ACCESSIBILITY OF

UNAVAILABLE MEDICATION

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ANDY-VINCE FALZON

Department of Pharmacy

University of Malta

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Abstract

Accessibility and availability to adequate treatment always impacted public health, especially in the aftermath of geopolitical and pandemic exigencies. This research aims to establish an evidence-based framework that provides a rational and prompt medicine accessibility strategy based on availability while meeting the needs of the patients.

The research design involved two phases, a retrospective quantitative analysis of medicinal sales over the previous decade from within the Mater Dei Hospital (MDH). A trend and statistical analysis were carried out for each medication. Graphs and statistical results generated allowed the identification of positive and negative correlations across the data collected. It was subsequently distinguished that the ten most requested statistically significant medications exhibited the highest positive correlation coefficients across the duration of data collected. These preparations are potassium bicarbonate and chloride effervescent tablets, phenobarbital sodium 30mg tablets, propranolol 10mg, cyclizine 50mg, labetalol 200mg, acetazolamide 250mg tablets, propranolol 10mg, nifedipine 10mg modified release tablets, pentoxifylline 400mg tablets, iron preparation syrup and metoprolol 100mg tablets. Additionally, data collected also provided the opportunity to identify medications with a negative correlation. Notably, clozapine 100mg tablets and methylphenidate 10mg tablets exhibited the strongest negative correlations.

The second phase related to the thematic analysis of data gathered across focus groups from healthcare professionals representing different specialities or fields. Each focus group represented the surgical, medical, intensive care, operating theatre and pharmacy settings within the MDH. Data collected identified six main challenges encountered across the listed clinical areas affecting the accessibility and availability aspects of

medications. Primarily acknowledging the need for communication and collaboration across all stakeholders.

Additionally, the data collected aided in developing a local evidence-based framework to safeguard treatment accessibility while maintaining an updated healthcare aspect. The framework captures operational and therapeutic assessments to aid in the prior identification of drug shortages and mitigation strategies. Framework also integrates an impact analysis, capturing the importance of the identification and logistical processes associated with ensuring the availability and accessibility of appropriate medication. The importance of constant communication among all stakeholders for the implementation and prevention of drug shortages is highlighted.

In conclusion, this study identified frequent medications requested from the MDH pharmacy from within the community. The findings provide an opportunity to increase the accessibility and availability of medicines to the local community by private community pharmacy suppliers.

Keywords: accessibility, availability, outpatient pharmacy, hospital pharmacy, formulary list

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List of Abbreviations

ASHP	American Society of Health-System Pharmacists
CMA	Critical Medicine Alliance
COVID-19	Coronavirus disease 2019
CPSU	Central Procurement Supplies Unit
EMA	European Medicines Agency
EML	Essential Medicines List
EU	European Union
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
FREC	Faculty Research Ethics Committee
GDPR	General Data Protection Regulation
GFL	Government Formulary List
HERA	Health Emergency Preparedness and Response Authority
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economic, Social, and Cultural Rights
MDH	Mater Dei Hospital
MSSG	Medicine Shortages Steering Group
NHS	National Health System
NMP	Novel Medicines Platform
SAMOC	Sir Anthony Mamo Oncology Centre
UK	United Kingdom
UREC	University of Malta Research and Ethics Committee
WHO	World Health Organisation

Chapter 1

Introduction

1.1 Health

Health continues to be considered a multifaceted aspect, with countries facing different degrees of difficulties in safeguarding this aspect. Health has been described by the World Health Organisation (WHO) as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*".[1] The inclusion of all its multifactorial aspects has also been extensively acknowledged as a fundamental human right by the WHO within its founding constitution in 1947. This right was established in 1966 when 169 national governments ratified the International Covenant on Economic, Social, and Cultural Rights (ICESCR)[2].

This importance can be further evidenced by the endorsement by the United Nations through the Sustainable Development Goals concerning universal health coverage, introducing it as one of the most prominent global health policies. Aiding in implementing and committing to achieving universal health coverage by 2030, fulfilling access to quality essential healthcare services, medications, and vaccines for all[3].

This assistance further extends its contribution to policymakers when confronting complicated choices, such as which health issues require prioritisation and moving from out-of-pocket payments to prepayment through the pooling of funds (Ottersen and Norheim 2014).

[1] Constitution of the World Health Organization, Signed on July 22, 1946, in New York City. New York, USA: Cambridge University Press; 1947 Feb;1(1):225–39. Available from: https://api.istex.fr/ark:/67375/6GQ-28ZH03KG-B/fulltext.pdf
[2] International Covenant on Economic, Social and Cultural Rights [Internet]. [cited 2023 Nov 16]. Available from: https://www.ohchr.org/en/instruments-mechanisms/instruments/international-covenant-economic-social-and-cultural-rights
[3] United Nations General Assembly (UNGA) Resolution adopted by the General Assembly on 13 December 2018 (2018) UN Doc A/RES/73/131

Nonetheless, respective agencies can interpret and employ these reports and treaties in their national policies. This guidance maximises population health, safeguarding the most vulnerable demographics while limiting health-related financial risks (Voorhoeve et al. 2017).

1.2 Essential Medicines

As medication plays a vital role in the right to health, the WHO also extends technical assistance in defining essential medications. Achieved through a voluntary guideline for national formularies to implement, aimed to satisfy the priority healthcare concerns of the population. Medications are selected to international public health prevalence and based on efficacy, safety, and cost-effectiveness (Duong et al. 2019; Laing et al. 2003)

1.2.1 WHO Essential Medicine List

In 1977 the WHO issued the first Essential Drug List, which was later changed to the Essential Medicines List (EML) (Laing et al. 2003). The first list contained 186 different types of medications, outlining guidelines and criteria for the country-appointed representatives to follow in establishing an individualized list. The WHO also offered further assistance to countries where individuals with adequate training were not locally available[4]

[4] The selection of essential drugs : second report of the WHO Expert Committee. Geneva: World Health Organization; 1979. (World Health Organization technical report series ; 641).

The EML is updated every two years to continuously reflect the inclusion of novel treatment options for conditions and current healthcare requirements while maintaining the same aims. Following the initial years, this concept of essential medicines evolved to include an emphasis on the importance of adequate procurement, distribution, and rational use for the benefit of the patients and further strengthening health systems[5].

The 2023 EML includes 502 medications compared to the 479 medicines listed in 2021[6]. While still maintaining the importance of scientific evidence concerning effectiveness, safety, and cost-effectiveness.

The inclusion of cost and cost-effectiveness principles when chartering a framework can create a certain degree of conflict. In 1989, although the WHO Expert Committee recognised the impact associated with viral conditions, principally human immunodeficiency virus (HIV), retroviral medications were not included[7]. Only being slowly introduced in the late 1990s, even though they were judged to be expensive, with the Committee's judgement on affordability for low-income countries being the limiting factor (Hwang et al. 2022).

The addition of antineoplastic and antiretroviral agents in the treatment of HIV promoted a change in assessing the inclusion of new essential medicines. Such as that the cost of medication should not be an exclusion factor if it still meets all other necessary criteria. While incorporating that the aspect of cost-effectiveness should only be considered within

[5] Bigdeli M, Peters D, Wagner A. Medicines in health systems: Advancing access, affordability and appropriate use. Alliance for Health Policy Systems and WHO. Geneva. 2014 [cited 2023 October 18] Available from URL: https://iris.who.int/handle/10665/179197?locale=ar&null
[6] World Health Organisation. Essential medicines and health products. 2020 [cited 2023 Oct 16] Available from URL: https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2023.02
[7] World Health Organisation. The Use of Essential Drugs (1989) - TRS 796. 1989 [cited 2023 Oct 17] Available from URL: https://www.who.int/publications/i/item/9241207965

and not between therapeutic areas[8]. Highlighting that the only limiting factor for consideration into the EML would primarily be based on clinical evidence and not cost.

Resulting in the introduction of innovative medicines to the EML, in the treatment of tuberculosis, hepatitis C and cancer, facilitating access to new therapies.[9,10]

1.3 Access to healthcare

The definition of accessibility has been broadly defined in numerous dynamic expressions, varying across time and different authors. Different barriers are present that predominantly take into consideration either the differences within the demand and supply of the healthcare system or attributes to how care is obtained from healthcare services provided (Penchansky and Thomas 1981; Bigdeli et al. 2013; Levesque et al. 2013; Saurman 2016).

1.3.1 WHO Access Framework

WHO developed a four-part framework to aid and facilitate cooperation between all responsible members in solving the complex challenge of ensuring accessibility to resolve common health problems (WHO 2004). The four sections specified as playing vital roles in ensuring accessibility in different national health systems:

[8] World Health Organization. WHO medicines strategy: report by the secretariat. Accessed October 17, 2023. https://www.who.int/publications/i/item/1066578389
[9] Lo C. WHO's Essential Medicines List: discussing innovation and access. Pharmaceutical Technology. 2019 [cited 2023 Oct 17] Available from URL: https://www.pharmaceuticaltechnology.com/features/who-essential-medicines-list/
[10] WHO Updates Essential Medicines List with New Advice on Use of Antibiotics, and Adds Medicines for Hepatitis C, HIV, Tuberculosis and Cancer. Washington, D.C: Targeted News Service; 2017 Jun 6; Available from: https://search.proquest.com/docview/1906411340

I. **Rational Selection** of medicines, based on the development of national lists of essential medicines enforcing the need to provide the best evidence-based health care.

II. **Affordable prices** aspect achieved through price competition, equitable pricing negotiation, bulk procurement, and generic medicine policies.

III. **Sustainable financing / Pharmacoeconomics** ensures adequate public funds are available while reducing out-of-pocket spending and expanding health insurance through various schemes.

IV. **Reliable supply systems** are supported through a holistic approach to ensure the organised acquisition/production of medicines through the reasonable application of regulatory control.

Figure 1.1: Access Framework based on WHO guidelines

The four sections that are crucial in promoting accessibility within the national healthcare system

Figure based on: World Health Organisation. Equitable access to essential medicines: a framework for collective action. WHO policy perspectives on medicines. Geneva. 2004 [cited 2024 Jan 04] Available from: https://apps.who.int/iris/bitstream/handle/10665/68571/?sequence=1

The six A's of Access

Access was defined in 1981 by Penchansky and William Thomas, as the degree of "fit" between the health services attributes and attributes expected by the clients, incorporating five different concepts (availability, accessibility, accommodation, affordability and acceptability). Awareness was later proposed as a missing aspect from the initial definition. Allowing for effective in-context communication to maintain active consideration of the desired outcomes with the relevant users (Saurman 2016). Thus, highlighting the importance of accessibility to healthcare and essential medication continues to play a vital role in fulfilling the fundamental right to health (Muscat 2020).

i. **Availability**

Availability refers to the relationship between the existing services provided and the needs of the community it is meant to address or resolve. This term also denotes the timely and accessible provision of healthcare services, facilities (such as hospitals, clinics and pharmacies), and professionals for necessary treatment (Penchansky and Thomas 1981; Muscat 2020).

ii. **Accessibility**

Accessibility alludes to the proximity and ease of connecting the client to the area of service. Taking into consideration the patient's attributes such as transportation, time, distance, and cost in obtaining the necessary healthcare service (Penchansky and Thomas 1981).

iii. **Accommodation**

The Accommodation aspect revolves around the aspect of convenience. Such as that resources and services provided are coordinated effectively while considering the effective ease of compliance for the patient (Penchansky and Thomas 1981)

iv. **Affordability**

The affordability of healthcare services refers to the extent to which patients can pay for medical care without facing financial burdens (Penchansky and Thomas 1981). This aspect also takes into consideration any indirect or opportunity costs within the patient's perceptions of value (Muscat 2020).

v. **Acceptability**

Acceptability is the degree to which the services provided by the system align with the patient's preferences and factors (Russell et al. 2013). Where aspects of satisfaction can also be expressed, which take into consideration different dimensions such as the overall facility and the relationship with healthcare providers (Penchansky and Thomas 1981). Noting that higher levels of concordance exert an improvement in care and self-management of chronic diseases than with a pharmaceutical care plan (Kerse et al. 2004; Chatterjee 2006; Cousin et al. 2012; Miller 2015).

vi. **Awareness**

Although not originally listed by Penchansky and William Thomas, the aspect of awareness was later introduced as another dimension for healthcare access. This was achieved through effective communication and understanding by policymakers, healthcare professionals and patients (Russell et al. 2013). Thus, allowing the possibility

to make a conscious and robust informed decision about the best available service within specific contexts (Saurman 2016)

Access continues to be an area of major concern within healthcare policy, irrespective of the developmental characteristics of the country (Goodson 2010; Bigdeli et al. 2013). Thus, highlighting the interdependence of the different aspects of access, while emphasising the importance of policy and constitutional changes required to address these challenges holistically (De Jongh et al. 2021; Perehudoff et al. 2010).

Figure 1.2: Six Dimensions of Access

As outlined in the following publications:

Penchansky R, Thomas WJ. The concept of access: definition and relationship to consumer satisfaction.Medical Care. 1981; 19: 127-140.

Saurman E. Improving access: modifying Penchansky and Thomas's Theory of Access. Journal of Health Services Research & Policy. 2016; 21(1):36-39.

Russell DJ, Humphreys JS, Ward B, Chisholm M, Buykx P, McGrail M, et al. Helping policy-makers address rural health access problems. Australian Journal of Rural Health 2013; 21:61–71.

1.3.2 Novel Medicines Platform

This need for cooperation between different sectors led to the introduction of the Oslo Medicine Initiative in 2020, led by the WHO Regional Office for Europe, the Norwegian Ministry for Health and Care Services and the Norwegian Medicines Agency[11]. This initiative aimed to identify measures to increase patient accessibility to "effective, novel, high-cost medicines", such as advanced therapy medicinal products, within the WHO European Region[12].

In 2022, during the 72nd session of the WHO Regional Committee for Europe, this initiative was further developed into the Novel Medicines Platform (NMP), to continue acting as a neutral facilitator to improve accessibility to novel medicines within the region[13].

The main objectives of this initiative concern achieving sustainable health systems and industry growth, through collaborative mechanisms while addressing market failures and unmet needs. This initiative incorporated four distinctive working groups, each defining an aspect of transparency, solidarity, sustainability and novel antimicrobials while sharing the same aims and guiding principles.

Working group 1's theme focuses on transparency, specifically determining which information can be disclosed about various health markets. While identifying key

[11] The Oslo Medicines Initiative [Internet]. World Health Organization; [cited 2024 Apr 5]. Available from: https://www.who.int/europe/initiatives/the-oslo-medicines-initiative
[12] Final report of the Oslo Medicines Initiative. Improving access to novel, high-priced medicines in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2022. Licence: CC BY-NC-SA 3.0 IGO.
[13] 1. Who/Europe's novel Medicines Platform Launches Working Group on transparency to improve access to medicines [Internet]. World Health Organization; [cited 2024 Apr 6]. Available from: https://www.who.int/europe/news/item/03-01-2024-who-europe-s-novel-medicines-platform-launches-working-group-on-transparency-to-improve-access-to-medicines#:~:text=The%20NMP%20was%20created%20at,Initiative%20(2020%E2%80%932022).

performance markers to improve indicators that can effectively measure the patients' access to novel, cost-effective medicines. Detecting factors that impact patient access via a standard collection, analysis and utilization of metrics that impact patient access to novel medications (WHO 2024).

Working group 2 concerns the solidarity aspect, exploring possible ways to strengthen existing efforts to coordinate coherently both the demand and purchasing of novel medicines. Extending also into the accrual and compilation of economic and pharmacovigilance evidence of novel treatments while on the market (WHO 2024).

Working group 3 examines the sustainability aspect through the review of affordable pricing principles while determining central elements required for market governance (WHO 2024).

Working group 4 focuses on novel antimicrobials, primarily in the identification of policy options to allow sustainable innovation and access to novel antimicrobials. Reviewing incentive coordination mechanisms to safeguard and enable sustainable research and development (WHO 2024).

Figure 1.3: Novel Medicines Platform Four Working Groups

1.3.3 Barriers to Accessibility

As previously described and further outlined by Abbas *et al.* (2019), Saurman (2016) and Peters *et al.* (2008), accessibility ensures that patients receive the right treatment, from the right provider, at the right time and place. Hence access to medicine is achieved when such characteristics correspond to the aspects of the services provided at a reasonable cost (Whitehead 1992)

Barriers can be considered as limiting this ability, preventing individuals from obtaining the medication and treatment that they require. Similarly, societal and cultural themes continue to play an intrinsic role when seeking health services (Ensor and Cooper 2004; Rutherford et al. 2010; Perehudoff et al. 2019).

Barriers to accessing healthcare services are further differentiated from either the demand side or the supply side (Ensor and Cooper 2004; O'Donnell 2007). Each aspect although intrinsically interdependent, requires the need to be addressed holistically and concurrently (James et al. 2006; O'Donnell 2007).

Supply-side barriers are inherent to the healthcare service and can be described as issues associated with irregular allocation, quality and cost of healthcare treatment. Other policies regarding pharmaceutical governance, such as regulatory affairs, and pharmacovigilance also affect supply barriers issues (Jacobs et al. 2012; Bigdeli et al. 2013; Muscat 2020). Demand-side barriers can be attributed to differences in the expectations and factors influencing the ability to access the necessary health services. (Ensor and Cooper 2004; Jacobs et al. 2012; Levesque et al. 2013). This is evident that healthcare delivery is dependent on different factors, each exerting an effect on the level of care that can be provided.

1.4 The Maltese Scenario

Malta is one of the smallest countries in the European Union (EU) with a population of around 519,000[14]. The population finances the National Health System (NHS) through national insurance and general tax contributions, under the tutelage of the Ministry of Health and Ministry for the Family and Social Solidarity. Ministry of Health provides health services, regulations, and standards, while the Ministry for the Family and Social Solidarity is responsible for social policies and benefits (Azzopardi-Muscat et al. 2017).

The NHS closely resembles the one adopted within the United Kingdom (UK), allowing access to healthcare services at no additional charge when accessing the system if the person is eligible for healthcare benefits (Muscat et al. 2006). This difference between the models refers to the aspect that eligibility is dependent on the applicant's social security regulations. Where employment status and national security contributions as determined by the Social Security Act (Cap. 318) 1987 (Mlt)[15]. Whereas the UK system is the integration of a cost-sharing aspect in requiring patients to make co-payments for services that are either provided through the NHS or for private treatment. This is evident in the pharmaceutical care aspect, requiring patients to be charged per prescription unless the patient is enrolled through a capped subscription. Exemptions are based on age, financial income, during pregnancy and for chronic conditions[16].

[14] Malta NSO-. Census of Population and Housing 2021: Final Report: Population, migration and other social characteristics (Volume 1) [Internet]. 2023 [cited 2023 Nov 23]. Available from: https://nso.gov.mt/events/census-of-population-and-housing-2021-final-report-population-migration-and-other-social-characteristics/

[15] Ministry for Justice. Chapter 318 Social Security Act. Malta: The Ministry; 1987 [cited 2023 Nov 23]. Available from URL: http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8794

[16] Anderson M, Pitchforth E, Edwards N, Alderwick H, McGuire A, Mossialos E, Hernández- Quevedo C (2022), The United Kingdom: Health System Summary, 2022. WHO/European Observatory on Health Systems and Policies, Brussels.

Additionally, the Maltese healthcare system also comprises a private healthcare system complementing the public healthcare system, primarily through primary care and outpatient services. This private healthcare system is funded by supplementary voluntary health insurance or out-of-pocket payments, primarily complementing primary care and outpatient services (Muscat et al. 2006).

Through the public healthcare system, primary care is delivered and operated through nine public Health Centres in Malta and one in Gozo, which operates on a 24/7 basis and offers various specialised services[17]. Secondary and tertiary care aspects are provided through other hospitals. Principally Mater Dei Hospital (MDH), acts as the general teaching hospital, catering for specialized inpatient care services (Muscat et al. 2006; Azzopardi-Muscat et al. 2017).

[17] Overview - health services [Internet]. Minsitry of Health; [cited 2023 Nov 24]. Available from: https://healthservices.gov.mt/en/phc/Pages/Health-Centres/Overview.aspx

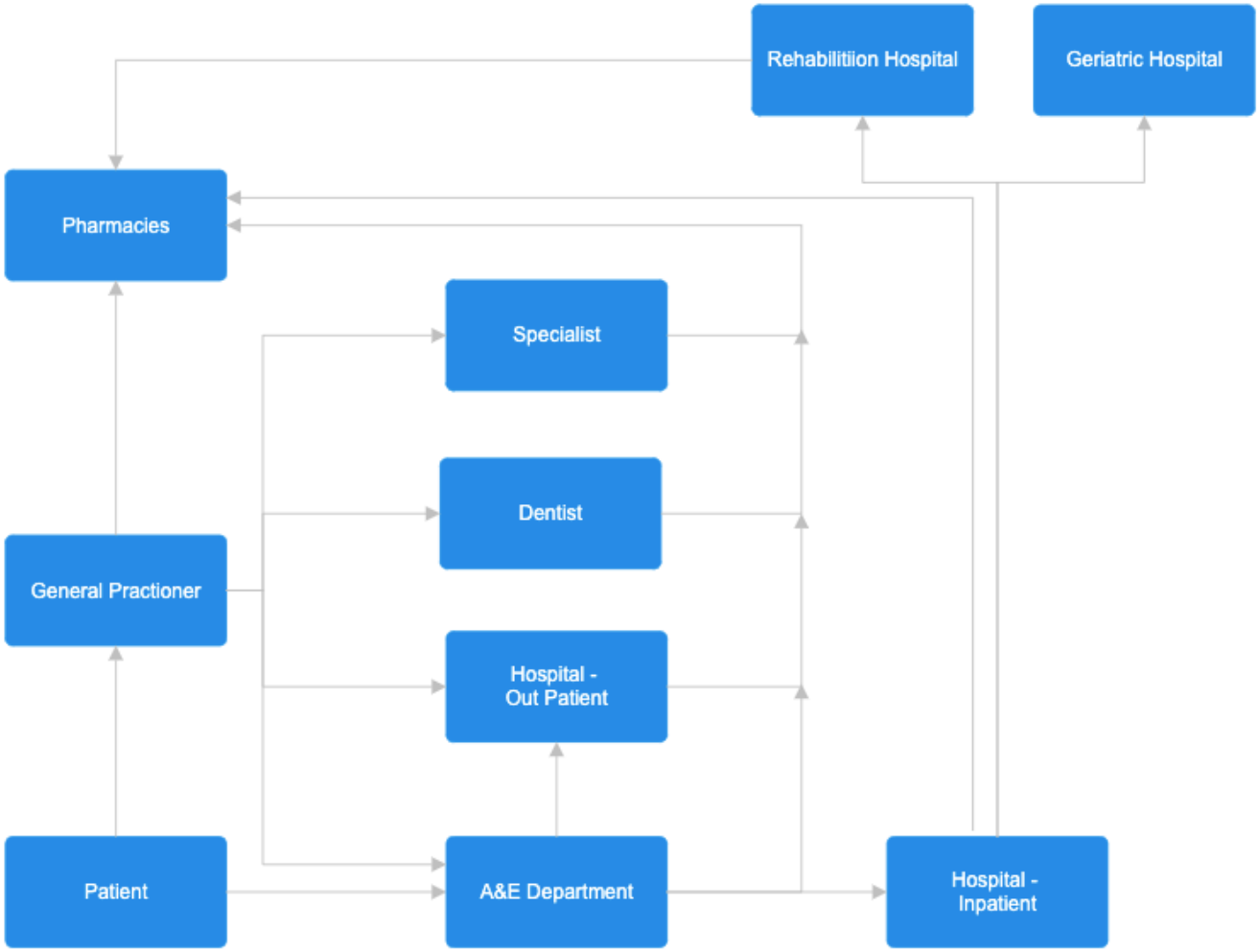

Figure 1.4: Patient pathway to access the public health care system

Replicated from: Azzopardi-Muscat N, Buttigieg S, Calleja N, Merkur S. Malta: Health System Review. Health Syst Transit; 2017;19(1):1–137.

1.4.1 Medicines Entitlement

Social Security Act (Cap. 318) 1987 (Mlt) also entitles eligible applicants to free medicinal treatment, based on the presence of valid conditions[11]. Patients diagnosed with a chronic condition listed in Schedule V are entitled to free medication listed on the Government Formulary List (GFL) for that specific disease, regardless of means, income, or age[18]. Patients who require medicines not listed on the GFL or non-entitled patients, purchase medicines through out-of-pocket expenses from private community pharmacies.

Patients may also be entitled through Schedule II of the Social Security Act, commonly referred as the Pink Card, based on social assistance criteria for low-income patients. Such criteria include unemployment, single parent and low-income aid as determined through a means testing assessment. However, entitlement is only limited to a list of essential medicines and medicinal products marked as 'pink positive' on the GFL for acute and chronic conditions.

In the management of chronic conditions through both procedures, patients collect an 8-week supply of medicinal treatment from their preferred community pharmacy registered under the Pharmacy of Your Choice (POYC) Scheme. A pharmacist dispenses treatment against a prescription issued by a general practitioner or consultant specialist. The specialist visit is also vital for the respective treatment to be renewed or extended, especially for protocol-regulated treatment. Concerning other non-protocol-regulated medications, general practitioners can amend the dose of treatment for conditions that require constant monitoring.

[18] Government of Malta. Pharmacy of Your Choice - Schedule V. 2021 [cited 2023 Nov 25]. Available from URL: https://healthservices.gov.mt/en/poyc/Pages/Schedule-V.aspx#:~:text=%E2%80%8BPatients%20are%20entitled%20to,covers%20a%20total%20of%2083.

Conditions that fall outside existing policies or require specific medical treatment (not listed on the GFL) are reviewed by the Exceptional Medicinal Treatment Committee[19]. Initially set up in 2018 under Legal Notice 58: Health Act (Cap. 528), aiding patients suffering from atypical conditions, requiring low quantities of specific medicinal treatment[20]. Applications are submitted by a medical consultant and counter-endorsed by the respective clinical chair for evaluation by the EMTC as per the Exceptional Treatment Policy. Following approval, medicinal treatment is procured on a named-patient basis and made available through the respective entities.

[19] Government of Malta. Exceptional Medicinal Treatment. 2024 [cited 2024 Feb 27]. Available from URL: https://healthservices.gov.mt/en/pharmaceutical/Pages/EMT.aspx#:~:text=In%20brief%2C%20an%20EMT%20Request,Medicinal%20Treatment%20Committee%20(EMTC)

[20] Ministry for Justice. Subsidiary Legislation 528.08 Exceptional Medicinal Treatment Committee Regulations. Malta: The Ministry; 2018 [cited 2024 Feb 27]. Available from URL: https://legislation.mt/eli/sl/528.8/eng

1.5 Medical Treatment Procurement

The Central Procurement and Supplies Unit (CPSU) is the entity responsible for the efficient procurement and supply of materials, works and services across all National Healthcare entities[21]. This includes the procurement of medicines, medical devices and technologies listed on the GFL, thus including the Hospital Formulary and the Outpatients Formulary. Cooperation with the Directorate of Pharmaceutical Affairs (which is responsible for maintaining, updating and reviewing prescribing protocols attributed to the GFL) delivers technical assistance regarding the establishment of technical specifications for the procurement of medicines[22].

The CPSU employs a public tendering procedure to stimulate the market and mitigate influential spending. This ensures competitiveness by allowing various pharmaceutical economic operators to compete on an equal footing. This competition grants the possibility of achieving quality medication and treatment while safeguarding the financial sustainability of the healthcare system.

The dynamic collaboration and this tendering process allow the possibility of introducing new medications in the national formulary. Such efforts are visible in the introduction of new treatments, such as Dipeptidyl Peptidase 4 inhibitors, Direct Oral Anticoagulants, and new psychiatric formulations, or the inclusion of new conditions to already listed

[21] Government of Malta. Central Procurement and Supplies Unit – Corporate identity. 2023 [cited 2023 Nov 30]. Available from URL: https://healthservices.gov.mt/en/cpsu/Pages/About-Us/Corporate-Identity.aspx

[22] Government of Malta. Directorate for Pharmaceutical Affairs – Formulary Management Unit. 2023 [cited 2023 Nov 30]. Available from URL: https://healthservices.gov.mt/en/pharmaceutical/Pages/formulary.aspx

medications. These efforts result in the advancement and constant renewal of the GFL, to consider a more patient-regulated approach.

Once medical supplies are procured, these are delivered to the POYC unit, which ensures responsibility for adequate distribution and supply to all 220 participating community pharmacies to be dispensed to the 120,000 registered patients[23].

1.5.1 Local Acute Hospital setting

Mater Dei Hospital (MDH) has been the main acute general hospital for the Maltese Islands since its inauguration in June 2007, with another acute hospital situated in Gozo (Bugeja et al. 2019). As such, MDH has been providing a wide range of healthcare services from intensive care treatment to routine outpatient services. Specialized oncological treatment is provided through the Sir Anthony Mamo Oncology Centre (SAMOC), situated in front of MDH, which was inaugurated in 2015[24].

The pharmacy situated within MDH provides a comprehensive range of services to both the MDH and SAMOC. Services provided involve dispensing to both hospital and outpatient settings, clinical pharmacy services, and preparation of oncological and extemporaneous treatment, while also covering additional auxiliary services[25].

Medication available from the hospital pharmacy also includes protocol-regulated items, that affects the dispensing procedure. Normal formulary items are dispensed against a

[23] Government of Malta. Central Procurement and Supplies Unit – POYC Information. 2023 [cited 2023 Nov 30]. Available from URL: https://healthservices.gov.mt/en/cpsu/Pages/POYC-OOS.aspx#NAVMENU

[24] Times Of Malta. Oncology Centre inaugurated. Times of Malta [Internet]. 2015 Sep 20 [cited 2023 Dec 01]; Available from: https://timesofmalta.com/articles/view/oncology-centre-inaugurated.585210

[25] Government of Malta. Mater Dei Hospital – Pharmacy Services 2023 [cited 2023 Dec 02]. Available from URL: https://healthservices.gov.mt/en/cpsu/Pages/News/Medicine-Alerts.aspx

valid Schedule V, corresponding prescription, control card if the medication is listed under the Dangerous Drug Act[26], and identification documents of both the patient and the person collecting the medication instead of the patient. Protocol-regulated items follow the same dispensing procedure, with the exception that the patient must have prior active approval from POYC.

Dispensing to the public includes a wide array of services, such as discharged patients, the sale of medications not available from within the community and antithrombotic treatment to gestational patients. This also includes medication listed as "To Be Dispensed From Hospital" on the Outpatient Formulary. Which currently lists 114 medications that can only dispensed from MDH for Malta and Gozo General Hospital for Gozo. Medications delineated by these criteria cover a wide array of conditions, examples include oncological treatment, antifibrinolytic and antipsychotic medications.

When treatment is not available from community pharmacies, such as during a shortage, or after hours during the night, these can be purchased from the hospital dispensary provided that the item is listed on GFL. Sales from the hospital dispensary are only permitted against a valid legal prescription and endorsed by Community Pharmacists, confirming that the prescribed medication is not available within their respective pharmacies.

[26] Ministry for Justice. Subsidiary Legislation 101.02 Internal Control of Dangerous Drugs Rules: The Ministry; 1939 [cited 2023 Nov Dec 9]. Available from URL: https://legislation.mt/eli/sl/101.2/eng/pdf

1.6 Shortage

Drug shortages have been noted to have an impact on drug therapy. These supply issues give rise to safety risks, concerns with delaying medical treatment, unsuitable medical alternatives, and medication errors resulting in patient harm (Kaakeh et al. 2011; Ventola 2011)

Starting in 2013, the European Association of Hospital Pharmacists began analysing the challenges posed by medicine shortages in Europe. Conducting two pan-European surveys in 2014 and 2018 to collect data on the prevalence, nature, and consequences of these shortages. The Medicine Shortage position paper published in 2019 reported an increase to 91.8% from 86.2% of hospital pharmacists reporting that drug shortages still constitute difficulty in delivering quality care to patients[27].

The pandemic in 2019 further exposed the vulnerability affecting supply chains in both the EU and the United States of America (Ammar et al. 2021; Beck and Buckley 2022). This led to new policies and regulations to minimise future similar events, particularly aimed at aiding all members to prevent critical shortages of essential medicines and safeguard supply chains. The EU issued Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices[28]. Conversely, the United States Food and Drug Administration (FDA) issued guidance documents under Section 506C of

[27] EAHP position paper on medicines shortages - European. [Internet]. EAHP; 2019 [cited 2024 Feb 16]. Available from: https://www.eahp.eu/sites/default/files/eahp_position_paper_on_medicines_shortages_june_2019.pdf

[28] Council Regulation (EU) 2022/123 of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

the FD&C Act, regarding notification of discontinuation or interruption of medicinal treatment[29].

Regulation (EU) 2022/123 established the Executive Steering Group on Shortages and Safety of Medicinal Products, also referred to as the Medicine Shortages Steering Group (MSSG). Efficiently focusing on major public health emergencies which necessitate the provision of robust responses, along with the urgent coordination of medicinal product supply within the European Union. Thus, ensuring a coordinated approach to the distribution of medicinal products across the region, thereby mitigating the impact of any public health crises and emergencies. Allowing the prior joint task force on the Availability of Authorised Medicines for Human and Veterinary Use established in 2016 to focus on structural and strategic solutions during non-critical phases[30].

MSSG recommendations would be reviewed on a case-by-case basis, taking into consideration proportionality, and tailoring an individual response depending on the medicinal treatment. While also cooperating and assisting the Medicine Shortages Single Point of Contact Working Party, whether decisions were adequate or required exceptional flexibility[31].

[29] Notifying the Food and Drug Administration of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability [Internet]. Washington: Federal Information & News Dispatch, LLC; 2020 Apr p. 18247. (The Federal Register / FIND; vol. 85). Available from:https://search.proquest.com/docview/2384788891

[30] HMA / EMA task force on the availability of authorised medicines for human and veterinary use [Internet]. European Medicines Agency; [cited 2024 Mar 11]. Available from: https://rb.gy/rd33m2

[31] European Medicines Agency. MSSG Toolkit on recommendations on tackling shortages of medicinal products. 2023 [cited 2024 Mar 06] Available from URL: https://www.ema.europa.eu/en/documents/other/mssg-toolkit-recommendations-tackling-shortages-medicinal-products_en.pdf

European Medicines Agency (EMA) collects and consolidates all relevant information and coordinates with the member states involved. Through the arrangement of meetings between the donating member state, the receiving party, and other relevant participators. If no member states would be able to provide support, the respective member state would be able to further explore alternative options. Promoting further discussions at the MSSG level, primarily aimed. to explore additional solutions[32].

Other European initiatives include the synergy of the Heads of Medicines Agencies and the EMA leading to the Task Force on the Availability of Authorised Medicines for Human and Veterinary Use (TF-AAM). Falling under the European Medicines Agencies network strategy to 2025[33]. Designed to act as a focal point for supply and availability, primarily aimed to harmonise and streamline while avoiding duplication of work within the regulatory network. These initiatives particularly focus on developing strategies and encouraging the best practices to improve the prevention and management of shortages caused by disruptions in the supply chain. While also fostering active collaboration and facilitating communication of effective practices with different stakeholders within the EU[34].

Similarly, the FDA authority was further expanded in 2012 through the Food and Drug Administration Safety and Innovation Act (FDASIA). The introduction was particularly aimed at promoting innovation to hasten patient access to safe and effective treatment. At

[32] European Medicines Agency. MSSG Solidarity Mechanism. 2023 [cited 2024 Mar 26] Available from URL: https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf
[33] European Medicines Agency. European medicines agencies network strategy to 2025. 2023 [cited 2024 Mar 30] Available from URL: https://www.ema.europa.eu/en/documents/report/european-union-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf
[34] European Medicines Agency. HMA / EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use. 2023 [cited 2024 Mar 30] Available from URL: https://rb.gy/cvixvu

the same time, increasing different stakeholders' involvement in FDA processes and safeguarding the drug supply chain (Kramer and Kesselheim 2012).

Furthermore, provisions under Title X of FDASIA allow the opportunity for the FDA to mitigate drug shortages. Resulting in requiring all manufacturers of certain vital medications to inform the authority of permanent discontinuance or temporary manufacturing interruption. A priori only certain medication manufacturers for certain conditions were required to notify the FDA of any discontinuation[35]. Whereas previously FDA received notifications voluntarily from other manufacturers.

These provisions also require the FDA to establish a Drug Shortage task force to develop a strategic plan concerning drug shortages to submit to Congress. Particularly aimed to strengthen mitigation responses and develop long-term prevention strategies. Achieved through coordination and streamlining of internal procedures to enhance cooperation between different units within the FDA (FDA 2013).

Compiled information from the submitted notifications, medication extended use dates and task force efforts are made available to the public. Shortage Information is categorised under current/resolved shortages, discontinuations or therapeutic categories to facilitate query research. This online repository also allows receiving updates via electronic mail alerts[36].

Furthermore, in addition to previously outlined procedures, the Critical Medicines Alliance (CMA) was established under HERA, the Health Emergency Preparedness and

[35] Food and Drug Agency. Fact Sheet: Drug Products in Shortage in the United States. 2018 [cited 2024 Mar 31] Available from URL: https://rb.gy/odax32
[36] Food and Drug Agency. Drug Shortages. 2024 [cited 2024 Mar 31] Available from URL: https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

Response Authority, in January 2024[37]. The alliance is a consultative mechanism bringing together relevant stakeholders from EU Member States, the scientific representatives and the industry. The Alliance aims to identify key areas and priorities for action, proposing solutions to strengthen the supply of critical medicines in the EU, with the final objective to enhance efforts to prevent and address shortages effectively. Malta is currently being represented by two different working groups the CPSU and the Medicines Authority (May 2024).

Professional associations such as the American Society of Health-System Pharmacists (ASHP) provide guidelines on managing shortages and similar online information regarding current and previous drug shortages (Fox and McLaughlin 2018). Similarly, entries in the online repository are recorded by shortage status, revision date and created date. While also cataloguing resolved drug shortages, discontinued drugs and commercially unavailable preparations[38].

1.6.1 Local Shortage

The United Kingdom has been a vital market for medicines for the Maltese Islands. The shared common language reduces the need for translation or repackaging, facilitating the distribution of medications between countries. This was portrayed in over a third of

[37] European Neighbourhood Policy and Enlargement Negotiations (DG NEAR) [Internet]. Commission launches the Critical Medicines Alliance to help prevent and address shortages of critical medicines; [cited 2024 Jun 3]. Available from: https://neighbourhood-enlargement.ec.europa.eu/news/commission-launches-critical-medicines-alliance-help-prevent-and-address-shortages-critical-2024-04-24_en
[38] American Society of Health-System Pharmacists. Drug shortages list [Internet]. [cited 2024 Apr 4]. Available from: https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=All

marketing authorisation holders being either based in the UK or the Maltese Authorisation based on the prior authorisation issued from the UK[39].

This over-dependence on one market has been extensively described in a report issued by the European Commission in 2012, indicating a predisposition to issues concerning accessibility to medicinal problems in small Member States such as Malta and Cyprus.

Such a consequence results in the over-reliance on Article 126a of Directive 2001/83/EC, whose main intention was to be an exception in providing an easier route for registering medicinal products for the benefit of public health.

This was highlighted following the major issues caused by Brexit, where the UK seceded from the EU in January 2020, with a transitionary period till December 2020[40].

The effects and consequences of Brexit, particularly on the Maltese market, have been extensively studied by Doubara in 2021, presenting numerous accessibility issues. The main themes involve increases in cost, stock outages and bureaucracy limiting medicine accessibility.

[39] Farrugia C. Malta: preparations for the impact of Brexit on the pharmaceutical supply chain in Malta-The perfect storm. PharmaWorld. 2018 [cited on 2023 Dec 04] Available from URL: https://www.pharmaworldmagazine.com/preparations-forimpact-of-brexit-pharmaceutical-supply-chain-malta/

[40] Council of the European Union; 2020 [cited 2023 Dec 23]. Available from: https://www.consilium.europa.eu/en/press/press-releases/2020/01/30/brexit-council-adopts-decision-to-conclude-the-withdrawal-agreement/

1.7 Aim and Objectives of the Study

The research aims to establish a scientific framework that provides a rational and prompt medicine accessibility strategy based on availability while meeting the needs of patients.

The objectives are to:

I. Retrospectively analyse queries related to medicine sales from within the hospital pharmacy setting

II. Set up focus groups with healthcare professionals to identify treatment barriers associated with accessibility and availability issues experienced by inpatients at Mater Dei Hospital.

III. Propose a framework to deal with medicine availability and affordability issues.

Chapter 2

Methodology

2.1 Overview

The research study consisted of two phases. Phase I involved a retrospective analysis of medication requests and sales recorded at the MDH. Phase II consisted of establishing focus groups across different healthcare speciality settings to identify treatment barriers associated with accessibility within MDH, concluding in developing an innovative framework to address any shortcomings in accessing treatments.

2.2 Literature Review

A comprehensive literature search of peer-reviewed information from scientific journals was conducted by applying Medical Subject Heading (MeSH) terms and relevant keywords. Pertinent keywords used were accessibility, availability, affordability, hospital setting, patient care in Pubmed®, Hydi Hybrid Discovery search gateway (through Library Services of the University of Malta), and Google Scholar online literature databases.

Local and European legislation related to accessibility and availability within the medical aspect were also consulted. Particularly EU Directive 2001/83EC[41], the Maltese Social Security Act (Cap. 318)[42] and the Medicines Act (Cap 58)[43]. Relevant reports and dissertations were also reviewed.

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[41] European Commission. Directive 2001/83/EC of the European Parliament and of the Council on the community code relating to medicinal products for human use. 2001 [cited 2023 May 06]. Available from:
URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf

[42] Ministry for Justice. Chapter 318 Social Security Act. Malta: The Ministry; 1987 [cited 2023 Nov 23]. Available from: URL: https://legislation.mt/eli/cap/318/eng/pdf

[43] Ministry for Justice. Chapter 458 Medicines Act. Malta: The Ministry; 2003 [cited 2023 May 06]. Available from URL:
http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8924&l=1

2.3 Research Design

An exploratory convergent parallel mixed method approach was implemented, focusing on collecting both quantitative and qualitative data[44]. This systematic approach was implemented to garner a more comprehensive understanding while meeting the study objectives.

The primary phase involved adopting a pragmatic quantitative approach for extracting past sales data, and classifying the most widely requested medication. A twenty-hour research and observational placement was carried out over two weeks in February 2024 within the dispensary section of the MDH. Allowing the possibility to observe daily dispensing procedures and systems.

The secondary phase consists of focus group sessions with various healthcare personnel within the general hospital. Collected information was analysed and corroborated to aid in risk identification associated with accessibility and availability issues across medical experiences.

The gathered data was used to identify barriers and challenges, which were then utilised to develop a scientific framework based on current common practice literature to address accessibility issues.

[44] Creswell JW. Research design: Qualitative, Quantitative and Mixed Methods Approaches [Internet]. Los Angeles ; London ; New Delhi ; Singapore ; Washington DC: SAGE; 2014. Available from: http://bvbr.bib-bvb.de:8991/F?func=service&doc_library=BVB01&local_base=BVB01&doc_number=025960655&sequence=000002&line_number=0001&func_code=DB_RECORDS&service_type=MEDIA

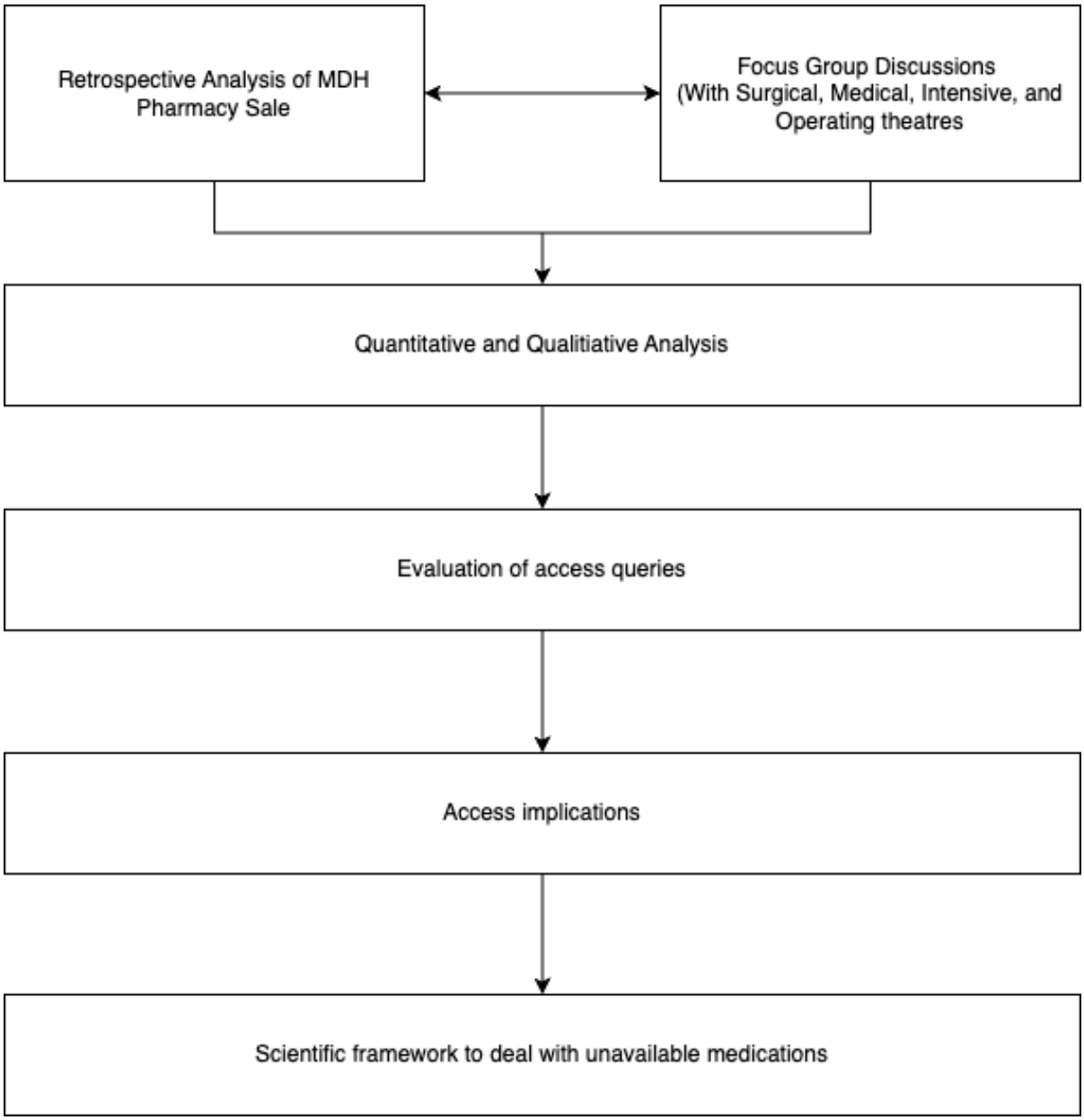

Figure 2.1: Flowchart of research methodology

2.4 Research Setting

The research was conducted at the MDH. The main hospital of the national health system of the Maltese Islands was inaugurated in 2007 to serve as the general acute hospital for the Maltese Islands[45]. Delivering a wide range of different clinical services in preserving public health. This is achieved and maintained through collaboration with the CPSU, responsible for acquiring and distributing all necessary supplies. Coordination between these entities facilitates access to medications safeguarding availability and continuation of treatment.[46]

2.5 Ethics Approval

Ethics approval from the University of Malta Research and Ethics Committee (UREC) was sought before conducting the research. The Faculty Research Ethics Committee (FREC) self-assessment application indicated that only submission for record purposes was required, due to no direct contact nor collection of sensitive information would be utilised. The research considered the General Data Protection Regulation (GDPR), requesting institutional approval from the Chief Executive Officer MDH, Director of Pharmacy, Data Protection Officer, and Speciality Head of Departments before initiating the research study. These were submitted to the UREC together with the research proposal and study protocol for record purposes.

Focus group participants signed a consent form and were informed verbally and in writing about the scope of the study, and their right to withdraw from it at any time without consequences.

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[45] Busuttil C. Mater Dei Hospital inauguration Tonight [Internet]. Allied Newspapers; 2007 [cited 2023 Jul 15]. Available from: https://timesofmalta.com/articles/view/mater-dei-hospital-inauguration-tonight.12977

46 CPSU [Internet]. [cited 2023 Aug 13]. Available from: https://healthservices.gov.mt/en/cpsu/Pages/Home.aspx

2.6 Phase 1: Retrospective Analysis of Out-Patient Sale Data

Retrospective data on Outpatient sales from the past decade was made available through an intermediary, responsible for the medicinal logistics within the MDH. An observational study of twenty hours was also carried out over two weeks to gain more insight into the different daily perspectives and interactions.

2.6.1 Data Extraction of Outpatient Sale Data

Comprehensive retrospective extraction of sales data through the MDH pharmacy Outpatient setting from December 2013 to November 2023 was carried out in Microsoft Excel®. Further systematic classification and statistical analysis of sale data took place into different dosage forms to identify purchasing trends related to treatment availability issues by physicians within the public service setting.

2.7 Phase 2: Focus group

Focus groups were chosen to effectively explore participants' experiences, perceptions, and attitudes towards specific topics (Kitzinger 1995; Bowling 2014). Principally focus group facilitate discussion, where a moderator asks questions in an interactive setting and participants can share their opinions with other group members (Plummer-D'Amato 2008a; Krueger and Casey 2014). To maintain a convenient scheduling and minimise disruptions sessions took place during normal working hours. Focus group sessions were audio recorded and subsequently transcribed in English with consent from participants.

2.7.1 Out-Patient Focus Group Protocol

Participants from the current personnel within the outpatient pharmacy were identified. Inclusion criteria incorporated either knowledge, extensive experience of the concerning practices, experiences of working night duties or being directly involved with the management of the outpatient setting. Due to changes in policies and protocols, participants with 5 or more years of work experience were preferred, allowing the possibility to illicit and compare a wide array of experiences.

An electronic invitation and an information sheet (Appendix I) were sent to healthcare professionals to confirm their availability and attendance to participate in a focus group on medicines sales and requests.

The focus group protocol was based on outlines described by Kitzinger (1995) and Plummer-D'Amato (2008b), which included an introductory, rapport-building in-depth discussion, and closure section with the session lasting one hour.

The focus group was led by a moderator who was responsible for creating a balanced and permissive atmosphere to facilitate discussions. An open discussion was maintained by facilitating open communication without being dominant so as not to inhibit discussion. The researcher followed the focus group and notes of the discussion outcomes were recorded and transcribed to facilitate thematic analysis.

General questions are portrayed in a triangular structure as proposed by Hurworth (1996) and described by Plummer-D'Amato (2008b). Implementing the use of a broad opening question as an introductory statement to initiate the discussion and followed with

transitionary and key questions. A set of leading questions was prepared based on this principle for the panel and used to guide an open discussion (Appendix II).

2.7.2 Speciality Focus Group

A randomised purposive sampling strategy was applied to a list provided by the MDH administration to identify participants representing different departments. Wards were listed alphabetically within the various subgroups (according to their speciality) and attributed a unique number. A random number generator was then used to create different random numbers falling within the range of the speciality areas. These numbers matched the respective wards, including the following wards or speciality areas.

Specialities represented included 1) surgical; 2) general medicine; 3) intensive care and 4) operating theatre. This entailed stratifying different wards based on their areas of profession while ensuring that every sub-group/category is properly represented. This diversification allows the possibility to maximise the exploration of different perspectives and attitudes across diverse departments, acknowledging the possibility of acquiring the widest possible overview of the impact on accessibility and availability.

Participants were approached according to previously outlined protocols and exclusion criteria in section 2.7.1. and four separate focus groups were held. An electronic invitation and an information sheet (Appendix I) were sent to different healthcare professionals of each speciality to act as representatives. Thus, allowing the consideration of a wide array of diverse experiences, resulting in the broadest possible overview impact concerning accessibility across different speciality groups.

The respective healthcare professionals confirmed their availability and attendance to participate in a separate focus group per speciality. A case-study approach was utilised, to discuss and observe the impact of the recent experiences: expected (Brexit) and unforeseen (COVID-19) situations on medication availability within their speciality area.

During the separate focus groups, a similar approach outlined in section 2.7 was employed with the different questions (Appendix II) prepared to guide the moderator in maintaining and prompting an open discussion.

2.8 Data Analysis

The data analysis consisted of quantitative analysis (Section 2.6.1) and qualitative analysis (Section 2.7). To identify the most requested medication from the Outpatient pharmacy and the barriers encountered in ensuring treatment accessibility.

2.8.1 Quantitative analysis

The data collected was filtered and divided according to different dosage forms (e.g. tablets, powder, etc). Compiled data was inputted in IBM SPSS®, and the Shapiro-Wilk test was carried out on all the sample data. The Shapiro-Wilk test was utilised to determine whether a score distribution is normal or skewed (non-normal). The null hypothesis specifies that the score distribution is normal and is accepted if the p-value exceeds the 0.05 level of significance. The alternative hypothesis specifies that the score distribution is skewed and is accepted if the p-value is less than the 0.05 criterion.

The Spearman correlation test (ρ) (non-parametric) was then used to investigate whether the relationship between two non-normally distributed variables is significant. The null

hypothesis specifies no relationship between the two variables and is accepted if the p-value exceeds the 0.05 significance level. The alternative hypothesis specifies a significant relationship between the two variables and is accepted if the p-value is less than the 0.05 criterion.

The Pearson Correlation coefficient (r) was used to investigate the relationship between normally distributed data. The null hypothesis is defined by the aspect of no relationship between the two variables and is accepted if the p-value exceeds the 0.05 significance level. The alternative hypothesis specifies a significant relationship between the two variables and is accepted if the p-value is less than the 0.05 criterion.

The Spearman and the Pearson correlation coefficients measure the strength of the relationship between the two continuous variables expressed in value within the range -1 and 1. A positive correlation coefficient indicates a positive relationship between the two variables, while a negative correlation coefficient indicates a negative relationship. The Spearman (non-parametric) and the Pearson (parametric) are used to investigate whether the relationship between the two relationship is significant or not. Both null hypotheses specify no relationship between the two variables and are accepted if the p-value exceeds the 0.05 significance level. The alternative hypothesis specifies a significant relationship between the two variables and is accepted if the p-value is less than the 0.05 criterion.

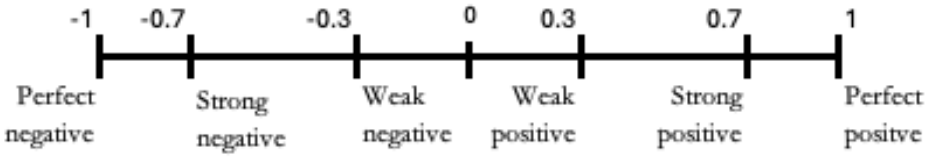

Figure 2.2: Values and labels of the correlation coefficients

2.8.2 Qualitative Data

Transcribed qualitative data collected throughout the focus groups were analysed according to Attride-Stirling's thematic analysis. Empirical data was broken down and systemised into different themes, to create an overview of the most important subjects within the data set. This thematic analysis contains six steps: 1) coding of material, 2) identification of themes, 3) construction of thematic networks, 4) description and exploration of the thematic networks, 5) summary of the thematic networks and 6) interpretation of patterns.

This thematic network is created based on a list of codes derived from the data, which are then grouped to represent common and significant subjects to define the basic themes. The connection and correlation of the basic themes were then used to define the organised themes leading to the characterisation of the global themes. Thematic network was described based on these principles and relevant quotes were derived, allowing the identification of patterns which could then be interpreted and discussed.

2.9 Development of the accessibility evidenced-based framework

Personal experience gathered through active involvement and observation was gained while working at the Dispensary Section within the MDH Pharmacy Section. Providing the possibility to acquire first-hand experience regarding medicine accessibility issues and how they are mitigated at the dispensing level. Either through clinical research for a suitable available alternative or a different clinical procedure suggestion utilising a patient-specific approach. This has led to the design of an innovative evidence-based process framework based on feedback from current practices to improve accessibility and availability issues.

Chapter 3

Results

3.1 Overview

The results were split into two stages:

I. Retrospective analysis of queries related to medicine sales from MDH pharmacy setting. The outcome outlined the most widely requested or prescribed medications which are not easily accessible within community pharmacies.

II. Thematic analysis through focus group sessions to identify treatment barriers experienced within different settings associated with accessibility and availability issues within MDH.

Scientific framework aiding different departments and personnel in resolving accessibility issues, based on results from the analysis.

3.2 Results of Retrospective Sale Analysis

The Hospital GFL consists of one thousand three hundred twenty-nine (1329) medications of which 62% (N=824) of preparations are sold to private clients due to public health needs. Data was adjusted and grouped according to dosage formulation characteristics, to examine and determine accessibility issues encountered by Maltese patients. Aiming to define and identify medication requests which have been increasing, aiding in the inclusion of the medication from within community pharmacies.

3.2.1 Categorisation of Outpatient Sales

Different types of sales were categorised per medicinal product and dosage form, with 824 items sold, compiled monthly. This resulted in fifteen (15) different categories of dosage formulations/properties:

- Tablets (n=404, 49.0%)
- Injections (n=155, 18.8 %)
- Syrups (n=63, 7.6%)
- Narcotics (n=39, 4.7%)
- Creams (n=37, 4.5%)
- Ophthalmic (n=35, 4.2%)
- Rectal (n=22, 2.7 %)
- Powders and Sachets (n= 20, 2.4 %)
- Pulmonary (n=16, 1.9%)
- Vaccines (n= 10, 1.2 %)
- Extemporaneous Preparations (n=7, 0.8 %)
- Feeds (n=6, 0.7%)
- Spray (n=6, 0.7%)
- Depot injections (n=2, 0.2%)
- Patches (n=2, 0.2%)

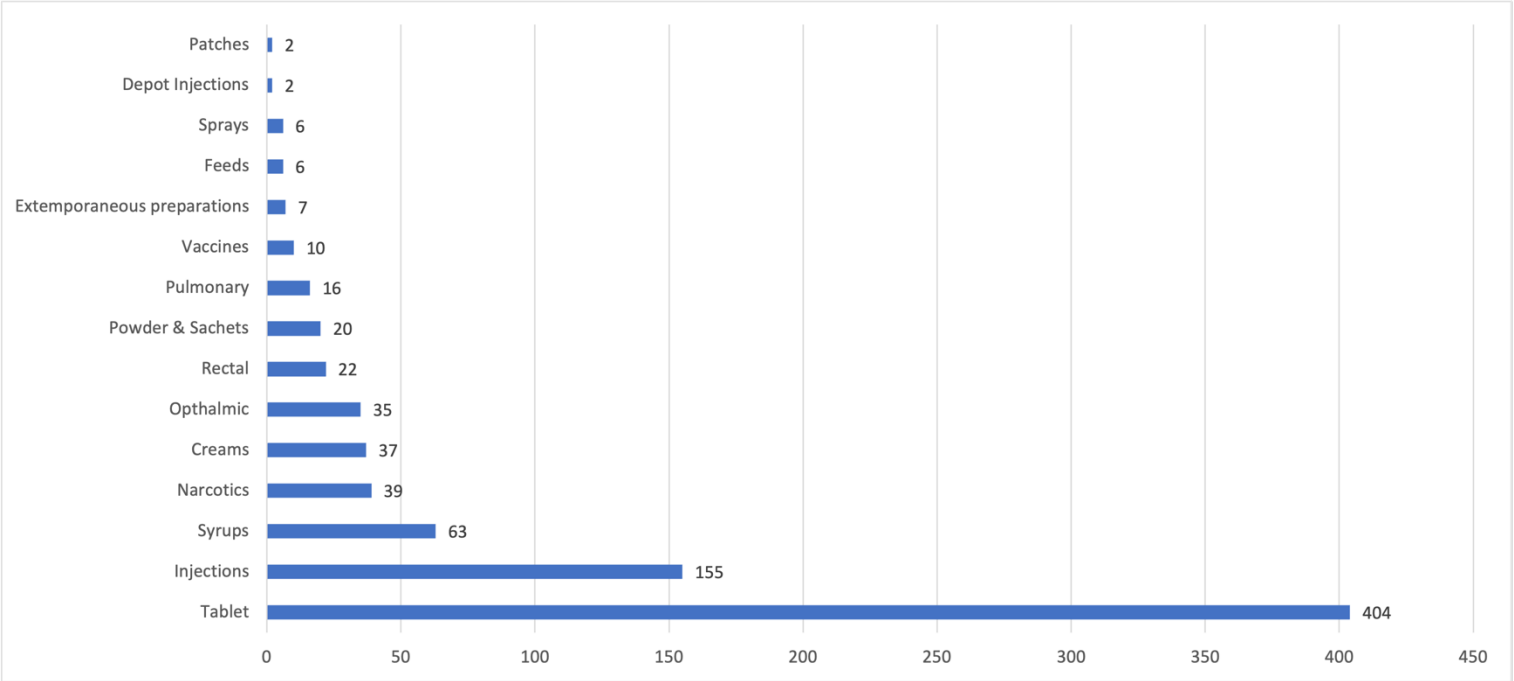

Figure 3.1: Categorisation of sales by dosage formulation (N=824)

3.2.2 Trend Analysis in Sales

Retrospective analysis of dispensing history allowed for identifying trends over the 120 months (December 2013 till November 2023) and examining accessibility challenges or missed treatment opportunities within the community. Most of the medication sold consisted of oral formulations, principally tablets or capsules (49%), covering four hundred and four (n=404) different medications. Notably, the subsequent most requested medications were injectable drugs (n= 155, 18.65%) and syrup (n=63, 7.6%) preparations.

Compiled results include the sale of extemporaneous medications. Formulated primarily to facilitate administration, into dispersible sachets (clobazam sachets) or oral suspensions (phenobarbitone solution).

The large period of data collected allowed for observing the context of medication sales. Highlighting, the varying quantity of sales significantly across medicinal preparations.

Representing quantity sold against months into individual line charts per each medication (N=824), enabled the illustration of sales trends. Allowing the possibility to identify constant, sporadic or declining trends. noting low quantity sales of co-amoxiclav 375mg, diclofenac 25mg, metoclopramide 10mg, paracetamol 120mg/5ml suspension, omeprazole 20mg, valsartan 80mg, simvastatin 40mg, salbutamol 100mcg inhaler and codeine phosphate 30mg. Other observed trends included the exponential increase in sales followed by a sudden decline, as seen with levothyroxine 100mcg, enalapril 5mg, and enalapril 20mg.

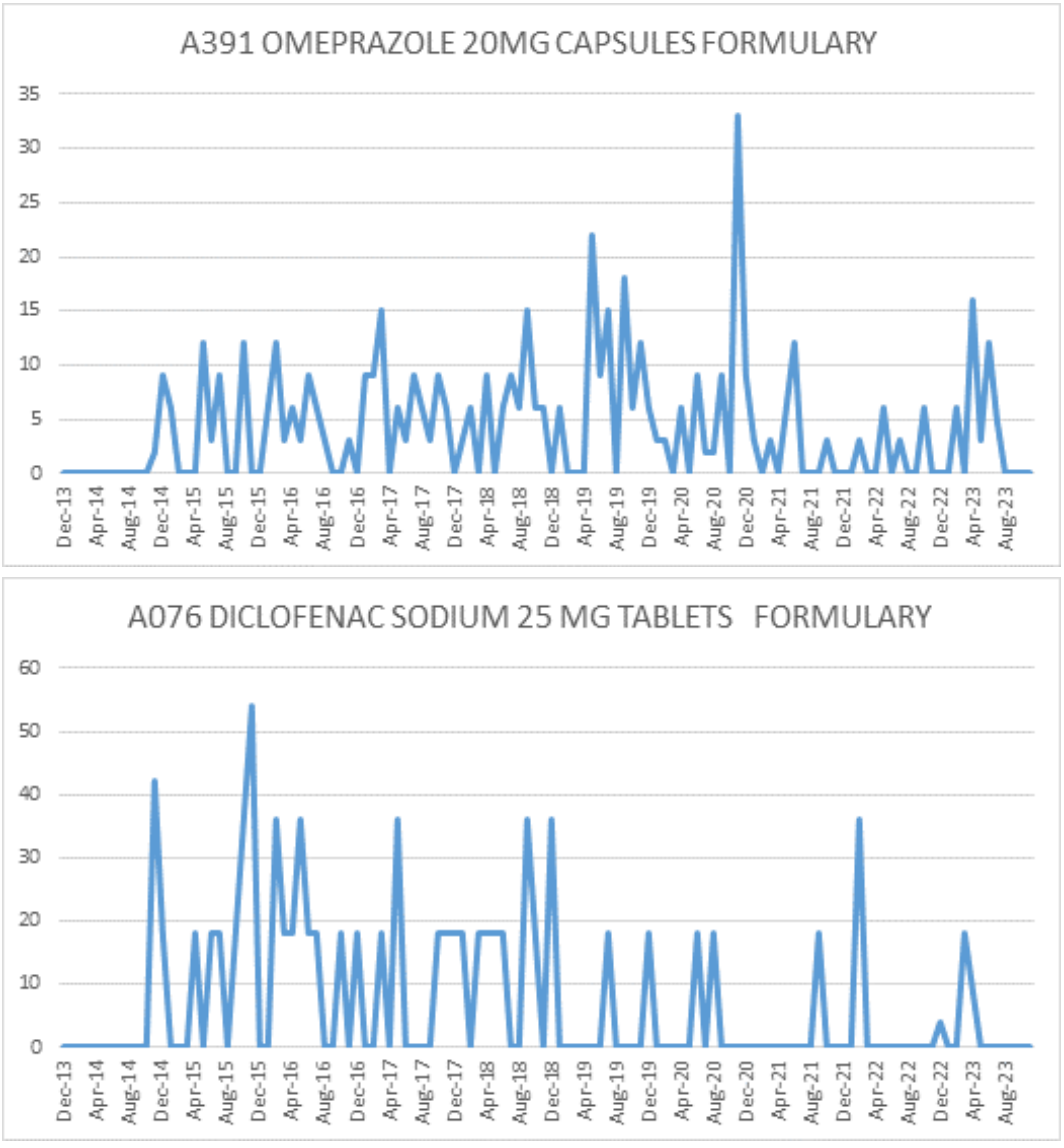

Figure 3.2: Constant low sale trends of medications sold from MDH

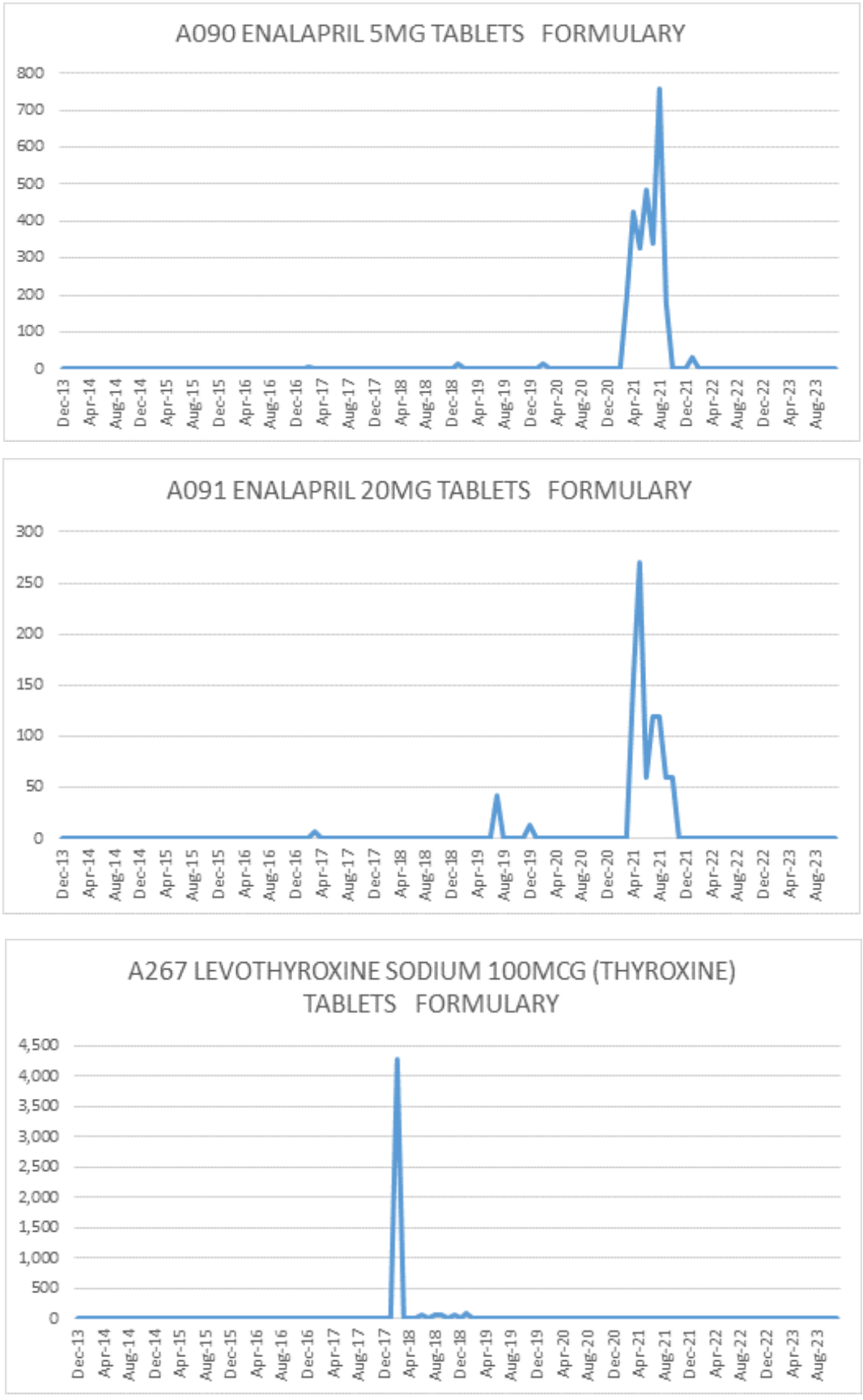

Figure 3.3: Sporadic exponential sale trends of medications sold from MDH

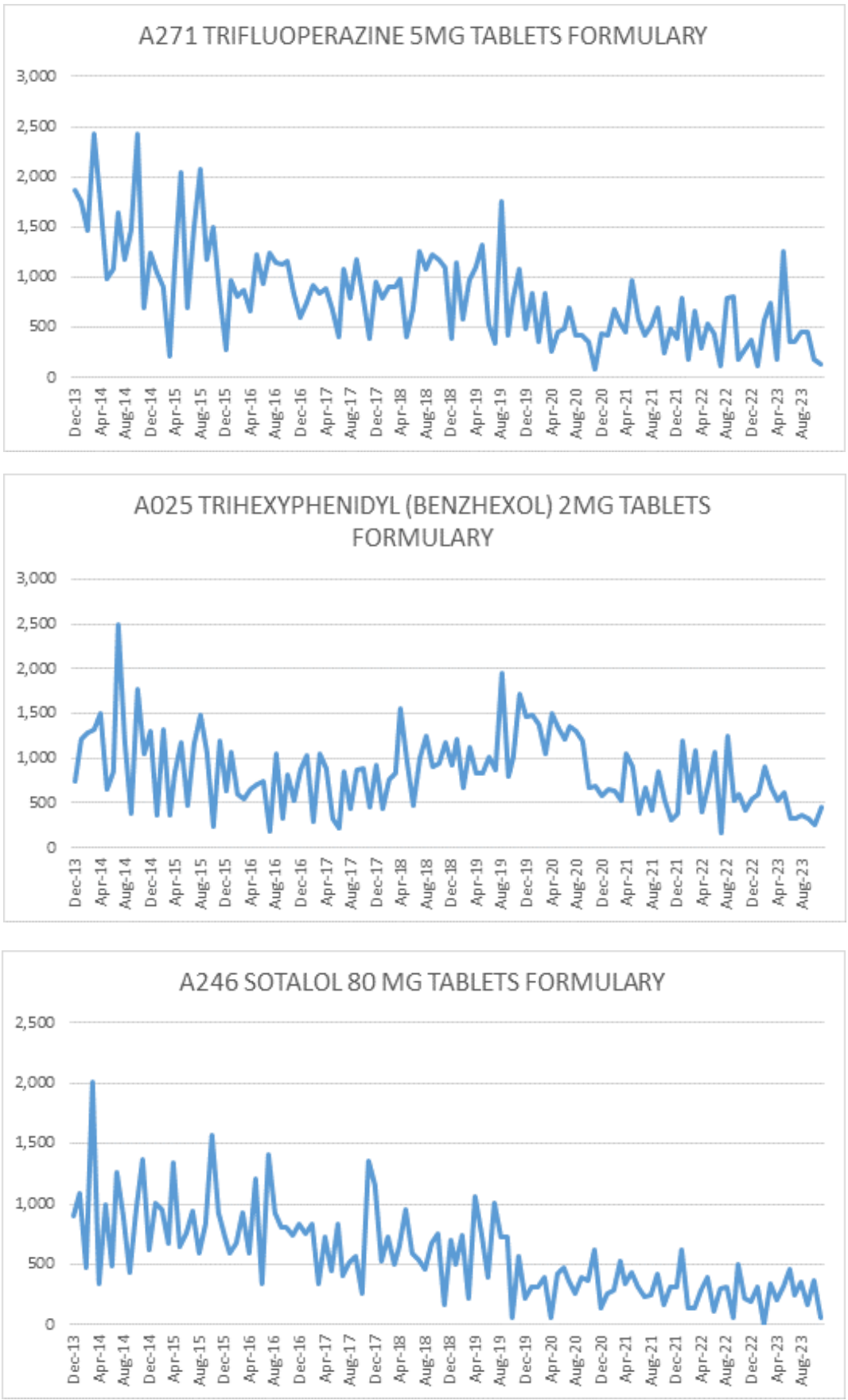

Figure 3.4: Declining sale trends of medications sold from MDH

3.3 Phase 1: Retrospective Analysis

Shapiro-Wilk analysis was carried out on the sample data to determine the normality of the data set. Only six medications (Table 3.1) exhibited a p-value greater than 0.05, thus the inferential statistic Pearson Correlation Coefficient (*r*) was utilised to define the significance of the relationship between the two variables.

As Spearman and Pearson's statistical tests measure the strength of a monotonic relationship, a value of 0 in a quadratic relationship would incorrectly reflect no relationship between the variables. Consequently, the graphical data generated allowed the possibility to rule out this occurrence from the data collected.

Table 3.1 All results p = > 0.05 for the Shapiro-Wilk test and corresponding Pearson correlation coefficient.

	Shapiro-Wilk Sig.	Pearson Correlation Coefficient (*r*)	Sig (2-tailed)
Acetazolamide 250mg tablets	0.173	.697	<.001
Propranolol 10mg tablets	0.442	.693	<.001
Propranolol 40mg tablets	0.344	-0.068	0.461
Propylthiouracil 50mg tablets	0.13	0.084	0.360
Quinine 200mg & 300mg tablets	0.06	-.643	<.001
Sulfasalazine 500mg tablets	0.17	0.011	0.904

Table 3.1 shows a Significant (2-tailed) ≤ 0.05 criterion (in green), for acetazolamide 250mg, propranolol 10mg and quinine 200mg & 300mg indicating a significant relationship between quantity sold and time. A Pearson Correlation coefficient of 0.697 (Acetazolamide 250mg) and 0.693 (propranolol 10mg) indicate a strong and positive linear relationship between the two variables (time and quantity sold). While the Pearson Correlation coefficient of -0.643 (quinine 200mg & 300mg) describes a strong and negative relationship between the two variables.

The majority (n=818, 99.3%) of analysed data had a p-value less than 0.05, indicating a skewed distribution. Consequently, the non-parametric Spearman Correlation coefficient (ρ) was utilised to assess the correlation between the variables.

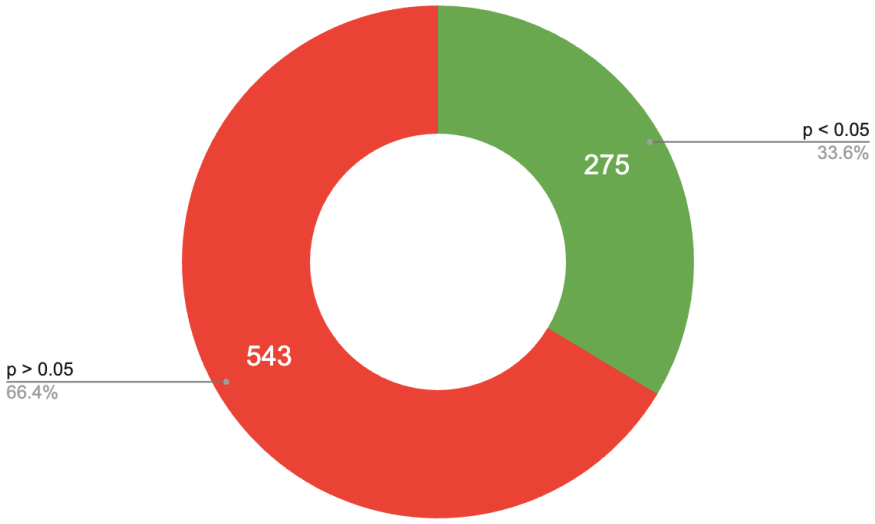

Figure 3.5: Categorisation of statistical significance (n=818)

Figure 3.2 shows that only 33.6% (n=275) of the medicinal products show a significant relationship between the two variables, indicated by a Spearman Correlation p-value of less than 0.05. Many statistically significant relationships were observed within the tablet and capsule formulation (n=106), followed by syrups (n=27) and injections (n=25) (Figure 3.3).

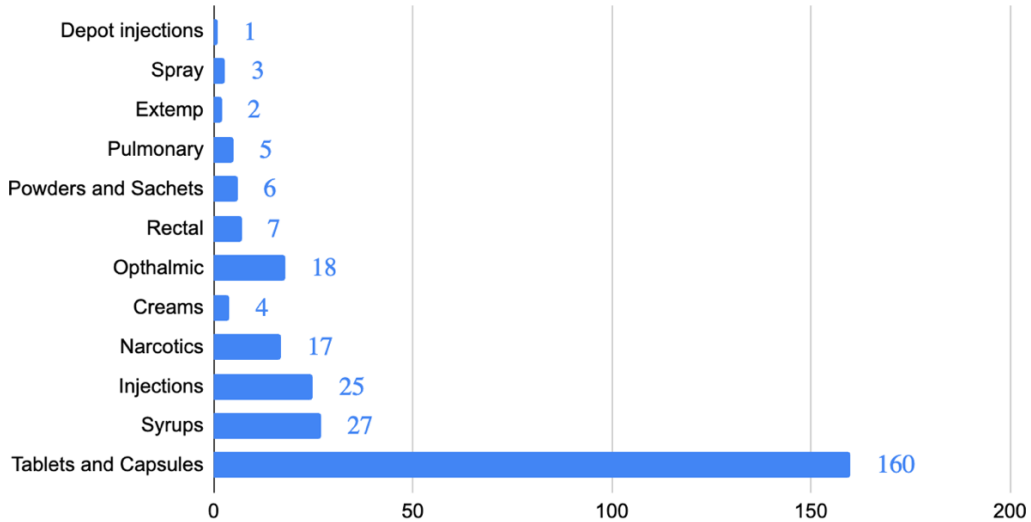

Figure 3.6: Categorisation by dosage formulations of statistically significant relationships (n=275)

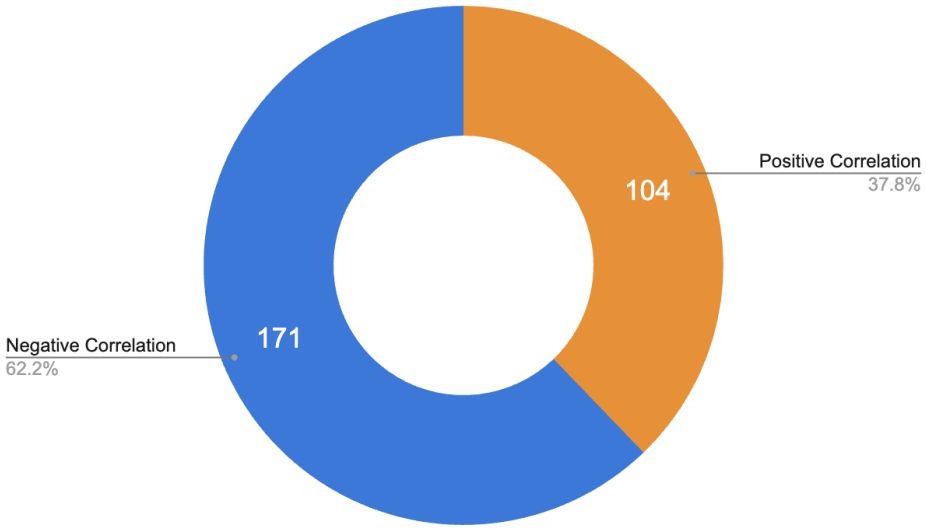

Figure 3.7: Statistically significant Positive (n=104) and Negative (n=171) Spearman Correlation Coefficients

Figure 3.4 displays the prevalence of statistically significant negative correlation coefficients. Figure 3.5 showcases the different demographic characteristics relating to positive and negative correlation, again tablets and capsules present the largest faction in both correlations.

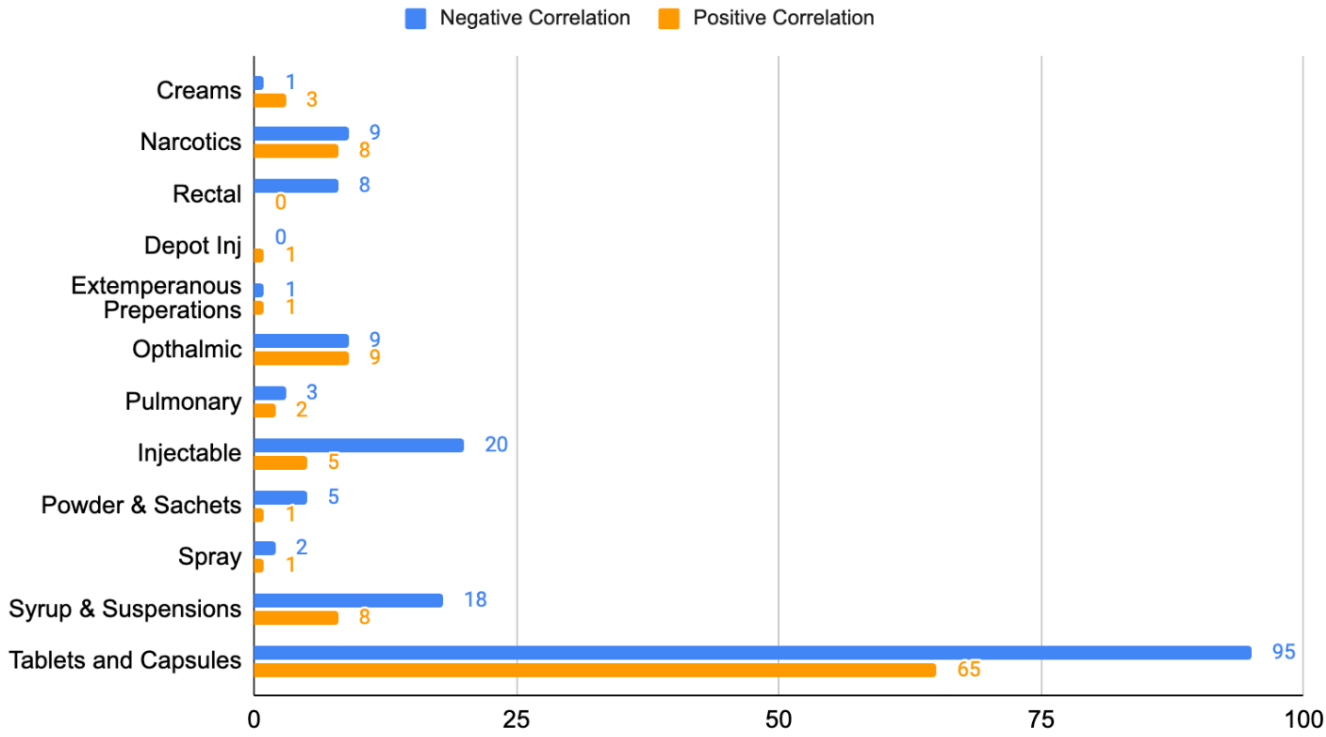

Figure 3.8: Demographic data of Statistically Positive (n=104) and Negative (n=171) Spearman Correlation Coefficient

3.3.1 Spearman Positive Correlation Coefficient

Spearman's correlation analysis did not identify any medicinal products with a correlation coefficient (ρ) ≥ 0.8, indicating the absence of strong perfect positive correlations.

Table 3.2 and Table 3.3 statistically significant (Sig. (2-tailed) < 0.05) indicate correlations across different dosage formulations are reported below in descending order of strength.

Taking into consideration the high ρ values (>0.6) of potassium bicarbonate and chloride effervescent tablets, phenobarbital sodium 30mg tablets, cyclizine 50mg tablets, labetalol 200mg tablets, nifedipine 10mg modified release tablets, pentoxifylline 400mg tablets, repackaged iron preparation syrup and metoprolol 100mg tablets.

Table 3.3 shows all statistically significant (Sig. (2-tailed) < 0.05) medicinal products (n=75) with ρ values between 0 and 0.4 in descending order, indicating a weak to no relationship. No medicinal product exhibited a ρ value of 0, as such no medication had a completely neutral correlation.

Table 3.2: Strong to moderate positive correlation results of quantity of sales against duration (n=29) (0.8 > ρ ≥ 0.4)

	Shapiro-Wilk Sig.	Spearman Correlation Coefficient (ρ)	Sig (2-tailed)
potassium bicarbonate and chloride effervescent tablets	<.001	0.771	<.001
phenobarbital sodium 30mg tablets	<.001	0.739	<.001
cyclizine 50mg tablets	<.001	0.734	<.001
labetalol 200mg tablets	0.023	0.722	<.001
nifedipine 10mg mr tabs	<.001	0.658	<.001
pentoxifylline 400mg tablets	<.001	0.621	<.001
repackaged iron preparation syrup x100ml	<.001	0.610	<.001
metoprolol 100mg tablets	<.001	0.600	<.001
pancreatin 10000 capsules creon	<.001	0.584	<.001
folic acid 2.5mg/5ml solution	<.001	0.563	<.001
mycophenolate mofetil 500mg tablets	<.001	0.555	<.001
rifampicin / isoniazid 300/150mg tablets	<.001	0.536	<.001
acitretin 10mg capsules	<.001	0.533	<.001
pethidine hcl 100mg/2ml injections	<.001	0.519	<.001
levetiracetam syrup 100mg/ml	<.001	0.509	<.001
ursodeoxycholic acid 250mg caps	<.001	0.488	<.001
pilocarpine 2% drops	<.001	0.484	<.001
ispaghula husk	<.001	0.473	<.001
somatropin 5.3mg cartridges genotropin®	<.001	0.47	<.001
erythromycin ethyl succ 200-250mg/5ml suspension	<.001	0.467	<.001
hydrocortisone 10mg tablets	<.001	0.466	<.001
calcipotriol & betamethasone ointment	<.001	0.461	<.001
mesalazine 400mg tabs	<.001	0.457	<.001
indometacin 25mg tablets	<.001	0.441	<.001
Entacapone & co-careldopa tablets	<.001	0.433	<.001
isosorbide mononitrate sr 60mg tablets	<.001	0.426	<.001
ivermectine 3mg tablets	<.001	0.42	<.001
theophylline 200mg uniphyllin prolonged release	<.001	0.403	<.001
gentamycin 0.3% eye ear drops	<.001	0.4	<.001

Table 3.3: Weak positive correlation results of quantity of sales against duration (n=75) (0.4 > ρ > 0)

	Shapiro-Wilk Sig.	Spearman Correlation Coefficient (ρ)	Sig (2-tailed)
betamethasone 0.025% ointment	<.001	0.396	<.001
moxifloxacin 400mg tablets	<.001	0.39	<.001
theophylline 200mg sr tablets	<.001	0.387	<.001
cyproterone acetate 50mg tablets	<.001	0.385	<.001
rifampicin & isoniazid 150/100mg tablets	<.001	0.379	<.001
pilocarpine 2% drops (box by 2)	<.001	0.366	<.001
aspirin 300mg eff. tablets	<.001	0.363	<.001
metolazone 5mg tablets	<.001	0.356	<.001
oxybutynin 5mg tablets	<.001	0.353	<.001
ropinerole 5mg tablets	<.001	0.35	<.001
brimonidine 0.2% eye drops	<.001	0.344	<.001
pyridostigmine bromide 60mg tablets	<.001	0.339	<.001
isoniazid 100mg tablets	<.001	0.332	<.001
fluorouracil 5% cream	<.001	0.328	<.001
acetylcysteine 5% eye drops	<.001	0.323	<.001
atropine 1% eye drops single dose unit	<.001	0.317	<.001
magnesium glycerophosphate 97.2mg tablets	<.001	0.312	0.001
conjugated oestrogens 0.625mg tablets	<.001	0.311	0.001
cabergoline 0.5mg tablets	<.001	0.306	0.001
ferrous sulphate (providing iron 65mg-70mg)	<.001	0.291	0.001
ibuprofen 100mg/5ml syrup	<.001	0.289	0.001
tacrolimus 0.5mg capsules	<.001	0.289	0.001
norfloxacin 400mg tablets	<.001	0.285	0.002
phosphate supplement eff. tablets	<.001	0.285	0.002
gabapentin 100mg tablets	<.001	0.284	0.002
albendazole 400mg tablets	<.001	0.281	0.002

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hydrocortisone 20mg tablets	<.001	0.28	0.002
nimodipine 30mg tablets	<.001	0.278	0.002
tamoxifen 20mg tablets	<.001	0.271	0.003
fentanyl 50mcg/hour transdermal patch	<.001	0.27	0.003
prednisolone 5mg tablets	<.001	0.269	0.003
ursodeoxycholic acid 150mg capsules	<.001	0.266	0.003
ceftriaxone 2g iv injection	<.001	0.265	0.003
budesonide enteric coated tablets 3mg	<.001	0.26	0.004
Co-amoxiclav 625mg tablets	<.001	0.257	0.005
erythromycin 125mg 5ml suspension	<.001	0.254	0.005
vancomycin 500mg injections	<.001	0.253	0.005
atorvastatin 40mg tablets	<.001	0.251	0.006
medroxyprogesterone 100mg tablets	<.001	0.251	0.006
fentanyl 25mcg/hour transdermal patch	<.001	0.249	0.006
benzathine penicillin 1.2million units injection	<.001	0.248	0.006
bromazepam 3mg tablets	<.001	0.245	0.007
pilocarpine 1% drops	<.001	0.244	0.007
carvedilol 6.25mg scored tablets	<.001	0.244	0.007
verapamil 40mg tablets	0.048	0.244	0.007
pilocarpine 4% drops	<.001	0.241	0.008
ciprofloxacin 250mg/5ml suspension	<.001	0.233	0.011
zuclopentixol 25mg tablets	<.001	0.229	0.012
leflunomide 10mg tablets	<.001	0.227	0.013
liothyronine 25mcg tablets	0.036	0.227	0.012
nevirapine 200mg tablets	<.001	0.224	0.014
atomoxetine 18mg capsules	<.001	0.222	0.015
pethidine hcl 50mg ml injections	<.001	0.221	0.015
rifaximin 200mg tablets	<.001	0.22	0.016
leflunomide 20mg tablets	<.001	0.219	0.016
nitazoxanide 500mg tabs	<.001	0.218	0.017
pyridoxine 10mg tablets	<.001	0.217	0.017
lisinopril 10mg tablets	<.001	0.216	0.018

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diazepam rectal solution 5mg	<.001	0.214	0.019
beclometasone 50mcg nasal spray	<.001	0.214	0.019
beclometasone 250mcg inhaler	<.001	0.212	0.020
haloperidol 2mg/ml syrup 30ml	<.001	0.208	0.023
goserelin depot 3.6mg injection	<.001	0.207	0.023
risperidone 25mg im vial	<.001	0.203	0.026
repaglinide 0.5mg tablets	<.001	0.203	0.026
flucloxacillin 125mg/5ml suspension	<.001	0.199	0.029
enalapril 20mg tablets	<.001	0.196	0.032
nifedipine s.r. 20mg tablets	<.001	0.194	0.034
morphine 30mg/ml injections	<.001	0.188	0.040
fluticasone 50mcg inhaler	<.001	0.185	0.044
phenytoin 100mg capsules	<.001	0.185	0.043
methyldopa 250mg tablets	0.04	0.182	0.046
vancomycin 125mg tablets	<.001	0.182	0.047
chloramphenicol 0.5% drops x 10mls	<.001	0.181	0.048
tacrolimus 1mg capsules (adoport)	<.001	0.180	0.049

Table 3.4 lists statistically significant (Sig. (2-tailed) < 0.05) medicinal products (n=124) with weak negative correlations (ρ values between 0 and -0.4) in descending order. Indicating that most medicinal products (n=121) exhibit a weak negative correlation between the variables.

Table 3.4: Weak negative correlation results of quantity of sales against duration (n=121) (0 > ρ ≥ −0.4)

	Shapiro-Wilk Sig.	Spearman Correlation Coefficient (ρ)	Sig (2-tailed)
metronidazole 500mg supps	<.001	-0.18	0.049
Co-careldopa 110mg tablets carbidopa and levodopa	<.001	-0.181	0.048
topiramate 25mg tablets	<.001	-0.182	0.047
warfarin 3mg tablets	<.001	-0.182	0.047

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demeclocycline 300mg capsules	<.001	-0.183	0.046
atenolol 25mg tablets	<.001	-0.184	0.044
thiamine 50mg tablets	<.001	-0.184	0.044
salbutamol 4mg tablets	<.001	-0.185	0.043
estradiol valerate 2mg / norgestrel 0.5mg tabs	<.001	-0.188	0.04
simvastatin 40mg tablets	<.001	-0.189	0.038
isophane insulin cartridge gensulin N	<.001	-0.191	0.037
mesalazine 500mg supps	<.001	-0.191	0.037
phosphate enema	<.001	-0.191	0.037
dexamethasone 0.1% drops	<.001	-0.192	0.036
triamcinolone 40mg ml injections	<.001	-0.192	0.036
olanzapine 5 mg tablets	<.001	-0.192	0.036
fusidic acid 1% eye drops	<.001	-0.194	0.034
somatropin 6mg cartridges	<.001	-0.195	0.033
betamethasone / salycylic acid cream	<.001	-0.196	0.032
fluphenazine 25mg injection	<.001	-0.196	0.032
bumetanide 1mg tablets	<.001	-0.196	0.032
bupivacaine 0.5% 10mls injection	<.001	-0.197	0.031
bromocriptine 2.5 mg tablets	<.001	-0.197	0.031
tetrabenazine 25mg tablets	<.001	-0.197	0.031
sodium citrate 0.3m in 30ml oral solution	<.001	-0.199	0.029
metformin 500mg tablets	<.001	-0.199	0.029
amikacin 500mg injection	<.001	-0.201	0.028
flupentixol decanoate 100mg ml injection	<.001	-0.201	0.028
pethidine 50mg tablets	<.001	-0.203	0.026
chlorpromazine 50mg 2ml injection	<.001	-0.204	0.026
oxybupirocaine 0.4% single dose units	<.001	-0.207	0.023
Co-amoxiclav 600mg injection	<.001	-0.207	0.024
prednisolone 20mg/100ml enema	<.001	-0.207	0.023
furosemide 1mg/ml syrup	<.001	-0.207	0.023
gentamycin & hydrocortisone drops	<.001	-0.209	0.022

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enoxaparin 4000iu injection (inhixa ®)	<.001	-0.209	0.022
bromhexine 8mg/10ml syrup	<.001	-0.211	0.021
lamotrigine 5mg dispersable tablets	<.001	-0.211	0.021
flucloxacillin 250mg capsules	<.001	-0.214	0.019
metronidazole 200mg tablets	<.001	-0.214	0.019
calcitonin 100iu ml in 1 ml injection	<.001	-0.217	0.018
trimipramine 50mg tablets	<.001	-0.218	0.017
amoxicillin sachets 3g	<.001	-0.22	0.016
sulphasalazine 250mg/5ml suspension	<.001	-0.222	0.015
simvastatin 20mg tablets	<.001	-0.222	0.015
mianserin 10mg tablets	<.001	-0.223	0.014
bowel cleansing preperation picolax	<.001	-0.224	0.014
levetiracetam 500mg tablets	<.001	-0.224	0.014
domperidone 30mg supps	<.001	-0.225	0.013
epoetin 3000 iu prefilled iv sc	<.001	-0.227	0.013
isosorbide dinitrate 10mg tablets	<.001	-0.23	0.011
misoprostol 200mcg tablets	<.001	-0.232	0.011
xylomethazoline 0.05 paed	<.001	-0.234	0.010
diclofenac sodium 25 mg tablets	<.001	-0.234	0.010
metoclopramide 10mg/2mls injection	<.001	-0.235	0.010
hydralazine 25mg tablets	<.001	-0.241	0.008
clonazepam 0.5mg tablets	<.001	-0.243	0.007
chloramphenicol 1% ointment	<.001	-0.243	0.008
chloroquine phosphate 250mg tablets	<.001	-0.243	0.008
morphine sulphate 30mg sr tablets	<.001	-0.25	0.006
ciprofloxacin 250mg tablets	<.001	-0.25	0.006
naltrexone 50mg tablets	0.002	-0.255	0.005
haloperidol 2mg/ml syrup 100ml	<.001	-0.256	0.005
fluconazole 50mg/5ml suspension	<.001	-0.258	0.004
co beneldopa 62.5mg tablets	<.001	-0.26	0.004
lenalidomide 15mg tabs	<.001	-0.261	0.004
trihexyphenidyl (benzhexol) 2mg tablets	0.001	-0.262	0.004

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rifampicin 100mg/5ml syrup	<.001	-0.263	0.004
oxybutynin 2.5mg/5ml syrup	<.001	-0.264	0.004
tetracycline 250mg tablets	<.001	-0.266	0.003
terbutaline sulphate 0.5mg turbohaler	<.001	-0.268	0.003
paracetamol 10mg/ml x 100mls i.v	<.001	-0.268	0.003
calcium eff. 400mg-500mg tablets	<.001	-0.269	0.003
dorzolamide & brinzolamide eye drops	<.001	-0.27	0.003
bezafibrate 400mg tablets	<.001	-0.272	0.003
flupenthixol decanoate 20mg/ml injection	<.001	-0.274	0.002
trimethoprim 100mg tablets	<.001	-0.276	0.002
atenolol 100 mg tablets	<.001	-0.278	0.002
complete nutritional preparation 500ml	<.001	-0.279	0.002
clarithromycin 250mg tablets	<.001	-0.28	0.002
desmopressin 0.1mg tablets	<.001	-0.281	0.002
sodium fusidate 250mg tablets	<.001	-0.281	0.002
azathioprine 50 mg tablets	<.001	-0.282	0.002
bromazepam 1.5mg tablets	<.001	-0.286	0.002
lopinavir 200mg + ritonavir 50mg tablets	<.001	-0.287	0.001
glyceryl trinitrate 500mcg tablets	<.001	-0.289	0.001
phenoxybenzamine 10mg capsules	<.001	-0.289	0.001
mianserin 30mg tablets	<.001	-0.291	0.001
sulpiride 50mg tablets	<.001	-0.291	0.001
glucagon 1mg injection	<.001	-0.292	0.001
fenofibrate 67mg tablets	<.001	-0.296	0.001
levobunolol minims	<.001	-0.297	0.001
cefuroxime 750mg injection	<.001	-0.297	0.001
atropine 600 mcg tablets	<.001	-0.307	0.001
carbamazepine 400mg s.r. tablets	<.001	-0.32	<.001
framycetin & dexamethasone & gramicidin drops	<.001	-0.322	<.001
flavoxate 200mg tablet	<.001	-0.324	<.001

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morphine sulphate 10mg sr tablets	<.001	-0.326	<.001
co beneldopa 250mg tablets	<.001	-0.328	<.001
mycophenolic acid e.c. 360mg tablets	<.001	-0.328	<.001
paracetamol 500mg tablets	<.001	-0.332	<.001
ferrous gluconate 300mg tablets	<.001	-0.335	<.001
selegiline 5mg tablets	<.001	-0.336	<.001
baclofen 5mg/5ml solution	<.001	-0.339	<.001
extemp ready made lugol s iodine x 20ml	<.001	-0.34	<.001
carvedilol 6.25mg tablets	<.001	-0.341	<.001
desmopressin 100mcg/ml nasal solution	<.001	-0.347	<.001
desmopressin 100mcg nasal solution	<.001	-0.347	<.001
maprotiline 25mg tablets	<.001	-0.355	<.001
clarithromycin 125mg/5ml suspension	<.001	-0.356	<.001
cyclophosphamide 50 mg tablets	<.001	-0.36	<.001
cyproheptadine 4 mg tablets	<.001	-0.36	<.001
demeclocycline 150mg capsules	<.001	-0.362	<.001
calcium resonium powder	<.001	-0.37	<.001
indometacin 100mg supps	<.001	-0.376	<.001
lamivudine 150mg + zidovudine 300mg tablets	<.001	-0.376	<.001
sulpiride 40mg/ml syrup	<.001	-0.378	<.001
co-amoxiclav 156mg/5ml suspension	<.001	-0.384	<.001
iron preparation syrup	<.001	-0.385	<.001
liothyronine 20mcg tablets	<.001	-0.391	<.001
amoxicillin 250mg capsules	<.001	-0.397	<.001

Table 3.5 presents statistically significant medicinal products (n=48) with moderate negative correlations (ρ values between -0.4 and -0.8) in descending order. Table 3.5 also includes medications with negative to strong correlations, such as prazosin 1mg, sotalol 80mg, medroxyprogesterone 150mg/ml, ranitidine syrup, colchicine 500mcg, metoprolol 50mg, and hydroxocobalamin 1mg injection.

Table 3.5: Moderate negative correlation results of quantity of sales against duration (n=48) (-0 .4 > ρ ≥ −0.8)

	Shapiro-Wilk Sig.	Spearman Correlation Coefficient (ρ)	Sig (2-tailed)
loperamide 1mg/5ml liquid	<.001	-0.403	<.001
clindamycin 150mg tablets	<.001	-0.404	<.001
trifluoperazine 1mg tablets	<.001	-0.406	<.001
digoxin 0.05mg/ml elixir	<.001	-0.410	<.001
orphenadrine 50mg tablets	<.001	-0.412	<.001
cyclizine 50mg injections	<.001	-0.423	<.001
chloramphenicol 0.5% drops	<.001	-0.424	<.001
Co-amoxiclav 375mg tablets	<.001	-0.428	<.001
high protein 90% powder x 225g	<.001	-0.432	<.001
dapsone 50 mg tablets	<.001	-0.435	<.001
disulfiram 200mg tablets	<.001	-0.439	<.001
trimipramine 25mg tablets	<.001	-0.443	<.001
mesalazine 500mg tabs (pentasa ®)	<.001	-0.448	<.001
furosemide 40mg / amiloride 5mg tablets	<.001	-0.452	<.001
budesonide nebul.sol 0.5mg/ml	<.001	-0.454	<.001
ondansetron 4mg tablets	<.001	-0.465	<.001
hydrocortisone 5mg tablets	<.001	-0.471	<.001
domperidone 1mg/ml suspension	<.001	-0.478	<.001
medroxyprogesterone 5mg tablets	<.001	-0.495	<.001
amylobarbitone 50mg & quinalbarbitone 50mg tabs	<.001	-0.496	<.001
fludrocortisone 0.1mg tablets	<.001	-0.502	<.001
hydrocortisone foam enema	<.001	-0.502	<.001
haloperidol 0.5mg tablets	<.001	-0.505	<.001
chlorpromazine 25mg tablets	<.001	-0.507	<.001
prednisolone 1mg tablets	<.001	-0.509	<.001
diltiazem 60mg tablets	<.001	-0.527	<.001
dihydrocodeine tartrate 30mg tablets	<.001	-0.534	<.001
imipramine 25mg tablets	<.001	-0.537	<.001
ondansetron 8mg tablets	<.001	-0.545	<.001
amoxicillin 125mg/5ml suspension	<.001	-0.552	<.001

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dipyridamole 100mg tablets	<.001	-0.553	<.001
haloperidol 1.5mg tablets	<.001	-0.612	<.001
phenoxymethylpenicillin 250mg tablets	<.001	-0.627	<.001
zuclopentixol 2mg tablets	<.001	-0.646	<.001
clonazepam 2mg tablets	<.001	-0.649	<.001
trifluoperazine 5mg tablets	<.001	-0.660	<.001
promethazine 10mg tablets	<.001	-0.665	<.001
dipyridamole 25 mg tablets	<.001	-0.673	<.001
mesalazine 400mg tablets	<.001	-0.673	<.001
promethazine 25mg tablets	<.001	-0.677	<.001
carbamazepine 100mg/5ml syrup	<.001	-0.690	<.001
prazosin 1mg tablets	<.001	-0.708	<.001
sotalol 80 mg tablets	<.001	-0.718	<.001
medroxyprogesterone 150mg/ml prefilled syringe	<.001	-0.752	<.001
ranitidine 75mg/5ml syrup	<.001	-0.760	<.001
colchicine 500 mcg tablets	<.001	-0.782	<.001
metoprolol 50mg tablets	<.001	-0.789	<.001
hydroxycobalamin 1mg injection	<.001	-0.791	<.001

Table 3.6 highlights clozapine 100mg and methylphenidate 10mg as exhibiting the strongest statistically significant negative correlation, indicating a significant decrease in medication sales during the study period. With no medicinal product displaying a perfect negative relationship.

Table 3.6: Strong negative correlation results of quantity of sales against duration (n=2) (-0 .8 > ρ ≥ −1)

	Shapiro-Wilk Sig.	Spearman Correlation Coefficient (ρ)	Sig (2-tailed)
clozapine 100mg tablets	<.001	-0.831	<.001
methylphenidate 10mg tablets	<.001	-0.879	<.001

3.4 Phase 2 - Focus Group

As outlined in Section 2.7, focus groups were held in April and May 2024 with healthcare professionals representing different specialities and lasted one hour. The time limitation was implemented to encourage participation without impacting the working exigencies while maintaining participants' concentration. Twenty-six healthcare professionals participated, including 11 pharmacists, 1 pharmaceutical technologist, 7 nurses, and 6 physicians. Participants are classified according to their focus group speciality representations (Table 3.7)

Table 3.7: Representatives and their different characteristics in the FG

Representatives	Number (N)	Group Characteristics
Group 1: Outpatient pharmacy	9	Outpatient pharmacy setting
Group 2: Surgical	3	Surgical setting
Group 3: Medical	5	Medical setting
Group 4: Intensive care	5	Specialised intensive therapy setting
Group 5: Operating Theatre	4	Operating theatres setting

Based on steps 1-3, outlined in section 2.6.2, established preliminary connection and relationship between basic themes leading to the core of organised themes. Table 3.8 provides a visual example, and Appendix IV summarises the thematic network analysis and focus group extracts.

Table 3.8 Steps 1-3 in the thematic analysis and focus group extract – an example

Code	Basic theme	Organised Theme	Global Theme
stock, procurement, medication availability	Challenges related to medication availability, procurement processes, and stock management issues.	Medication Availability and Procurement	Colloboration across different entities and personnel.

Thematic analysis revealed six major themes: 1) medication availability and accessibility, 2) Communication challenges, 3) inventory management and tracking, 4) regulatory compliance and documentation, 5) personnel allocation and management 6) patient care and treatment delays.

Theme 1: Medication availability and accessibility

All participants agreed upon the constant challenges met with a limited formulary, especially concerning the unpredictability of available medications. The Outpatient Pharmacy participants specifically emphasised the accessibility of certain medications available exclusively from MDH and the difficulties patients encounter in accessing such treatment.

> *"Certain medicines aren't available in the private market such as propranolol, labetalol and acetazolamide."*

> *"Introduce the same concept to all the different pharmacies of the same entity to widen the accessibility of medicines."*

Furthermore, the different specialities experiences revolve around the unpredictability and limited availability of medications. Each speciality strives to find alternatives, either from those available on the GFL or, when possible, purchased through the private sector by the patient's relatives.

"Patients resorted to the private sector to mitigate the shortage of medicines, otherwise the patients would have remained without these tablets."

"Available medicines are limited to the formulary. For a medicine to be available, it has to be available on the formulary and it has to be ordered by the procurement section of the pharmacy."

Theme 2: Communication Challenges

The occurrence of communication challenges across different entities and healthcare professionals affects the accessibility and availability of the appropriate type of care provided.

"The communication is sent once the drugs are no longer available."

"There is no communication between the pharmacy and the nurses/doctors that a medication is Out of Stock."

"Drugs go out of stock and we're not given any indications and if we're given any indication and it would be one of the three hundred emails we get every week, plus communication gets lost."

"An item is declared out of stock at MDH but in CPSU there is stock"

The introduction of an online POYC repository allowed for an instantaneous simplified enrolment application and accessibility to patients' Schedule V permits and current treatments by physicians and pharmacists. Providing an opportunity to facilitate the continuation of care and treatment for the patient between the different entities, being in

the community and or while admitted to the hospital. This aspect can be further explored to include additional communicative aspects across the healthcare providers.

> *"The POCY care online helped tremendously. If there was an online system it would help much better. Even communication - you would speak with the pharmacist of the POYC in lieu of an issue."*

> *"Highlights the need of direct communication between different healthcare professionals within different settings. With a good IT system, you can resolve this issue, both in-patient and in the community. There is traceability and rights of each pharmacist at a different level."*

In addition, several healthcare professionals mentioned issues associated with the constant change of medicine available. Either with the language or particular brand of certain medications, especially associated with strength or formulation.

> *"The language on the boxes of the medications causes an issue."*

> *"However, lately, certain drugs have been coming in foreign languages that have no English language therefore this can be problematic. In a fast-paced environment, conversions to drugs and language barrier enhance medication errors therefore, the patient would be at risk."*

Theme 3: Inventory Management and Tracking

Many healthcare professionals commented on the challenges faced concerning medication management and distribution. Where admitted patients' relatives might not be bringing medications that they regularly collect through their Schedule V and POYC schemes. This gives rise to patients being dispensed the same medication, which might lead to overstocking and wastage once the patient is discharged. Thus, affecting the availability aspect across the entire healthcare system, particularly if the quantity of medication is limited.

> *"Then upon discharge, another inhaler is dispensed and then the patient ends up with multiple inhalers of the same drug."*

> *"Sometimes patients do not have relatives for the meds to be bought so they wouldn't be able to get them."*

> *"Overstocking in wards is a real problem because certain drugs aren't used and left to rot and those who need the drug wouldn't have the access to it."*

Some participants stated that introducing an electronic inventory system might aid in the traceability and management of medications.

> *"We need to have a good, centralised stocking system between the pharmacies and where the medicines are distributed. If the patient stopped taking a drug, you would know the stock take of that drug on that patient, [and] traceability of batch recall. Every pharmacist would have different levels of access on this system where they would know what meds there are and the quantity.*

> *"Electronic centralised systems would benefit greatly"*

Theme 4: Regulatory Compliance and Documentation

Participants across all groups expressed their difficulties and frustrations involving protocol-regulated, off-licence or unlicensed medications, associated prescribing criteria and the restrictive endorsement approval. Particularly the obligatory conditions limiting accessibility if the disorder/symptom is not indicated or listed according to the relevant medication.

> *"There are some medications which can only be prescribed by a diabetologist or cardiologist that also limits the accessibility of meds."*

> *"There is a lot of paperwork that needs to be filled and signatures of particular persons that are not at the ward [and] therefore are more difficult to get a hold of such as protocol regulated, off licence."*

Additionally, participants also recommended that the formulary requires constant monitoring and updating. Acknowledging that ideally, a completely dedicated task force is responsible for the management and continued expansion of the GFL according to the needs across all healthcare environments. Thus, increasing the accessibility and availability of new and contemporary medical treatment.

> *"You need an active formulary that is manned by a task force that is reviewing meds and updating the list."*

> *"Certain protocols and procedures have not been updated in years. It has to be revamped."*

Theme 5: Personnel Allocation and Management

Regardless of the area of speciality, personnel allocation and management issues were underlined as a constant limiting factor within the in-patient participants. Particularly highlighting the absence of dedicated pharmacists. Acknowledging the lack of dedicated personnel that would be able to focus and maintain effort regarding any changes concerning the availability and accessibility of medications.

> *"Personnel is an issue because we have to dedicate a person to the pharmacy."*
>
> *"A pharmacist on board would be ideal in order to ensure patient safety".*
>
> *"You need an active formulary that is manned by a task force that is reviewing meds and updating the list."*
>
> *"There are no entities/managerial positions that are tackling the accessibility of medicines."*

Theme 6: Patient Care and Delays

Many of the participants mentioned the impact associated with treatment delay. Participants within the pharmacy aspect commented on the lack of a 24-hour open pharmacy within the community. Noting that the MDH pharmacy is the only pharmacy available for emergencies during the night but is limited to medications available on the GFL. Furthermore, other participants expressed the limitations in treatment available during the after-hours.

> *"So there might need to be an inclusion of a pharmacy roaster open 24 hours a day."*

"Certain drugs are better than others that are provided by the hospital, one has to go and buy them."

3.5 Evidenced-based Framework

Participation and observational opportunities provided a unique possibility to learn and witness current procedures implemented to address accessibility issues. The ASHP model (Fox and McLaughlin 2018) was used to propose a local policy to address the different operational responses encountered.

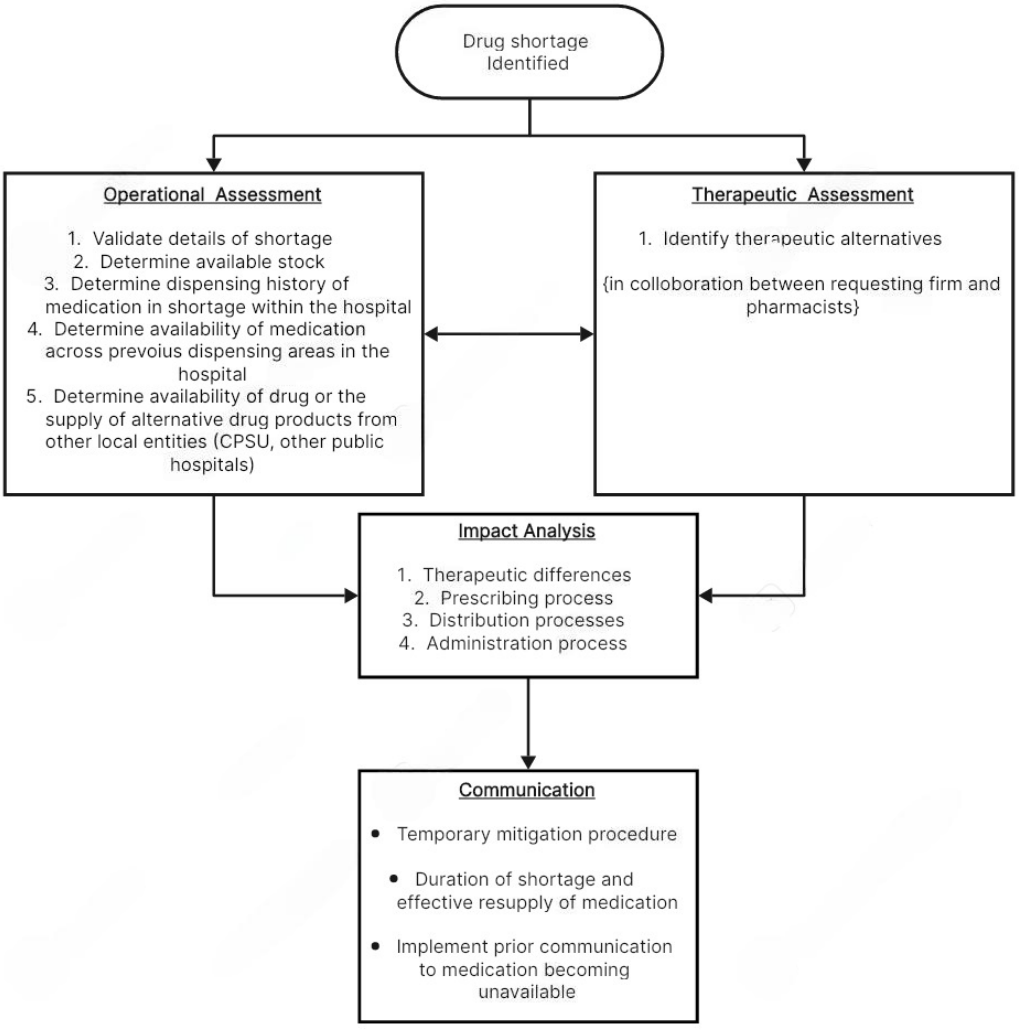

Figure 3.6: Schematic flow diagram to mitigate and resolve drug availabilities

Proposed local framework based on Fox E, McLaughlin M. ASHP guidelines on managing drug product shortages. England: Copyright American Society of Health-System Pharmacists, Inc. All rights reserved; 2018 Nov 1;75(21):1742–50. Available from: https://shorturl.at/aid3l

As depicted in Figure 3.6, the identification or alert of a drug shortage triggers operational and therapeutic assessments. Defined by Fox and McLaughlin, the therapeutic assessment aspect revolves around classifying primary patient cohorts and available therapeutic alternatives listed and unlisted medications within the GFL. While also underlining the importance of expediting the purchase of unlisted options. Restricting the use of limited supplies in the primary patient cohort also aids in safeguarding medication use when substitutions are contraindicated or not ideal.

The operational assessment follows the same characteristics as outlined by Fox and McLaughlin (2018), but in comparison highlights the importance of identification and the redistribution of current and available products across the healthcare system members. This could be further improved upon through the implementation of the previously mentioned electronic stock system through CPSU, so the logistical and administrative aspects of redistribution between the relevant parties are centralised and documented.

The shortage impact analysis evaluates and incorporates all factors from the operational and therapeutic assessments relevant to the shortage, determining the impact of shortages on patient care and treatment availability. Fox and McLaughlin had proposed relocating patients to other facilities that are not experiencing the same shortages. However, this is not feasible in the local context, as there is only 1 general acute hospital available. However, the model was applied to include suggesting therapeutic alternatives and changing the prescribing process to reflect the appropriate use to meet new demands accordingly.

The conclusive encapsulating characteristic is the importance of prior and constant communication in identifying the shortage, alternative therapeutic substitutions and the

necessary guidelines and procedures to effectively mitigate the shortage. These must be in line with a revamp and constant updates of the government formulary.

Chapter 4

Discussion

4.1 Context

Findings from this research identified accessibility and availability issues while providing insight into the perceptions, challenges and knowledge within MDH. Furthermore, this study highlighted that limitations and challenges are not unique but experienced across the health care system within MDH. Recognition of these difficulties allows the possibility of addressing and overcoming these limitations.

The insights represented and collected through this study also support the importance of collaboration between the different entities. Thus, presenting a unique possibility to address key areas for potential change and to strengthen current procedures to increase accessibility and availability.

4.2 Retrospective Sale Analysis

Retrospective analysis across a decade showed the sale of a substantial number (62%) of medicinal products listed on the GFL. The high percentage of medication sold could be due to the short or prolonged unavailability or accessibility issues of necessary medicinal treatment within the community. Thus, leading patients to purchase medicines from the hospital until they become available, contributing to the high sales figures.

Graphs illustrated in Appendix III highlight this aspect, with certain medications displaying either frequent sporadic low-volume sales, short periods of exponential sales or continuous monotonic relationships. Particularly noting, low quantity sales of commonly available medicines, such as anti-infectives, analgesics, anti-emetics and anti-hypertensive medications. Sales were attributed to the fact that community pharmacies are closed such as at night.

Exponential increases in sales of medications can be attributed to disruptions within the community or private sector, where previously commonly accessible and available medications experience supply or shortage issues. This can be observed concerning levothyroxine 50mcg, where availability issues were experienced within the private sector in 2017[47]. Resulting in the exponential sale of the medication from the MDH pharmacy.

Statistical analysis helped to identify the statistically significant positive and negative correlation coefficients of sales trends across the study period. This process isolated one hundred and four different medications which exhibit a statistically significant positive correlation, with one hundred seventy-one medications exhibiting a statistically significant correlation. The considerably larger number of medicines exhibiting a decrease might be indicative of accessibility or availability issues which had been resolved. This could be due to the patient either applying for the required Schedule V or introducing the same medicinal product or a suitable alternative within the private sector. Considering clozapine 100mg ($\rho = -0.831$), which is still a hospital-only medication since it requires continuous monitoring as per psychiatry department consensus, with regular blood tests before dispensing. While methylphenidate exhibits the greatest negative correlation ($\rho = -0.879$) may also be attributed to patients applying for Schedule V and POYC scheme.

By contrast, medicines or preparations which exhibit a statistically significant positive correlation coefficient infer the identification of continuously increasing accessibility challenges. Recognising these medications provides the opportunity to address and

[47] The Malta Indepedent. Updated: Private pharmacy thyroid medication shortage solved. The Malta Independent [Internet]. 2018 Mar 3 [cited 2024 May 28]; Available from: https://www.independent.com.mt/articles/2018-03-03/local-news/Hospital-pharmacy-selling-Thyroid-medication-to-private-patients-due-to-private-pharmacy-shortage-6736185592

resolve these shortcomings from the private or community aspect. The top ten medications (Table 4.1) exhibiting the highest correlation coefficients do not require additional or constant monitoring. Hypertensive medications (n=4) make up the most requested medications, followed by supplementary medications (n=2), with the last three being a diuretic, a sedative, a vasoactive agent and an anti-emetic.

Table 4.1: Top ten medications with the highest correlation coefficients of quantity of sales against duration

	Spearman Correlation Coefficient (ρ)	Pearson Correlation Coefficient (*r*)
potassium bicarbonate and chloride effervescent tablets	0.771	
phenobarbital sodium 30mg tablets	0.739	
cyclizine 50mg tablets	0.734	
labetalol 200mg tablets	0.722	
acetazolamide 250mg tablets		0.697
propranolol 10mg		0.693
nifedipine 10mg mr tabs	0.658	
pentoxifylline 400mg tablets	0.621	
repackaged - iron preparation syrup x100ml	0.610	
metoprolol 100mg tablets	0.600	

Nonetheless, medicines with lower correlation coefficients should still be considered. Weak positive correlation coefficients (attributed to a low number of sales) still indicate availability issues that can be addressed.

Initiatives and actions toward the introduction of these medications through community pharmacies can exert a substantial impact on patient care and well-being. These are

achieved through effective contributions provided by community pharmacists, which is associated with improved medication adherence across all patient treatments while still ensuring continuation of care (Choi and Lee 2022). Decentralisation of these medications from the hospital pharmacy to the community is linked to higher patient satisfaction, including reduced waiting time, improved quality of care, and better treatment information (Ferrández et al. 2024). Acknowledging pharmacists within MDH to provide additional clinical services across the healthcare environment.

4.3 Thematic Analysis

This study used focus group sessions across different specialities and healthcare professionals to evaluate experiences, perceptions and attitudes towards accessibility and availability issues within the main acute hospital. Six major themes emerged from these sessions which will be discussed with reference to published literature.

Theme 1: Medication availability and accessibility

Participants' opinions from the outpatient pharmacy perspective focused on accessibility and availability issues of certain medications available exclusively from MDH and the difficulties patients encounter in accessing such treatment. Statistical analysis findings validate these beliefs, as one hundred and four exhibit positive sales trends from MDH pharmacy. As previously stated, this suggests the presence of continuous accessibility and availability issues to certain medications not being addressed by the community or private sector. These requests can also be attributed to a lack of information by the prescribing physicians about other suitable alternatives within the private sector. If the private sector does not address this issue, decentralising the sale of these products to other potential government entities could help reduce the burden on general hospitals and optimise staff

resources. Thus, increasing the ease of treatment accessibility and preventing the necessity of travelling to the hospital.

Focus groups within different specialities mentioned the limitations associated with the unavailability of medications on the formulary. Asserting the efforts and difficulties in identifying suitable alternatives from the formulary or compelling patients to purchase medications when possible. Indicating the absence of a contingency plan or a national advisory setup once a medication is no longer available. National committees or setups have been considered predominantly positive in mitigating and providing decision-making assistance during drug shortages (Fox and McLaughlin 2018; Poulsen et al. 2023).

Theme 2: Communication Challenges

A constant challenge mentioned during the study was the communication aspect between healthcare providers and stakeholders within the health system. Every section of participants expressed a certain degree of lack of communication within their area. Particularly with the lack of warning, the absence of such systems is recognised by the ASHP as one of the main sources of a drug shortage crisis (Fox and McLaughlin 2018). As such the introduction of advance notice systems, commonly managed by regulatory authorities, is an important factor in alleviating and mitigating drug shortage issues (Iyengar et al. 2016; Bochenek et al. 2018). Although CPSU provides an online repository listing medications currently experiencing sourcing issues, most clinical participants were unaware of this information.

Additionally, participants suggested that the current email dissemination practice regarding medication changes is not ideal. Promoting the need for direct communication

through alternative means concerning drug shortages or changes in formulation. Unfortunately, participants were not aware that the Maltese Medicines Authority provides the opportunity to receive text messages and email notifications, concerning medicines information, product recalls and safety circulars[48]. However, participants were unaware that CPSU also maintains online public repositories listing items with sourcing issues and unavailable medications. The list includes an estimated resolution timeframe with the reason causing the supply delay.[49] While similarly issuing and keeping records of all Medicine Alerts released concerning changes concerning medications listed on the GFL. Such changes listed include changes in brands, concentration, volume, pack size or change in salt of the active pharmaceutical ingredient[50].

These online databases allow the possibility of active guidance to assist both patients and healthcare providers, from community pharmacists to prescribing physicians, in making informed decisions while safeguarding the continuation of treatment. The definitive assistance, as outlined by the participants, would be in publishing alternative therapeutic options and protocols to further aid in mitigating the effect of drug shortages.

The Outpatient pharmacy participants expressed their difficulties in providing a holistic approach to treatment due to the lack of communication and accessibility issues to the medication dispensed through the POYC from the community. This aspect hinders the possibility of facilitating medication reconciliation following release from the hospital. However, participants agreed on the advantages of recently introducing an online source

[48] Medicines Authority [Internet]. Subscribe for sms and e-mail notifications; [cited 2024 Jun 4]. Available from: https://medicinesauthority.gov.mt/newsletter?l=1

[49] Government of Malta. Central Procurement and Supplies Unit – Items Problematic to Source. 2023 [cited 2023 Nov 30]. Available from URL: https://healthservices.gov.mt/en/cpsu/Pages/Items-Problematic-To-Source.aspx

[50] Government of Malta. Central Procurement and Supplies Unit – Medicine Alerts. 2023 [cited 2023 Nov 30]. Available from URL: https://healthservices.gov.mt/en/cpsu/Pages/News/Medicine-Alerts.aspx

to check patient medication entitlement. Particularly concerning protocol regulations, named patient items and exceptional medications. However, they highlighted that the possibility of accessing the patient's dispensing history would aid in preventing dispensing of the same medications, stating that this would assist in mitigating wastage.

Theme 3: Inventory management and tracking

Participants unanimously agreed on the importance of maintaining efficient and effective management throughout the hospital. Highlighting the importance of preventing wastage and hoarding to ensure a consistent medicinal supply. As stockpiling before anticipated shortage can further aggravate the shortage of medications diverting supplies from areas and patients in need (Myers 1999). A potential solution to reduce waste is implementing IT systems that provide stock information across different sections and entities within the hospital. This should incorporate four principal areas: i) the physical system, ii) the planning and control system, iii) the information system and iv) the organisational system to address supply challenges associated with the hospital setting (de Vries 2005). Such systems also require strong cooperation and involvement of different stakeholders, each with unique responsibilities to safeguard the beneficial outcomes of supply chain management, controlling costs and inventory forecasting (de Vries 2011). The introduction of such an innovative aspect would make the hospital more resilient to drug shortages or disruptions (Sabahi and Parast 2020) Additionally, such systems also allow the possibility to assess the inventory at hand and reserve the limited supplies for specific patient groups where alternatives are not suitable (Fox and McLaughlin 2018).

Theme 4: Regulatory compliance and documentation

Restricting medications in the formulary based on prescribing criteria is a common practice to ensure patient safety, promote effective utilisation, and reduce costs. One challenge mentioned by the participants concerns the time perspective in requesting and the availability of the medication with approval conditions within their clinical setting. Within the clinical setting, participants expressed frustration with requiring written approval according to the prescribing criteria of the restricted medication. They also acknowledge that such medicines have these restrictions to ensure patient safety and the appropriate utilisation but believe that facilitating the current documentation would decrease treatment delay. Especially when the same medication can have multiple indications in different specialities but is only limited to certain indications and prescribing criteria. This is suggestive of the importance of having dedicated management of the GFL that complements contemporary medical procedures and guidelines.

Theme 5: Personnel allocation and management

In the various clinical settings, participants from all specialities mention the absence of pharmacists from the multidisciplinary team. The rationale for including pharmacist interventions is to address appropriate medication use while safeguarding patient wellbeing. Participants also recognised the lack of dedicated personnel who could serve as a focal point regarding the frequent drug issues related to medication accessibility and availability issues.

Theme 6: Patient care and treatment delays

Different aspects of delay in treatment concerning the clinical setting have been extensively described in the previous themes. The outpatient pharmacy participants identified a different characteristic affecting patient care. Primarily due to requests from patients occurring late at night, after the normal closing hours of community pharmacies. This is due to the absence of 24-hour pharmacies open within the community. Additionally, treatment available is limited to medications listed on the GFL, resulting in restricted treatment options.

The involvement and introduction of a multidisciplinary input suggest the importance of a collaboration network across all the different entities and stakeholders within the NHS and not restricted to the hospital setting. Thus, contributing to the appropriate use of national resources to mitigate drug shortages and prevent the critical escalation of such consequences.

4.4 Evidence-based Framework

The framework outlined in Section 3.5 is based on the guideline issued by the ASHP to address and mitigate frequent drug shortages by implementing an infrastructure before they occur. Such infrastructure would incorporate aspects of planning and responding to manage, prevent and mitigate drug shortages. The guidelines outlined by the ASHP consider two factors associated with a drug shortage, the operational and therapeutic assessment. The operational assessment relates to the shortage's details, including the drug's supply, availability from other complementary sources, previous usage and the possibility of using alternative therapies (Fox and McLaughlin 2018). Allowing the possibility to take into consideration all the available inventory across the different

stakeholders, acknowledging the possibility of stock transfer throughout the different healthcare systems entities. Thus, allowing the opportunity to mitigate and endure the shortage providing the opportunity to resupply or search for alternatives, while safeguarding the continuation of treatment. This underscores the need for implementing an integrated inventory management system, across all other organisations that dispense medications through or on behalf of the NHS, including the community pharmacies participating in the POYC scheme.

The therapeutic assessment, on the other hand, aids in identifying possible therapeutic alternatives with adequate supplies. While also concentrating on necessary changes in the related protocols and administration guidelines with the benefit of an interdisciplinary team. It is essential to establish a short-term ethical framework for allocating medications with limited supply and to provide evidence-based assistance in selecting an appropriate alternative (Rosoff 2012).

This can be further augmented and achieved through the integration of additional technological aspects, such as computerised physician order entries facilitating medication orders and robots facilitating medication distribution. The implementation of robots within the general hospital has already been identified and announced[51], enabling efficient medication distribution and human resources while reducing the waste of medicine. Encapsulating the same themes while ensuring that the main themes encountered across the different focus groups are met in safeguarding accessibility and availability.

[51] Agius R. Robots to distribute medicines to wards at Mater Dei [Internet]. TVMnews.mt. 2018 [cited 2024 Oct 14]. Available from: https://tvmnews.mt/en/news/robots-se-jibdew-robots-to-distribute-medicines-to-wards-at-mater-dei-l-medicina-ghall-pazjenti-u-jwassluha-fis-swali-ta-mater-dei/

This mitigation strategy would allow the possibility to access voluntary solidarity mechanisms, such as those introduced under the remit of the MSSG. Allowing EU member states to request assistance with medications when certain conditions had been met and all other possibilities were exhausted. Following the request, member states would be asked to respond, regardless of their ability to assist.

4.5 Strengths and Limitations

The study allowed the possibility of compiling an understanding of previous measures undertaken to mitigate drug availability and accessibility, attributed to the questions outlined. Although steps were taken to reduce subject and participant bias (through the confidentiality and anonymisation of data) participants might still have not divulged their true personal opinions. This can also be compelled by the researcher's presence eliciting biased responses.

A limitation of this study may be that despite taking all necessary measures to ensure random focus group participants and data collection, the findings may not be universal across other specialities. Noting, the exclusion of certain specialities, particularly oncology, which is provided by a different entity outside MDH. Thus, limiting the full context of accessibility and availabilities issues experienced across various specialities.

Another limitation of the research was the absence of the patient perspective from the focus group aspect. Preventing the understanding of the distinctive difficulties on the patient's behalf, thus restricting the possibility of addressing holistically accessibility issues.

4.6 Recommendation for further studies

The inclusion of highly specialised areas such as oncology and radiology would provide valuable insights into specific therapeutic issues. Incorporating a wider array of healthcare professionals who might have experienced limitations and disruptions in providing care attributed to unavailability or accessibility issues, such as dental professionals may add different perceptions.

Additionally, the validation by a diverse group of individuals of the process framework would be beneficial and provide a starting point for future improvement.

4.7 Conclusion

This study has identified frequently requested medications from the MDH hospital that can be introduced within the community pharmacy aspect profile. Additionally acknowledging the importance of providing effective communication, evidence-based framework, transparent formulary management and conveying effective drug policies in safeguarding treatment availability. Improving medicine accessibility to a wider population, allows MDH pharmacists to pursue additional opportunities. The system developed can contribute to safeguarding treatment accessibility while maintaining an updated healthcare aspect.

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Appendix I – Ethics Acknowledgment

Draft/Submitted REDP Forms

Show 10 entries Search:

Application ID	Application Date	Project Title	Faculty	Status
MED-2023-00250	28/10/2023	Accessibility of Unavailable Medication	Faculty of Medicine & Surgery	Acknowledged

Showing 1 to 1 of 1 entries Previous 1 Next

Submit New REDP Form

Appendix II – Focus Group Information Sheet

Information Sheet for participants

Dear Participant,

I invite you to participate in this focus group as part of a dissertation entitled "Accessibility of Unavailable Medications". Please be aware that participation is voluntary and refusal to participate will not disadvantage you in any way.

What is the research about?
The main objective is to identify challenges associated with the accessibility of unavailable medications across different specialities within Mater Dei Hospital. The evaluation across different aspects of care would provide an opportunity to devise a framework to improve the current framework to enhance patient outcomes.
The research will be carried out in fulfilment of a Doctorate in Pharmacy at the University of Malta

Conducting the focus group
The focus group will consist of other healthcare professionals in your speciality and will last for approximately 1 hour. The lead researcher will lead and guide the discussion by the focus group through the different issues. This is not a search for the correct answer but rather the identification of your insight and experiences.

What will happen to the results?
Focus group discussions will be recorded through a voice recorder and transcribed to be analysed for common factors and themes which can then be addressed. The main objective is to publish and disseminate the findings in a peer-reviewed academic journal.

What about the confidentiality aspect?
Recordings of the sessions will not be made available to anyone and will be encrypted on a password-protected computer to ensure confidentiality. However, please be aware that you will be assigned an anonymous identifier in the recordings. There is a possibility that other members might recognize you based on the content of your speech or the context of the conversation. The researcher might quote what you say during the focus group to highlight certain points, but these quotes will not reveal your identity. All voice recordings will be permanently erased once they are transcribed.

Withdrawal from the study
Participants may withdraw from the study at any time by notifying the lead researcher using the contact information provided below.

Additional questions?
For any additional questions regarding the research, please contact the lead researcher using the contact information provided below.

Contact Details
Name and Surname: Andy-Vince Falzon
Mobile Number:
Email: andy.v.falzon.11@um.edu.mt

Appendix III – Focus Group Questions

Out-patient Focus Group Questions

a) What are your thoughts on the impact of medicine accessibility and availability on patient outcomes?

b) Based on your background and experience, what are some contributing factors/barriers associated with patients seeking medication from the hospital Outpatient Pharmacy?

c) Are you aware of others who are working to address this issue?

d) Are you aware of any services removed from the Out-Patient Pharmacy portfolio? How did this impact the other services offered?

e) Depending on your daily interaction and knowledge, can you suggest any kind of strategy that might be developed and/or deliver educational resources to address this issue? Please do not hesitate to suggest bold concepts for addressing this issue.

Speciality Focus Group Questions

a) What factors do you believe affect medicine accessibility in the hospital?

b) Are there any policies or protocols in place to address medication availability and accessibility issues? If yes, how effective are they?

c) Are there any challenges that you face when it comes to ordering and restocking medications in the hospital?

d) Have you ever had to prescribe or administer a medication that was not available in the hospital? If so, how did you handle the situation?

e) Have you ever experienced medication errors due to a lack of availability or accessibility of medications?

f) Have you ever had to decide to substitute one medication for another due to availability issues? If yes, can you provide an example?

g) Is there anything else you want to mention or believe that might have been overlooked?

Appendix IV - Thematic Analysis

Code	Basic theme	Organised Theme	Interview extract
stock, procurement, medication availability	Challenges related to medication availability, procurement processes, and stock management issues.	Medication Availability and Procurement	*Increase in population, change in demographic has hindered accessibility*
			Drugs go out of stock and we're not given any indications... communication gets lost
			One second there the stock is available and the next it isn't, which was less of an issue in the past and for the past year and half to two years it's been astounding
			In samoc there are some meds which are not available locally. Usually patients have to apply through the community chest fund in order to access these meds because of the high cos
			One brand of medications because treatment is bought on tender.
			Certain meds aren't available in the private market such as propranolol, labetalol and acetazolamide.
			Patients resorted to the private sector to mitigate the shortage of meds, otherwise the patients would have remained without these tablets.
			An item is declared out of stock at mdh but in CPSU there is stock

Code	Basic theme	Organised Theme	Interview extract
communication, language barriers, information sharing	Difficulties in communication among healthcare professionals, language barriers on medication labels, and the importance of effective information sharing Difficulties in communication among healthcare professionals, language barriers on medication labels, and the importance of effective information sharing	Communication Challenges	*The POYC care online helped tremendously. If there was the online system it would help much better. Even communication -you would speak with the pharmacist of they POYC in lieu of an issue.*
			Doctors need to have a system where they can see what is available at mdh and with their registration number, the pharmacist can also see both their name and what the doctor prescribed.
			There is no direct communication between pharmacies and doctors.
			Highlights the needs of direct communication between different healthcare professionals within different settings. With a good it system you can resolve this issue, both in-patient and in the community. There is traceability and rights of each pharmacist at a different level.
			It was suggested that if the stocks are decreasing, there is communication to the doctors as well as to the nurses, in order to bring it to the doctors attention that certain drugs will soon be out of stock.
			Drugs go out of stock and we're not given any indications and if we're given any indication it would be one of the three hundred emails we get every week, which communication gets lost.
			The communication is sent once the drugs are no longer available.
			The language on the boxes of the medications cause an issue
			However, lately, certain drugs have been coming in foreign languages that have no English language therefore this can be problematic. In a fast paced environment, conversions to drugs and language barrier enhance medication errors therefore, the patient would be at risk.
			There is no communication between the pharmacy and the nurses/doctors that a medication is oos.

Code	Basic theme	Organised Theme	Interview extract
inventory, tracking, stock management	Concerns regarding inventory management, tracking systems, and the need for efficient stock management practices Concerns regarding inventory management, tracking systems, and the need for efficient stock management practices	Inventory Management and Tracking:	*Then upon discharge, another inhaler is dispensed and then the patient ends up with multiple inhalers of the same drug*
			We need to have a good centralised stocking system between the phy's and where the meds are distributed. If the patient stopped taking a drug, you would know the stock take of that drug on that patient, traceability of batch recall. Every pharmacist would have different levels of access on this system where they would know what meds there are and the quantity.
			Electronic centralised systems would benefit greatly
			Sometimes patients do not have relatives for the meds to be bought so they wouldn't be able to get them.
			Overstocking in wards is a real problem because certain drugs aren't used and left to rot and those who need the drug wouldn't have the access to it.

Code	Basic theme	Organised Theme	Interview extract
regulatory, paperwork, compliance	Challenges related to regulatory compliance, paperwork completion, and the impact of bureaucratic processes on medication access.	Regulatory Compliance and Documentation	*There is a lot of paperwork that needs to be filled and signatures of particular persons that are not at the ward therefore are more difficult to get a hold of such as protocol regulated, off licence.*
			Renewal of the permits affects the accessibility of medications.
			In casualty, there is protocol to give this type of medication however in the wards there are no protocols as to administer this drug.
			You need an active formulary that is manned by a task force that is reviewing meds and updating the list
			Certain protocols and procedures have not been updated in years. It has to be revamped.

Code	Basic theme	Organised Theme	Interview extract
personnel, staff shortages, allocation	Issues related to personnel allocation, staff shortages, and the management of pharmacy personnel Issues related to personnel allocation, staff shortages, and the management of pharmacy personnel	Personnel Allocation and Management	*Staff demand has increased, wards have increased*
			Personnel is an issue because we have to dedicate a person to the pharmacy
			A pharmacist on board would be ideal in order to ensure patient safety.
			You need an active formulary that is manned by a task force that is reviewing meds and updating the list
			There are no entities/managerial positions that are tackling the accessibility of meds.

Code	Basic theme	Organised Theme	Interview extract
treatment delays, accessibility to meds, medication administration treatment delays, accessibility to meds, medication administration	Concerns about delays in treatment due to medication accessibility	Patient Care and Treatment Delays	*So there might need to be an inclusion of a pharmacy roaster open 24 hours a day. The uni phy should have been a 24 hour phy which has still not been done*
			When brands change, some dosages change too. Therefore when morphine was changed to 20mg/ml instead of 10ml/ml, it was accustomed to pull it in 10mls therefore the patients were getting an overdose of morphine
			Treatment is not being distributed in the community pharmacy or in the health centres.
			Certain drugs are better than others that are provided by the hospital, one has to go and buy them.