Short of drugs? Call upon operations and supply chain management

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Abstract

Purpose – This "impact pathways" paper argues that operations and supply chain management (OSCM) could help address the worsening drug shortage problem in high-income countries. This significant societal problem poses difficult challenges to stakeholders given the complex and dynamic nature of drug supply chains. OSCM scholars are well positioned to provide answers, introducing new research directions for OSCM in the process.
Design/methodology/approach – To substantiate this, the authors carried out a review of stakeholder reports from six European countries and the academic literature.
Findings – There is little academic research and no fundamental agreement among stakeholders about causes of shortages. Stakeholders have suggested many government measures, but little evidence exists on their comparative cost-effectiveness.
Originality/value – The authors discuss three pathways of impactful research on drug shortages to which OSCM could contribute: (1) Developing an evidence-based system view of drug shortages; (2) Studying the comparative cost-effectiveness of key government interventions; (3) Bringing supply chain risk management into the government and economics perspectives and vice versa. Our study provides a baseline for future COVID-19-related research on this topic.

Keywords Drug shortages, Supply chain risk management, Interventions, Review, COVID-19
Paper type Research paper

1. Introduction

An "ongoing and worsening drug shortage crisis" (FDA, 2019, p. 5) emerged before COVID-19 in various countries and is aggravating (Farmanco, 2020). Consequences include considerable time and effort confronting shortages, delays in treatment, suboptimal treatment and cancellation of care (EAHP, 2019; FDA, 2019). In the Netherlands, the estimated annual total cost is between 45 and 105 million euros (MvVWS, 2019).

A drug shortage has been defined as a period when demand or projected demand for a drug exceeds its supply (FDA, 2019). Using SCRM terminology, we see shortages as arising from events or conditions adversely affecting a supply chain (Ho *et al.*, 2015). Following others

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(e.g. Jia and Zhao, 2017), we refer to such events or conditions as *causes*. Abnormal causes are rare external events, such as pandemics. Normal causes occur frequently, typically originating within the supply chain, such as fluctuations in demand, production problems or delays in distribution (Ho *et al.*, 2015; Sodhi and Tang, 2012). We use the term interventions for measures taken to decrease the likelihood of adverse events and their impact. Interventions resemble SCRM strategies, typically concerned with how *companies* can mitigate risk in their supply chains (Tang, 2006; Roscoe *et al.*, 2020). In contrast, we focus on *governmental* measures that may mitigate the risk of shortages. Government action is believed to be crucial here (De Weerdt *et al.*, 2015), and COVID-19 is reinforcing this belief. When deciding which government intervention(s) to implement, several questions arise: What are the causes? What is their relative importance? How are they interconnected? Which interventions are likely to be most effective, and at what cost?

This impact pathways paper argues that OSCM could help answer these questions. We present an agenda for further research, based on a review of the academic literature on drug shortages combined with an analysis of secondary data pre-COVID from six European countries.

Our study focuses on off patent and generic prescription drugs, which represent most drug shortages (EAHP, 2019; FDA, 2019) and provides a baseline for future COVID-19-related research on this topic. Both supply chain risk management (SCRM) (Sodhi and Tang, 2012) and resilience (Van Hoek, 2020) provide useful perspectives, where some see the first as an enabler of the latter. Research on resilient medicine supply chains has been very scant (cf. Lücker and Seifert, 2017; Tucker *et al.*, 2020). We agree with Ellis (2020) that risk management in pharmaceutical supply chains should be a "strategically imperative exercise that is regularly revisited, not one to dust off when a disruption occurs" (p. 8).

2. Stakeholder perceptions of causes and interventions

We searched websites of stakeholder organizations in Belgium, France, the Netherlands, Norway, Sweden, and the United Kingdom for material on drug shortages published between January 1st 2010 and December 31st 2019 resulting in 134 relevant sources. For each country, two researchers were involved in coding and analyzing the data. Further details are provided the online addendum, section A.

2.1 Claim 1: There is no real agreement among stakeholders about causes of drug shortages

First, many sources report first-level causes and do not link them to underlying issues. Typically, manufacturing problems, and "other supply chain related problems" are listed as key causes, with no mention of possible underlying economic causes (NoMA, 2019), for example price, tendering and reimbursement policies. Such policies can affect supply bases, inventories, production quality and capacity, and lead times, but there is little evidence. It has been shown in other sectors that pressure on prices results in outsourcing manufacturing to low-cost economies, making supply chains more vulnerable to disruptions (Van Hoek, 2020).

Second, though dozens of causes can be identified, sources typically report a small subset which differs substantially *between* countries. For example, Belgian and UK sources make no reference to impacts of prices and margins on inventories, and only the Netherlands and France report effects of quality issues. Sources also differ *within* countries. Norwegian pharmaceutical manufacturers list manufacturing problems and demand increases as key causes (LMI, 2018), whereas the Directorate of Health emphasizes long lead times, just-in-time inventory management, hoarding, and market size (HDir, 2019). Similarly, the UK's National Pharmacy Association (2020) highlights quota systems imposed by manufacturers as an important cause, while manufacturers point to pharmacies and wholesalers exporting medicines intended for the UK (ABPI, 2019).

2.2 Claim 2: Many suggested interventions but little evidence or knowledge of what works

Most shortages are managed reactively instead of proactively, focusing "more on decreasing the effects of shortages or dealing with their consequences than on the underlying causes" (MvVWS, 2019, p. 19). There is vast diversity among additional interventions considered, many resembling SCRM-strategies, such as better information sharing and adding *redundancy* through emergency stock. Interventions to enhance the *flexibility* (Tang, 2006) are also frequently suggested, such as awarding contracts to multiple suppliers to counter monopoly formation and ensure a "supply base that can be drawn upon in the event of a failure" (SRF, 2018, p. 98). Stakeholders also consider numerous interventions not easily categorizable in SCRM frameworks such as substituting medicines that are out of stock and rationing and allocating scarce supplies. Widely recommended is bringing production back to Europe. This resembles the make or buy SCRM strategy (Tang, 2006), but uses government incentives as opposed to in-house vs outsourcing decisions by manufacturers.

However, stakeholders provide little evidence on cost-effectiveness. For example, the Dutch government analyzed the effects of 27 interventions and concluded they were mostly difficult to assess or unknown (MvVWS, 2019). We found no analysis of which interventions are more cost-effective than others.

3. What research has contributed so far

We identified 506 articles in our scientific literature review and read 79 in depth, and classified each article in terms of context, purpose, type of evidence provided, intervention analysis, cause analysis and research methodology. Three of the authors were involved in coding to secure inter-rater reliability. See the online addendum, section B for details of search terms and inclusion criteria.

3.1 Claim 1: OSCM has so far played a marginal role in studying the drug shortage problem

We identified only ten articles on drug shortages in OSCM-related journals (Azghandi *et al.*, 2018; Chang *et al.*, 2019; Dai *et al.*, 2016; Jia and Zhao, 2017; Kochan *et al.*, 2018; Liao *et al.*, 2015; Lu and Shi, 2019; Shiau, 2019; Tucker *et al.*, 2020; Zadeh *et al.*, 2014). The remaining identified articles make little use of models, tools or concepts from our field.

3.2 Claim 2: More research presenting a comprehensive view on shortage causes is necessary

Scholars agree that recent increases in drug shortages are driven by several trends (De Weerdt *et al.*, 2015; Heiskanen *et al.*, 2017; Pauwels *et al.*, 2014; Tucker *et al.*, 2020; Yurukoglu *et al.*, 2017). However, most papers that express a view on the causes present either no new evidence or evidence relating to first level causes only. Papers aiming to assess the causes comprehensively use mainly expert opinion and mechanism-based reasoning, regarded by health scientists as relatively weak evidence (Van de Klundert, 2016). Studies examining causal interrelations are particularly scarce.

Like stakeholder reports, academic papers report primarily on first-level causes. Indeed, Pauwels *et al.* (2014) conclude that "no efforts [have yet been made] to unveil the root causes" (p. 7). This may be the consequence of eliciting stakeholder views on causes of *specific* shortages, directly or via reporting platforms.

Heiskanen *et al.* (2017) and Pauwels *et al.* (2015) do reveal several underlying causes but provide no new evidence on how these factors could be interrelated or impacted further upstream. Woodcock and Wosinska (2013) explore such interrelationships with economic theory to argue that disincentives in the pharmaceutical market can worsen shortages. De Weerdt *et al.* (2015) use inference from economic mechanisms and stakeholder reports to indicate how European and national laws might affect drug shortages. We found only three

studies that apply econometric modeling to study causality between shortage and pricing. Yurukoglu *et al.* (2017) showed that shortages rose for drugs whose prices decreased most significantly. Ridley *et al.* (2016) revealed that a higher price is associated with a lower likelihood of shortage. Parsons *et al.* (2016) show that having maximum four suppliers makes shortages more than twice as likely to occur compared to having five or more suppliers.

3.3 Claim 3: More work is needed to assess holistically the cost-effectiveness of suggested government interventions

To assist governmental decision-making, there is a need for research that (1) examines proposed interventions for which cost-effectiveness is unclear, (2) provides strong evidence of comparative cost-effectiveness and (3) assesses the direct and indirect implications for all relevant stakeholders. For example, to assess the impact of changes in procurement one should consider effects on market attractiveness and the number of suppliers. Only 18 studies provide any evidence on implementation costs and/or effectiveness of proposed interventions. All papers that present *empirical* evidence (7 of the 18) comprise case studies of a specific stakeholder's response to a shortage. Similarly, more than half of the papers that present evidence from *modeling* and numerical simulation consider a single stakeholder and a single intervention (cf. Zadeh *et al.*, 2014). Reliance on such local optimization can miss implications for upstream and downstream parts of the supply chain (Settanni *et al.*, 2017). Two modeling/simulation papers (Azghandi *et al.*, 2018; Kochan *et al.*, 2018) account for multiple stakeholders but do not consider the government. Dai *et al.* (2016) study how the US government could mitigate shortages of an influenza vaccine through incentivizing a manufacturer to initiate early production, and Jensen and Throckmorton (2015) investigate how the US Food and Drug Administration (FDA) collaborated with manufacturers to take last-minute risk-mitigation actions. Half the articles cover reactive interventions, like rationing, allocation or substitution, and last-minute risk mitigation. Accordingly, there is great potential for research on proactive interventions that governments *could* consider.

We identified two papers that illustrate urgently needed research taking a systems perspective (capturing multiple stakeholders, causes beyond first-order ones, interdependencies of causes). Jia and Zhao (2017) model the impact of increasing prices and failure-to-supply penalties on manufacturers' inventory and capacity decisions, and the subsequent effect of those decisions on shortages. Tucker *et al.* (2020) use a multi-stage stochastic model to simulate how government interventions affect a manufacturer's decisions on supply chain design and inventories and estimate how this affects societal costs and shortages.

4. Pathways for future research

4.1 Pathway item 1: Develop an evidence-based system view

Sections 2.1 and 3.2 describe limited evidence on the causes of shortages, their relative importance, and how they interrelate. With the notable exception of a study on the link between the number of suppliers and shortages (Parsons *et al.*, 2016), we found no studies that quantify the cause-and-effect relationships linking causes related to pricing, tendering and reimbursement to shortages. That means a serious risk of stakeholders and academics missing important dynamics and knock-on effects. For example, we did not identify any modeling studies that capture how interventions impact the number of suppliers, even though it is widely believed that they may. Furthermore, research on how interventions can backfire is needed. For example, joint tendering is claimed to increase appeal for their markets (Eversana, 2020), while France argues that it could *decrease* the number of suppliers and increase vulnerability (SRF, 2018).

We therefore advocate further research that can (1) establish sound evidence on understudied cause and effect relationships and (2) combine it with evidence from existing literature to establish a system view of the problem. We need research that builds the whole from the parts. OSCM expertise in studying and modeling complex dynamic systems will be paramount here, combined with expertise from the health sciences and economics. We see a large potential role for system dynamics modeling and econometric models that assess causality. These methods would be very suitable for studying links between prices and other underlying causes and manufacturing disruptions, inventories, parallel trade, lead times and the number of manufacturers. Building on the leading studies identified in this review, such research could complement publicly available data sets, with direct engagement with relevant stakeholders.

4.2 Pathway item 2: Studying the comparative cost-effectiveness of key government interventions

Section 3.3 highlights the paucity of evidence on the cost-effectiveness of proposed governmental interventions. We therefore call upon OSCM researchers to develop and parametrize models for this:

Establishing strategic stocks. Legal requirements for inventory levels (or lead times) and corresponding failure-to-supply penalties have been considered in several countries. Countries struggle to decide how high such inventory levels should be, where the inventory should be kept, whether and how to differentiate by medicine, how to finance, and how to enforce. The challenge of specifying legal requirements differs from traditional inventory management, notably that a policy should be expressed in relatively simple language – e.g. keep a safety stock of x months of demand for medicines with characteristics y and z. Furthermore, evaluations should take into consideration that such interventions can change the "future state" of the system. For example, there are concerns that increasing penalties carries the risk that manufacturers with small revenues or low prices will withdraw from the market. OSCM scholars have the potential to inform this debate by developing models to optimize market-wide inventory policies and failure-to-supply penalties and account for market withdrawals. Such models can be parametrized using publicly available data on drug demand, prices, market authorization holders and shortages.

Reshoring of drug manufacturing. The OSCM community possesses much expertise that could inform debates around reshoring of drug manufacturing. COVID-19 has led to many calls for action and the comparative cost-effectiveness of possible strategies is hugely interesting. Reshoring will certainly increase costs (France24, 2020), and it is questionable to what extent it will resolve problems, partly because upstream supply chains (e.g. for Active Pharmaceutical Ingredients) may remain global. There is a clear need for more OSCM research on the total system cost-effectiveness of reshoring, how it differs for specific drugs and countries, how it depends on other countries' reshoring decisions, and how it compares to the effects and costs of other interventions.

Revising pricing, tendering and reimbursement practices. Interventions that tackle economic causes – pricing, tendering and reimbursement practices – are a third important research area. Since tackling these practices is perceived to conflict with the objective of maximizing affordability, a delicate balance needs to be struck (cf. Musazzi *et al.*, 2020). OSCM expertise on game theoretic modeling and mechanism design, parametrized using data on shortages, prices, numbers of market authorization holders, and expertise on procurement practices could help address this question.

Future research in this area would also benefit from a behavioral OSCM perspective (Bendoly *et al.*, 2010) to examine how cognitive and psychological factors impact contractual relationships in drug supply chains. For instance, *framing bias* is relevant to consider when

designing tenders and contracts (Selviaridis and van der Valk, 2019), e.g. whether switching from a predominant "prevention" contract framing (emphasizing control and penalties to suppliers) to a "promotion" (stressing supplier rewards) could help instigate collaboration and flexibility in supplier relationships. Studying how *perceptions* of fairness (e.g. regarding pricing), trust and power influence contractual negotiations would also be a fruitful avenue for further research.

4.3 Pathway item 3: Bringing the government perspective and economics into supply chain risk management and vice versa

Many interventions suggested by stakeholders could be classified using common SCRM frameworks. We nevertheless see two fundamental differences that can push the frontiers of SCRM research. First, interventions could be addressed from a government perspective, and thus complement existing SCRM studies. Governments and their policies have a critical role in mitigating supply chain disruptions (Scholten *et al.*, 2020). As they are rarely directly engaged in the production and distribution of medicines, interventions are usually indirect. COVID-19 shows that governments are increasingly intervening to avoid or minimize shortages. For example, they have traditionally not been involved in decisions on production locations, but some plan to influence them through economic incentives. Similarly, most governments have not stocked medicines but are now planning to influence stocks kept by firms by introducing regulations and fines. Studying inventory management and facility location from a company perspective can hence be fundamentally different from studying stockpiling and production reshoring resulting from government regulations. The same applies to procurement, distribution, quality and capacity management, and so on. Sound analyses of government policies' effect on supply chains have received limited attention (Scholten *et al.*, 2020). Second, although maintaining a diverse supply base is recognized as a SCRM strategy, supply base decisions have typically been made by existing supply chain members, i.e. the buying organization. Our context highlights the need to understand how supply base design is impacted by other actors' decisions to enter or exit a market.

It would be very helpful to have models that capture these decisions. Several general supply chain economics models are available (Corbett and Karmarkar, 2001; Korpeoglu *et al.*, 2020), but they include some assumptions that do not hold for medicine supply chains. They also analyze outcome variables other than availability, or study interventions and decision variables that may not apply. We therefore advocate that researchers should develop models that capture (1) relevant interventions, (2) their impact on entry/exit decisions, and (3) the direct and indirect implications for supply chain risk. Collaboration between economists and OSCM researchers is essential here.

To summarize, our suggested pathways are graphically depicted in Figure 1.

4.4 Final remarks

We have seen many calls for OSCM scholars to increase the relevance of their research (Van Wassenhove, 2019) and undertake studies that are practice-based and responsible (Lee and Tang, 2018), contributing toward more sustainable and resilient supply chains (Sarkis, 2021), but accounting for difficult trade-offs (Matos *et al.*, 2020). The continuing problem of drug shortages demands that the OSCM community gets more involved and provides us with a great opportunity: (1) the problem has substantial patient and economic impacts; (2) it poses complex questions for stakeholders to which there is no obvious answer; (3) OSCM scholars are well positioned to address these questions; and (4) the problem introduces fundamentally new research directions for OSCM and pushes the frontiers of our discipline. COVID-19 has amply demonstrated why such work is urgently needed. The pandemic has substantially worsened the situation, not only for COVID-related medicines and vaccines, but also in terms

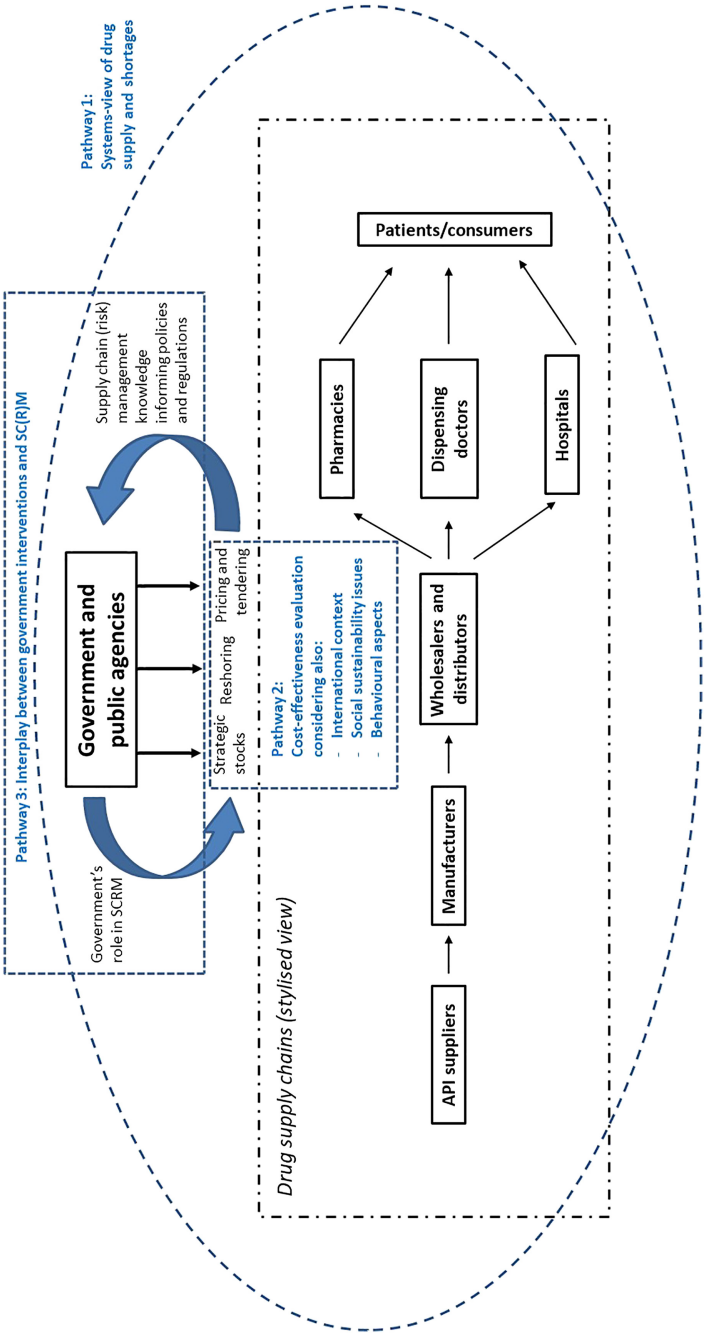

Figure 1.
Visualizing the
suggested pathways

of strong knock-on effects on regular drug supply, particularly in low- and middle-income countries. More resilient and sustainable drug supply chains will provide better global long-term access.

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Appendix

The supplementary file is available online for this article.

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