Development of a pharmacy-led technical assessment pathway for personal protective equipment

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Background

During the COVID-19 pandemic, the Medicines Optimisation Innovation Centre (MOIC) utilised pharmacist skills to undertake technical assessment of all Personal Protective Equipment (PPE) items procured for use across Health and Social Care Northern Ireland (HSCNI). A technical assessment process was developed in partnership with the Business Services Organisation Procurement and Logistics Service (BSOPaLS) and regional Infection Prevention and Control (IPC) colleagues in response to the outbreak of COVID-19 and escalating demand for PPE.

Process

- MOIC reviewed and validated all technical documentation associated with each PPE product, to ensure that items procured were genuine, fit for purpose and met the relevant standards and regulations.
- Benchtop assessments were carried out by IPC colleagues.
- BSOPaLS carried out all procurement due diligence checks

Unprecedented demand on supply chains. New PPE and medical device Manufacturers/Suppliers. Counterfeit goods on the healthcare market.

PPE items for HSCNI procured from reputable market leaders

March 2020 COVID-19 Pandemic in Northern Ireland

Initial assessment process developed¹



- on potential suppliers.
- Some reasons for rejection included documentation deficiencies and misleading labelling.
- The initial assessment process¹ was then refined and evolved into the 7-step technical assessment process shown in Figure 2.

• The relevant technical and regulatory documentation is received from the Manufacturer or Supplier via BSO PaLS.

 Documentation (e.g. conformity documentation, test reports etc.), packaging and sample are assessed against relevant standards (e.g. ISO standards) and EU regulations (PPE or Medical Devices legislation).

• The physical design of the sample is assessed to ensure HSCNI and product standard requirements are met. IPC colleagues assess physical design to confirm user acceptability and product performance.

 If any deficiencies are identified, the product is either rejected or issues rectified as appropriate. Inappropriate physical design or unsuitable performance (as confirmed by IPC) will result in definitive product rejection.

 BSO PaLS conveys decisions and/or requests for clarifications to potential Manufacturers/Suppliers.

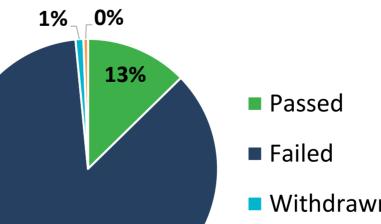
• Post sample delivery checks are carried out to ensure that delivered

World Health Organization (WHO) guidance formed the basis of COVID-19 PPE ensemble recommendations

Figure 1. The HSCNI procurement process before and after the global COVID-19 pandemic is declared by WHO in March 2020.

Outcomes & Conclusions

- A total of 205 items have been assessed for compliance between June 2020 and December 2022 (Figure 3). A breakdown of the product type and outcomes are shown in Table 1.
- This process has resulted in procurement of only safe and effective products, putting safety of HSCNI staff and patients at the forefront.
- This process has now been implemented into the PPE procurement pathway for all HSCNI purchases, enabling the application of due diligence in a transparent, robust and evidence-based manner.
- Provided there is opportunity to develop an appropriate knowledge base of the relevant regulations and standards, this process is transferable across many healthcare organisations.



86%

Figure 3. Total assessment outcomes for all PPE products assessed by MOIC between June 2020 – December 2022.

Withdrawn by Supplier

Still Open



5

4

2

products are the same as those approved, prior to distribution to Users in HSCNI Trusts.

 Detailed assessment records are kept documenting product compliance with the essential and desirable criteria from standards and overarching regulations. A product sample and packaging log is also kept to compliment these assessment records.

Figure 2. The refined MOIC 7-step technical assessment process for PPE items.

Table 1. Breakdown of PPE items assessed by MOIC and assessment outcomes.

Product type	Total no. assessed	Passed	Failed	Withdrawn by Supplier	Still open
Type IIR Masks	13	7	5	1	0
FPP3 Masks	127	8	119	0	0
Gloves	34	4	30	0	0
Gowns	1	0	1	0	0
Theatre caps	7	3	4	0	0
Transparent Face Masks	6	4	0	1	1
Face Shields	17	0	17	0	0

References

1. Burnett K, Martin S, Goudy C, et al. Ensuring the quality and quantity of personal protective equipment (PPE) by enhancing the procurement process in Northern Ireland during the coronavirus disease 2019 pandemic: Challenges in the procurement process for PPE in NI. Journal of Patient Safety and Risk Management. 2022;27(1):42-49. doi:10.1177/25160435211057385.

Smarter Medicines Better Outcomes



