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Supply chain design considering correlated failures and inspection in pharmaceutical and food supply chains

Mahmood Pariazar [a], Sarah Root [b], Mustafa Y. Sir [c,*]

[a] American Airlines, Fort Worth, TX 76155, United States
[b] Department of Industrial and Manufacturing Engineering, Pennsylvania State University, University Park, PA 16801, United States
[c] Health Care Systems Engineering, Mayo Clinic, Rochester, MN 55905, United States

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ABSTRACT

This paper studies the impact of correlated supplier failures as well as inspection to detect these failures in the context of a supplier selection problem. A two-stage stochastic programming model is developed to explore the tradeoffs between costs and risk when designing a supply network. The first-stage decisions include the strategic decisions of determining which suppliers should be selected considering suppliers location and capacity while in the second stage, operational decisions related to transportation and inspection are determined. Several computational results are presented examining the effect of supplier correlation and inspection on supplier selection, transportation, and inspection strategies. A sensitivity analysis is also performed to explain the effect of key parameters on expected total cost and expected cost of shipped tainted materials.

1. Introduction

Issues in supply chain are of both practical and theoretical importance, as demonstrated both by the amount of research in supply chain field and the increasing prevalence of supply chain issues in the popular media (Japan & the global supply chain, 2011; Lohr, 2011; When the chain breaks, 2006). The supply chain comes under particular scrutiny when there are failures that either prevent necessary items from being supplied, or cause damaged goods to reach consumers. This research studies how supply chains should be designed to mitigate the effects of supplier failures, and explores how integrating inspection policy decisions into facility location and network design can impact the solutions that are obtained.

This research is motivated by several recent examples of supply chain failures that occurred in the pharmaceutical and food supply chains. In 2008, tainted heparin – a widely-used anticoagulant produced from the mucous membranes of pig intestines – was widely distributed and administered to patients. Tainted heparin was responsible for 81 patient deaths and hundreds of allergic reactions in the United States alone. Tainted heparin also affected patients in an additional eleven countries (Harris, 2008). In 2011, lettuce, cucumbers, and tomatoes were recalled in Germany before ultimately determining that E. coli-contaminated sprouts were responsible for the deaths of 31 people and making more than 3,000 gravely ill (E. coli death toll rises to 31, 2011). Similarly in the United States in 2010, more than 500 million eggs were recalled after salmonella-tainted eggs made more than 1,500 people ill (Egg contamination & recalls, 2010). These examples illustrate how serious supply chain failures can be, particularly when compromised goods reach consumers.

Motivated by these cases, this research considers supplier sourcing in two-tiered supply chains. First-tier suppliers are those who produce a product from raw materials or subassemblies. In the case of heparin, for example, this research assumes pharmaceutical manufacturers are the first-tier suppliers. Second-tier suppliers harvest or produce the raw materials or subassemblies that are ultimately shipped to the first-tier suppliers. In the heparin example, pig farmers who sell their pigs to pharmaceutical companies are examples of second-tier suppliers. This research assumes that customers (typically healthcare or group purchase organizations or large food companies) must partner with one or more first-tier suppliers to obtain the required demand for quality products. Therefore, "opening a facility" in this research is equivalent of entering a long-term contractual agreement with a first-tier supplier. Although the suppliers typically produce high-quality product, suppliers can fail and produce (at least partially) tainted product. Such failures require customers to build in redundant capacity that can be used to obtain quality product in the face of supplier failures.

* Corresponding author.
E-mail address: Sir.Mustafa@mayo.edu (M.Y. Sir).

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One of the issues raised by the motivating examples is the issue of correlated supplier failure. In the case of heparin, quality problems were ultimately traced to the contaminated pig intestines used to produce the drug. Blue pig ear disease, a highly-contagious reproductive and respiratory disease that affects droves of pigs, swept through the region in China where pigs were raised to produce heparin. As a result, at least 12 Chinese companies produced and shipped tainted heparin throughout the world (Wassener, 2010).

These failures were not independent – rather, failures were all the result of a disease outbreak that affected an entire region. Similar correlated failures were responsible for the food contamination. E. coli contamination in produce such as sprouts is caused when animal waste is used either as a fertilizer or contaminates groundwater. When groundwater becomes contaminated, it can affect many farms in an area. Both of these examples illustrate how supply chain disruptions are often not independent, but instead the result of a shared underlying cause for the disruption. Such correlation in supply failures can also occur for other reasons such as inclement weather, political unrest in a region, or labor issues such as strikes that affect multiple facilities. As a result, it is critical to consider the correlation between suppliers when considering their failure probabilities since supplier failures are often not independent as is typically assumed in this type of research (Snyder, 2006).

Another issue raised by these supply chain disruptions is that of supplier inspection. Prior to the deaths and illnesses of patients, heparin plants were rarely inspected by regulatory agencies such as the FDA. However in the aftermath of the heparin incident, an inspection of the Changzhou SPL facility that produced heparin did not have "adequate systems for evaluating the suppliers of crude heparin materials, or the crude materials themselves, to ensure that these materials are acceptable for use" (Wechsler, 2008). Subsequent testing was developed to detect tainted heparin. Similarly, food can be tested to ensure that it is free of contaminants such as salmonella or *E. coli*. Had these inspections and tests been performed prior to the shipment of tainted produce, perhaps lives could have been saved and illnesses prevented.

Also, in pharmaceutical and food supply chains, inventory shortages and unavailability of products are as problematic as the shipment of tainted products. For example, the unavailability of heparin can cause serious complications for surgery patients since substitutions for this drug cannot be easily made. Therefore, care should be taken when selecting suppliers so that products are available even in the face of failures and disruptions.

2. Literature review

In this section, a brief review of the relevant studies is provided. As described in Section 1, inspection can be an effective method to ensure that only high-quality products reach to customers when a disruption occurs. Several papers (*e.g.*, Chen, Yao, & Zheng, 2001; Chun, 2010; Hariga & Azaiez, 2006) studied inspection decision in their models. For example, Chun (2010) designed a Bayesian inspection procedure for a production process, which was subject to a random failure. The model simultaneously determined how often to inspect items, how to search economically to detect more defective items, and finally decided when to stop the search process.

In many real world applications, it is possible that low-quality products are shipped to customers even after inspection. A related branch of literature (*e.g.*, Ben-Daya & Rahim, 2003; Khan, Jaber, & Ahmad, 2014) studied the impact of inspection errors[1] on inspection effectiveness. For example, Khan et al. (2014) developed a model to determine an optimal vendor-buyer inventory policy. The model minimized the joint annual cost by considering quality inspection errors at the buyer's end. The presented numerical results indicated that Type I error has a more distinct effect on the costs as compared to the Type II errors.

There are several papers (*e.g.*, Berger, Gerstenfeld, & Zeng, 2004; Ruiz-Torres & Mahmoodi, 2007; Sawik, 2011) that studied the effect of product unavailability. For example, Sawik (2011) developed mixed integer programming model for the supplier selection and order allocation problem. He assumed that supplies were subject to random local and global disruptions. In the model, disruption risk was controlled through the use of (conditional) value-at-risk approach.

Several typologies have been proposed to categorize risks in the supply chain (Gaonkar et al., 2004; Iakovou, Vlachos, & Xanthopoulos, 2007). For a research overview of facility location under uncertainty, the reader is referred to a survey by Snyder (2006).

There is a growing body of literature that integrates tactical level decisions when making strategic level facility location decisions (*e.g.*, Erlebacher & Meller (2000) and Daskin, Coullard, & Shen (2002) which considered the integration of facility location and inventory decisions; Min, Jayaraman, & Srivastava (1998) and Nagy & Salhi (2010) which offered surveys of location-routing problems).

The previous research (*e.g.*, Li & Ouyang, 2010; Liberatore, Scaparra, & Daskin, 2012) on correlated supplier failures is limited. For example, Li and Ouyang (2010) studied spatial correlation among facility disruptions in the context of the reliable uncapacitated fixed charge location problem. A model was developed to minimize the costs of non-failure and failure scenarios by considering a different structure of the spatial correlation and used the continuum approximation method to solve the model. Smith, Garza, and Hasenbein (2006) proposed a set of stochastic models for ordering policy by incorporating interaction between co-suppliers and the interaction between suppliers characteristics. The results showed that considering interaction effects could lead to choosing significantly different co-suppliers.

The problem identified by this research is best categorized as one that designs supply chains considering supply side disruptions – that is, this paper want to locate facilities so that systems are able to perform their intended functions well when the network is transformed due to the failure of suppliers. This study implicitly relax the assumption that suppliers fail independently of each other (through scenario generation), and simultaneously consider whether or not inspection should be instituted at each facility when determining which facilities should be opened. It is shown how this problem can be modeled as a facility location problem under uncertainty. In this study, opening a facility means entering a long-term contractual agreement with a first-tier supplier. The fixed cost of opening a facility therefore is not the cost of building the facilities, but the legal fees and other costs associated with signing a long-term contract.

The remainder of the paper is organized as follows. In Section 3, the problem is defined along with details of mathematical model and the solution methodology. The proposed model is exercised in Section 4 and several analyses are provided on the effect of capacity, supplier quality, correlation, and inspection both on the selected suppliers, and the total cost of the solutions. Finally in Section 5 conclusions and directions for future research are offered.

3. Model

As described in the introduction, this research considers supplier sourcing in two-tiered supply chains. Recall that first-tier

[1] a Type I error is the incorrect rejection of a true null hypothesis (a "false positive"), while a Type II error is incorrectly retaining a false null hypothesis (a "false negative").