Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	**Personal protective equipment gowns for health and social care workers**
Topic exploration report number:	TER209

Introduction and aims

In guidance produced by Public Health England on COVID-19 infection prevention and control, long-sleeved fluid repellent disposable gowns are recommended as part of the Personal Protective Equipment (PPE) for health and social care workers involved in aerosol generating procedures (Public Health England, April 2020).

The Health and Safety Executive (HSE) and the Medicines and Healthcare products Regulatory Agency (MHRA) produced guidance (applicable during the COVID-19 outbreak) on essential technical requirements for PPE where no CE mark has been obtained. The guidance specifies that before PPE is procured by Government, it must meet certain criteria. It must be designed and manufactured in accordance with a relevant harmonised European standard, any standard referred to in the WHO guidelines or any other non-EU standard, provided that the product complies with applicable essential health and safety requirements. For gowns, the applicable standard is listed as 'BS EN 13795-1:2019 Surgical clothing and drapes – Requirements and test methods'.

The focus of this review was on two specific aspects of the BS EN 13795-1:2019 standard:

1. **Hydrostatic head performance:** Measured by subjecting the fabric to purified water, applied with increasing hydrostatic pressure until leakage appears on the other side of the fabric. Head height results are recorded in centimetres of water pressure on the sample. The required standard is 100cm or more for high performance gowns or 20cm or more for standard performance gowns.
2. **Tensile strength:** Measured by clamping a strip of fabric and pulling apart at a constant rate of extension. The amount of force (in Newton) required to break the fabric is recorded. The required standard is 20N or more.

To address the questions of what levels of resistance to liquid penetration and tensile strength are required to provide sufficient protection for health and social care workers managing people with COVID-19, Health Technology Wales researchers searched for evidence of the clinical and cost effectiveness of:

- Low (less than 20cm or less than 100cm) compared with high (20cm or greater or 100cm or greater) hydrostatic head performance in PPE gowns/coveralls/aprons used by healthcare workers managing people with suspected COVID-19.
- Low (less than 20N) compared with high (20N or greater) tensile strength in PPE gowns/coveralls/aprons used by healthcare workers managing people with suspected COVID-19.

Health Technology Wales researchers planned to include evidence which did not specifically refer to the management of people with suspected COVID-19, such as other infections which are spread via droplets e.g. flu and MERS-CoV.

Summary of evidence

An initial high-level search was carried out, focusing on relevant secondary evidence (evidence-based guidelines, systematic reviews, technology assessments). The evidence identified is summarised below.

UK Guidelines and HTA organisations

NICE has produced several rapid guidelines in the area of COVID-19. NG159 (published 20 March 2020 and updated 29 April 2020) focuses on critical care in adults. The guideline includes a recommendation that appropriate UK government guidance on infection prevention and control is followed, which includes recommendations on PPE. There were no specific references in the guideline to the technical specifications of PPE, such as hydrostatic head performance and tensile strength.

Health Protection Scotland and Nation Services Scotland recommend based on a literature review of PPE for Infectious Diseases of High Consequence' that:

- All PPE must bear a CE mark that signifies compliance with the Personal Protective Equipment Regulations 2002
- Fluid-resistant, disposable gowns must comply with the requirements for a 'standard performance' surgical gown according to EN 13795, at a minimum.
- Coveralls must achieve the highest classification for protection against biological agents in accordance with EN14125:2003 (type 3-B, 4/5/6).

HSE and Public Health England produced a rapid review of PPE in health care settings to manage risk during the COVID-19 outbreak. The review suggests that aprons and gowns both appear to be suitable for managing people with suspected COVID-19, while there is weak evidence suggesting that gowns are more effective. There were no specific conclusions regarding the technical specifications of PPE, such as hydrostatic head performance and tensile strength. The review does not specifically define the type of gowns and aprons considered, but highlights the relevant standards for aprons and gowns as ;BS 3314:1982: Aprons for wet work' for aprons, and both 'BS EN 13795-1 2019: Surgical clothing and drapes. Requirements and test methods' and 'BS EN ISO 22610: 2006/2018: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment' for gowns.
Health Information and Quality Authority (HIQA) have produced a database of public health guidance on COVID-19, which includes a section on guidance relating to PPE. The database cites the NHS England guidance discussed above, such as the HSE and MHRA guidance on technical specifications of PPE.

Secondary literature

We identified two Cochrane reviews. One Cochrane review (Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare

staff, Verbeek et al, 15 May 2020) sought to update previous versions published in 2016 and 2019. The review considers whether and how the use of PPE in clinical practice will prevent contamination and infection, rather than the technical physical standards which apply to the PPE. As such, no specific conclusions are made regarding the technical specifications of PPE, such as hydrostatic head performance and tensile strength.

A second rapid Cochrane review produced to inform the COVID-19 pandemic considered barriers and facilitators to healthcare workers' adherence to infection prevention and control guidelines, including qualitative and mixed- methods studies (Houghton et al, 21 April 2020). The review found that in most included studies, healthcare workers were concerned about the adequacy of provision of PPE. Five included studies noted that healthcare workers needed reassurance that the available PPE was of a high standard. Three included studies found that some healthcare workers identified that poor quality of the PPE available was a barrier to adherence. No specific reference is made in the Cochrane review to the technical specifications of gowns, such as hydrostatic head performance and tensile strength.

Two reviews were identified on Medline. One study was identified which reviews laboratory studies, regulations, guidelines and standards pertaining to isolation gowns, characterization problems, and other potential barriers of isolation gown selection and use (F. Selcen Kilinc Balci, 2016). The study finds that "there have been many clinical studies in regard to the barrier effectiveness of protective clothing in healthcare and laboratory studies evaluating the barrier effectiveness under various conditions". The review specifically notes that one study found that disposable polypropylene isolation gowns which can withstand 11.5cm of hydrostatic pressure do not offer added protection against vancomycin-resistant enterococci infection over glove use alone in an intensive care unit of a hospital with endemic infection. The review identifies three studies which identify factors related to barrier properties of surgical gowns, such as "amounts and durations of pressure exerted on gowns the period of time that the gown was worn, and pre-wetting of the fabric with blood or other liquids". On this, the review concludes that the information provided by these studies on gown characteristics is too restricted to identify gown characteristics that relate to barrier efficiency.

One rapid review of the effectiveness of PPE for healthcare workers caring for patients with Filovirus disease found that reporting of PPE components was poor and that there was insufficient evidence to make conclusions on the comparative effectiveness of different types of PPE (Hersi et al, 2015).

Primary studies

One randomised trial (Mana et al 2019) was identified in the Cochrane library. Mana et al, (2018) compared contamination of healthcare workers during doffing of two different cover gowns, one of which was designed with snugness of fit at the wrist and to allow easy removal at the neck. However, it is not clear whether the study considers gown characteristics such as hydrostatic head performance or tensile strength.

Seven further studies were identified in Medline. One study (Smith & Nichols, 1991) compared blood strike-through in 1440 samples of gown fabric subjected to pressures of 0.25 to 2.0 psi and times 1 second to 5 minutes. The study found that 'only those [fabrics] with an impervious plastic reinforcement offer complete protection'.

A further study (McCullough et al 1993) evaluates liquid and microbial barrier properties of 13 reusable and disposable gowns using tests including 'the Viral Resistance Test'. The study found that reinforced gowns are generally liquid-proof and often resistant to viral penetration.
One randomised study (Pissiotis et al, 1997) compared the barrier function in terms of 'strike through', comfort and protection of four disposable single layer gowns, 1 reusable cloth gown

and four disposable reinforced gowns. The study found that strike through occurred in 90% of reusable gowns, 11% of single layer gowns and 3% in disposable reinforced gowns. No further information was available on the composition of the gowns.

Leonas and Jinkins (1997) compared eight different surgical gowns, including five disposable and three reusable (made from woven fabrics). The authors state that standard tests were used to evaluate properties of the fabrics including thickness, weight, pore size, oil and water repellency. The measure of performance was the resistance of the fabrics to penetration of microorganisms under a hydrostatic pressure. The study found that construction, repellency and pore size contributed to gown performance. In addition, the authors conclude that higher repellency ratings and smaller pore size generally corresponded with higher performance, though effect sizes were not reported.

One study (Leonas, 1998) evaluated five reusable gowns, four of which were produced from woven fabrics while the fifth was a 3-layer composite including a microporous membrane between a woven and knit fabric. The gowns were laundered 25-50 times and then assessed for resistance to transmission of microorganism suspensions under hydrostatic pressure. The study found that two fabrics which were reinforced with a second fabric layer showed no significant increase in the amount of bacteria transmitted through the fabric.

Zareba et al, (2012) tested multiple-use cotton and synthetic textiles and disposable multilayer surgical drapes, after subjecting the fabrics to processes simulating conditions of use. The study measured resistance to microbial wet penetration according to the PN-EN ISO 22610:2007 standard. The study found that 'disposable synthetic laminates with many layers guarantee impermeability for bacteria and may be applied in operative blocks without restrictions'.

Kahveci et al (2019) considered the barrier performance of glove-gown interface in a simulated surgical setting. The study included three gown and four glove models, and concluded that gowns and gloves should be designed together to minimise fluid leakage.

Schwartz & Saunders (1980) studied microbial penetration of four surgical gowns using a method involving a soy broth containing microorganisms and placement of the materials on blood agar. The study concluded that '140 thread count cloth fails to act as a microbial barrier' whereas Spunbonded olefin, Tyvek 1444A, Spunlaced wood pulp-polyester fabric, Fabric 450 and treated 270 plus pima cotton Liquashield were effective barriers.

Other

An additional relevant study was identified by the topic proposer (Hall et al, 2018). The UK-based study evaluated one 'basic level' and five 'suspected case' PPE ensembles for first assessment and care of people with suspected high-consequence infectious diseases. All PPE components included in the study met their relevant material standards. The study did not consider the effectiveness of individual PPE items.

Areas of uncertainty

No secondary or primary literature which was identified specifically addressed the hydrostatic head performance or tensile strengths of PPE gowns.

Conclusions

No secondary or primary literature compared low and high hydrostatic head performance or tensile strength in PPE gowns/coveralls/aprons. Several primary studies were identified which assessed the barrier efficacy of gowns of different materials (e.g. cotton, synthetic) and constructions (e.g. reinforced, multi-layered).

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source for the search terms 'personal protective equipment' 'hydrostatic' 'tensile strength' 'gown'
Health Technology Assessment Group	The following potentially relevant resource was found for the search term 'PPE covid-19' https://healthservice.hse.ie/filelibrary/staff/safe-ppe-a4-poster.pdf We did not identify any relevant evidence from this source for the search terms 'hydrostatic' 'tensile strength' 'gown'
Health Information and Quality Authority	Database of public health guidance on COVID-19: https://www.hiqa.ie/reports-and-publications/health-technology-assessment/covid-19-public-health-guidance-database We did not identify any relevant evidence from this source for the search terms 'hydrostatic pressure' or 'tensile strength'
UK guidelines and guidance	
www.gov.uk	https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control https://www.gov.uk/government/collections/coronavirus-covid-19-personal-protective-equipment-ppe https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/883334/Essential_Technical_Specifications__5_.pdf).
SIGN	We did not identify any relevant evidence from this source for the search terms 'personal protective equipment' 'hydrostatic' 'tensile strength' 'gown' or 'Covid-19'
NICE	COVID-19 rapid guideline: critical care in adults NICE guideline [NG159] Published date: 20 March 2020 Last updated: 29 April 2020
HSE	Research: review of personal protective equipment provided in health care settings to manage risk during the coronavirus outbreak https://www.hse.gov.uk/news/face-mask-equivalence-aprons-gowns-eye-protection-coronavirus.htm We did not identify any relevant evidence from this source for the search terms 'covid-19 hydrostatic pressure' or 'covid-19 tensile strength' 'gown hydrostatic pressure' 'gown tensile strength' 'PPE hydrostatic pressure healthcare'
Secondary literature and economic evaluations	
ECRI	We did not identify any relevant evidence from this source for the search terms 'hydrostatic pressure' and 'tensile strength'

EUnetHTA	We did not identify any relevant evidence from this source
Cochrane library	11 Cochrane Reviews matched the search term 'personal protective equipment', of which the following were deemed potentially relevant: Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff Jos H Verbeek, Blair Rajamaki, Sharea Ijaz, Riitta Sauni, Elaine Toomey, Bronagh Blackwood, Christina Tikka, Jani H Ruotsalainen, F Selcen Kilinc Balci. Intervention Review 15 May 2020 Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis Catherine Houghton, Pauline Meskell, Hannah Delaney, Mike Smalle, Claire Glenton, Andrew Booth, Xin Hui S Chan, Declan Devane, Linda M Biesty. Qualitative Review 21 April 2020
Medline	**In a search combining the MeSH subject heading 'Personal Protective Equipment/' with HTW search filters for systematic reviews, reviews and economic studies, 88 results were screened of which the following were deemed potentially relevant:** 25. Barriers and facilitators to healthcare workers' adherence with infection prevention and control (IPC) guidelines for respiratory infectious diseases: a rapid qualitative evidence synthesis. Houghton C; Meskell P; Delaney H; Smalle M; Glenton C; Booth A; Chan XHS; Devane D; Biesty LM. Cochrane Database of Systematic Reviews. 4:CD013582, 2020 04 21. [Journal Article. Meta-Analysis. Systematic Review] UI: 32315451 26. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Verbeek JH; Rajamaki B; Ijaz S; Sauni R; Toomey E; Blackwood B; Tikka C; Ruotsalainen JH; Kilinc Balci FS. Cochrane Database of Systematic Reviews. 4:CD011621, 2020 04 15. [Journal Article. Meta-Analysis. Research Support, Non-U.S. Gov't. Systematic Review] UI: 32293717 27. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Verbeek JH; Rajamaki B; Ijaz S; Tikka C; Ruotsalainen JH; Edmond MB; Sauni R; Kilinc Balci FS. Cochrane Database of Systematic Reviews. 7:CD011621, 2019 07 01. [Journal Article. Research Support, Non-U.S. Gov't. Research Support, U.S. Gov't, P.H.S.. Systematic Review] UI: 31259389 71. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. [Review] Verbeek JH; Ijaz S; Mischke C; Ruotsalainen JH; Makela E; Neuvonen K; Edmond MB; Sauni R; Kilinc Balci FS; Mihalache RC. Cochrane Database of Systematic Reviews. 4:CD011621, 2016 Apr 19. [Journal Article. Research Support, Non-U.S. Gov't. Review. Systematic Review] UI: 27093058 76. Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use. [Review] Kilinc Balci FS. American Journal of Infection Control. 44(1):104-11, 2016 Jan 01. [Journal Article. Review] UI: 26391468 80. Effectiveness of Personal Protective Equipment for Healthcare Workers Caring for Patients with Filovirus Disease: A Rapid Review. [Review] Hersi M; Stevens A; Quach P; Hamel C; Thavorn K; Garritty C; Skidmore B; Vallenas C; Norris SL; Egger M; Eremin S; Ferri M; Shindo N; Moher D. PLoS ONE [Electronic Resource]. 10(10):e0140290, 2015. [Journal Article. Research Support, Non-U.S. Gov't. Review] UI: 26451847
Primary studies	

Cochrane library	**No trials matched the search terms 'personal protective equipment hydrostatic' or 'personal protective equipment tensile strength'.** **12 trials matched the search term 'personal protective equipment gown', of which the following were deemed potentially relevant:** A Randomized Trial of Two Cover Gowns Comparing Contamination of Healthcare Personnel During Removal of Personal Protective Equipment TSC Mana, ME Tomas, JL Cadnum, AL Jencson, CT Piedrahita, CJ Donskey Infection control and hospital epidemiology, **2018**, 39(1), 97-100 | added to CENTRAL: 31 January 2019 | 2019 Issue 1 A randomized trial of two cover gowns comparing contamination of healthcare personnel during removal of personal protective equipment Infection control and hospital epidemiology, **2018**, 39(1), 97-100 | added to CENTRAL: 31 August 2018 | 2018 Issue 8 A crossover trial comparing contamination of healthcare personnel during removal of a standard gown versus a modified gown with increased skin coverage at the hands and wrists Infection control and hospital epidemiology, **2019** | added to CENTRAL: 29 February 2020 | 2020 Issue 02
Medline	No relevant records were identified for the search 'hydrostatic pressure' OR 'tensile strength' AND 'Personal Protective Equipment' No relevant records were identified for the search 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Assurance, Health Care/' No relevant records were identified for the search 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Control/' **For the search 'tensile strength.mp. OR 'hydrostatic pressure.mp.' AND 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Control/' the following studies were deemed potentially relevant:** The relationship of selected fabric characteristics and the barrier effectiveness of surgical gown fabrics.Leonas KK; Jinkins RS. *American Journal of Infection Control. 25(1):16-23, 1997 Feb.* Effect of laundering on the barrier properties of reusable surgical gown fabrics. Leonas KK.*American Journal of Infection Control.* *26(5):495-501, 1998 Oct.* **For the search 'personal protective equipment/ or protective clothing/' AND 'barrier.mp' the following studies were deemed potentially relevant:** Isolation gowns in health care settings: Laboratory studies, regulations and standards, and potential barriers of gown selection and use. [Review] Kilinc Balci FS. American Journal of Infection Control. 44(1):104-11, 2016 Jan 01. The evaluation of bacteria penetration by medical textiles for multiple use and disposable multilayer surgical drapes, according to the PN-EN ISO 22610 standard. [Polish] Badanie przenikania bakterii przez tkaniny medyczne przeznaczone do wielokrotnego uzycia oraz wielowarstwowe oblozenia chirurgiczne jednorazowego uzytku, wedlug normy PN-EN ISO 22610. Zareba T; Zawistowska A; Kruszewska H; Mrowka A; Tyski S. Medycyna Doswiadczalna i Mikrobiologia. 64(3):261-70, 2012.

	Effect of laundering on the barrier properties of reusable surgical gown fabrics. Leonas KK. American Journal of Infection Control. 26(5):495-501, 1998 Oct. Factors that influence the effectiveness of surgical gowns in the operating theatre. Pissiotis CA; Komborozos V; Papoutsi C; Skrekas G. European Journal of Surgery. 163(8):597-604, 1997 Aug. The relationship of selected fabric characteristics and the barrier effectiveness of surgical gown fabrics. Leonas KK; Jinkins RS. American Journal of Infection Control. 25(1):16-23, 1997 Feb. Methods for determining the barrier efficacy of surgical gowns. McCullough EA. American Journal of Infection Control. 21(6):368-74, 1993 Dec. Barrier efficiency of surgical gowns. Are we really protected from our patients' pathogens?. Smith JW; Nichols RL. Archives of Surgery. 126(6):756-63, 1991 Jun. **For the search 'surgical gown.mp. or Surgical Attire/' and 'barrier.mp.' 'tensile.mp.' 'hydrostatic.mp' 'quality.mp.' the following results were deemed potentially relevant:** Critical investigation of glove-gown interface barrier performance in simulated surgical settings. Kahveci Z; Selcen Kilinc-Balci F; Yorio PL. Journal of Occupational & Environmental Hygiene. 16(7):498-506, 2019 07. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. [Review] Verbeek JH; Ijaz S; Mischke C; Ruotsalainen JH; Makela E; Neuvonen K; Edmond MB; Sauni R; Kilinc Balci FS; Mihalache RC. Cochrane Database of Systematic Reviews. 4:CD011621, 2016 Apr 19. Effect of laundering on the barrier properties of reusable surgical gown fabrics. Leonas KK. American Journal of Infection Control. 26(5):495-501, 1998 Oct. The relationship of selected fabric characteristics and the barrier effectiveness of surgical gown fabrics. Leonas KK; Jinkins RS. American Journal of Infection Control. 25(1):16-23, 1997 Feb. Microbial penetration of surgical gown materials. Schwartz JT; Saunders DE. Surgery, Gynecology & Obstetrics. 150(4):507-12, 1980 Apr.
Ongoing primary or secondary research	
PROSPERO database	No results were found for the search terms 'surgical gown', 'hydrostatic' 'tensile strength' 'barrier performance'
Clinicaltrials.gov	No results were found for the search terms 'surgical gown', 'hydrostatic' or 'tensile strength'

Other	
Information on EN 13795	https://www.halyardhealth.co.uk/media/17525831/hc519-02-uk_en13795norm_2015.pdf
Evidence identified by the topic proposer	J Hosp Infect. 2018 Jun;99(2):218-228. doi: 10.1016/j.jhin.2018.01.002. Epub 2018 Jan 8. Use of ultraviolet-fluorescence-based simulation in evaluation of personal protective equipment worn for first assessment and care of a patient with suspected high-consequence infectious disease.Hall S[1], Poller B[2], Bailey C[3], Gregory S[2], Clark R[2], Roberts P[3], Tunbridge A[2], Poran V[4], Evans C[2], Crook B[3].J Hosp Infect. 2018 Jun;99(2):229-235. doi: 10.1016/j.jhin.2018.01.021. Epub 2018 Feb 5. 'VIOLET': a fluorescence-based simulation exercise for training healthcare workers in the use of personal protective equipment. Poller B[1], Hall S[2], Bailey C[2], Gregory S[3], Clark R[3], Roberts P[2], Tunbridge A[3], Poran V[4], Crook B[2], Evans C[3]. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/medical-gowns http://www.nipcm.hps.scot.nhs.uk/resources/literature-reviews/ https://hpspubsrepo.blob.core.windows.net/hps-website/nss/2178/documents/1_tbp-lr-enhanced-PPE-for-infectious-diseases-of-high-consequence-v2.1.pdf

Date of search:	18/05/2020- 20/05/2020
Concepts used:	'personal protective equipment' 'hydrostatic' 'tensile strength' 'gown' 'PPE covid-19' 'surgical gown' 'barrier performance' **Medline searches** **Secondary studies and economic evaluations** MeSH subject heading 'Personal Protective Equipment/' with HTW search filters for systematic reviews, reviews and economic studies **Primary studies** 'hydrostatic pressure' OR 'tensile strength' AND 'Personal Protective Equipment' 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Assurance, Health Care/' 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Control/' 'tensile strength.mp. OR 'hydrostatic pressure.mp.'AND 'personal protective equipment/ or protective clothing/ or "health care (non mesh)"/' AND 'Quality Control/'

	‘personal protective equipment/ or protective clothing/AND barrier.mp.’