPE, shortage of these medical supplies is an extremely critical issue which arose around the world during this pandemic situation. The safety and efficacy of the PPE supplied to HCWs were of serious concern. In some areas, supplies of PPE failed the quality requirement for the standard used to handle COVID-19. The unmet need for safer and more effective PPE is still the major challenge across the globe, even with all the recommendations formulated from various organizations such as the WHO, the National Health Service (U.K.), and the Centers for Disease Control and Prevention in the U.S. concerning the specification and use of PPE.[25] These issues severely affected Thailand's healthcare system, where the supply of PPE gowns previously relied entirely on imports and no standard testing has ever been developed before.

Standards and test methods focusing on the synthetic blood and virus penetration test method: In order to control and prevent infection during the COVID-19 pandemic, the use of personal protective clothing has dramatically increased worldwide. One possible means of exposure to biological fluid contaminated with COVID-19 is by penetration through

protective clothing. Hence, healthcare professionals must wear suitable and effective protective apparel when caring for patients with suspected or confirmed COVID-19 infection. There are two major regulatory standards: (i) EN14126:200324 and (ii) ANSI/AAMI PB 70:2012,[1] to evaluate the penetration resistance of protective clothing. The European Union commonly uses the EN14126:2003 standard, while the United States of America generally uses the ANSI/AAMI PB 70:2012 standard. The EN14126:2003 consists of five test methods to assess the barrier performance of protective clothing against infective agents and biological fluids (**Table 1**). The EN14126:2003 uses various types of micro-organisms in different test methods to evaluate the resistance of a garment against penetration by infectious agents; and uses synthetic blood as a surrogate for biological fluid (ISO 16603).[26] The ANSI/AAMI PB 70:2012 uses four test methods to evaluate liquid barrier performance and to classify protective apparel intended for use in a healthcare setting (**Table 2**). Among the series of test methods from both standards, the synthetic blood penetration test (ISO 16603 and ASTM F1670)[27] and viral penetration test (ISO 16604 and ASTM F1671) are the critical assays to evaluate the efficacy of protective clothing for protection against COVID-19.

Table 1. Test methods for EN14126:2003

Test method	Test description	Types of contaminations	Approximate contaminant size
ISO 16603	Determination of the resistance of protective clothing materials to penetration by blood and body fluids	Synthetic blood	–
ISO 16604	Determination of the resistance of protective clothing materials to penetration by blood-borne pathogens	Phi-X 174 bacteriophage	0.03 mm[28]
ISO 22610	Determination of the resistance to wet bacterial penetration	Bacillus atrophaeus contaminated liquid	1.0–1.6 mm (length); 0.6–0.9 mm (diameter)[29]
ISO/DIS 22611	Determination of the resistance to penetration by biologically contaminated aerosols	Staphylococcus aureus contaminated aerosols	1 mm[30]
ISO 22612	Determination of resistance to dry microbial penetration	Bacillus subtilis contaminated talcum powder	0.9–1.5 mm (length); 0.4–0.7 mm (diameter)[29]

Table 2. Test methods for ANSI/AAMI PB 70:2012

Test method	Test description	Challenge liquid
AATCC 42	Water resistance: impact penetration	Water
AATCC 127	Water resistance: hydrostatic pressure	Water
ASTM F1670	Determination of the resistance of protective clothing materials to penetration by synthetic blood	Synthetic blood
ASTM F1671	Determination of the resistance of protective clothing materials to penetration by blood-borne pathogens	Phi-X 174 bacteriophage

ISO 16603 and ASTM F1670 are screening assays that evaluate the barrier performance of clothing material against penetration by synthetic blood solution. The key factor for these tests is the surface tension of the challenge liquid. Liquids with high surface tension tend to stay on the surface of the material, while liquids with lower surface tension are more likely to penetrate through a garment. The surface tension of synthetic blood solution (≈ 42 mN/m) used in these assays is close to that of blood (≈ 50 mN/m),[31,32] sweat (≈ 40 mN/m)[33] and saliva (≈ 40 mN/m),[33] while water has higher surface tension than biological fluids (≈ 70 mN/m). Hence, test methods using water as the challenge solution are not appropriate to be used for this purpose.

ISO 1660417 and ASTM F167127 are the assays used for evaluation of the resistance of protective clothing to viral penetration. These two tests are similar to ISO 16603 and ASTM F1670; however, they use Phi-X 174 bacteriophage suspension as the challenge liquid, rather than a solution of synthetic blood. For ISO 16604 and ASTM F1671, after exposure to a bacteriophage suspension at a certain pressure and duration, the opposite side of the tested garment is rinsed with an assay fluid; this assay fluid is further cultured with host bacteria, *Escherichia coli*, to investigate plaque formation. If the tested garment is resistant to penetration by bacteriophages, no liquid is observed to penetrate the tested specimen and no plaques are formed in the *Escherichia coli* cultures treated with the assay fluid.

The choice of virus used in the challenge solution is a critical factor for the viral penetration test. Due to its size, the Phi-X 174 bacteriophage is a good surrogate microbe for evaluation of the penetration resistance of protective clothing against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus. The Phi-X 174 bacteriophage is a non-pathogenic virus with diameter of 0.03 mm, less than one third the size of the SARS-CoV-2 virus (SARS-CoV-2 ≈ 0.1 mm in diameter[34]). In the other standard tests, e.g. ISO 22610, ISO/DIS 22611 and ISO 22612, the size of the micro-organisms used in these assays are much larger than the SARS-CoV-2 virus (**Table 2**). Hence, only ISO 16604 and ASTM F1671 tests provide appropriate conditions for investigation of the barrier performance of a material against SARS-CoV-2.

The pressure level used in the test is another important factor for the viral penetration assay. The major difference between the ISO *vs.* ASTM tests is the amount of pressure applied in performing the tests. In ASTM F1670 and ASTM F1671, tests are conducted with only one pressure level (13.8 kPa (2 psi)). Hence, the ASTM test can provide clear delineation regarding whether a material is protective or not, under specified conditions; however, it is a poor approach to categorize the barrier performance of materials against viral penetration.[35] To overcome this limitation, ISO adopted and modified the ASTM F1670 and ASTM F1671 tests to create ISO 16603 and ISO 16604 by using a series of pressure levels (from 0 kPa to 20 kPa) in the test procedure. Hence, ISO 16603 and ISO 16604 can be used to rank the barrier performance of a tested garment into classes (**Table 3**). Note that 14 kPa in ISO 16603 and ISO 16604 is the closest equivalent pressure to the ASTM methods.

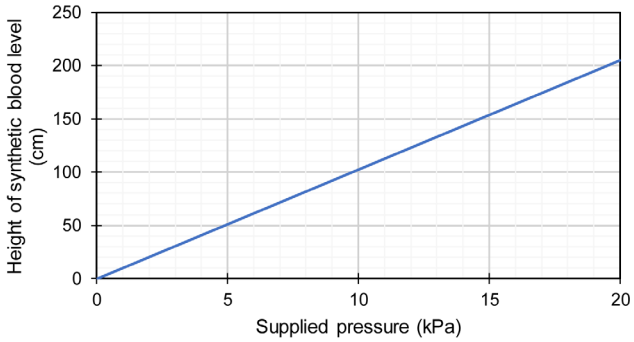
Table 3. ANSI/AAMI PB70 and EN14126:2003 classification of the level of barrier performance

Level	Test methods	Criteria
ANSI/AAMI PB70 standard		
1	AATCC 42	≤ 4.5 g
2	AATCC 42	≤ 1.0 g
	AATCC 127	≥ 20 cm
3	AATCC 42	≤ 1.0 g
	AATCC 127	≥ 50 cm
4	ASTM F1670	No penetration at 13.8 kPa
	ASTM F1671	No penetration at 13.8 kPa
EN14126:2003 standard		
1	ISO 16603 & ISO 16604	0.0 kPa
2	ISO 16603 & ISO 16604	1.75 kPa
3	ISO 16603 & ISO 16604	3.5 kPa
4	ISO 16603 & ISO 16604	7.0 kPa
5	ISO 16603 & ISO 16604	14.0 kPa
6	ISO 16603 & ISO 16604	20.0 kPa

Lesson for development of a standard test from first principles; development of adaptive equipment: as a result of the COVID-19 pandemic in early 2020, the demand for PPE for medical personnel increased exponentially. Most countries suffered particularly from a lack of medical gowns. In Thailand, an urgent plan for medical gown production was established by cooperation among governmental and non-governmental sections. At the outset, the most significant issue was the selection of textile and/or fabric material for the gowns. Clothing materials must be tested according to standards such as ANSI/AAMI PB70 (2012) and BS EN14126 (2003) which evaluate their resistance to synthetic blood penetration. Unfortunately, the testing equipment referred to in the ISO standard (ISO16603, 2004), known as "penetration test apparatus", is very hard to find or invent during an urgent period. An ad hoc device was therefore developed as a substitute for the penetration test apparatus specified in the ISO standard. In this section, the details of the test equipment developed in-house will be described.

The equipment consisted of two main parts, namely a penetration test cell and a pressure supply unit. The penetration test cell was made from two 20-mm thick transparent acrylic plates. A large opening was made in the top plate to investigate blood penetration while a circular groove was provided on the surface of the bottom plate to install an O-ring. A small hole was drilled in the middle of the bottom plate to supply synthetic blood under pressure. This small hole was connected to the pressure supply unit through a control valve. To test a material, a sample was cut of approximately the same size as the acrylic plate and installed on top of the O-ring. During testing, the specimen was sandwiched between the top and bottom plates and screws at the four corners of the plates were tightened to hold it in position. The pressure supply unit consisted of a cylindrical tank to hold the synthetic blood and apply pressure to the penetration test cell. The pressure was controlled by adjusting the elevation of the tank, which is similar to hydrostatic pressure. The pressure supply unit could generate a head of pressure up to approximately 2 m of the synthetic blood level, which was sufficient for the penetration test with a controlled pressure range of 0–20 kPa. The resolution of the supplied pressure could be controlled at 1 mm of the synthetic blood level (approximately 10 Pa). By comparing with readings from a pressure gauge, it was verified that the generated pressure could be calculated by multiplication of the weight of the synthetic blood unit and the synthetic blood level. The relationship between the height of the synthetic blood level and the supplied pressure is presented in **Figure 1**.

The obvious advantages of this adaptive testing equipment were its simplicity and low production cost, meaning that it could be easily reproduced for widespread utilisation. The pressure supply unit was able to provide a precise and stable pressure throughout the tested specimen especially in the low-pressure range. The use of transparent acrylic plates for the penetration test cell provided clear visibility during testing. The acrylic plates were also easy to clean after each test. This adaptive equipment could also be further modified for multiple testing. Moreover, the results of synthetic blood penetration



Supplied pressure (kPa)	0	1.75	3.50	7.00	14.00	20.00
Height of synthetic blood level (cm)	0	17.9	35.9	71.8	143.6	205.1

Figure 1. Relationship between height of synthetic blood level and supplied pressure.

tests based on the adaptive equipment were compared with the results of samples tested using the penetration test apparatus specified in the ISO standard and no significant difference was found between the results.

Conclusion and perspectives: Due to the recent COVID-19 outbreak, an increase in the number of cases of infection among frontline HCWs has been reported all over the world.[36] Before the availability of a safe and effective vaccination programme, implementation of preventive measures, particularly regarding the use of PPE (e.g. gloves, masks, face/eye protectors and gowns), remained the only option to reduce the risk SARS-CoV-2 infection in these particular groups. However, the global shortage of PPE and resultant price rises during the first wave of COVID-19 became a major problem especially in many developing and low-income countries.[37] This raises an important issue as well as self-awareness regarding the national security of the supply of medical products in each country. Therefore, strengthening of the clothing and garment industries to increase their capabilities regarding production of medical textiles is one of the strategies adopted in many countries including Thailand. The Thai Food and Drug Administration together with the Medical Products Consortium of Thailand and other partners set up a national platform to promote the development of medical textiles and medical devices. Such implementation not only supported the self-sufficiency of the country but also opened up the possibility of launching their products onto the global markets. This strategy is in-line with the estimation that the global demand for PPE is 100 times the normal level.[38]

From the technological viewpoint of PPE testing, it has been documented that the surgical and isolation gowns available in the global marketplace varied remarkably in terms of their resistance to blood and viral penetration, which depended on the fabric used, the design of the gown and the interface.[5] Most protective gowns have been classified into different levels and tested according to international standards (ASTM F2407, ANSI/AAMI PB70, EN 13795 and EN 14126) as described in the main text. For the viral penetration test, international standards such as ASTM 1671 and ISO 16604 recommend use of the bacteriophage Phi-X-174 as the test model. However, it is questionable whether the use of this bacteriophage is appropriate to ensure the resistance of clothing material against SARS-CoV-2 penetration due to the disparity in shape, size and polarity.[39] According to our experience, the application of other types of virus such as the influenza virus may be a better model, more representative of SARS-CoV-2 in the viral penetration test. Supportive evidence can be found in the N95 filtering test using viable H1N1 influenza virus (ATCC VR-95).[40] Moreover, additional testing such as antiviral activity of the modified fabric used in protective gown development may be recommended by international standards in the near future.

Author contributions

Conceptualisation: JAL; validation: CI; formal analysis, data curation, and writing—original draft preparation: VB, AS, SL, TB, CI, JAL; investigation: SL, TB; resources: AS, SL, TB, JAL; manuscript review and editing: JAL; supervision: AS, CI; funding acquisition: AS, JAL. All authors have read and agreed to the published version of the manuscript.

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Conflicts of interest statement

The authors declare no competing financial interests.

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