

2023

Individuals' Lived Experiences with Pharmaceutical Patient Assistant Programs

Marcia Clarke-Burke
Walden University

Follow this and additional works at: <https://scholarworks.waldenu.edu/dissertations>



Part of the [Health and Medical Administration Commons](#)

This Dissertation is brought to you for free and open access by the Walden Dissertations and Doctoral Studies Collection at ScholarWorks. It has been accepted for inclusion in Walden Dissertations and Doctoral Studies by an authorized administrator of ScholarWorks. For more information, please contact ScholarWorks@waldenu.edu.

Walden University

College of Health Sciences and Public Policy

This is to certify that the doctoral dissertation by

Marcia Clarke-Burke

has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

Review Committee

Dr. Raymond Thron, Committee Chairperson, Health Services Faculty

Dr. Aaron Mendelsohn, Committee Member, Health Services Faculty

Chief Academic Officer and Provost

Sue Subocz, Ph.D.

Walden University

2023

Abstract

Individuals' Lived Experiences with Pharmaceutical Patient Assistant Programs

by

Marcia Clarke-Burke

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Health Care Administration

Health Services

Walden University

August 2023

Abstract

Pharmaceutical patient assistance programs (PAPs) were introduced as an alternative to address patients' inability to obtain necessary prescription drugs. However, individuals were not fully exploring the beneficial nature of PAPs due to a poor understanding of the programs. Additional research is needed to understand how PAPs impact patients' outcomes and costs of care. Grounded in Andersen and Newman's model of health care utilization, this qualitative research was guided by the hermeneutic phenomenological research design. Data were collected during interviews with 11 participants located in various states regarding their participation in PAPs and their lived experiences in using PAPs. Collected data were analyzed utilizing QDA Miner Lite software. Data analysis resulted in the identification of three constitutive patterns: lived experiences with eight related codes, benefits and limitations with three related codes, and perceived barriers with two related codes. From these patterns, three related themes were identified: (a) affordability, (b) accessibility, and (c) accountability. The themes showed a relationship to the health utilization model's core focus of predisposition and benefits using PAPs. The findings of this research have potential implications for positive social change that include the development of enhanced processes for PAP use, which could lead to improved patient outcomes and greater access to programs and other sources of funding support for healthcare needs of the United States.

Individuals' Lived Experiences with Pharmaceutical Patient Assistant Programs

by

Marcia Clarke-Burke

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Health Care Administration

Health Services

Walden University

August 2023

Table of Contents

| | |
|--|----|
| List of Tables | v |
| List of Figures | vi |
| Chapter 1: Introduction to the Study | 1 |
| Introduction..... | 1 |
| Background | 2 |
| Problem Statement | 3 |
| Purpose of the Study | 5 |
| Research Questions..... | 5 |
| Theoretical Framework..... | 6 |
| Nature of the Study | 6 |
| Definitions | 7 |
| Assumptions..... | 8 |
| Scope and Delimitations | 9 |
| Limitations | 9 |
| Significance..... | 10 |
| Summary | 11 |
| Chapter 2: Literature Review | 12 |
| Introduction..... | 12 |
| Literature Search Strategy..... | 12 |
| Theoretical Foundation | 13 |
| Literature Review..... | 14 |

| | |
|---|----|
| Quantitative Methods..... | 14 |
| Qualitative Methods..... | 15 |
| Pharmaceutical Patient Assistance Programs | 15 |
| Health Concerns Impacted..... | 32 |
| Summary and Conclusions | 37 |
| Chapter 3: Research Method..... | 38 |
| Introduction..... | 38 |
| Research Design and Rationale | 38 |
| Role of the Researcher | 40 |
| Interview Protocol..... | 41 |
| Research Questions..... | 42 |
| Research Methods and Design Procedures | 42 |
| Methodology | 43 |
| Population and Sample | 43 |
| Instrumentation | 43 |
| Recruitment, Participation, and Data Collection | 44 |
| Data Analysis Plan..... | 46 |
| Issues of Trustworthiness..... | 47 |
| Credibility | 48 |
| Transferability..... | 48 |
| Dependability | 48 |
| Confirmability..... | 48 |

| | |
|--|----|
| Ethical Procedures | 49 |
| Summary | 50 |
| Chapter 4: Results | 51 |
| Introduction..... | 51 |
| Setting | 52 |
| Demographics | 53 |
| Data Collection | 54 |
| Data Analysis | 56 |
| Evidence of Trustworthiness..... | 57 |
| Credibility | 58 |
| Transferability..... | 58 |
| Dependability | 59 |
| Confirmability..... | 59 |
| Results..... | 59 |
| Lived Experiences of Participants in PAPs | 60 |
| Perceived Benefits and Limitations of PAPs | 61 |
| Perceived Barriers Impacting Use of Services Offered by PAPs | 62 |
| Affordability, Accessibility, and Accountability | 62 |
| Summary | 64 |
| Chapter 5: Discussion, Conclusions, and Recommendations | 66 |
| Introduction..... | 66 |
| Interpretation of the Findings..... | 66 |

| | |
|--|----|
| Limitations of the Study..... | 67 |
| Recommendations..... | 68 |
| Implications..... | 69 |
| Conclusions..... | 72 |
| References..... | 76 |
| Appendix A: Request to Conduct Research..... | 86 |
| Appendix B: Patient Recruitment Flyer..... | 87 |
| Appendix C: Interview Protocol..... | 88 |
| Appendix D: Interview Discussion..... | 90 |
| Appendix E: Search Terms..... | 92 |
| Appendix F: Summary of Interview Response..... | 93 |

List of Tables

Table 1. Participant Demographics..... 54

List of Figures

Figure 1. Heart Disease Death Rates, 2014–2016 30

Chapter 1: Introduction to the Study

Introduction

In the United States, many patients lack the financial means to pay for their prescription medications, creating poor patient outcomes. An individual perspective of pharmaceutical patient assistance programs (PAPs) was revealed when Schencker (2015) highlighted the circumstance surrounding Andre Rucker's diagnosis with multiple myeloma, a blood cancer disease, and the financial plight he faced when his health plan was insufficient to cover the associated health costs of his drug treatment. Rucker received the benefits of a PAP, which gave him the ability to access the drug required for his health treatment. This case called attention to the urgent need for programs that focus on patients' needs to access medication in their treatment (Schencker, 2015).

Gordon (2018) highlighted the plight of a mother who attributed the death of her son to his inability to afford the insulin he required for his Type 1 diabetes. The young man was employed full-time but was unable to afford a health policy to manage his healthcare. The young man's death drew attention to the efforts of the American Diabetes Association to address the increasing costs of medication in the treatment of diabetes (Gordon, 2018). This case again highlighted the problem of individuals being unable to purchase drugs required for treating health concerns, many of which are life-threatening (Gordon, 2018).

This research was conducted as a review of the nature and structure of PAPs, how they are applied and used in the healthcare delivery process, the perceived accessibility of such programs, the need these programs address, and the views of patients regarding the

relevance of these programs. In this study, I compared and contrasted the positive and negative attributes of PAPs. The goal of this research was to aid in the development of processes to improve services relevant to healthcare needs of members of the populace. By determining the extent to which patients experience a limitation or absence of knowledge about PAPs that would afford them access to needed medication, the hope is to avoid situations like the young man who could not afford to treat his diabetes (see Gordon, 2018).

Chapter 1 is focused on the background of the study, the purpose and nature of the study, and the theoretical framework for the study. The research questions will be highlighted, as well as definitions of key terms. The chapter will conclude with a review of limitations, scope and delimitations, assumptions, and a summary.

Background

PAPs are geared toward providing medication at low or no cost to individuals who, in most instances, are financially challenged and lack prescription drug coverage (Choudhry et al., 2009). PAPs grew out of the desire to focus on enabling patient cost sharing, leading to a reduction in cost via copayments, coinsurance, and deductibles or, in some instances, individuals obtaining medication at no charge (Howard, 2014). In many cases, PAPs are funded and facilitated by pharmaceutical and medical supply manufacturers. The goal of PAPs is to ensure the benefits are extended to individuals who stand to gain from obtaining needed medication (Choudhry et al., 2009).

In this research, I collected data from participants in PAPs regarding their lived experiences, the value they attach to their experiences, and their perceptions of potential

improvements to the system. I conducted a literature review to explore the history of PAPs, how the programs are applied, and views about the beneficial or detrimental effects of such programs. This research will contribute to the existing literature on this topic by adding the lived experiences of participating individuals.

Problem Statement

PAPs were introduced to aid in making prescription drugs accessible to individuals in need of the programs' support (Choudhry et al., 2009). However, Zafar et al. (2017) found that the programs are underutilized and that the impact on individuals served needed to be better understood. There is a gap in the literature regarding the lived experiences of individuals served by PAPs.

Efforts to increase the standard of care for United States citizens led to the introduction of PAPs to aid in providing access to needed medication and to allow for an ongoing review of these programs (Howard, 2014). Choudhry et al. (2009) drew attention to these programs when they noted that the beneficial effects of PAPs are hindered through limitations that include a poor understanding of how patients are impacted through PAP services. Choudhry et al. (2009) and Weinberg (2009) advocated for a better understanding of these programs, particularly how they are perceived by individuals the services are meant for and the impact these programs could have on the healthcare system. The authors have suggested a gap exists in the literature with regards to research on the impact of PAPs from patients' perspectives.

Felder et al. (2011) concluded that PAPs have the potential to improve prescription drug accessibility for eligible patients but there is limited information

regarding the programs' impact on patients' lived experiences. Chu et al. (2012) indicated that further studies are needed to foster an understanding of the extended role of PАПs in the environment of health care reform. Zafar et al. (2017) continued the call for more research focused on formulating an understanding of how the programs impact patients' outcomes and the overall cost of care.

Choudhry et al. (2009) revealed that one third of Americans of all ages and two thirds of elderly Americans have reported difficulty paying for medications. A quarter of patients had not filled a prescription or reduced prescribed dosage because of high out-of-pocket costs (Choudhry et al., 2009). Choudhry et al.'s research delved into the benefits of PАПs offered by pharmaceutical manufacturers. In exploring the plight of millions of Americans considered to be needy, ineligible for comprehensive assistance program as well as being unable to afford needed medications, the researchers sought to determine whether PАПs fell under the category of safety net. While identifying the limitations of the programs, their research also highlighted the poor understanding of whether these programs benefited individuals as intended.

The findings of this research could have far-reaching impacts socially and economically. Data released by the Centers for Disease Control and Prevention (CDC, 2018a) revealed in 2018 that 90% of the nation's \$3.3 trillion in annual health care expenditures was for people with chronic and mental health conditions requiring high-cost medication. Raghupathi and Raghupathi (2018) also revealed that chronic diseases are responsible for 7 out of 10 deaths in the United States, killing more than 1.7 million Americans each year. Additionally, more than 75% of the \$2 trillion spent on public and

private healthcare in 2005 went toward chronic diseases (Raghupathi & Raghupathi, 2018). These health statistics indicate the need for PAPs to help patients receive necessary treatment.

Purpose of the Study

The purpose of this study was to explore the lived experiences of participants in PAPs and determine the perceived barriers they experience when they seek to use the benefits these programs provide. I used a qualitative approach with an investigative process allowing participants to present views, opinions, and perceptions of their experiences while participating in the program. The effort to promote healthy lifestyles and foster accessibility to needed drugs could be aided with a better understanding of the lived experiences of individuals who use PAPs. Fielder et al. (2011) revealed in their assessment that, from a patient or health care institution perspective, PAPs have not been adequately evaluated by researchers. The findings of this study could also help address issues around the inability of individuals to afford medication, for healthcare professionals to have medical resources required to positively impact the healthcare needs of their patients, and for authorities to formulate policies that will govern public health agencies facilitate PAPs.

Research Questions

The following research questions guided this study:

RQ1: What are the lived experiences of individuals who participate in PAPs?

RQ2: What are the perceived benefits and limitations of PAPs?

RQ3: What are the perceived barriers impacting the use of PAP services?

Theoretical Framework

The theoretical framework for this study was grounded in Andersen and Newman's (2005) model of health care utilization. First developed in the 1960s, Andersen and Newman's behavioral model of health care utilization has undergone progressive improvements over the years. The fourth phase of its development, which occurred in the 1990s, was focused on the provision of measures of access to medical care. Andersen (1995) focused on three characteristics driving the use of health services: (a) predisposing factors, (b) enabling factors, and (c) need factors. Under this theoretical framework and in an attempt to fill a gap in the research, an in-depth assessment was made of the factors impacting the implementation and use of PAPs from patients' perspectives (Miles et al., 2014). In this research, I focused on fostering an understanding of the experiences of patients who sought a solution to their healthcare problem through PAPs (see Creswell, 2013).

Nature of the Study

This hermeneutic phenomenology study (van Manen, 1990) allowed for an in-depth qualitative assessment of patients' perceptions for whom the ability to obtain needed medication at minimal or no cost could be impactful (Creswell, 2013). Rudestam and Newton (2015) further qualified the hermeneutic phenomenological methodological design noting that this type of research allowed for an in-depth exploration of the lived experiences, which are of individuals who are participants in PAPs.

Interviews were conducted to collect data to describe and outline the experiences of individuals to develop a better understanding of the situation from patients' points of

view. Semi structured interviews were conducted in the hope of identifying the structure of PAPs, the perceived accessibility of the programs, the need these programs facilitate, and the views of a sample of individuals regarding the relevance of these programs. Semi structured interviews were conducted because they allow for follow-up questions (Rubin & Rubin, 2012). To obtain the personal feelings and beliefs of individuals, asking follow-up questions is crucial. Participants may experience reassurance that their opinions are relevant to the success of the research.

Definitions

Financial toxicity: The impact that out-of-pocket (OOP) costs of cancer care have on patients' well-being, leading to lower quality of life, less compliance with prescribed therapy, and poorer outcomes including increased mortality (Morel, 2018).

Grey literature: Information produced internally in a noncommercial form, such as government reports, policy statements, issues papers, and conference proceedings by agencies including hospitals, government, and businesses (Börjesson, 2015; Felder et al., 2011; Happe & Walker, 2013).

Hermeneutic phenomenology: A focal methodology that is interpretive and applicable in studies seeking to explore the lived experiences of individuals impacted by the phenomena of their experience (Sloan & Bowe, 2014).

Methodology: How problems are explored, and answers are sought and how research is conducted into situations and circumstances that drive or shape behaviors (Taylor et al., 2016).

Pharmaceutical patient assistance program (PAP): A program introduced to provide uninsured or underinsured individuals with access to brand-name medications at little or no cost (Choudhry et al., 2009; Zafar & Peppercorn, 2017).

Phenomenology: The method or methodology employed to ascertain meanings individuals ascribe to their experiences (Sloan & Bowe, 2014).

Purposeful sampling: Individuals are purposefully chosen to participate in research for specific reasons, including having had an individual experience, having knowledge of a particular phenomenon, residing in a specific location, or some other reason (Ravitch & Carl, 2016).

Semi structured interview: An interview instrument is used to organize and guide an interview and include specific, tailored follow-up questions within and across interviews (Ravitch & Carl, 2016).

State pharmaceutical assistance programs: State-run programs that vary by state and assist low-income seniors and adults with disabilities in paying for their prescription drugs (Felder et al., 2011).

Assumptions

I considered relevant assumptions and limitations as far as they applied to the process of recruiting participants. I assumed that participants would be truthful, open, and honest in disclosing their personal experiences, but this may not be the case, and they may not be a complete representation of the experiences of the populace. The possibility also exists that participants answered interview questions based on their perceptions of what was required rather than their individual and personal experiences. Because the goal

was to seek to assist in the development of an understanding of the lived experiences of individuals who are participants in PAPs, I sought information regarding these experiences. This necessitated that research participants be open and honest in disclosing their experiences. Therefore, I endeavored to focus on building a relationship that elicited trust that would lead to open and frank interviews.

Scope and Delimitations

Specific to the research was the attempt to ensure that participants experienced confidence in me as the researcher that enabled them to share their relevant lived experiences regarding obtaining needed medication via PAPs. The enabling and need factors of the health services behavioral model (Babitsch et al., 2012) had some bearing on this process. My responsiveness also fostered a level of openness from the participants that resulted in insight beneficial to the study (Rubin & Rubin, 2012). While the research was limited to the lived experiences of participants in PAPs, these experiences could be transferrable to individuals who could not participate. The concerns and opinions of those individuals who could not participate in the PAP process could be explored in another research context.

Limitations

This phenomenological study was geared toward understanding participants' lived experiences, but there may be limitations associated with the method used. The research method was designed with an in-depth interview process with questions geared toward preventing bias while eliciting the free flow of information from the participants (see Appendix C), but information may not be as forthcoming or relevant to the study

being conducted. The sample size could also present some limitations as there may be difficulty in gaining full participation and representation at the locations selected. Given the possible limitations, I made an effort to achieve active involvement of the facilities approached to allow for the distribution of flyers to everyone who displayed an interest in the research.

The ability to capture honest and accurate information from participants could be a limitation also impacted by individuals' recall processes guided by the lapse in time and variation between actual experiences and external sources. This could also have a bearing on participants' perceptions. To eliminate the possibility of limitations mentioned, I focused on developing a level of trust that allowed for the free flow of information, effectively synthesizing and interpreting findings, and objectively reporting the findings (see Janesick, 2016).

Significance

A gap exists in the literature regarding the lived experiences of participants in PAPs. I conducted this study to help fill this gap by focusing specifically on individuals PAPs are designed to aid and while exploring their perceptions. Developing this understanding could assist these individuals and further impact policy decisions for future improvement of the programs. I used this process to address the call from Choudhry et al. (2009) for research to facilitate a greater understanding of PAPs, particularly in aiding the development of policy decisions for more significant improvement for patients. The cost of medications, particularly for chronic illnesses, increases yearly as new and improved drugs are developed , creating a need to ensure that such programs are beneficial for

participants (Raghupathi & Raghupathi, 2018). Qualitative research allowed for an in-depth assessment of the factors impacting the implementation of PAPs through the identification of problematic areas, the presence of barriers, and could help lead to solutions beneficial to all individuals the programs seek to serve (see Miles et al., 2014).

Summary

PAPs can be beneficial for individuals struggling to access medication needed for medical conditions. In Chapter 1, I identified the background, the problem statement, the purpose of the study, the research questions, the theoretical framework, the nature of the study, and definitions. I also reviewed the assumptions, scope and delimitations, limitations, and significance for this study. In Chapter 2, I present a review of the literature about PAPs and identify the need for contributions to attempt to explore participants' opinions on PAPs. I also present an outlook and the history of PAPs and views derived from research conducted exploring the applicability of PAPs.

Chapter 2: Literature Review

Introduction

In the United States, many patients lack the financial means to pay for their prescription medications, creating poor patient outcomes. This study was conducted to obtain patient perceptions of PAPs to review the nature and structure of PAPs, how they are applied and used in the healthcare delivery process, and the accessibility, need, and relevance of these programs. I explored the positives and negatives of PAPs during this research process. The findings of this research will impact processes to aid in improving the delivery of healthcare services to members of the populace. In this study, I sought to determine the extent to which the programs are impacted by a limitation or absence of knowledge among patients (see Gordon, 2018). In Chapter 2, I present an exploration of the literature regarding the phenomenon under study. I review the literature search strategy, the theoretical foundation, and the primary research methods applicable to this research, leading to a focus on research materials relevant to studies of PAPs.

Literature Search Strategy

The process of reviewing the literature began in summer 2017 when I began to explore the experiences of individuals who either participated in PAPs or were not able to. The existing research in this context proved to be extremely broad. The intention was to explore the lived experiences of individuals with the possibility of positively impacting and improving such experiences, but the topic evolved into one that was more specific. I decided to focus my research on the phenomenology of individuals who are participants in PAPs.

I researched literature relevant to the introduction and support for PAPs in an ongoing process that allowed for a deeper understanding of these programs, their application to promote a healthy lifestyle among citizens, and increased accessibility to needed pharmaceuticals. I retrieved literature from many sources, including Google Scholar, ProQuest, Walden Dissertations, and library resources, such as books, health magazines, scholarly journals, report abstracts, and periodicals that were PAP related. Search terms included a combination of relevant words, including *pharmaceutical patient assistance programs*, *patient assistance programs*, *qualitative research*, *quantitative research*, and *340B Drug Discount Program*. For a full list of search terms used, see Appendix D.

Theoretical Foundation

Andersen and Newman's (2005) model of health care utilization is a framework that fits this study. The health care utilization model is the basis for a level of understanding between a researcher and participants that allows for insightful and in-depth assessments of participants' lived experiences. Andersen's (1995) framework for health services utilization has as its core focus three characteristics that drive the use of health services: (a) predisposing factors, (b) enabling factors, and (c) need factors. These factors highlight the interrelatedness of the process of life and the connectivity of various characteristics systematic or external in nature. The predisposing factors that encompass the sociocultural attributes of individuals that exist before their illnesses include social structure, health beliefs, and demographics such as age and gender (Andersen, 1995). Enabling factors are the logistical aspects of obtaining care (Andersen, 1995). Enabling

factors start with consideration for the family, which is personal and extends to the community and includes health personnel and facilities, waiting time, and additions such as genetic factors and psychological characteristics. Finally, need factors encompass the most immediate cause of health service use, from functional and health problems that generate the need for health care services to the perception of the importance and magnitude to seek professional help (Andersen, 1995). Need factors include individuals making decisions possibly influenced by situations both controllable and, in many instances, impacted by external forces or possibilities. I used this foundation to guide this research in understanding the lived experiences of patients to aid the process of improving healthcare delivery.

Literature Review

In completing the literature review, I made an effort to explore the body of literature relevant to the experiences of individuals who are participants in PAPs. I focused on studies into this phenomenon in which researchers used either the quantitative or qualitative methods. The basis presented in support of the need for PAPs was explored as also the argument discounting the beneficial effect of PAPs for patients as opposed to all other stakeholders, including pharmaceutical companies and government entities.

Quantitative Methods

Quantitative research is focused on convergent reasoning dealing in numbers, logic, and objectivity to determine the relationship between one variable and another within a population (Labaree, 2016). Quantitative designs could be descriptive, establishing a connection or an association between variables, or experimental,

establishing causality through the explanation of observed data. In this process, I will look at the quantitative aspect with data revealed to support the reviewed research material as individuals seek to substantiate the presented point of view.

Qualitative Methods

In showing support for the qualitative research process, Sloan et al. (2014) highlighted the comparison that portrays quantitative methodologies as requiring rigidity in data as opposed to qualitative methodologies that are used to focus on the portrayal of a socially constructed world with complex and ever-changing situations and circumstances that speaks to the uniqueness of individuals and their experiences. Taylor et al. (2016) supported this, indicating that qualitative research offers a descriptive view of human behaviors through their works and records of their behaviors. Ravitch and Carl (2016) noted that the methodological approach is derived from the conceptual framework of a study and can vary in each study. Researchers either begin by working from an approach or arrive at an approach (Ravitch & Carl, 2016).

Pharmaceutical Patient Assistance Programs

In Chapter 1, I noted that PAPs began because of a desire to focus on enabling patient cost sharing, leading to a reduction in costs via copayments, coinsurance, and deductibles (Howard, 2014) or, in some instances, patients obtaining medication at no charge. In this regard, I conducted a review of literature and studies relevant to PAPs. Healthcare is necessary for effective functioning of each member of society and includes the ability to access needed medication. Gao et al. (2016) demonstrated that PAPs play a significant role in assisting patients in obtaining prescription medications. PAPs take

various forms, which Robinson and DeGraff (2017) termed *legacy programs*. Robinson and DeGraff (2017) categorized these as PAPs, copayment support programs, and charitable foundation patient support and outlined them as follows:

Patient Assistance Programs. PAPs are pharmaceutical manufacturer-sponsored programs for the uninsured and, in some cases, the underinsured. Pharmaceutical manufacturers make drugs available at no charge to patients who meet income and other eligibility requirements.

Copayment Support Program. Copayment support programs are pharmaceutical manufacturer-sponsored programs for commercially insured patients. These programs reduce copayments for a drug to a fixed-dollar amount per 30-day (or in some cases, 90-day) supply or a percentage of cost, subject to a maximum amount. Beneficiaries in federal or state health programs are ineligible for this type of copayment support.

Charitable Foundation Patient Support. These programs are offered by 501(c)(3) charitable organizations to provide support to patients with specific diseases and may include beneficiaries in federal or state health programs. The types of support vary greatly, and patients must submit applications to receive assistance. (p. 10-11)

Cauchi et al. (2016) added state pharmaceutical assistance programs to Robinson and DeGraff's list of programs. State pharmaceutical assistance programs are state-run programs that vary by state. State pharmaceutical assistance programs assist low-income individuals with paying for prescription drugs (Cauchi et al., 2016). This adds to the list

of the number of programs available to individuals requiring assistance as they seek to financially cover their prescriptions.

Nature of PAPs

Choudhry et al. (2009) noted that the beneficial effects of PAPs are hindered by limitations that include a poor understanding of how patients are impacted through PAP services. Choudhry et al. (2009) and Weinberg (2009) both advocated for a better understanding of these programs, particularly how they are perceived by the individuals meant to receive the service and the impact this could have on the healthcare system. These authors suggest a gap exists in the literature with regards to research on the impact of PAPs from patients' perspectives.

Felder et al. (2011) concluded that PAPs have the potential to improve prescription drug accessibility for eligible patients but there is limited information regarding their impact on the lived experiences of these individuals. Chu et al. (2012) focused on this gap in the research and found that further studies are needed to foster an understanding of the extended role of PAPs in the environment of health care reform. Additionally, Zafar et al. (2017) called for research that was focused on formulating an understanding of how the programs impact patient outcomes and the overall cost of care.

Brody and Light (2011) drew attention to how pharmaceuticals are marketed to patients with the aid of physicians by way of the inverse benefit law. The inverse benefit law, which sought to highlight the assumption that "low- and high-risk populations receive different degrees of benefit and harm from the administration of a drug," (p. 2) had its foundation in the inverse care law proposed by Julian Tudor Hart in 1971. The

focus on this law drew attention to the tendency for the availability of proper medical care to vary inversely with the need for such care in the population being served (Brody & Light, 2011).

Brody and Light (2011) sought to highlight the process of commercial marketing of pharmaceuticals. The party played by physicians in support of the promotion of pharmaceuticals beneficial to them rather than pharmaceuticals beneficial to the patients was also highlighted. This resulted in their call for more evidence-based prescribing and regulators actively embarking on a process where consideration regarding accessibility to drugs in a marketplace that is safe (Brody & Light, 2011). Felder (2010) sought to present a view that spoke to the beneficial effects of programs that provide an alternative for individuals uninsured who need prescription drugs. While at the time of Felder's research, the United States was on the verge of implementing health insurance reform slated to provide 32 million people with healthcare insurance coverage, the impact on the cost of prescription drugs to consumers was uncertain. Felder (2010) highlighted the results of research conducted to explore the ability of PAPs to positively impact patients' accessibility to prescription drugs, noting the limited information on PAP use and effectiveness. Felder identified beneficial effects for some stakeholders, including patients, healthcare institutions, providers, and pharmaceutical companies themselves. Noting drawbacks in the application process, Felder found that a universal simplification of PAP processes would be vital in fostering a better understanding of patients and providers views in relation to this complex venture. Felder recommended for future studies of PAPs to be focused on the patient population, which would be beneficial in the

decision-making process to improve healthcare, insurance, and prescription drug coverage.

History of PAPs

A key ingredient in the process of ensuring that the healthcare needs of the nation's citizenry are provided for effectively is the ability to access the prescription drug. Kleinke (2001) drew attention to this in the published work titled "The price of progress: Prescription drugs in the health care market." Kleinke explored how pharmacy costs were increasing, which was believed to be more than general and medical cost inflation. This research leads to calls for price and utilization control by the public and private players (Kleinke, 2001).

Noting that access to more and better drugs was available to Americans, Kleinke revealed that the number of prescriptions filled in the United States increased from 2.0 billion in 1994 to 2.5 billion in 1998 and was projected to reach 2.9 billion in 2000; more than 35 percent of the \$100 billion spent on prescription drugs in 1998 went for drugs introduced since 1991 (Kleinke, 2001). This information, along with the data presented, suggests that there were additional costs for all stakeholders.

The history of PAPs in the United States could be considered to be very in-depth and complicated. Cauchi et al. (2016) allowed for an opposing view in their research on state pharmaceutical assistance programs, which they revealed dated back to 1975 when states first actively participated in the effort to address the issue revolving around the plight of residents who either lack insurance coverage or were ineligible for governmental programs to fund their medication needs.

State pharmaceutical assistance programs are subsidized programs utilizing state funds to partially fund the cost of pharmaceuticals for members of the populace defined to meet the enrollment criteria established accordingly. It was revealed that between 2000 and 2006, approximately 26 states supported variations of this program, and by 2009 that number had grown to include approximately 42 states but that the passage of the federal Affordable Care Act (ACA) resulted in less involvement of state legislatures in these activities (Cauchi et al. 2016). The needs of the populace for assistance have not diminished.

The value of PAPs cannot be overstated. However, attention has also been drawn to the process involved in making PAP accessible to patients by Clay, Vaught, Glaros, Mangum, Hansen, and Lindsey (2007) in their research termed “Costs to physician offices of providing medications to medically indigent patients via pharmaceutical manufacturer prescription assistance programs.” Clay et al. (2007) listed their objective as being to measure the costs incurred by a medical clinic that provided chronic prescription medications via PAPs, and this spoke to the beneficial nature for stakeholders other than patients, as noted by Felder (2010).

Clay et al. (2007) delved into the process of PAPs, the treatment of individuals dealing with chronic illness, and how needed drugs are obtained via the pharmaceutical industry’s participation. The part played in the application process by physician offices. In their conclusion, they indicated that the number of PAP applications required per patient per medication impacted clinic time and financial resources.

Kesselheim (2013) drew attention to rising prescription drug costs which reportedly was straining the budgets of patients and health insurers and was also directly responsible for promoting adverse health outcomes resulting in reduced adherence to essential medications. Focusing on the correlation between “Rising health care costs and drug life-cycle management in the pharmaceutical market,” Kesselheim highlighted that brand-name drugs’ participants form periods of market exclusivity, allowing for increased pricing in the bid to cover initial investment in research and development.

A highlighted revelation from Kesselheim’s research was that drug spending for approximately 20% of the United States prescriptions but conversely 80% of the costs (Kesselheim, 2013). The data presented would seem to support the belief that the responsibility for creating a balance where cost savings are achieved without adversely impacting public health lies in the hands of policymakers.

The discussion was taken to another level by Ball and Mackert (2013) with their “Exploration of pharmaceutical advertising practitioners’ approach to trust and emotion” by way of direct-to-consumer pharmaceutical advertising. Notably, the researchers explored the advertising aspect of drug promotion, the views of consumers and healthcare providers. They dealt with how this transcended to the use of pharmaceuticals and sought to look into the matter from the advertising professionals’ perspectives. While there were indications that consumer trusts played a significant role in the application and utilization of prescribed drugs impacted by the marketability of certain pharmaceuticals, this did not address the ability of patients to utilize the medications via PAPs effectively.

The passage of the years saw great attention being paid to the rising cost of pharmaceuticals to patients. Huebner (2014) reviewed arguments put forward to support and justify the claim that it was the ‘special’ moral obligation of the research-based pharmaceutical industry to play an active role in the provision of lifesaving medications to the needy, either free-of-charge or at a reduced rate relative to the cost of manufacture. Huebner was conclusive in the assessment that there is no justification for this claim but highlighted the debate that there is a moral obligation to address the healthcare needs of individuals reliant on the products provided by pharmaceutical companies.

Huebner’s claim of a moral obligation drew attention to the moral obligation that providers and their clinical staff also have as they seek aid for those patients willing to partake of the products provided by pharmaceutical companies. One key aspect of this process is knowing the opinions of patients, which could be ascertained through discussions.

Beard, (2008) in “Cost as a feature of medication management communication in medical visits” and Patel and Wheeler, (2014) in “Physician-patient communication on cost and affordability in asthma care. Who wants to talk about it and who is doing it,” highlighted the importance of discussions that delved into affordability, accessibility, and consistency in the drug treatment process? As indicated earlier, PAPs take varied forms from state to state, and the full impact of PAPs on the patient populace would help assess the success of these programs.

One program that comes to note is the 340B Drug Discount Program. Zeta (2015) revealed in “Comprehensive Legislative Reform to Protect the Integrity of the 340B Drug

Discount Program” that the 340B Program is a federally facilitated program established in 1992. The author further revealed that this program was part of the Veterans Health Care Act. Its core requirement was that drug manufacturers provide steep discounts on outpatient prescription drugs to qualifying safety net healthcare providers, which total 20 to 50 percent off the market price (Zeta, 2015).

Zeta (2015) highlighted the concern that there had been a marked lack of oversight or program guidance, and as such, the beneficial effect meant for patients were being exploited. Zeta further noted that healthcare providers and contract pharmacies were instead the beneficiaries through the process of dispensing discounted drugs at a total price to privately insured patients. According to Zeta, healthcare providers and contract pharmacies would then pocket the spread or the difference between the discounted drug price and the amount paid by patients and their insurers. From the author’s point of view, such action overrode the process, which was beneficial for low-income patients. The process highlighted is yet another area for which the views and opinions of those patients who are participants in PAPs and similar programs would be vital and could impact the regulatory process and the development and improvement for future healthcare activities.

Another program for individuals 65 and over is the optional United States Federal-Government Medicare prescription drug benefit program known as Medicare Part D, designated to assist Medicare beneficiaries in paying for self-administered prescription drugs. The Centers for Medicare and Medicaid Services (CMS) outlined on its website the importance attached to PAPs allowing for their enrollees to obtain

prescription drug coverage benefits by virtue of pharmaceutical manufacturers sponsoring PAPs, which in turn interfaces with Medicare Part D plans by operating “outside the Part D benefit” (CMS.gov). This is facilitated through the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) which the President signed on December 8, 2003, Public Law 108-173, and went into effect on January 1, 2006 (CMS.gov). It was highlighted that this level of assistance on behalf of the PAP enrollee did not count towards the total out-of-pocket costs, formally true-out-of-pocket cost for the Part D beneficiary. The site provided links that explained that total out-of-pocket costs' importance lies in the process of calculating and determining whether an individual had reached the threshold for catastrophic coverage under the Part D benefit (CMS.gov). Individuals to the site were also asked to review the CMS's Coordination of Benefits and Recovery (COB&R) guidance outlined on a separate link. They provided an overview of CMS's policy about PAPs and their interaction with Part D plans.

Application of PAPs

Felder, Palmer, Lal, and Mullen (2011), in “What is the evidence for pharmaceutical Patient Assistance Programs (PAPs)? A systematic review,” utilized this medium to present their assessment of PAPs. Felder et al. derived information from reviews of commercially published studies and grey literature sources, including information obtained from the government, academics, business, or industry sources. The researcher focused on examining PAPs, their usage, the impact of these on healthcare outcomes in patients, and the cost of facilitating assistance in furthering the enrollment process for these programs.

These individuals indicated that they were motivated by the belief that while PAPs offered the potential to lead to improved prescription drug accessibility for eligible patients, this beneficial effect was hindered because there was a limitation of information that spoke to the programs' effectiveness. These individuals noted that the relevance of PAPs was called into question in light of the Patient Protection and Affordable Healthcare Act of 2010, which addressed health insurance and specifically prescription drug coverage of the nation's populace extending to 32 million people.

Felder et al. (2011) proceeded to present data to support the claim that PAPs still maintained their relevance. This was particularly so in cases where individuals were suffering from chronic diseases. The authors noted that individuals suffering from chronic diseases showed improved disease indicators, aided by increased accessibility to medication free of cost. The authors further indicated that the relevance of PAPs could also be seen in cases where financial inability could motivate individuals to be open to the use of less expensive brand products. Of note was their revelation that the services offered in these programs were inadequately researched and that more investigative research was required to assess these programs' impact accurately.

Chu, Lal, Felder, and Rosenau (2012) indicated their aim to examine eligibility criteria for PAPs as this relates to prescriptions commonly dispensed in the United States. They titled their study "Evaluation of Patient Assistance Program Eligibility and Availability for Top 200 Brand Name and Generic Drugs in the United States". The researchers presented a view to encourage uninsured and underinsured patients to

comply with their medication regimens. One method was to utilize the strategy of referring them to industry-sponsored PAPs.

They indicated that this process was particularly appealing and driven by prescription drugs' rising cost, which has led to patients either reducing their medication doses or even electing not to fill prescriptions for needed medication. A review of the patients' perception in this regard could prove invaluable.

Clarkson's, Linley's, Frank's, and Selleck's (2016) research titled "Introduction and implementation of a pharmaceutical Patient Assistance program in a free clinic in Birmingham, Alabama in December 2012" was noteworthy. Clarkson et al. (2016) highlighted pertinent issues that could hamper the success of this venture. However, it also presented a situation of hope fueled by the effort of healthcare personnel and pharmaceutical companies to meet the needs of their patients (Clarkson et al., 2016). The revelation from Clarkeson et al. research was relevant and vital as more attention was drawn to situations reflective of the increased presence of indigent patients in our communities who find it exceedingly difficult to finance prescription drugs needed for their treatment.

Zafar and Peppercorn (2017), in "Patient Financial Assistance Programs: A Path to Affordability or a Barrier to Accessible Cancer Care?" explored the sponsorship of pharmaceutical manufacturers or charitable foundations copay assistance programs geared towards the assistance of insured patients who face high out-of-pocket costs from copayments, coinsurance, or deductibles.

While highlighting the importance of having the level of support that assures patients the ability to meet their healthcare needs, the authors suggested that PAPs have the impact of minimizing political pressure to focus on costs which would, in turn, lead to greater use of drugs, increase total health care expenditures and company profits. The views of Zafar and Peppercorn (2017) would indicate a win-win situation, but this leads to the question of how impactful this was on the patients who have and are still benefiting from the variation of PAPs available.

The drive to promote a healthy lifestyle among the nation's citizenry intensified over the years. However, the reality is that a large number of the nation's populace is impacted with chronic illnesses, many of which are among the nation's leading cause of death, and which has been termed as the most prevalent and costly health conditions in the United States (Raghupathi & Raghupathi, 2018). The deciding factor in this scenario is the opportunity for individuals to access drugs critical to their ability to control their treatment and stay alive (Raghupathi & Raghupathi, 2018).

In an article updated in 2017, Nichols (2017) noted that among the top 10 leading causes of death in the United States were listed heart disease, cancer, chronic lower respiratory disease, accidents, stroke, Alzheimer's disease, diabetes, influenza, and pneumonia, kidney disease, and suicide. Nichols (2017) presented statistics from 2014 that supported the claim that heart disease is the leading cause of death for both men and women in the United States, accounting for 23.4 percent of total death in the country and cancer following closely in the lead, accounting for 22.5 percent of the death.

The Centers for Disease Control and Prevention (CDC) in 2018 confirmed that chronic diseases - such as heart disease, cancer, diabetes, stroke, and arthritis - are the leading causes of disability and death in New York State and throughout the United States. It was revealed that over 40% of New York adults suffered from a chronic disease and that chronic diseases were responsible for 23% of all hospitalizations in New York State (NY.gov, 2016). Of note was the revelation that chronic diseases caused six out of every ten deaths in New York State. Heart disease and cancer accounted for over half of all deaths in that state. It was further revealed that 90% of the nation's \$3.3 trillion in annual health care expenditures were focused on individuals dealing with chronic and mental health conditions (CDC, 2018a).

It was further revealed that stroke, one of the most common cerebrovascular diseases, the others being transient ischemic attack (TIA), subarachnoid hemorrhage, and vascular dementia, was responsible for the death of over 795,000 people in the United States each year, and interestingly, in 2009, 24 percent of people hospitalized for stroke were younger than 65 years (Nichols, 2017).

Another chronic disease impacting the nation is dementia characterized by declining cognitive functions, and Alzheimer's disease is one type of dementia. From Nichols' (2017) revelation, an estimated 5.4 million Americans have Alzheimer's disease currently, including approximately 200,000 individuals younger than 65 who have younger-onset Alzheimer's. The most alarming revelation, however, was that Alzheimer's disease is one of the most expensive conditions in the nation and that this was the only cause of death in the top 10 that could not currently be cured, prevented, or

slowed. Nichols further noted that in 2015, the cost of Alzheimer's in the United States was estimated at \$226 billion and was expected to cost an estimated \$1.2 trillion (in today's dollars) in 2050 (Nichols, 2017).

Another statistic of note was the revelation that diabetes was the seventh leading cause of death in the United States, accounting for 2.9% and further that this disease could be instrumental in contributing to the development of other serious health complications, including heart disease, blindness, kidney failure, and the need for amputation of the lower extremities or limbs (Nicholas, 2017). In continuing the statistical revelation, Nichols (2017) noted that the ninth leading cause of death in the United States is chronic kidney disease (CKD). Chronic kidney disease reportedly impacts an estimated 10% of adults in the United States - more than 20 million people and is responsible for 1.8% of the death in the country (Nichols, 2017).

Nichols' revelation not only highlighted the problematic situation presented by chronic diseases to the nation's nationals but brought to the fore the costly process of health care (Nichols, 2017). While it is noted that chronic diseases are linked to lifestyle choices and are often preventable, the reality is that the concern is present and desirous of attention (Nichols, 2017). The Centers for Disease Control and Prevention Chronic Kidney Disease Surveillance System, United States (CDC, 2018b) revealed fascinating observations and data that spoke to the comment of Nichols. A diagrammatic representation of statistical data from the CDC Prevention Chronic Kidney Disease Surveillance System between 2015 and 2016 obtained from the National Health and Nutrition Examination Survey (CDC, 2018b) revealed that African Americans,

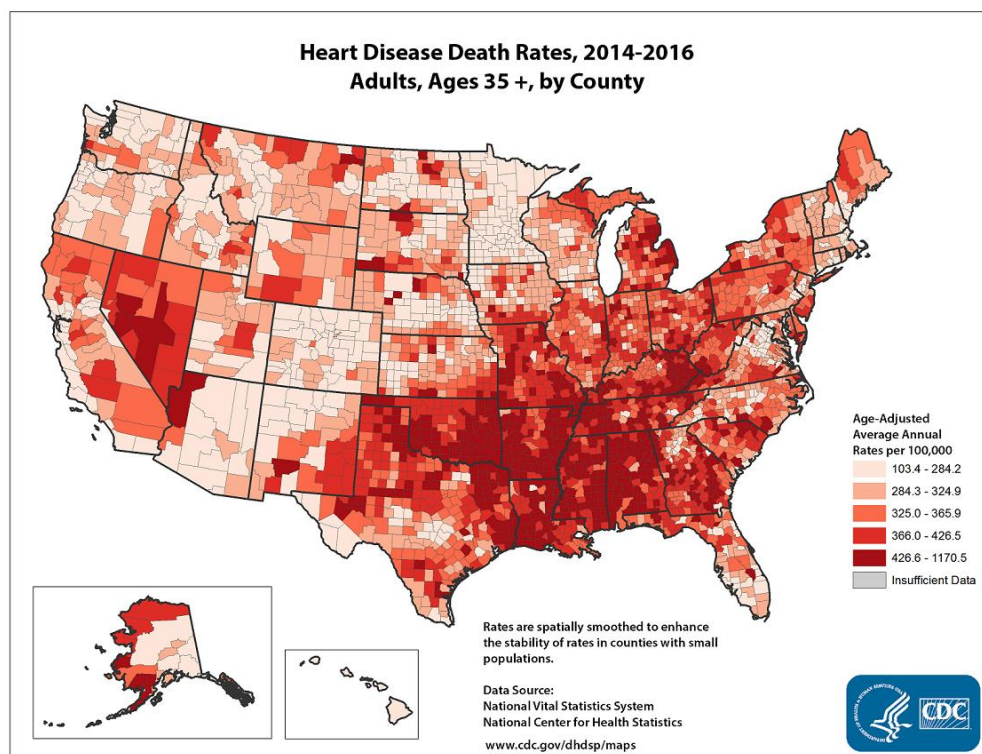
Hispanics, and American Indians are at high risk for developing kidney failure which is attributed to the high rates of diabetes and high blood pressure in these communities (CDC, 2018b).

The CDC further revealed the statistical data relevant to the United States Department of Veterans Affairs (VA) population presenting a diagrammatical representation of individuals impacted by chronic kidney disease. (CDC, 2018b).

Between 2005 and 2017, there was a steady increase in Non-Hispanic White, while the number remains constant among non-Hispanic Black and Hispanic individuals.

Figure 1

Heart Disease Death Rates, 2014-2016



Source: Figure 1 is taken from the CDC's Heart disease facts – Heart Disease in the United States - <https://www.cdc.gov/heartdisease/facts.htm>

The CDC further revealed that chronic diseases have significant health and economic costs in the United States. Figure 1 is a diagrammatic representation of the heart disease rate in 2014-2016. The CDC reported that the cost to the United States, inclusive of health care services, medications, and lost productivity each year is approximately \$200 billion. Over 1.7 million people are diagnosed with cancer. Almost 600,000 dies, making it the second leading cause of death (CDC, 2018a). The data presented by the CDC confirmed Nichols' (2017) report and went further in revealing that the cost of cancer care continues to rise and is expected to reach almost \$174 billion by 2020 (CDC, 2018a).

Financially, it was revealed that every year diabetes costs the United States health care system and employers \$245 billion and statistically impacts over 29 million Americans diagnosed with the disease and 86 million adults with a condition called prediabetes, which puts them at risk for type 2 diabetes (CDC, 2018a). Another impressive necessary piece of statistical data is relevant to Alzheimer's disease, which in 2010, reportedly had an estimated treating cost of the costs of treatment falling between \$159 billion and \$215 billion and are projected to increase to between \$379 billion and \$500 billion annually by the year 2040 (CDC, 2018a).

The statistical data highlighted are relevant to a few of the diseases and illnesses impacting the nation's healthcare processes. As indicated previously, medication cost is a vital ingredient in the cost scenario. The statistical reports presented by the CDC

(2022) indicate that healthcare costs are not diminishing but increasing, particularly for heart disease and, a focus on the implementation of processes and procedures that will ensure that the individuals in need of medication can access these is vital. Choudhry et al. (2009) raised the concern that while drug-company-sponsored PAPs had many beneficial effects, such programs may inhibit cost-effective medication use, thereby impacting public drug spending.

Health Concerns Impacted

Asthma

As the research progress, it is vital to note that the key in the process is understanding the lived experiences of patients, their perception of the healthcare they require or are receiving, and their financial standing or ability to afford the level of care they e. Patel and Wheeler (2014) utilized their research termed “*Physician-patient communication on cost and affordability in asthma care. Who wants to talk about it and who is doing it,*” as a forum to highlight the beneficial effect of understanding patients’ needs in ascertaining their level of treatment and determining an active process that will assure of obtaining drug care required to address their illness at any stage.

The researchers concluded that:

patients are interested in low-cost options and a venue for addressing their concerns with a care provider; therefore, a greater understanding is needed in how to effectively and efficiently integrate these conversations and viable solutions into the delivery of health care (Patel & Wheeler, 2014).

They further indicated that added research was required to explore the collaborative process, resulting in the provision of options that effectively addressed patients' drug needs, which is where PAPs can be seen as impactful.

Multiple Sclerosis

The progression of the years lends itself to advances in healthcare processes, and Cutler (2016), in the research titled "Giving voice to multiple sclerosis: A patient and provider investigation," focused on how pharmaceutical corporations utilized the telephonic and technological healthcare revolution to contract with services providers to aid the process of improving patient compliance and quality of life. In this regard, multiple sclerosis was the illness of focus. However, the reality is that pharmaceutical input is vital in any stage of the healthcare process, particularly in the "evolving telehealth and technologically based healthcare workplace" (Cutler, 2016).

Rheumatology

The subsequent illness of focus is rheumatology. Bailey's (2016) research titled "The pharmaceutical industry's effect on rheumatologists' patterns of care" dealt with the relationship between rheumatologists and the pharmaceutical industry and how this impacts patient care. Noting that minimal information existed on the level of the pharmaceutical industry's influence on rheumatologists and ultimately on the delivery of patient care, Bailey's (2016) research sought to explore this and gain relevant data on medication access and patient financial assistance.

Cancer

Cancer is the next illness of note. There has been considerable concern over the increased number of individuals impacted with this illness and the possibility of the required drug being unaffordable owing to the rising cost of cancer drugs. For Gao, Joseph, Santoro-Levy, Multz, and Gotlieb (2016), the focus was on researching the “Utilization of Pharmaceutical Patient and Prescription Assistance Programs via a Pharmacy Department Patient Assistance Program for Indigent Cancer Patients.”

The researchers revealed that while advances in cancer treatments had netted the result of a consistent decrease in the mortality rates in this country, this has also resulted in substantial increases in the cost of cancer care and to counter the increasing cost patient and prescription assistance programs (PPAPs) have been explored and utilized (Gao et al. 2016). To examine evaluate how PAP impacted service provision to disadvantaged cancer patients at a public hospital, the researchers followed enrolled PAP patients in receipt of chemotherapy assistance from January 2011 to December 31, 2012.

Gao et al. (2016) presented vital statistics, including that, in the period under review, there were progressive increases in the number of patients the program served from 347 in 2011 to 579 in 2012. The researchers noted that this resulted in cost savings of \$1,066,000.00 in 2011 and \$1,715,538.00 in 2012 in medications, giving defined benefits and supporting the relevance of PAPs. The researchers concluded with the revelation that the combination of PPAPs and PAPs provided a safety net that spoke to the need of indigent cancer patients in need of drug assistance (Gao et al., 2016).

The years did not minimize the utilization of PAPs nor the impact on patients' usage. Researchers Mitchell, Muluneh, Patel, and Basch (2018), whose research was titled "Pharmaceutical assistance programs for cancer patients in the era of orally administered chemotherapeutics," focused on the provision of drug assistance even when, as they indicated, the overall usage of PAPs within cancer care delivery was unknown. The situation is more compelling as there is a statistic to support the information that the utilization of PAPs is continually increasing. However, no overall statistic exists to provide light on the lived experiences of participants in these programs.

Mitchell et al. (2018) further revealed that PAPs have been increasing in numbers over the years, that multiple entities, including state governments and large healthcare systems, have established formalized programs to help their patients navigate PAPs. Mitchell et al. (2018) noted that there still was a limitation in knowledge about the full impact of these programs. They also went on to note that barriers to access these programs could be extended to individuals currently participating in the programs hence the need to develop a better understanding of the experience of participants in PAPs.

With the focus still being on cancer, Morel (2018) research titled "Advanced cancer patients' medical decision-making while experiencing financial toxicity" sought to inquire into the impact that financial toxicity (FT) had on advanced cancer patients' lives and their health care decision-making. Morel (2018) defined financial toxicity (FT) as the impact that out-of-pocket (OOP) costs of cancer care have on patients' well-being, leading to lower quality of life, less compliance with prescribed therapy, and poorer outcomes, including increased mortality.

The researcher was interested in understanding the emotional experiences of patients and how these impacted their decision-making process. The intention was to possibly influence the development of strategies to address what was stated as the declines in health outcomes and decreased quality of life for patients with FT (Morel, 2018). A key revelation is that the participants in the research reported that they would decline care if out-of-pocket costs were high, and FT was present.

Diabetes

Another notable illness is diabetes, and Challen, Kelso, Pautler, and Benanti (2016) dealt with the attending challenges in the research titled “Diabetes Outcomes: Comparison of Patient Assistance Programs to 340B Drug Pricing”. The researchers, while indicating that investigation and literature review showed improved health outcomes for patients enrolled in PAPs, also noted that they failed to identify any studies to date that compared the outcomes and adherence of patients receiving medications through PAPs to patients receiving discounted 340B medication pricing (Challen et al., 2016). Therefore, they revealed that the purpose of their study was to determine whether primary care patients who receive insulin from PAPs have an improved change in A1C compared to 340B patients (Challen et al., 2016).

Challen et al. (2016) revealed that their research did not show a marked variation in behaviors. The researchers, however, did suggest that inquiry into patient perspectives and the effect of PAP or 340B pricing on quality of life may provide institutions with additional insight into the benefits of offering such programs to their patients.

Summary and Conclusions

The goal around the aim of effecting change, whether by way of processes or behaviors. A review of existing literature will to some degree, present a point of view that will, in effect, aid the process of effective change in functions vital to policy decisions, attitudes, or perceptions. Chapter 3 focuses on the research method involved in this process.

Raghupathi and Raghupathi (2018) research focused on understanding chronic diseases in the United States while analyzing public health. However, it could be seen that having a better understanding of the experiences of the individuals impacted would provide a more significant benefit in the drive to develop policies and procedures that would positively impact healthcare.

The methodology relevant to this research was outlined in Chapter 3. The research design, the rationale for the selected research design, and the researcher's role as this relates to the effectiveness of the study will also be factored in. Also, I will address instrumentation, recruitment, participation, data collection, analytical data strategies and will discuss trustworthiness which incorporates—credibility, transferability, dependability, and confirmability. The final aspect of Chapter 3 was a discussion on ethical procedures relevant to the research process.

Chapter 3: Research Method

Introduction

In the United States, many patients lack the financial means to pay for their prescription medications, creating poor patient outcomes. This study was conducted to obtain patient perceptions of PAPs to review the nature and structure of PAPs, how they are applied and used in the healthcare delivery process, and the accessibility, need, and relevance of these programs. I compared and contrasted the positives and negatives of PAPs. The findings of this research will impact processes to aid in improving the delivery of healthcare services to members of the populace. In this study, I sought to determine the extent to which the programs are impacted by a limitation or absence of knowledge among patients (see Gordon, 2018).

In this chapter, I explore the methodology relevant to the research and the rationale for the research design selected. I highlight the role of the researcher as it relates to the effectiveness of the study. In this chapter, I also discuss instrumentation, recruitment, participation, data collection, and analytical data strategies. I review trustworthiness, including credibility, transferability, dependability, and confirmability. A discussion on ethical procedures follows, and Chapter 3 ends with a summary and a transition to Chapter 4.

Research Design and Rationale

Qualitative research begins with assumptions and interpretive/theoretical frameworks that inform the study of research problems addressing the meaning individuals or groups ascribe to a social or human problem (Creswell, 2013). According

to Creswell, to study a problem, qualitative researchers use an emerging qualitative approach to inquire. Researchers collect data in a natural setting sensitive to the people and places under study, and data analysis is both inductive and deductive and used to establish patterns or themes (Creswell, 2013).

The use of qualitative research in this inquiry significantly aided my effort to explore the experiences of participants in PAPs. I sought to bring to the fore the reality of these individuals' experiences, which could reflect varied and multiple meanings (see Creswell 2017). I intended to conduct the research at facilities where permission was obtained in an attempt to follow Creswell's suggestion that a natural setting allows for close interaction and the building of reliance on the researcher. The researcher is a crucial instrument in data collection and promotes the sharing of confidences and freely (Creswell, 2013). I approached two facilities in this regard for potential participation (see Appendix A).

The hermeneutic phenomenological approach also gave a measure of substance to the research process related to data collection and analysis. There are two approaches applicable to this research design—descriptive and interpretive—and I explored both. However, I focused on the interpretive role in presenting participants' lived experiences.

Moustafas (1994) indicated that the descriptive phenomenological method requires a researcher to adopt a role directed at disengaging their feelings, experiences, and knowledge via a process called bracketing. Bracketing allows participants to be in control of how their personal experiences are expressed (Moustafas, 1994). In the interpretive or hermeneutic role, a researcher and study participant play an equal role in

co-creation, allowing each to make a unique contribution to that particular individual (Benner, 1994). This role speaks to the assumption that researchers cannot completely disengage from their feelings, experiences, and knowledge.

Role of the Researcher

In a hermeneutic phenomenological study, unique challenges occur as a researcher seeks to ensure their interaction with participants is objective and devoid of bias (Creswell 2013). In phenomenology, a researcher transcends or suspends past knowledge and experience to understand experiences at a deeper level. In this study, the experiences I focused on were the lived experience of individuals who are participants in PAPs.

This research was conducted in an ethical and objective manner. The role of the researcher was vitally important in ensuring that participants were comfortable in volunteering their personal experiences and feelings freely. In this regard, I presented a sincere attitude. Creswell (2013) noted that researchers reveal ethical practices in recognizing the importance of the subjectivity of their lens. Creswell further pointed out that acknowledging the commanding position a researcher has in the research process should lead researchers to construct and conduct their activities in a manner that does not allow for any doubt of their sincerity.

The setting in which interviews are held plays an essential role in participants' comfort. Therefore, I asked participating facilities to assist in recruiting participants and to offer accommodations for interviews. The intention was to have the process span over 4 days in a 2-week period: 2 days for the interviews and 2 days for review and follow-up

interviews. While I did not intend to provide any form of incentive for participation, I did arrange for refreshments to be provided at the interview sessions, which created a relaxed atmosphere allowing for open and frank discussions.

Interview Protocol

I created an interview protocol to ensure the process was conducted seamlessly. The protocol was designed in three stages. The first stage focused on my initial meeting with the staff of the participating facilities, updating them on the purpose of the study, outlining procedures for flyer dissemination, and answering questions. I sought to ensure that everyone involved in this phase of the process was knowledgeable of the research and the goals so they could effectively communicate this to potential participants when disseminating the flyers. I would then call or meet with individuals who indicated willingness to participate in the study. At that point, I would outline the purpose of the study for them again and provide the informed consent form.

After consent was obtained and confidentiality was established, interviews were scheduled and conducted. I served refreshments to allow for an introductory meet-and-greet process geared toward building confidence with participants. The closedown procedure was the third stage and entailed participants being allowed to review the transcript from their interview and add or delete as they saw fit in a follow-up meeting.

I conducted a focus group study of the interview questions (Appendix C) with four friends and family members, including two individuals in the medical field. This study was done to check for validity and understanding and to determine the length of time it would take to answer the questions effectively. Process time ranged from 15 to 20

minutes. I sought suggestions and or recommendations for improvement to lead to a better understanding, but the consensus among the focus group was that no changes were needed as the questions could be easily interpreted and answered.

Research Questions

The following research questions guided this study:

RQ1: What are the lived experiences of individuals who are participants in PAPs?

RQ2: What are the perceived benefits and limitations of PAPs?

RQ3: What are the perceived barriers impacting the utilization of services offered by PAPs?

These questions guided the interview process by focusing on how participants' quality of life has been impacted, if at all, through their participation in PAPs.

Research Methods and Design Procedures

This research project was designed to involve capturing and analyzing qualitative data relevant to the process and application of PAPs. Maxwell (2013) spoke to the interactive and inductive nature of qualitative research, which gives credence to the use of this method in this research process. Rubin and Rubin (2012) advocated for responsive interviewing during data collection; such techniques are beneficial in aiding a researcher's understanding of the situation. In this study, data were collected from interviews of individuals who are participants in PAPs and a review of research conducted previously on PAPs. The research was guided by the hermeneutic phenomenological methodological design, which allowed for an in-depth exploration of the lived experiences of participants in PAPs and their perceptions of the benefits from

such participation. I facilitated the process of discovering through active listening and observing, which assured that the participants willingly and freely outlined their experiences (see Rudestam & Newton, 2015).

Methodology

Population and Sample

For this research, the only requirement for participation was that individuals should be participants in PAPs. There was no intention to target any specific group and the participants were recruited by the participating facilities. Initially, I approached two facilities and discovered that their patients were predominantly African American and Hispanic/Latino individuals (Appendix A). The facilities supplied statistics to support their claim while indicating there was no exclusion, and all individuals were welcome. Flyers were given out, and a protocol for the staff of the institution to disseminate flyers was established to aid the process and ensure that all interested patients were allowed to participate. Selection was made based on the timeliness of the response to the flyers. While the goal was to have 15 participants, I intended that all who responded would be allowed to participate. Sampling size is dependent on the population being researched and the type of research being conducted (Gentles et al., 2015). For hermeneutic phenomenology research, a sampling size could range between 10 and 30 to allow for saturation (Gentles et al., 2015).

Instrumentation

This research process was set to utilize purposeful sampling with the effort being made to recruit individuals who are participants in PAPs and who was in a better position

to give an adequate evaluation of the benefit they received and how they have been impacted by this process (Ravitch & Carl, 2016). Organizations focus on individuals predisposed to be challenged in financing their medical needs, and an effort was made to interview individuals serviced by these organizations. Two such organizations were approached (Appendix A). The distributing flyers were utilized to drive interest (Appendix B), and participants were selected from those responding to the flyers. The input of these organizations was sought in the development of the flyers. I sought to ensure that the research was presented in a manner that was easily understood by the individuals serviced in these locations and which I was seeking to attract.

A semi-structured interview process was developed for utilization in the research. It was guided by a process that allows for follow-up questions and possible counter questions based on the response from the participants (Ravitch & Carl, 2016). The interview will follow a guide (Appendix C) that allows for additional questions based on responses from the respondents and should allow for open expressions of personal feelings, beliefs, and expectations.

Recruitment, Participation, and Data Collection

It was the intention to obtain permission from medical facilities in New York where PAPs are utilized to assist patients in obtaining needed drugs. Contact was made to facilities open to this process, and two facilities have been formally approached (Appendix A). Their participation was dependent however on this research receiving IRB approval (IRB approval 03-18-200394578).

When permission was obtained, the following process was to get a firm commitment from the facilities and then use flyers to gain participation. A protocol for the staff of the Institution to disseminate flyers was developed as a guide for the staff and to ensure that all possible participants are allowed to decide about their participation. Interested individuals will also be encouraged to share the flyers with others interested in sharing their personal experiences, expressions, and possibly their expectations for future improvements in the PAPs.

The interviewing process was utilized to gain a thorough understanding of the participants' personal experiences. Interviews were conducted, and these were audio-taped with the participants' consent. The process of audio-taping the sessions assures validity while safeguarding the data collected. The desire to have 15 participants was set to be conducted on the first responder's basis, and with a reserve, a pool would be kept allowing for responders changing their minds or who failed to show up for their interview.

A consenting process was included where the purpose of the research would be emphasized, and the participants' consent obtained. The interview questions' guide (Appendix C) will be followed. Participants would be assured that their response would be treated with the utmost confidence and that the opportunity would be given to review the transcribed notes. Following a review of the notes, participants would be able either to confirm the notes or make corrections should they desire.

The process allowed for the sharing of transcripts with participants to ensure that they were confident that these were an accurate reproduction of their personal

experiences and allow for the provision of additional or follow-up information. The plan included the setting up of second meetings to allow for review of transcripts and inclusion of additional information participants consider to be relevant.

Data Analysis Plan

The concept of caring is fundamental to healthcare provision, and the ability to access needed services such as medication at little or no cost is vital in this process. Being able to access medication at little or no cost is a benefit of PAPs available throughout the country, and which is structured and applied in manners that, in some regards, appear to be rather complicated (Augstums, 2015). With this in mind, the Partnership for Prescription Assistance was created in April 2005 to aid in educating and empowering patients to address barriers to accessing prescription medicines through these programs (Augstums, 2015). There was no indication that the situation had improved. This research aimed to arrive at a better understanding of what was required to foster improved utilization of PAPs from the participants' perspective.

The analytical process sought to contextualize all participants' experiences and perceptions while summarizing key attributes and ideas, including those that would support the need for changes or adjustments to improve PAPs. Creswell (2014) suggested the process of purposefully selecting participants. Therefore, the effort was made to garner the support of medical facilities with a large patient population who are willing to participate in this research process and who have been able to participate in the programs based on the criteria for participation in PAPs.

The analysis of collected data was vitally important to the presentation of unbiased information. So, Saldana's (2016) recommendation to utilize a process of codifying and categorizing was explored as this allows for systematically arranging data. The codifying and categorizing process could also allow for a balanced interpretation of data and structured explanations (Saldana, 2016). Also, the qualitative process has the appeal of allowing for ongoing analysis, and this assures a better analysis of the data collected.

Creswell (2014) highlighted the benefits of having an analytical process that allows for ongoing analysis of data collected, and QDA Miner Lite, a qualitative data analysis software that allows for effective coding and comparison promptly, was utilized in this process. The assumption was that this software was helpful in this process as it is marketed as effective in analyzing research processes such as interviews and open-ended responses, which incorporates textual data (<https://provalisresearch.com>). Qualitative validity was maintained through researcher checks for accuracy of findings. Qualitative reliability was achieved through the researcher's consistency in the approach utilized in data collection and analysis (Creswell, 2014).

Issues of Trustworthiness

With trustworthiness being central to the standards adhered to in this process, Ravitch & Carl (2016) defining acceptable concepts for assessing rigor was followed as these are effective in the process to conceptualize, engage with and plan for possible aspects of validity that could present themselves (Ravitch & Carl, 2016). Credibility,

transferability, dependability, and confirmability are valued and upheld in this research process.

Credibility

The process also required a concerted effort to implement triangulation strategies, which will allow to have open and prolonged discussions with participants and rechecking for understanding, using peer de-briefers and review to eliminate bias and establish credibility (Ravitch & Carl, 2016).

Transferability

The goal was to gather data applicable to developing an understanding of the participants' lived experiences in the context of their participation in the PAP process. Doing so would require having detailed descriptions of the data collected and the context in which these are collected. However, there was the knowledge that such data could be applicable and transferable to other processes and even future research (Ravitch & Carl, 2016).

Dependability

Ravitch & Carl (2016) indicated that dependability entails that you have a reasoned argument for collecting the data and that the data are consistent with your argument, that is, answering the research questions, which was the central theme of this research.

Confirmability

Staying true to the concept of eliminating bias and presenting a personal view, the effort was made to identify and acknowledge possible biases and prejudices and to

mediate or eliminate these through the structured reflexivity process (Ravitch & Carl, 2016). The interviewing process allowed sharing of transcripts with the participants to elicit comments on accuracy and suggestions and also included the process of self-reflection to ensure that personal opinions are not playing a significant role in the process.

Ethical Procedures

In any endeavor in life, it is vitally important that there be an overall commitment to the upholding of ethical standards, and in the healthcare context, this is vitally necessary. This researcher aimed to develop a relationship with participants that elicited confidence and comfort, leading to open and honest discussions about their lived experiences as participants in PAPs. A relational approach that incorporates a reflective process was the hallmark of this research. A concerted effort was made to adhere to formalized guidelines for ethical research set by Walden and the IRB to gain consent from participants and ensure that confidentiality is maintained (Ravitch & Carl, 2016).

In seeking the support of facilities where the effort was made to gain participatory support, there was full disclosure about the research and how it would be conducted. The research allowed for the inclusion of an interviewing aspect, and as such, consent would also be required to allow for the recording of the interviewing process.

In defining qualitative research, Creswell (2013) noted that the final written report or presentation includes participants' voices, the reflexivity of the researcher, description and interpretation of the problem, and its contribution to the call for change. This was the cornerstone of this research. The process of research, according to

Creswell, is viewed as flowing from philosophical assumptions to the interpretive lens and on to the procedures involved in studying social or human problems. The voice of the participants was represented in the final written report as directed by Creswell (2013).

Summary

The practical nature of having systems in place to meet the needs of individuals in society with like needs cannot be downplayed. However, as stated previously, the process is more impactful if the individuals to benefit from the service are knowledgeable of the service, can access and utilize the service, and, more importantly, can experience a sense of wellbeing.

This research aimed chiefly to ensure that the lived experiences of those individuals identified as needing the service offered by PAPs and who are participants in the programs are highlighted and effort made to ascertain perceived barriers that, if addressed, could lead to impactful social change. The ‘hermeneutic circle’ highlighted by Sloan et al. (2014) speaks to the development of a level of understanding gained through the exploration of the lived experience of individuals, and this is so important particularly for growth and development and is critical in the drive to address aspects of the nation’s healthcare needs effectively. This chapter highlighted the structure set to facilitate an effective research process allowing for open and honest disclosure of participants’ lived experiences. This process was significantly impacted by the pandemic COVID 19 and necessitated drastic changes, highlighted in the ongoing chapters.

Chapter 4: Results

Introduction

The purpose of this qualitative research was to explore participants' lived experiences with PAPs and any perceived barriers in utilizing the benefits of these programs. I used an investigative process, allowing the participants to present their opinions and perceptions of their experiences participating in the program. Promoting healthy lifestyles and fostering accessibility to needed drugs is necessary and can be aided with a better understanding of the lives of individuals who benefit from PAPs. From a patient or health care institution perspective, PAPs have not been adequately evaluated by researchers (Fielder et al., 2011). The process could also help address issues around the inability of individuals to afford medication, for healthcare professionals to have medical resources required to impact the healthcare needs of their patients positively, and for authorities to formulate policies that will govern public health agencies which facilitate PAPs. The research was guided by the following research questions:

RQ1: What are the lived experiences of individuals who are participants in PAPs?

RQ2: What are the perceived benefits and limitations of PAPs?

RQ3: What are the perceived barriers impacting the utilization of the services offered by PAPs?

Hermeneutic research is interpretive and concentrates on historical meanings of experience and their developmental and cumulative effects on individual and social levels. This methodology requires a researcher to be reflective, insightful, sensitive to

language, and constantly open to experience (van Manen, 1997). The goal was that this research would significantly contribute to efforts to understand better the lived experiences of individuals using PAPs. In this chapter, I present the results of the research study. I sought to focus on the lived experiences of 11 individuals who consented to share their experiences of seeking and participating in PAPs. In this chapter, I also describe the setting, the data collection process, the analysis procedures, and a summary of each participant's interview findings.

Setting

After receiving IRB approval, I attempted to recruit participants for this study using several sources. Recruiting participants involved flyer (Appendix A) distribution by facilities in community settings and libraries in New York, Maryland, and Georgia. However, challenges arose as IRB approval was granted right at the start of the COVID-19 pandemic. As states enforced a state of emergency and workers began working from home, no one visited libraries and medical facilities saw fewer patients. Therefore, a great deal of effort was placed on using online methods to distribute flyers to interested individuals. Flyers were emailed to anyone who indicated an interest in participating in the research. These individuals then shared them with friends and family members.

After a participant initiated contact, I confirmed they were appropriate for the study by outlining the reason for the research and enquiring how participants cover the drug required for their treatment. Initially, I experienced difficulty securing participants' consent because of the social distancing requirements of the pandemic. Therefore, I

sought and obtained IRB approval to use an email process to secure consent. I also obtained permission to conduct telephone interviews instead of face-to-face interviews.

The COVID-19 pandemic severely hindered the research process. There were instances in which individuals who agreed to participate became ill and withdrew from the process. Some individuals were too concerned with the well-being of their family members to take the time to participate. A few individuals questioned the nature of the study because of the uncertainty existing at the time, and they were concerned about the impact this could have on their ability to continue receiving health benefits.

Demographics

A summary of the participant demographics is presented in Table 1. The participant sample consisted of two men and nine women and was drawn from four different states. Participants varied in age and employment status, but all shared the need for help to access medication required to treat their illnesses. Diversity showed in the levels of employability, resident location, and type of assistance program used in accessing medication.

Table 1*Participant Demographics*

| Participants | State | Status | Plan |
|--------------|------------|----------|----------------------|
| A | Maryland | Retired | GoodRx |
| B | Maryland | Retired | Script |
| C | Maryland | Disabled | Medicaid |
| D | Georgia | Employed | Unlisted |
| E | Georgia | Retired | Medicare |
| F | Maryland | Retired | Medicaid & GoodRx |
| G | New York | Employed | GoodRx |
| H | New York | Employed | GoodRx |
| I | New York | Employed | Script & GoodRx |
| J | New York | Employed | Castle Hill Pharmacy |
| K | New Jersey | Employed | GoodRx |

Data Collection

In this research study, I investigated the experiences of individuals using various PAPs. I collected data regarding their lived experiences as they sought to obtain prescribed drugs as part of their medical treatment. The first obstacle I encountered concerned the communication process. Flyers were distributed by the facility that initially agreed to do so, but fewer individuals were visiting the facility, and services were restricted because of the COVID-19 pandemic. However, staff did their best and passed out flyers to patients who did visit the facility. Flyers were also posted on community bulletin boards and were distributed at libraries, churches, and medical facilities. Outreach was extended to New York, New Jersey, Maryland, and Georgia. However, the first response came through a verbal connection through a close acquaintance of mine. With the constraints of COVID 19, many participants came through verbal communication from one person to the next.

I shared the informed consent form via mail and email. However, the postal service was impacted, and many willing participants experienced challenges with technology and formulating a response via email. We used the mail in some instances however, because of COVID 19, the process took longer. I sought the input of the IRB, which led to approval for participants to receive the consent form via email and respond, “I consent.” The interviewing process progressed slowly; I focused on participant’s experiences related to the study topic. However, I followed any areas participants wished to explore.

Aid of Rev Call Recorder, which allowed for phone recording and verbatim transcription. I explained the informed consent at the beginning of the interview and obtained participants consent to record. Interviews spanned an average of 10 minutes. I shared transcripts with those individuals who indicated a desire to review them, but many of the interviewees opted not to receive a transcription of the interview.

The restrictions relating to COVID-19 pandemic impacted the interview process, which lasted 9 months between July 2020 and April 2021. In some instances, individuals first refused to participate but months later inquired about the research and decided to participate. One possible participant first agreed to be interviewed in May 2020 but became sick and efforts to contact her were futile. In July 2021, while analyzing the interviews, she approached me wishing to participate. I scheduled a time to meet with her, but the process was interrupted because of responsibilities she needed to address.

Participants from New York were particularly wary of participating but consented to be interviewed in April 2021. In December 2020, the owner/operator of an assisted

living facility offered to speak to the facility's residents upon hearing of the difficulty I was encountering attracting participants. I outlined the flyer and the consent process for the owner/operator. A number of the residents immediately consented to participate; however, the facility was locked down as workers and residents became infected with COVID-19. Out of concern for the welfare of workers and residents, participation in the research was suspended.

Data Analysis

Working with the hermeneutic spiral as a process of understanding required an awareness of interpretive preunderstanding. The aim of participant selection in phenomenological and hermeneutic phenomenological research is to select participants who have lived experience that is the focus of the study and who are willing to talk about their knowledge to enhance possibilities of rich and unique stories of the particular experience (van Manen, 1997). In focusing on affordability, diversity showed a marked difference between those employed and those retired and more so for the individual who was disabled. The analytical process using QDA Miner Lite (2019) software was informative and contributed positively to understanding the lived experiences of individuals in the PAP process. This process allowed the transcripts to be reviewed in totality to give an overall impression of the data. Units of meaning were formed from codes organized, resulting in central themes being identified by questioning the units and how these answered the study purpose of ascertaining the lived experiences of persons obtaining pharmaceutical patient assistance. Identifying patterns in coding and relationships between assigned codes and other categorical properties proved helpful.

In this research, I considered the thematic analysis method developed by Braun and Clarke (2006) for research in psychology. Allowing for both the inductive and deductive analytical approaches, the process enables a researcher first to review the data collected in totality to become familiar with the data. This leads up to coding, which is then combined, generating themes by the patterns identified. The review of identified themes is conducted ongoing as comparisons are made and themes defined and named. The final process involves writing up the analysis of the data, giving results explaining the themes.

The aim of participant selection in hermeneutic phenomenological research is to select participants who have lived experience that is the focus of the study and who are willing to talk about their experiences. In this regard, the process consisted of individuals who heard about the research and wanted to share their experiences of living through seeking and obtaining assistance in funding for their medication. For this research, the goal was 15 participants to be representative of the entire source for studies of this type. However, the extenuating circumstances of COVID-19 resulted in difficulty obtaining participants. When 11 participants had been interviewed, the analytical process was conducted.

Evidence of Trustworthiness

Vital to the research process was the need to have ethical matters at the forefront throughout the research. Hence the process of ensuring that before each interview, written consent was signed with a guarantee of confidentiality for the information given during the interview.

As outlined previously, with trustworthiness being central to the standards adhered to in this process, Ravitch & Carl (2016) defining acceptable concepts for assessing rigor was followed as these are effective in the process to conceptualize, engage with and plan for possible aspects of validity which could present themselves (Ravitch & Carl, 2016). Credibility, transferability, dependability, and confirmability are valued and upheld in this research process.

Credibility

A concerted effort was made to implement triangulation strategies that included having open discussions with participants and rechecking for understanding, and using peer de-briefers, fellow researchers, and review to eliminate bias and establish credibility (Ravitch & Carl, 2016). The four individuals who agreed to review their transcripts followed up by sharing their impression of the interview and how their experiences and opinions were recorded and reported.

Transferability

The goal was to gather data applicable to developing an understanding of the participants' lived experiences in the context of their participation in the PAP process. To do so it is required to have detailed descriptions of the data collected and the context in which these are managed. Still, there was also the knowledge that such data could be applicable and transferable to other processes and even future research (Ravitch & Carl, 2016).

Dependability

Ravitch & Carl (2016) indicated that dependability entails having a reasoned argument for collecting the data and that the data are consistent with your statement, answering the research questions. This was the central theme of this research.

Confirmability

Staying true to the concept of eliminating bias and presenting a personal view, the effort was made to identify and acknowledge possible biases and prejudices and to mediate or eliminate these through the structured reflexivity process (Ravitch & Carl, 2016). The interviewing process will include sharing transcripts with the participants to elicit comments on accuracy and suggestions. It will also have self-reflection to ensure that personal opinions are not playing a significant role in the process.

Results

Assessing the lived experiences of individuals benefiting from PAPs highlighted several relevant to the process. Of note is the method taken by many states to actively support their citizens through state funding of their drug purchase, and while this is not unusual, it tells of the consideration placed into the process. It also highlighted the reality that the process does require improvement from the perspective of the participants. For Maryland, it is Medicaid, and for Georgia, it is Medicare. The three questions were categorized as lived experiences (RQ1), benefits and limitations (RQ2), and perceived barriers (RQ3). From analysis of the data, 13 codes emerged: (a) concerns, (b) COVID-19, (c) experience, (d) illness, (e) knowledge, (f) program, (g) state, (h) status and

position, (i) aid (j) finance, (k) treatment, (l) future, (m) improvement. These codes led to three overriding themes: (a) affordability, (b) accessibility, and (c) accountability.

Lived experience was covered in RQ1 and encompassed concerns relevant to the future of the program they were enrolled in; participants' experiences and what led to the need to be in the program; the nature of their illness; knowledge spoke to the information participants have on the program be discussed; what program they were enrolled in and the state where participant resided speaking to demographics and the possible impact COVID 19. RQ2 was focused on benefits and limitations and examined how financing impacted their access to medication and treatment. RQ3 was used to identify perceived barriers and focused on the future and required improvement - explored the future of the program and their concerns about being able to use the program in the future and what improvement can be made to eliminate perceived barriers.

Lived Experiences of Participants in PAPs

In exploring the participants' lived experiences, it was necessary to overview the state they reside in and explore their work status and positions. Only 9 participants outright shared their status and position, and all willingly indicated where they resided and the nature of their illness, which required medication treatment. They all willingly volunteered their participation in programs that aided their ability to afford their medication financially, but one participant was reluctant to name the program that afforded this assistance. Of the respondents, 10 were very forthcoming of their experience in dealing with their experience of living with an illness that required medication that was pricy and fast progressing beyond their reach. While being relieved

that they discovered an affordable option, only six of these individuals were fully knowledgeable about the program they were on, and seven indicated the concern of not knowing the length and extent to which the coverage they currently have would continue. This significantly impacted their daily lives. The onset of the COVID 19 pandemic impacted the ability to secure willing participants in the research, but only three of the participants interviewed highlighted a concern over the present and possible future impact on their lives or the lives of others. It was noted that Georgia and Maryland had great focus on providing governmental assistance in securing medication for retirees. It was also noted that GoodRx was extensive and was chiefly promoted by pharmacists in many instances.

Perceived Benefits and Limitations of PAPs

Of the 11 participants, ten participants spoke about how obtaining assistance in accessing needed medication greatly aided their treatment process. Some individuals highlighted how they first considered not obtaining the medication because of the cost factor. Seven participants focused on how their concerns led to them either research the process themselves or how relieved they were when the availability of assistance was brought to their attention. There were limitations as, in some instances, their medication had to be adjusted to be accommodated in the program they were in. One individual's participation in PAPs was discontinued because this was being done with their health insurance. Their insurance decided to discontinue support of their medication, which increased by the cost factor. For many, the benefits and limitations are not perceived but real.

Perceived Barriers Impacting Use of Services Offered by PAPs

In exploring the perceived barriers impacting the utilization of the services offered by PAPs, there was a disconnect between physicians and pharmacists. In many instances, participants were alerted to the services by the pharmacists. One participant indicated that she was so concerned that she took the matter to her superiors at her job, seeking to have them make a valued input in securing assistance for employees who faced high medication costs not covered by their health insurance. There is also concern among approximately 72% of the individuals interviewed over the lack of knowledge among the general public about the availability of pharmaceutical assistance. One individual took this further in making it her responsibility to alert individuals to this assistance.

Affordability, Accessibility, and Accountability

The themes emerging from the interviews conducted are affordability, accessibility, and accountability. The financial aspect was key and significantly impacted whether to undergo the treatment recommended by their physicians or to live without this treatment. Accessing an aide allowed for a viable option, but the ability to access and participate in the option was also called into question. Questions arose about whose responsibility it was to ensure that the option was readily available and communicated to those most needing assistance.

Affordability

The importance of affordability cannot be understated and leads to the relevance of the GoodRx program. As seen from the interviews, each individual had a different opinion of the process, enrollment, and medication impact.

A visit to the GoodRx site indicates that this is a prescription assistance program that utilizes discount coupons to offer a reduction in prescription drugs. The site indicates that the program is open to everyone irrespective of whether they have insurance or not. It could be combined with the insurance to lower the individual's copay but would not be applied towards the deductible (Goodrx.com). The GoodRx Prescription Discount Card was being promoted, always being 100% free for everyone, and individuals did not need to register or sign up to use GoodRx coupons. The site advised that if individuals wanted to make saving even more manageable, they should get the app to search medications, compare prices, and find current coupons on the go. The program was promoted as being able to allow individuals to save approximately 80% at over 70,000 pharmacies in all 50 states, Puerto Rico, and the United States Virgin Islands.

The situation is viewed differently by those interviewed however, some became aware of the program over the media while others were introduced to the program by a pharmacist. While the site indicated that there was no associated cost for the card, one interviewee highlighted that the use had become so great that the program was now offering levels of membership with a cost factor being associated with greater benefit and a higher level of membership.

Script is the other benefactor highlighted and is, in fact, ScriptSave WellRx. The program's site offers a prescription savings card which allows for the provision of prescription discount prices on medications; there is also an application that could be utilized instead of the card (Wellrx.com).

Accessibility

Knowledge plays a significant role in the ability to access aid and living in a time of uncertainty where individuals were so concerned about their well-being from a financial perspective, the situation brought about by COVID-19 only served to further compound the level of uncertainty being experienced. A number of the individuals interviewed had concerns over the medication accessibility, and one shared that she had and still is using her capacity to share with patients and individuals the resources available to them that allowed for obtaining their medication at a reduced cost.

Accountability

Who should be held accountable in this regard? One of the interviewees is a director of a primary care program. She spoke to the effort she extended to ensure that she directed patients to the pharmacy she discovered that provided a PAP program that was very beneficial? Having participated in the program herself, she was ideally placed to recommend the service. However, she saw promotion as a challenge to address—sharing information via flyers or websites promoting their service is ideal.

Summary

A summary of the participant demographics is presented in Table 1. However, the key to this is the revelation that there is a great need for financial assistance in accessing

medication needed to aid their healthcare treatment across the country, specifically from New York to Georgia. The lived experience of individuals being faced with choices relevant to their healthcare treatment highlights concerns for their future and the future of others, whether working or retired, for there to be an improvement in how information relevant to PAPs is shared. The challenges faced in identifying, locating and interviewing participants for this research have been outlined but this did not prevent the completion of the process. The participants, while being reserved in some instances provided data relevant to the research process. The process was further aided by the analytical process using QDA Miner Lite (2019) software, which was highly informative as effort was made to come to a clear understanding of the lived experiences of individuals in the PAP process.

The process of analyzing the data included the identification of patterns in coding and relationships between assigned codes and other categorical properties. As outlined previously, analysis of the data led to the emergence of 13 codes which led to three themes: (a) affordability, (b) accessibility, and (c) accountability. The result highlighted the role that finances, or lack thereof played in the reasons individuals participated in PAPs and spoke to the concerns displayed as they questioned the future of the programs and the ability to access medication and treatment relevant to their respective health concerns. In Chapter 5, I will review the analysis, discuss key interpretation of the results of the research and offer recommendations.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

In this chapter, I emphasized the purpose and nature of the research and summarized the key findings of the study. I will also present an analyzes and key interpretation of the results of the research in the context of the theoretical and conceptual framework as deemed appropriate and describes the limitations to trustworthiness that appeared during the research process. Recommendations are offered that may be useful for further research, particularly to strengthen the results and alleviate the weaknesses of this research. I continued the process with an explanation for positive social change. Also presented is a description of the methodological and theoretical implications and as well as presented recommendations for professional practice going forward. The process is completed with a concluding message that displays the main essence of the study.

Interpretation of the Findings

As previously noted in Chapter 2, the health care utilization model was the basis for formulating a level of understanding between researcher and participants, which would allow for insightful and in-depth assessments of participants' lived experiences. The health care utilization model framework with its core focus of predisposing factors, enabling factors and need factors presented by Andersen and Newman (1995) offered effective guidelines by which an assessment could be made of the data collected in the research (Andersen, 1995).

Andersen and Newman's framework for health services utilization has as its core focus three characteristics that drive the utilization of health services: (a) predisposing factors, (b) enabling factors, and (c) need factors (Andersen, 1995). Armed with the ideas presented by the authors, the conviction that understanding the lived experiences of patients would aid the process of improving healthcare delivery in this country grew. To reiterate Andersen's and Newman's perspectives, the enabling factors are the logistical aspects of obtaining care and enabling factors to start with consideration for the family, which is personal and extends to the community, which is inclusive of health personnel and facilities, waiting time, and possible additions such as genetic factors and psychological characteristics. Finally, need factors to encompass the most immediate cause of health service use, from functional and health problems that generate the need for healthcare services to the perception of the importance and magnitude of seeking professional help (Andersen, 1995). Further, the authors noted that need factors point to an observation that individuals make decisions with consideration and are possibly influenced by controllable situations but in many instances are impacted by external forces or possibilities. This process manifested itself throughout this research.

Limitations of the Study

Chapter 1 highlighted the reality that the phenomenological study is geared towards understanding participants' lived experiences but that there may be limitations associated with the method utilized. The research method included an in-depth interview process with questions geared towards preventing bias while eliciting the free flow of information from the participants (Appendix C); it was highlighted that information

might not be as forthcoming or relevant to the study being conducted and also that the sample size could also present some limitation as there may be difficulty in gaining full participation and representation at the locations selected as research centers. Gaining involvement of the targeted research centers, however, was not the problem posed. The real threat came by way of COVID 19. Individuals were concerned about addressing health issues that may occur with the onset of the pandemic and how states elected to address the issue.

To eliminate the possibility of limitations mentioned, I focused on developing a level of trust which allowed for the free flow of information, effectively synthesizing and interpreting findings, and objectively reporting the results (Janesick, 2016). However, other situations played an active role, including the fear that participants' involvement could impact the benefits received through participation in PAPs. To the extent that one participant, while willing to be in the research, would not reveal the name of the program enrolled in and, when pressed, pretended to have forgotten the name.

Recommendations

This research study was conducted to contribute to help fill the gap surrounding information related to participants' lived experiences in PAPs. While the health events in existence relevant to COVID 19 severely hampered the process of gaining participants, the participant's willingness to be actively involved in the process contributed in a meaningful manner to moving a step closer to understanding the participants' experiences. I embarked on this study to fill the gap concerning the lived experience of participants in PAPs. The 11 participants readily shared their information, although there

was some reluctance to participate in the research. Such hesitation merits attention as there is the concern that sharing relevant information could negatively impact their ability to obtain assistance going forward. One participant is still reluctant to disclose the name of the PAP program enrolled in. Future investigators could be more impactful and make their research more meaningful if the process is conducted once concerns over the COVID 19 pandemic subsides and normalcy is returned. Future researchers could also add to this research by exploring the experiences of those individuals who could not participate in PAPs and obtain any form of support in acquiring medication required to treat their health concerns effectively.

Implications

While this research was significantly impacted by COVID 19 and the ability to access individuals willing to share their experiences was difficult, researchers can still use this current research and its potential to establish a social change in many regards. Having a method of communication that seeks to educate both those in the healthcare profession and members of the populace about the level of assistance available to ensure that individuals can effectively address their healthcare needs is critical. Such knowledge could also lead to a change in behavior and attitude related to sharing their experiences and openly communicating what they believe could positively impact their personal and lived experiences. For change to be effective, active participation is required. Knowing the lived experiences and the individuals' perceptions could strengthen the awareness of policymakers, stakeholders, and the community at large in the drive to have a healthy population.

In Chapter 3, it was outlined that Patel and Wheeler (2014) utilized their research termed “Physician-patient communication on cost and affordability in asthma care. Who wants to talk about it and who is doing it,” as a forum to highlight the beneficial effect of understanding patients’ needs in ascertaining their level of treatment and determining an active process that will assure of obtaining drug care required to address their illness at any stage. The researchers concluded that “patients are interested in low-cost options and a venue for addressing their concerns with a care provider; therefore, a greater understanding is needed in how to effectively and efficiently integrate these conversations and viable solutions into the delivery of health care” (Patel & Wheeler, 2014). They further indicated that added research was required to explore the collaborative process, resulting in the provision of options that effectively address patients’ drug needs, which is where PAPs can be seen as impactful. A visit to the Asthma & Allergy Foundation of America webpage (aafa.org) saw the provision of a list of organizations they indicated would provide assistance in this regard. It was also highlighted that many pharmaceutical companies, state programs, and nonprofits have drug assistance programs (PAPs) that offer free or low-cost medicines if you do not have insurance or are underinsured and cannot afford your medicine.

Programs and program benefits vary. Depending on insurance and medicine, individuals may be eligible for help to reduce their medicine copay. The organization further indicated that individuals might qualify for free medication if they did not have health insurance, did not have enough health insurance to cover their medicines, or met specific criteria. The organization is listed as a not-for-profit organization founded in

1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. This is all very enlightening and informative, but in this research, four states were covered, and at no time did any of the participants reference being able to communicate with any organization that took the time to investigate their lived experience or sought to fully understand their experiences as they cope with needing medication that they may not be able to fund.

In 2020 Hood, J. C. (2020) reviewed the process of Independent Charity Patient Assistance Programs (PAPs), which are primarily funded by the pharmaceutical industry, and which he reportedly indicated dispense billions of dollars of aid annually to help financially vulnerable patients afford their prescription drugs (Hood, 2020). While revealing the beneficial nature of these programs, the focus was on the continued scrutiny the charitable entities and their drug company donors faced due to the Anti-Kickback Statute (AKS). The review titled “are good deeds being punished? independent charity patient assistance programs and the anti-kickback statute” highlighted those charitable entities offer a financial refuge for ailing Medicare beneficiaries struggling to afford their prescription drugs. However, federal prosecutors, qui tam relators, and regulators have increasingly scrutinized the relations between the pharmaceutical industry and Independent Charity PAPs. This scrutiny has exposed uncertainty about the applicability of the AKS to Independent Charity PAPs and their donors. These charitable entities and their drug company donors have recently faced mounting legal scrutiny for allegedly funneling illegal kickbacks to Medicare beneficiaries. To preserve the safety net assistance provided by Independent Charity PAPs and guard against the risk that misuse

of these entities will lead to waste and abuse of federal health insurance program resources, it may be necessary for the OIG to promulgate an AKS regulatory safe harbor for Independent Charity PAPs and their donors.

Throughout this research process, it has been maintained that PAPs are relevant and offer a sense of safety that is needed with so many of the nation's populace requiring prescription medication to address health concerns effectively. The applicability of the programs, irrespective of who provides the programs, and the relevance to the lived experience of the persons these programs are intended to service remains in question.

Conclusions

In the interest of holding to the research process and the fact that the study was inspired by the phenomenological interest about lived experiences of individuals and the hermeneutic interpretative understanding of the meaning attached to these experiences, there follows a detailed look at the information gained from the research.

A weighted point of interest throughout the process was the revelation by Choudhry et al. (2009) previously reported that one-third of Americans of all ages and two-thirds of the elderly reported difficulty paying for medications and that a quarter of the patients had not filled a prescription or have reduced a prescribed dosage because of its high out-of-pocket cost (Choudhry et al., 2009). This was arrived at during their research which delved into the benefits of patient assistance programs offered by pharmaceutical manufacturers questioning whether these programs were the actual "safety net for millions of needy Americans who were not eligible for comprehensive

assistance programs and were unable to afford their medications.” This research sought to arrive at a better understanding of these individuals’ lived experiences, given the thought process that there was a poor understanding of how beneficial PAPs are primarily for the individuals they were meant to offer a safety net. The interpretation of the findings will speak to this thought process.

2020 was an eventful year in the lives of many individuals, and key in this regard is the impact on this research process which had to be reconfigured due to the COVID 19 events. COVID 19 timeline presented some challenges to the time limit of this research. The CNN, in its timeline, indicated that January 1, 2020, commenced with the Chinese Health authorities being concerned over the discovery that a virus of concern may be connected to wild animals sold at the Huanan Seafood Wholesale Market. By January 7, they confirmed that they had identified this virus as a novel coronavirus initially named 2019-nCoV by WHO (cnn.com). WHO, CNN, and the NY Times remain consistent in their timeline of reporting incidents relevant to the discovery and naming of this unknown pneumonia, with the first case being reported in the US on January 21, 2020. On January 30, 2020, WHO determined that the outbreak constituted a Public Health Emergency of International Concern (PHEIC) but WHO did not officially name the virus COVID 19 until February 11, 2020 (cnn.com).

With the knowledge that each state in the United States was experiencing a different level of concern about the existence of the COVID-19 virus, the arrival of March came with states instituting a state of emergency – for Georgia; it was March 2;

Maryland was March 5; New York it was March 7, and for New Jersey, it was March 9, 2020.

On March 11 – WHO declared COVID-19 a pandemic, and on March 13, President Trump declared COVID-19 a national emergency (ajmc.com). On March 15, 2020, the Centers for Disease Control and Prevention advised no gatherings of 50 or more people in the United States over the next eight weeks. The recommendation included weddings, festivals, parades, concerts, sporting events, and conferences. The following day, Mr. Trump advised citizens to avoid groups of more than 10. This saw New York City's public schools' system, the nation's largest with 1.1 million students, announcing that it would close (nytime.com).

While this was taking place, the request for research approval was before the IRB, and Approval was received on March 18, 2020. However, by this time, many states were under various State of Emergency with the libraries and many health facilities operating at reduced capacity. I first encountered difficulty with the distribution process of flyers, and procedures for interviews were also impacted as well as obtaining consent from those individuals who were willing to participate in the interviewing process. I returned to the IRB, and on June 17, 2020, I received approval for my request to utilize alternative data collection formats. The interviewing process experienced challenges in conducting interviews, and on March 17, 2021, I received permission to extend my data collection process.

This study intended to investigate lived experiences of persons participating in PAPs and ascertain the social implications to be impacted by gaining a better

understanding of this process. Hermeneutic phenomenology, by its very name, is an interdisciplinary approach that takes from across disciplines and has a compelling yet distinct set of principles that are essentially targeted to uncover a better understanding of a phenomenon.

As a school of philosophy, phenomenology is growing in recognition, and this is undoubtedly influencing how individuals view the exploration of a phenomenon. In this research, the hermeneutic phenomenology, which is an interdisciplinary approach, allowed for the utilization of a distinct set of principles that are facilitated and open the process leading to a better understanding of the lived experience of individuals participating in PAPs. The process was impacted by COVID 19 and its attending problems, but this research spoke to a more urgent need to be fully conversant with the requirements of individuals as this relates to their ability to fund medication needs. Having to decide whether or not you are going to obtain the medication needed to treat an illness because of financial concerns and in one interviewee's case, electing to not take medicine for this exact reason, is concerning as the nation strive to ensure that its populace health needs are effectively address.

References

- Andersen, R. M. (1995). Revisiting the behavioral model and access to medical care: Does it matter? *Journal of Health and Social Behavior*, 36(1), 1–10.
<https://doi.org/10.2307/2137284>
- Andersen, R., & Newman, J. F. (2005). Societal and individual determinants of medical care utilization in the United States. *Milbank Quarterly*, 83(4).
<https://doi.org/10.1111/j.1468-0009.2005.00428.x>
- Asthma and Allergy Foundation of America. (2021) Drug assistance programs.
<https://www.aafa.org/patient-assistance-medicine-drug-programs>
- Augstums, I. (2015). The partnership for prescription assistance: A history of caring. *PhRMA*. <https://catalyst.phrma.org/the-partnership-for-prescription-assistance-a-history-of-caring>
- Babitsch, B., Gohl, D., & von Lengerke, T. (2012). Re-revisiting Andersen’s behavioral model of health services use: A systematic review of studies from 1998–2011. *GMS Psycho-Social-Medicine*, 9, Doc11. <http://doi.org/10.3205/psm000089>
- Bailey, F. (2016). *The pharmaceutical industry’s effect on rheumatologists’ patterns of care* [Doctoral dissertation, Walden University]. ScholarWorks.
<https://scholarworks.waldenu.edu/dissertations/2063/>
- Ball, J., & Mackert, M. (2013). Pharmaceutical advertising practitioners’ approach to trust and emotion. *International Journal of Pharmaceutical and Healthcare Marketing*, 7(3), 244–264. <https://doi.org/10.1108/IJPHM-04-2013-0021>
- Beard, A. J. (2008). *Cost as a feature of medication management communication in*

medical visits [Doctoral dissertation, Eshelman School of Pharmacy]. University of North Carolina Digital Repository.

<https://cdr.lib.unc.edu/concern/dissertations/xg94hp755?locale=en>

Benner, P. A. (1994). *Interpretive phenomenology: Embodiment, caring, and ethics in health and illness*. Sage Publications.

Börjesson, L. (2015). Grey literature – grey sources? Nuancing the view on professional documentation. *Journal of Documentation*, 71(6), 1158–1182.

<https://doi.org/10.1108/JD-09-2014-0137>

Brody, H., & Light, D. W. (2011). The inverse benefit law: How drug marketing undermines patient safety and public health. *American Journal of Public Health*, 101(3), 399–404. <https://doi.org/10.2105/ajph.2010.199844>

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77–101.

<https://doi.org/10.1191/1478088706qp063oa>

Cauchi, R., Hanson, K., & Landess, S. (2016). State pharmaceutical assistance programs. National Conference of State Legislatures.

<http://www.ncsl.org/research/health/state-pharmaceutical-assistance-programs.aspx>

Centers for Disease Control and Prevention. (2018a). Health and economic costs of chronic diseases. <https://www.cdc.gov/chronicdisease/about/costs/index.htm>

Centers for Disease Control and Prevention . (2018b). Chronic kidney disease surveillance system—United States - Crude prevalence of CKD stages 1–4 by

race/ethnicity 2015–2016, National Health and Nutrition Examination Survey.

<https://nccd.cdc.gov/CKD/detail.aspx?QNum=Q9&Strat=Race%2fEthnicity>

Centers for Disease Control and Prevention. (2022). Heart disease fact sheet.

<https://www.cdc.gov/heartdisease/facts.htm>

Centers for Medicare and Medicaid Services. (n.d.) Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

[https://www.cms.gov/Medicare/Prescription-Drug-](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData)

[Coverage/PrescriptionDrugCovGenIn/PAPData](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData)

Challen, L., Kelso, C., Pautler, H. M., & Benanti, G. (n.d.). Diabetes outcomes:

Comparison of patient assistance programs to 340B drug pricing. *Journal of Health Care for the Poor and Underserved*, 27(3), 1192–1198.

<https://doi.org/10.1353/hpu.2016.0108>

Choudhry, N., Lee, J., Agnew-Blais, J., Corcoran, C., & Shrank, W. (2009). Drug company-sponsored patient assistance programs: a viable safety net? *Health Affairs*, 28(3), 827–834. <https://doi.org/10.1377/hlthaff.28.3.827>

Chu, C., Lal, L.S., Felder, T. M. & Rosenau, P. (2012). Evaluation of patient assistance program eligibility and availability for top 200 brand name and generic drugs in the United States. *Innovations in Pharmacy*, 3(1): Article 71.

<http://pubs.lib.umn.edu/innovations/vol3/iss1/8>

Clarkson, E. B., Linley, A., Frank, J. S., & Selleck, C. S. (2016). The Implementation of a Patient Assistance Program in a Free Clinic Setting: A Case Report. *Journal of health care for the poor and underserved*, 27(3), 1183–1191.

<https://doi.org/10.1353/hpu.2016.0148>

Clay P, Vaught E, Glaros A, Mangum S, Hansen D, Lindsey C. (2007). Costs to Physician Offices of Providing Medications to Medically Indigent Patients via Pharmaceutical Manufacturer Prescription Assistance Programs. *Journal of Managed Care Pharmacy*, 13(6). doi: 10.18553/jmcp.2007.13.6.506.

<https://digitalcommons.kansascity.edu/studentpub/422/>

CNN Health. (2021). Covid-19 pandemic timeline fast facts.

<https://www.cnn.com/2021/08/09/health/covid-19-pandemic-timeline-fast-facts/index.html>

Creswell, J. W. (2013). *Qualitative inquiry & research design. Choosing among five approaches*. Thousand Oaks, SAGE Publications.

Creswell, J. W. (2014). *Research design: Qualitative, quantitative, and mixed methods approaches*. Thousand Oaks, SAGE Publications.

Creswell, J. W., & Poth, C. N. (2017). *Qualitative inquiry and research design: Choosing among five approaches*. Thousand Oaks, SAGE Publications.

Cutler, A. J. (2016). *Giving voice to multiple sclerosis: A patient and provider investigation*

https://digital.library.unt.edu/ark:/67531/metadc955054/m2/1/high_res_d/CUTLER-THESIS-2016.pdf

Dodgson, J. E. (2017). About research: Qualitative methodologies. *Journal Of Human Lactation*, 33(2), 355-358. doi:10.1177/0890334417698693

Felder, T. M. (2010). *Exploring the use of pharmaceutical patient assistance programs as*

an option to improve access to and affordability of prescription drugs. Texas

Medical Center Dissertations (via ProQuest). AAI3398971

<https://digitalcommons.library.tmc.edu/dissertations/AAI3398971>

Felder, T., Palmer, N., Lal, L., & Mullen, P. (2011). What is the evidence for pharmaceutical patient assistance programs (PAPs)? A systematic review. *Journal of Health Care for the Poor and Underserved*, 22(1), 24–49.

<https://pubmed.ncbi.nlm.nih.gov/21317504/#:~:text=https%3A//doi.org/10.1353/hpu.2011.0003>

Ganguli, A., Clewell, J., & Shillington, A. (2016). The impact of patient support programs on adherence, clinical, humanistic, and economic patient outcomes: a targeted systematic review. *Patient Preference and Adherence*, 2016(1), 711-725

Gao, L., Joseph, J., Santoro-Levy, M., Multz, A. S., & Gotlieb, V. K. (2016). Utilization of Pharmaceutical Patient and Prescription Assistance Programs via a Pharmacy Department Patient Assistance Program for Indigent Cancer Patients. *Hospital pharmacy*, 51(7), 572–576. <https://doi.org/10.1310/hpj5107-572>

Gentles, S. J., Charles, C., Ploeg, J., & McKibbin, K. A. (2015). Sampling in qualitative research: Insights from an Overview of the Methods Literature. *The Qualitative Report*, 20(11), 1772-1789. Retrieved from

<http://nsuworks.nova.edu/tqr/vol20/iss11/5>

GoodRx (2023). Free Rx Coupons & Savings

<https://www.goodrx.com/official/site>

Gordon, S. (2018) A young life lost to high insulin prices. Retrieved from

<https://consumer.healthday.com/diabetes-information-10/insulin-news-414/a-young-life-lost-to-high-insulin-prices-734118.html>

Happe, L. E., & Walker, D. (2013). Using grey literature to prepare pharmacy students for an evolving healthcare delivery system. *American journal of pharmaceutical education*, 77(4), 82. <https://doi.org/10.5688/ajpe77482>

Hood, J.C. (2020). Are Good Deeds Being Published? Independent Charity Patient Assistance Programs and the Anti-Kickback Statute. *Florida Law Review*, 72(3), 639-672. http://www.floridalawreview.com/wp-content/uploads/4_Hood_BOOK15437.pdf

Howard, D. H. (2014). Drug companies' patient-assistance programs - Helping patients or profits? *The New England Journal Of Medicine*, 2(97).
doi:10.1056/NEJMp1401658

Huebner, J. (2014). Moral psychology and the intuition that pharmaceutical companies have a 'special' obligation to society. *Journal of Business Ethics*, 122(3), 501-510. doi:10.1007/s10551-013-1773-4

Janesick, V. (2016). "*Stretching*" exercises for qualitative researchers (4th ed.). Thousand Oaks, SAGE Publications

Kesselheim, A. S. (2013). Rising health care costs and life-cycle management in the pharmaceutical market. *PLoS Medicine*, 10(6), e1001461.
<http://dx.doi.org/10.1371/journal.pmed.1001461>

Kleinke J. D. (2001). The price of progress: prescription drugs in the health care market. *Health affairs (Project Hope)*, 20(5), 43–60.

<https://doi.org/10.1377/hlthaff.20.5.43>

Labaree, R. (2016). *Types of research designs. Organizing your social sciences research papers: Types of designs research guide*. USC Libraries, 2016. Retrieved from https://apus.libguides.com/research_methods_guide/research_methods_quantitative

Maxwell, J. (2013). *Qualitative research design. An interactive approach*. Thousand Oaks, SAGE Publications. Miles, M. B., Huberman, A. M., & Saldana, J. (2014). *Qualitative data analysis: A methods sourcebook* (3rd ed.). Thousand Oaks, SAGE Publications.

Mitchell, A., Muluneh, B., Patel, R., & Basch, E. (2018). Pharmaceutical assistance programs for cancer patients in the era of orally administered chemotherapeutics. *Journal of Oncology Pharmacy Practice*, 24(6), 424–432. <https://doi.org/10.1177/1078155217719585>

Morel, H. L. (2018). *Advanced cancer patients' medical decision-making while experiencing financial toxicity* (Order No. 10817453). [Dissertations & Theses @ Walden University] <https://scholarworks.waldenu.edu/cgi/viewcontent.cgi?article=6509&context=dissertations>

Moustakas, C. (1994). *Phenomenological research methods*. Thousand Oaks, SAGE Publications.

New York Department of Health. (2016). Chronic Diseases and Conditions. Retrieved from <https://www.health.ny.gov/diseases/chronic/>

New York Times (2021) A Timeline of the Coronavirus Pandemic

<https://www.nytimes.com/article/coronavirus-timeline.html>

Nichols, H. (2017). The top 10 leading causes of death in the United States. Retrieved

from <https://www.medicalnewstoday.com/articles/282929.php>

Patel, M. R., & Wheeler, J. R. C. (2014). Physician-patient communication on cost and affordability in asthma care. Who wants to talk about it and who is actually doing it. *Annals of the American Thoracic Society*, *11*(10), 1538–1544.

<https://doi.org/10.1513/AnnalsATS.201408-363OC>

QDA Miner Lite. (2019). QDA miner lite – Free qualitative data analysis software.

Retrieved from <https://provalisresearch.com/products/qualitative-data-analysis-software/freeware/>

Raghupathi, W., & Raghupathi, V. (2018). An Empirical Study of Chronic Diseases in the U: A Visual Analytics Approach. *International journal of environmental research and public health*, *15*(3), 431. <https://doi.org/10.3390/ijerph15030431>

Ravitch, S. & Carl, N. (2016). *Qualitative research: Bridging the conceptual, theoretical, and methodological*. Thousand Oaks, SAGE Publications.

Robinson, S.W. & DeGraff, J. (2017). PBMs Emerge as New Partners in Drug Discount Programs. Retrieved from <https://www.jdsupra.com/legalnews/health-update-april-2017-91485/>

Rubin, H. & Rubin, I. (2012). *Qualitative interviewing: The art of hearing data*.

Thousand Oaks, SAGE Publications

Rudestam, K. & Newton, R. (2015). *Surviving your dissertation – A comprehensive guide*

to content and process (4th ed.) Thousand Oaks, SAGE Publications

Saladana, J. (2016). *The coding manual for qualitative researchers*. Thousand Oaks, SAGE Publications

Schencker, L. (2015). Lifesavers or kickbacks? *Modern Healthcare*, 45(10), 20 Retrieved from

<https://www.modernhealthcare.com/article/20150307/MAGAZINE/303079980/lifesavers-or-kickbacks-critics-say-patient-assistance-programs-help-keep-drug-prices-high>

ScriptSave WellRx (2023). Savings average 65% and, in some cases, can be 80%* or more at over 65,000 pharmacies nationwide.

<https://www.wellrx.com/prescription/savings>

Sloan, A., & Bowe, B. (2014). Phenomenology and hermeneutic phenomenology: The philosophy, the methodologies, and using hermeneutic phenomenology to investigate lecturers' experiences of curriculum design. *Quality & Quantity: International Journal of Methodology*, 48(3), 1291–

1303. <https://doi.org/10.1007/s11135-013-9835-3>

Taylor, S. J., Bogdan, R., & DeVault, M. L. (2016). *Introduction to qualitative research methods: A guidebook and resource*. Hoboken, Wiley.

van Manen, M. (1990). *Researching lived experience: Human science for an action sensitive pedagogy*. Albany: State University of New York Press

van Manen, M. (1997). *Researching lived experience: Human science for an action sensitive pedagogy* (2nd ed.). The Althouse Press. (Original work

published 1990) van Maanen, J. (2006).

Weinberg M. (2009). Reforming patient assistance programs: perfect world meets real world. *Health Affairs (Project Hope)*, 28(3):839-842. DOI: 10.1377/hlthaff.28.3.839. PMID: 19414895.

World Health Organization (2020) Listings of WHO's response to COVID-19

<https://www.who.int/news/item/29-06-2020-covidtimeline>

Zafar, S. Y., & Peppercorn, J. (2017). Patient financial assistance programs: A path to affordability or a barrier to accessible cancer care? *Journal of Clinical Oncology* 35(19), 2113-2116. doi: 10.1200/JCO.2016.71.7280

Zafar, S. Y., Peppercorn, J., Asabere, A., & Bastian, A. (2017). Transparency of industry-sponsored oncology patient financial assistance programs using a patient-centered approach. *Journal Of Oncology Practice*, 13(3), e240-e248.
doi:10.1200/JOP.2016.017509

Zeta L. M. (2015). Comprehensive Legislative Reform to Protect the Integrity of the 340B Drug Discount Program. *Food and drug law journal*, 70(4), 481-i.

Appendix A: Request to Conduct Research

January 28, 2019

Vocational Instruction Project, Inc.
VIP Community Services

Sr. Director of Health Services/Wellness

Re: Request for Assistance with Ph.D. Research

Dear Madam:

I am a Doctoral student at Walden University, and I am currently in the process of preparing my Proposal leading to my Dissertation. I am writing to request permission to seek the participation of the patients at the facility you operate in my research study which is entitled 'Exploring the Lived Experience of Individuals with Access to Pharmaceutical Patient Assistance Programs (PAPs).'

I hope that once IRB approval has been obtained, the administration of this institution will allow me to recruit participants from among the patient base utilizing the attached flyer.

If approval is granted, respondents to the flyer was interviewed, and both the participants and the individual result of this study will remain confidential and anonymous. No cost was incurred by either your institution or the individual participants.

Your approval to conduct this study was greatly appreciated.

Sincerely,

Enclosure

ARE YOU A PARTICIPANT IN A PHARMACEUTICAL PATIENT ASSISTANCE PROGRAM?

**CONSIDER PARTICIPATING IN A
RESEARCH STUDY TO TALK
ABOUT YOUR EXPERIENCE WITH
THE PHARMACEUTICAL PATIENT
ASSISTANCE PROGRAM AND
HOW IT AFFECTS YOUR MEDICAL
CARE**

**EMAIL:
mclarkebur@gmail.com**

SEEKING ADULT PATIENTS WHO WOULD LIKE TO EXPRESS THEMSELVES:

- **ABOUT BEING
ABLE TO RECEIVE
TREATMENT**
- **HOW EASY WAS
IT TO GET
ENROLLED?**
- **WHAT ARE YOUR
FEELINGS ABOUT
THE PROGRAM**

TO PARTICIPATE:

**Call, text or email –
Marcia Clarke-Burke
(Ph.D. Student)**

***Mobile phone:**

443-985-5639

***Email :**

mclarkebur@gmail.com

**PLEASE BE A PART OF
THIS STUDY.**

Appendix C: Interview Protocol

- 1) Interview Set-Up Procedures
 - a) Meet with staff and thank them for assistance in the distribution of flyers
 - b) Explain study purpose, methodology, and procedures for the flyer dissemination
(See Appendix D)
 - c) Researcher returns emails and calls potential participant and discusses the study and its purpose as well as answer any question the individual may have. Explain to the patients the importance of their full expression of their experience in having assistance in obtaining medical treatment at minimal or no cost with pharmaceutical patient assistance programs and how this has impacted their lives and health care decision-making.
 - d) Then sets up an interview if the participant agrees.
 - e) Send consent form to the participant by email or mail.
 - f) Interviews will be conducted in a private room at the institution
- 2) On-site interview procedures for the study
 - a) The researcher will arrive early and make observations in the interview setting.
 - b) Greet participants as they arrive, welcome them to the interview and introduce self.
 - c) Describe the process of the interview explaining that their information will be held in the strictest confidence and that their private and confidential information will be safeguarded.
 - d) Show them the informed consent and ask them to sign it.

- e) Ask if the interview can audio recorded so the researcher can concentrate on the conversation and not try to write all their words down.
 - f) Transition to interview guide (Appendix D) questions
- 3) Interview close down procedures
- a) Explain to the participants that they will be given the opportunity to review the transcript and that if there is anything they wanted to add or delete this would be facilitated. Ask if participants would be willing to meet again to follow-up with this process. In agreement the date and time would be set up for this.
 - b) Thank the participants for their participation after the interview.

Appendix D: Interview Discussion

The interview process was guided by the Research Questions as listed under:

1. What are the lived experiences of individuals who are participants in PAPs and the perceived benefits and limitations of these programs?
2. What are the perceived barriers impacting the utilization of the services offered by PAPs?

The process will commence with the researcher introducing herself and thanking the participants as they arrive for their willingness to participate in the research study. The informed consent document was reviewed, questions answered, and the document signed. After obtaining consent to record the interview, the process began.

1. Tell me about yourself, your name, where you live, are you currently employed and the nature of your illness.
2. As you know, I am researching the impact that participating in the pharmaceutical patient assistance program has had on you and your treatment process; please tell me which program you are enrolled.
3. How did you get to hear about this program and in what way has this facilitated your healthcare treatment?
4. At what point in your treatment process did you learn about PAPs and how easy was it for you to enroll in the program?
5. Before enrolling in PAPs, did you consider the financial cost of your treatment and were you concerned that you may have difficulty paying for your treatment?

6. Do you have concerns about the program presently and your continued treatment?
7. Do you believe that the program can be improved and what would your suggestion for improvement be?

Appendix E: Search Terms

Pharmaceutical Patient Assistance Programs (PAPs)

Phenomenology

Hermeneutic phenomenology

Methodology

Financial Toxicity (FT)

Qualitative Hermeneutic Phenomenological Study

Chronic Illnesses

State Pharmaceutical Assistance Programs (SPAPs)

340B Drug Discount Program

Appendix F: Summary of Interview Response

Participant A

Participant A, a retired lady in Maryland was troubled when she learned that her illness required her to have very expensive medicines, she was not able to afford and actually considered going without until she was advised by her doctor that her condition would worsen without the medication. She was advised by a pharmacist of GoodRx which resulted in her being able to fill her prescription at a greatly reduced price. She took the time to research the process and also consulted with her doctor. She is concerned for those individuals without knowledge and without access to a computer to research and identify this process. She feels that just as she first intended, they too will opt to forgo the medication rather than deal with the expense.

Participant B

Participant B, also a retired lady in Maryland found herself in a situation whereas a retired employee the state endeavored to provide prescription support but over the years benefit changed and she ended up with Script. While she feels that this is a good option for both her and her husband, she is concerned that the process may change, and she will find herself in a situation where she could not afford her medication. To this end she has explored other avenues and GoodRx is one of those options. She feels improvement is necessary for individuals such as herself but has no idea what format this improvement would take.

Participant C

Participant C is also a lady from Maryland, but she is disabled and suffering from multiple illness – high blood pressure, diabetes, severe arthritis and slow heart rate. She received assistance for her prescription through the state – Medicaid. She has had the experience of participating in pharmaceutical programs but is satisfied with the benefit that having Medicaid affords. Her concern lies in the uncertainty of the program because it requires recertification and from her perspective information is not adequately available to aid the process. She mentioned how COVID 19 has negatively impacted the process of security needed medication and is particularly concerned for those individuals without the knowledge that there is assistance available to aid their medication purchase and treatment.

Participant D

Participant D, a male from Georgia is employed and suffer from hyperlipidemia, high blood pressure and TENS implantation. He was introduced to a pharmaceutical patient assistance program by his physician and at a great savings for him. While being willing to share this information, he was unwilling to disclose the name of the program but indicated that it subsidized his health insurance. In his case the situation changed when the health insurance company decided to change the medication and so that impacted the program. He told of the physician's attempt to have him stay on the program with the same drug or to have another program, but such efforts were resisted by his health insurance company. This drew attention to the plight of physicians seeking

to find help and affordable medication for their patients and impact from health insurance companies for those individuals working.

Participant E

Participant E was supportive of this research process and wanted to highlight Medicare. She is a retired lady in Georgia suffering from multiple ailments including spinal stenosis, sleep apnea, knee problems and lymphedema. She was happy the state provided this service as it greatly reduced her contribution towards her medication purchase. She had no concerns as she was satisfied with the service she received.

Participant F

Participant F is a gentleman from Maryland who has Medicaid but also utilizes GoodRx. He had a stroke and a pacemaker. He wasn't very impressed with GoodRx because it did not greatly reduce his medication. During discussion it was disclosed that the physician did not play a great role in aiding the process of medication cost reduction. He is also concerned for those individuals faced with high cost of medication and who had no savings access.

Participant G

Participant G who lives and works in New York indicated that she suffers from acidity reflux and borderline cholesterol. She indicated that her medication is not covered by her health insurance and so she uses GoodRx which she initially saw on the television and upon additional research discovered that this offered great savings. This participant's concern is that she does not know when GoodRx will stop or if the savings will continue to be great. There is a degree of uncertainty and so she has taken her

concern to her company as she is of the opinion that employers had a responsibility to workers and members of the population. She tells of being stressed whenever the period of her medication is up for renewal as she is not sure what the cost will be even with GoodRx.

Participant H

Participant H is a working lady who lives in New York. She is diabetic and had stomach problems. She indicated she was introduced to GoodRx by a representative of her health insurance company. According to her, the problem started with a change in her insurance and the medication had become expensive and wasn't fully covered. She has no concerns as she is of the opinion that GoodRx will continue to cover her medication. She is recommending that others try this plan as the results will be good.

Participant I

Participant I live and work in New York. She indicated she found out about GoodRx while she was online looking for coupons. She indicated she is using what is called a 'no cost program' but noted that GoodRx has now advanced and is offering varying levels and that one level is called gold program. She expressed concerns for individuals with fixed income not being able to finance their medication and suggests that there should be some correlation between the physicians and companies such as GoodRx whereby an effective program could be worked out that is beneficial to individuals who need the medication they are unable to afford.

Participant J

Participant J also lives and works in New York, and she indicated that she is asthmatic, and she has been obtaining her medical supplies from a ‘mom and pop’ pharmacy called Castle Hill Pharmacy. This is a community pharmacy which provides pharmaceuticals at reduced prices for members of the community. She indicated that she had made it her goal to forward individuals she come into contact with to the pharmacy and she is confident that they will continue to be beneficial to the community. She was also impressed that the situation surrounding COVID 19 did not impact their service to the community.

Participant K

Participant K is employed, and she lives in New Jersey. She tells a story of needing mediation and not having health insurance and she was able to get the card of the Pharmacy. She was not sure but believed it was GoodRx. She later confirmed that it was GoodRx. This was beneficial to her because she was able to obtain her medication at a reduced price. Although she doesn’t currently need medication, she still has the card and is confident that should her need arise, she would be able to use the card.