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Medicine shortages – A study of community pharmacies in Finland

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ABSTRACT

Objectives: To explore the frequency, the reasons behind, and the consequences of medicine shortages in Finnish community pharmacies.
Methods: During the 27-day study period in the autumn of 2013, randomly selected pharmacies reported on medicines that were in short supply from orders made to wholesalers.
Results: Altogether 129 (66%, $n = 195$) pharmacies participated in the study, and the study material consisted of 3311 report forms. Of the study pharmacies, 79.8% had medicine shortages daily or almost daily. Medicines in short supply were most commonly medicines that affect the nervous system (30.8%) and the cardiovascular system (17.5%). The reason behind the shortage was reported to the pharmacies in 11.2% of the shortage cases. The medicine shortages caused problems for the pharmacies in 33.0% of the cases. In most cases (67.0%) the medicine shortages did not cause problems for the pharmacies, usually because a substitutable product was available (48.5%).
Conclusions: Medicine shortages are common in Finnish community pharmacies. Medicines in short supply were commonly used medicines. The reason behind the shortage was rarely told to the pharmacies. Medicine shortages caused problems for the pharmacies in one-third of all the shortage cases. These shortages may be significant for the customers or the pharmacies, as they cause customer dissatisfaction and increase the workload of the pharmacy staff.

1. Introduction

Good availability of medicines has been stated as a political goal internationally [1]. Regardless, medicines are not always readily available and medicine shortages occur. A medicine shortage can be defined as "a drug supply issue requiring a change that impacts patient care and requires the use of an alternative agent" [2]. Several reasons related to demand or supply causes may be behind medicine shortages [2,3]. For example, demand-related factors include changes in demand like increased demand and non-traditional demands like parallel trade [2]. Medicine supply problems may be related to raw and bulk material issues (e.g., raw material shortage), manufacturing issues (e.g., limited manufacturing capacity or changes/problems in the production process or business-related decisions to cease production due to poor demand and profit), wholesale and distribution issues (e.g., inventory management practices or delays in the distribution chain), market structure issues (e.g., single- or

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limited-source products due to mergers and consolidations or the generic medicines market), regulatory issues (e.g., batch recall or stringent regulatory requirements that delay production), and communication issues (e.g., lack of information or reluctance to share details of shortages) [2,3]. There may also be multiple simultaneous reasons behind a shortage. A shortage can emerge at any stage in the life cycle of a medicine and in any part of the pharmaceutical distribution chain (pharmacy, pharmaceutical company, or wholesaler) [2].

There are a limited number of research publications dealing with medicine shortages. In addition, the studies have primarily been conducted in hospitals. Some studies have reported the impact of medicine shortages on patient safety and patient care [4–11]. Medicine shortages may cause several issues related to patient care, such as medication errors, inefficient medical care, and side effects or allergies when the medicine is changed due to the shortage. In addition, due to medicine shortages, the patient's care may be delayed and in some cases the patient may not receive recommended treatment at all [8–10]. Furthermore, sometimes due to shortages the treatment may be more expensive than the originally selected treatment [8–11]. Patients may also experience stress or frustration when shortages occur [11]. Moreover, medicine shortages may also cause significant harm to health care professionals, as shortages increase the workload of physicians and pharmacists [8–10,12,13].

A few studies have reported the frequency of medicine shortages. According to a study conducted in hospitals in the United States, nearly all the hospitals suffered from medicine shortages at least once within the last 6 months [6]. Of these hospitals, 44% reported 21 or more shortages within the last 6 months. According to a Canadian study conducted in pharmacies, medicine shortages were even more common, as almost 94% of respondents reported shortages during the last week and 81% during their last shift [11]. The shortages had complicated dispensing of an average of ten prescriptions during the last week. Of the respondents, 89% agreed that the number of medicine shortages had increased notably during the last year.

Medicine shortages have been an internationally recognized current topic lately [2,3,14–17], and have also been addressed in an international summit [2]. According to the report of the international summit on medicine shortages, medicine shortages have become a growing global issue, and in some countries the number of shortages has tripled between 2005 and 2010. However, medicine shortages are still a rarely investigated subject and the information currently available is insufficient for assessing the extent and characteristics of medicine shortages at a country-specific and international level.

1.1. Study context

In Finland, the pharmaceutical market is small [18]. In 2013, total sales of pharmaceuticals at wholesale prices were approximately €2 billion, which was divided into sales to pharmacies (72%), sales to hospitals (26%), and sales to retailers and others (2%) [19]. Most pharmacy sales (87%) consisted of sales of prescription medicines, of which a majority (78%) were reimbursed medicines [19,20]. The share of the global pharmaceutical market is approximately 0.3%, and of the European pharmaceutical market, approximately 1.3%. The majority of medicines sold in Finland come from abroad, mostly from EU countries [18].

Community pharmacies have the sole right to sell prescription and over-the-counter (OTC) medicines (excluding nicotine replacement therapy) to the public in Finland. There is a privately owned pharmacy system, with 615 pharmacies and 185 subsidiary pharmacies in 2013 [21]. Subsidiary pharmacies are privately owned, small pharmacy outlets that the pharmacy owner possesses along with the main community pharmacy. Subsidiary pharmacies are placed in areas where pharmaceutical service is needed but there is no need for an independent main community pharmacy. In addition, there are two community pharmacies owned by two universities: the University Pharmacy of Helsinki, with 16 subsidiary pharmacies, and the University Pharmacy of Eastern Finland. The university pharmacies operate like the privately owned community pharmacies. The staff in pharmacies consists of the pharmacy owner (M.Sc. in pharmacy), pharmacists (M.Sc. in pharmacy), prescriptionists (B.Sc. in pharmacy), and, for example, pharmacy technicians. Furthermore, 59% of the staff has a pharmaceutical education. A pharmacist is a person with 5-year education and a prescriptionist is a person with 3-year education at the university. Both pharmacist and prescriptionist dispense medicines independently and ensure their safe and proper use among the public by patient counseling, but pharmacists also act as manager. The average pharmacy in Finland delivered about 72,000 prescriptions in 2013 [22].

The pharmacy business is strictly regulated in Finland. The Finnish Medicines Agency (FIMEA) controls the location, number, and ownership of pharmacies [23]. The pharmaceutical network in Finland is comprehensive, as there is at least one pharmacy in almost every municipality [24]. There is one pharmacy per 6000 inhabitants. The prices of medicines are the same in all pharmacies [23]. Sales of medicines constitute 94% of the turnover of pharmacies [25].

In Finland, there are two pharmaceutical wholesalers with a distribution system that covers the whole country. Finnish wholesale distribution of medicines is based on a single-channel system [26]. This means the pharmaceutical manufacturer makes a sole-distribution contract covering all its products with a wholesaler, and pharmacies or hospitals can acquire a certain pharmaceutical product though that wholesaler only.

Generic substitution (GS) and a reference price system (RPS) are in use in Finland [27,28]. According to the Medicine Act 80/2003, pharmacists are obligated to substitute the prescribed product with the cheapest or close to the cheapest interchangeable product if the price of the product is higher than the reference price. If the customer objects to the substitution, the customer has to pay the price difference between the reference price and the chosen medicine out of pocket. The reference price is determined quarterly by the least expensive medicine in every reference price group. The reference price is the price of the cheapest product +€1.50 if the price is under €40, and