
# Community Pharmacists' Perceptions and Experiences of Medicine Shortages in Disruptive Situations, in Durban, South Africa

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## DECLARATION

In fulfilment of the requirements of the coursework degree of Master of Pharmacy, in the Discipline of Pharmacy, University of KwaZulu-Natal, Durban, South Africa, I, Rivana Bachoolall, declare as follows:

i. That the work described in this thesis has not been submitted to UKZN or other tertiary institution for purposes of obtaining an academic qualification, whether by myself or any other party.

ii. The research reported in this dissertation, except where referenced, is my original work.

iii. This dissertation does not contain other person's text, tables, data, graphs or other information, unless specifically acknowledged as being sourced from other persons.

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   a) Their words have been rewritten but the general information attributed to them has been referenced;
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Signed:  Dated: 8 February 2024

# PREFACE

This is a mini dissertation comprising of 50% research project component. The University of KwaZulu-Natal CR13 (c) directs that a dissertation "*may comprise one or more papers of which the student is the prime author, published or in press in peer-reviewed journals approved by the relevant college academic affairs board or in manuscripts written in a paper format, accompanied by introductory and concluding integrative material*". As such a standalone methodology is not required, as it forms part of the submitted paper/manuscript chapter. The outline of each chapter is presented at the end of Chapter 1.

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## ABBREVIATIONS AND ACRONYMS

| Abbreviation | Description/Meaning |
|---|---|
| **ADR/s** | Adverse drug reaction/s |
| **APIs** | Active pharmaceutical ingredients |
| **ARV** | Antiretroviral |
| **COREQ** | Consolidated criteria for reporting qualitative research |
| **COVID-19** | Coronavirus disease 2019 |
| **HCPs** | Healthcare professionals |
| **ICPA** | Independent Community Pharmacy Association |
| **LMICs** | Lower and middle-income countries |
| **OOP** | Out-of-pocket |
| **OTC** | Over-the-counter |
| **TB** | Tuberculosis |
| **WHO** | World Health Organization |

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## ABSTRACT

**Background:** Medicine shortages are a challenge in upper, lower and middle-income countries, including South Africa. In recent years, community pharmacists in Durban, South Africa, have experienced disruptions such as the COVID-19 pandemic, flooding, civil unrest and electricity disruptions. Little is known about the impact of these disruptive situations on medicine shortages in community pharmacies.

**Aim:** Exploring the perceptions of community pharmacists and their experiences with medicine shortages during the COVID-19 pandemic and other disruptive situations.

**Method:** A qualitative methodology was employed to explore the topic in-depth. Convenience and snowball sampling were used to recruit 15 community pharmacists in Durban, South Africa. Semi-structured interviews were conducted in person or via an online video conferencing platform. All interviews were audio-recorded and transcribed verbatim. The transcripts were coded deductively on NVivo 14 software, using the Framework Method of thematic analysis. Initial codes and themes were informed by a literature review and final themes were identified on review.

**Results:** A total of fifteen community pharmacists were interviewed. Five major themes were identified from thematic analysis, viz. the perceptions of medicine shortages, the impact of disruptive situations, the consequences of medicine shortages, mitigation strategies; and further suggestions and resources. Perceptions were that shortages were exacerbated by the disruptive situations. Participants perceived a negative financial impact on patients and pharmacies, with out-of-pocket costs affecting the former and loss of income affecting the latter. The mitigation strategies used were contacting stakeholders, medicine substitution and stock management.

**Conclusion:** Community pharmacists felt that medicine shortages required improved communication, collaboration, policies, notification systems and guidelines to mitigate the problem further. These should be investigated for possible implementation to create more transparency in the event of shortages.



**Keywords:** medicine shortages, disruptive situations, community pharmacists, South Africa

# Chapter 1: Introduction

This chapter describes the problem of medicine shortages and highlights the need to explore the issue from a community pharmacist perspective, during disruptive situations. The background, problem statement, aim, objectives, conceptual framework, research questions, research methodology and layout of the dissertation are presented.

## 1.1. Background

Medicine shortages are an ongoing problem that affects upper, lower and middle-income countries (LMICs). While developed countries have policies and guidelines in place to manage medicine shortages, LMICs lack these preventative strategies (Rinaldi et al., 2017; Shukar et al., 2021). The consequences of medicine shortages are twofold, affecting patients and healthcare professionals (HCPs). Patients are adversely affected when medicine shortages lead to economic outcomes such as out-of-pocket (OOP) costs; clinical outcomes - including mortality, adverse drug reactions (ADRs), drug errors, hospitalisation status changes and reduced quality of care; and humanistic outcomes such as increased travel time, frustration, anger and anxiety (Phuong et al., 2019).

HCPs in the Eastern Cape province, in South Africa, felt that dealing with medicine shortages was stressful and reported that patients were dissatisfied and lost confidence in public sector healthcare services (Ndzamela, 2020). Similarly, researchers in Pakistan found that community pharmacists experienced reduced sales, profits and incentives when patients lost trust in them and did not return to the pharmacies with medicine shortages (Omer et al., 2021). Furthermore, dealing with medicine shortages is time-consuming. In Belgium, community pharmacists reported spending a median time of 25 minutes per week, whereas hospital pharmacists reported spending a median time of 109 minutes per week on medicine supply problems and shortages (De Weerdt, De Rijdt, et al., 2017; De Weerdt, Simoens, et al., 2017).

The main reasons for medicine shortages are manufacturing issues, logistical issues and the lack of sufficient active pharmaceutical ingredients (APIs). Additional reasons include unexpected demand, raw materials shortages and epidemics. (Bogaert et al., 2015; Fox et al., 2014). The COVID-19 pandemic has exacerbated medicine shortages and several strategies have been suggested for pharmacists to mitigate the issue (Badreldin & Atallah, 2021). However, little is known about the implementation of these strategies in community pharmacies. Researchers in several countries have explored medicine shortages from a community pharmacy perspective. A quantitative study, in Finland, found that medicine shortages occurred frequently, decreased customer satisfaction and increased staff workload (Heiskanen et al., 2015).

Qualitative studies in Australia and Canada explored medicine shortages during normal situations; and studies in Pakistan and India were conducted during the COVID-19 pandemic (Omer et al., 2021; Panic et al., 2020; Ramakrishnan et al., 2023; Tan et al., 2016). These researchers found various mitigation strategies, such as medicine substitution, contacting stakeholders and stock management.

Medicine shortages are a challenge in South Africa, where the healthcare system consists of the public and private sectors (Gray, 2014). Previous medicine shortage studies conducted in South Africa are limited to hospital pharmacies and community healthcare centres in the public sector (Chigome et al., 2019; Hodes et al., 2017; Hwang et al., 2019; Modisakeng et al., 2020; Ndzamela, 2020; Zuma, 2022). Therefore, medicine shortages in South African community pharmacies have not been explored, nor has the financial impact on patients and HCPs.

### 1.2. Problem Statement

The lack of clear guidelines and legislation to prevent medicine shortages in LMICs has consequences for patients and the healthcare system (Phuong et al., 2019; Shukar et al., 2021). The economic impact is apparent when patients spend OOP costs. Community pharmacists in Pakistan attributed a loss of income due to medicine shortages and those in hospitals and community pharmacies, in Belgium, highlighted that there was a time investment when dealing with medicine shortages (Omer et al., 2021).

Various mitigation strategies have been used in response to the issue. Hodes et al. (2017) found that public health facilities, in the Eastern Cape, used strategies such as an informal borrowing system and communication network; and a partial supply of medicines to patients. In Canadian community pharmacies, Panic et al. (2020) found that the main solutions were medicine substitution with generic or originator brand equivalents; and contacting suppliers and other pharmacies. Tan et al. (2016) found workarounds such as contacting the prescriber for a therapeutic equivalent, accessing products from overseas and ordering extra stock in Australian community pharmacies. Ramakrishnan et al. (2023), who explored the challenge from a COVID-19 perspective, found that the strategies used by community pharmacies in India were alternative procurement methods and medicine substitution, after communicating with prescribers.

Most studies exploring medicine shortages have been conducted during normal situations and have not explored the effect during other disruptive situations, apart from the COVID-19

pandemic. Community pharmacists in Durban, South Africa, have encountered several disruptions in recent years, such as civil unrest, flooding and electricity disruptions. To date, no studies in South Africa have explored community pharmacists' experiences with medicine shortages. This study will address the gap in the literature regarding medicine shortages in community pharmacies during disruptive situations; and explore the perceived financial impact on patients and pharmacists.

### 1.3. Aim

This study aimed to explore community pharmacists' perceptions and their experiences with medicine shortages during the COVID-19 pandemic and other disruptive situations.

### 1.4. Objectives

- To explore the perceptions and experiences with medicine shortages faced by community pharmacists during the COVID-19 pandemic and other disruptive situations;
- To describe the strategies that community pharmacists have used in response to medicine shortages;
- To provide suggestions to mitigate the challenge of medicine shortages in community pharmacies during a pandemic and other disruptive situations; and
- To describe the perceived cost and financial impact of medicine shortages on patients and the healthcare system.

### 1.5. Conceptual Framework

Several concepts pertinent to the study are defined below:

- "Community pharmacies" – retail pharmacies in the private sector of the healthcare system, where pharmacists dispense prescription and over-the-counter (OTC) medicines to patients. In South Africa, there are corporate pharmacy chains and independently owned community pharmacies (Gray et al., 2016).

- "Consequences" – the financial or economic, clinical and humanistic outcomes in patients, that occur as a result of medicine shortages (Phuong et al., 2019).

- "Contacting stakeholders" – communicating with other pharmacies, suppliers (wholesalers), or prescribers, to mitigate medicine shortages (Panic et al., 2020; Tan et al., 2016).

- "COVID-19" – the coronavirus disease that originated in 2019 and was declared a pandemic by the World Health Organization (WHO) in 2020 is defined as "a highly contagious viral illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)." (Cascella et al., 2023).

- "Financial or economic outcomes" – any cost experienced by patients or pharmacies, for example, out-of-pocket costs in the former and loss of income in the latter (Omer et al., 2021; Phuong et al., 2019).

- "Medicine shortages" – the concept of medicine shortages has several definitions, however, for the purpose of this study the WHO definition from the demand side was used, which states: "When demand exceeds supply at any point in the supply chain and may ultimately create a "stock-out" at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient." (World Health Organization, 2017).

- "Medicine substitution" – replacing unavailable medicines with alternative medicines, for example, by dispensing a generic, therapeutic or brand equivalent (Panic et al., 2020; Tan et al., 2016).

- "Mitigation strategies" – any form of action taken to reduce the problem of medicine shortages, such as medicine substitution, contacting stakeholders or stock management.

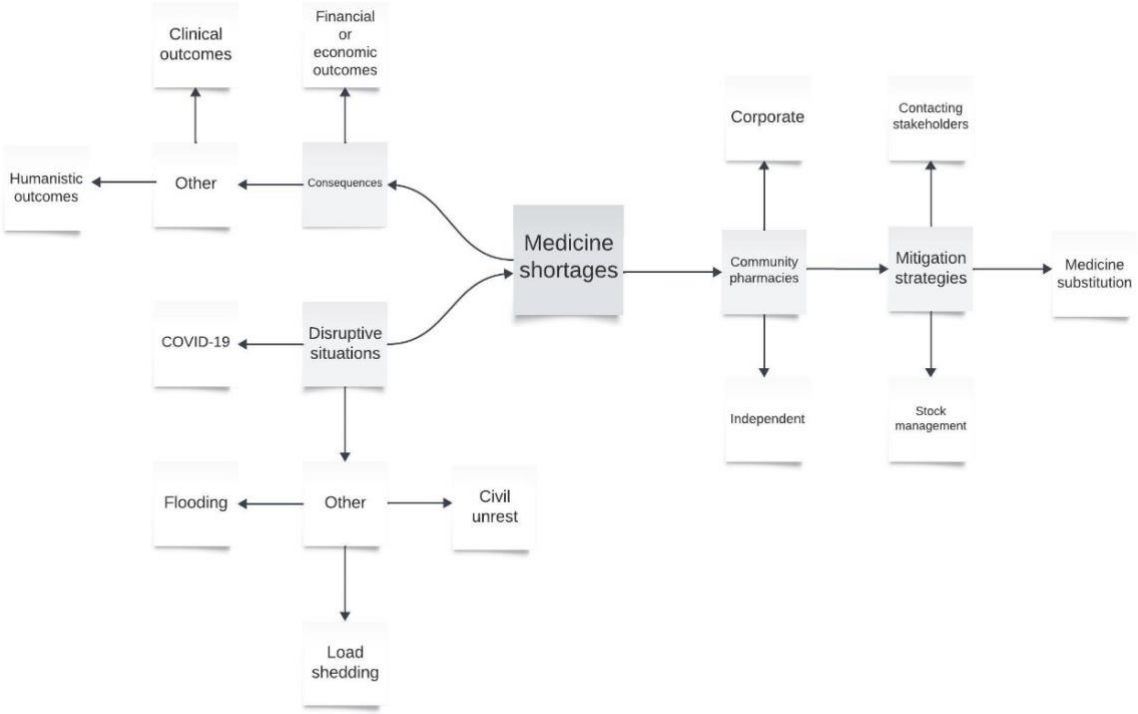
- "Other disruptive situations" – a group of situations unique to the pharmacists in Durban, South Africa, in recent years, which includes civil unrest, flooding and load shedding.

- "Stock management" – a mitigation strategy involving the procurement and storage of medicines, for example, previously used strategies included ordering extra stock, informal borrowing of stock and alternative procurement methods (Hodes et al., 2017; Ramakrishnan et al., 2023; Tan et al., 2016).

The relationships between the defined concepts are illustrated in Figure 1. The focal concept, medicine shortages, affects corporate and independent community pharmacies, which are also impacted by COVID-19 and other disruptive situations such as civil unrest, flooding and load

shedding. The consequences of medicine shortages lead to financial/economic and other outcomes, which include clinical and humanistic outcomes. The mitigation strategies are the current solutions that pharmacists have used in response to the challenge, which include medicine substitution, contacting stakeholders and stock management.

**Figure 1.** The Conceptual Framework




### 1.6. Research Questions

From the research objectives, the following research questions were derived:

- What are the perceptions and experiences of community pharmacists with medicine shortages during the COVID-19 pandemic and other disruptive situations?
- What strategies have community pharmacists used in response to the challenge of medicine shortages?
- What suggestions can community pharmacists provide, to help alleviate the problem of medicine shortages?
- According to community pharmacists, what is the perceived financial or economic impact of medicine shortages on patients and pharmacies?

## 1.7. Research Methodology

### *1.7.1. Study Design*

This was a qualitative, exploratory study.

### *1.7.2. Study Setting*

The study was conducted at community pharmacies in Durban, South Africa.

### *1.7.3. Sampling Strategy*

Data was collected through a convenience sample, using a snowball technique, where participants referred the researcher to other participants. Initial participants were independent community pharmacists, who were recruited via an e-mail sent to them by the Independent Community Pharmacist Association (ICPA), on behalf of the researcher, inviting them to participate in the study. If the recommended people who were approached to participate declined, they were then asked to recommend a colleague. Subsequent participants were invited using messages, telephone calls or in-person contact.

*Study Population*

Community pharmacists in independent and corporate community pharmacies, for which gatekeeper letters were obtained, were interviewed. The following inclusion and exclusion criteria were used to select participants:

*a. Inclusion Criteria*

Permanently employed, full-time community pharmacists in the private sector were invited to participate in the study.

*b. Exclusion Criteria*

Locum pharmacists, who practice only part-time and rotate across various pharmacies, were excluded, due to the lack of a consistent work environment and irregular working hours. Pharmacist interns and community service pharmacists were excluded, due to the lack of sufficient work experience.

### *1.7.4. Sample Size*

Initially, a sample size of a minimum of 12 pharmacists was selected. This sample size was based on the findings of Guest et al. (2020), where 95% saturation was reached after 11 to 12 interviews. The final sample size consisted of 15 participants.

### *1.7.5. Ethical Considerations*

Gatekeeper permission was obtained from the Independent Community Pharmacy Association (ICPA) and the head of stores of a corporate pharmacy chain before the commencement of data collection at each of the sites (Appendix A). Ethics approval for the study was granted by the University of KwaZulu-Natal's Biomedical Research Ethics Committee (Reference no: BREC/00005865/2023) (Appendix B). Informed consent letters were signed by each participant before commencing each interview (Appendix C). Each participant was assigned a participant number for confidentiality and identification purposes.

### *1.7.6. Data Collection*

The data collection occurred over four weeks, from the 30$^{th}$ of August to the 27$^{th}$ of September 2023. Community pharmacists were interviewed, using a semi-structured interview guide adapted from a study by Bogaert et al. (2015) (Appendix D). The World Health Organization's definition of medicine shortages, from the demand side, was included in the interview guide to promote understanding of the concept (World Health Organization, 2017). Questions regarding the time investment of community pharmacists and the cost/financial consequences of medicine shortages were added – as this is one of the objectives of the study. To be relevant to a South African setting, further adaptations to the interview guide included civil unrest as an unpredictable cause of medicine shortages and excluded some of the European-based legal questions used by Bogaert et al (2015).

Semi-structured interviews were chosen to enable deeper delving into the research problem, by allowing participants to answer open-ended questions (DeJonckheere & Vaughn, 2019). Interviews were conducted either in person or via an online video conferencing platform. All interviews were audio-recorded on a mobile voice recording application, with the informed consent of all participants. Participant demographics were taken before the start of the recordings and included gender, age, qualification, job description, number of years of experience in community pharmacy and the type of community pharmacy. Thereafter, participants answered open-ended questions in four areas – general questions, legal aspects, communication and solutions. Field notes were taken after each interview, which noted the environment, observations, participant background information, interesting points and notes to self. Interviews were conducted until data saturation was reached and no new themes were identified (Saunders et al., 2018).

### *1.7.7. Data Analysis*

Thematic analysis was conducted according to the Framework Method outlined by Gale et al. (2013), which is a commonly used method for the analysis of transcripts from semi-structured interviews. The method was followed in a stepwise fashion, which provided a systematic approach to analysing the qualitative data (Figure 1).

*a. Transcription*

The interviews were transcribed verbatim, which was simultaneously a data immersion exercise.

*b. Familiarisation*

All recordings were re-listened to and the transcripts were re-read to allow for familiarisation.

*c. Coding*

The data were assigned codes deductively, using NVivo 14 software. Initial codes and themes were based on previous literature. Initial coding was done by the researcher. This was validated by the research supervisor, through discussion, until agreement on the final codes and themes was reached.

*d. Analytical framework development*

A working analytical framework was developed after coding. This encompassed grouping codes together to find categories. This was repeated throughout the interview process until no new codes were identified.

*e. Application*

Each code was defined in the working codebook, which was edited as new codes and categories were identified. The categories formed the resulting sub-themes and themes.

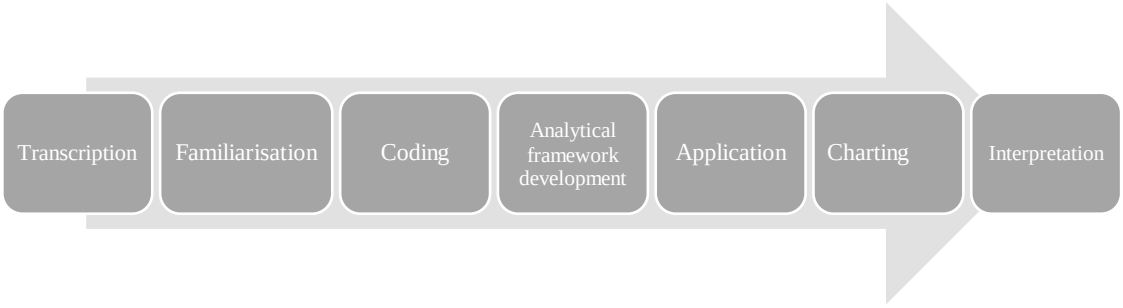
*f. Charting*

The data from each theme was charted into a framework matrix, using Nvivo 14 software, which was thereafter exported to Microsoft Excel. Each framework matrix consisted of a table with the participant number along the vertical axis and the sub-themes, categories and codes along the horizontal axis.

*g. Interpretation*

The data characteristics were looked at, using the framework matrices. Interpretation involved analysing the codes and categories and identifying similarities and differences. Lastly, summaries were made for each sub-theme.

**Figure 2.** The Framework Analysis Method




### *1.7.8. Reporting, Rigour and Trustworthiness*

The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was utilised for reporting (Tong et al., 2007) (See Chapter 3). The rigour and trustworthiness of the study are described, using the quality criteria described by Korstjens and Moser (2018) - credibility, transferability, dependability and conformability.

*a. Credibility*

Prolonged engagement was used to build rapport and trust with the participants. Persistent observation was exercised throughout the data collection, data familiarisation and coding processes. Field notes were made after conducting each interview. The audio recordings were re-listened to and transcripts were re-read, while first impressions were documented. The codes, categories and themes were revised throughout the application of the working analytical framework.

*b. Transferability*

The research setting, context, sampling strategy, sample size, inclusion and exclusion criteria, and the semi-structured interview guide were clearly described. This information enables the reader to decide whether the findings are transferable to their own setting.

*c. Dependability and Conformability*

The research steps that were followed were described transparently. Consistency and neutrality were employed throughout the data collection and analysis process, ensuring dependability and conformability.

## 1.8. Layout of the Dissertation

The dissertation is presented in four chapters.

### *1.8.1. Chapter 1*

This chapter describes the background of the research problem and the need to explore the perceptions and experiences of community pharmacists with medicine shortages in disruptive situations. It gives a brief overview of the previous literature and includes the problem statement, aim and objectives of the research. Several concepts relevant to the study are defined and the relationships between them are illustrated through a conceptual framework. This is followed by the research methodology used and the layout of the dissertation.

### *1.8.2. Chapter 2*

This chapter presents a literature review, which further explains the main concepts of the research. Thereafter, previous studies conducted in local public sector pharmacies and international community pharmacies are critically analysed. This analysis highlights the gap in the literature.

### *1.8.3. Chapter 3*

This chapter contains the research paper submitted to the International Journal of Clinical Pharmacy, as per the journal's author submission guideline. The title page and the main text are presented and reference is made to the supplementary material.

### *1.8.4. Chapter 4*

This chapter synthesizes and concludes the dissertation by explaining how the aim and objectives were reached. The summary and significance of the findings, the strengths and limitations of the study and further recommendations are discussed.

## 1.9. Summary

Chapter 1 outlined the context of the study and the layout of the dissertation. South Africa is affected by the global challenge of medicine shortages, and the need to explore the perceptions and experiences of community pharmacists in disruptive situations has been discussed. The aim and objectives are listed and a conceptual framework was used to explain the definitions and relationships between the relevant concepts. Research questions, that were derived from the objectives, were listed. The research methodology described the study design, setting, sampling strategy, sample size, ethical considerations, data collection and data analysis. Lastly, the contents of each chapter in this dissertation were presented.

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# Chapter 2: Literature Review

The focus of the literature review is twofold – firstly, to define the concepts relevant to the research topic. Secondly, to critically analyse previous medicine shortage studies conducted in hospital and community pharmacies; and to highlight the gap in the literature.

## 2.1. Definition of Concepts

### *2.1.1. Medicine Shortages*

Several definitions of medicine shortages exist across European countries. De Weerdt et al. (2015) identified definitions that were either from the demand side, the supply side or based on the delivery or availability of a drug. However, the authors identified the need for a more uniform definition across European countries. The World Health Organization (WHO) (2017) defined that a shortage occurs "when the supply of medicines, health products, and vaccines identified as essential by the health system is considered to be insufficient to meet public health and patient needs." This definition takes into consideration the supply side. The WHO further identified a definition from the demand side, which states that a shortage occurs "when demand exceeds supply at any point in the supply chain and may ultimately create a "stock-out" at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient." For this research study, the definition from the demand side will be used and the term "stock-out" will be considered synonymous with the term "medicine shortage." Medicine shortages may be exacerbated in disruptive situations, necessitating alternate strategies by community pharmacies to maintain good patient outcomes.

### *2.1.2. The COVID-19 Pandemic*

A pandemic refers to a worldwide epidemic, which is "the occurrence in a community or region of a group of illnesses of similar nature, clearly in excess of normal expectancy, and derived from a common or from a propagated source" (Gordis, 2014). The novel coronavirus outbreak was first reported on the 31$^{st}$ of December 2019 in Wuhan, located in the Hubei Province of China. Patients presented with pneumonia of an unknown cause. The virus has since spread across all continents and on the 30$^{th}$ of January 2020, WHO declared the virus a "Public Health Emergency of International Concern" (Ciotti et al., 2020; World Health Organization, 2020). Initially referred to as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus was renamed on the 11$^{th}$ of February 2020 to COVID-19 or coronavirus disease 2019. The WHO declared COVID-19 a global pandemic on the 11$^{th}$ of March 2020 (Cucinotta & Vanelli, 2020; World Health Organization, 2020). The index case in South Africa was reported

on the 5th of March 2020 and a "National State of Disaster" was declared by the government on the 15th of March 2020 (Government Gazette, 2020). In response to the growing number of infections in the country, a national lockdown was implemented on the 27th of March 2020, with varying stages to open the economy announced thereafter. A risk-adjusted lockdown strategy with five different alert levels was implemented, ranging from the most stringent containment measures (level 5) to the least stringent (level 1). Curfews, limitations on travel and gathering restrictions were imposed and adjusted according to each level being implemented. Social distancing, hand hygiene and the wearing of face masks remained the mainstay of preventing transmission throughout all lockdown levels (Moonasar et al., 2021).

The first COVID-19 vaccines became available globally in December 2020 (World Health Organization, n.d.). However, the national vaccination rollout in South Africa only began on the 17th of February 2021, which targeted healthcare workers via the Sisonke Programme, using the Janssen COVID-19 vaccine (Phase 1). The national rollout of the Pfizer Comirnaty vaccine began on the 17th of May 2021, amongst those who were 60 years or older. (Phase 2). A risk-based approach was used to sequentially vaccinate other age/population groups, ending with those between the ages of 18 and 45 (Phase 3) (Discovery, 2021). The National State of Disaster, together with all lockdown restrictions, was lifted by the South African government on the 4th of April 2022 (The Presidency: Republic of South Africa, 2022).

#### *2.1.3. Other Disruptive Situations*

Beyond the COVID-19 pandemic, other disruptions may impact the supply of medicines. These situations provide a set of unique circumstances in which pharmacists in Durban, KwaZulu-Natal faced medicine shortages.

*a. Public Unrest*

The province of KwaZulu-Natal faced medicine shortages of a critical nature in July 2021; following the looting of pharmacies and the destruction of a local pharmaceutical manufacturing plant (Knowler, 2021). This disruptive effect mirrors the case of Venezuela, where protests adversely affected healthcare services. The availability of medicines and other medical supplies became severely compromised. The shortage of medicines created an additional challenge during a period of protests against crime, inflation and shortages of goods (Robertson, 2014).

*b. Natural Disasters*

From the 10th to the 12th of April 2022, severe rainfall led to unprecedented flooding on the east coast of South Africa. This caused widespread damage and led to over 500 deaths (Thoithi et al.,

2023). Following the COVID-19 pandemic, the president of South Africa declared a National State of Disaster on the 18th of April 2022 (South African Government, 2022). Natural disasters can disrupt the provision of healthcare services, making it difficult to manage chronic conditions. Medicine shortages are one of the barriers that limited community pharmacists in their ability to respond to the effects of Hurricane Maria in Puerto Rico (Melin & Rodríguez-Díaz, 2018).

*c. Load Shedding*

Load shedding, which is a planned interruption of electricity, occurs "when the demand for electricity exceeds the available supply" The national electricity utility; Eskom, rotates the available supply between its customers (City of Johannesburg, 2018; Shah et al., 2023). South Africa has been experiencing load shedding since 2007. However, the frequency has increased to over four times in 2022, compared to 2021. The presidency once again declared a State of National Disaster on the 9th of February 2023, but this was revoked on the 5th of April 2023 (Langerman, 2023; South African Government, 2023). Nevertheless, this disruptive situation may impact the supply chain, when wholesalers, distributors and manufacturers do not have backup power supplies.

### *2.1.4. The Role of the Community Pharmacist*

South Africa has a two-tiered healthcare system, which consists of the public and private sectors. The division arose because of the apartheid regime. In the public sector, pharmacists are employed in hospitals, community health centres, as well as other areas such as medical stores and offices (district, provincial or national). Pharmacists in the private sector are employed either in private hospitals or in community pharmacies. South African pharmacists predominantly practice in community pharmacies, which are either owned independently or by pharmacy chains. These pharmacies are mainly situated in urban areas and tend to service the population who belong to medical aids (Gray et al., 2016).

Pharmacists are the custodians of medicine and provide services relating to the medicine needs of the public (The South African Pharmacy Council, 2010). South African community pharmacies provide both prescription and non-prescription services. Prescription medicines can be legally substituted with generic medicines by pharmacists, with the consent of the patient (Bangalee, 2015). Generic substitution occurs when "a generic drug is substituted for a brand-name drug. However, both drugs have the same active chemical ingredient, same dosage strength and same dosage form" (Morrell, 2009). Non-prescription services include the

provision of pharmacist-initiated therapy to patients, which involves the sale of OTC medicines (Gray et al., 2016).

Community pharmacists are also responsible for the procurement and stock management of medicines (The South African Pharmacy Council, 2010). The traditional role of the community pharmacist expanded during the COVID-19 pandemic, to include COVID-19 vaccinations, testing, patient education; as well as disease and medication management (Strand et al., 2020). In Jordan, the challenge of medicine shortages faced by community pharmacists was exacerbated by the public's panic buying and stockpiling of medicines, during the COVID-19 pandemic. Therefore, there is a need for clear guidelines in order to manage medicine shortages during crises (Al Zoubi et al., 2021).

## 2.2. Previous Studies

The section will first look at the medicine shortage studies conducted locally, and then internationally. PubMed and Google Scholar databases were searched using the following search terms: (medicine OR medication OR drug) AND (shortage OR stock-out OR unavailability) AND "South Africa". For international studies, the terms (community pharmacy OR pharmacist) were included; and the search term "South Africa" was excluded. The date range was filtered to include studies from the last 10 years. The inclusion criteria were qualitative or quantitative studies, with healthcare professionals - including pharmacists - as participants; and medicine shortages were highlighted as a challenge. For international studies, the additional criterion of community pharmacies as a setting was included.

### *2.2.1. South African Studies*

Hodes et al. (2017) conducted a qualitative study in 2016, in the Eastern Cape province of South Africa, investigating the response of front-line workers to shortages of essential medicines. Fifteen healthcare workers were interviewed in several public healthcare facilities (clinics, hospitals and a community healthcare facility). The participants were not limited to pharmacy staff – interviews were conducted amongst hospital management, doctors, nurses, administrative and ground staff. Thereafter, 5 interviews were conducted with healthcare workers, who were involved directly with medical supply management. The authors found that an informal borrowing system was used in response to stock-outs, which was accessed via social networking on the mobile phone application, WhatsApp. A differentiation was made between "minor" stock-outs, which could be managed by informal borrowing and "full-blown" stock-outs, which could not. In the event of a "full-blown" stock-out, patients would end up being turned away. Alternatively, patients would be provided with in-stock medicines and advised to return to the

facility to collect the balance. The authors highlight that this is an unsuitable long-term solution, especially for patients taking chronic medicines. Furthermore, there is a need for a more uniform understanding of stock-out definitions, as well as more consistency in the reporting of both types of stock-outs.

The challenge of shortages of antiretroviral (ARV) and tuberculosis (TB) medicines has been looked at quantitatively by Hwang et al. (2019). A cross-sectional telephonic survey was conducted across 2370 healthcare facilities, in 2015. There was one participant in each facility, with preference given to pharmacy staff (pharmacists or pharmacy assistants), followed by nursing staff. Stock-outs were defined as "the complete absence of a specific formulation and/or dosage of medicine at a given facility." The results showed that stock-outs of ARVs and TB medicines were highly prevalent, with major differences between provinces. The authors suggest that this could be attributed to varying levels of ability to manage stock-outs between provinces. More than one-third of the surveyed facilities experienced a stock-out in the 3 months before the survey; and one-fifth on the day of the survey. The facilities reported that 25% of stock-outs resulted in a high impact on patients, who would receive a partial or no supply of medicines. However, these quantitative results only reveal the extent of the stock-outs – and not the solutions used to mitigate the problem.

A quantitative study by Chigome et al. (2019) investigated the use of therapeutic interchange policies in response to medicine shortages across South African hospitals, in the public sector. Therapeutic interchange is defined as "the practice of replacing, with the prescribing practitioner's approval, a prescription medicine originally prescribed for a patient with an alternative prescription medication" (Academy of Managed Care Pharmacy, 2021). In 2018, an electronic survey was sent to all public sector hospitals in the country, with one pharmacist participating per hospital. The response rate to the researchers' online survey was only 33.5%. From these responses, it was ascertained that therapeutic interchange policies were not widely used or understood. However, most pharmacists contacted the prescriber for substitution. By investigating only one mitigation strategy, others may be overlooked as the study did not allow for open-ended questions. Therefore, a qualitative method will be more suitable to elicit additional strategies.

A qualitative study, conducted by Ndzamela (2020) at an Eastern Cape community healthcare centre, looked at the experiences of both healthcare professionals and patients with medicine shortages. The researchers conducted in-depth interviews with 12 healthcare professionals and 8

patients, who were recruited via a convenience sample, over two days. Thematic analysis revealed that both groups of participants were affected psychologically by medicine shortages, there were perceived causes of medicine shortages, as well as compensatory measures in response to the problem. As with the study by Hodes et al. (2017), an informal network of borrowing medicines between facilities was noted in the results. Ndzamela (2020) found that patients also borrowed medicines from others, or the funds to purchase medicines from pharmacies in the private sector. Therefore, the experiences of the participants highlight borrowing as the main mitigation strategy. The authors suggest a formal borrowing system on social media as a short-term solution. In the long term, improved communication and flow of information are suggested across all areas of the supply chain, ultimately preventing medicine shortages and its associated challenges. Ndzamela (2020) mentions the Stop Stock-outs Project (SSP), which is an organisation that aims to report and monitor shortages of essential medicines, in the public sector of South Africa (Stop Stockouts Project, 2024). While this national tool allows for transparency of medicine shortages in hospitals and clinics, there is a lack of similar resources in the private, community pharmacy sector.

Modisakeng et al. (2020) sought to describe procurement challenges and medicine shortages among hospitals, in the public sector of Gauteng. Ten qualitative, in-depth interviews were conducted with pharmacy managers, using purposive sampling, between September to December 2017. Thematic content analysis was conducted and revealed several challenges – including difficulty procuring medicines from non-contracted suppliers, poor supplier performance and the lack of confidence among staff to use RxSolution (an electronic system for inventory management). Despite the small sample size and limitation to only one province in South Africa, the authors believe that the findings can be replicated in other provinces – as they capture the essence of pharmacy managers' experiences. Although this qualitative study elucidated the challenges associated with medicine shortages, it did not provide solutions to the problem.

A qualitative study was conducted by Zuma (2022), in eight of the nine provinces in South Africa, to assess the challenge of stock-outs at public healthcare facilities. Semi-structured interviews were conducted with 15 pharmaceutical managers, who were identified by the researcher as information-rich participants. Thematic analysis was used to analyse the data inductively. The findings revealed that rural healthcare facilities were more prone to medicine shortages. Furthermore, poor stock control, manual ordering systems and insufficient staff had an impact on stock-outs. The suggested strategies to mitigate the issue were electronic stock

management, keeping buffer stock, monitoring stock availability, contacting suppliers, forecasting stock needs, involving all stock management role-players and adjusting the quantities of stock issued to all patients, while awaiting replenishment. However, all of these solutions pertain to procurement strategies, specific to public healthcare facilities. Furthermore, all South African studies discussed in this section were conducted in the public sector and did not address the issue of stock-outs and medicine shortages in community pharmacies. Therefore, a gap exists in the South African literature.

### *2.2.2. International Studies*

Several countries have investigated medicine shortages from a community pharmacy perspective. In Finland, a quantitative study was conducted by Heiskanen et al. (2015) over a 27-day period in 2013. The researchers used a random sample of 194 community pharmacies that were privately owned. They found that commonly used medicines were in short supply and the reasons were not communicated to the pharmacies. Their findings highlighted that one-third of the cases were affected by shortages, while the rest could be remedied by substitution with available medicines. However, the medicines that could not be substituted posed a significant problem to both patients and the pharmacy staff, by decreasing customer satisfaction and increasing staff workload. While this study depicts the frequency of medicine shortages as well as its impact, it does not describe the experiences of the participants. Therefore, there is a need to explore the problem from a qualitative perspective.

An exploratory qualitative study was conducted in Australia by Tan et al. (2016) between August and September 2015. The researchers explored the incidence, impact as well as management strategies of medicine shortages, by using a convenience sample. A passive snowballing technique was used to recruit the participants. 20 semi-structured interviews were analysed using thematic analysis, even though saturation was reached after 14 interviews. Despite the small sample size, the researchers feel that they investigated the problem sufficiently, as interviews were conducted beyond saturation. Themes were analysed using the framework approach, which starts with data immersion – listening to the recordings of the interviews and re-reading transcripts to find recurring themes. Once data saturation is reached, the subsequent steps are indexing, charting, mapping and interpreting the data.

The emerging themes found by Tan et al. (2016) were contextual (prevalence of medicine shortages and workarounds), diagnostic (causes and impacts), evaluative (notifications about shortages and opinions about the national website for the reporting of shortages) and strategic (suggestions). Furthermore, a “vicious cycle” was described – where shortages led to the

increased demand for alternative medicines, creating additional shortages. The participants' mitigation strategies, in the form of workarounds, were limited to medicine substitution and the stockpiling of medicines (the ordering of extra stock to avoid being out-of-stock). However, some participants were against stockpiling, due to costs and favouring "just-in-time inventory" – where the order frequency is increased, instead of the quantity. This leaves little time to respond to medicine shortages when they do occur. Suggestions were limited to the facilitation of better communication with doctors, to prevent the prescribing of out-of-stock medicines.

Panic et al. (2020) explored how community pharmacy staff managed medicine shortages in Ontario, Canada. The study participants were 14 pharmacists, as well as 7 pharmacy technicians. As with the previous study, the researchers also used convenience sampling with the snowball method. The authors define this as a "method in which early study participants were invited to nominate a colleague they were aware of who may have used an interesting strategy to manage drug shortages in practice." Additionally, stratification was done to be more representative of the different pharmacy ownership types. The interviews were conducted one-on-one and focused on the strategies used to mitigate the problem of medicine shortages in real-world practice. Qualitative content analysis was employed to identify themes until saturation was reached. The results included leaning on or following up with the suppliers for medicines that were on backorder, substitution to available generic or brand options, checking with other pharmacies or ultimately, switching the patient to a different medicine. These strategies were identified as mid- to long-term by the participants and the results could not be generalizable to a wider population, due to the purposive sampling method used. Real-world solutions were provided and the authors highlighted the need for further research, regarding medicine shortages.

A qualitative study conducted in Pakistan took a broader overview of the problem, as interviews were conducted across 3 cities, from February to May 2021. Omer et al. (2021) explored how community pharmacists managed medicine shortages, as well as the resources employed. Face-to-face interviews were conducted with 31 participants, who were recruited purposively. This was followed by qualitative content analysis. The emerging themes were the current scenarios in community pharmacies, the barriers encountered, the impact of the problem, the corrective actions taken and the interventions to prevent shortages in the future. The corrective actions identified were considered proactive measures – maintaining the inventory, building relationships with distributors and staff training. Additionally, counteractive measures were identified as using medicine alternatives, patient counselling, communication with other

pharmacies in the area and limiting the quantity dispensed to patients. Further interventions included the proper monitoring of medicine usage, fair distribution, circulating information about medicine shortages and collaboration. The latter two studies do not mention specific strategies in response to the pandemic. Therefore, it is necessary to further investigate mitigation strategies under such disruptive circumstances.

Ramakrishnan et al. (2023) investigated how the COVID-19 pandemic impacted the supply of chronic medicines by exploring the experiences of community pharmacists in India. Twelve participants were recruited purposively and interviewed telephonically until data saturation was achieved. The resulting themes were the challenges faced in the workplace (commute, working hours, staffing, coping with COVID-19, profit margin and systematic work approach) the management of medicine supply (procurement challenges, management of expired products, stockpiling storage and medicine shortages), the dispensing of medicine (management of over-the-counter medicine and precautions taken), barriers to service provision (delivering of medicines to customers, management of customer complaints and patient counselling), arranging for medicines that were unavailable (alternatives, use of personal transport and contacting stockist distributors) ADR management (consulting with physicians, companies or pharmacists) and the inputs of pharmacists in response to the various challenges (overcoming medicine distribution, sales and staffing challenges as well as improving customer service).

The phenomenon of stockpiling discussed by Al Zoubi et al. (2021) was also highlighted as an issue, as patients in Jordan were panic buying medicines, due to the fear of out-of-stocks. This further exacerbated the problem, as Ramakrishnan et al. (2023) found that chronic medicines were in short supply across various categories. In response to the arrangement of unavailable medicines, the participants reported alternative procurement methods and medicine substitution. Some participants contacted local stockists without difficulty, while others had to utilise their own transport to procure medicines. The participants also mentioned contacting doctors, to substitute with alternative medicines. While the selection of study participants from an individual location is noted by the researchers as a limitation, they believed the impact of the COVID-19 pandemic to be the same across most parts of India. The outcomes of this qualitative study focussed on the needs and expectations of community pharmacists; as well as barriers faced with regards to the supply of medicines during the COVID-19 pandemic. Only two methods were employed for the arrangement of unavailable medicines. Therefore, a gap exists in the literature for further mitigation strategies in response to medicine shortages, during the COVID-19 pandemic and other disruptive situations.

A recent quantitative survey was conducted by the European Association of Hospital Pharmacists (EAHP) between the 27th of February and the 19th of May 2023 (Miljković et al., 2024). The EAHP has collected data on medicine shortages since 2014, including the causes, mitigation strategies and effects on patients. There were 1497 hospital pharmacists, from various European countries, who responded to the 2023 survey. Physicians, nurses and other healthcare professionals also participated in the survey, whereas patients received a different survey. The study revealed that antimicrobial agents were the most common medicines that were in short supply, in hospital pharmacies across Europe. Additionally, the researchers found that there were shortages of medical devices and critical medicines. The main causes were attributed to active ingredient shortages and problems with manufacturing, the supply chain or legislation. COVID-19, energy and war crises were identified as contributing factors that may have exacerbated medicine shortages.

The study found that the impact on patients had increased in comparison to the previous survey. In response to medicine shortages, patients received alternative medicines, were advised to reduce their doses, or received no doses at all. Miljković et al. (2024) highlighted that the mitigation strategies used were inadequate to reduce the impact on patients. Current reporting systems, national task forces, notification systems, protocols, contingency plans and risk assessments are insufficient to address the problem. Several solutions were suggested – such as early notification of medicine shortages, collaboration between countries and institutions within Europe; and mandatory communication amongst the various stakeholders. While the survey provides insight into medicine shortages from a European hospital pharmacy perspective, there is a gap in the literature for exploring medicine shortages from a community pharmacy perspective in South Africa.

### 2.3. The Financial Impact of Medicine Shortages

When medicines shortages occur, there may be an increase in costs. This financial burden is imposed on both patients and the healthcare system (Alsheikh et al., 2021; Atif et al., 2021).

#### *2.3.1. Patients*

Patients experience an increase in out-of-pocket and treatment costs as a result of medicine shortages. Researchers (Atif et al., 2021). Phuong et al. (2019) have identified that increased costs are due to switching to either the originator brand or the alternative of the medicine in short supply. Additionally, fuel costs may increase for travelling to alternate pharmacies, where medicines are in stock. However, productivity costs - in the form of time off work - were not

reported by the patients interviewed. The authors attribute this to a possible bias for health research towards clinical outcomes, instead of economic outcomes.

#### *2.3.2. The Healthcare System*

The economic impact was also reported by institutions interviewed by Phuong et al. (2019). The costs of procuring medicines in short supply increased, as well as the staff costs to manage these shortages. Productivity and efficiency are affected when additional time is spent to communicate with manufacturers and to identify and procure alternative medicines (Caulder et al., 2015). In community pharmacies, time investment increased when staff informed patients about medicine shortages and contacted prescribers to make changes to prescriptions (De Weerdt et al., 2017). The additional workload added pressure to pharmacy staff; as time had to be utilized for the management of medicines shortages, instead of other work activities. Furthermore, medicine shortages resulted in sales targets not being achieved. This adversely affected pharmacy staff, who experienced dissatisfaction due to the non-achievement of incentives. The pharmacist-patient relationship was impaired when patients placed the blame on the staff for medicine shortages and did not return to the pharmacy for medicines (Omer et al., 2021).

Patients and healthcare workers are both adversely impacted by the effects of medicine shortages. Therefore, it is necessary to highlight both the impact and the solutions to the problem. This qualitative study will address the gaps in the literature concerning mitigation strategies for medicine shortages under disruptive circumstances, in community pharmacies, in Durban, South Africa. Additionally, it will describe the financial impact of medicine shortages on both patients and the healthcare system.

### 2.2. Summary

This chapter defined the main concepts relevant to this study, which included medicine shortages, the COVID-19 pandemic, other disruptive situations and the role of the community pharmacist. Secondly, it critically analysed previous medicine shortage studies in South Africa and internationally. Lastly, the financial or economic impact on patients and the healthcare system was discussed.

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## Chapter 3: Submitted Paper

This article has been submitted to the International Journal of Clinical Pharmacy. See the submission acknowledgement email as proof (Appendix E) and supplementary material (Appendix F).

This chapter presents the submitted paper as per the journal stipulated format https://link.springer.com/journal/11096/submission-guidelines and limitations in terms of graphs, tables and word count. Written permission to conduct the study was sought from and granted by the Biomedical Research Ethics Committee of the University of KwaZulu-Natal, (Reference no: BREC/00005865/2023 and Appendix B). See also the Independent Community Pharmacy Association (ICPA) and the corporate chain pharmacy permission letters (Appendix A). See too the data collection sheet and informed consent documents (Appendices C and D).

Rivana Bachoolall (RB) was responsible for proposal development, data collection and analyses; and the write-up. Prof. Fatima Suleman (FS) served as supervisor.

### 3.1. Title Page

**Manuscript title:**

Community Pharmacists' Perceptions and Experiences of Medicine Shortages in Disruptive Situations: A Qualitative Study

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### 3.2. Main Text


## ABSTRACT

**Background:** Medicine shortages are a challenge in upper, lower and middle-income countries, including South Africa. In recent years, community pharmacists in Durban, South Africa, have experienced disruptions such as the COVID-19 pandemic, flooding, civil unrest and electricity disruptions. Little is known about the impact of these disruptive situations on medicine shortages in community pharmacies.

**Aim:** Exploring the perceptions of community pharmacists and their experiences with medicine shortages during the COVID-19 pandemic and other disruptive situations.

**Method:** Convenience and snowball sampling were used to recruit community pharmacists in Durban, South Africa. Semi-structured interviews were conducted in person or via an online video conferencing platform. All interviews were audio-recorded and transcribed verbatim. The transcripts were analysed thematically on NVivo 14 software, using the Framework Method.

**Results:** A total of 15 community pharmacists were interviewed. Five major themes were identified from thematic analysis, viz. the perceptions of medicine shortages, the impact of disruptive situations, the consequences of medicine shortages, mitigation strategies; and further suggestions and resources. Perceptions were that shortages were exacerbated by the disruptive situations. Participants perceived a negative financial impact on patients and pharmacies, with out-of-pocket costs affecting the former and loss of income affecting the latter. The mitigation strategies used were contacting stakeholders, medicine substitution and stock management.

**Conclusion:** Community pharmacists felt that medicine shortages required improved communication, collaboration, policies, notification systems and guidelines to mitigate the problem further.



## KEYWORDS

Medicine shortages, disruptive situations, community pharmacists, South Africa


## IMPACT STATEMENTS

- Community pharmacists experienced an increase in medicine shortages during disruptive situations such as the COVID-19 pandemic, civil unrest and flooding.

- Out-of-pocket costs were perceived to be the main financial impact of medicine shortages on patients.
- Patients were perceived to suffer poor health outcomes and negative emotions when medicines went out of stock.
- Pharmacies faced a loss of income and invested additional time dealing with medicine shortages.
- Medicine shortages were perceived to impair the pharmacist-patient relationship.

## INTRODUCTION

Medicine shortages impact patients and healthcare professionals (HCPs) globally [1,2]. According to the World Health Organization (WHO), medicine shortages occur when the demand for medicines is greater than the supply, which may create a medicine "stock-out" and the patient's clinical needs are not met [3]. Consequently, patients face the financial burden of increased medicine and out-of-pocket (OOP) costs. Medicine shortages can lead to adverse drug reactions and other poor clinical outcomes, due to compromised or delayed treatment; and humanistic outcomes such as time wastage and negative emotions of patients [4,5]. Similarly, pharmacists in Belgium and Pakistan reported that dealing with medicine shortages was time-consuming and often led to a loss of trustworthiness and revenue for the pharmacy, respectively [6,7]. HCPs in a public community healthcare centre, in South Africa, experienced an increased workload and frustration when dealing with medicine shortages [8].

South Africa's healthcare system consists of the public and the private sectors [9]. Medicine shortage studies in South Africa are limited to the public sector and have explored the perspectives of patients, pharmaceutical staff and other HCPs [8, 10-13]. Researchers in Saudi Arabia, Canada and Australia have explored medicine shortages from a community pharmacy perspective during normal situations [14-16]. A recent study in India explored the impact of the COVID-19 pandemic on the medicine supply chain at community pharmacies [17]. The COVID-19 pandemic provided a unique circumstance whereby the supply chain was constrained globally.

The causes of medicine shortages may be due to supply, demand or regulatory issues. Supply issues encompass problems with production, manufacturing or shipping delays and the unavailability of raw materials or active pharmaceutical ingredients. Demand issues include increased product demand and rarely, damage to manufacturing sites by natural disasters or

inclement weather conditions [1,18]. How HCPs, especially pharmacists experience these events and deal with them is unclear.

## AIM

This study sought to explore the perceptions of community pharmacists and their experiences with medicine shortages during the COVID-19 pandemic and other locally disruptive situations. Additionally, the study sought to describe the perceived financial impact of medicine shortages on patients and pharmacies; and explore the mitigation strategies used.

## ETHICS APPROVAL

Ethics approval was granted by the University of KwaZulu-Natal's Biomedical Research Ethics Committee (Reference no: BREC/00005865/2023). Participants were required to sign informed consent forms before the interviews took place. Participation was voluntary and participants had the option to withdraw from the study at any point. Each participant was assigned a participant number to maintain confidentiality.

## METHOD

### Study design, setting and subjects

This was a qualitative, exploratory study. The data collection occurred over four weeks. Semi-structured interviews were conducted with community pharmacists in Durban, South Africa, as these were identified as information-rich participants, having been exposed to several disruptive situations in recent years.

### Participant recruitment

Participants were recruited by a convenience sample, using a snowball technique, where participants referred the researcher to other possible participants. Initial participants were invited by e-mail. Subsequent participants were invited using messages, telephone calls or in-person contact. The following criteria were used to select participants:

#### *Inclusion criteria*

Permanently employed, full-time community pharmacists in the private sector.

#### *Exclusion criteria*

Locum pharmacists, pharmacist interns and community service pharmacists.

**Data collection**

Semi-structured interviews were used to collect the qualitative data. This method allowed participants to answer open-ended questions, which enabled deeper delving into the research problem [19]. The semi-structured interview guide (See electronic supplementary material Appendix S1) was adapted from a study conducted by Bogaert et al [20]. The interviews were conducted in person, in a private area, or via an online video conferencing platform. All interviews were audio recorded and participant demographics were noted before the audio recording commenced. Participants were asked open-ended questions in four areas – general questions, legal aspects, communication and solutions. Interviews were conducted until data saturation was reached and no new themes were identified [21]. Field notes were made after each interview. The interviewer (RB) is employed as a community pharmacist in Durban and has an interest in medicine shortages. Participants were made aware of the interviewer's profession and research interests. Any potential bias in interpreting the data is acknowledged.

**Data analysis**

Thematic analysis was conducted using NVivo 14 software (QSR International, Burlington, Massachusetts, United States). The Framework Method outlined by Gale et al. was used [22]. Interviews were transcribed verbatim, which was followed by data familiarisation: re-listening to the recordings and re-reading the transcripts. Codes were assigned to the transcripts deductively. Initial codes and themes were informed by a literature review. A working analytical framework was developed, by grouping codes to find categories until no new codes were identified. The coding was validated by the research supervisor (FS). Each theme was charted into framework matrices on NVivo 14. Data interpretation involved making summaries for each sub-theme, after the identification of similarities and differences.

**Reporting**

The Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist was utilised (See electronic supplementary material Appendix S2) [23].

**RESULTS**

Fifteen pharmacists were interviewed between the 30$^{th}$ of August and the 27$^{th}$ of September 2023 at which point data saturation was reached. Participant demographics are presented in Table 1. The median number of years of experience as a community pharmacist was 8 years (interquartile range = 6.25). The duration of each interview ranged from 16 to 41 minutes.

**Table 1.** Participant Demographics

| Characteristics | Options | n | % |
|---|---|---|---|
| Gender | Male | 7 | 46.7 |
| | Female | 8 | 53.3 |
| Age | 25-34 years old | 8 | 53.3 |
| | 35-44 years old | 0 | 0 |
| | 45-54 years old | 5 | 33.3 |
| | ≥ 55 years old | 2 | 13.3 |
| Qualification | Bachelor of Pharmacy (Honours) (B.Pharm) | 15 | 100.00 |
| Job description | Responsible Pharmacist | 7 | 46.7 |
| | Pharmacist | 7 | 46.7 |
| | Pharmacy owner | 1 | 6.6 |
| Experience in community pharmacy (years) | 1-10 years | 8 | 53.3 |
| | 11-20 years | 0 | 0 |
| | 21-30 years | 4 | 26.7 |
| | ≥31 years | 3 | 20.0 |
| Type of community pharmacy | Independent | 12 | 80.0 |
| | Corporate | 3 | 20.0 |
| Interview method | In-person | 12 | 80.00 |
| | Video Conference | 3 | 20.00 |

**Table 2.** Themes and Sub-themes

| Themes | Sub-themes |
|---|---|
| The perceptions of medicine shortages | Perceived definitions<br>Frequency and duration of medicine shortages<br>Dynamics of medicine shortages<br>Medicines and medicine categories<br>Perceived causes |
| The impact of disruptive situations | The COVID-19 pandemic<br>Other disruptive situations |
| The consequences of medicine shortages | Cost or financial impact<br>Emotional impact<br>Impact on health outcomes<br>Impact on the roles and responsibilities of a pharmacist |
| Mitigation strategies | Medicine substitution<br>Contacting stakeholders<br>Stock management |
| Further suggestions and resources | Collaboration<br>Communication<br>National policy changes<br>Notification systems and guidelines |

Five themes were identified using the Framework Method - (1) the perceptions of medicine shortages, (2) the impact of disruptive situations, (3) the consequences of medicine shortages,

(4) mitigation strategies and (5) further suggestions and resources. In addition, eighteen sub-themes were found (Table 2). Each of these themes is further unpacked below with supporting quotations from the participants themselves. Words appearing in square brackets were added by the interviewer, to provide context. Ellipses were used to depict where parts of the verbatim quotes were omitted, as the quotations were corrected for grammar. The participant numbers appear in round brackets after each quote.

**Theme 1: The Perceptions of Medicine Shortages**

***Perceived definitions***

Participants agreed that medicine shortages occurred when the demand for medicines was greater than the supply, which resulted in patients not receiving medicines.

> *"When we cannot get a supply of the medicine we require for a patient."* (P1)
> *"Anything that is in demand or need but not readily available to dispense to the patient."* (P9)

***Frequency and duration of medicine shortages***

While several participants experienced shortages every week or every month, some experienced the problem daily or infrequently. The duration of medicine shortages was either more than a week or more than a month. However, some medicines were out of stock for an undefined period.

> *"I would say it varies but from my personal experience… I would say more than a month or indefinitely*." (P7)

***Dynamics of medicine shortages***

Participants acknowledged that medicine shortages manifested themselves during the procurement process or when they were informed of the shortage by pharmaceutical representatives. There were disparate views regarding the dynamics of medicine shortages in recent years.

> *"I think it's worsened because every week that I'm ordering, there's something that's unavailable, actually, a whole list of things."* (P10)
> *"I'd say with a lot more generics on the market, it hasn't intensified."* (P3)

Participants highlighted that there was a "ripple effect" - when a specific brand of medicine went out of stock, all the other alternative medicines would subsequently go out of stock.

> *"One of the companies will go short, and then there's a knock-on effect, all the other molecules start going out [of stock]."* (P14)

***Medicines and medicine categories***

Participants stated that the categories of medicines that went out of stock the most were antibiotics, medicines used to treat chronic conditions (such as diabetes and hypertension) and pain medicines, among others (Table 3).

**Table 3.** Out-of-stock Medicine Categories and Medicines

| **Medicine Categories** | **Medicines** |
|---|---|
| Antibiotics | Azithromycin tablets<br>Cefpodoxime suspension<br>Combination tablets for tuberculosis<br>Moxifloxacin tablets |
| Anti-diabetic medicines | Injectable pre-filled pens such as dulaglutide, liraglutide and semaglutide<br>Slow-release metformin tablets |
| Anti-hypertensive medicines | Amlodipine tablets<br>Lercanidipine tablets |
| Anti-inflammatories | Combination of naproxen/omeprazole tablets<br>Lornoxicam tablets<br>Mefenamic acid syrup/suppositories |
| Anti-migraine medicines | Clonidine tablets |
| Human growth hormone | Somatropin injection |
| Topical anaesthetics | Amethocaine cream<br>Lidocaine jelly |
| Smoking cessation aids | Varenicline tablets |

***Perceived causes***

Participants discussed the unpredictable causes of medicine shortages - raw material shortages, outbreaks, epidemics and pandemics, manufacturing problems, civil unrest and natural disasters were highlighted. The predictable causes included product discontinuation, rationing or quotas and industry consolidation. Participants perceived other causes to be due to prescribing habits, a poor economy, insufficient staff, off-label use of medicines, and war.

> *"Raw material shortages have become prevalent mainly after COVID."* (P4)

*"There's been a lot of [product] discontinuation recently."* (P13)

*"I think it's the economy."* (P15)

**Theme 2: The Impact of Disruptive Situations**

***The COVID-19 pandemic***

Participants agreed that the COVID-19 pandemic created an unexpected demand for medicines. Vitamins, immune boosters, analgesics, antibiotics, antivirals, mucolytics and oral corticosteroids were in short supply. One participant felt that the pandemic created a chain reaction.

*"I actually think COVID started the cascade. Before this, I never really noticed there to be such a major issue with regard to out-of-stocks."* (P13)

Changes in prescribing habits, stockpiling and social media trends played a role in the unexpected demand for novel medicines.

*"Every week there was, depending on what... was trending, people were rushing in to buy that product. Suddenly you go out of stock with it, whether it works or not, we don't know."* (P4)

***Other disruptive situations***

Participants recalled the civil unrest which adversely impacted the medicine supply chain. Flooding posed a similar dilemma, and alternative wholesalers had to be utilised.

*"We had unrest, I think it was a year or two ago... there was a major issue with suppliers not being able to meet the demands of the pharmacies... vehicles were stolen, or the wholesalers were ransacked."* (P12)

*"We did experience the floods and it was quite disastrous. It impacted our supply because the wholesaler couldn't physically get the stock to us... But the wholesaler managed to re-route via other wholesalers in the country and they did manage to bring in the stock."* (P14)

**Theme 3: The Consequences of Medicine Shortages**

***Cost or financial impact***

Increased medicine costs impacted both the patients and the pharmacy, due to the higher prices of alternative suppliers or alternative medicines. Participants highlighted the main financial

impact on patients was OOP costs. Others mentioned travel, doctor consultations, telephone, blood tests and delivery costs. Participants felt that dealing with medicine shortages was time-consuming. The time investment included making telephone calls to various stakeholders, including medical aids, to authorise alternatives. Some of these alternatives were non-formulary, impacting patient OOP costs.

> *"If they [medical schemes] said this brand [is covered] and you're using another, they just don't approve it, and then the patient has to pay out-of-pocket."* (P11)

Consequently, pharmacies faced a loss of income when patients opted to go to another pharmacy.

> *"If the patient loses faith in our services… then he will leave our business and go to another pharmacy. So, from a financial point of view, that's like a loss of income as well."* (P7)

***Emotional impact***

Participants agreed that patients experienced stress, frustration and dissatisfaction in response to medicine shortages. Furthermore, there was hesitancy and confusion when patients were offered alternative medicines, especially among elderly patients.

> *"The patients get frustrated; they get upset with you."* (P13)
> *"Suddenly an item goes out of stock and they're [the elderly patients] very hesitant, very resistant to change."* (P12)

***Impact on health outcomes***

Some participants mentioned that patients who took alternatives experienced side effects. Patients who were non-compliant due to refusal to use alternatives or patients for whom there were no alternatives available, were perceived to suffer negative health outcomes.

> *"In many instances, there's no generic and the patient has to stop taking the drug, compromising their health."* (P4)
> *"There's no continuation of treatment and then you get patients getting sick."* (P9)
> *"The patient doesn't get the care that they are meant to, so... it affects their health, it affects their well-being."* (P14)

***Impact on the roles and responsibilities of a pharmacist***

Participants felt that medicine shortages impaired the pharmacist-patient relationship, causing a break in trust. Patients did not understand when the issue occurred at a higher level in the supply chain, instead, they placed the blame on the pharmacy.

> *"Patients do not understand why there is a shortage… so it hampers the relationship between patient and pharmacist."* (P7)

One participant highlighted that it impacted the pharmacist's duty.

> *"The most important consequence is that the patient is not going to receive the care that I took an oath to fulfil."* (P15)

**Theme 4: Mitigation Strategies**

***Medicine substitution***

Participants mainly substituted out-of-stock medicines with generic or therapeutic equivalents. Some participants substituted with originator brands, different dosage forms; or split fixed-dose combinations into individual medicines.

> *"The first is to, like offer generics… Say, for example, the patient's generic is out of stock, and we have to give them the originator."* (P3)
> *"Then [we] look for a therapeutic equivalent."* (P6)
> *"If for example, a slow-release drug is out of stock, and only the plain version is available, we'd have to discuss it as well."* (P10)
> *"We would give the individual ingredients separately, so the patient is not left without any form of treatment."* (P7)

***Contacting stakeholders***

Participants contacted various stakeholders in response to medicine shortages, including wholesalers and other pharmacies - via telephone or group messaging applications. When no generics were available, prescribers were called to suggest therapeutic equivalents. Some participants contacted manufacturers to confirm or to provide information about a medicine shortage.

*"We look at alternative suppliers if we can."* (P15)
*"We just put it on the WhatsApp group, I'm looking for a particular item."* (P6)
*"If all else fails, then the doctor has to give an alternative."* (P10)
*"Once the suppliers tell me it's a manufacturer issue, then I phone the manufacturer."* (P8)

***Stock management***

Participants mentioned keeping buffer or bulk stock as a preventative strategy. However, some felt that holding high stock volumes restricted cash flow.

*"I think the best way is to keep bulk [stock]."* (P2)
*"We don't want to keep too much money in stock because stock is expensive."* (P6)

Other procurement strategies entailed higher stock days, having access to multiple wholesalers or branches, forecasting, or increasing order and delivery frequency. Stock rationing was based on a patient's disease severity or whether they were regular customers at the pharmacy.

**Theme 5: Further Suggestions and Resources**

***Communication***

All participants agreed that the communication regarding medicine shortages was insufficient. They felt that shortages should be announced via a reliable party and method such as e-mail, allowing sufficient time to acquire buffer stock and communicate with patients.

*"They [The manufacturers] don't communicate, that's the biggest problem in this country."* (P1)

***Collaboration***

Participants expressed that all stakeholders needed to collaborate to reduce medicine shortages. Some highlighted the need for manufacturers and wholesalers to improve transparency, communication, planning and forecasting. Participants agreed that the health authorities need to play a greater role.

*"I think all role-players should be involved."* (P9)
*"I believe they [the health authorities] should have a more active role… in managing these shortages."* (P7)

There were mixed views about whether a committee would be effective in handling medicine shortages.

> *"Most definitely, if it is set up, and well-balanced."* (P5)
> *"It's not going to be possible."* (P8)

***National policy changes***

All participants were unaware of laws that influenced medicine shortages, locally and internationally. There were contrasting views as to whether new legislation would be useful.

> *"If something goes wrong in production, even if there's a law, if it goes wrong, it goes wrong. So, I think it'll be a bit hard to bring in laws for that."* (P2)
> *"I think it should be a law… especially when it comes to chronic medication, there needs to be sufficient projection by the [manufacturing] companies to know that they have enough of that medication to service their customers."* (P9)

Other suggestions included implementing laws for communication and distribution, reducing the patent period, limiting registration time and broadening pharmacists' scope of practice.

***Notification systems and guidelines***

The need for out-of-stock letters from manufacturers was highlighted by participants. Some felt that word-of-mouth notifications from pharmaceutical representatives (reps) were at times inaccurate and could not be trusted.

> *"Sometimes the reps do tell us, but I never know whether they just want us to buy extra stock, or not."* (P14)

One participant felt that guidelines should be put in place, in the form of standard operating procedures (SOPs). Another suggested that a national database should be implemented to report shortages.

> *"I believe there should be some form of… database or a system put in place."* (P7)

## DISCUSSION

### Statement of key findings

The findings describe the perceptions of community pharmacists and their experiences with medicine shortages during the pandemic and other disruptive situations in one city in South Africa. Five main themes were identified, which were the perceptions of medicine shortages, the impact of disruptive situations, the consequences of medicine shortages, mitigation strategies; and further suggestions and resources.

Community pharmacists understood the term "medicine shortages" and experienced the issue at varying frequencies and durations. While most participants felt that medicine shortages had increased in recent years, others felt that the problem had not worsened. Chronic medicines, pain medicines and antibiotics were perceived to go out of stock the most. The main perceived causes of medicine shortages were raw material shortages, outbreaks, epidemics, pandemics, manufacturing problems, civil unrest, natural disasters, product discontinuation, rationing or quotas and industry consolidation.

Participants felt that the COVID-19 pandemic created an unexpected demand for medicines. Other disruptive situations such as civil unrest and flooding were perceived to impair the supply chain. Patients were perceived to suffer poor health outcomes and negative emotions as a result of medicine shortages. The main financial consequence for patients was OOP costs, and pharmacies experienced a loss of income when medicine shortages caused patients to go to other pharmacies. Community pharmacists felt that dealing with medicine shortages was time-consuming and the issue caused patients to lose trust in them, impairing the pharmacist-patient relationship.

The main mitigation strategies used were medicine substitution, contacting stakeholders and stock management. However, these strategies alone were insufficient to address the problem. Community pharmacists further suggested improved communication and collaboration between stakeholders; and the implementation of new legislation, notification systems and guidelines.

**Strengths and weaknesses**

To the best of our knowledge, this is the first qualitative study to explore medicine shortages from a community pharmacy perspective in South Africa. This study cannot be generalised nationally or to other countries; as the sample size was small and limited to one city. However, this study sought to explore the in-depth experiences of community pharmacists in Durban, South Africa, as these were identified as information-rich participants. Furthermore, Recall bias may be a limitation, as some of the responses were based on past experiences.

**Interpretation**

Participants explained the term “medicine shortages” fairly similarly to the World Health Organization’s definition [3]. This contrasts with the findings of Bogaert et al., who interviewed various stakeholders [20]. Opposing views on the dynamics of medicine shortages in recent years may be attributed to recall bias. The “ripple effect” - when medicine shortages led to alternatives subsequently going out of stock - is congruent with the “vicious cycle” described by Tan et al. [16]. Some of the perceived unpredictable reasons for medicine shortages included pandemics, natural disasters and civil unrest. This builds on the previously reported supply, demand and regulatory causes [1,18].

The COVID-19 pandemic was believed to impair the supply chain. The phenomenon of patients panic buying or stockpiling medicines aligns with the findings of studies in Pakistan and India [7,17]. Additionally, this study highlights that disruptive situations such as civil unrest and flooding were perceived to exacerbate supply chain issues. However, the influence of planned electricity outages on medicine shortages was not discussed, which may be due to the installation of generators or other strategies to overcome the electricity disruptions.

Medicine shortages may result in poor financial, emotional and health outcomes for patients. Patients were perceived to pay OOP costs when higher-priced alternatives were dispensed, which is in line with prior studies [1,4,5]. Furthermore, non-formulary substitutions incurred co-payments with medical aids, which some pharmacists felt was time-consuming to resolve. When medicines were out of stock with no alternative, the roles and responsibilities of the pharmacist were unfulfilled, damaging the pharmacist-patient relationship. Comparable outcomes occurred in Belgium and Pakistan, where pharmacists reported an increased workload and a loss of income [6,7].

From the mitigation strategies used, contacting other pharmacies via group messaging applications mirrors previous findings [8,12,15]. In addition to the generic, therapeutic and originator brand medicine substitution mentioned by previous researchers, this study highlights dispensing different dosage forms or splitting fixed-dose combinations into individual medicines [15-17]. The strategy of keeping bulk stock was perceived to restrict cash flow, similar to the findings of Tan et al. [16].

Communication, collaboration and policy changes were all highlighted to better manage medicine shortages, as reported in previous studies [1,5,7,8,14-16]. Furthermore, this study

highlights the need for out-of-stock letters from manufacturers, instead of word-of-mouth notifications from pharmaceutical representatives. While Canada and Australia have national medicine shortage websites, pharmacists felt that it was difficult to navigate and lacked familiarity [15,16]. Therefore, this study shows that there is a need for a user-friendly national database or notification system in South Africa.

### Further research

It is recommended that further quantitative and qualitative research on medicine shortages should be conducted amongst patients, to explore their experiences with medicine shortages.

## CONCLUSION

Medicine shortages are an ongoing challenge, which community pharmacists in Durban, South Africa experienced during the COVID-19 pandemic and other disruptive situations. More effective communication and collaboration between all stakeholders is recommended. The findings of this study are relevant to other countries in that the perceptions and experiences explored in this study can aid decision-makers, both locally and in lower and middle-income countries with developing policies, notification systems and guidelines for medicine shortages, to limit the impact on patients and pharmacies.

## STATEMENTS AND DECLARATIONS

### Acknowledgements

The authors wish to acknowledge the pharmacists who participated in this study.

### Funding

The authors declare that no funds, grants, or other support were received during the preparation of this manuscript.

### Conflicts of Interest

The authors have no conflicts of interest to declare.

### Author Contributions

Both authors contributed to the study conception and design. Data collection and analysis were performed by Rivana Bachoolall. Data validation and supervision were performed by Fatima Suleman. The first draft of the manuscript was written by Rivana Bachoolall and both authors commented on previous versions of the manuscript. Both authors read and approved the final manuscript.

### Data Availability

The datasets generated during and/or analysed during the current study are not available publicly due to privacy and ethical reasons but are available from the corresponding author upon reasonable request.

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# Chapter 4: Synthesis, Conclusion and Recommendations

## 4.1. Introduction

Previous South African studies have explored medicine shortages in public sector healthcare facilities (Chigome et al., 2019; Hodes et al., 2017; Hwang et al., 2019; Modisakeng et al., 2020; Ndzamela, 2020; Zuma, 2022). Researchers in Saudi Arabia, Pakistan, Australia and Canada have investigated medicine shortages from a community pharmacy perspective. However, most of these studies took place either before or towards the beginning of the COVID-19 pandemic (Alsheikh et al., 2021; Omer et al., 2021; Panic et al., 2020; Tan et al., 2016). A study in India, conducted by Ramakrishnan et al. (2023), explored community pharmacists' experiences with the supply chain of chronic medicines during the COVID-19 pandemic. Therefore, there was a paucity of research exploring medicine shortages, in community pharmacies, during disruptive situations.

## 4.2. Summary of Findings

This study aimed to explore community pharmacists' perceptions and their experiences with medicine shortages during the COVID-19 pandemic and other disruptive situations. There were four objectives, for which the following conclusions have been reached.

### *4.2.1. To explore the perceptions and experiences with medicine shortages faced by community pharmacists during the COVID-19 pandemic and other disruptive situations*

Community pharmacists understood the concept of medicine shortages fairly similar to the World Health Organization's definition from a demand perspective (World Health Organization, 2017). However, the frequency and duration of medicine shortages varied between participants. While some shortages were resolved within a month, others went on indefinitely. Some community pharmacists felt that the problem has worsened in recent years, however, others felt that there has been a decrease in medicine shortages. All pharmacists agreed that disruptive situations such as the COVID-19 pandemic, civil unrest and flooding exacerbated medicine shortages.

A "ripple effect" was found when one brand of medicine went out of stock, all other alternatives would subsequently go out of stock. Chronic medicines, pain medicines and antibiotics were reported to commonly go out of stock. The perceived causes of medicine shortages included raw material shortages, outbreaks, epidemics or pandemics, civil unrest and natural disasters - such as flooding. Supply issues included manufacturing problems, product discontinuation,

rationing/quotas and industry consolidation. Other perceived causes were changes to prescribing habits, the off-label use of medicines, a poor economy, insufficient staff and international disruptions such as war.

#### *4.2.2. To describe the strategies that community pharmacists have used in response to medicine shortages*

Community pharmacists used several strategies to mitigate medicine shortages. The main response was medicine substitution. Generic substitution, therapeutic substitution and originator brand substitution paralleled previous findings (Panic et al., 2020; Ramakrishnan et al., 2023; Tan et al., 2016). However, this study found other substitution methods such as dispensing different dosage forms or splitting fixed-dose combinations into individual medicines.

Contacting stakeholders such as other pharmacies, wholesalers, prescribers and manufacturers was highlighted as a mitigation strategy. Lastly, stock management was used to mitigate medicine shortages. Keeping bulk or buffer stock was agreed upon, however, some community pharmacists felt that it was not worth spending money on extra stock. Other procurement strategies entailed having accounts with multiple wholesalers, forecasting medicine usage, increasing ordering frequency, delivery frequency and number of stock days. Rationing of stock was based on a patient's disease severity or whether they were regular customers at a particular pharmacy.

#### *4.2.3. To provide suggestions to mitigate the challenge of medicine shortages in community pharmacies during a pandemic and other disruptive situations*

Apart from the mitigation strategies mentioned above, community pharmacists provided further suggestions. This included improving communication, particularly from manufacturers. All role-players, including the health authorities, are needed to collaborate to ensure that medicine shortages are minimized. While there were ambivalent views towards implementing new legislation and appointing a committee to handle medicine shortages; community pharmacists felt that notification systems and guidelines would be a useful tool.

#### *4.2.4. To describe the perceived cost and financial impact of medicine shortages on patients and the healthcare system*

Patients and pharmacies were both perceived to suffer financially as a result of medicine shortages. The main financial impact on patients was OOP costs, due to alternative medicines being more expensive or not covered fully by medical aids. Other costs included travel expenses, additional doctor consultations, telephone expenses, blood tests and delivery or

courier fees. Furthermore, patients for whom there were no alternatives or those who refused to use alternatives sometimes went without medicines. Community pharmacists perceived that both of these scenarios resulted in poor health outcomes.

The main financial impact on pharmacies was a loss of income, as patients lost trust in the pharmacy as a result of medicine shortages. Once the pharmacist-patient relationship was impaired, patients either took their prescriptions to other pharmacies or did not purchase the medicine at all. The time investment used to confirm a medicine shortage with suppliers and/or manufacturers, source alternative medicines, contact the prescribers for substitutions and authorise alternative medicines on medical aids; may have resulted in additional staff costs. Lastly, delivery costs were identified as a pharmacy expense when patients did not want to return to the pharmacy to collect alternative medicines.

### 4.3. Significance of the Findings

The findings are significant in the following ways:

- Community pharmacists perceived medicine shortages to be exacerbated by disruptive situations such as the COVID-19 pandemic, civil unrest and flooding, during which mitigation strategies became imperative.
- The reported mitigation strategies were medicine substitution, contacting stakeholders and stock management. However, these solutions are inadequate to address the issue.
- There is a need for further interventions, such as more effective communication regarding medicine shortages, collaboration between all role-players, national policy changes, notification systems and guidelines.
- The financial burden was perceived to impact both patients and pharmacies. Therefore, medicine shortages may have detrimental consequences for both parties.

### 4.4. Strengths and Limitations

- To the best of my knowledge, this is the first qualitative study to describe medicine shortages from a community pharmacy perspective in South Africa.
- This study had a small sample size and was geographically limited to one city; therefore, it cannot be generalised to the greater population. However, this study sought to explore the unique experiences of community pharmacists in Durban, as these were identified as information-rich participants.
- Another potential limitation is recall bias, as the participants' answers were self-reported and based on their past experiences.

## 4.5. Recommendations

The following recommendations are based on the results of this qualitative study.

### *4.5.1. Communication and collaboration*

More effective communication and collaboration are needed between all stakeholders, including pharmacists, prescribers, wholesalers, manufacturers and the health authorities. In particular, official out-of-stock letters from manufacturers are needed, to ensure that pharmacists are fully aware of which medicines are unavailable and take the necessary actions.

### *4.5.2. National policy changes*

The findings of this study can aid decision-makers in implementing new legislation to help reduce medicine shortages. Regulating the following areas may be useful: stipulating mandatory communication, reducing the patent period, fast-tracking medicine registrations and broadening the scope of practice of pharmaceutical staff.

### *4.5.3. Notification systems and guidelines*

Medicine shortages should be accessible on a user-friendly platform such as a national database or website. Accurate and timely notifications are needed to ensure that pharmacists are well informed and can notify patients and dispense alternative medicines, to avoid interruption to their treatment regimens. Furthermore, there is a need for clear guidelines on dealing with medicine shortages, such as standard operating procedures (SOPs).

### *4.5.4. Further research*

It is recommended that further quantitative and qualitative research on medicine shortages should be conducted amongst patients, to explore their experiences with medicine shortages.

## 4.6. Conclusion

Community pharmacists in Durban, South Africa, experienced the issue of medicine shortages in excess, during disruptive situations. Communication, collaboration, national policy changes, notification systems and guidelines are recommended to be considered to reduce the impact of medicine shortages and limit the negative financial impact on patients and pharmacies.

## References: Synthesis, Conclusion and Recommendations


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# APPENDICES

## Appendix A – Gatekeeper Permission Letters

ICPA
INDEPENDENT COMMUNITY PHARMACY ASSOCIATION
ICPA (NPC), Block "O", Greenford Office Estate, Punters Way, Kenilworth, Cape Town, 7708
**Tel:** +27 21 671 4473 | **Fax:** +27 86 5152 000 | **Website:** www.icpa.co.za.
**CIPC Reg. No:** 2012/021809/08 | **NPO Reg. No:** 141-903 | **VAT Reg. No:** 4420262976

27 July 2023

University of Kwa-Zulu Natal
School of Health Sciences

To whom it may concern

This serves to confirm that Ms Rivana Bachoolall, Student Number 208 504 185 has permission from the Independent Community Pharmacy Association (ICPA) to conduct research on 'Community Pharmacist's Perceptions and Experiences of Medicine Shortages in Disruptive Situations in Durban, South Africa', providing her access to ICPA member pharmacies in Durban.

We wish Ms Bachoolall well in her research project which will no doubt add to the body of knowledge to enhance access to medicines, particularly in disruptive situations.

Kind regards

[redacted]

AHMED BAYAT
COO

[redacted]

23 August 2023

Rivana Bachoolall (B. Pharm)
Master of Pharmacy student
University of Kwa-Zulu Natal (UKZN)

Dear Sir/ Madam

Authorization is hereby granted to Rivana Bachoolall, a Master of Pharmacy student at the University of Kwa-Zulu Natal (UKZN), to conduct interviews as part of her studies by interviewing a minimum of 12 pharmacists for approximately 40 minutes from [redacted].

Her research project is titled "Community Pharmacists' Perceptions and Experiences of Medicine Shortages in Disruptive Situations, in Durban, South Africa".

Approval granted with the following conditions:

- Any research data relating to [redacted] cannot be made available publicly.
- Survey research - consent should be obtained from each survey correspondent.
- General communication to respondents should be channeled via [redacted].
- Responses back and feedback from respondents must be channelled directly back to researcher (via email address or researcher portal).
- Final report to be forwarded to [redacted]

Yours sincerely,

[redacted]

[redacted]

Direct: [redacted]
Email: [redacted]

[redacted]

# Appendix B – BREC Approval

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

28 August 2023

**Miss Rivana Bachoolall (208504185)**
**School of Health Sciences**
**Westville**

**Dear Miss Bachoolall,**

**Protocol reference number: BREC/00005865/2023**
**Project title: Community Pharmacists Perceptions and Experiences of Medicine Shortages in Disruptive Situations, in Durban, South Africa**
**Degree: Masters**

EXPEDITED APPLICATION: APPROVAL LETTER

A sub-committee of the Biomedical Research Ethics Committee has considered and noted your application.

The conditions have been met and the study is given full ethics approval and may begin as from 28 August 2023. Please ensure that any outstanding site permissions are obtained and forwarded to BREC for approval before commencing research at a site.

PLEASE NOTE: Study is only approved for those sites for which gatekeeper permissions have been received by BREC.

This approval is valid for one year from 28 August 2023. To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on RIG on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2020) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be noted by a full Committee at its next meeting taking place on 12 September 2023.

Yours sincerely,

[redacted]

Prof D Wassenaar
Chair: Biomedical Research Ethics Committee

**Biomedical Research Ethics Committee**
**Chair: Professor D R Wassenaar**
**UKZN Research Ethics Office Westville Campus, Govan Mbeki Building**
**Postal Address:** Private Bag X54001, Durban 4000
**Email:** BREC@ukzn.ac.za
**Website:** http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

**02 October 2023**

**Miss Rivana Bachoolall (208504185)**
**School of Health Sciences**
**Westville**

**Dear Miss Bachoolall,**

**Protocol reference number: BREC/00005865/2023**
**Project title: Community Pharmacists Perceptions and Experiences of Medicine Shortages in Disruptive Situations, in Durban, South Africa Degree: Masters**
**Supplement Number 1151**

We wish to advise you that your application received on 14 September 2023 submitting [redacted] gatekeeper permission for the above study has been noted (Recruitment can now include participants from this site) by a subcommittee of the Biomedical Research Ethics Committee.

The committee will be notified of the above at its next meeting to be held on 14 November 2023.

Yours sincerely

[redacted]

.....
Ms. A Marimuthu
(for) Prof D Wassenaar
Chair: Biomedical Research Ethics Committee

## Appendix C – Informed Consent Letter

Information Sheet and Consent to Participate in Research

Date: __/__/20__

Dear Sir/Madam

WHO AM I AND WHAT IS THIS STUDY ABOUT?

My name is Rivana Bachoolall and I am currently pursuing a Master of Pharmacy degree, in Pharmacoeconomics, at the College of Health Sciences, University of KwaZulu-Natal (UKZN).

My contact details are as follows:

Contact number: 27 74 738 1645

Email address: 208504185@stu.ukzn.ac.za

You are being invited to consider participating in a study that involves qualitative research. The aim and purpose of this research is to explore the perceptions of community pharmacists and their experiences with medicine shortages, during the COVID-19 pandemic and other disruptive situations (such as looting, flooding and load shedding). The study is expected to enrol a minimum of 12 participants in Durban, KwaZulu-Natal. It will involve semi-structured, face-to-face, or Zoom interviews with community pharmacists. The duration of your participation, if you choose to enrol, is expected to be approximately 40 minutes. No funding was received for conducting this study.

WHAT ARE THE RISKS AND BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no risks to participating in this study. The study will provide no direct benefits to participants. However, it is hoped that this study will highlight mitigation strategies, in response to medicine shortages in community pharmacies, during outbreaks, natural disasters and other disruptive circumstances.

WHAT ARE THE ETHICAL CONSIDERATIONS?

This study has been ethically reviewed and approved by the UKZN Biomedical Research Ethics Committee (approval number TBC).

In the event of any problems or concerns/questions you may contact the researcher at:

Contact number: 27 74 738 1645 Email: 208504185@stu.ukzn.za

Or the UKZN Biomedical Research Ethics Committee, contact details are as follows:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001 Durban 4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

Participation in this research is voluntary and participants may choose to withdraw from participation at any point. In the event of refusal/withdrawal of participation, participants will not incur any penalty. There are no costs incurred by participants as a result of participation in the study, nor are there any incentives or reimbursements for participation in the study.
The confidentiality of all participant information and responses will be maintained throughout the study. All participants will remain anonymous and be assigned a participant number, for identification purposes in the study. The interviews will be audio-recorded using an Android application on a tablet. Thereafter, the researcher will transcribe the audio recordings for analysis. All recordings and transcriptions will be saved on a password-protected laptop, to which only the researcher will have access. The research supervisor will also have access to the data, on request.

DECLARATION OF CONSENT

I, _____ have been informed about the study entitled "Community Pharmacists' Perceptions and Experiences of Medicine Shortages in Disruptive Situations, in Durban, South Africa" by Rivana Bachoolall.

I understand the purpose and procedures of the study.

I give consent for my interview to be audio-recorded. I understand that the recording will be saved on a password-protected laptop, with access restricted to the researcher and the research supervisor.

I have been given an opportunity to answer questions about the study and have had answers to my satisfaction.

I declare that my participation in this study is entirely voluntary and that I may withdraw at any time, without any penalty.

If I have any further questions/concerns or queries related to the study, I understand that I may contact the researcher at

Contact number: 074 738 1645 Email address: 208504185@stu.ukzn.ac.za

If I have any questions or concerns about my rights as a study participant, or if I am concerned about an aspect of the study or the researchers then I may contact:

BIOMEDICAL RESEARCH ETHICS ADMINISTRATION

Research Office, Westville Campus

Govan Mbeki Building

Private Bag X 54001 Durban 4000

KwaZulu-Natal, SOUTH AFRICA

Tel: 27 31 2602486 - Fax: 27 31 2604609

Email: BREC@ukzn.ac.za

| | |
|---|---|
| _____ | _____ |
| Signature of Participant | Date |
| _____ | _____ |
| Signature of Witness<br>(Where applicable) | Date |
| _____ | _____ |
| Signature of Translator<br>(Where applicable) | Date |

## Appendix D – Data Collection Tool

### 1. Introduction

1.1. Purpose and objectives of the study

1.2. Informed consent

1.3. Voluntary participation

1.4. Confidentiality

1.5. Permission to audio record

### 2. Experience and Demographics

2.1. Gender

2.2. Age

2.3. Qualification

2.4. Job description

2.5. Number of years of experience in community pharmacy

2.6. Type of community pharmacy – corporate, independent, or franchise

### 3. General questions

3.1. What is your understanding of the term "medicine shortages"? Allow the participant to answer and then read out the definition, used for the purpose of this study – The World Health Organization defines a medicine shortage as follows: "when demand exceeds supply at any point in the supply chain and may ultimately create a "stock-out" at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient."

3.2. How often have you been encountering the problem of medicine shortages in your own professional practice? Interviewer to tick off the appropriate box, if applicable.

**Table 1**. Frequency versus Duration of Medicine Shortages

| **Duration** | **Frequency** | | | | |
|---|---|---|---|---|---|
| | Every week | Every month | Every 3 months | Every 6 months | Every year |
| Less than 1 week | | | | | |
| 1 week to 1 month | | | | | |
| More than 1 month | | | | | |
| Undefined or unlimited | | | | | |

*Note.* This table is based on the interview guide for pharmacists from the supplementary material in "A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian. French and the European Union's Perspectives" by Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A., 2015, *PloS one 10*(5), p. 1, Copyright 2015 by Creative Commons Attribution License.

3.3. What are the dynamics of medicine shortages in recent years? Has the problem intensified or decreased?

3.4. How do medicine shortages manifest themselves and influence your institution?

3.5. What medicines or categories of medicines do you experience the most shortages with?

3.6. How much of time do you spend, on average, to resolve medicine shortages?

3.7. What are the reasons for medicine shortages in your opinion? Ask what they regard as the principal causes then show Table 2 and ask questions about relevant reasons for the shortages: According to some researchers, there are predictable and unpredictable reasons for medicine shortages. In your opinion what is the influence of each of those factors? Do you think other reasons could be added to this table? Could you rate their importance (1-3)?

**Table 2.** Reasons for Medicine Shortages

| **Unpredictable Reasons** | **Predictable Reasons** |
|---|---|
| ▪ Natural disasters<br>▪ Manufacturing problems<br>▪ Raw material shortages<br>▪ Non-compliance with regulatory standards<br>▪ Packaging shortages<br>▪ Unexpected demand<br>▪ Outbreaks, epidemics, or pandemics<br>▪ Parallel distribution<br>▪ Competitive issues<br>▪ Foreign currency exchange effect<br>▪ Sovereign issues (financial crisis, debt, default)<br>▪ Other, e.g., Civil unrest | ▪ Product discontinuation<br>▪ Industry consolidation (mergers & acquisitions)<br>▪ Limited manufacturing capacity<br>▪ Just-in-time inventories<br>▪ Rationing/quotas<br>▪ Deliberately induced shortages to manipulate pricing<br>▪ Market shifts<br>▪ Launch of a new competitor, new formulation, or expiry of a patent<br>▪ Other |

*Note.* This table is based on the interview guide for pharmacists from the supplementary material in "A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian. French and the European Union's Perspectives" by Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A., 2015, *PloS one 10*(5), p. 2, Copyright 2015 by Creative Commons Attribution License.

3.8. What are the most important consequences of medicine shortages in your opinion? What is the cost/financial impact on patients and the pharmacy?

**4. Legal aspects**

4.1. Do you know about any laws and/or regulations that may influence the occurrence of medicine shortages?

4.2. Do you think new legal regulations and organizational solutions could be implemented in order to reduce the problem of medicine shortages? Please, address this issue in more detail.

4.3. Do you know any examples of such regulations in place in other countries?
4.4. Which ones out of the existing legal regulations and organizational solutions could be changed in order to reduce the problem of medicine shortages?
4.5. Could the rules of stock management implemented in your organization somehow influence the occurrence of medicine shortages?

**5. Communication**

5.1. What do you think about the communication regarding the medicine shortages?
5.2. Who should be responsible for the communication regarding the medicine shortages?
5.3. When should medicine shortages be announced?
5.4. How should medicine shortages be announced?
5.5. Are you warned of prospective medicine shortages before they occur?
5.6. Do you warn customers of a prospective or an existing medicine shortage? How is this done?

**6. Solutions**

6.1. Do the wholesalers or health authorities suggest any solutions to alleviate the problem?
6.2. Which specific action do you take when a medicine, required by a patient, is out of stock?
6.3. Which specific measures are taken by your institution to reduce or prevent medicine shortages? Are there any other measures, in your view, that could be implemented?
6.4. How could other stakeholders in the supply chain contribute to reducing medicine shortages?
6.5. In some countries, special committees have been set up to reduce medicine shortages. Do you think such an institution might be useful in South Africa?

**7. Conclusion**

7.1. Please may you recommend a colleague who you feel will be interested in participating in this study?
7.2. Thank you for your participation. Do you have any questions?

## Appendix E – Proof of Submission

# IJCP-D-24-00085 - Submission Confirmation

**International Journal of Clinical Pharmacy (IJCP)** <em@editorialmanager.com>

Wed, Jan 31, 1:18 PM

Dear Mrs Bachoolall,

Thank you for submitting your manuscript, Community Pharmacists' Perceptions and Experiences of Medicine Shortages in Disruptive Situations: A Qualitative Study, to International Journal of Clinical Pharmacy .

The submission id is: IJCP-D-24-00085
Please refer to this number in any future correspondence.

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With kind regards,
Springer Journals Editorial Office
International Journal of Clinical Pharmacy

## Appendix F – Supplementary Material

**Appendix S1. Semi-structured interview guide**

**1. Introduction**

1.1. Purpose and objectives of the study

1.2. Informed consent

1.3. Voluntary participation

1.4. Confidentiality

1.5. Permission to audio record

**2. Experience and Demographics**

2.1. Gender

2.2. Age

2.3. Qualification

2.4. Job description

2.5. Number of years of experience in community pharmacy

2.6. Type of community pharmacy – corporate, independent, or franchise

**3. General questions**

3.1. What is your understanding of the term "medicine shortages"? Allow the participant to answer and then read out the definition, used for the purpose of this study – The World Health Organization defines a medicine shortage as follows: "when demand exceeds supply at any point in the supply chain and may ultimately create a "stock-out" at the point of appropriate service delivery to the patient if the cause of the shortage cannot be resolved in a timely manner relative to the clinical needs of the patient."

3.2. How often have you been encountering the problem of medicine shortages in your own professional practice? Interviewer to tick off the appropriate box, if applicable.

**Table 1**. Frequency versus Duration of Medicine Shortages[1]

| **Duration** | **Frequency** | | | | |
|---|---|---|---|---|---|
| | Every week | Every month | Every 3 months | Every 6 months | Every year |
| **Less than 1 week** | | | | | |
| **1 week to 1 month** | | | | | |
| **More than 1 month** | | | | | |
| **Undefined or unlimited** | | | | | |

3.3. What are the dynamics of medicine shortages in recent years? Has the problem intensified or decreased?

3.4. How do medicine shortages manifest themselves and influence your institution?

3.5. What medicines or categories of medicines do you experience the most shortages with?

3.6. How much of time do you spend, on average, to resolve medicine shortages?

3.7. What are the reasons for medicine shortages in your opinion? Ask what they regard as the principal causes then show Table 2 and ask questions about relevant reasons for the shortages: According to some researchers, there are predictable and unpredictable reasons for medicine shortages. In your opinion what is the influence of each of those factors? Do you think other reasons could be added to this table? Could you rate their importance (1-3)?

[1] *Note.* This table is based on the interview guide for pharmacists from the supplementary material in "A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian. French and the European Union's Perspectives" by Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A., 2015, *PloS one 10*(5), p. 1, Copyright 2015 by Creative Commons Attribution License.

**Table 2.** Reasons for Medicine Shortages[2]

| Unpredictable Reasons | Predictable Reasons |
|---|---|
| ▪ Natural disasters<br>▪ Manufacturing problems<br>▪ Raw material shortages<br>▪ Non-compliance with regulatory standards<br>▪ Packaging shortages<br>▪ Unexpected demand<br>▪ Outbreaks, epidemics, or pandemics<br>▪ Parallel distribution<br>▪ Competitive issues<br>▪ Foreign currency exchange effect<br>▪ Sovereign issues (financial crisis, debt, default)<br>▪ Other, e.g., Civil unrest | ▪ Product discontinuation<br>▪ Industry consolidation (mergers & acquisitions)<br>▪ Limited manufacturing capacity<br>▪ Just-in-time inventories<br>▪ Rationing/quotas<br>▪ Deliberately induced shortages to manipulate pricing<br>▪ Market shifts<br>▪ Launch of a new competitor, new formulation, or expiry of a patent<br>▪ Other |

3.8. What are the most important consequences of medicine shortages in your opinion? What is the cost/financial impact on patients and the pharmacy

**4. Legal aspects**

4.1. Do you know about any laws and/or regulations that may influence the occurrence of medicine shortages?

4.2. Do you think new legal regulations and organizational solutions could be implemented in order to reduce the problem of medicine shortages? Please, address this issue in more detail.

4.3. Do you know any examples of such regulations in place in other countries?

---

[2] *Note.* This table is based on the interview guide for pharmacists from the supplementary material in "A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian. French and the European Union's Perspectives" by Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A., 2015, *PloS one 10*(5), p. 2, Copyright 2015 by Creative Commons Attribution License.

4.4. Which ones out of the existing legal regulations and organizational solutions could be changed in order to reduce the problem of medicine shortages?
4.5. Could the rules of stock management implemented in your organization somehow influence the occurrence of medicine shortages?

**5. Communication**

5.1. What do you think about the communication regarding the medicine shortages?
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6.1. Do the wholesalers or health authorities suggest any solutions to alleviate the problem?
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6.5. In some countries, special committees have been set up to reduce medicine shortages. Do you think such an institution might be useful in South Africa?

**7. Conclusion**

7.1. Please may you recommend a colleague who you feel will be interested in participating in this study?
7.2. Thank you for your participation. Do you have any questions?

**Appendix S2. Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist**[3]

| No. Item | Guide Questions/Description | Notes (Page number) |
|---|---|---|
| **Domain 1: Research team and reflexivity** | | |
| The research team consisted of a Master of Pharmacy (M.Pharm) student, Rivana Bachoolall (RB) and the research supervisor, Professor Fatima Suleman (FS). | | |
| *Personal Characteristics* | | |
| **1. Interviewer/ facilitator** | Which author/s conducted the interview or focus group? | RB |
| **2. Credentials** | What were the researcher's credentials? E.g., PhD, MD | RB: B.Pharm<br>FS: B.Pharm, M.Pharm, PhD. |
| **3. Occupation** | What was their occupation at the time of the study? | RB: Pharmacy manager and M.Pharm student<br>FS: Research Professor |
| **4. Gender** | Was the researcher male or female? | Female |
| **5. Experience and training** | What experience or training did the researcher have? | RB: Pharmacy management experience; and training in research ethics and qualitative analysis. |
| *Relationship with participants* | | |
| **6. Relationship established** | Was a relationship established prior to study commencement? | 5 participants knew the interviewer prior, from the retail pharmacy environment. The remaining 10 participants met the researcher for the first time, during participant recruitment. |

[3] *Note.* This table is based on "Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups" by Tong A., Sainsbury P. & Craig, J., 2007, *International Journal for Quality in Health Care 19*(6), p. 352.

| | | |
|---|---|---|
| **7. Participant knowledge of the interviewer** | What did the participants know about the researcher? e.g., personal goals, reasons for doing the research | The participants were aware that the interviewer is currently employed by a community pharmacy, in Durban, while studying toward a master's degree part-time. The researcher outlined personal interest in the topic. |
| **8. Interviewer characteristics** | What characteristics were reported about the interviewer/facilitator? e.g., Bias, assumptions, reasons and interests in the research topic | The interviewer (RB) expresses a personal interest in the research topic and experiences the issue in her professional practice. Any potential bias in interpreting the data is acknowledged. |
| **Domain 2: Study Design** | | |
| *Theoretical framework* | | |
| **9. Methodological orientation and Theory** | What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis | The Framework Method of thematic analysis was used. |
| *Participant selection* | | |
| **10. Sampling** | How were participants selected? e.g. purposive, convenience, consecutive, snowball | Convenience sampling with a snowball technique. |
| **11. Method of approach** | How were participants approached? e.g. face-to-face, telephone, mail, email | Convenience sample: via e-mail.<br>Snowball technique: messages, telephone calls or face-to-face. |
| **12. Sample size** | How many participants were in the study? | There were fifteen participants in total. |

| | | |
|---|---|---|
| **13. Non-participation** | How many people refused to participate or dropped out? Reasons? | None of the participants dropped out. From the snowball technique, 9 people declined to participate. This was due to time constraints, preference towards a survey as opposed to an interview, or not relating to the research problem. |
| *Setting* | | |
| **14. Setting of data collection** | Where was the data collected? e.g. home, clinic, workplace | Either in a private area at the participants' workplace (empty counselling room, clinic or kitchen), a coffee shop (Participant 14) or via online video conferencing. |
| **15. Presence of non-participants** | Was anyone else present besides the participants and researchers? | No, only the participant and the researcher were present. |
| **16. Description of sample** | What are the important characteristics of the sample? e.g. demographic data, date | Refer to Table 1 in the results section. |
| *Data collection* | | |
| **17. Interview guide** | Were questions, prompts, guides provided by the authors? Was it pilot tested? | The interview guide was adapted from "A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian. French and the European Union's Perspectives" by Bogaert, P., Bochenek, T., Prokop, A., & Pilc, A., 2015, *PloS one 10*(5). No pilot testing was done in this study, however, Bogaert et al. did pilot test the original interview guide. |

| | | |
|---|---|---|
| **18. Repeat interviews** | Were repeat interviews carried out? If yes, how many? | Yes, one repeat interview was carried out due to a recording issue (Participant 14). |
| **19. Audio/visual recording** | Did the research use audio or visual recording to collect the data? | Yes, all interviews were audio-recorded after receiving informed consent from the participants. |
| **20. Field notes** | Were field notes made during and/or after the interview or focus group? | Yes, field notes were made after the interview. |
| **21. Duration** | What was the duration of the interviews or focus group? | Interviews ranged from 00:15:31 to 00:40:39. |
| **22. Data saturation** | Was data saturation discussed? | Yes, under "Participant Recruitment" and "Data Collection" in the method section and the results section. |
| **23. Transcripts returned** | Were transcripts returned to participants for comment and/or correction? | No, as these were not requested by the participants. |
| **Domain 3: Analysis and Findings** | | |
| *Data analysis* | | |
| **24. Number of data coders** | How many data coders coded the data? | RB coded the data and FS validated the qualitative analysis. |
| **25. Description of the coding tree** | Did authors provide a description of the coding tree? | An initial codebook was used, as deductive coding was employed. The final codebook was generated using the coding software and is available on request. |
| **26. Derivation of themes** | Were themes identified in advance or derived from the data? | Themes were identified deductively, based on existing literature. The resulting themes were slightly adapted. |
| **27. Software** | What software, if applicable, was used to manage the data? | NVivo 14. |
| **28. Participant** | Did participants provide feedback on the | No member was checking |

| | | |
|---|---|---|
| **checking** | findings? | performed. |
| *Reporting* | | |
| **29. Quotations presented** | Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number | Yes, all verbatim quotes presented were followed by the participant number in parenthesis. |
| **30. Data and findings consistent** | Was there consistency between the data presented and the findings? | The findings are consistent with the data presented. |
| **31. Clarity of major themes** | Were major themes clearly presented in the findings? | Yes, five major themes were identified in the results section and Table 2. |
| **32. Clarity of minor themes** | Is there a description of diverse cases or discussion of minor themes? | Yes, eighteen sub-themes were described in the results section and Table 2. Participants with opposing views are discussed, as well as sub-themes with one participant. |