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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

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Abstract

This article outlines the purchasing process for personal protective equipment that was established for Health and Social Care in Northern Ireland in response to the outbreak of coronavirus disease 2019. The Business Services Organisation Procurement and Logistics Service, who are the sole provider of goods and services for Health and Social Care organisations, was faced with an unprecedented demand for personal protective equipment in response to the coronavirus disease 2019 pandemic. The usual procurement process was further complicated by changing messages within guidelines which resulted in confusion and anxiety when determining whether or not a product would meet the required safety guidance and was therefore suitable for purchase. In order to address these issues in a rapidly changing and escalating scenario the Department of Health asked the Business Services Organisation Procurement and Logistics Service to work with the Medicines Optimisation Innovation Centre to maximise the availability of personal protective equipment whilst ensuring that it met all requisite quality and standards. A process was implemented whereby the Medicines Optimisation Innovation Centre validated all pertinent essential documentation relating to products to ensure that all applicable standards were met, with the Business Services Organisation Procurement and Logistics Service completing all procurement due diligence tasks in line with both normal and coronavirus disease 2019 emergency derogations. It is evident from the data presented that whilst there were a significant number of potential options for supply, a large proportion of these were rejected due to failure to meet the quality assurance criteria. Thus, by the process that was put in place, a large number of unsuitable products were not purchased and only those that met extant standards were approved.

Keywords

Product liability, organisational learning, risk management, support for clinical staff

Introduction

Coronavirus disease 2019 (COVID-19), caused by the novel coronavirus SARS coronavirus-2 (SARS-CoV-2), was first identified following a cluster of pneumonia cases of unknown cause in Wuhan, China in December 2019.[1,2] Following subsequent rapid spread, both locally and globally, and with an acknowledgement of the severity of the disease, the World Health Organization (WHO) declared the outbreak a pandemic on 11 March 2020,[3] at which point there were almost 126,000 confirmed global

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COVID-19 cases. As of 13 May 2020 there had been 4,298,269 confirmed COVID-19 cases globally with an attributed 293,514 deaths.[4]

COVID-19 infections typically present clinically with fever, cough and a shortness of breath,[5] which are all relatively non-specific symptoms, making differential diagnosis difficult and requiring specific testing. Transmission can be direct or indirect, with direct transmission via droplets and aerosols, and indirect via fomite transmission.[2]

Personal protective equipment (PPE)

The coronavirus outbreak of 2020 has resulted in an unprecedented demand for PPE within Health and Social Care (HSC), and the wider global workforce.

PPE is, by definition, intended in use to protect the wearer against health and safety hazards and is regulated under the European Union (EU) Regulation 2016/425.[6] This is in contrast to medical devices which are intended to protect the patient and are regulated under Directive 93/42/EEC, implemented by the Medical Devices Regulations (MDR).[7] Manufacturers wishing to claim that their product is suitable for both purposes, must ensure that the product complies with MDR and meets the relevant health and safety requirements of the PPE Directive. The distinction between PPE and medical devices can be confusing, as surgical masks used to protect the wearer during COVID-19 would be classified as PPE, whereas surgical masks worn during routine surgery to protect the patient, rather than the user, would be medical devices. The Medicines and Healthcare products Regulatory Agency (MHRA) have produced guidance for manufacturers on the legislation in recognition of the potential for confusion.[8]

The EU Personal Protective Equipment Regulation 2016/45[6] defines three categories of PPE:

- Category I is a simple design PPE to protect users carrying out specified minimal risk activities and which can be self-certified as being manufactured in accordance with health and safety requirements of the Directive.
- Category II covers PPE which is neither simple nor complex and is to protect users carrying out activities not covered in Categories I or III and must be independently tested by a Notified Body.
- Category III is complex design PPE and is to protect users carrying out activities with associated risks which have very severe consequences, and which must be independently tested by a Notified Body and be manufactured under an assessed quality management system.

Using these definitions any PPE being procured for use in the COVID-19 pandemic should comply with the requirements of Category III of the regulations.

In May 2020 Public Health England (PHE) provided guidance[9] on the types of PPE which should be worn in different clinical settings. This guidance should be used in conjunction with standard Infection Prevention and Control guidelines such as hand washing. Enhanced respiratory protective equipment must be worn by HSC workers when risk of transmission of the virus is greatest during: (1) Aerosol Generating Procedures (AGPs), (2) caring for possible or confirmed COVID-19 cases, or (3) as indicated by local risk assessments. Enhanced respiratory protective equipment includes: a fit-tested filtering face piece respirator of class 3 (FFP3) worn with a full-face shield or visor; a long-sleeved disposable fluid repellent gown which covers arms and body, or disposable fluid repellent coveralls; and, gloves. For other inpatient areas a fluid resistant (Type IIR) surgical facemask should be worn, and depending on local risk assessment, aprons and gloves may also be required.[9]

There has been guidance on the standards to be applied to PPE issued from a wide number of sources[9–11] and it is now recognised that the inconsistent messages within these guidelines results in confusion and anxiety when procurement teams are determining whether or not a product will meet the required safety guidance and is therefore suitable to purchase.[12] The Health and Safety Executive (HSE) carried out a rapid analysis of the standards and guidance being provided by WHO, the official UK guidance, and PHE posters.[13] They found inconsistencies in relation to the classification of areas of clinical working and the protective equipment recommended to be worn in these areas. For instance, WHO only has recommendations for workers carrying out direct care of patients with COVID-19 and those undertaking AGPs; while the official UK guidance covers four areas – entry to a cohorted area, within 1 metre of a patient with possible or confirmed COVID-19, high risk units where AGPs are being conducted, and AGPs in any setting. Further, WHO recommended the use of goggles or a face shield for the direct care of patients with COVID-19, while official UK guidance recommended only a risk assessment when working within 1 m of a patient with confirmed COVID-19. Standards are a safety net – they are there to maximise patient and staff safety in all sectors; they are not an unnecessary bureaucratic process to be applied. However, in order to apply them effectively, consistency is required.

The shortage of PPE for healthcare workers has been widely publicised.[12,14–16] The concomitant worldwide demand has de-globalised the supply chain in a way that has never previously been seen. This has resulted in offers of PPE being widely received from new suppliers with whom there has been no previous experience or relationship development. The UK government issued guidance for existing manufacturers who were considering making and supplying high volumes of PPE to the UK health service for items which would not have a CE

mark, along with technical advice.[17,18] This guidance explained how the rules for product certification would be applied in response to the pandemic.

The guidance provided information depending on whether a supplier intended just to supply their product to the NHS during the COVID-19 pandemic via the UK Government, or whether they intended to provide their PPE to distributors, retailers or directly to the public. In the latter case the products need to be confirmed as meeting the essential requirements for that product by a Notified Body, for example, British Standards Institute.

In the case of products to be supplied to the NHS via the UK Government the guidance detailed that suppliers must meet the essential health and safety requirements and manufacture PPE either in accordance with a relevant harmonised European or WHO approved Standard, or to an alternative technical solution (self-certify). Manufacturers who are using an alternative technical solution for their product must still deliver adequate safety and meet essential health and safety requirements.[17]

Procurement teams have to apply due diligence to any offers of PPE in a process which must be transparent, equitable, robust, efficient and evidence-based. The evidence for assessing if a product is suitable for the purpose for which it is intended comes from relevant standards and guidance, and it is therefore essential that these are clear, transparent, consistent and unambiguous so that they can be consistently applied.[12]

Aim of this paper

This article outlines the purchasing process for PPE that was established for HSC in Northern Ireland (NI) in response to the outbreak of COVID-19.

Organisations involved in this process in Northern Ireland (NI)

A number of organisations were involved in meeting the increased need for PPE in NI. The Business Services Organisation Procurement and Logistics Service (BSOPaLS), are the sole provider of goods and services for HSC in NI. As such they are responsible for procuring all items of PPE on behalf of the region. When progressing contract adjudications, BSOPaLS establish specific contract adjunction groups and the Regional Infection Prevention and Control group provide expertise regarding items of PPE. The Medicines Optimisation Innovation Centre (MOIC) is a regional centre focused on improving the health of the population of NI. Staff within MOIC have a broad range of expertise and this was effectively deployed during the pandemic. Invest NI is the regional business development agency for NI. As such its role is to grow the economy in NI through helping new and existing businesses.

Procurement process applied in NI

As previously described, during the COVID-19 emergency, BSOPaLS had to amend its procurement processes and engage in more negotiated spot buying rather than its usual competitive tendering. The main reason for this was the significant increase in demand for all PPE products. In addition, there were a number of products indirectly impacted by COVID-19 for which demand significantly increased. This was due either to government guidance or a change in HSC Trust practices. For example, there were significant increases in demand for hand hygiene products such as liquid hand soap and hand sanitiser and for re-usable scrubs (in place of uniforms) and patient gowns (in place of patients wearing their own nightwear).

The following purchasing process was established for HSC. The Central Procurement Directorate placed a notice on the procurement website eTenders and subsequently NI Direct for any interested companies to list their interest. This was not undertaken as a formal tender process. In addition, prior to this and in parallel with this process, BSOPaLS received leads directly from a number of sources including suppliers, DH and HSC Trusts.

Modelling figures became available in April 2020, albeit BSOPaLS were working to figures which they had drafted based on intelligence and feedback as well as information from national meetings which had been attended. BSOPaLS staff were working to source very large numbers of PPE products – sometimes 35–40 times more than the usual annual figure.

BSOPaLS received in excess of 2000 individual product leads for various PPE products during the initial stages of the pandemic. These were in addition to the correspondence that was on-going with current contractors for PPE products. Current contractors were the first point of contact, however, many of the current contractors no longer had a secure supply of products as their normal supply chains were severely disrupted. As such BSOPaLS had to enter into discussions with suppliers who operated directly or indirectly in markets with which there was a lack of familiarity.

Partnership between BSOPaLS and the MOIC

In order to address the challenges outlined in a rapidly changing and escalating scenario the DH asked BSOPaLS and MOIC to work together to maximise the availability of PPE but of the requisite quality and standards to ensure that the needs of the population were met.

This resulted in the redesigned process outlined below, whereby MOIC validated all pertinent essential documentation relating to products to ensure all that applicable

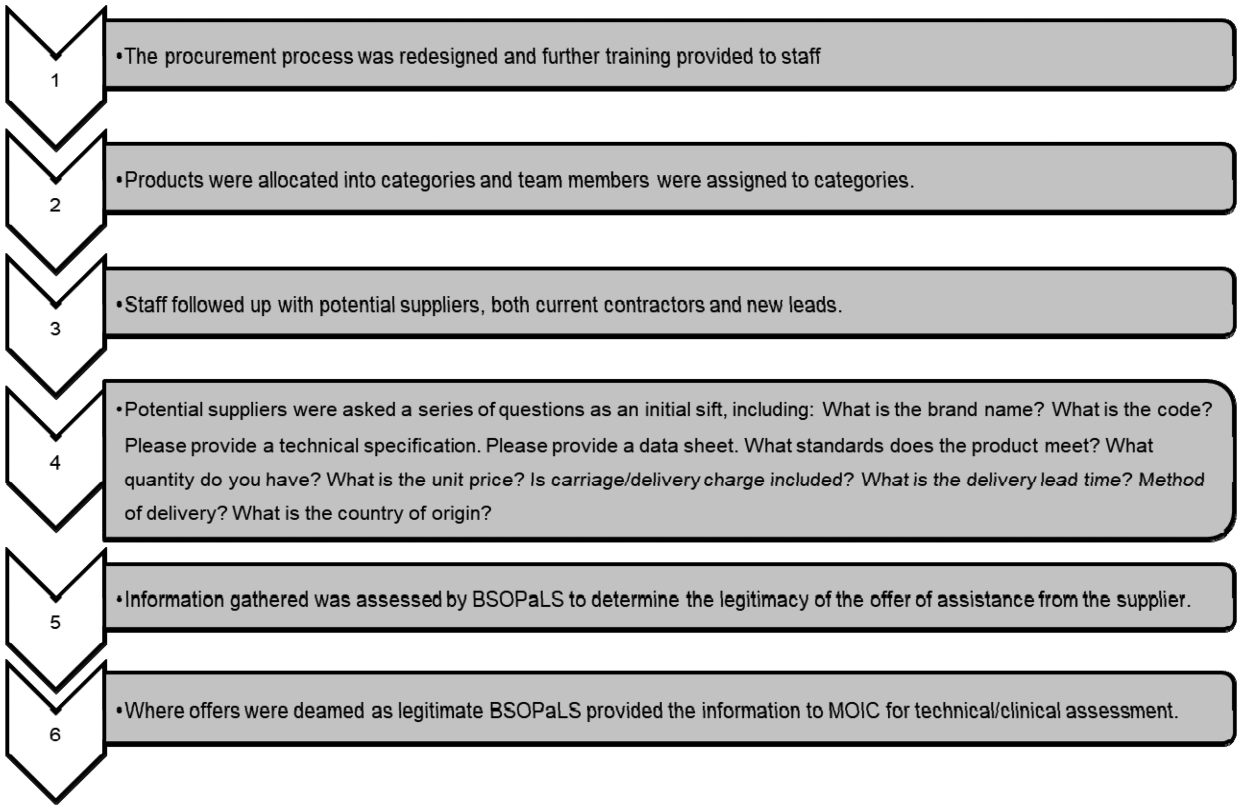

Figure 1. The Business Services Organisation Procurement and Logistics Service (BSOPaLS) process.

standards were met, with BSOPaLS completing all procurement due diligence tasks in line with both normal and COVID-19 emergency derogations (Figures 1 and 2 respectively).

Assessments completed by MOIC

Table 1 outlines the number of products sent to the MOIC team for assessment during a six week period from 1 April – 15 May. In total, during this period the MOIC team received 592 items to review from 248 suppliers.

The greatest number of requests for product assessments was for the PPE category of masks, with the MOIC team receiving 363 requests. At the time of writing, of the 363 requests 35 (9.64%) were approved and 187 (51.52%) were rejected. Over a third of the requests for evaluation remain open due to the often lengthy process of obtaining all relevant paper work and having it verified. In addition, it often took up to two weeks for samples to be received for assessment.

In many instances there was more than one reason for eliminating masks. Reasons for rejection differed slightly by the category of mask and included:

- FPP2/KN95/N95 – use of earloops and misleading labelling, for example, masks labelled as both N95/FFP2 or masks labelled as N95 and box labelled FFP2.
- FFP3 – vast majority of offers rejected because they were not true FFP3 masks.
- Type IIR – most type IIR masks were rejected because certificates could not be verified or due to information in the test reports. Another key reason for rejection was due to issues with packaging, that is, that packaging did not state Type IIR.

Protective clothing products were the second most commonly reviewed product, with 89 items being assessed over the six-week period. Similarly to masks, a substantial proportion of protective clothing products ($N = 32$, 35.96%) were rejected. Reasons for rejection of protective clothing were varied and included:

- Issues with certification.
- Samples not matching documentation.
- Items being backless and therefore not acceptable for infection prevention and control reasons.
- A number of offers were also closed due to lack of response from suppliers or offers being withdrawn due to supply issues.

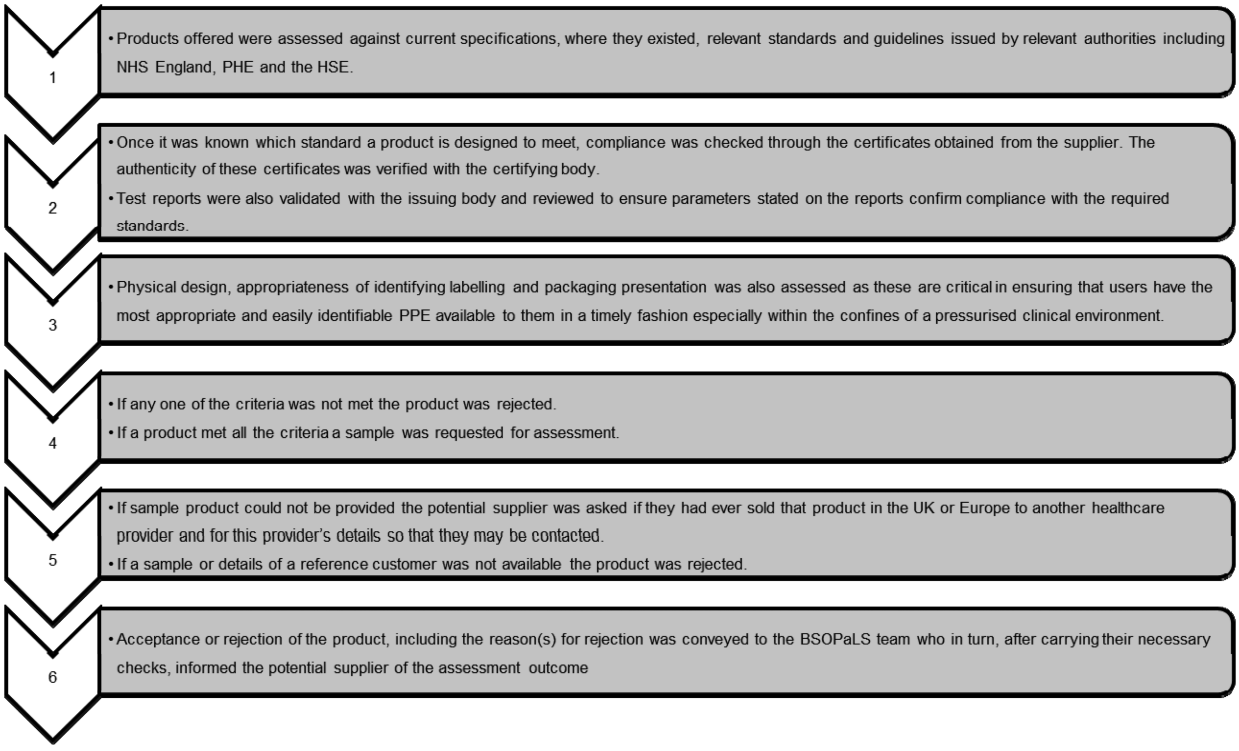

Figure 2. The Medicines Optimisation Innovation Centre (MOIC) process.

The PPE product with the highest level of approvals was gloves (66% of the 50 items reviewed were approved). For the 11 gloves that were rejected the most common reason for elimination ($N = 7$, 63.64%) was issues with certification or test reports.

In relation to protective eyewear (googles and face shields) over 40% of products assessed were rejected, however, face shields have a higher approval rate to date with approximately a third of products ($N = 10$, 30.30%) being accepted. Reasons for rejection differed between the two categories of products with 87.50% ($N = 14/16$) of goggles being rejected as certification or test reports were unable to be verified, either because information had been falsified or because suppliers did not respond to requests for additional information. All rejected face shields ($N = 14$) were discounted following inspection of samples due to reasons such as: the face shield not being wide enough, the item requiring assembly, or issues with comfort.

As assessments of products is ongoing the final number of approvals and rejections and the associated reasons are not yet available, however, the data to date does highlight the common reasons for rejection, which could be used to streamline and expedite the assessment process.

Further steps in the procurement process

Once a product from a supplier met the technical/clinical assessment from MOIC and/or the suitability assessment from the Regional Infection Prevention and Control group, BSOPaLS would negotiate with the suppliers on price and payment terms, and place an order. BSOPaLS relied on Public Contracts Regulations 2015 Regulation 32 for these procurements, as it was not possible to avail of a competitive tendering process due to the unforeseen nature of the pandemic.

Discussion and conclusions

It is apparent that the advent of the COVID-19 virus led to significant pressures in the supply chain with regard to PPE as a result of the vastly increased quantities required to ensure compliance with best practice in terms of managing patients with this disease state. This pressure was compounded by the fact that there was a steep learning curve with regard to the particular items that were necessary in the different patient settings which led to relatively frequent changes to guidance with resultant exacerbation of the supply chain constraints. There was a very heavy overreliance on China as the main country of supply, and thus given the resultant extended supply chain and COVID-19 lockdown restrictions, supply chain stresses became quickly apparent. In addition to this massively constrained normal supply chain, there was the additional factor of a relatively large number of new companies/entrants into this market with the vast majority having no experience in the healthcare sector. The result of this duality was a large increase

Table 1. Number of assessments carried out by MOIC (1 April 2020–15 May 2020).

PPE category	Total number of offers	Number of offers approved (%)	Number of offers open* (%)	Number of offers rejected (%)
Masks	363	35 (9.6%)	141 (38.8%)	187 (51.5%)
• FFP2/N95/KN95	195	17 (8.7%)	71 (36.4%)	107 (54.9%)
• Type IIR	131	13 (9.9%)	58 (44.3%)	60 (45.8%)
• FFP3	36	5 (14.0%)	11 (30.6%)	20 (55.6%)
• Unknown	1	0 (0.0%)	1 (100.0%)	0 (0.0%)
Protective clothing	89	10 (11.2%)	47 (52.8%)	32 (36.0%)
• Gown	63	8 (12.7%)	30 (47.6%)	25 (39.7%)
• Coverall	20	2 (10.0%)	14 (70.0%)	4 (20.0%)
• Scrubs	4	0 (0.0%)	1 (25.0%)	3 (75.0%)
• Coat	2	0 (0.0%)	2 (100.0%)	0 (0.0%)
Other	140	53 (37.9)	42 (30.0%)	45 (32.1%)
• Gloves	50	33 (66.0%)	6 (12.00%)	11 (22.0%)
• Goggles	35	4 (11.4%)	15 (42.9%)	16 (45.7%)
• Face shield	33	10 (30.3%)	9 (27.3%)	14 (42.4%)
• Thermometer	11	1 (9.1%)	7 (63.6%)	3 (27.3%)
• Miscellaneous	11	5 (45.5%)	5 (45.5%)	1 (9.1%)
Grand total of offers (%)	592	98 (16.6%)	230 (38.8%)	264 (44.6%)

MOIC: Medicines Optimisation Innovation Centre; PPE: personal protective equipment; FFP3: fit-tested filtering face piece respirator of class 3.
*Open are those products still being assessed at the time of writing.

in the workload associated with the task of enabling the availability of all the requisite PPE to meet our needs.

It is evident from the data presented that whilst there were a significant number of potential options for supply, a large proportion of these were rejected due to inability to verify documentation, failure to provide requisite additional information or valid certificates.

Thus, by the process put in place through the new partnership between BSOPaLS and MOIC, a large number of unsuitable products were not purchased and only those that met extant standards were approved. However, based on the work done over this period and feedback from staff wearing PPE, there is a need to enhance the specification of certain products as some of the approved items had practical deficiencies when used in the real world setting, despite meeting standards. This will ensure that the product fully meets user requirements and is key to maintaining confidence in PPE. This will be undertaken by continued enhanced working with colleagues in the HSE regarding more robust specifications and requirements to meet the needs of HSC staff.

In conclusion, the rapid introduction of this assurance process ensured that, to the best level possible in very challenging circumstances, PPE meeting the requisite extant standards were procured at the best Value for Money pertaining at the relevant time.

For the future, BSOPaLS are preparing to have compliant mechanisms available to procure PPE by establishing a Dynamic Purchasing System. This will allow HSC to have a vehicle to procure PPE products more flexibly and with greater agility in the longer term through a series of competitions. The MOIC technical component will be embedded in this new BSOPaLS and Regional Infection Prevention and Control group process consolidating and developing expertise.

Consideration is also being given to measures that would reduce the dependency on supply of PPE products from the Far East by identifying alternative suppliers. InvestNI is the regional economic development agency for NI and work has been carried out between Invest NI and the Central Procurement Directorate to engage with local companies who have re-purposed existing machinery or are investing in new machinery to manufacture within NI.

Recommendations

Based on the work of BSOPaLS and MOIC and the identified issues in the PPE procurement process, the following recommendations were made aiming at further strengthening the structure and robustness of the procurement system:

1. To formalise the process of PPE purchasing and supply fully integrating BSOPaLS, MOIC and Regional Infection Prevention and Control group inputs to deliver a robust mechanism for achieving optimised product use at optimal value.
2. To link regularly with HSE regarding PPE.
3. To enhance product specifications used to tender for PPE in NI to reflect service need and user preference where applicable.

4. To reduce over reliance on the previous globalised supply chain and develop more locally focused supply options.
5. To put in a dynamic purchasing system to ensure a more flexible and responsive process.

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Supplemental material

Supplemental material for this article is available online.

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