Strategies to Manage Product Recalls in the COVID 19 Pandemic: An Exploratory Case Study of PPE Supply Chains

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Strategies to Manage Product Recalls in the COVID 19 Pandemic: An Exploratory Case Study of PPE Supply Chains

Abstract:

**Purpose:** The purpose of this paper is to investigate strategies to manage product recalls where shortages are a critical threat, with impacts such as loss of life. We aim to identify key supply chain strategies and opportunities for theoretical advancement by taking a resilience perspective on temporary supply chain design.

**Design/methodology/approach:** First, we conducted an impact event analysis of product recalls by exploring the RAPEX database and official statements of individual country regulators. Second, we conducted an exploratory case study with the Cambridge University Hospitals on Personal Protective Equipment to explore product recall risks, utilising an action research methodology.

**Findings:** Additional processes, mainly testing, can compensate for the risks that may arise from temporary supply chains, where changes in location and product design are not possible due to the immediate nature of demand caused by COVID 19 pandemic. This finding reflects on the resilience of designing and implementing temporary supply chains from the perspective of product, process and location.

**Research limitations/implications:** This paper does not employ an in-depth multiple case study methodology. However, we argue that the role of institutional actors in global supply chains and its implications on product safety needs to be empirically studied in order to expand existing supply chain management theories to cover resilience in emerging, mature and temporary supply chains.

**Practical implications:** Managers can learn from the Cambridge University Hospitals case study that a downstream quality inspection system can be deployed to manage product quality and safety risks where recalls are not an option, such as in critical situations during the COVID 19 pandemic.

**Social implications:** Our observations suggest that governments may be socially responsible for implementing rigorous mechanisms to manage product recall risks that compromise consumer safety.

**Originality/value:** Our study is uniquely designed and studies various specific phenomena of product recalls risks during the COVID 19 pandemic. The unique design features include a dynamic and recent database analysis involving a product, process and location centric perspective complemented with a Cambridge University Hospitals case study.

**Keywords:** COVID 19; Product recalls; Supply chain risk management

**Paper type:** Research paper
Strategies to Manage Product Recall In COVID 19 Pandemic: An exploratory Case study of PPE Supply Chain

1. Introduction

Supply chain risk and resilience research studies the vulnerabilities of systems against certain events. These events have their own unique characteristics in terms of duration of impact, type of impact, disruptions to operations, and access to raw materials along with existing inefficiencies in the supply chain (Christopher and Peck, 2004; Kleindorfer and Saad, 2009; Sheffi and Rice, 2005; Wagner and Bode, 2006). Respiratory protective devices, such as surgical masks, are critical in preventing the spread of infectious respiratory diseases (Chu et al., 2020; Greenhalgh et al., 2020; Patel et al., 2017). At the same time, the market for Personal Protective Equipment (PPE) shows an unprecedented level of demand due to the highly infectious nature of the novel coronavirus (COVID 19) and the associated regulations for containing it. Surging demand, exacerbated by panic buying and excessive stockpiling, has amplified the disruption in supply chains via a runaway bullwhip effect (van Hoek, 2020; Ivanov and Dolgui, 2020; Park et al., 2020). Most of the PPE used in Europe is produced offshore. Medical face masks, which are almost exclusively produced in China, have seen shortages in many industrialised countries which do not produce them (Chopra, 2020). Strict lockdowns and other quarantine measures imposed in supplier countries exacerbated this situation. For example, manufacturing operations in China have seen severely reduced capacity as workers are kept home by lockdown measures, driving a 6% reduction in China’s economic growth (McKibbin and Fernando, 2020). This industrial impact suggests that the COVID 19 pandemic is one of such events with a unique characteristics that expose the varied global supply chain vulnerabilities (Table 1).

| Table 1. COVID19 event characteristics and supply chain vulnerabilities (Sources: Chopra, 2020; Park et al., 2020). |

The disruption in such a critical and life-saving PPE supply chain has led many countries to enact restrictions on the export of raw materials and supplies (Park et al., 2020). Domestic shortages of these products and high uncertainty about future demand causes governments and business leaders to be cautious. The shortages driven by these disruptions have prompted many domestic companies to rapidly reconfigure their supply chains (Chopra, 2020; Schatteman et al., 2020).

This rapid reconfiguration of supply chains has given rise to temporary supply chains, where rapid action must be taken in an uncertain and emergent environment (Lundin and Söderholm, 1995). From a supply chain point of view, temporary organisations have been studied in project industries (Fernandes et al., 2018) and humanitarian operations (Schiffling et al., 2020; Tatham and Kovács, 2010). However, during the COVID 19 pandemic, there has been a dramatic increase in the need for temporary supply chains in commercial settings, including medical PPE, large scale testing, and food wholesalers.

As the rise of temporary organisations, particularly in the PPE context, has increased demand rapidly, we have observed three responses to the COVID 19 pandemic. Firstly, some firms are scaling up their existing supply chain by increasing production and distribution capacities (Park et al., 2020). For example, shortly after the outbreak of the COVID 19 pandemic, Chinese production of face masks scaled up from 20 million face masks per day in January 2020 to about 116 million face masks per day at the end of February with an increasing outlook (OECD,
2020). Secondly, several companies are repurposing their existing production capacities for new products (Greenhalgh et al., 2020; Huddleston, 2020; Shokrani et al., 2020). For example, companies like L’Oreal have repurposed their existing production facilities, which are intended for producing fragrances and hair gels, in order to produce hand sanitizers (Seifert, 2020). Thirdly, firms are extending their supply chains by creating alternative channels of supply by either creating a more local supply chain or by restructuring international purchasing operations as happened with many critical goods, such as PPE (Chopra, 2020; Seifert, 2020).

All these aforementioned temporary organisations have improved the ability of firms to deliver their products and services, but there are risks that cannot be ignored. Therefore, in this paper we study how firms in temporary supply chain operations can respond to quality and recall risks under disruptions. In addition, we deliberate the theoretical shortcomings surrounding the underlying mechanisms of risks resulting from temporary supply chain operations. We aim to answer the following research question:

(1) How can organisations respond to product safety risks under disruption to avoid recalls of scarce products in emergency supply chains?

Our work has several contributions for practice and theory. First, we apply institutional theory in the context of PPE supply chains to better understand the role of institutional actors in the purchase and distribution of PPE products. Through our analysis of recent PPE recalls during the COVID 19 pandemic we identify the most common root causes for these recalls. In our case study with a major UK hospital we highlight what measures can be taken to test the functionality of products and prevent recalls of scarce PPE products during the pandemic where possible. The remainder of this paper is as follows: We start in section 2 by embedding our work in a theoretical context. After that, we present a conceptual framework for managing product safety risks in the context of COVID 19. Section 3 presents our research approach, while Section 4 and 5 present our results of our impact events analysis and a case study involving a major UK hospital. Finally, Section 6 summarises this exploratory work by highlighting theoretical shortcomings and suggesting future areas of research.

2. Research Foundations
In order to conduct a pragmatic analysis of the impact of COVID 19 on actual operations, in this research we perform both an analysis of the existing, relevant literature (Tranfield et al., 2003) and a real-world case study (Gibbert et al., 2008) in parallel. The theoretical lens, the root causes of complex supply chains for PPE products, and the implications of this complexity for product safety risks are detailed in the following sub-sections.

2.1. Theoretical Background
We apply Institutional Theory to decode the basic underlying mechanisms leading to product recalls during the COVID 19 pandemic. In the context of organisational studies, institutional theory focuses on the processes “by which structures, including schemas, rules, norms and routines, become established as authoritative guidelines for social behaviour” (Richard, 2004).

In this context, institutional Theory focuses on the isomorphism of organisations. Isomorphism refers to the adoption of similar structures across different organisations (Kauppi, 2013). Here, various external influences, such as social or cultural, regulatory and normative pressures, are the determinants of organisational isomorphism (Zsidisin et al., 2005). These influences can result in changes to organisational processes, routines, and structures, and counter the efficiency arguments of traditional economic thought (Kauppi, 2013).
The intervention of institutional actors has taken a dominant role during the response efforts against the pandemic (McKibbin and Fernando, 2020). Decisions that determine the distribution of goods through supply chains are no longer determined by economic drivers but are influenced by political decisions and social pressure. In particular, the provision of PPE to public institutions has led governments to regulate and, in some cases, control the supply chain themselves (Schutt, 2020). These changes are expected to be temporary as the COVID 19 pandemic runs its course (Scudellari, 2020).

As external pressures can be decisive for institutional actors in terms of structure and action, social pressure on institutional actors has been the most acute and far-reaching external factor for action during the COVID 19 pandemic. In a very short period of time, health ministries had to ensure the provision of basic services with PPE, although they are not normally entrusted with such tasks to this extent. The application of Institutional Theory provides new insights to answer the question how regulatory voidness and relaxation affects the compliance performance of emerging and temporary supply chains and how isomorphism applies to supply chains which have not been exposed to external pressures for a substantial period of time.

We argue that the implications of institutional constraints on supply chains require not only an economic view but also an approach to product safety: Institutional regulation challenges the paradigm of efficient global supply chains, as visibility in institutionally affected supply chains is limited by spatial distance. There is evidence that the resulting risks from changes in governance increase product recall risks caused by counterfeit products and material substitutes in production (Levine, 2020). Therefore, we argue that product, process and location related attributes determine COVID 19 related supply chain vulnerabilities. In addition, the involvement of institutional actors in the supply chain presents a theoretical development opportunity in relation to the Institutional Theory. While governments enter supply chains as active players, they operate in an environment of incomplete information. We argue that this incomplete information is due to complex supply chains and is amplified by the temporary and transient nature of supply chain changes during the COVID 19 pandemic.

2.2 Managing PPE Product Recalls: A Conceptual Framework
Investigating the basic underlying root causes for product recall risks serves as a good basis to provide a management framework for emergency supply chains. We conceptualised our framework based on our analysis of product-, process- and location related characteristics that determine supply chain complexity, which we describe in section 2.3. The domains are illustrated in figure 1. Each domain appears as a box and is linked with an arrow to supply chain complexity.

![Figure 1 about here](image)

**Figure 1.** Product recall risk management framework (developed based on the authors elaboration).

The central weakness of complex supply chains is the end-to-end supply chain information asymmetry between buyer and supplier, which leads to risks in the procurement of face masks. In temporary operations, information asymmetry is amplified by the lack of trust and visibility between partners (Tatham and Kovács, 2010). We argue that reduced information asymmetry leads to reduced product recall risks. Although information asymmetry may be due to location-related characteristics, such as geographical complexity, these characteristics cannot be
changed in the short term. The production of face masks, for example, cannot be relocated to another region of the world in the short term. Similarly, the functional product characteristics of face masks for clinical use are narrowly defined and raw materials for production are predefined. For this reason, we argue that short-term changes to prevent associated risks must be made by changing processes in the procurement of masks. From a downstream buyer perspective, there are two options to reduce information asymmetry, either by implementing measures downstream by testing the product, or upstream by testing the product and monitoring the supplier. We illustrated this process in our framework. We proceed by elaborating on the components of our research framework.

2.3 Root Causes of Recalls

Root causes of product recalls are well documented in extant literature. Reasons for product recalls is mainly attributed to supply chain complexity. However, a product recall root cause categorisation in the context of the COVID 19 pandemic is needed. The following sections presents a review of root causes of product recalls.

2.3.1 Supply Chain Complexity

Supply chain management has become increasingly important in the areas of sustainability and environmental standards. In recent years, many companies have pledged publicly to only work with suppliers that meet their environmental and sustainability standards. In reality, these standards are not often met. First-tier suppliers are often not interested in enforcing their buyers’ standards on lower-tier suppliers and these lower-tier suppliers are existentially depending on their buyers in a highly competitive environment. Hence, it is often less-known and less-visible lower-tier suppliers that do not meet the standards (Villena and Gioia, 2020). This lack of implementation of specified standards by the buyer downstream in the supply chain is caused by lack of transparency and lack of incentives upstream in the supply chain. To that end, it is imperative to understand the reasons for this lack of transparency and incentives.

The term “supply chain complexity” has often been used in the extant literature in relation to product recall risks and recalls. Deep and dispersed supply chains are often characterised as part of the causes of these risks and can also describe a serial interconnection of suppliers in a geographically dispersed system (Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Speier et al., 2011; Steven et al., 2014; Tse and Tan, 2012). While the term “complexity” has been used for over 20 years, the concept of complex supply chains has only recently gained momentum and a solid base of empirical evidence to explain disruptions and lack of transparency and traceability in supply chains (Bode and Wagner, 2015; Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Steven et al., 2014). There is general consensus that the complexity of supply chains increased over the last decades and that supply chain complexity is negatively associated with firm performance (Bode and Wagner, 2015; Bozarth et al., 2009).

Notwithstanding that the concept of “complexity” is used in many research areas, the term often comprises common characteristics among these, namely the number of components of a system and the intensity of interaction between these components (Bode and Wagner, 2015). For example, (Novak and Eppinger, 2001) defined product complexity according to three characteristics: (i) the number of components, (ii) the intensity of component interactions, and (iii) product novelty. Extant research in supply chain management has vastly adopted the same characteristics in the conceptualisation and either uses it in concrete terms or abstracts it in relation to the system under consideration. The constitution of the components of a system in
the context of supply chains is characterised by the diversity over the meaning of supply chains in the academic language. For example, this can be the number of suppliers, customers or products in a supply chain, and can be referred to as the “detail complexity” of a supply chain (Bozarth et al., 2009) or the “numerousness” (Vachon and Klassen, 2002). In addition to the number of components, supply chains are also called complex because they are considered unpredictable in nature (de Leeuw et al., 2013). This complexity is driven by the interconnectedness of the components comprising the system and is referred to as the “dynamic complexity” (Bozarth et al., 2009). The definition of Bode and Wagner (2015) about supply chain complexity describes a sequential arrangement of suppliers as upstream vertical supply chain complexity but extends this understanding of complexity by including upstream horizontal complexity and the geographical dispersion of suppliers. Upstream horizontal supply chain complexity refers to the number of suppliers on a single tier, whereas the geographic dispersion of supply chains refers to a location related measure. Consequently, this definition includes vertical, horizontal and geographical complexity of supply chain structures.

In summary, the term supply chain complexity encompasses several aspects, including the fragmentation of supply chains at vertical, horizontal and geographical level, which can be described as "detail complexity". The resulting interconnectedness and increased interactions between the individual units within the supply chain adds to the complexity and can be described as "dynamic complexity".

We argue that in the context of PPE supply chains, complexity is determined by product, process and location characteristics. These characteristics may have interdependencies. For example, the product architecture affects the degree of outsourcing (Ülkü and Schmidt, 2019), leading to geographical dispersion in some cases, whereas location dependent attributes such as minimum local content requirements for assembly processes can determine the architecture of the product (Pavlínek and Ženka, 2015). In the case of PPE supply chains, geographical dispersion is low as the majority of the equipment is produced in China with local resources (Chopra, 2020). However, geographical distance and location dependency are emerging as part of a new paradigm of distributed manufacturing (Srai et al., 2016) and in this case can be defined as a major vulnerability (Park et al., 2020). On the other hand, PPE products are characterised by low product complexity and can be achieved through comparatively short supply chains and low costs. In addition, PPE products can be manufactured with a relatively low number of processing steps compared to more complex products, such as automobiles. For example, masks could be easily reproduced by multiple actors in multiple locations during the COVID 19 pandemic, thus suggesting low process complexity. However, we could observe a particularly sharp increase in the breadth of supply chains due to new suppliers or the development of alternative supply chains/repurposing manufacturing. Products from unregistered Chinese suppliers have entered the market, which have increased the risk of defective products and fraud. The geographical distance, pandemic restrictions, rapid surge of demand and governments as buyers and suppliers make it difficult to trace certification and the flow of materials and products through the supply chain.

2.3.2 Product Characteristics and Product Recalls
Studies on product related operational drivers of product recalls are still scarce in the academic literature (Shah et al., 2017). Product attributes of low complexity and low cost, among other factors, are often decisive for outsourcing production (Novak and Eppinger, 2001; Steven et al., 2014). PPE products are defined by these characteristics and are largely manufactured in China (Chopra, 2020), which explains the large physical distance between suppliers and end users in other countries and continents. Furthermore, PPE supply chains have low agility and
minimal surge production capacity in the short term. Inherent product characteristics, such as low raw material substitutability and critical functional properties for use, are critical determinants that affect these capabilities of scaling-up production. For example, both the materials and equipment for producing the melt-blown fabric that is essential to face mask production have become scarce. A particular problem here is the short-term lack of substitutability of raw materials for the product, making scaling-up a significant industrial challenge (Park et al., 2020). Although governments have stepped in with measures to support scaling-up of production at existing mask manufactures, the high risk of counterfeit products reaching the market remains.

This is not a new phenomenon. Globally dispersed and complex supply chains have always meant an increased risk of substitution with counterfeits, as for example, the use of alternative ingredients in pharmaceutical products. Highly regulated industries such as the pharmaceutical industry are confronted with a growing problem in which counterfeiters exploit high costs for pharmaceuticals by offering them at lower prices. In order to keep the production costs low, counterfeiters may use none or incorrect amounts of active raw materials (Marucheck et al., 2011). Incidents related to counterfeit, illegal diversion or theft of pharmaceuticals, have increased by approximately 70% from 2015 to 2019 (PSI, 2019). Risk controlling regulatory bodies have shown themselves to be ineffective in low visibility, globally dispersed supply chains. We have seen similarities with protective masks during the COVID 19 pandemic in a recent case of product recalls for KN95 masks issued by the Netherlands. The counterfeiter succeeded in getting the masks past three government bodies in China, Spain and the Netherlands (euronews, 2020).

2.3.3 Process Characteristics and Product Recalls

Research discussing process characteristics in relation to product recalls is relatively new and provides a new understanding of the role of supplier-buyer relationships in product safety and compliance. The studies on this topic particularly examine the effects and management of communication and coordination barriers between the focal firm and its suppliers, such as language and cultural differences, contractual and cooperative coordination between OEM and contract manufacturers, application of formal assessment processes, supplier selection and development processes, etc. (Gray and Handley, 2015; Gray and Massimino, 2014; Tse et al., 2019). The studies on this topic show that the conformity of supplied products requires both the pre-selection of suppliers and the cooperation with suppliers after the decision to cooperate at different levels. Moreover, it has been shown that the processes related to the coordination of a broad supply base incurring these barriers is associated with significant costs and product recall risks (Gray and Massimino, 2014; Handley and Gray, 2015).

In the context of product recall literature, these problems can be systematized with Transaction Cost and Principal Agent Theory (Steven et al., 2014). Using this theoretical framework, it is argued that information asymmetry between two parties can lead to opportunistic behaviour of one party due to incentive misalignments, which may be suboptimal for one party (Eisenhardt, 1989). In a supplier-buyer relationship, information asymmetry due to complex supply chains may increase quality risks as it is costly for a buyer to monitor the supplier’s effort. This poses an incentive for a supplier to deliver lower quality than if such effort could be monitored (Steven et al., 2014). We argue that PPE supply chains with high complexity increases quality risks as supply chains move across various nodes and national boundaries. Consequently, this complexity may be a reason for increased product counterfeit and recalls as buyers of face masks often do not know their suppliers and possibilities to monitor quality is limited.
2.3.4 Location Characteristics and Product Recalls

Industrial value creation has experienced increasing globalisation in recent decades, with outsourcing and offshoring being driven by cost savings in addition to many other factors (Steven et al., 2014). Analogously to problems with the availability of information in buyer-supplier relationships, problems with the availability of information can also arise with outsourced locations associated with increased physical distance. Several empirical studies, particularly in the context of location related characteristics and product recalls, have explored this relationship (Gray et al., 2011; Steven, 2015; Steven et al., 2014; Steven and Britto, 2016). The empirical results from these studies suggest that the spatial and organisational distance between buyers and suppliers as well as a geographically diversified supply base hinders an effective communication between buyers and suppliers, leading to information asymmetry, incentive misalignments and consequently product recalls (Chao et al., 2009; Steven, 2015; Steven et al., 2014; Steven and Britto, 2016). Conversely, a concentrated supply base and the co-location of facilities may enhance communication more effectively and lower product recall risks (Gray et al., 2015; Steven et al., 2014).

Extant research extends the conceptual understanding of location related characteristics from a consideration of spatial distance and inter-firm boundaries to institutional and legislative, cultural, infrastructural and market aspects (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). Immaturities related to these characteristics suggest increased product safety risks. These include poor traceability, weak legislation, inadequate warehousing facilities, cultural distance, among others. Consequently, environments related to poor performance in these characteristics are significant determinants for product safety and consequently product recalls (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). We argue that geographical distance and local factors, such as lack of enforcement of existing legislation on the production of protective masks in affected manufacturing countries, have encouraged the marketing of counterfeit PPE products.

3. Research Approach

Our research approach is twofold. First, we conducted an impact event analysis of 30 product recalls in relation to protective masks by exploring the RAPEX database and official statements from individual country regulators. For this purpose, the databases have been searched for PPE equipment during the first outbreak of the COVID 19 pandemic in spring 2020, from March until the end of May 2020. The complete list of results of this search have been analysed and summarised for protective mask recalls with regard to the country of origin of the product, description of the reason for the recall, and the countermeasures taken. Based on this analysis, we identified three core causes for recalls in this context.

Secondly, we conducted an exploratory case study with the Cambridge University Hospitals, utilising action research. The hospital has set up a temporary supply chain for PPE products during the COVID 19 pandemic in order to accommodate demand surges. We engaged with representatives of the hospital's Clinical Engineering Unit and analysed which processes were implemented to mitigate product risks in connection with non-compliant face masks. A typology of appropriate countermeasures was developed by incorporating literature and case study data. The study utilised the action research methodology, which is recognised for its ability to help researchers learn directly from applied activity in operations and supply chain management (Coughlan and Coghlan, 2002; Müller, 2005). Researchers were embedded within the operation for its entire lifecycle, from March to August 2020. Data was recorded in a journaling exercise, later this was reviewed and analysed alongside documentary evidence and retrospective interviews with participants in the operation. Combined, this provides data
triangulation that enables this research to explore a temporary PPE supply chain in an internally valid way.

4 PPE Product Recall Analysis

In this section, we briefly describe our exploratory analysis of PPE product recalls during the COVID 19 pandemic in spring 2020. We collected the data by accessing public databases and filtering for Personal Protective Equipment. We then filtered specifically for face mask recalls and alerts. The results were analysed by reading the recall and alert descriptions and summarising them according to recall/alert reasons and countermeasures taken. The following table illustrates the nature and root causes of product recalls and alerts in the context of COVID 19.

[Table 2 about here]

Table 2. Major product recall causes in PPE during COVID 19.

We observed three reasons for alerts. First, product malfunctions, where insufficient protection is provided. For example, in many cases, the particle retention rate of face masks was either insufficient or not compliant with normative specifications. Some masks with filtration specification KN95 showed particle retention rates of well below 50%. Second, counterfeits, for example fake Conformité Européenne (CE) marks. Furthermore, masks with fake manufacturer's marks were put on the market. Finally, there are those with misleading descriptions. For example, masks were put into circulation which were declared as "COVID 19 safe" or which were declared to help filter up to 90% of all bacteria without a corresponding proof of this product characteristic. The tidal wave of counterfeit certificates indicates that the supply chain is currently subject to fraudulent behaviour by many manufacturers. Even legitimate manufacturers are experiencing problems with production as they attempt to rapidly scale-up to meet demand.

Various measures have been taken at the regulatory level in response to these risks. These measures include the ban and withdrawal of the product from the market. On the other hand, products can be labelled with the corresponding risks during use if the product deviates from the specifications. Which products remain suitable for clinical use in critical situations, such as the COVID 19 pandemic, depends upon the tested and confirmed product properties, such as the particle retention rate.

As many products with functional defects have been put on the market during this period and recalls have only been ordered retrospectively by the relevant supervisory authority, the regular procedures for determining the functionality, such as checking the CE mark, are not sufficient. Countermeasures to contain risks must therefore focus on functional product characteristics. In the following case study we describe which measures can be taken to contain product recalls.

5 Exploratory PPE Case Study

In this section, we present the findings from an exploratory case study in a temporary PPE supply chain. The development of the organisation and its response to product quality issues, driven by supply chain complexity, validate our theoretical development and provide advice for practitioners.
The exploratory case study was set in the temporary, emergency PPE supply chain set up to support a surge in demand at Cambridge University Hospitals (CUH). CUH anticipated PPE shortages at the beginning of the COVID 19 pandemic, based on the experience of their procurement and supply chain management department. In order to face this challenge, a temporary PPE supply chain was established. The organisation included procurement, warehousing, packing, and last mile logistics capabilities. The primary source of PPE products was via donations in kind from supporters.

From a product quality perspective, two challenges emerged during the temporary operation that put stress on the system: (a) products not matching claimed specifications and (b) products that were outright counterfeits. Initially, these problems were of a trivial scale. However, as the operation expanded in scale and scope in response to the deepening impact of the pandemic, the impact became increasingly material and drew concern from managers.

Donations in kind have been recognised to create additional complexity and heterogeneity in relief supply chains (Falagara Sigala et al., 2020). When CUH put out a larger call for PPE donations in an attempt to mitigate the impact of product safety challenges, the effects only deepened. Sarah Greasley, Head of Clinical Engineering at CUH, was responsible for quality control of the PPE products. During a review of products stored in the temporary warehouse (at some points over 1 million in number), her team noted that over 70% of the donated masks had a mismatch between functional specification and actual product characteristics, indicating either deliberate counterfeiting or a lack of capability in the supply chain. Sarah Greasley commented that, “We get hundreds of emails offering us PPE, we can tell immediately that most of it is fake.”

One example that stuck with many of the management team behind the operation, was a donation equivalent to 100 days of usage of masks by the entire hospital. However, the manufacturer’s certificates turned out to be out of date, there was no evidence to back up the claimed CE mark, and the packaging was covered in confusing claims. Greasley explains that the masks claimed to be ‘type IIR’ (the highest UK standard) and ‘95% bacterial filtration’ – yet the type IIR standard requires 98% filtration. It was not clear to managers whether this was the result of deliberate and malicious counterfeiting (a type B problem as above) or simply a lack of understanding or technical capability with suppliers (a type A problem).

In a normal situation, this would lead to a recall and withdrawal of these masks from the supply chain. Yet, with the hospital in urgent need of masks and no resources to facilitate reverse logistics, recall was not an option in this setting. Instead, the temporary organisation rapidly established a two-channel response.

First, experts from the clinical engineering and procurement teams established a procedure for validating claims and certificates. This is not normally required in a rapid response type setting, as suppliers are instead evaluated at the selection phase. This process enabled CUH to retrospectively approve suppliers and products rapidly, avoiding the need for recalls. Second, Greasley and her colleagues developed an investigation testing procedure, working with the UK’s National Physical Laboratory. This process was able to both validate claims and investigate products with confused specifications, as in the example of the masks above.

Responding rapidly and dynamically in this temporary organisation was critical to CUH continuing to have a reliable supply of PPE throughout the first wave of the COVID 19 pandemic. The temporary operation was wound down in August 2020, when the global PPE
supply chain had recovered from the demand shock. In the next section, we discuss what the examples from this exploratory case study can do to inform practitioners in other settings.

6. Discussion and Conclusion

In this section, first, we discuss the practical implications of the analysis of recent global COVID 19 related recalls and the case study. Second, we suggest that the role of institutional actors and its implications on product recall risks need to be empirically studied in order to expand existing organizational theories that support supply chain and operations management research.

Cases like those at CUH inform us about how a firm can respond to quality and recall risks under disruptions. There are two ways in which a firm can respond to this situation, either by mitigating the product quality risks upstream in the supply chain or managing the risks further downstream.

First, to mitigate the risks, firms’ processes need to be agile and compliant. Our study suggests that setting up an inspection system as early upstream in the supply chain as possible is favourable, avoiding expensive backward processing and reverse logistics. Here, testing for certificates and product characteristics precedes the delivery. If it turns out that the product does not meet the given specifications, an export will not take place.

Second, to manage the risks, implement formal incoming inspection processes downstream in the supply chain. Here, agile process management is key; broad supply chains with many suppliers from different manufacturers can quickly lead to a bottleneck in the chain. The inspection process should include sample testing for compliance as well as a review of the CE certification.

In our case study we focused on changes in processes to mitigate product recall risks associated with protective face masks. However, we observed further countermeasures that were implemented in the context of the pandemic to cope with the shortages, including, for example, approaches to create a localised supply chain, which would serve the sharp rise in demand for medical equipment by repurposing existing production capacities.

Further to our concluding remarks for practice, we elaborated on the effects of institutional actors on supply chains and consequently products safety risks. Extant literature on institutional theory in the context of supply chains have so far mainly focused on the implications of institutional pressure on the conformance of firms (Kauppi, 2013)). Our paper extends this perspective and considers institutional actors not as exogenous regulators but as active players in the supply chain. The increased breadth of supply chains and the distribution of products through institutions and new channels rather than through regular supply chain operations has led to increased risks. Our study finds that the involvement of institutional actors can exacerbate supply chain risks that ultimately can lead to product recalls. Nevertheless, the necessity of this involvement of institutions to secure supply-critical products is beyond question.

Therefore, the impact of this paper is: (a) to present a description of product recall risks from the perspective of product process location and (b) to provide arguments for why institutional theory needs to be further investigated because institutional actors have emerged as buyers and suppliers in the supply chain. Future research could extend this approach and investigate what measures can be taken at the regulatory level to ensure product safety in these cases. In addition,
the COVID 19 pandemic raises the question where existing organisational theories such as resource based theory, where companies can create a unique competitive advantage by employing unique resources (Makhija, 2003); dynamic capabilities, which is a company-focused view on distinctive processes and assets (Teece et al., 1997) and industry competitiveness or market based view, where companies compete with homogenous resources (Makhija, 2003), fall short of providing useful insight. We argue that a combination and extension of theories specifically involving institutional theory may provide useful insights and tools to study and develop practices to mitigate product recall risks within the context of the COVID 19 pandemic. This is pertinent particularly in the perspective of a second wave of COVID 19 infections, as increasing infections may also increase the demand for PPE products.

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[The Acknowledgements are included in the ‘Title Page’ file, uploaded separately, for ensuring anonymity]

References


Abstract:

Purpose: The purpose of this paper is to investigate strategies to manage product safety risks within the Covid-19 context in order to identify key shortages that are a critical threat, with impacts such as loss of life. We aim to identify key supply chain strategies and opportunities for theoretical advancement opportunities in the field of Supply Chain Management by taking a resilience perspective on temporary supply chain design.

Design/methodology/approach: First, we conducted an impact event analysis of product recalls by exploring the RAPEX database and official statements of individual country regulators. Second, we conducted an exploratory case study with the Cambridge University Hospitals on Personal Protective Equipment to explore product safety recall risks, utilising an action research methodology.

Findings: Additional processes, mainly testing, can compensate for the risks that may arise from reconfigured temporary supply chains, where changes in location and product design are not possible due to the immediate nature of demand caused by Covid-COVID 19 pandemic. This finding reflects on the resilience of designing and implementing temporary supply chains from the perspective of product, process and location.

Research limitations/implications: This paper does not employ an in-depth multiple case study methodology. However, we argue that the role of institutional actors in global supply chains and its implications on product safety needs to be empirically studied in order to expand existing organizational theories that support supply chain management theories to cover resilience in emerging, mature and temporary supply chains.

Practical implications: Managers can learn from the Cambridge University Hospitals case study that a downstream quality inspection system can be deployed to manage product quality and safety risks where product recalls are not an option, such as in critical situations during the COVID 19 pandemic.

Social implications: Our observations suggest that governments may be socially responsible for implementing rigorous mechanisms to manage product safety recall risks that compromise consumer safety.

Originality/value: Our study is uniquely designed and studies various specific phenomena of product safety recalls in Covid during the COVID 19 pandemic. The unique design features include a dynamic and recent database analysis involving a product, process and location centric perspective complemented with a Cambridge University Hospitals case study.

Keywords: CovidCOVID 19; Product recalls; Supply chain risk management

Paper type: General Review Research paper

1. Introduction
Supply chain risk and resilience research studies the vulnerabilities of systems against certain events. These events have their own unique characteristics in terms of duration of impact, type of impact, disruptions to production, logistics and business processes, and access to raw materials along with existing inefficiencies in the supply chain (Christopher and Peck, 2004; Kleindorfer and Saad, 2009; Sheffi and Rice, 2005; Wagner and Bode, 2006). For example, respiratory protective devices, such as surgical masks, are critical in preventing the spread of infectious respiratory diseases (Chu et al., 2020; Greenhalgh et al., 2020; Patel et al., 2017). In addition, the market for Personal Protective Equipment (PPE) shows an unprecedented level of demand due to the highly infectious nature of the novel coronavirus (Covid-19) and the associated regulations for containing it. Surging demand, exacerbated by panic buying and excessive stockpiling, has amplified the disruption in supply chains via a runaway bullwhip effect (van Hoek, 2020; Ivanov and Dolgui, 2020; Park et al., 2020). Medical face masks, which are almost exclusively produced in China, have seen shortages in many industrialised countries which do not produce them (Chopra, 2020). Strict lockdowns and other quarantine measures imposed in supplier countries exacerbated this situation. For example, manufacturing operations in China have seen severely reduced capacity as workers are kept home by lockdown measures, driving a 6% reduction in China’s economic growth (McKibbin and Fernando, 2020). This brief analysis on supply chain impacts suggests that the Covid-19 pandemic is one of such events with the following unique characteristics that expose the varied global supply chain vulnerabilities inserted in (Table 1).

| Table 1 | EventCOVID19 event characteristics and supply chain vulnerabilities (Sources: Chopra, 2020; Park et al., 2020). |

The disruption in such a critical and life-saving PPE supply chain has led many countries to enact restrictions on the export of raw materials and supplies (Park et al., 2020). Domestic shortages of these products and high uncertainty about future demand causes governments and business leaders to be cautious. The shortages driven by these disruptions have prompted many domestic companies to rapidly reconfigure their supply chains (Chopra, 2020; Schatteman et al., 2020).

In this ongoing research, The disruption in such a critical and life-saving PPE supply chain has led many countries to enact restrictions on the export of raw materials and supplies (Park et al., 2020). Domestic shortages of these products and high uncertainty about future demand causes governments and business leaders to be cautious. The shortages driven by these disruptions have prompted many domestic companies to rapidly reconfigure their supply chains (Chopra, 2020; Schatteman et al., 2020).

This rapid reconfiguration of supply chains has given rise to temporary supply chains, where rapid action must be taken in an uncertain and emergent environment (Lundin and Söderholm, 1995). From a supply chain point of view, temporary organisations have been studied in project...
industries (Fernandes et al., 2018) and humanitarian operations (Schiffling et al., 2020; Tatham and Kovács, 2010). However, during the COVID 19 pandemic, there has been a dramatic increase in the need for temporary supply chains in commercial settings, including medical PPE, large scale testing, and food wholesalers.

As the rise of temporary organisations, particularly in the PPE context, has increased demand rapidly, we have observed three responses to the Covid-COVID 19 pandemic. Firstly, some firms are scaling up their existing supply chain by increasing production and distribution capacities (Park et al., 2020). For example, shortly after the outbreak of the Covid-COVID 19 pandemic, Chinese production of face masks scaled up from 20 million face masks per day in January 2020 to about 116 million face masks per day at the end of February with an increasing outlook (OECD, 2020). Secondly, several companies are repurposing their existing production capacities for new products (Greenhalgh et al., 2020; Huddleston, 2020; Shokrani et al., 2020). For example, companies like L’Oreal have repurposed their existing production facilities, which are intended for producing fragrances and hair gels, in order to produce hand sanitizers (Seifert, 2020). Thirdly, firms are extending their supply chains by creating alternative channels of supply by either creating a more local supply chain or by restructuring international purchasing operations as happened with many critical goods, such as PPE (Chopra, 2020; Seifert, 2020).

All these aforementioned rapid changestemporary organisations have improved the ability of firms to deliver their products and services, but there are risks that cannot be ignored. Therefore, in this general review paper we study how firms in temporary supply chain operations can respond to quality and recall risks under disruptions. In addition, we deliberate the theoretical shortcomings that create an understanding of surrounding the underlying mechanisms of risks resulting from reconfiguredtemporary supply chain operations. We aim to answer the following research question:

(1) How can organisations respond to product safety risks under disruption to avoid recalls of scarce products in emergency supply chains?

Our research approach is twofold. Firstly, our work has several contributions for practice and theory. First, we conducted an impact eventapplying institutional theory in the context of PPE supply chains to better understand the role of institutional actors in the purchase and distribution of PPE products. Through our analysis of product recalls in relation to protective masks by exploring the RAPEX database and official statements from individual country regulators. For this purpose, the databases have been searched for PPE equipment since the outbreak of the Covid-recent PPE recalls during the COVID 19 pandemic. The results of this search have been analysed and summarised we identify the most common root causes for protective mask recalls with regard to the country of origin of the product, description of the reason for the recall, and the countermeasures taken. Based on this analysis, we identified three core causes for recalls in this context. Secondly, we conducted an exploratory case study with the Cambridge University Hospital. The major UK hospital has set up a rapid response warehouse for incomingwe highlight what measures can be taken to test the functionality of products and prevent recalls of scarce PPE products during the Covid-19 pandemic in order to accommodate products for surging demand. We engaged with representatives of the hospital’s Clinical Engineering Unit and analysed which processes were implemented to mitigate product risks in connection with non-compliant face masks. A typology of appropriate countermeasures is developed by incorporating literature and case study data.
where possible. The remainder of this paper is as follows: Section 2 presents the arguments by embedding our work in response to supply chain disruptions in a theoretical context of Covid-19. Thereafter, Section 3 presents our research approach, while Section 4 presents an event analysis of 30 major recalls of PPE in different countries. Section 5 presents our research approach, while Section 6 summarises this exploratory work by highlighting theoretical shortcomings and suggesting future areas of research.

2. Research Foundations

Considering the pragmatic dimensions and actual ramifications of Covid-19, in this research the object of scrutiny is an analysis of the existing literature (Tranfield et al., 2003) and a real-world case study (Gibbert et al., 2008). The theoretical lens along with the root causes of complex supply chains for PPE products and the implications of this complexity for product safety risks are detailed in the following sub-sections.

2.1. Theoretical Background

In order to conduct a pragmatic analysis of the impact of COVID-19 on actual operations, in this research we perform both an analysis of the existing, relevant literature (Tranfield et al., 2003) and a real-world case study (Gibbert et al., 2008) in parallel. The theoretical lens, the root causes of complex supply chains for PPE products, and the implications of this complexity for product safety risks are detailed in the following sub-sections.

2.1. Theoretical Background

We apply an institutional theoretical view (Institutional Theory) to decode the basic underlying mechanisms leading to product safety risks (recalls) during the Covid-19 pandemic. In the context of organisational studies, institutional theory focuses on the processes “by which structures, including schemas, rules, norms and routines, become established as authoritative guidelines for social behaviour” (Richard, 2004).

In this context, institutional Theory focuses on the isomorphism of organisations. Isomorphism refers to the adoption of similar structures across different organisations (Kauppi, 2013). Here, various external influences, such as social or cultural, regulatory and normative pressures, are the determinants of organisational isomorphism (Zsidisin et al., 2005). These influences The intervention of institutional actors has taken a dominant role during the response efforts against the pandemic (McKibbin and Fernando, 2020). Decisions that determine the distribution of goods through supply chains are no longer determined by economic drivers but are influenced by political decisions. In particular, the provision of PPE to public institutions has led governments to regulate and, in some cases, control the supply chain themselves (Schutt, 2020). This institutional pressure can result in changes to organisational processes, routines, and structures, and counter the efficiency arguments of traditional economic thought (Kauppi, 2013).

The intervention of institutional actors has taken a dominant role during the response efforts against the pandemic (McKibbin and Fernando, 2020). Decisions that determine the distribution of goods through supply chains are no longer determined by economic drivers but are influenced by political decisions and social pressure. In particular, the provision of PPE to public institutions has led governments to regulate and, in some cases, control the supply chain themselves (Schutt, 2020). These changes are expected to be temporary as the COVID-19 pandemic runs its course (Scudellari, 2020).
As external pressures can be decisive for institutional actors in terms of structure and action, social pressure on institutional actors has been the most acute and far-reaching external factor for action during the COVID 19 pandemic. In a very short period of time, health ministries had to ensure the provision of basic services with PPE, although they are not normally entrusted with such tasks to this extent. The application of Institutional Theory provides new insights to answer the question how regulatory voidness and relaxation affects the compliance performance of emerging and temporary supply chains and how isomorphism applies to supply chains which have not been exposed to external pressures for a substantial period of time.

We argue that the implications of institutional constraints on supply chains require not only an economic view but also an approach to product safety: Institutional regulation challenges the paradigm of efficient global supply chains, as visibility in institutionally affected supply chains is limited by spatial distance. There is evidence that the resulting risks from changes in governance increase product safety recall risks caused by counterfeit products and material substitutes in production (Levine, 2020). Therefore, we argue that product, process and location related attributes determine COVID-related supply chain vulnerabilities. In addition, the involvement of institutional actors in the supply chain presents a theoretical development opportunity in relation to the Institutional Theory. While governments enter supply chains as active players, they operate in an environment of incomplete information. We argue that this incomplete information is due to complex supply chains and is amplified by the temporary and transient nature of supply chain changes during the COVID 19 pandemic.

2.2 Managing PPE Product Recalls: A Conceptual Framework

Investigating the basic underlying root causes for product recall risks serves as a good basis to provide a management framework for emergency supply chains. We conceptualised our framework based on our analysis of product-, process- and location related characteristics that determine supply chain complexity, which we describe in section 2.3. The domains are illustrated in figure 1. Each domain appears as a box and is linked with an arrow to supply chain complexity.

[Figure 1 about here]

Figure 1. Product recall risk management framework (developed based on the authors elaboration).

The central weakness of complex supply chains is the end-to-end supply chain information asymmetry between buyer and supplier, which leads to risks in the procurement of face masks. In temporary operations, information asymmetry is amplified by the lack of trust and visibility between partners (Tatham and Kovács, 2010). We argue that reduced information asymmetry leads to reduced product recall risks. Although information asymmetry may be due to location-related characteristics, such as geographical complexity, these characteristics cannot be changed in the short term. The production of face masks, for example, cannot be relocated to another region of the world in the short term. Similarly, the functional product characteristics of face masks for clinical use are narrowly defined and raw materials for production are predefined. For this reason, we argue that short-term changes to prevent associated risks must be made by changing processes in the procurement of masks. From a downstream buyer perspective, there are two options to reduce information asymmetry, either by implementing measures downstream by testing the product, or upstream by testing the product and monitoring.
the supplier. We illustrated this process in our framework. We proceed by elaborating on the components of our research framework.

2.3 Root Causes of Recalls
Root causes of product recalls are well documented in extant literature. Reasons for product recalls is mainly attributed to supply chain complexity. However, a product recall root cause categorisation in the context of the COVID-19 pandemic is needed. The following sections present a review of root causes of product recalls.

2.3.1 Supply Chain Complexity
Supply chain management has become increasingly important in the areas of sustainability and environmental standards. In recent years, many companies have pledged publicly to only work with suppliers that meet their environmental and sustainability standards. 2.2. Root Causes of Recalls

Root causes of product recalls are well documented in extant literature. Reasons for product recalls is mainly attributed to supply chain complexity. However, a product recall root cause categorisation in the context of the Covid-19 pandemic is needed. The following sections present a review of root causes of product recalls.

2.2.1 Supply Chain Complexity
Supply chain management has become increasingly important in the areas of sustainability and environmental standards. In recent years, many companies have pledged publicly to only work with suppliers that meet their environmental and sustainability standards. Unfortunately, in reality, these standards are not often met in reality. First-tier suppliers are often not interested in enforcing their buyers’ standards on lower-tier suppliers and these lower-tier suppliers are often existentially dependent on their buyers in a highly competitive environment. Hence, it is often less-known and less-visible lower-tier suppliers that do not meet the standards (Villena and Gioia, 2020). This lack of implementation of specified standards by the buyer downstream in the supply chain is caused by lack of transparency and lack of incentives upstream in the supply chain. To that end, it is imperative to understand the reasons for this lack of transparency and incentives.

The term “supply chain complexity” has often been used in the extant literature in relation to product safety, recall risks and recalls. Deep and dispersed supply chains are often characterised as part of the causes of these risks and can also describe a serial interconnection of suppliers in a geographically dispersed system (Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Speier et al., 2011; Steven et al., 2014; Tse and Tan, 2012) (Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Speier et al., 2011; Steven et al., 2014; Tse and Tan, 2012). While the term “complexity” has been used for over 20 years, the concept of complex supply chains has only recently gained momentum and a solid base of empirical evidence to explain disruptions and lack of transparency and traceability in supply chains (Bode and Wagner, 2015; Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Steven et al., 2014) (Bode and Wagner, 2015; Lyles et al., 2008; Marucheck et al., 2011; Sheffi and Rice, 2005; Steven et al., 2014). There is general consensus that the complexity of supply chains increased over the last decades and that supply chain complexity is negatively associated with firm performance (Bode and Wagner, 2015; Bozarth et al., 2009) (Bode and Wagner, 2015; Bozarth et al., 2009).
Notwithstanding that the concept of "complexity" is used in many research areas, the term often comprises common characteristics among these, namely the number of components of a system and the intensity of interaction between these components (Bode and Wagner, 2015). For example, (Novak and Eppinger, 2001) defined product complexity according to three characteristics: (i) the number of components, (ii) the intensity of component interactions, and (iii) product novelty. Extant research in supply chain management has vastly adopted the same characteristics in the conceptualisation and either uses it in concrete terms or abstracts it in relation to the system under consideration. The constitution of the components of a system in the context of supply chains is characterised by the diversity over the meaning of supply chains in the academic language. For example, this can be the number of suppliers, customers or products in a supply chain, and can be referred to as the “detail complexity” of a supply chain (Bozarth et al., 2009) or the “numerousness” (Vachon and Klassen, 2002).

In addition to the number of components, supply chains are also called complex because they are considered unpredictable in nature (de Leeuw et al., 2013). This complexity is driven by the interconnectedness of the components comprising the system and is referred to as the “dynamic complexity” (Bozarth et al., 2009). The definition of Bode and Wagner (2015) about supply chain complexity describes a sequential arrangement of suppliers as upstream vertical supply chain complexity but extends this understanding of complexity by including upstream horizontal complexity and the geographical dispersion of suppliers. Upstream horizontal supply chain complexity refers to the number of suppliers on a single tier, whereas the geographic dispersion of suppliers supply chains refers to a location related measure. Consequently, this definition includes vertical, horizontal and geographical complexity of supply chain structures.

In summary, the term supply chain complexity encompasses several aspects, including the fragmentation of supply chains at vertical, horizontal and geographical level, which can be described as "detail complexity". The resulting interconnectedness and increased interactions between the individual units within the supply chain add to the complexity and can be described as "dynamic complexity".

We argue that in the context of PPE supply chains, complexity is determined by product, process and location characteristics. These characteristics may have interdependencies. For example, the product architecture affects the degree of outsourcing (Ülkü and Schmidt, 2019), leading to geographical dispersion in some cases, whereas location dependent attributes such as minimum local content requirements for assembly processes can determine the architecture of the product (Pavlinek and Ženka, 2015). In the case of PPE supply chains, geographical dispersion is low as the majority of the equipment is produced in China with local resources (Chopra, 2020). However, geographical distance and location dependency are emerging as part of a new paradigm of distributed manufacturing (Srai et al., 2016) and can be defined as a major vulnerability (Park et al., 2020). On the other hand, PPE products are characterised by low product complexity and can be achieved through comparatively short supply chains and low costs. In addition, PPE products can be manufactured with a relatively low number of processing steps compared to more complex products, such as automobiles. For example, masks could be easily reproduced by multiple actors in multiple locations during the Covid-19 pandemic, thus suggesting low process complexity. However, we could observe a particularly sharp increase in the breadth of supply chains due to new suppliers or the development of alternative supply chains/repurposing manufacturing. In this context, products from unregistered Chinese suppliers have entered the market, which have increased the risk of defective products and fraud. The geographical distance, pandemic...
restrictions, rapid surge of demand and governments as buyers and suppliers make it difficult to trace certification and the flow of materials and products through the supply chain.

2.23.2 Product Characteristics and Product Recalls

Studies on product related operational drivers of product recalls are still scarce in the academic literature (Shah et al., 2017). Product attributes of low complexity and low cost, among other factors, are often decisive for outsourcing production (Novak and Eppinger, 2001; Steven et al., 2014). PPE products are defined by these characteristics and are largely manufactured in China (Chopra, 2020), which explains the large physical distance between suppliers and end users in other countries and continents. Furthermore, PPE supply chains have low agility and minimal surge production capacity in the short term. Inherent product characteristics, such as low raw material substitutability and critical functional properties for use, are critical determinants that affect these capabilities of scaling-up production. For example, both the materials and equipment for producing the melt-blown fabric that is essential to face mask production have become scarce. A particular problem here is the short-term lack of substitutability of raw materials for the product, making scaling-up a significant industrial challenge (Park et al., 2020). Even though governments have stepped in with measures to support scaling-up of production at existing mask manufactures, there remains a high risk of counterfeit products reaching the market.

This is not a new phenomenon. Globally dispersed and complex supply chains have always meant an increased risk of substitution with counterfeits, as for example, the use of alternative ingredients in pharmaceutical products. Highly regulated industries such as the pharmaceutical industry are confronted with a growing problem in which counterfeiters exploit high costs for pharmaceuticals by offering them at lower prices. In order to keep the production costs low, counterfeiters may use none or incorrect amounts of active raw materials (Marucheck et al., 2011). Incidents related to counterfeit, illegal diversion or theft of pharmaceuticals, have increased by approximately 70% from 2015 to 2019 (PSI, 2019). Risk controlling regulatory bodies have shown themselves to be ineffective in low visibility, globally dispersed supply chains. We have seen similarities with protective masks during the Covid-19 pandemic in a recent case of product recalls for KN95 masks issued by the Netherlands. The counterfeiter succeeded in getting the masks past three government bodies in China, Spain and the Netherlands (euronews, 2020).

2.23.3 Process Characteristics and Product Recalls

Research discussing process characteristics in relation to product recalls is relatively new and provides a new understanding of the role of supplier-buyer relationships in product safety and compliance. The studies on this topic particularly examine the effects and management of communication and coordination barriers between the focal firm and its suppliers, such as language and cultural differences, contractual and cooperative coordination between OEM and contract manufacturers, application of formal assessment processes, supplier selection and development processes, etc. (Gray and Handley, 2015; Gray and Massimino, 2014; Tse et al., 2019). The studies on this topic show that the conformity of supplied products requires both the pre-selection of suppliers and the cooperation with suppliers after the decision to cooperate at different levels. Moreover, it has been shown that the processes related to the coordination of a broad supply base incurring these barriers is associated with significant costs and product recall risks (Gray and Massimino, 2014; Handley and Gray, 2015).
In the context of product recall literature, these problems can be systematized with Transaction Cost and Principal Agent Theory (Steven et al., 2014). Using this theoretical framework, it is argued that information asymmetry between two parties can lead to opportunistic behaviour of one party due to incentive misalignments, which may be suboptimal for one party (Eisenhardt, 1989). In a supplier-buyer relationship, information asymmetry due to complex supply chains may increase quality risks as it is costly for a buyer to monitor the supplier’s effort. This poses an incentive for a supplier to deliver lower quality than if such effort could be monitored (Steven et al., 2014). We argue that PPE supply chains with high complexity increases quality risks as supply chains move across various nodes and cross-national boundaries. Consequently, this complexity may be a main reason for increased product counterfeits and recalls as buyers of face masks often do not know their suppliers and possibilities to monitor quality is limited.

2.23.4 Location Characteristics and Product Recalls

Industrial value creation has experienced increasing globalisation in recent decades, with outsourcing and offshoring being driven by cost savings in addition to many other factors (Steven et al., 2014). Analogously, to problems with the availability of information in buyer-supplier relationships, problems with the availability of information can also arise with outsourced locations associated with increased physical distance. Several empirical studies, particularly in the context of location related characteristics and product recalls, have explored this relationship (Gray et al., 2011; Steven, 2015; Steven et al., 2014; Steven and Britto, 2016). The empirical results from these studies suggest that the spatial and organisational distance between buyers and suppliers as well as a geographically diversified supply base hinders an effective communication between buyers and suppliers, leading to information asymmetry, incentive misalignments and consequently product recalls (Chao et al., 2009; Steven, 2015; Steven et al., 2014; Steven and Britto, 2016). Conversely, a concentrated supply base and the co-location of facilities may enhance communication more effectively and lower product safety recall risks (Gray et al., 2015; Steven et al., 2014).

Extant research extends the conceptual understanding of location related characteristics from a consideration of spatial distance and inter-firm boundaries to institutional and legislative, cultural, infrastructural and market aspects (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). Immaturities related to these characteristics suggest increased product safety risks. These include poor traceability, weak legislation, inadequate warehousing facilities, cultural distance, among others. Consequently, environments related to poor performance in these characteristics are significant determinants for product safety and consequently product recalls (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). We argue that geographical distance and local factors, such as lack of enforcement of existing legislation on the production of protective masks in affected manufacturing countries, have encouraged the marketing of counterfeit PPE products.

3. Research Approach

Our research approach is twofold. First, we conducted an impact event analysis of 30 product recalls in relation to protective masks by exploring the RAPEX database and official statements from individual country regulators. For this purpose, the databases have been searched for PPE equipment during the first outbreak of the COVID 19 pandemic in spring 2020, from March until the end of May 2020. The complete list of results of this search have been analysed and summarised for protective mask recalls with regard to the country of origin of the product.
description of the reason for the recall, and the countermeasures taken. Based on this analysis, we identified three core causes for recalls in this context.

Secondly, we conducted an exploratory case study with the Cambridge University Hospitals, utilising action research. The hospital has set up a temporary supply chain for PPE products during the COVID-19 pandemic in order to accommodate demand surges. We engaged with representatives of the hospital’s Clinical Engineering Unit and analysed which processes were implemented to mitigate product risks in connection with non-compliant face masks. Extant research extends the conceptual understanding of location-related characteristics from a pure consideration of spatial distance and inter-firm boundaries to institutional and legislative, cultural, infrastructural and market aspects (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). Immaturities related to these characteristics suggest increased product safety risks. These include poor traceability, weak legislation, inadequate warehousing facilities, cultural distance, among others. Consequently, environments related to poor performance in these characteristics are significant determinants for product safety and product recalls (Gray et al., 2011; Steven, 2015; Steven and Britto, 2016). We argue that geographical distance and local factors, such as lack of enforcement of existing legislation on the production of protective masks in affected manufacturing countries, have encouraged the marketing of counterfeit PPE products.


Based on our analysis, we conclude that supply chain complexity is determined by product, process and location characteristics. The complexity determined by these characteristics consequently creates product safety risks. Figure 1 visualises the conceptualisation of this deduction.

(Figure 1 about here)

**Figure 1.** Product safety risk management framework.

The central weakness of complex supply chains is the end-to-end supply chain information asymmetry between buyer and supplier, which leads to risks in the procurement of face masks. Although information asymmetry may be due to location-related characteristics, such as geographical complexity, these characteristics cannot be changed in the short term. For example, the production of face masks cannot be relocated to another region of the world in the short term. Similarly, the functional product characteristics of face masks for clinical use are narrowly defined and raw materials for production are predefined. For this reason, we argue that short-term changes to prevent associated risks must be made by changing processes in the procurement of masks. These countermeasures are the reduction of the information asymmetry regarding the supplier and the product characteristics. Countermeasures can be taken upstream in the supply chain or downstream in the supply chain. In the case study, we will briefly examine the advantages and disadvantages of both processes associated with these measures.

4. PPE Product Recalls during the Covid-19 Pandemic

We studied a group of 30 product recalls during the Covid-19 pandemic involving databases such as RAPEX and individual country regulators. A typology of appropriate countermeasures was developed by incorporating literature and case study data. The study utilised the action research methodology, which is recognised for its ability to help researchers learn directly from applied activity in operations and supply chain management (Coughlan and Coghlan, 2002; Müller, 2005). Researchers were embedded within the operation for its entire lifecycle, from March to August 2020. Data was recorded in a journaling exercise; later this was reviewed and
analysed alongside documentary evidence and retrospective interviews with participants in the operation. Combined, this provides data triangulation that enables this research to explore a temporary PPE supply chain in an internally valid way.

4 PPE Product Recall Analysis
In this section, we briefly describe our exploratory analysis of PPE product recalls during the COVID-19 pandemic in spring 2020. We collected the data by accessing public databases and filtering for Personal Protective Equipment. We then filtered specifically for face mask recalls and alerts. The results were analysed by reading the recall and alert descriptions and summarising them according to recall/alert reasons and countermeasures taken. The following table illustrates the nature and root causes of product recalls and alerts in the context of COVID-19.

We observed three reasons for alerts. First, product malfunctions, where insufficient protection is provided. For example, in many cases, the particle retention rate of face masks was either insufficient or not compliant with normative specifications. Some masks with filtration specification KN95 showed particle retention rates of well below 50%. Second, counterfeits, for example fake Conformité Européenne (CE) marks. Furthermore, masks with fake manufacturer's marks were put on the market. Finally, there are those with misleading descriptions. For example, masks were put into circulation which were declared as "COVID-19 safe" or which were declared to help filter up to 90% of all bacteria without a corresponding proof of this product characteristic. The tidal wave of counterfeit certificates indicates that the supply chain is currently subject to fraudulent behaviour by many manufacturers. Even legitimate manufacturers are experiencing problems with production as they attempt to rapidly scale-up to meet demand.

Various measures have been taken at the regulatory level in response to these risks. These measures include the ban and withdrawal of the product from the market. On the other hand, products can be labelled with the corresponding risks during use if the product deviates from the specifications. Which products remain suitable for clinical use in critical situations, such as the COVID-19 pandemic, depends upon the tested and confirmed product properties, such as the particle retention rate.

As many products with functional defects have been put on the market during this period and recalls have only been ordered retrospectively by the relevant supervisory authority, the regular procedures for determining the functionality, such as checking the CE mark, are not sufficient. Countermeasures to contain risks must therefore focus on functional product characteristics. In the following case study we describe which measures can be taken to contain product recalls.

5. Exploratory PPE Case Study
Like any health centres and hospitals, the In this section, we present the findings from an exploratory case study in a temporary PPE supply chain. The development of the organisation and its response to product quality issues, driven by supply chain complexity, validate our theoretical development and provide advice for practitioners.
The exploratory case study was set in the temporary, emergency PPE supply chain set up to support a surge in demand at Cambridge University Hospitals (CUH) also faced a dreadful problem of. CUH anticipated PPE shortages at the beginning of the Covid-19 pandemic, based on the experience of their procurement and supply chain management department. In order to face this challenge, a rapid response PPE warehouse was set up with the key purpose of procuring PPE products involving multiple donors. However, while running this procurement operation temporary PPE supply chain was established. The organisation included procurement, warehousing, packing, and last mile logistics capabilities. The primary source of PPE products was via donations in kind from supporters.

From a product quality perspective, two challenges emerged during the temporary operation that put stress on the system: (a) products not matching claimed specifications and (b) products that were outright counterfeits. Initially, these problems were of a trivial scale. However, as the operation expanded in scale and scope in response to the deepening impact of the pandemic, the impact became increasingly material and drew concern from managers.

Donations in kind have been recognised to create additional complexity and heterogeneity in relief supply chains (Falagar Sigala et al., 2020). When CUH put out a larger call for PPE donations in an attempt to mitigate the impact of product safety emerged: (a) not matching specifications and (b) counterfeit. As time passed, these problems became more intense. The PPE response team started working with clinical staff in the hospital after realising that over 70% of the donated masks had a mismatch between functional specification and actual product characteristics, indicating either deliberate counterfeiting or a lack of capability in the supply chain. Sarah Greasley commented that, “We get hundreds of emails offering us PPE, we can tell immediately that most of it is fake.”

Rob Glew, manager of the rapid response PPE warehouse at CUH describes the impact on them: “The UK is one of the world’s worst hit nations and there has been an enormous surge in PPE demand. We put a call out for donations of PPE to help support CUH’s existing supply chain, which has been severely disrupted.” However, as these products started to arrive, problems began to appear. The PPE response team started working with clinical staff in the hospital after realising that over 70% of the donated masks had a mismatch between functional specifications, suggesting they were counterfeit. “We get hundreds of emails offering us PPE,” says Sarah Greasley, Head of Clinical Engineering at CUH, further commenting that “we can tell immediately that most of it is fake.”

Greasley stated that there was more than enough to provide the hospital with masks for 100 days. One example that stuck with many of the management team behind the operation, was a donation equivalent to 100 days of usage of masks by the entire hospital. However, the manufacturer’s certificates turned out to be out of date, there was no evidence to back up the claimed CE mark, and the packaging was covered in confusing claims. Greasley explains that the masks claimed to be ‘type IIR’ (the highest UK standard) and ‘95% bacterial filtration’ – yet the type IIR standard requires 98% filtration. It was not clear to managers whether this was the result of deliberate and malicious counterfeiting (a type B problem as above) or simply a lack of understanding or technical capability with suppliers (a type A problem).
In a normal situation, this would lead to a recall and withdrawal of these masks from the supply chain. Yet, with the hospital in urgent need of masks and funds, no resources to facilitate reverse logistics, this recall was not an option. In this setting, instead, the temporary organisation rapidly established a two-channel response.

First, experts from the clinical engineering and procurement teams established a procedure for validating claims and certificates. This is not normally required in a rapid response type setting, as suppliers are instead evaluated at the selection phase. This process enabled CUH to retrospectively approve suppliers and products rapidly, avoiding the need for recalls. Second, Greasley and her colleagues developed an investigation testing procedure, working with the UK’s National Physical Laboratory, that can attempt to trace back. This process was able to both validate claims and check certifications for the investigate products. With this, with confused specifications, as in place, the team was able to confirm that the example of the masks could be used above.

Responding rapidly and dynamically in this temporary organisation was critical to CUH continuing to have a reliable supply of PPE throughout the first wave of the COVID-19 pandemic. The temporary operation was wound down in August 2020, when the global PPE supply chain had recovered from the demand shock. In the next section, we discuss what the examples from this exploratory case study can do to inform practitioners in other settings.

6. Discussion and Conclusion

In this section, first, we discuss the practical implications of the analysis of recent global Covid-19 related recalls and the case study. Second, we suggest that the role of institutional actors in global and its implications on product safety needs recall risks need to be empirically studied in order to expand existing organizational theories that support supply chain and operations management research.

Cases like those at CUH inform us about how a firm can respond to quality and recall risks under disruptions. There are two ways in which a firm can respond to this situation, either by mitigating the product quality risks upstream in the supply chain or managing the risks further downstream.

First, to mitigate the risks, firms’ processes need to be agile and compliant. Our study suggests that setting up an inspection system as early upstream in the supply chain as possible is favourable, avoiding expensive backward processing and reverse logistics. Here, testing for certificates and product characteristics precedes the delivery. If it turns out that the product does not meet the given specifications, an export will not take place.

Second, to manage the risks, implement formal incoming inspection processes downstream in the supply chain. Here, agile process management is key; broad supply chains with many suppliers from different manufacturers can quickly lead to a bottleneck in the chain. The inspection process should include sample testing for compliance as well as a review of the CE certification.

In our case study we focused on changes in processes to mitigate product safety recall risks associated with protective face masks. However, we observed further countermeasures that were implemented in the context of the pandemic to cope with the shortages, including, for example, approaches to create a localised supply chain, which would serve the sharp rise in demand for medical equipment by repurposing existing production capacities.
Further to our concluding remarks for practice, we elaborated on the effects of institutional actors on supply chains and consequently products safety risks. Extant literature on institutional theory in the context of supply chains have so far mainly focused on the implications of institutional pressure on the conformance of firms (Kauppi, 2013)). Our paper extends this perspective and considers institutional actors not as exogenous regulators but as active players in the supply chain. The increased breadth of supply chains and the distribution of products through institutions and new channels rather than through regular supply chain operations has led to increased risks. Our study finds that the involvement of institutional actors can exacerbate supply chain risks that ultimately can lead to product recalls. Nevertheless, the necessity of this involvement of institutions to secure supply-critical products is beyond question.

Therefore, the impact of this general review paper is: (a) to present a description of product safety recall risks from the perspective of product process location and (b) to provide arguments for why institutional theory needs to be further investigated because institutional actors have emerged as buyers and suppliers in the supply chain. Future research could extend this approach and investigate what measures can be taken at the regulatory level to ensure product safety in these cases. In addition, the Covid-COVID 19 pandemic raises the question where existing organisational theories such as resource based theory, where companies can create a unique competitive advantage by employing unique resources (Makhija, 2003); dynamic capabilities, which is a company-focused view on distinctive processes and assets (Teece et al., 1997) and industry competitiveness or market based view, where companies compete with homogenous resources (Makhija, 2003), fall short of providing useful insight. We argue that a combination and extension of theories specifically involving institutional theory may provide useful insights and tools to study and develop practices to mitigate product safety recall risks within the context of the Covid-COVID 19 pandemic. This is pertinent particularly in the perspective of a second wave of Covid-COVID 19 infections, as increasing infections may also increase the demand for PPE products.

Acknowledgements
[The Acknowledgements are included in the ‘Title Page’ file, uploaded separately, for ensuring anonymity]

References


Table 1: COVID19 event characteristics and supply chain vulnerabilities (Sources: Chopra, 2020; Park et al., 2020).

<table>
<thead>
<tr>
<th>Key Characteristics</th>
<th>Example</th>
<th>Supply Chain Vulnerabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demand surge for certain products</td>
<td>Increase in demand for face masks, protective gloves, ventilators, testing kits</td>
<td>Stockpiling, Capacity overload, Rapid supply chain reconfiguration</td>
</tr>
<tr>
<td>Rapid emergence of alternative supply chains</td>
<td>Distribution of PPE and ventilators purchased from unregistered manufacturers and distributed by governments</td>
<td>Reduced or no visibility of the upstream supply chain</td>
</tr>
<tr>
<td>Geographical restriction on logistical flow</td>
<td>Export restrictions on supply critical goods such as drugs, PPE</td>
<td>Supply shortages</td>
</tr>
<tr>
<td>Restricted movement/ no movement of people</td>
<td>Quarantine restrictions, travel warnings, border closures</td>
<td>Capacity loss in production and warehousing</td>
</tr>
<tr>
<td>Institutional actors as buyers and suppliers</td>
<td>Governments buying medical equipment</td>
<td>Ad-hoc supply to end users without regular conformity checks, Stockpiling, surging demand</td>
</tr>
</tbody>
</table>
**Figure 1.** Product recall risk management framework (developed based on the authors' elaboration).
Table 2. Major product recall causes in PPE during the COVID 19 pandemic.

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Product Affected</th>
<th>Responsible Manufacturer</th>
<th>Country of Origin</th>
<th>Recall/Alert Reasons</th>
<th>Measures Taken</th>
</tr>
</thead>
</table>
| State Admin. Market Regulation (China) | Protective Mask | Various | China | Product functionality failure | • 89 million face masks withdrawn  
• Quality enhancement inspection |
| Missouri State Emergency Management Agency (USA) | Protective Mask | Huabai, SANQUI, etc. | China | Product functionality failure | • Masks withdrawn |
| RAPEX (Belgium, Poland, Germany, etc.) (26 alerts) | Protective Mask | Yicheng Yi Liao, Teyouda, Foshan, AMO (potentially counterfeit), HUABIWEI, etc. | China, Mexico | Product functionality failure | • Ban on marketing  
• Import rejection  
• Masks withdrawn  
• Marking with additional warnings |
| Health Ministry Netherlands | Protective Mask | Unknown | China | Product functionality failure | • Masks withdrawn |
| RAPEX (Denmark, Belgium) | Protective Mask | MLKD, Sinpul, 3M, etc. | China, Denmark | Counterfeit CE or branding | • Marketing ban |
| RAPEX (Denmark) | Protective Mask | Jtrip, HANVICO | China, Vietnam | Wrong labelling/ misleading functional description | • Marketing ban  
• Withdrawal  
• Temporary supply ban |