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Understanding the Knowledge, Perception, and Experiences of Patients about Precision Medicine and Biobanking; A Qualitative Study

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Understanding the Knowledge, Perception, and Experiences of Patients about Precision Medicine and Biobanking; A Qualitative Study

by

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Abstract

Chronic Kidney Disease (CKD) patients' knowledge, perception, and experiences surrounding Precision Medicine (PM) and biobanking were explored in this study.

This study used a qualitative methodology. Data was collected by individual virtual interviews utilizing a semi-structured open-ended interview guide. Framework analysis was used on the resulting transcripts. Methodological rigor was achieved through credibility, reliability, and reflexivity.

Four themes were identified concerning CKD patients' knowledge, perception, and experiences of PM: benefits, concern, perceived barriers to implementing PM, and preferences on the informed consent model. Another four themes were identified regarding CKD patients' knowledge, perception, and experiences of biobanking: benefits, concern about biobank research or donation of samples, factors that influence participation in biobank research, and ownership of donated samples.

This unique study investigated the knowledge, perception, and experiences of CKD patients about PM and biobanking. The study results may help support programs and provisions that aim to overcome challenges that hinder a patient's participation in PM and biobank research and consequently amplify patient engagement and awareness in PM and biobank research studies. In the end, the information gained from this study will add value to future PM and biobank research and clinical initiatives.

Preface

This thesis is original, unpublished, independent work by the author, Mohammad Mokammel Haque. The study conducted was covered by Ethics Certificate number REB20-0036, issued by the University of Calgary, Canada, Conjoint Health Research Ethics Board (CHREB) on 10-Mar-2020 for the project titled “Understanding the knowledge, perception, and experiences of patients about precision medicine and biobanking: a qualitative study.”

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List of Abbreviation

CKD	Chronic Kidney Disease
eGFR	Estimated Glomerular Filtration Rate
ESRD	End-Stage Renal Disease
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
ESKD	End-Stage Kidney disease
CIHI	Canadian Institute for Health Information
HRQOL	Health-Related Quality of Life
PM	Precision Medicine
GWASs	Genome-wide association studies
GTC	Genomic Testing in Cancer
GEP	Gene Expression Profile
PCPs	Primary Care Providers'
KPC	Kaiser Permanente Colorado
ACT	Adult Changes in Thought
GNC	German National Cohort
EPIC	European Prospective Investigation into Cancer and Nutrition
NHGRI	National Human Genome Research Institute
Can-SOLVE CKD	Canadian Seeking Solutions and Innovations to Overcome Chronic Kidney Disease
CHREB	Conjoint Health Research Ethics Board
PKD	Polycystic Kidney Disease

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CHAPTER 1: INTRODUCTION

1.1 Chronic Kidney Disease

Chronic kidney disease (CKD) is a heterogeneous disorder of the kidney that impacts its function and structure (Levey & Coresh, 2012). The etiology, pathology, severity, and rate of progression influence CKD expression (Levey & Coresh, 2012). CKD is often asymptomatic in the early stages and can be reversible (Levey & Coresh, 2012). CKD may progress to an advanced stage and, in the minority, may progress to end-stage renal disease (ESRD), also known as end-stage kidney disease (ESKD) (Haynes & Winearls, 2010; Fraser & Blakeman, 2016). This end stage is the final and permanent stage of chronic kidney disease, where kidney function has declined to the point that the kidneys can no longer function on their own. The treatment of kidney failure is renal replacement therapy (dialysis or kidney transplantation) (Good et al., 2010; Levey & Coresh, 2012).

CKD is defined as diminished kidney function measured by estimated glomerular filtration rate [eGFR] (sustained reduction in glomerular filtration rate [GFR] <60 mL/min per 1·73 m^2) (Fraser & Blakeman, 2016; Levey & Coresh, 2012) and elevated urinary albumin excretion (albuminuria >3 mg/mmol) with the presence or absence of anomalous kidney structure (Fraser & Blakeman, 2016) for three months or more, regardless of the underlying cause (Levey & Coresh, 2012; Webster et al., 2017). Based on the function of GFR in the pathophysiology of the disease, CKD is categorized into five stages of progressive severity (Levey & Coresh, 2012). Patients in the early stages of CKD often do not show symptoms; therefore, CKD is difficult to detect or diagnose.

The current method of detecting CKD is non-specific and shows late manifestations of kidney damage (Good et al., 2010). There are other more specific methods used to detect the

presence of CKD, such as persistent haematuria, structural anomalies of the kidney (detected by ultrasound scanning or other radiological tests), and chronic glomerulonephritis (detected by histological examination of kidney tissues-biopsy) (Thomson & Taylor, 2015).

The two leading causes of CKD are diabetes and hypertension (Drawz & Rahman, 2015; McManus & Wynter-Minott, 2017). Additional causes of CKD include kidney infections, glomerulonephritis, genetic diseases (adult polycystic kidney disease), and medications (non-steroidal anti-inflammatory drugs [NSAIDs], lithium, acetaminophen, ASA, cyclosporin, etc.) (Evans & Taal, 2011).

The risk factors associated with CKD can be classified into two categories: (a) initiating factors that elevate the risk of developing CKD and (b) perpetuating factors that elevate the probability of CKD progression to ESRD (Evans & Taal, 2015). The initiating factors include older age, gender, ethnicity, family history of CKD, socio-economic factors, high normal urinary albumin excretion, dyslipidemia, nephrotoxins (NSAIDs, antibiotics, radiological contrast), primary renal disease, urological disorders (obstruction, recurrent urinary infections), metabolic syndrome, cardiovascular disease, diabetes mellitus, and, acute kidney injury (Evans & Taal, 2015; Taal & Brenner, 2006). Perpetuating factors include high dietary protein intake, hypertension, obesity, anemia, dyslipidemia, smoking, nephrotoxins, and cardiovascular disease (Evans & Taal, 2015; Taal & Brenner, 2006). CKD is an independent risk factor for outcomes such as cardiovascular disease, cognitive dysfunction, hospitalization, and all-cause mortality (Drawz & Rahman, 2015). Complications of CKD include anemia, electrolyte disturbances, bone disease, secondary hyperparathyroidism, and vascular complications (Drawz & Rahman, 2015).

1.2 The Burden of Chronic Kidney Disease

There has been a substantial rise in chronic kidney disease (CKD) incidence worldwide (Alebiosu & Ayodele, 2005). The prevalence of kidney diseases is higher in developing nations than in the developed world. In developed countries, the prevalence of CKD is generally higher in the elderly (70-90 years of age). This may be due to the increasing prevalence of diseases like diabetes and hypertension, which are the leading causes of CKD (Alebiosu & Ayodele, 2005). The number of patients with CKD in Canada is on the rise as well. Approximately one in ten Canadians suffer from kidney disease, and millions more are at risk (KFOC, 2020). An estimated 4 million Canadians have chronic kidney disease (KFOC, 2020), and many are unaware that they have kidney disease. CKD ranked 10th in the leading causes of death in Canada in 2018 (KFOC, 2020).

According to Canadian Institute for Health Information (CIHI), 40,289 people in Canada (excluding Quebec) have End-Stage Kidney disease (ESKD), which is a 35% increase in the number of people suffering from ESKD since 2009 (CIHI, 2019). Overall, 6,045 ESKD patients started renal replacement therapy (dialysis or transplant) in 2018, an increase of 32% from 2009 (CIHI, 2019). CKD is considered a public health burden (Arora et al., 2013) and has a consequential liability on the Canadian health care system (Manns et al., 2017). The cost of health care for patients with CKD is more than 40 billion dollars per year (Manns et al., 2017). The cost of dialysis treatment varies from $56,000 to $ 107,000 per patient per year depending on the kind of dialysis treatment (Klarenbach et al., 2014). Dialysis treatment alone resulted in a $2.5 billion (CAD) yearly expenditure for the Canadian health care system (Manns et al., 2017).

The burden of dialysis treatment and treatment expenditures have a significant financial and social impact on patients and their families (Manns et al., 2017). Each dialysis takes four to five hours, and patients with kidney disease need to undertake hemodialysis treatments three

times per week (KFOC, 2020). Transportation to and from dialysis can be a significant and costly challenge. Patients who are suffering from advanced kidney disease or living with kidney failure and undergoing dialysis lose their capacity to work partially or totally and must commit a significant amount of time to treatment (Manns et al., 2017). Consequently, kidney disease significantly impacts their income and causes enduring financial challenges and substantial monetary burdens (Manns et al., 2017).

Fewer than 20% of patients with ESRD who are undergoing dialysis are capable of working. This is due to several factors including health consequences of the diseases and complications caused by treatment (Manns et al., 2017). As a result, patients are unable to contribute to their savings and are unable to pay taxes to the government (Manns et al., 2017). Individuals' inability to work, reduced capacity to work, and decreased time at work due to kidney disease and related conditions can cause high costs to employers, private insurers, and the federal government as they must make disability payments to these patients (Manns et al., 2017). In Canada, the total disability insurance cost for advanced kidney failure is at least $217 million per year (Manns et al., 2017).

There is an increase in expenses for patients undergoing dialyses, such as costs for medication and transportation to treatment facilities. It is reported that the annual household income of Canadians undergoing dialysis decreases after dialysis starts (KFOC, 2018). The average annual out-of-pocket cost of Canadians due to dialysis treatment ranges from $1400 to $2500 (KFOC, 2018). This is a substantial portion of income for those Canadian families reporting an annual income of $20000. Many households reported an inability to afford food or basic necessities because of expenditures related to dialysis treatment (KFOC, 2018).

Patients experience a tremendous physical and psychological impact due to kidney disease and its treatment (KFOC, 2020). CKD patients often need heterogenous treatment procedures due to other comorbidities like hypertension, cardiovascular disease, and diabetes that hamper their daily routine, including food habits, self-care, and time available for spare time (Subramanian et al., 2017). Because of comorbidities, CKD affects quality of life and impacts a patient's family, lifestyle, relationships, and employment (Subramanian et al., 2017). Additionally, patients sometimes experience unfavorable treatment complications (Manns et al., 2017). The likelihood of losing cognitive ability is higher in patients suffering from CKD than in those who are not (Tian et al., 2019). There is a possible correlation between ESRD magnitude, reduced cognitive functioning, and a higher risk of dementia (Tian et al., 2019). A decrease in cognitive ability will likely impact the patient's capacity to comprehend and sort out information, participate in the decision-making process about their healthcare, follow intricate therapeutic treatment, or precisely observe dietary instructions (Tian et al., 2019).

Moreover, patients with declined cognitive abilities are in danger of increased hospitalization, mortality, and inferior quality of life (Tian et al., 2019). Patients suffering from ESRD and undergoing dialysis have an inferior health-related quality of life (HRQOL) (Chen et al., 2016). Depression and anxiety are more prevalent in patients diagnosed with CKD (Goh & Give, 2018). There are significant ongoing mental adjustments patients with CKD need to make during the period of their diseases, such as embracing the life-threatening diagnosis and the requirement for long term treatment, learning dialysis techniques, incorporating therapeutic regiment into their daily routine, and enduring treatment transitions/failures, side effects, and complications (Goh & Give, 2018).

CKD is also associated with complications such as cardiovascular disease, nutritional disorder, dyslipidemia, anemia, mineral bone disease (Thomas et al., 2008). As the disease progresses, a patient's day-to-day life is hindered by ESRD symptoms such as fatigue, dry skin, pruritus, itchiness, bone/joint pain, and sleep disturbances (Chen et al., 2016). The presence of these comorbidities significantly impacts the health-related quality of life of a patient. Therefore, CKD is very often progressive in nature and should be diagnosed in the initial phases and treated as early as possible. Despite the modern method of treatment, which delays the progression of CKD to ESRD by limiting and regulating the risk markers (blood pressure, glucose, and albuminuria), the probability of renal and cardiovascular morbidity and mortality is still high. Therefore, there is a demand to discover novel drugs and treatments to stop the progression of CKD.

1.3 Present Challenges of CKD Diagnosis and Treatment

CKD patients may not show any symptoms until the disease progresses to an advanced stage (Bidin et al., 2019; Chen & Harris, 2015). In the early stages of the disease, the majority of people with CKD are unaware of their condition (Bidin et al., 2019; Chen & Harris, 2015). This creates a significant challenge for health care professionals to initiate treatment or prevent CKD (Bidin et al., 2019). Diagnosis of CKD is problematic, and it is diagnosed by measurements of serum creatinine and corresponding calculations of eGFR (Bidin et al., 2019). Furthermore, there are disputes with the present staging system of CKD, particularly in the methodology used to diagnose and prognosticate CKD (Bidin et al., 2019) (regarding the use of GFR estimating equations and of albuminuria). There are also disputes regarding the overuse or misdiagnosis of CKD, the appropriateness of the thresholds or cut-offs for CKD diagnoses, and CKD without any consideration of aetiologies (Polkinghorne, 2011). To overcome challenges related to the current

staging system of CKD, there is an unequivocal requirement for revision to include new research findings and recent progress in the diagnosis and management of CKD (Polkinghorne, 2011).

The sensitivity of proteinuria, serum creatinine, eGFR, and other traditional markers are questionable, and increasing dependency on these test results may cause a delay in diagnosis and the initiation of timely interventions (Bidin et al., 2019). Thus, there is a requirement for better biomarkers to help nephrologists focus on CKD patients with complex and unique pathophysiological mechanisms (Bidin et al., 2019). Furthermore, the complex mechanisms of all the underlying pathophysiological processes involved in CKD make it exceedingly difficult for a single marker to be able to predict the progression of CKD (Bidin et al., 2019). Therefore, Bidin et al. (2019) suggested that "a focused panel of biomarkers will be most rewarding for specially targeted CKD segment" (p. 9).

Modern treatment cannot cure CKD; current treatment cannot reverse the loss of renal function in CKD (Breyer & Susztak, 2016). Treatment relies on blood pressure control through blockade of the renin-angiotensin system and glycemic control (Breyer & Susztak, 2016). This treatment strategy only slows down CKD progression to ESKD and can cause notable side effects (Breyer & Susztak, 2016). As mentioned earlier, CKD is often unrecognized because it is usually asymptomatic. Quite often, CKD is not diagnosed at all or is not diagnosed until a later stage. Among patients with CKD who progressed to ESKD requiring dialysis, 25% of them were referred to nephrologists so late that they need dialysis within three months (Chen & Harris, 2015).

With the progression of kidney disease, patients sometimes manifest an array of symptoms that make it difficult for the nephrologist to determine whether these symptoms are a consequence of advancing CKD or the outcome of many comorbidities or medications

prescribed (Cabrera et al., 2017). Also, there are questions regarding the timing of dialysis initiation, and nephrologists find it challenging to know whether the initiation of dialysis will ease symptoms (Cabrera et al., 2017).

The initiation of dialysis can result in various effects on a patient's health-related quality of life (HRQOL) (Cabrera et al., 2017). Peritoneal dialysis-related issues that affect patients' health-related quality of life include weight gain, peritoneal access issues, peritonitis, daily dialysis routine, visits to dialysis facilities, exit-site infections, and ultrafiltration problems, encapsulating peritoneal sclerosis (Cabrera et al., 2017). Hemodialysis-related issues are myocardial stunning, post-dialysis recovery time, vascular access issues, sepsis, three or more times per week treatment, transportation to hemodialysis unit, and endotoxemia (Cabrera et al., 2017). The magnitude of disability and the burden of symptoms in patients with advanced CKD may not inevitably be ameliorated by dialysis (Cabrera et al., 2017). Dialysis may or may not result in an improvement in the patient’s quality of life and functional status (Cabrera et al., 2017).

Kidney transplantation is considered the most cost-effective treatment for ESRD (Reyna-Sepulveda et al., 2017). However, various pathological and surgical complications can occur in kidney transplant patients postoperatively (Reyna-Sepulveda et al., 2017). Pathological complications involve rejection, infection, and cardiovascular events, while surgical complications include vascular (Reyna-Sepulveda et al., 2017) and nonvascular complications (Kobayashi et al., 2007). Nonvascular complications are mainly urologic complications (e.g., ureteral obstruction, urine leak) and perigraft fluid collection (e.g., lymphocele, abscess, hematoma, urinoma) (Kobayashi et al., 2007). Additionally, despite the continuous progress of modern treatment methods, graft-endangering complications can arise, mainly of vascular

etiology (Reyna-Sepulveda et al., 2017). Vascular complications include thrombosis or stenosis of the renal artery or vein (Reyna-Sepulveda et al., 2017). Further scarce complications include the formation of aneurysms, arteriovenous fistulas, or hematomas (Reyna-Sepulveda et al., 2017). Risk factors involved in kidney transplant surgery include poor surgical technique, torsion or compression of vessels, the presence of multiple renal vessels, or a renal artery atheroma (Reyna-Sepulveda et al., 2017). Additionally, kidney transplant surgery is a challenge for the transplant surgeon due to factors including the presence of anatomical variations, such as double ureters and multiple renal arteries or veins (Reyna-Sepulveda et al., 2017).

There are many causative factors, practices, and conditions that lead to the development of CKD. Many of the causes, practices, and conditions leading to CKD are not entirely understood and curable (Persson & Rossing, 2019). The complexity of the molecular nature of CKD, along with its co-morbidities, impedes and hinders the development of ideal therapeutic targets (Cisek et al., 2016). Many major clinical trials failed due to these factors (Cisek et al., 2016). Also, the approach to these trials failed to address 'the underlying molecular causes of the disease (directly targeting the affected cellular pathways)' (Cisek et al., 2016, p. 1). Multifaceted pathology coupled with the varied epidemiology of CKD generates obstacles for drug invention and biomarker identification (Cisek et al., 2016). Considering the intricate mechanisms of the disease pathogenesis, inferior outcomes in patients with advanced kidney disease, and the disappointing results of the population-based studies (Moradi & Kalantar-Zadeh, 2018), there is ample demand for greater knowledge of pathology, advanced risk identification, and determination of prognosis of CKD (Persson & Rossing, 2019). Research efforts are directed towards developing improved and potent treatments to slow down or prevent the disease

progression and to developing precise, safe, competent, and non-invasive biomarkers that support the efficient diagnoses and staging of CKD (Cisek et al., 2016).

1.4 Definition and Understanding of Precision Medicine

The term *precision medicine* was first introduced into the scientific world by Clayton Christensen, a business strategist at Harvard Business School in Boston, USA (Katsnelson, 2013). He used the term in his book *The Innovator's Prescription* published in 2009 to describe 'how molecular diagnostics allow physicians to unambiguously diagnose the cause of a disease without having to rely on intuition' (Katsnelson, 2013, p. 249). The term came to light in 2011 when the US National Research Council published a report known as 'Toward Precision Medicine'. The report outlined a framework to update the taxonomy of human disease based on molecular biology such as causal genetic variants rather than a symptom-based classification system (Katsnelson, 2013; National Research Council, 2011).

Precision medicine refers to tailoring diagnostics or therapeutics to individual patients based on their unique genetic and physiologic characteristics (National Research Council, 2011). The National Research Council (2011) stated:

> Precision medicine does not literally mean the creation of drugs or medical devices that are unique to a patient, but rather the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease, in the biology and prognosis of those diseases they may develop, or in their response to a specific treatment. Preventive or therapeutic interventions can then be concentrated on those who will benefit, sparing expense and side effects for those who will not. (p. 7)

The National Research Council (2011) further stated that the term *personalized medicine* "is sometimes misinterpreted as implying that unique treatments can be designed for each individual" (p. 8), which is not the case. The National Research Council (2011) emphasized that *"*in precision medicine the word precision is being used in a colloquial sense, to mean both accurate and precise" (p. 8). McAllister et al. (2017) stated that *precision medicine* represents an extension of conventional personalized care through more precise individualization of diagnosis, prognosis, and therapy estimates for each patient using sophisticated molecular diagnostics and imaging made possible by recent technological advances.

1.5 Importance of Precision Medicine in the Treatment and Diagnosis of CKD

This chapter will discuss how *precision medicine* (PM) uses the emerging knowledge and application of 'omics' to identify specific biomarkers or accurate diagnostic modalities and develop targeted therapy (using the right dose and time) for patients with CKD.

Typically, the development and application of medical treatments focuses heavily on randomized clinical trials, and the result of these trials determines the potency of therapy on an average patient (Moradi & Kalantar-Zadeh, 2018). As a result, therapeutic treatments that have a statistically significant expected outcome in a large number of patient populations are considered efficacious and are approved for specific patient populations overall (Moradi & Kalantar-Zadeh, 2018). It is crucial to be aware that despite the generally favorable findings of a particular clinical trial, the therapy being administered is not effective and beneficial for some patients within the study (Moradi & Kalantar-Zadeh, 2018). On the other hand, despite the negative findings of a given clinical trial, some patients benefit from the therapy (Moradi & Kalantar-Zadeh, 2018). Hence, the main drawback of this approach is that the outcome of a given treatment is not considered for a considerable number of patients (Moradi & Kalantar-Zadeh,

2018). PM can address this discrepancy and predict the most effective treatment in each case (Moradi & Kalantar-Zadeh, 2018). By analyzing genetic, environmental, lifestyle characteristics and preferences that are distinctive for every individual, PM can identify the intricacy and heterogenicity of different mechanisms in individuals with the same condition (Moradi & Kalantar-Zadeh, 2018).

Current advances in the field of human 'omics' empowered by large sets of molecular and clinical data comprising genomics, proteomics, peptidomics, transcriptomics, and metabolomics have opened the possibility for incorporating 'omics' datasets to develop an extensive, broad, and detailed mathematical model for molecular changes in CKD which will enable accurate biomarker and medication invention (Cisek et al., 2016). Deidda et al. (2015) defined 'omics' as a 'group of analytical methodologies that aim to achieve the collective characterization and quantification of pools of biological molecules, such as genes, transcripts, proteins, and metabolites, which translate into the structure, function, and dynamics of cells, tissues, or organisms'. By utilizing the 'omics' dataset, a molecular map can be effectively and non-invasively retrieved from patient samples (e.g., urine) during different CKD stages, enabling practitioners to trace appropriate clinical molecular changes with the progression of the disease (Cisek et al., 2016). Thus 'omics' data integration is capable of mapping disease phenotypes, tracking disease progression, explaining molecular mechanisms of disease, and identifying novel therapies (Cisek et al., 2016).

CKD through the renal fibrosis pathway leads to ESRD (Cao et al., 2019). To prevent progression to ESRD, early and well-timed diagnosis and treatment are pivotal, but that may not be possible as symptoms in early-stage CKDs (Stages 1 to 3) are not definite or absent (Cao et al., 2019). The current diagnostic method is not as effective in diagnosing advanced kidney

dysfunction in the preliminary stage (Nkuipou-Kenfack et al., 2014). The 'omics'-based technologies, including proteomics and metabolomics, empower further understanding of CKD mechanisms, which allow ameliorating treatment of CKD by providing stage-specific biomarkers (Nkuipou-Kenfack et al., 2014). However, there is a scarcity of ideal and accurate biomarkers to precisely predict the risk of developing CKD as well as the progression of CKD to ESRD, and the identification and development of precise and reliable biomarkers for the prognosis of CKD progression to advanced states presents a more significant challenge (Nkuipou-Kenfack et al., 2014).

A biomarker is a quantitative biological molecule or pathological process typically used to diagnose a disease or assess disease activity (Sun et al., 2017). Biomarkers used in CKD typically identify proteins and metabolites from the blood, urine, and biospecimens of the kidney, and currently, molecules from DNA and miRNA analyses can also be biomarkers (Sun et al., 2017).

Proteomic methods are not only broadly utilized to identify potential biomarkers in tissues and biological matters such as urine (Nkuipou-Kenfack et al., 2014), but are also a diagnostic method (Sun et al., 2017). Proteomics refers to "the systematic study of proteins to provide a comprehensive view of the structure, function, and regulation of biological systems" (Deidda et al., 2015, p. 1). Urinary proteins carry significant amounts of information on renal pathogenesis (Sun et al., 2017). Proteomic studies on urinary proteome generate substantial molecular information that may replace kidney biopsies and enable the early detection of CKD and prognosis of progression (Sun et al., 2017).

Metabolomics refer to "comprehensive and quantitative analysis of all metabolites" (Ma et al., 2018, p. 1). Metabolomics encompass a series of metabolites that provide information

about metabolisms. In contrast, the focal point of conventional clinical practices and biochemical approaches are on a single metabolite (Sun et al., 2017) or a few numbers of metabolomes of a patient, and interactions of these molecules are overlooked (Trivedi et al., 2017). This inadequate information makes it difficult for physicians to provide the highest quality treatment (Trivedi et al., 2017). Therefore, metabolomics has been broadly embraced for biomarker discovery (Trivedi et al., 2017).

It was reported that a urinary metabolite-based profile has diagnostic and monitoring values in CKD (Nkuipou-Kenfack et al., 2014). In combination with genomics, metabolomics likely has the ability to provide disease-related causes of disease pathology (Trivedi et al., 2017). The majority of diseases result from the complex interplay between genetic and environmental factors (e.g., gut microbiome and epigenome) (Ma et al., 2018). In addition, metabolomics is effective in evaluating drug response. Reactions to drugs among individuals are highly variable, and an individual's drug metabolism depends on ethnicity, age, gender, weight, and diet, and other physiological variables (Wishart, 2016). Therefore, predicting reactions to a drug in an individual based on genotype alone is difficult (Wishart, 2016). Metabolomics provide an opportunity to measure the combination of genotype, environmental and physiological effects which are of key significance for discovering novel drug targets (Ma et al., 2018; Wishart, 2016) and also allow us to monitor drug reactions, customize drug therapy, and evaluate therapeutic effectiveness (Wishart, 2016). Both proteomics and metabolomics appear to have the ability to predict renal function and can identify CKD stages with ease (Nkuipou-Kenfack et al., 2014).

Genomics is defined as a "comprehensive analysis of DNA structure and function" (Deidda et al., 2015, p. 1). Genome-wide association studies (GWASs) are used to screen the genome for disease associations (O'Seaghdha & Fox, 2011). Piras et al. (2017) stated that

"understanding the genetic basis of CKD could provide a better knowledge of the biology of the involved pathways, thus potentially leading to novel tools for the diagnosis, prevention, and therapy of CKD" (p. 1) The major promising aspect of GWASs is that they can provide information about genetic variants of CKD that can unveil the pathways and pathogenesis of CKD as well as characterize elements of an individual's predisposition to a disease, and possibly aid in the identification of novel therapeutic targets (O'Seaghdha & Fox, 2011; Sun et al., 2017). In the end, in combination with proteomics, genomics, and metabolomics, the omics data set can provide information on causes of CKD pathology, identify specific biomarkers or accurate diagnostic modalities, and develop targeted therapy.

1.6 Biobanking

Biobanking has been defined in different ways over the years. The Organization for Economic Co-operation and Development (OECD) defines a biobank as "a collection of biological material and the associated data and information stored in an organized system, for a population or a large subset of a population" (Kinkorova, 2016, p. 2). According to the International Society for Biological and Environmental Repositories (ISBER), a biobank "is an entity that receives, stores, processes, and disseminates specimens as needed. It encompasses the physical location as well as the full range of activities associated with its operation" (Kinkorova, 2016, p. 2). The simplest definition of a biobank is "an organized collection of human biological material and associated information stored for one or more research purposes" (Kauffmann & Cambon-Thombsen, 2008, p. 1). Artene et al. (2013) suggested that a biobank has two components: (a) collection, processing, storage, inventory, and distribution of biospecimen and biological samples; (b) the database which has demographic and clinical data of biospecimen and biological samples (Artene et al., 2013; Kinkorova, 2016). Biobanks meet present-day molecular

pathology and medicine requirements and demands by preserving and annotating human biospecimens (Zatloukal & Hainaut, 2010). Biobanks also include the concept that disease varies between individuals in terms of molecular characteristics and their ability to react to drugs (Zatloukal & Hainaut, 2010). Therefore, biobanking carries out two roles: (a) it offers a platform for research to gain greater knowledge on the molecular variation of diseases condition and for detecting and discovering new drug targets for personalized treatment, and (b) it lays the foundation for integrating tailored individualized therapies into clinical practice by providing human biological specimens conserved in a state which is suited for the analysis of biomarkers that predict treatment outcomes (Zatloukal & Hainaut, 2010)

1.7 Biobanking for Precision Medicine

Biobanks provide infrastructure and access to biological specimens like tissues, cells, blood, serum, plasma, saliva, urine, stool, bone marrow, or other body fluids. Human biospecimens stored in biobanks are the source of proteins, germline DNA, RNA, and other metabolites (Liu & Pollard, 2015, p. 56). Aanalysis of these biological specimens and associated clinical data using a broad spectrum of analytical technologies and comparing molecular findings with clinical data generate a wealth of information (pathological, clinical, patients' characteristics, diseases, and epidemiological, environmental, lifestyle, and societal data) (Kinkorova, 2016; Zatloukal et al., 2018). This data is generated from biospecimens and can be used for genetic, proteomic, epigenetic, metabolomic, and biochemical analysis (Liu & Pollard, 2015, p. 3). Thus, biobanks are data or resource repositories that can be used for basic, translational, and clinical research (Liu & Pollard, 2015, p. 56), which help to understand the entire spectrum of each disease entity (Scolyer & Thomson, 2013). This knowledge enhances the development of new novel therapies and identifies biomarkers (Liu & Pollard, 2015), which is

imperative to enrich PM. In this way, biobanking provides a pivotal scientific platform for the development and advancement of PM.

In PM, therapies are determined for an individual patient based on various biomarkers in the patient's blood and other biological specimens (Hewitt, 2011). Here, the importance of biobanks is pivotal as they provide resources by acquiring, storing, processing, and allowing for the usage of biospecimens, which is a prerequisite for research to identify biomarkers (Hewitt, 2011). In the end, the importance of biobanks in the development of PM is vital as they facilitate scientific progress in the stratification of population, identification of new biomarkers for various physiological and pathophysiological states that can be used in patient diagnosis, discovery, and development of new drug targets, disease predictions, follow-up and monitoring of treatment (Kinkorova, 2016).

1.8 Patient Engagement in Precision Medicine

Realizing the implementation or application of genetic and genomic information into health care and PM requires the involvement of different stakeholders including donors, biomedical researchers, pathologists, clinicians, ethicists, regulatory bodies, funders, government, patients, and patient organizations, public, and health care providers. Among all stakeholders, patients can play a vital role in implementing PM regarding governance, priority setting, research, and knowledge translation (Budin-Ljøsne & Harris, 2015). Therefore, patients are considered not only as active and engaged but also as knowledgeable, conscientious, and contributing partners of PM (Budin-Ljøsne & Harris, 2015). Additionally, Simmons et al. (2014) defined patient engagement as (a) understanding the significance of taking an active role in one's health care; (b) having knowledge, skills, and confidence to manage health/disease/conditions; and (c) applying knowledge in health-promoting behaviors. In this

context, knowing the degree of patient engagement enhances clinicians' understanding of particular problems such as a patient's knowledge of their diseases or condition, their confidence to manage healthy behaviors, and differences in their understanding between their actual current health status and their predicted future health status. This information could assist clinicians individualized treatment plan within the context of patients' real lives" (Simmons et al., 2014, p. 11).

The engagement of patients can occur at two levels: clinical and research. At the clinical level, patients can be involved in the decision-making process for their own health, such as prevention, diagnosis, and treatment (Budin-Ljøsne & Harris, 2015). By providing their risk disposition to health care providers, patients can help outline tailor-made treatments (Budin-Ljøsne & Harris, 2015). Patients can endorse PM treatment strategies based on their genetic profile (Budin-Ljøsne & Harris, 2015).

At the level of health research, patients can be participants in the research project or partners as members of the research team. Patients can enhance PM research endeavors by furnishing a variety of information such as 'omics' data, imaging, clinical, environmental, behavioral, and socio-economic data, and by giving consent that their biological samples as well as relevant clinical data to be used for PM research (Budin-Ljøsne & Harris, 2015). Patients can share their individual and distinctive experiences and understandings obtained through living with a condition or disease, as well as their impression of treatments and the health care system (CIHR, 2014). Patients can also play an instrumental part in the development of patient registries, which could be made accessible to researchers (Budin-Ljøsne & Harris, 2015). They can inform research communities about their patient values and expectations for translating research findings into clinical practice (Budin-Ljøsne & Harris, 2015).

Patients can assist in the design of PM by working closely with public health authorities, policymakers, health care providers, and drug manufacturers. For example, they can help promote the discovery of targeted medication or active involvement in selecting and substantiating the latest diagnostics and therapeutics (Budin-Ljøsne & Harris, 2015). Patients can participate in the design of PM and create educational tools to notify a wider population regarding genetics and PM (Budin-Ljøsne & Harris, 2015). Overall, patients can be contributing partners to PM by following early prevention methods, engaging in the decision-making process concerning their treatment, sharing their genetic risk profile with health care providers, providing consent to use to their samples and clinical data for PM research, and by taking part in public debates and dialogues to discuss the design and development of PM (Budin-Ljøsne & Harris, 2015). Patient organizations representing patient communities and their interests can provide pertinent and relevant information about the needs and concerns of patient communities regarding the implementation of PM (Budin-Ljøsne & Harris, 2016). Patients and their interest organizations (PIO) can relay practical direction to deal with potential ethical and social challenges during PM implementation (Budin-Ljøsne & Harris, 2016).

When partnering as a member of a research team, the patient plays important roles in research (a) as an active partner in health research involved in crucial governance structures and decision-making processes; (b) as a research committee member engaged in planning, designing, and guiding the research project; (c) as a competent patient engaging researchers so they can identify the right research question, study design, recruitment, data collection, and analysis of findings; and (d) as a supporter of participant-friendly research studies that improve access to other patients and more difficult-to-reach patients via peer networks and groups (CIHR, 2014). Therefore, partnering with patients in research results in research projects that

are focused on patient-identified priorities, and the application of this knowledge improves patient outcomes and healthcare system practices (CIHR, 2014). Specifically, there are several benefits of partnering with patients in research. At system level these partnerships improve (a) access to the health care system, (b) quality of health care, and (c) cost-effectiveness (CIHR, 2014).

At the patient level, the overall benefit of participating in research is the improvement of health outcomes that are important to patients. At the level of health research, patient participation improves research quality, accountability, transparency, and relevancy, all in all enabling new prospective that prompt novel research discoveries (CIHR, 2014).

It is crucial to understand the patient's knowledge, experiences, attitude, and interest in PM research and practice. This, in turn, will help health care providers and policymakers assess the degree of support, information, and provision that are needed for the successful implementation of PM initiatives.

1.9 Study Rationale

As discussed earlier, several stakeholders play important roles in biobank and PM research. These stakeholders include donors, biomedical researchers, pathologists, clinicians, ethicists, regulatory bodies, funders, government, patient and patient organizations, public and private health care providers. These stakeholders have a formidable impact on the activities of biobanks and PM. Many ethical, legal, and social implications exist to challenge biobanking and PM activities. These challenges include informed consent, protection of data privacy and security, therapeutic misconception and uncertainty, the permissibility of clinical versus research uses, compensation and other benefits from donated tissues, nature of research, participating researchers, the storage period of biospecimens and information, the right to withdraw, questions

regarding the return of research results, patient versus physician literacy, and understandings around actual versus potential implications of PM. The success of biobanking and PM is dependent on the assistance, understanding, and participation of different stakeholders. Among them, the engagement of patients in biobank and PM research is vital.

Conventionally, patients have been included as participants or donors but not as collaborators in biobank research or health research in general; therefore, their involvement was considered passive (Mitchell et al., 2015). But over the years this has changed, and there is a growing interest in patients' involvement and engagement in health research (Mitchell et al., 2015). Patients can be involved in the research process not only by helping to identify and prioritize research topics, by participating in research advisory groups, and by reporting and communicating research findings, but also by maintaining research standards, pertinence, and suitability (Mitchell et al., 2015).

There is a generalized acceptance that patients can add value to biobanking initiatives by informing their establishment, continuous operation, and administration (Mitchell et al., 2015). Patients can provide an abundance of information and unparalleled views on biobanking research, making patients extremely useful contributors (Mitchell et al., 2015). The degree of patient involvement can range from sharing experiences, knowledge, expertise, expectations, and feedback regarding the use, sharing, and transfer of biobank samples, to the areas of communication, advocacy, and recruitment (Mitchell et al., 2015). Lately, a patient-led and patient-run biobank began operation, making it possible for patients to contribute and influence research on preferred diseases (Mitchell et al., 2015).

Among the stakeholders mentioned at the beginning of this chapter, the perspectives and involvement of patients in PM research initiatives are critical (Budin-Ljøsne & Harris, 2015).

Patients are a source of clinical, environmental, behavioral, and socioeconomic health information contributing to the PM research endeavor (Budin-Ljøsne & Harris, 2015). The extensive implementation of PM as a novel method of care requires the trust, engagement, participation, and understanding of key stakeholders such as patients who could benefit from PM. Therefore, it is imperative to gain insight into patients' knowledge, attitude, and understanding of biobanks and PM to (a) fill knowledge gaps in the literature; (b) add value to health authorities, policymakers, and healthcare providers to implement policy and program, and knowledge translation agenda on biobanking and PM; (c) to safeguard that the policies regarding biobanking and PM implemented in the future will be best aligned with the opinions and perspectives of those served by those policies.

1.10 Study Significance

This study employed the qualitative research methodology. Data was analysed by framework analysis. The findings of this study will contribute and help to enhance patient engagement and awareness in biobanking and PM research studies. Moreover, by gaining insight into the patient's view of the key ethical, legal, and social implications around biobanking and PM, knowledge translation activities can be developed to overcome misinformation and misunderstandings that may impede the biobank research and practice of PM clinically. This study's findings may help support programs and provisions concerning biobanking and PM that are responsive to patients' specific needs and situations. In the end, the awareness and information generated from this study will be valuable to contribute to future biobank and PM research and clinical initiatives.

1.11 Statement of Purpose

There were two main objectives of this study. The first was to investigate CKD patients' knowledge about PM and to explore their views on the perceived advantages and disadvantages of PM, the ethical, legal, and social implications related to PM, the barriers that delay PM integration into the Canadian Health Care System, and to discover patient preferences regarding informed consent models. The second objective was to examine CKD patients' understanding and experiences with biobanking and to find out their opinions on the perceived benefits and drawbacks of biobanking, the ethical, legal, and social implication of biobanking, the ownership of donated samples, and the factors that influence them to participate in biobank research. These objectives were investigated through a qualitative lens using semi-structured virtual interviews with patients with CKD and a framework analysis method.

1.12 Research Questions:

There were two research questions for this study. They are:

1. What knowledge, perceptions, and experiences do CKD patients have about PM?
2. What knowledge, perceptions, and experiences do CKD patients have about biobanks?

CHAPTER 2: LITERATURE REVIEW

2.1 Patient Participation in PM Research

In this thesis “PM” refers to "precision medicine" and is intended to encapsulate a broad definition reflecting the individualization of diagnosis, prognosis, and therapy based on data derived from broader populations and subgroups. The focal point of PM is to customize treatment or therapy for an individual. A PM approach, undertaken by health care providers and patients collectively, is based on all-inclusive health status, risk assessment, shared goals, and tracking measures (Simmons et al., 2014). The idea is to orchestrate and administer individualized, customized care, and directly involve the patient in health care and self-management of their health (Simmons et al., 2014).

There have been a lot of changes occurring in the healthcare system regarding policy and technology. One of the critical aspects of change is patient involvement. So far, the involvement of patients and their advocacy groups in medical research is in the translational phase (Adams & Peterson, 2016). Recently, the healthcare system changed its strategies by providing a scope for patients to engage, which in turn may assist PM to progress (Adams & Peterson, 2016). A systematic review conducted by Simmons et al. (2014) demonstrated the positive relationship between patients’ participation in disease management interventions and better health outcomes.

A considerable amount of literature has been published about patients’ views, understanding, and engagement on PM. To retrieve published literature addressing both public and patient-based perspectives and engagement on PM, a search of the following databases was performed: PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, EMBASE, and Google Scholar. This search included the last 20 years of peer-reviewed literature and was confined to English-language articles. The following keywords were included

in the search: precision medicine, personalized medicine, pharmacogenomics, pharmacogenetics, knowledge, attitude, perception, understanding, belief, participation, engagement, involvement, challenges, feasibility, issues, and barriers. Previous literature discussed patients' interests, knowledge, perceived advantages and disadvantages of PM, obstacles to implementing PM, and ethical, legal, and social issues related to PM that affect patient engagement in PM.

2.1.1 Patient Interest, Awareness, Knowledge, and Expectation of PM

A qualitative study by Budin-Ljøsne and Harris (2016) investigated patients and their interest organizations' views and perspectives on PM. A semi-structured interview guide was used to conduct telephone interviews. The participants were representatives of thirteen Patient Interest Organizations located across Europe and North America. The results showed that the patients and their organizations were positively interested in PM implementation (Budin-Ljøsne & Harris, 2016). They expressed unhappiness with current medical practices due to shortcomings such as side effects, overtreatment, and undertreatment; therefore, they were enthusiastic about individualized therapy, which they believed had no downsides or disappointments (Budin-Ljøsne & Harris, 2016). However, the concept of PM among many patients was not fully clear (Budin-Ljøsne & Harris, 2016). A qualitative study (formative, semi-structured interviews) was conducted by Gray et al. (2012) with randomly selected patients with colorectal, breast, and lung cancer to investigate levels of awareness regarding PM and genetic testing among patients. These findings suggested that the majority of the patients were not familiar with the term PM and that the term was not meaningful to many patients (Gray et al., 2012).

The recent genomic era, marked by meteoric developments in genetic and molecular research, has enhanced the scope of personalized cancer treatment (Blanchette et al., 2014). Sequencing of gene technology allows for profiling of a patient's tumor on a molecular basis and

provides an opportunity to recognize important clinically relevant somatic mutations that dictate treatment decisions (Blanchette et al., 2014). This novel procedure is known as genomic testing in cancer (GTC). There are paucities of knowledge among patients regarding genomic testing in cancer care (Blanchette et al., 2014).

Blanchette et al. (2014) assessed the knowledge, attitude, and expectations of cancer patients in the Prince Margaret Cancer Canter, Toronto, Ontario, about GTC using a self-administered questionnaire (Blanchette et al., 2014). This study was one of the first studies to evaluate patient knowledge about GTC (Blanchette et al., 2014). The results of this study showed that though some cancer patients have a good fundamental understanding of cancer biology and genomics, most did not know the importance of the genomic complexity of cancer (Blanchette et al., 2014). Instead, they emphasized the hereditary form of cancer (Blanchette et al., 2014). Patients commonly associated genes with familial inheritance and did not know that most genetic mutations resulting in cancer are acquired or happen spontaneously (Blanchette et al., 2014).

This poor level of knowledge among cancer patients who undergo GTC resulted in incorrect conceptions of the possible advantages, hazards, and limitations of genetic testing (Blanchette et al., 2014). Miller et al. (2014) conducted a qualitative sub-study alongside a multicenter pilot feasibility study of DNA sequencing of metastatic tumor biopsies in adult patients with late-stage cancer. They investigated "the experiential context in which much of personalized cancer care will be developed and evaluated" (Miller et al., 2014, p. 4)**.** The primary objective of the Miller et al. (2014) study was to investigate the feasibility of genomic sequencing to be utilized as a clinical tool to dictate cancer treatment. Given all the interest in PM, there is a lack of experiential research about the awareness, expectations, and exposure of patients and health care providers participating in this kind of biomedical research (Miller et al.,

2014). The researchers of this study used an open-ended, semi-structured questionnaire to conduct face-to-face interviews. They investigated the attitudes and experiences of patients and physicians who were involved in research involving genome sequencing of tumor biopsies and its associated results (Miller et al., 2014). As well, they investigated the expectations of these patients and doctors in terms of how they thought these results might contribute to health care (Miller et al., 2014). The study revealed that patients were hopeful that information from DNA sequencing of their cancer cells would offer novel and possibly personalized therapeutics, but they were displeased due to non-findings in the results and the unavailability of clinical trials (Miller et al., 2014).

Pharmacogenomics or pharmacogenetics is the study of the role of a person's genome or genetic makeup in their response to drug therapy (Haddy et al., 2010). Using gene sequencing, pharmacogenomics/ pharmacogenetics promises to deliver personalized therapeutic options (Haddy et al., 2010). Currently, there is a growing trend towards using diagnostics and therapeutics based on pharmacogenomics science in PM applications (Issa et al., 2009). However, there is a lack of literature exploring how pharmacogenomics is adopted and accepted by patients (Issa et al., 2009).

Issa et al. (2009) investigated patients' knowledge of PM and the decision-making process of pharmacogenomic testing and personalized therapeutics. They also investigated patients' acceptance of pharmacogenomic-based PM compared to traditional methods of diagnosis and treatment procedure. The study used a semi-structured interview guide to conduct a focus group, and participants were patients recruited from out-patient clinics at The Methodist Hospital in Houston, Texas, USA (Issa et al., 2009). The majority of the patients had some level of knowledge and perception of the term PM, and the source of their information was reported to

be newspaper articles, radio, and television (Issa et al., 2009). On the contrary, patients were less aware of the term *pharmacogenomics* (Issa et al., 2009). It was also found that a large number of patients indicated a preference for the application of genomic diagnostics and targeted therapeutics to promote PM (Issa et al., 2009).

So far, few studies have explored patients' opinions regarding the barriers that prevent pharmacogenetics from being applied in clinical practice (Haddy et al., 2010). A qualitative study by Haddy et al. (2010) explored consumers' knowledge of PM and their preference regarding "the use of genetics to determine medication selection" (Haddy et al., 2010, p. 2). This study also investigated consumers' opinions regarding their current use of medication, their experiences of medication side effects, and the storage of medical and genetic data (Haddy et al., 2010). Participants were individuals from the general population who previously suffered a chronic medical condition and had a close family member with a chronic medical condition. Participants were divided into three separate age groups (18-35 years, 36-60 years, and over 60 years), and focus groups were used for data collection (Haddy et al., 2010). Many of the participants referred to PM as 'individualized drug treatment plans'. Some patients referred to PM as 'nonpharmacological-based treatments', 'lifestyle changes', 'super pill', 'alternative health-care practitioners, 'medicines made to an individual's requirements, rather than a manufacturer's set dosage', etc. (Haddy et al. 2010, p. 5). The consensus amongst participants regarding PM is that PM is a personal drug regime for an individual's condition where patients play a vital role in the decision process (Haddy et al., 2010). Participants of this study conveyed their dismay towards the current trial and error methods of treatment (Haddy et al., 2010).

De Marco et al. (2010) conducted a study to assess the attitudes and perceptions of prescription drug consumers regarding PM and genetic testing. The study also investigated race-

based differences (African American and White) in attitudes and perceptions regarding PM and genetic testing (De Marco et al., 2010). A focus group was conducted among study participants taking prescribed drugs aged between 25 and 70 years (De Marco et al., 2010). They were recruited from two clinics and a family practice center in a central North Carolina city (De Marco et al., 2010). Though participants had a positive approach, they did not have a proper understanding of PM and genetic testing (De Marco et al., 2010). They were hopeful that PM has a promising future and that it will reduce the risk of errors and side effects associated with the standard one size fit all treatment approach (De Marco et al., 2010).

2.1.2 Barriers to Implement PM

Previous literature discusses patients' views regarding barriers to the implementation of PM. The barriers revealed to patients include the cost of PM, paucities of knowledge of PM among patients and healthcare providers, and inadequate healthcare structure to support PM, etc. These barriers are discussed in the sections below.

2.1.2.1 PM Might be Expensive

In Budin-Ljøsne and Harris's study, patients expressed their concern about the financial cost involved in PM (Budin-Ljøsne & Harris, 2016). The cost of conventional treatment is increasing day by day, and patients fear the cost involved with more individualized drug treatment would be higher (Budin-Ljøsne & Harris, 2016). In addition, genetic tests involved in PM may require frequent medical and physician follow-ups, increasing the cost (Budin-Ljøsne & Harris, 2016).

An alternative view expressed regarding the cost of PM was that, because PM treatments are targeted, PM would minimize expenses due to decreased misuse of resources. Still, in the

beginning PM requires a considerable cost, and many countries in the world do not have enough resources to replace conventional treatments and implement PM (Budin-Ljøsne & Harris, 2016). Furthermore, patients and their interest organizations expected that PM would not be equitable as the higher cost involved will make it less accessible to certain social groups (Budin-Ljøsne & Harris, 2016).

The study by De Marco et al. (2010) discussed earlier revealed that both groups of participants (African American and White – terms described by authors) were concerned about the cost of applying genetic testing to PM (De Marco et al., 2010). They feared that genetic testing would be too expensive to afford. African American participants pointed to a lack of insurance or a limited ability to pay out-of-pocket for the procedures involved in PM (De Marco et al., 2010). White participants in this study feared insurance companies would not cover the expenses associated with PM because of the high cost (De Marco et al., 2010).

Almarsdóttir et al. (2005) investigated lay perspectives regarding future research and the development of pharmaceuticals, notably pharmacogenomics. The researchers involved in this study collected data by conducting eight focus groups of randomly selected (N=42) persons from the general population (both urban and rural) in Iceland (Almarsdóttir et al., 2005). An interview guide with open-ended questions was used to gather information on participants' recommendations and insights regarding the future of pharmacogenomics (Almarsdóttir et al., 2005). It is predicted that medication will be personalized or tailored to each patient according to the individual's genetic predisposition. Participants in the study responded to this prediction and expressed that they believe this new type of medication would be costly compared to the conventional drugs and will create global inequality (between rich and developing countries) and as well as create inequality within societies (Almarsdóttir et al., 2005).

A qualitative and public deliberation study by Bombard et al. explored citizens' informed and reasoned values and expectations regarding PM and gene expression profiling (GEP) (Bombard et al., 2013). This study was conducted in Ontario, Canada. Participants were organized in a 14-person citizens' reference panel on health technologies, aged 18-71 years, in which five participants were women and nine participants were men. Participants were recruited using the 'civic lottery system' (Bombard et al., 2013). The panel met five times over a period of 18 months to discuss, review, and deliberate the general topic of PM and GEP (Bombard et al., 2013). The citizen's panel members expected that PM has the potential to improve care if it is "clinically valid and effective" (Bombard et al., 2013, p.1). But the panel expressed concern over "cost, access, need and feasibility on the adoption into health system" (Bombard et al., 2013, p. 2). The citizen panel agreed there is an inherent cost involved in developing and integrating PM technologies, and they questioned the interest and reason of producers of this kind of technology (Bombard et al., 2013). The panel also referred to the opportunity cost of allocating resources to assist and finance the integration of PM into the health care system (Bombard et al., 2013).

2.1.2.2 Paucities of Knowledge of PM Among Patients, General Practitioners, and Policy Makers

The study by Budin-Ljøsne and Harris showed that some patients and their interest organizations expressed concerns about their lack of knowledge about PM (Budin-Ljøsne & Harris, 2016). Patients are often lacking in general health literacy, and PM is a relatively new topic in this field that is even more challenging for them to understand (Budin-Ljøsne &Harris, 2016). There was also uncertainty about patients' preparedness to know their genetic profile, as some findings could be unforeseen and harder to take in (Budin-Ljøsne & Harris, 2016). This view was rejected by other patients and their interest organizations, who expressed eagerness to

learn their genetic profiles (Budin-Ljøsne & Harris, 2016). A few representatives of patients and interest organizations expressed their concern about the lack of knowledge amongst general practitioners regarding genetics to use in PM strategies (Budin-Ljøsne &Harris, 2016). Consequently, they expressed their anxiety about policymakers' failure to understand PM's importance (Budin-Ljøsne & Harris, 2016).

A study was conducted in The Netherlands by Baars et al. (2005) using a questionnaire to evaluate the knowledge and awareness of genetics and genetic test among general practitioners (GPs), gynecologists (GYNs), and pediatricians (PEDs). This study revealed deficiencies in knowledge of genetics among these health care providers (Baars et al., 2005). The authors of this study suggest that the GPs' level of knowledge is inadequate to answer any questions asked by patients about genetics and genetic tests (Baars et al., 2005).

A qualitative study by Caroll et al. (2016) investigated the perception, experience, and role of Primary Care Providers' (PCPs') in PM, focusing on cancer. This study collected data by conducting a focus group consisting of 51 PCPs recruited from urban and rural interprofessional primary care team practices in Alberta and Ontario, Canada (Caroll et al., 2016). The study results showed that PCPs' understanding of PM was vague, and that they had little or no knowledge of recent developments in PM, of genetic testing that is available, or triggers for proper referral of a patient to receive genetic testing and counseling (Carroll et al., 2016). In addition, their experience of PM was mainly limited to cancer (specifically genomic testing for hereditary breast cancer) and some in prenatal care (Carroll et al., 2016). They also revealed that patients are the primary catalyst for genetic tests and referrals, and patients were more knowledgeable than the PCPs about the genetic testing that is available. (Carroll et al., 2016).

Canadian physicians were surveyed by Bonter et al. (2011) to investigate their roles, perceptions, and experiences in relation to PM, as well as what they perceive to be benefits of using PM and what they perceive to be barriers that prevent the adoption of PM. It was the first national survey of physicians on this topic. The researchers sent surveys to oncologists, cardiologists, and family physicians across Canada by mail, fax, and email (Bonter et al., 2011). Only 21% of respondents revealed that they were well informed and confident in PM, and 29% agreed that they understand and can interpret the results of genetic tests (Bonter et al., 2011). Reasons mentioned for limited knowledge in this field include lack of formal education, limited time and limited availability of resources (Bonter et al., 2011).

Participants' responses/concerns about PM and biobanking may reflect an inadequate understanding of the protections afforded by this legislation, and this is an area where public education could be enhanced. The Genetic Non-Discrimination Act (GNDA) passed into law on May 4th, 2017. The GNDA, along with amendments in the Canadian Labour Code and the Canadian Human Rights Act, prohibits companies and employers from requiring genetic testing or the results of genetic testing from employees. Without legislation, results of genetic testing could limit a person's ability to receive life or disability insurance. It could also significantly raise insurance premiums for those whose tests reveal they are at risk of developing serious medical conditions.

2.1.2.3 Inadequate Mechanisms and Infrastructures to Support PM

In a study by Budin-Ljøsne and Harris (2016), patient interest organizations were found to believe that the mechanisms and infrastructure in place for PM were inadequate. For example, they reported that delays in the approval of new drugs and licenses caused delays in starting PM. In addition to new drugs and licenses, there is also a need to put data-sharing regulations in place

to protect the rights and interests of patients (Budin-Ljøsne & Harris, 2016). On the contrary, some patient interest organizations thought this sort of regulation would hamper the research process (Budin-Ljøsne & Harris. 2016).

In a study by Bombard et al. (2013), a citizens' panel questioned the current preparedness of the health care system to integrate and incorporate PM technologies. The panel members commonly agreed that there is a need to strengthen public awareness about this new PM technology. Their suggestions included the provision of counseling services to help people make choices and decisions about when and how to use PM technology. They also suggested restructuring the laboratory facilities and preparing and training health care providers so they can accurately interpret the results of personalized genetic tests (Bombard et al., 2013).

In the Bonter et al. (2011) study, physicians mentioned some barriers to adopting PM into health care systems such as the unavailability of genetic text in their practice settings, the length of time it takes to obtain results, lack of practice guidelines, limited provider knowledge, and lack of evidence-based clinical information. The authors concluded that Canada is trailing some other countries that have more resources in place to support PM (Bonter et al., 2011).

2.1.3 Patients' Concern about Ethical, Legal & Social Issues Related to PM

In PM, genomic and molecular data are used to tailor therapy for individuals. Generally, patients reveal an interest in this genetic and molecular informed treatment procedure but convey anxiety over privacy risks. A study by Rogith et al. (2014) investigated patients' privacy concerns over genomic data and molecular testing. This descriptive study recruited a sample of female patients with breast cancer. The interviewer used questionnaires to evaluate patients' attitudes and preferences to privacy concerns, genetic data sharing, and the potential risk of insurance and employment discrimination (Rogith et al., 2014). The majority of the participants

suggested that genomic data should be protected, and they worried more about insurance discrimination than employment discrimination (Rogith et al., 2014). Concerning genomic and molecular data privacy, they were less confident in governments and commercial drug companies than they were in research institutes (Rogith et al., 2014). Most participants agreed to share de-identified data with researchers who were not involved in their treatment (Rogith et al., 2014). The majority of the participants did not care about the link between genomic data and their identity, billing, insurance, or clinical data. They did not mind the storage of their DNA and their genetic test results if their data were not identifiable (Rogith et al., 2014). The Issa et al. (2009) study, which was discussed earlier, revealed that participants were anxious about disclosure, privacy, and confidentiality of genetic test results, particularly concerning access to information by insurers and employers. Participants raised concerns about unfavorable genetic test results if they were to be shared with life insurance companies, and that those companies might take the opportunity to raise premiums (Issa et al., 2009).

Participants in the Haddy et al. (2010) study expressed anxiety about privacy regarding the storage of genetic test results and who has access to those results. They conveyed that genetic data should only be shared with health insurers and employers when it is a matter of public safety (Haddy et al., 2010). Though participants had a positive attitude towards genetic approaches which provide the opportunity to select optimum medication and dosage, participants expressed doubts and distrusts about pharmaceutical companies conducting genetic tests and getting access to genetic information (Haddy et al., 2010). Participants suspect that these commercial companies would utilize this opportunity for profit (Haddy et al., 2010). Participants also conveyed their distrust of physicians, and they feared that due to the influence and incentives of pharmaceutical companies, doctors would share genetic information with them

(Haddy et al., 2010). Participants also feared public and personal discrimination due to genetic test results, such as discrimination against immigrants due to genetic makeup, difficulty getting medical insurance, etc. (Haddy et al., 2010).

In the stydy by De Marco et al. (2010), both groups of participants (African American and White) expressed concerns about PM and genetic testing regarding equity and privacy of genetic test results. They believed that results could be exploited, or that privacy could be compromised (De Marco et al., 2010). White participants of the De Marco et al. (2010) study feared that discrimination might occur in insurance and employment situations due to evidence of a "genetic predisposition for a specific disease or from simply being tested" (p. 5). Even with PM, medical mistrust would be an issue among African American participants (De Marco et al., 2010). The authors of this study suggested that a way to tackle this issue is by informing patients about the Genetic Information Non-discrimination Act (GINA) (De Marco et al., 2010). This legislation, signed in 2008, would protect patients from discrimination by their health insurers and employers based on their genetic data (De Marco et al., 2010).

McGowan et al. (2014) investigated the understanding of different stakeholders (who engaged in PM in a wide range of organizational and professional settings) regarding "the challenges of integrating genomic testing and targeted therapies into clinical oncology" (p. 1). Semi-structured in-depth interviews were conducted by phone or in-person with 117 basic scientists, translation researchers, commercial and non-profit developers, clinicians in private practice, health professional educators and advocates, research funders, medical journal editors, academic PM program directors, and health care providers in academic medical centers (McGowan et al., 2014). Though stakeholders were exuberant about PM, they raised concern over many ethical and social challenges that may hinder its integration, such as "informed

consent for genetic testing of cancer, privacy, confidentiality, and disclosure of genetic test results, access to genomic testing and targeted therapies in oncology" (McGowan et al., 2014, p. 1). Participants of this study shared concerns that informed consent is a significant obstacle to integrating PM into cancer care. A primary reason cited was the lack of genetic knowledge among patients' (McGowan et al., 2014). They pointed out that patients could not understand the pharmacogenetic testing, specifically the psychological impact of germline and somatic genetic testing (McGowan et al., 2014). The results of this study showed patient concerns about privacy and confidentiality of personal genomic data and the risk of discrimination (McGowan et al., 2014). Interviewees of this study identified that disparities exist in terms of access to and allocation of genomic testing because genetic testing is governed by patients' social and economic conditions, insurance providers, and cancer care sites (McGowan et al., 2014).

2.1.4 Summary

The findings of this literature review regarding patients' views about PM, understanding of PM, and engagement with PM are summarized in this section. Patients had favorable views on PM and preferred PM over traditional medicine, which many believe has shortcomings. The concept of PM was not clear to many patients and knowledge of PM among patients is limited.

The literature review revealed patients' views on the barriers to the integration of PM in the current health care system. Some of the barriers noted include: PM could be expensive, there is a lack of knowledge about PM among public and physicians, there is inadequate healthcare infrastructure to support PM, and there are ethical, legal, and social issues related to PM. Patients conveyed their concerns about the cost of PM and expected it might be expensive. Moreover, patients believe there is an inherent cost involved in developing and integrating PM technologies in current healthcare systems. Patients felt there is inadequate knowledge of PM among the

public and physicians, which poses a challenge to implementing PM. There are several ethical, legal, and social issues related to PM that were retrieved from the literature review. Those issues are (a) data privacy and security, (b) confidentiality, (c) breach of trust, (d) data sharing, (e) risk of insurance and employment discrimination, (f) disclosure of genetic test results, and (g) trust (or mistrust) in physicians.

2.2 Patient/Public Engagement in Biobank Research

As mentioned earlier, the biobank is a significant source of human biospecimen, genomic data, and clinical information. These human biological samples and related genetic and medical data are being used in basic health and biomedical research and research on PM, stratified medicine, widespread and rare diseases. There is an increasing number of biobanks established all over the world. Current developments in research on human biospecimens have paved the way for identifying genomic variations, such as acquired mutations, which could indicate risk factors for certain diseases (Abdelhafiz et al., 2019). By utilizing human biological samples and analyzing their associated demographic, clinical, and genetic data being stored in biobanks, researchers are able to identify biomarkers that enable early detection of certain diseases (Abdelhafiz et al., 2019). This may eventually allow clinicians to make early diagnoses, more accurate prognoses of diseases, and create individualized therapeutic strategies (Abdelhafiz et al., 2019). However, the success of biobank research depends on public and patient awareness, attitudes, knowledge, and trust in biobank research. It depends on their willingness to participate and donate biospecimen samples for research purposes and to agree to sample storage (Abdelhafiz et al., 2019).

Simultaneously, biobanking research is associated with several ELSI's and governance challenges (Bossert et al., 2018) such as informed consent, the right to withdrawal, personal

benefits, questions on returning research results, protection of data privacy and security, nature of research, participating researchers, and storage periods of biospecimens and information. Previous works of literature have discussed patients' and/or public understanding of biobank research, their attitude regarding participation, and their concerns about ethical, legal, and social issues in the context of biobank research.

A search was conducted in PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, EMBASE, and Google Scholar. The search criteria included English-language articles and the previous 20 years of peer-reviewed literature. The following keywords were included in the search: biobank, biorepository, genetic database, genomic database, knowledge, attitude, belief, perception, understanding, belief, participation, engagement, involvement, challenges, feasibility, issues, and barriers. Reference lists of relevant articles were also hand-searched to retrieve additional studies that the electronic search may have missed.

2.2.1 Patient/Public Awareness and Attitudes about Biobank Research and Their Willingness to Donate Biospecimens

Bossert et al. (2018) conducted a postal survey among the population of Hanover, Germany, to assess public attitudes and awareness regarding biobank research and public willingness to donate biological samples. The survey results revealed that public awareness of biobank research is low (Bossert et al., 2018). Only a third of respondents had heard about biobanks, but their attitude towards biobanks as a means of medical research was mainly positive (Bossert et al., 2018). Furthermore, most survey participants (70.4%) expressed their willingness to donate biospecimens to biobank (Bossert et al., 2018). A similar study was carried out in Italy using questionnaire surveys, and the study participants were family members of patients visiting

outpatient departments for a geriatric or neurological reason (Porteri et al., 2014). Results showed that 86% of participants were willing to donate biological samples to the biobank for research purposes, and their attitude towards biomedical research was more favorable than those who were not willing to donate biological samples (Porteri et al., 2014).

Gaskell et al. (2013) conducted two studies: a social survey (quantitative) and a focus group (qualitative) to assess the European public's willingness to engage in biobank research, preferences for consent, and opinions on data privacy, security, and trust in key players who are involved in biobank research. The results showed that two-thirds of the participants mentioned that they were not familiar with the term biobank (Gaskell et al., 2013). There was variation visible regarding the public's willingness to participate in biobank research; people from North European countries were more willing to participate than other European countries (Gaskell et al., 2013). A higher awareness of biobank research was visible in Iceland, Sweden, and Finland (Gaskell et al., 2013). Respondents' higher percentage of willingness to participate in biobank research depends on their country's higher level of engagement (Gaskell et al., 2013).

Tozzo et al. (2017) conducted a questionnaire survey among students in an Italian University to assess their awareness about biobanking, their views on its usefulness and risk, and their perception of donating biospecimens for biobank research. The study revealed that many Italian students had previously heard the term biobank, and 91% of the students reportedly had a positive idea of giving biological materials for biobank research for altruistic reasons (Tozzo et al., 2017).

A mixed-method study in the UK by Lewis et al. (2013) investigated the general public's willingness to give biospecimens to biobanks. Twelve focus groups, consisting of 81 people (48 women and 33 men), were conducted across the UK. Participants were recruited from the streets,

and purposeful sampling methods were used to represent a wide variety of demographic groups (Lewis et al., 2013). Significant findings and themes gathered from the focus group discussions were used to develop and reframe quantitative survey questions, and 1110 participants were recruited using stratified sampling methods to complete the survey (Lewis et al., 2013). The study results revealed that the public in the UK generally had a positive approach to donating biological samples for research purposes (Lewis et al., 2013). Eighty seven percent of survey responders stated that the donation of human biological samples is vital, and those who had some level of knowledge about medical research were more in favor of donation (Lewis et al., 2013). These participants said they were willing to donate biological samples to support the development of medication and therapeutic strategies, as well as the belief that they and their family members could benefit from biomedical research (Lewis et al., 2013).

An experimental survey study was conducted by Sanderson et al. (2017) in the USA to investigate individuals' desires to participate in biobank research and their willingness to engage with different consent and data sharing conditions/models. Participants were either patients themselves or had a child (minor dependent) in one of the 11 US healthcare systems in the Electronic Medical Records and Genomics (eMERGE) Network and were recruited by a disproportionate stratified sampling scheme (Sanderson et al., 2017). The strata were categorized as cross-classification of different age groups, sex, race, ethnicity, education, and resident of rural/urban/suburban groups (Sanderson et al., 2017). The study results revealed that 66% of participants expressed their eagerness to participate in biobank research, and their willingness was the same between three different consent models (Sanderson et al., 2017). Willingness to participate was linked to white race, higher educational status, lower religiosity, perceiving more research benefits, fewer concerns, and more occasional information needs (Sanderson et al.,

2017). The majority of participants were concerned about the exploitation of their health data (Sanderson et al., 2017).

A qualitative study by Heredia et al. (2017) used a focus group to investigate factors that influenced the willingness of Mexican Americans (located in Houston, El Paso, and Brownsville, Texas, USA to engage in biobanking research. The study found that most participants had never heard of the term biobanking (Heredia et al., 2017). Participants were confused about biobanking and biospecimen donation or diagnostic procedure (Heredia et al., 2017). There were many barriers stated by the participants, including little or no knowledge of biobanking due to lack of familiarity with the health care system and research in general, little information about donors' responsibility, risk or impact associated with participation, fear of not receiving research results, fear of experiencing pain or harm as a result of donating a specimen for biobanking, and distrust or negative views of healthcare research system (Heredia et al., 2017). Facilitators stated that reasons given for participating in biobanking and specimen donation included altruism, safety, understanding biobanking procedures and purposes, perceived advantages to participation, and culturally fitting enrollment strategies (Heredia et al., 2017).

2.2.2 Patient/Public Perceived Benefits of Biobank Research

Population-based biobanks are vital resources for genomic research (Rahm et al., 2013) that has the potential to advance the translation of biomedical research into clinical practice and advance PM. This progress towards new dimensions of research and treatment acts as a catalyst for the rapid rise of biobank research worldwide (Rahm et al., 2013). But this endeavor could potentially depend on individuals' perceptions of the benefits of biobank research and their participation in such initiatives. Rahm et al. (2013) conducted a 20-question survey to explore participants' perceived benefits and opinions of biobanking, as well as their willingness to

contribute a blood sample to a biobank. Participants were individuals with health insurance with Kaiser Permanente Colorado (KPCO), an integrated healthcare delivery system that provides health insurance. KPCO was planning to develop a population-based biobank comprised of blood samples from its adult members (Rahm et al., 2013). Participants were approached to complete the survey while they were waiting for appointments in clinic waiting rooms, and 203 members participated in the survey (Rahm et al., 2013). The study showed that even though more than two-thirds of participants had never heard the term biobank, they were willing to give blood samples for future biobank research (Rahm et al., 2013). In addition, 74% of participants would donate a sample because they believed "it is important to contribute to future research" and 47% believed that biobanking would benefit them and their family members (Rahm et al., 2013). The survey results also showed that 62% of participants thought their donation to the biobank would help KPCO in their efforts to conduct research to further the understanding of genetics and disease risk/survival/treatment (Rahm et al., 2013).

A telephone survey combining open-ended and forced-choice questions was conducted by Ludman et al. (2010) to find the reasons that influence study participants to reconsent for the submission of their existing data to the federal database of Genotypes and Phenotypes (dbGaP). The researchers recruited participants from the members of the ongoing Adult Changes in Thought (ACT) Study (a longitudinal cohort study of aging and dementia funded by the National Institute on Aging) (Ludman et al., 2010). The ACT study recruited participants from the greater Seattle area who were aged ≥65, had no signs of dementia and were members at Group Health (a prepaid health plan serving approximately 600,000 members in Washington and Idaho) (Ludman et al., 2010). The results showed that 81.1% of the participants thought that research using this biorepository is very important to improve patient care and to prevent and treat many diseases.

Moreover, most (75.1%) of participants indicated that biorepository research could help increase knowledge for society (Ludman et al., 2010).

Oberby et al. (2015) surveyed 169 adult patients from two outpatient practices of the University of Maryland (UMD) Faculty Physicians, Inc. to investigate "mutable attitudes and opinions commonly correlated with biobank participation" (p. 1-2). Initially, participants were shown a 6-minute informational video containing information about a planned University of Maryland biobank (UMBiobank) initiative and were then asked to complete the survey (Oberby et al., 2015). The results showed that 51% of participants intended to participate in the biobank initiative (Oberby et al., 2015). Additionally, most of the participants agreed that joining biobanks could ameliorate their health (64%), better the health of their loved ones (70%), improve the health of people of the same race or ethnicity (68%), and improve the health of people in general (73%) (Oberby et al. 2015).

A systematic review conducted by Nobile et al. (2013) addressed participants' reasons to participate in biobank research and the factors that influence their decisions. The study revealed subjective perceptions of the benefits of participating in biobank research, including benefits to participants themselves, future generations, participants' families, and individuals of their ethnic group (Nobile et al., 2013).

A qualitative study by Nobile et al. (2016) investigated factors that influence participants' decisions to participate in a cohort study with an attached biobank. Participants were recruited from two different research projects—the German National Cohort (GNC) and the European Prospective Investigation into Cancer and Nutrition (EPIC) (Nobile et al., 2016). The GNC, launched in 2014, is a German-wide population-based prospective study, and the EPIC study, launched in 1992 across 10 European countries, is an ongoing and multi-center prospective

cohort study with an attached biobank (Nobile et al., 2016). The sampling procedure was purposive to obtain gender balance and sufficient age variance, and a semi-structured interview guide was used for interviews (Nobile et al., 2016). The factors that influenced the participants' decision-making process were possible benefits and risks related to participation, practical considerations, and external elements such as the name of the organizing institution (Nobile et al., 2016). Participants stated that benefits such as getting a medical exam and discovering unexpected findings from exam results were motivating reasons to participate in biobank research (Nobile et al., 2016). Benefits to others was also cited as a reason to enroll, including benefits to their own family and the overall population (Nobile et al., 2016).

2.2.3 Patient/Public Preference of Consent Model for Biobank Research

There are ongoing debates on the ethical and practical aspects of informed consent regarding large population biobanks that store biological specimens and health information. Options for informed consent include no consent, opt-out, opt-in, case-by-case, tiered or categorical, and broad or blanket consent (Garrison et al., 2016). Studies cited public opinion on the ethical, legal, and social aspects of each option. Knowing the publics' or patients' attitudes and preferences for consent models is essential for researchers to know so that they can choose which model to utilize (Platt et al., 2014) and help augment a system of informing and consenting prospective biobank donors that are trusted by patients and ethically sound (Simon et al., 2011).

Kaufman et al. (2009) surveyed (online) 931 veterans' affairs patients in the USA to investigate their willingness to participate and their concerns about establishing an extensive database of genetic information and medical records and their preferences about some aspects of study design. The results showed that 71% agreed to participate in the research overall, and their

preference for different types of consent was mixed. Of the participants surveyed, 47% chose to provide blanket consent, whereas 43% preferred to give separate consent for each research project (Kaufman et al., 2009). The rest (10%) would prefer to select broad categories of research they find acceptable at the outset of the study (Kaufman et al., 2009).

Platt et al. (2014) conducted an online survey among US adults to investigate the association between "consent preference and demographic factors, beliefs about privacy and the value of research, and the perceived trustworthiness of researchers" (p. 1) about a national cohort study proposed by the National Human Genome Research Institute (NHGRI). An online survey consisting of 177 items along with a three-minute video describing the goals and design of the proposed cohort study by NHGRI was distributed among a representative sample of 4,659 US adults (Platt et al., 2014). Broad consent was chosen by 52% of responders, and 48% preferred study-by-study consent models. Study-by-study consent was preferred mainly by black non-Hispanic over white non-Hispanic participants (Platt et al., 2014). Older participants and men mostly preferred broader consent (Platt et al., 2014). In terms of gender, 54% of men and 48% of women prefer broad consent over study-by-study consent (Platt et al., 2014). The reason participants in the survey chose broad consent was that they preferred not to be disturbed with several requests for consent, and they expected that the study results that would bring better treatment (Platt et al., 2014). Preference for study-by-study consent related to participants' fears about research and a desire to have their consent respected by requesting it for each specific research study (Platt et al., 2014).

Simon et al. (2011) used a mixed-method study design to investigate "public attitudes, preferences, and concerns toward (1) biobanking and the potential importance of biobank research; (2) prospective opt-in and opt-out frameworks for providing initial consent to

participate in a biobank; and (3) consent models that address the scope of future research with biobank samples and health information, including broad, categorical, and study-specific consent" (Simon et al., 2011, p. 2). All forty-eight participants (that participated in seven focus groups) and 751 survey participants were recruited from residents in the catchment area of a comprehensive biobank being developed at the University of Iowa and were contacted by telephone using random digit dialing (Simon et al., 2011). Though the term biobank was unknown to nearly all participants, they were enthusiastic about the future of genomic research endorsed by biobanks (Simon et al., 2011). There was strong support for consent during the biobank research process, and prospective opt-in consent was favored by most participants (both in the focus group and survey) over the opt-out consent model (Simon et al., 2011). For the scope of future research use, participants choose broad, research-unspecific consent over categorical and study-specific consent models (Simon et al., 2011).

2.2.4 Patient/Public Concern on Privacy, Confidentiality, and Data Sharing

Genomic information along with medical, lifestyle, and environmental data that are stored in biobanks is commonly used to examine the effects of these variables in the causation of chronic disease, but patient/public concern about data privacy influences them to participate in biobank research (Kaufman et al., 2009). Data sharing with the research fraternity creates conflict between fostering scientific objectives and safeguarding the privacy concerns of study participants (Trinidad et al., 2010). Therefore, it is imperative to understand the magnitude of patient views and concerns about data privacy and sharing concerns regarding biobank research participation (Kaufman et al., 2009). Kaufman et al. (2009) conducted an online survey among US adults to measure their willingness to participate in proposed biobank research as well as their privacy concerns, concerns about informed consent, and data sharing. The survey results

found that 60% of participants were willing to participate in biobank research if approached. However, 90% of participants were concerned about their data privacy, 56% were worried about biobank having their information, and 37% were concerned that data generated from the research could be used against them (Kaufman et al., 2009). The results also showed that 80% of participants would agree to allow government researchers to use their data. Further, 75% of participants would allow industry researchers access, whereas 92% of participants were open to allowing academic researchers to use their data (Kaufman et al., 2009).

A study by Trinidad et al. (2010) explored "the perceptions, beliefs, and attitudes of research participants and possible future participants regarding genome-wide association studies (GWAS) and repository-based research" (p. 1). This study conducted ten focus groups at Group Health Cooperative (a large health maintenance organization based in the Seattle metropolitan area) (Trinidad et al., 2010). Focus group participants were recruited from research participants of the Adult Changes in Thought (ACT) Study, a study about aging and dementia (Trinidad et al., 2010). The study participants of the focus group also included surrogate decision-makers on behalf of incapacitated ACT participants and three age-defined cohorts (18–34 years, 35–50, >50) who were not part of the ACT study (Trinidad et al., 2010). The results indicated that participants of this study understood the significance and benefit of broad data sharing, specifically in genomic research, and at the same time they pointed out some risks (Trinidad et al., 2010). Many acknowledged that the availability of de-identifiable data for research would bring greater good (Trinidad et al., 2010). Privacy and confidentiality were a general issue for the participants of this study but these issues were not impactful in their decision to participate in biobank research (Trinidad et al., 2010). Older participants were less concerned about the possible loss of confidentiality and expressed fewer privacy concerns over data sharing (Trinidad

et al., 2010). The majority of the participants had the trust to share their data with researchers at academic institutions as well as non-profit and public-interest research organizations (e.g., the American Cancer Society) (Trinidad et al., 2010). These participants reasoned that they trusted these types of organizations because they are considered "legitimate" and they intend to advance scientific knowledge to do greater good rather than trying to make a profit, as opposed to corporately funded or for-profit organizations (Trinidad et al., 2010).

In the Oberby et al. (2015) study, 68% of participants in the biobank research were concerned about data privacy and 55% indicated that the data gathered from the study could be used against them. Melas et al. (2010) investigated participants' unwillingness to provide consent to DNA biobanking in a population-based biobank at Karolinska Institute in Stockholm, Sweden. The study participants were recruited from PART (a longitudinal-based population study) which investigated mental health and wellbeing based on extensive questionnaires, registry data, and psychiatric interviews (Melas et al., 2010). Participants of this study were requested to contribute DNA in the form of saliva (Melas et al., 2010). Semi-structured telephone interviews were conducted among selected individuals who did not provide DNA to determine their motivation for non-participation (Melas et al., 2010). The results of this study revealed that participants were concerned about data privacy; they believed a person's genetic information was sensitive and should be personal (Melas et al., 2010). Few others stated that genetic information could be used to reveal their identities, and that "society could use DNA biobanking for purposes other than the ones it was supposed to" (Melas et al., 2010, p. 4).

2.3 Summary

The findings of this literature review of patients' views, knowledge, and engagement with regards to biobanking are summarized in this section. Though many patients were not familiar

with the concept of biobanking in general, patients had positive views about biobanking as a means of medical research. The majority of patients want to donate samples to biobanks. The reasons cited for contributing to biobank research were altruism, benefit to family and others, contribution to future research, improved treatment, improved health, etc. The literature review also revealed several barriers to biobank research from patient responses including little or no knowledge of biobanking due to a lack of familiarity with health care systems and research in general, little information about donors' responsibilities, potential risks or impacts associated with participation in research, fear of not receiving research results, fear of experiencing pain or harm because of donating a specimen for biobanking, and distrust or negative views of the healthcare research system. Moreover, the published information about ethical, legal, and social issues associated with biobanking include data sharing, privacy, security, confidentiality, trust in the research organization conducting the research, informed consent models, the right to withdraw from research, questions on the nature of the research, participating researchers, and storage periods of biospecimens and information.

2.4 Conclusion

Several studies that have been published on patients' and/or publics views, understanding, and engagement regarding PM and biobanking are discussed in this section. Literatures that used different methodology (qualitative study, quantitative study, systematic review), data collection methods (interview, focus groups, survey), and varied populations/patient groups are included in this discussion. But there has not yet been a single study conducted using qualitative research methodology to investigate the knowledge, perceptions, and experiences of Canadian CKD patients regarding PM and biobanking. Therefore, this study provides an opportunity to learn about these issues through the lens of

Canadian CKD patients. The results are anticipated to assist in understanding CKD patients' views, opinions, and challenges regarding PM and biobanking and perhaps to indicate the actions needed to overcome any associated issues and challenges.

CHAPTER 3: METHODS & METHODOLOGY

3.1 Overview

In this chapter, the research methods used to explore the research questions are presented. First, this chapter will discuss the study design including why a qualitative approach was chosen and what informed the choice to use Framework Analysis. Next the chapter will discuss study design, settings and study participants, instrumentation and data collection, and data analysis. Finally, methodological rigor for this study will be addressed.

3.2 Study Design

A qualitative approach was selected for this study. Framework Analysis was used to identify important points of CKD patients' knowledge, perception, and experience about biobanking and precision medicine. This qualitative study was completed by conducting individual virtual interviews with patients who have lived experience with varying stages of CKD. The patients were recruited from the Canadian Seeking Solutions and Innovations to Overcome Chronic Kidney Disease (Can-SOLVE CKD) network, the Kidney Foundation, and Alberta Health Services (AHS).

3.2.1 Qualitative Research

The information or data collected in analyzed qualitative research are “textual materials such as interview transcripts, field notes, and documents, and/or visual materials such as artifacts, photographs, video recordings, and Internet sites, that document human experiences about others and/or oneself in social action and reflexive states” (Saldana et al., 2011, p. 4). Qualitative research generates “knowledge to get to deeper meanings of experience while acknowledging the contextual, value-laden character of the knowledge constructed as a result of

the research" (Tilley, 2016, p. 28). Qualitative research involves "an interpretive, naturalistic approach to the world. This means that qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them*"* (Denzin & Lincoln, 2011, p. 3).

Undertaking qualitative research allowed me the opportunity to gain in-depth insight into CKD patients' knowledge, attitudes, and experiences in biobanking and PM. The qualitative research approach provided me with a platform to hear their voices. There is no theoretical framework for this study as the theory was interpreted from the data collected. I used Framework Analysis to analyze the data.

3.2.2 Framework Analysis

Framework analysis was used to identify crucial points of knowledge, attitudes, and experiences of CKD patients about PM and biobanking. Framework analysis was developed by researchers Jane Ritchie and Liz Spencer from the Qualitative Research Unit at the National Centre for Social Research in the United Kingdom in the late 1980s for use in large-scale policy research (Gale et al., 2013). Framework analysis approaches "identify commonalities and differences in qualitative data, before focusing on relationships between different parts of the data, thereby seeking to draw descriptive and/or explanatory conclusions clustered around themes*"* (Gale et al., 2013, p. 2). Thus, the framework analysis approach involves several stages to follow and construct "highly structured outputs of summarised data" (Gale et al., 2013, p. 2). Framework analysis is therefore effective where a project involves managing large data sets and obtaining a holistic, descriptive overview of the entire data set. It is an appropriate method of analysis suitable to the complex nature of the interviews for this study.

3.3 Setting & Study Participants

3.3.1 Setting & Context of the Research

This study targeted CKD patients who were recruited with the help of Can-SOLVE CKD. Can-SOLVE CKD works in partnership with patients, researchers, health care providers, and policymakers to transform treatment and care for Canadians living with or at risk for CKD. Participants of this study were also recruited from across Canada by the Kidney Foundation. This study also sought participants who were undergoing treatment for CKD at various AHS facilities.

3.3.2 Sampling

The target population of this study was CKD patients. The eligibility criteria included participants who were (a) diagnosed with CKD, (b) were 18 years or older, (c) were English speaking, and (d) who had the capacity to consent to research participation.

3.3.3 Study Participants Recruitment

The sampling strategy implemented in this study was convenience sampling. An invitation was made through different platforms, and all those who volunteered to participate in this study were included. Invitations to participate in the interviews were made through the Can-SOLVE CKD Network website in the KidneyLink research portal (www.kidneylink.ca). The Can-SOLVE CKD Network posted about the opportunity to participate in this study on their KidneyLink research portal (www.kidneylink.ca) platform for their users. Can-SOLVE CKD also sent an email blast to all their users with a listing of new opportunities including this study, and interested users emailed directly to express interest in participating in the study. Moreover, invitations for participation in interviews and study information were advertised/posted on the Kidney Foundation website (www.kidney.ca) for their users across Canada. The Kidney

Foundation also shared the opportunity to participate in this study on social media including Facebook and Twitter. Interested participants then contacted me to express their intentions.

Additionally, participants were recruited from AHS. These participants were CKD patients undergoing treatment in hospitals, clinics, and centres across Alberta. Fully executed administrative approval for the research was obtained from AHS. Printed copies of information about the study and invitations to participate were sent to kidney treatment facilities, hospitals, clinics, and centres of AHS across Alberta. Patients were approached at their regular clinic/hospital visits by receptionists or administrative staff who explained and provided verbal and printed copies of study information and determined their interest in participating.

Patients who expressed interest in participating in this study then contacted me either by phone or email. I provided further details about the study and decided the date and time of the interview according to patients' preferences. Prior to conducting the formal interview, the informed consent, and participants information form (PIF) was sent to participants by email. Participants had the chance to review and sign the informed consent form that contained the study's details, the purpose of the research, and an opportunity to acknowledge their informed consent. Participants could also provide their socio-demographic characteristics by filling the patient information form.

3.3.4 Honoraria and Reimbursement

Participants were provided with a CAD$25 gift card in appreciation for their time and any possible expenses associated with their participation in this study, as well as a letter thanking them for their participation.

3.3.5 Privacy and Confidentiality

Strict measures were undertaken to protect participants' identities and to ensure the confidentiality and security of the participants' data. Only I had access to participant files which consisted of transcripts, consent forms, patient information forms (which contain names, contact information, and socio-demographic information). I received signed consent forms and completed patient information forms from participants by email. All copies of signed consent forms, PIF's, interview recordings (audio files), and reimbursement documents are initially stored electronically in a password-protected file on my password-protected laptop. Later, these documents will be stored on a UC one drive server. During recruitment, the informed consent form was reviewed by each participant and signed (Appendix D).

At the beginning of each interview, I clearly and thoroughly explained the purpose of the research to all participants and provided them with an outline of how the information derived from their participation would be used. In addition, participants were instructed not to reveal their names or any identifying information during the interview. Therefore, each interview recording and transcript was saved electronically with the only identifier being a participant number (e.g., Participant no. 1, Participant no. 2, etc.). To conceal participant identities, interview recordings and transcripts do not include participant names or any other identifying information. Before each interview, I verbally reassured participants that all data would be confidential and reminded them that they were at liberty to decline to answer any questions they did not want to answer. I reminded them that they were free to withdraw their consent at any time without any adverse consequences. There is no identifying information about participants in the study findings section of this thesis. Limited sociodemographic information (age, sex, gender, level of education, and stage of kidney disease) is summarized and presented in this thesis. In case of any future presentation or publication of the results of this study, the only

identifiers that will be used are participant numbers. All personal and identifiable information will not be shared or disclosed to any third party. All participants in this research will remain unidentifiable, and any identifying information provided to me will remain confidential.

3.3.6 Ethical Approval

Once the proposal for this study was approved by the thesis supervisory committee and graduate program director of the Department of Community Health Sciences, University of Calgary, an ethics application was forwarded to the Conjoint Health Research Ethics Board (CHREB), and approval was secured (ethics certificate no. REB20-0036).

3.3.7 About the Researcher

Reflexivity involves a continuous process of reflection by the researcher regarding their values, considerations, preconceptions, and those of the participants, which influence analyzing and interpreting data (Primeau, 2003). I have tried my best to be honest and clear about my values and my background so that the reader can appreciate the potential for inherent biases that may influence my interpretation of the results.

My upbringing, education, and my work experience helped me to learn the importance of diversity and to develop an appreciation of different opinions, cultures, languages, and ways of life. As a result, I have a great interest in learning about people. I have learned to recognize the abundant diversity of cultures in our society. I have respect for cultural differences, and I acknowledge the validity of different expressions and contributions. I value and respect others.

Having a background in dentistry, I am comfortable with healthcare professionals and healthcare services. The MSc program in the Department of Community Health Sciences at the University of Calgary has helped me to develop a core set of skills to recognize, explore, and

solve problems at the intersection between population, public health, and education. The MSc program has broadened my horizons regarding issues in health care from biostatistics, disease, and population health to social and economic factors in community health, disability issues, delivery of health services, and more.

3.4 Instrumentation & Data Collection

3.4.1 Development of Interview Guide

In qualitative research, one-on-one interviews are a common and widely used data collection tool (Lambert & Loiselle, 2008). Information is collected about peoples' knowledge, views, and experiences through questions and responses. Interviews are an appropriate and valuable method in qualitative research that requires researchers to collect information, to explore people's accounts and opinions, and to compare this information with others to develop a theoretical understanding of the underlying structures of beliefs (Green & Thorogood, 2014, p. 97). Interviews are useful as a data collection method when the topic of inquiry relates to subjects that demand complex questioning and considerable probing.

Interviews in qualitative research involve open-ended questions that elicit a detailed and in-depth response from the interviewees. In my research, a semi-structured interview (interview guide) was employed. I used a set of predetermined questions (interview guide-Appendix) to capture participants' responses in their own words and in a comprehensive and systematic manner. I also asked additional questions to clarify and further expand on certain issues when needed. These semi-structured interviews allowed me to set the agenda in terms of topics I wanted to cover, and they generated data and information on those desired topics (Green & Thorogood, 2014, p. 96). At the same time, I was led by the participants during the interviews, and they guided the conversation by discussing what is important to them within the set topics

that I provided. The in-depth nature of the interviews allowed participants to develop their own accounts of the issues significant to them (Green & Thorogood, 2014, p. 96). This approach is considered the standard approach for the interview process, and I used the interview guide as a checklist to ensure that all respondents provided information on the same topics.

I developed an initial semi-structured interview guide that was developed by retrieving and using existing literature. I pilot tested the initial interview guide with the first two interviewees. After the initial two interviews, I reviewed the initial interview transcripts and re-assessed the interview guide's suitability as new themes arose from the pilot interviews. Prior to the rest of the interviews, I reviewed, revised, and finalized the interview guide. The carefully crafted questions serve as a guide to portray the knowledge, perception, and experiences of the participants regarding biobanking and PM.

3.4.2 Virtual Interview

Interviews were conducted during a period of public health restrictions due to the COVID-19 pandemic, so it was necessary to use virtual interviewing methods. I reviewed contact forms from people expressing interest in participating in the study; respondents were screened to ensure that they met the study's selection criteria, and all eligible participants were subsequently scheduled for an interview. All interviews were scheduled at a time that was convenient to the participants. Moreover, the virtual medium of the interviews was chosen according to the participants' preferences. Before the interview, the use of a recording device was also discussed with participants, and they informed me that they were comfortable using a recorder. All interviews were audio-recorded using the Recorder application (Voice memo) of iPhone and backup recordings were made using a digital recorder. Recordings were later

transcribed verbatim by me. I reviewed the initial transcripts for accuracy and compared the interview transcripts to the audio recordings.

The Patient Information Form included questions on the name, phone, email, age, sex, gender, level and type of education, stage of CKD, English language proficiency, number of years of seeing a kidney specialist, and prior research participation. After signing, participants returned the informed consent form and the PIF to me by email. Participants signed the consent form with their real names, but to maintain confidentiality their names were not used during the interviews. Before the interview, participants were welcomed to convey their concerns if they had any. The participants were informed in advance that if they felt uncomfortable, distressed, or did not want to participate anymore, the interview could be stopped, and they could withdraw their participation from the study at any time without any consequences. One-on-one interviews were conducted virtually and were guided by a general interview protocol. This allowed participants to discuss the topics freely without interruption and provided a chance for in-depth responses. As an interviewer, I engaged in active listening and tried to ensure participants were at ease sharing their knowledge and experiences and providing confidential information.

3.5 Data Analysis

3.5.1 Stages of Framework Analysis

In this study, my approach to data analysis was to use Framework Analysis. Using this method of analysis enabled me to develop themes both inductively from the accounts (experiences and views) of research participants and deductively from existing literature. This method of analysis involves the following stages: (a) transcription, (b) familiarization with the data, (c) coding, (d) developing a working thematic/ analytical framework, (e) applying the

analytical framework, (f) charting data into the framework matrix, (g) interpreting data (Ritchie & Spencer, 1994).

3.5.1.1 Transcription

I carried out transcriptions and examined the interview transcripts several times to ensure that the formatting was correct and to remove any inconsistencies. My focus and interests were primarily in the content rather than the structure of the participants' responses for analysis. However, I noted long pauses, interruptions, and nonverbal communication (such as laughter) within the text. All transcripts were checked for errors by listening to the audio-recording several times and reading the transcripts simultaneously. I made sure that the transcripts had large margins and adequate line spacing to accommodate coding and making notes later. The process of transcription allowed me to become immersed in the data.

3.5.1.2 Familiarisation with The Data

One crucial step of data analysis is to become familiar with the whole interview using the audio recordings and transcripts and any contextual or reflective notes recorded by the interviewer (Gale et al., 2013). I have read and re-read each interview transcript from this study thoroughly to familiarize myself with the whole set of data by listening back to the audio-recorded interviews. This process of familiarisation through reading and making notes helped me find my way through hundreds of pages of transcripts later in the analysis.

3.5.1.3 Coding

I completed coding after carefully reading each transcript line by line. During this coding process, I underlined segments of text that I felt were interesting and important and I described the content of each passage with a paraphrase or label (a code) in the left-hand margin of the

transcript. The text that I coded or labeled ranged from only a few words to parts of sentences and whole paragraphs. Additional notes and ideas were recorded in detail on the right-hand margin of each transcript, such as questions that arose in my mind as the analysis proceeded and elaborate explanations of ideas, concepts, and patterns in the data. My approach to analysis for this study was both inductive and deductive; therefore, both open coding (anything relevant and important from a different perspective or anything unexpected) and predefined coding (e.g., from an existing theory, idea, literature, or specific areas of interest to the project) were applied to ensure that important aspects of the data were not missed.

3.5.1.4 Developing A Working Thematic/Analytical Framework

At this stage, after reviewing the first few transcripts, I decided on a set of codes (each with a brief explanation). Next, codes were grouped into categories that were also clearly explained. This formed my initial analytical framework. All subsequent transcripts were coded using the initial framework and I added new codes and notes or impressions that were not in the initial framework. After coding all of the interview transcripts, I revised the initial framework to incorporate the new and refined codes. At this stage, I found out that some of the codes were conceptually related and so I grouped them to make an overarching category. The process of refining, applying, and refining my analytical framework was repeated until such time that no new codes were being generated. The final framework consisted of thirty-nine codes, clustered into eight categories, each accompanied by a brief explanatory description and examples of what ideas or elements might be summarised under that code. Composing brief explanations of each code helped to provide at least some consistency in coding across the team.

3.5.1.5 Applying the Analytical Framework

In this step, I applied the final analytical framework to each transcript using a qualitative data analysis software: NVivo 12. Systematically, I went through each transcript, highlighted each meaningful passage of text and attached any appropriate categories and codes from the final analytical framework.

3.5.1.6 Charting Data into The Framework Matrix

At this stage of the analysis, a Microsoft Excel spreadsheet was used to generate a matrix. After all the data had been coded using the analytical framework, the data was then summarized and charted into the matrix for each category from each transcript. The matrix structure dedicates one row per participant and one column per code. Thus, for each category, a separate sheet was used. Data was abstracted from the transcripts according to each participant and code, it was summarised using verbatim words, and was then inserted into its corresponding cell in the matrix.

3.5.1.7 Interpreting the Data

By extensively reviewing the matrix and making connections within and between each participant and category, themes were developed from the data set. Generating themes in this process of data analysis was influenced by the original research objectives, by prior concepts from existing literature, by new concepts emerging inductively from the data, and by finding connections between categories and exploring those relationships. A separate notebook was used to record impressions, ideas, and early interpretations of the data. This notebook was also used to record descriptions of each case that contributed towards developing themes and possible explanations for the data.

3.6 Methodological Rigor

Qualitative research is a complex process with diverse genera and forms; therefore, there is no consensus for evaluating any qualitative research study (Leung, 2015). However, many approaches suggest rigor in methodology and rigor of interpretation of results (Leung, 2015). The methodological rigor adhered to in this study is discussed below.

3.6.1 Credibility

Clear and accurate descriptive information on study settings including time and place, participant recruitment strategies, data collection methods, and data analysis processes were reported. Regarding the interpretation of results, participants' viewpoints, thoughts, intentions, and experiences were accurately reported. The interpretations were constructed by me but were grounded in the words and concepts that were provided by participants. Semi-structured open-ended audio recorded interviews allowed me to repeatedly revisit the data to check emerging themes and remain true to participants' accounts (Noble & Smith, 2015).

3.6.2 Reliability

The reliability of this research was enhanced by the consistency of a transparent and clear description of the research process from the beginning of the initial outline (thesis proposal and ethics application) through the study's purpose, participant recruitment and selection, the methods undertaken for data collection, and the reporting and interpretation of findings (Noble & Smith, 2015). Additionally, I ensured clear and accurate note-taking during the interviews, during the transcription of the interview recordings, and during any discussions regarding my analytical approach, coding scheme, and the development of themes.

3.6.3 Reflexivity

Reflexivity is a vital element of qualitative research methodology. Reflexivity refers to the extent of the impact that researchers apply intentionally or unintentionally on their research results (Jootun et al., 2009) and addresses the subjective nature of the research account as a narrative constructed by researchers (Primeau, 2003). Furthermore, the quality of research is strengthened by reflexivity through its ability to extend our understanding of how our positions and interests as researchers affect all stages of the research process (Primeau, 2003).

Researchers undertaking qualitative research should know that their preconceptions might influence the research process. Having participated in research as both a researcher and participant, I share experiences and views in common with participants. To address this, I developed the interview guide that was used for this study based on evidence that was available from the literature rather than from my personal experiences or opinions.

I also have potential preconceptions based on my previous research experience, such as interviewing and interacting directly with participants. Therefore, my perspective and experience likely affected the interview process and subsequent data analysis of this study. However, I tried my best to curtail my effect on participants' responses and our discussions while maximizing the quality of rigor data. I encouraged participants to express their opinions and experiences with freedom. I made every effort to ensure that participants were not exposed to any form of awkwardness, were not made to feel demeaned or unusually stressed, and I asked no leading or disconcerting questions.

CHAPTER 4: RESULTS

4.1 Participants' Characteristics

As discussed earlier, public health restrictions were in place across Canada and as a result all interviews were conducted virtually. Interviews commenced on May 15, 2020 and continued until September 10, 2020. While nineteen people responded initially, two respondents later chose not to participate after thorough reviews of informed consent releases. Thus, seventeen participants from various Canadian time zones ultimately participated in this study. Detailed information regarding study participants can be found in Table 1 and each participant's availability determined the timing of the interviews which were conducted virtually via Zoom, Skype, telephone and Facetime. Each individual interview was conducted in one virtual session. Briefly, participants varied in age, ranging from 25 to 85 years old. Twelve participants identified as male, and five identified as female. All participants were diagnosed with various stages of CKD. The educational achievements of participants ranged from holding high school diplomas to doctoral degrees. Nine participants had participated in previous research studies. Finally, interviews ranged in length from 22 minutes, 59 seconds to 1 hour, 5 minutes, 57 seconds.

Table 4.1: Study Participants Characteristics

Participants Characteristics							
	Age (Yrs)	Gender	Highest Level of Education	Stage of Kidney Disease	No. of Years Seeing a Kidney Specialist	Previous Experience of Research Participation	Length of Research Interviews (Mins: Sec)
Participant 1	60	Male	College or Non-University Certificate	Stage 5	>10 Years	Yes	37:52
Participant 2	69	Male	Bachelor's degree	Kidney Transplant	>10 Years	Yes	49:44

Participant 3	43	Female	College or Non-University Certificate	No Response	>10 Years	Yes	53:46
Participant 4	64	Female	Master's Degree	Stage 4	>10 Years	No	52:52
Participant 5	66	Male	High School Diploma	Stage 4	>10 Years	Yes	61:30
Participant 6	43	Female	High School Diploma	Stage 4	6-10 years	No	63:01
Participant 7	48	Female	Master's Degree	Stage 2	>10 Years	Yes	57:42
Participant 8	25	Male	High School Diploma	Stage 3	>10 Years	No	37:39
Participant 9	43	Female	College or Non-University Certificate	Stage 5	>10 Years	No	43:12
Participant 10	31	Male	Master's Degree	Stage 1	1-5 Years	Yes	65:39
Participant 11	32	Male	Doctorate	Stage 5	>10 Years	Yes	59:56
Participant 12	61	Male	High School Diploma	Stage 4	1-5 Years	No	37:16
Participant 13	54	Male	College or Non-University Certificate	Stage 5	>10 Years	Yes	1:05:57
Participant 14	71	Male	Master's Degree	Stage 5	>10 Years	No	61:01
Participant 15	63	Male	High School Diploma	Stage 5	6-10 Years	No	43:27
Participant 16	85	Male	University Certificate or Diploma	Stage 4	>10 Years	No	22:59
Participant 17	56	Male	University Certificate or Diploma	No Response	6-10 Years	Yes	57:43

4.2 Knowledge, perceptions, and experience of CKD patients about PM (Research Question 1)

Four major themes emerged about knowledge, perceptions, and experience of CKD patients about PM. These themes include: (1) benefits, (2) concern, (3) perceived barriers to implementing PM, and (4) informed consent model. Additionally, sub-themes were identified for each of these major themes. The themes and sub-themes are summarized in Table 2 (below) and are described in detail in the subsequent sections.

Table 4.2: Thematic Framework Analysis (Research Question 1)

Themes	Subthemes	Occurrences
Benefits	Improve Treatment and Diagnosis	8
	More Targeted/Tailored	20
	Less Expensive	7
	More Effective	12
Concern	More Expensive	11
	Privacy and Security of Data	15
	Undue Stress	4
	Insurance discrimination	16
	Employment discrimination	11
	Breach of trust	4
Barriers	Lack of Knowledge of PM among population	17
	Lack of knowledge of PM among physician	13
	Preparedness of Canadian Healthcare system	13
Informed Consent Model	Categorical Consent	7
	Broad Consent	6
	Study-by-study Consent	8

4.2.1 Benefits

The main theme of benefits encompasses five subthemes and 47 occurrences: improve treatment and diagnosis (n=8), more targeted/tailored (n=20), less expensive (n=7), and more effective (n=12).

4.2.1.1 Improve Treatment & Diagnosis

One of the subthemes of the benefits of PM is 'improve treatment and diagnosis'. Participants expected that PM would improve treatment and diagnosis. Participant 11 expected PM would:

"*Potentially better the future treatments and/or diagnosis available to patients in similar situations."*

Participant 10 participated in a trial sometime earlier in his life and expected it would aid in PM research contribute to finding better treatment or cure:

> *"Yeah, I think it's great. I mean, I think that's why I was part of that trial in the first place, you know. If they can identify the specific genes causing the issue that it takes(us) kind of one step closer to helping to find a treatment or some sort of therapy or solution too."*

Participant 12 compared traditional medicine to PM, describing the cons of trial and error of the former, and suggested that the application of PM would make diagnosis much more accurate:

> *"I'm no doctor, but I get the impression that they can use whatever you've already donated. They can look at it, and they've already done all these tests there. They figured out what you're made out of or whatever, and now they (traditional medicine) have to do a hundred tests to figure (out) why he is sick? Why is he throwing up all the time? Whereas you guys (PM) would have ahead of time all this information, and you can pretty well pin it down to why he was throwing up, because of kidney failure……I don't know just maybe get you quicker diagnosis. I don't know, but I'm only guessing I'm not a doctor."*

Participant 6 suggested PM will assist doctors in making the correct diagnosis, and will therefore guide them to deliver accurate treatment:

> *"(PM) could help doctors to make sure that they know what they are doing ..... the right treatment so that they know that they're giving their patients the best care possible, and you know yeah, I think that's pretty much."*

Participants 15 stated:

> *"Hopefully it (PM) would increase the quality of treatment by having an individual program."*

4.2.1.2 More Targeted/Tailored

Another subtheme of benefits of PM suggests treatment is more targeted or tailored for an individual. The current blockbuster approach to drug development presumes that all patients diagnosed with specific conditions/diseases will respond to a particular drug in the same way. All patients who are suffering from the same condition/disease are given the same treatment even though the treatment may not be effective for every patient. In PM, treatment can be tailored or targeted to the underlying cause based on individual characteristics as Participant 4 mentioned:–

> *"Tailoring it to each individual's unique situation. My understanding of precision medicine would be that it's directed to the specific patient that it's sort of tailor-made for that particular patient. So, it's kind of an individual approach instead of a one size fits all kind of approach in medicine."*

Participant 11 stated:

> "*Precision Medicine is essentially using a lot of detailed information from a patient-to-patient basis to help treat in a more targeted way for the patient with a given disease."*

The same participant added:

> "*One of the highest-level applications of precision medicine is typing tumors from oncology patients and treating them in a much more targeted fashion to increase the chance of survival to reduce morbidity mortality."*

Participant 10 mentioned:

> *"I think it's very precise medicine tailored specifically for yourself."*

The same participant further added:

> *"Medical treatments tailored to the specific individual and their needs, probably at its most advanced as opposed to just a generic one size fits all. I think the best benefit is that it's tailored to you. The wave of the future for medicine, and you know even if it's not so*

much and just a genetic sense, I think in general having more tailored medicine and more focus from doctors and medical practitioners on the individual not just on blanket solutions, I think is a good thing. So, I am having a hard time finding some negatives."

Participant 9 suggested that every individual should be treated according to their unique characteristics, and PM would make that possible:

"I think it would help distinguish patients that let's say they have a specific disease, if how their lifestyle, background or genes, they are just the way they are if that affects them differently than it would affect somebody with the same disease which is different. So, I'm just thinking that would be a way that they could help to treat the cause, and not every patient would need to be treated the same way."

PM addresses the heterogeneity in treatment effects across patients by targeting or tailoring treatments to individuals based on their characteristics. As a result, the most effective medication can therefore be prescribed as stated by Participant 5:

"Well, I think it would be more focused; the medication would be more focused on potential solving of what the medication is aimed to do."

Participant 4 suggested physicians should begin to tailor therapy rather than applying the "one size fits all" model of traditional medicine:

"Because I think there's way too much traditional medicine(that) is based on (a) one size fits all model. It's, I mean I have personally experienced that to my detriment. So, you know, I don't think physicians look enough at the individual you know they just kind of make this treatment for, you know the wider majority of people, but I think they need to start looking at more precision tightness and absolutely."

4.2.1.3 Less Expensive

One potential positive impact of PM is that it can reduce healthcare costs to sustainable levels. Participants expected PM would bring down overall healthcare costs. This is because PM can predict which treatments will work best for which specific patients. PM therefore customizes disease prevention strategies, prescribes more effective drugs, and avoids prescribing drugs with predictable side effects. In the end, treatment will be more effective and consequently, there will be less hospitalization. Participant 11 stated:

> *"I think overall you know at the end of the day if you have a healthier patient that means that (you have) a less costly patient. So, as long as Precision Medicine is implemented in a very smart and thoughtful way, I think that the long-term benefits are better overall treatment and care that probably reduce long-term costs of hospitalization, follow-up, unnecessary medicine, and treatments, etc."*

PM provides precise patient insights to physicians, which accelerate accurate diagnoses and influence the preventive care, treatment, and medications they choose for each patient. The quicker diagnosis and effective therapies afforded by the application of PM instead of traditional trial and error practice help drive down costs. Participant 4 stated:

> *"I think overall it would probably cost the system less than just, you know, kind of trial and error and putting or treating everybody sort of the same."*

Participant 6 suggested that while the initial costs of PM could be expensive, over time the costs would decrease:

> *"I'm assuming it would probably be expensive to begin with, but once there is a system in place, it would be more cost-effective because they're using it to make it for less hospital time, less more expensive procedures. So, in the long run, I would say it (would) probably*

be more cost-effective, it will be more expensive to implement in the first place, but once it's implemented, it will be less costly for health care."

Participant 5 thought PM would be effective; thus, the patient would recover in less time, which brings down the treatment cost:

"The only cost-saving I could see would be if the patient had a quicker time to recover or more effective time to recover as it wasn't so dependent on supports."

Participant 14 believed PM will save money:

"I say, it (PM) will save a lot of money, save time, save resources, you know, if it's done precisely, to treat an individual."

4.2.1.4 More Effective

PM is established on precise genetic and demographic characteristics, meaning the diagnosis/tests are on the mark, and patients are spared unnecessary and redundant procedures or medications. This makes PM more effective and therefore, the overall outcome of treatment will be improved. Participant 8 stated:

"I think it should be more effective in the long run just because it's happened attuned to the patient it can be, and it could target everything right that is needed to be targeted."

Participant 10 was optimistic:

"Hopefully have better outcomes for the patient, but yeah… that approach that you know works for that individual is not just for the broad population."

Participant 10 continued:

"It would be individualized based on personal background stuff. I think it would be more effective because, as I said, not every patient is the same, and not every patient has the same reasoning for their disease."

Participant 1 stated:

> *"Well, I mean, if we're not doing trial and error to find the best treatment for me, then yeah, it helps time and effort, right?"*

PM can identify whether a medication will work for patients before they ever take the medication. Most often, PM is based on the patient's genetic sequencing information. The treatment outcome is thus expected to improve significantly as the PM approach tailors treatments to each patient based on their individual clinical and genetic characteristics. Participants 5 stated:

> *"I think the potential is there for more effective clinical outcomes just because the doctor would have more information and be able to get quicker feedback on the impact of the medications that they are prescribing or the procedure they are prescribing."*

Participant 5 also stated:

> *"I think It would be effective because it's (going to) be able to help them to make sure that you know for one the best medications for the possible person to make sure they're addressing the proper issues, and it's helping everybody stay healthier longer."*

Participant 4 said:

> *"I think you have more optimal treatment, and you probably have more satisfied patients. So, I think you would have a probably faster recovery."*

Participant 4 further added:

> *"I think it probably would because I think you have healthier people, and probably I think you would see more optimum results in terms of recovery, treatment, cure if they did practice more precision medicine."*

Participant 16 added:

"They would have more information and more specific information, more detailed information, right? That's what I think. It's more effective."

4.2.2 Concern

The main theme of concern encompasses six subthemes and 61 occurrences: more expensive (n=11), privacy and security of data (n=15), undue stress (n=4), insurance discrimination (n=16), employment discrimination (n=11), and breach of trust (n=4).

4.2.2.1 More Expensive

Despite its benefits, the PM approach has been coupled with overwhelming cost challenges. While discussing the demerits of PM, participants pointed to potential cost challenges. Some participants expressed that PM would increase the cost of treatment as more logistics support is required. Participant 5 stated:

"I think it would be too expensive for us."

Participant 15 stated:

"Making individual plans for people sounds like that's time consuming and expensive. Can the system afford that kind of treatment?"

According to Participant 11:

"The resources required to process these samples and follow up with these patients as much greater than just running, you know, a kit sample analysis through the lab, for example. So, certainly increased costs associated, especially you know if you get into whole genome sequencing and things like that. However, in many instances, I'm sure that the benefits very much outweigh the cost for patient outcome."

Participant 10 also believed commodities, staff, and professionals required for PM will make it more expensive, stating:

> *"I guess it could be one downside. But, on the other hand, I think it'll be more expensive because it is more focused. But you know, having said that, you look at a lot of different things, and you know it's probably more of the commodities and stuff."*

Participant 3 had a similar opinion:

> *"I would think so, yes, because then you have to involve a lot more professionals."*

Additional participants shared the opinion that PM would be expensive. The resources required for PM as well as the implementation of targeted approaches and customized treatments would make it costly. Participant 9 stated:

> *"In my eyes, they might be more expensive just because of how it got to be individualized. Because it is tailored straight for you, and that requires a lot more work in the long run."*

Participant 8 said:

> *"Yes, it would be more likely to get more costly, but it would be more effective*."

Participant 5 mentioned:

> *"I think it would increase costs, Because I think just to get an accurate profile of the patient to be able to customize those medications, it would be expensive."*

Participant 2 believed customization of treatment put PM beyond affordability of the general population:

> *"Umm… financial would be a concern. These treatments could get so customized that someone could be not able to afford treatment because they don't have the resources to be able to afford it."*

4.2.2.2 Privacy and Security of Data

Data security and privacy are a significant concern for participants because the enormous volume of data, including genomic, environmental, lifestyle, and other sensitive personal data would be collected and required for the implementation PM. Security of patient data is the key challenge facing the PM initiative. Participants expressed concern as to whether adequate data security measures and mechanisms would be in place. Participant 11 stated:

> *"It's very important, especially in precision medicine where you're getting a lot of detailed information from the patient, to be able to protect this information at all costs. There's a lot of very sensitive information that's generated, and you would not want that falling into the wrong hands*."

In response to the possibility of the data falling into the wrong hands, Participant 4 said:

> "*Well, I would not be very pleased with that. I think that would be very unethical."*

Participant 10 said:

> *"Does the healthcare system have the capacity and the protections in place to store that kind of data? So, I'm quite concerned about that very thing I do by having the idea whether the system (will be) able to manage it."*

The same participant further added:

> "*I wouldn't want a life insurance company or employer necessarily being able to get access to that data unless I expressly provided it, so yeah, I'd have a very strong view on not being able to assess or share that data with anyone other than the express reason why it provided in the first place."*

Participant 12 expressed concerns about the protection of privacy and data and feared that study data could be used against them:

"That's scary. They could use your DNA in some murder case and then pin you on it, and I gave the DNA just to the hospital for research for something good, but someone used it in a murder case; well, look, we got this DNA, and it looks like he did the murder you couldn't do anything. You're helpless, looks dangerous kind of thing if it gets into the wrong hands."

Participants 5 expressed a similar concern:

"Well, I would have concerns about that. Someone to have my DNA and then abused that privilege to come back and accuse me of something that I know I didn't do……they've planted my DNA in a circumstance where it appears like I was involved. There's a small concern about that. I would expect that there be a commitment to secure up these samples, and that commitment would be honored."

Participants were clear and explicit about data privacy components and expressed their concerns about privacy breaches. Participant 6 said:

"*I think at this point with the social media and everything. I would think I would hope there wouldn't be a breach, but you know, I think sometimes it does happen."*

Participant 6 trusted physicians but was concerned that data could fall into the hands of the wrong people:

"My concern would be again a security breach where the information would get into the wrong hands, and somebody would use it, but I can't see doctors passing it on to commercial entities, I don't think."

Participant 10 had the same concern:

"*Yeah, it is a pretty serious breach, pretty serious worry if someone was to get a fair bit of your identity data and then your genetic data, your biological data. I think it's*

probably a fairly big worry. It is basically who you are, so if you can buy those two things here, it's not a good outcome."

Participant 10 did not find many disadvantages of PM but made comments concerning the security of data:

"I guess it would be the data side of things, and the data that's being collected, the potential privacy breaches and things like that. But I don't see such a whole lot of downside to medicine that is tailored specifically to the individual."

4.2.2.3 Undue Stress

The notable advances in PM produce concerns that must also be studied closely. Some critical issues arise when the volume of genetic, environmental, and lifestyle information generated for each patient is considered. Importantly, how should this information be interpreted? Participants suggested that some information generated will cause undue stress and harm to the patient as well as additional and considerable detrimental effect on mental health. The information can lead to extreme patient dissatisfaction. Participant 11 mentioned:

"*From a genetics point of view where results are generated sent to family physicians outside of the field of expertise or Precision Medicine, and they may overshare or misinterpret information that may have been given to them and cause undue stress or worry to patients."*

Participant 11 continued this discussion and further explained:

"From an ethical perspective, I think that it can be complicated and there are some gray zones which exist specifically in the fact that sometimes you can generate information which may be only partially actionable from either the physician or the participants' point of view, but may induce an undue stress or unnecessary stress to the participant. For

example having a predisposition to a heart condition may not necessarily mean that they will have heart disease in the future it may only mean that they have the genetic traits but sharing some of these details when it comes to Precision Medicine may cause more stress and harm than good."

4.2.2.4 Insurance Discrimination

PM has the potential to draw ever-finer distinctions among individuals and could contribute to discrimination based on genetics. For instance, genomic information could point out not only that an individual will likely develop a specific disease or illness in the future, but also that the individual would not be receptive and susceptible to typical medications, and might therefore be prone to increased morbidity and mortality risk. Participants raised concerns about insurance discrimination and whether their coverage could be negatively affected. The possibility of patients falling victim to genotype-based discrimination by insurance providers was one of the first concerns raised by participants in this area. Many participants were reluctant to undergo genetic testing, despite the clinical appropriateness of doing so if the testing could result in insurance discrimination. Genetic predisposition will be a factor that influences insurance companies to increase premiums or determine payout of insurance to customers. Participant 12 stated:

"Well, that's interesting about insurance though because if somewhere down the road even like 50 years from now they would find out, say my wife dies. And then they go check the health, DNA that she gave, well looks like she had a cancer DNA in there for 20 years. So we're not going to pay out any health insurance because it was an existing condition that the patient didn't disclose even if the patient did not know,

but just little things like that could be where things get pretty fouled up for insurance maybe, but that's only my imagination…. just a thought."

Participant 11 mentioned:

"My biggest fears in terms of especially Precision Medicine genetic or genome genotyping, is the fact that you can reveal a lot of a future risk involved with a participant. And if insurers get their hands on this information (they) may discriminate-even though this is against Canadian federal law-by either refusing to insure or raising insurance premiums knowing that this would be a participant predisposition."

Participant 12 added:

"This information may deter insurance or insurers from covering participants in certain disease categories depending on if they have a predisposition to these diseases. Again, Canada does have a law protecting the participants from this discrimination; however, it always seemed to me like a genuine risk in possibility."

Participant 1 had a similar opinion:

"We know your DNA, and now you're …… I'm not going to say predestined, but you have a better chance of having cancer because of this, then maybe we're not going to insure because of your DNA."

Participant 6 was denied insurance due to an existing health condition;

"Somebody who has a chronic issue you do get concerned that insurance will turn you down or you get to die for something things like that. I've already been denied life insurance company because I have high blood pressure."

In addition, Participant 6 had a concern about the consequence of insurance companies having a lot of information about consumers:

"*So, what would they do if they had that kind of information. You know it would be even worse. I would hope there would be some laws put in place regarding the insurance companies about not denying people. Could your insurance find out, could they deny you or make it more difficult to get the insurance? That would be my biggest fear*."

Participant 5 went through a similar experience:

"Yes, I have concerns because in my lifetime I've seen requests of people who have relatives… my relatives who have been forced to provide medical information before they would seek insurance that's now changed. And now they can't show that bias, but I think that's very harmful when insurance companies can select who they insure based on yeah medical samples."

Participant 3 had two important questions. Firstly, how would insurance companies react if they could access information pertaining to a patient's genetics, lifestyle choices or other personal details? Secondly, how would access to this information effect a patient's eligibility for insurance?

"I would like to know. Not everybody would like to know, but then would it affect if you apply for an insurance policy? And having like the underwriting of a policy, a life policy, or critical illness anything like that, is based on your health, so I'm not sure how that would affect if you would come to apply for a policy; that's my main concern."

Participant 3 continued:

"I know for myself I can't get any insurance, so for me, if I know or not, it doesn't matter when it comes to getting to a life insurance or any type of insurance because I always decline, so in my situation, I won't mind."

There is a chance insurance companies will raise premiums and make decisions regarding eligibility, coverage, underwriting, or premiums if they have knowledge of the patient's genomic

characteristics, environmental and lifestyle influences as well as other predisposing factors as Participant 10 stated:

> *"I think they would look at having a genetic disease or something like that; can raise premiums or have to have a cap or something like this, yeah actually it can happen with something, as I can imagine with the insurance companies."*

Participant 14 mentioned:

> *"Like insurance, they will probably increase your rate. It's happening now, like in my case, like traveling insurance, if you're high-risk person, your rates are very high."*

4.2.2.5 Employment Discrimination

The potential for employment discrimination was a critical issue for participants. Employment discrimination can occur if an individual is treated unfairly at work or in society based on his or her genetic predisposition or susceptibility to any disease or condition. Employers may want to use current or potential employees' genomic data to select, advance, not advance, or terminate individuals based on predictions of traits and other indicators influenced by genetic factors. While participants stated that legislation is in place to protect against employment discrimination and that employers are prohibited from using genetic information in employment decisions, there is still some discontent. Participant 11 said:

> *"I feel that employers may be less (likely) to (have) access or resources to be able to access this medical information, but it became a risk. I'd say I'm not worried only because I don't believe that employers would go through that kind of screening however if it ever became an issue then I certainly would be worried about that yes."*

Whereas Participant 10 actually had experienced employment discrimination:

"I have kind of seen it in a few times already and where I've seen it so, for example, my recent employment. No, I've seen it many times; it's quite brutal. So like I said, I am in Australia right now; be down here for a while. When I was going through the visa, one of the things they asked is do you have any health issues that might arise. You know they're looking for something out of paper to the Australian healthcare system immediately. I made the mistake of saying, yeah, I've got PKD (Polycystic Kidney Disease), and it's very mild, it's not an issue; it's never been an issue so far in my lifetime. You know, just try to be honest if it is a background check on the visa. Well, it just became this whole thing. It felt very much like there was an issue when actually there wasn't with my current employer. I could have just said no, I don't have any issues; we're good to go, and I would have passed the physical no problem. Instead again trying to be honest, it's PKD it's not an issue now, but now they need to get my nephrologists, and they need to talk to my GP."

Participant 6 had a different opinion:

"I think that's a personal preference as to what you bring up with your employers regarding your health. Personally, my employers know that because of me having to take time off to see doctors at any other stage when I don't feel great. You know it's they know why and what it is. I think it should be a personal preference whether you just disclose something or not, and obviously, there should be laws in place where they can't. I would like to assume that most companies and most employers are human themselves and are empathetic to people who have health conditions."

Participant 6 continued:

"*I'm just lucky, and I'm in a place where they do care. When I first started, I was kind of not 100 per cent. I brought it up slowly so just to kind of gauge where they were at and how*

they would deal with things, and once I realized that they were good people, and they were not going to discriminate on this factor when they know the whole issue."

4.2.2.6 Breach of Trust

Trust is considered a critical requirement for the successful deployment of PM initiatives. There is an increasing consensus that the notion of trust is paramount to derive maximum capabilities from PM. In PM, there are potential risks involved in the sharing of and further use of patient data. Breach of trust can pose a challenge for healthcare providers when delivering PM to diverse patients. Participants expressed their concern about the intended use of their genetic and other information. Participant 10 once participated in a clinical trial and expressed concern about the intended use of information:

"*I feel very betrayed; if I knew that DNA I provided with that express clinical trial was somehow given away to someone else without my consent, I would be very upset, yeah."*

Participant 12 mentioned:

"I have to give body parts or body tissue and blah blah…then if that gets stolen by people then whatever, they can blame you for murder. Like I don't know it's just a little weird thing. Just don't think the government should let that happen."

PM relies heavily on sensitive patient data that may be used for unintended purposes as Participant 2 said:

"I would have to say general concerns to make sure (data) would be used for purposes as intended as opposed to less than useful purpose."

Participant 2 wanted some guarantees:

"I probably would be, again, you know, at least some assurance that it would be used for research purposes and not necessarily for-profit purposes."

Participants were concerned about the breach of trust and the possibility that the genomic and other data collected to use in PM could be compromised. They also worried that information could be passed on to someone outside of research and used against them. Participant 11 mentioned:

> "*It's a huge problem because for example, you know in precedent situations such as disease especially in the state there have been issues where people have gone in for example genotyping and that some of this data may have leaked to insurance companies, for example. They would have higher premiums based off predispositions for disease, and just basic privacy breaches is just a huge deal."*

Participant 2 was critical about the intended use of genomic data:

> *"There is that whole aspect of how it is being used as opposed to the purpose of benefits. I would not be happy if it is being used for the benefit of profits at the expense of health."*

Participant 2 further added:

> *"If there is an assurance not for profit, not for spurious purposes. I would probably not care what studies it is used for. You know, for instance, if it were used to study the best way to genetically modify a person to accomplish an individual goal for their benefits, not to the benefit of the health, I would, of course, not be much interested in sharing it with someone like that."*

Participant 5 expressed concern that serious breach of trust might occur if the data used for a purpose that was not intended, such as profit:

> *"My concerns would be that the data are used for research purposes; they are not used for profit. So that would disturb me if I was giving something that I thought was for research and I found out that it was being used for profit."*

Participant 3 feared future consequences:

> *"What's my opinion? Of course, that would be very scary because there is a lot of fraud going on at identity tab discrimination, like I said, the insurance companies. Everything stays on your health, so if there's a breach or if that information is sold to the insurance companies……things like that… that can be scary. That is why privacy must be taken very seriously, and confidentiality is taken very seriously*,"

4.2.3 Barriers

Some perceived barriers to the implementation of PM into mainstream care emerged as the main theme in 43 occurrences between three subthemes: lack of knowledge of PM among the general population (n=17), lack of knowledge of PM among physicians (n = 13), and preparedness of the Canadian health care system (n=13).

4.2.3.1 Lack of Knowledge of PM Among the General Population

The implementation of PM into healthcare practice is driven by several factors, including the willingness of patients to adopt and understand new PM approaches, particularly concerning the use of their genetic information. PM initiatives involve determining an individual's potential risk for a disease or an illness using genetic tests and guiding the selection and dosing of medications with pharmacogenomic testing. Patients must have awareness of these procedures to provide consent to the testing. Patient acceptance the use of a PM approach is dependent on awareness. Acceptance could be hindered by numerous barriers such as lack of awareness and limiting patients' participation or ability to seek, obtain, and make informed PM healthcare decisions. Participants agreed there is a general lack of knowledge of PM among the general population. Participant 11 mentioned:

"I think there's a lack of knowledge in the general population about Precision Medicine. I know that Precision Medicine is a very young field, and I think that unless people are directly affected or have to go through the health care system and get involved in any kind of treatment involving Precision Medicine."

Additionally, Participant 11 added:

"I don't think that it's something that is known to the general population. That may be just a matter of disseminating this information to the general population and more so from the fact that it's a relatively young field…. so you know word of mouth probably hasn't had a chance to travel that much yet."

Participant 10 stated:

"Yes, probably there is a lack of knowledge. I think there's a lack of understanding."

Participant 12 stated it is difficult for the general public to know about PM if they have limited health care (i.e., illness) experience:

"I've never heard of it, but it doesn't mean other people don't. I am sure I don't hear about it anywhere, but I'd say the general public would not have heard of it cause if you're not sick, you don't deal with that. I went sixty years without the only time in the hospitals for tonsils out when I'm five years old. So, I had nothing to do with health, and nothing could care less. So yes, let's say the general Joe Blow on the street would know …. no."

Participant 9 had never heard of the term PM;

"I don't think so. As I said, I had not heard of it until you just said it. So, I think it's the lack of it cause, as I said, I had not heard of it other than before you said it."

Other participants had also either never heard of PM, or had any experience with it. Some participants also think people simply do not know about it. Participant 8 mentioned:

"Yeah, I've never really heard of it."

Participant 4 said:

"I don't think most people know anything about it."

Participant 3 stated:

"In my opinion, I think there would be a big lack of awareness."

Participant 2 stated:

"I'm well like myself. I'm not sure there's a lot of knowledge about it."

Participant 5 said the same:

"I think there's a lack of awareness. I feel that I'm fairly informed, and I've never heard of it."

Participant 6 compared how younger people might have a greater awareness of PM than those who are older: ;

"I think it's becoming more aware in the younger generations. In the older say probably not as much as they are just used to going to their family doctor and him giving them a pill for this. I think as the younger generations look at medicine, they're looking to see what we can do better how can we change it so that it helps people stay healthier longer. So, I think the younger generation would probably understand it more versus somebody in a senior generation. They might not want it, they might just be happy with the way their doctor is, in the way the doctor functions."

Participant 14 mentioned:

"I think there's a lack of knowledge. This is the first time I heard about this precision medication; you know."

Participant 16 stated:

"You know, people don't look it up unless they're told to look it up. But for an average Joe, you know, that word doesn't come across."

4.2.3.2 Lack of Knowledge of PM Among Physicians

Knowledge of PM among physicians plays an essential role in realizing, ,accepting, and using PM in the health care system. However, there is a probability physicians may have an absence of genetics and genomics training and knowledge. They may also lack the necessary specialized skills to interpret genomic information. These deficits in training, knowledge and specialized interpretation skills may hinder physicians' ability to offer an essential element of PM: the skill to interpret and utilize test results when advising patients. . Participant 10 stated:

"I see; yeah, there is a lack of knowledge. I also guess probably there is a lack of capacity in the system."

Participant 4 had a similar opinion:

"I don't think most of them (physician) have any knowledge about it."

Participant 8 believed some physicians have knowledge of PM while others do not:

"I believe some possibly do, but as much as those do, is probably a good portion that does not have any idea about it."

Participant 12 was unsure about physician awareness of PM;

"Yeah, I don't have a clue. I don't know; maybe Precision Medicine has been out for 20 years or 40 years, maybe they all know what from their schooling, or maybe it's a brand-new thing that they don't know. Yeah so many doctors I've dealt with haven't mentioned it ever …"

Participant 11 discussed and compared knowledge of PM among older and younger generations of physicians:

"It's a young field. I think that the new general physicians and specialists coming up through the programs now would probably-in the last two to five years-are getting a lot more insight on the concept of Precision Medicine. Before that, doctors that are in the field for several years that may not be keeping up-to-date with the new information, may not be very well versed in the option of pursuing Precision Medicine for their patients."

Participant 6 had a similar discussion:

"I think the younger ones are coming in, they know. I think there would be resistance from the older doctors, especially ones who are, let's say, closer to retiring then they don't necessarily want to do it because it's going to be more work for them. But, in contrast, the newer generation of doctors will be like how can we help our patients better. So, to them, they're going to see the good in it, they're going to be like okay, you know it's going to be a better way to help our patients."

Participant 9 shared their experiences of healthcare encounters over the years, and stated that despite consultations with multiple doctors, PM was never mentioned:

"I hadn't heard of it before, and I've seen a lot of doctors from here and multiple provinces, and I've never even had them not necessarily bring up Precision Medicine. So, I'm thinking, and maybe it's more in Alberta and BC, maybe they know more about it, but here in Newfoundland, I don't think so."

Participant 15 stated:

"The doctors I deal with have never mentioned it to me. That's all I can say."

4.2.3.3 Preparedness of Healthcare System

Despite recent development and the growing impetus behind PM, there are substantial challenges and barriers to its wider implementation and practice in medicine. Some critical and

fundamental issues need to be addressed if the full potential of PM is to be realized. These challenges and issues include: sustainable funding, consistent support from policymakers, addressing data-sharing needs, integration of genetic data into clinical care, capacity building of expertise and infrastructure not only in research and but also in clinical settings, addressing ethical, legal, and social issues, securing patients engagement and trust, etc. Participants shared their views on the Canadian health care system's preparedness to incorporate PM in clinical settings. Participant 12 believed the Canadian health care system is not ready and felt there are additional issues:

> *"I wouldn't think so because they don't seem to have enough money for enough hospital beds. So, I think that should be taken care of first, but I don't know where their priorities lie, but maybe their priority is the Precision Medicine, and then you will need the hospital bed."*

Participant 10 suggested the Canadian health care system is not yet ready for PM:

> *"I don't think it is, and I don't think it's right now. I think there's a lot of things potentially preventing a system from being able to fully take advantage of anything like that at the moment."*

Participant 10 continued:

> "*I just have a concern that it's going to be a long way off in our current healthcare system*."

Participant 6 was more pessimistic about the preparedness of the current health care system:

> *"Just knowing the interior healthcare system; it's taken too long, even just for things like electronic files. So, to me, I can't see it being implemented quickly; it's just not something that I see being done fast enough."*

Participant 4 pointed out that the approach of the Canadian healthcare system is conservative, and unmotivated to change the existing system and implement something new like PM;

> *"I don't mean to go off-topic, but I find the Canadian medical system (is) too conservative. People are terrified to try anything new, and they're always worried that all of this will cost us. And I don't think they're willing enough to look at maybe European models or, you know, try something a little different. So, I think it's way too stuck in the past."*

Participant 3 compared the readiness of different provinces to integrate PM into their current healthcare systems;

> *"If it's ready…it depends on the province. I think our province, I don't think so. In New Brunswick maybe, Ontario maybe, BC who knows, Alberta maybe, but I don't think it's all provinces, I don't think my province is ready*."

Participant 2 recommended public support for PM integration:

> *"I would be perfectly honest with you. From my experiences, I would think it would require some significant advocacy."*

Participant 15 was uncertain, but believed that there would be some difficulties in any attempts to integrate PM:

> *"I don't know how the health system works. I would guess there would be difficulties, but I don't specifically know. I don't specifically know what the difficulties would be, either. But change usually isn't easy so I'd assume there'd be some stumbling blocks."*

Participant 17 believed that the Canadian healthcare system is ready to add PM:

> *"Yes, they're ready to start down that path. I would say that, yes, they are ready."*

4.2.4 Informed Consent Models

The main theme of Informed Consent Models encompasses three subthemes and 21 occurrences: categorical consent (n = 7), broad consent (n = 6), and study-by-study consent (n=8). Informed consent is a crucial aspect for not only PM research, but all research. There are some specific issues related to informed consent regarding PM. Generally, informed consent is obtained at the beginning of the study. Participants agree and provide consent to participate in a single study using a single consent form with a pre-specified research objective and timespan. However, there are some challenges involved with the vast amount of genomic data needed for PM research, such as the future use and application of data, sharing data with outside researchers, use of data in future studies other than original research, risk, and benefits of data sharing at the point of consent, etc.

Nonetheless, questions remain about the ethical and practical acceptability of different consent models: broad, categorical, and study-by-study. The broad consent model is defined as an agreement wherein participants agree prospectively to have their genomic and other health data used for any future or unknown research deemed appropriate by relevant oversight bodies, subject to ethical review. Categorical consent demands that participants provide consent to a research category for which their genomic and other health data would be used; in this case by categories of disease (e.g., kidney disease, cancer). Lastly, the study-by-study consent model requires the researcher to obtain consent from participants on an ongoing basis as well as for every specific research. During their interviews, participants discussed their preferred consent models.

4.2.4.1 Categorical Consent

Participant 11 preferred categorical consent in most cases:

"I'd say categorical is appropriate in most context. Categorical, I believe is the best because then it gives you the flexibility to use these specimens in specific projects.

However, it also protects the participant somewhat from having unethical or outside of anticipated scope use on the samples donated".

Participant 10 chose categorical consent because it offers the participant a sense of control:

"*Where you just pick a list of diseases and say look okay, go ahead and run an experiment like that. But initially, I think because I haven't been exposed to it and I want to have that level of control at least initially."*

Participant 12 expressed that categorical consent provides an assurance that participants' specimens and other health information would be used for the intended purpose:

"Just 'cause you can put it, you know your stuff is going to a good cause for sure, and it's not anything weird I don't like."

4.2.4.2 Broad Consent

Participant 8 preferred broad consent because it would help the researcher to explore multiple research projects:

"Because, in the long run, it would be better to help with multiple things than just the one."

If there is a well-informed consent model, then broad consent would be preferable, as Participant 10 stated:

"*Broad is okay as long as the ICF (Informed Consent Model) very clearly words what kind of privacy is applied to these samples. So, from a broad perspective, it is okay to take these samples as long as they are very immediately completely anonymized and are not easily traced back to a participant's data or information".*

Participant 9 mentioned:

"I'm going with broad. Because I feel that once I give my sample, it is theirs. I give it, and I give my consent for them to have that sample and do whatever they deem necessary with it and test it on whatever they think necessary."

Participant 5 had chosen not to be bothered to provide consent for every research category or study:

"I will go with the broad. It is the one, not the hassle of having to make a decision each time."

Participant 4 trusted the researcher's intentions:

"Well, if it were me, I'd say the broad. I would go with the broad consent because to me, and they should be able to use it wherever the best would be. I would leave that up to the researcher."

Participant 5 further mentioned:

"Well, I guess I have a lot of trust umm…maybe too much, but I trust the researcher. If I'm going to, if I was to donate something you know I think I'll let them do with it what they think is going to be for the best you know for their research. I don't think I need to be all the time contacted and my permission is given over and over and over again. I'd say, you know, here's my tissue, here's my DNA, here's my blood, here's my sample, you know, do with it as you will, this is my attitude. I trust them that they're going to use it for ethical reasons for the good of humanity. So, I don't think I would even want to be contacted over and over and over all the time, you know I just would be that's it."

Participant 2 stated some of the advantages of broad consent:

"*Patients would be asked if they would be willing in the future to be contacted for research in a certain area; I find it one of the stumbling blocks. For example, in healthcare, there is a lack of access to patients to help with research, so if provided a broader scope of*

possibility to contact that individual for each type of research without having to sign another consent form, I think that would be beneficial for both the patient and to the healthcare research."

Participant 2 continued:

"It will provide that opportunity or a broader set of research to be done without continuously having to seek outpatients to see if they are willing to participate."

4.2.4.3 Study-By-Study Consent

Participant 10 felt comfortable with study-specific consent:

"*I would start with the study-to-study one, and I have a high level of comfort (that I) might be contacted …each time."*

Participant 6 explained that their choices and perspectives might change over time, and as a result preferred the study-by-study consent model:

"I think I would probably choose study-specific. I don't think I want them to have complete authority over it. And I think if I was asked each time for different studies because you sometimes know your thoughts and things change. So you know I might say no to a particular study now if I was asked. (But) if I was asked two years from now it might be a different answer."

Participant 5 was skeptical about the prospect of broad consent:

"If I give broad consent, how will I be assured that five years from now, the people aren't selling this information. The government decides that the way to balance the budget is to sell this information to a private researcher."

As a result, Participant 5 wished to be contacted on a study-by-study basis:

"I think I want to be informed if they were using that information for some other type of research."

Participant 3 shared the same vision:

"Yeah, I think I would like to be contacted so that I know who used it."

Participant 2 agreed with Participant 3:

"Well I think I lean towards the study-to-study only because it involved contacting the individual should they want to use it for other purposes."

Participant 15 stated preferred study-by-study consent*:*

"Once you agree to one study, they can use your sample for that study but future ones would require your approval. Because it's my sample I'm giving, and I don't want to just generically give it to use for whatever they want. I want it to be used on a study or research that either is important to me, or I agree with."

4.3 Knowledge, Perceptions, and Experience of CKD Patients About Biobank (Research Question 2)

Four major themes regarding knowledge, perceptions, and experience of CKD patients about biobanking were identified: (1) benefits, (2) concern about biobank research or donate samples, (3) factors influence to participate in biobank research, and (4) ownership of samples. Additionally, sub-themes were identified for each major theme. The themes and sub-themes with the number of occurrences from the framework analysis are summarized in Table 3 below and are described in detail in the subsequent sections.

Table 4.3: Thematic Framework Analysis (Research Question 2)

Themes	Subthemes	Occurrences
Benefits	Advance future medical research	20

	To Find a Cure/Treatment	15
	To Help	20
Concern	Breach of trust/Intended use	23
	Data Privacy and Security	26
Factors	Lack of trust in the research organization	8
	Lack of information about biobank research	12
	Details about research	21
	Financial benefit	13
	Return of research results	27
	Fear of pain	7
Ownership of Samples	Ownership to Donor	10
	Ownership to Biobank	13
	Ownership to Donor and Biobank	4

4.3.1 Benefits

Benefits emerged as the main theme through a total of 55 occurrences in the interview data over three subthemes: advance future medical research (n = 20); to find a cure/treatment (n=15), and to help (n = 20). Participants identified many benefits of biobanking, and there was a great deal of discussion about the benefits of biobanking.

4.3.1.1 Advance Future Medical Research

Advance Future Medical Research is one of the subthemes of the major theme of benefits of biobank research. Participants believed biobanks would advance or improve knowledge in the medical fields of research. Participant 11 stated:

> "*I know how important ultimately these tissue samples, our biological samples may be able to advance our understanding of current and future issues in the medical fields of research."*

The same participant also stated:

"*Donating these samples allows for advancement in research and science in general, and you know, even though there may not be direct repercussions or advantages to the participant themselves or myself specifically. So, I do take comfort in the idea of being able to help advance scientific research."*

Participant 8 mentioned:

"It would be helpful for the future in medicine, to progress with research and getting more samples means there are more variables that would be good."

Participant 10 hoped donating samples to biobank would help advance future research into the causes of Polycystic Kidney Disease (PKD):

"I've gotten from my experience with, you know, they're able to take a DNA sequence then they want one part of it contributes to a research study; and then another part also be able to identify the specific gene that is causing PKD in myself and my family says it's quite a benefit."

Participant 7 mentioned:

"I like the fact that other doctors and specialists can have access to it to help with their knowledge and learning process, and it can help scientists, researchers to learn different things."

Participant 5 compared the kidney transplant experiences of his family members, and noted that the dissimilar experiences are due to the evolution or development of science over the years. Thus, this same participant suggested donating samples to biobank research will only advance the medical research:

"I just admire people that are willing to do that. We need to know more scientifically about what impacts we can expect. We need to be able to modify the medications. I know that my

experience is way different from people who received transplants 25 years ago; it's different from those who received transplants 15 years ago. My brother just received a transplant last year, and his experience was different than mine ten years ago. So, I know that this is progressing research, and I know it's only helpful the more we know about this disease and the impact of medications and treatment."

Participant 4 preferred study of the human model rather than the animal model:

"Well, I think for a lot of chronic diseases today, there could be a lot better research if they use more human studies, you know DNA and more human cells tissues. I think they rely too much on animal models, and it's holding up a lot of research. I was a big proponent of stem cell research. For example, I think that's moving in the right direction. I think that it's unfortunate, for decades now, kind of held up by the religious right in America. You know, this sort of backward science we rely way too much on the animals and animal models, and everything takes a long time. You could progress faster in human studies if we had more donors that would let their tissues, DNA, stem cells, whatever you know be utilized. To me, I think it would benefit everybody because you could maybe potentially resolve some of the more you know difficult chronic diseases that we have out there."

The same participant stated biobank research would facilitate the progress of research into rare chronic disease:

"For my own benefit, well, I suffer from a chronic disease myself, so you know it potentially again could benefit me. Also, I have an orphan, but they call it an orphan disease, so you know it's well known, but few people have it, so it's one of those diseases where the research has been quite slow over decades. And so, for me, it would be beneficial if they can speed up the research on human models using some of these

scientific advances that would be a benefit and possibly solve in treating and maybe even eradicating this disease."

Participant 3 explained that participating in biobank research will advance medical research:

"Because all my family and I were all affected by kidney disease, so if (there's) anything I can do to help with the research. To me, it's important because without the research, I mean there won't be any advancements."

Participant 8 had the same opinion:

"Well, obviously, you could help with future research potentially make breakthroughs and advances technology."

Participant 6 stated:

"For me, I look at it as a possibility of learning more, and if I could help scientists learn more about different genetic conditions or, you know, more about chronic kidney disease."

The biggest motivator for Participant 2 is the knowledge gained from participating in biobank research:

"Outside of the knowledge that would potentially gain for health purposes, I wouldn't have any other motivator."

Participant 9 was hopeful that biobank research participation would advance research about finding the cause of disease:

"I just like to help people understand in the future why they would possibly have this disease or other diseases, and this could be something that could be discovered with this,"

Participant 14 believed biobanking will advance medical research and ultimately improve health:

"To advance the knowledge and also to be able to research…to improve humanity, you know. I mean as far as diseases and illnesses."

4.3.1.2 To Find a Cure/Treatment

Participants suggested that one of the benefits of biobank research is finding a cure for a disease or improve the treatment. Participant 10 was motivated to donate samples to help find a remedy for PKD:

"Probably the simplest answer is just to further contribute to the understanding of PKD, and you know in the hopes that it helps to find a cure or treatments or therapies for that disease."

Participant 17 stated:

"Development of new techniques, new therapies, new medications; that all stems from biobanking."

Participant 10 added:

"I think it's something that if you want to contribute to finding a cure for something like that,(you) kind of have to be part of the solution which is potentially donating or being part of biobanking. You know, donated some blood or tissue or whatever it takes."

Participant 7 had a similar opinion:

"For someone with a rare disease, I think it's a fascinating prospect. I think it will add to researchers' understanding of how, where diseases present medically and could potentially help to provide better treatment."

Participant 6 had been living with a condition and felt donating samples for biobank research would help find a cure for the disease:

"*I have what's called allergen syndrome, and not a lot is known about it. So, if doctors and scientists could use my blood to help learn more and help doctors learn how to deal with it and things like that, it would be helpful. So, to me, I see good in that but to help others to help possibly myself in the future to learn."*

Participant 6 said:

"It would be for scientists to learn more about the different genetic conditions, the different chronic conditions to help see if they can find solutions or better medications that would help see if there are possible ways to cure it, things like that."

Participant 4 hoped for better treatment in the future:

"Well, I have a chronic disease, so I'm always hoping that down the road will be a treatment or a cure, so for me, it would be very helpful."

Participant 3 hoped the same:

"Well, to me for sure that the research will find a treatment for a disease, find a cure, prevent a disease."

Participant 15 stated donating bio samples in biobanking will help find cure:

"Just to help in the cause of getting more information and finding cures to different conditions or developing better forms of treatments."

4.3.1.3 To Help

Many participants suggested that participation in biobank research is a way to help others, society, community, future generations, etc. Participant 10 stated:

"You know my nephrologists had mentioned it. So, I said, look anything I can do to be part of it, you know, helping out the broader PKD community especially get something as simple

as a swab test that has a great benefit of potentially identifying the gene in the sequence in my case."

Participant 2 had the same ambition:

"*That's why I got into the volunteering, especially because of the kidney community is because I wanted, they benefited from the research."*

Participant 5 believed the benefits of donating samples to the biobank for research was to help future generations:

"I think it's a good idea because it helps others, it helps people in the future. Umm, this disease is beatable, and I'm more than willing to do what I can do to help the future patients who have to encounter this disease."

Participant 9 had a similar opinion and explained his own experience:

"To help people, in my opinion, that would be the only reason somebody would want to do; it would be to help somebody else in the future. For example, I was diagnosed with my disease at 19 years old. If this could help somebody in the future to possibly delay dialysis or whether it's heart disease and delay something else, if that could help somebody, that would be great. So, if somebody else is doing that, I would hope that it was for that reason."

Participant 9 further mentioned:

"In my thought, the only person that would do the research would be somebody that would do it for the almighty good, not for anything other than that. So maybe I'm naive, but I think of when you think of research; when you think of donating for any reason, it's only for good purpose research and would only benefit people in the future as opposed to hurting people; that's how I feel."

Participant 2 stated being involved in biobanking would benefit the next generation:

"I think it would be a benefit to future generations. I believe that just because I have gone through the process and run through the challenges associated with the disease and treatments and so forth that I would like to alleviate that challenge from somebody who may benefit from research."

In response to the question of the benefit of participating in biobank research, Participant 1 stated:

"If I can give some part of myself to help research to help somebody down the road, then you know that's it's all altruistic, right?"

Participant 1 further added:

"*I'm quite happy to give up my DNA information for biobanking if it would help, you know, somebody down the road."*

The same participant's opinion of people who donate their blood and other body tissue that is stored for future medical research:

"I think it is being a part of society that it's an almost an obligation. Since we have social health care, so if it is something like giving after dead that's one thing, and giving during life, I mean I particularly have no problem with that. So, I am quite happy to help out."

Participant 6 suggested biobanking will help enable researchers and the public to learn more about different diseases:

"To me, I feel good about it because eventually, hopefully, it would help to learn. There are people out there that are very good at learning and studying and finding out the different facts, and to me, it's a good thing like it should be continued. But I think at this point, it can only help, especially with not only things like cancer and Alzheimer's but even chronic things like chronic kidney disease; things like that we could just help the patients."

Participant 4 was driven by altruistic motivations to donate samples to biobank:

"I think that we're all here to help each other, and so I think anything that we can do, you know, without putting ourselves at great harm that can help other people or potentially even ourselves down the road, you know if it's really necessary."

Participant 4 continued, stating:

"It's an admirable thing to do. I think people should think more about doing that. But, again, we're all here to help each other in this world, and if more people would take the time and be willing to volunteer more as long as they don't put themselves obviously at extreme medical risk. I think more people should do it because of a lot of diseases, a lot of illnesses, a lot of things could be helped if more people would take a more altruistic view."

Participant 14 has the same view as Participant 4 in regard to donating bio samples to biobank:

"Well, to help the society, you know. I guess every one of us should… We owe something to the society. That's my main goal; to help the world, really, you know."

Participant 7 also had a similar view:

"I have no concerns. I am a scientist, and I strongly believe in the benefits to humanity of research."

Participant 16 provided reasoning behind the donation of samples:

"I would like to help the research. I would like to help the cause."

4.3.2 Concern

Concern emerged as another major theme in the data through a total of 49 occurrences in the interview data over two subthemes: breach of trust (n = 23) and data privacy and security (n = 26). In addition, participants discussed their concerns and worry about donating samples for biobank research.

4.3.2.1 Breach of Trust

Trust is considered vital in biobank research because it substantially affects the willingness of participants to participate. Participants expressed their uneasiness and concern about biobank research, particularly breach of trust by the biobank; samples or donor information/data could be used without their consent or in a way that would breach trust. They also expressed concern about the intended use of samples, and whether data would be used for other purposes than usual, such as for-profits, or future use, etc. Although law exists regarding sharing a patient's information, there is always the possibility of breach of trust as stated by Participant 11:

> *"I know that the Canadian regulation covers and protects patient's rights when it comes to sharing of this medical information, but there are still some grey areas when it comes to having to divulge some information forcefully, for example, to law enforcement, insurance companies, things like that."*

The same participant provided an example of a previous incident:

> *"There has been an incident in the past for tissues collected to be used to create immortalized cell lines, for example, and of course, that's a big breach of trust when it comes to participant protection*."

Participant 10 also shared a previous experience to express concern about a breach of trust:

> *"When I provided my sample, it kind of went away and I didn't hear a whole lot back for a year, and then didn't hear anything else until my next appointment with my nephrologist. So yeah, I guess there is a bit of concern about what it might be used for, you don't know what checks and balances are in place to prevent what can happen to your sample."*

Participant 10 continued:

> *"How long is it stored, where is it stored, when is it destroyed, is it never destroyed? So, I think yeah, it many concerns that as someone who's provided sample doesn't know what's happened to it."*

According to participants, the risk associated with biobank research is the potential use of samples for unintended purposes, which is a clear breach of trust and could negatively affect participants' willingness to participate in the research. Participant 12 mentioned:

> *"They might clone me and have ten of me around, and that could ruin the world. So, we don't want that to happen."*

There is a chance that samples or data would be used without a participant's consent or in a way that would breach trust, and biobank will be held accountable as Participant 8 stated:

> *"If it does happen, and that should be on biobank like they should be accountable for this because it's a trust thing. If your information is out, it's bad. We don't know what could be happening with samples exactly. We don't know what it could be used for."*

Participant 6 expressed concern for the intended use of samples or data:

> *"I guess I would want to make sure that it's not going to be used for any nefarious purposes. You never know these days with things, so just mainly making sure it's kept secure and that it's being used properly*."

This breach of trust issue is a cause for concern for participant 10:

> *"So yeah, I'd be very uncomfortable with a breach like that. Yeah, I would be quite frankly worried. I think something to be said; depends on the type of experiment whether it can be done anonymously. You know, in that case, that's probably a good thing to*

depend on the kind of experiment, but if you're going to be using identifiable samples, I would be very concerned if there's some sort of breach like that."

Participant 5 stated:

"My concerns would be that the samples are used for research and are not used for profit. That would disturb me if I were giving something, and I thought it was for research, and I found out that it was being used for profit."

Participant 15 mentioned*:*

"I guess the wrong people getting the information, then using it for purposes that it wasn't intended for."

4.3.2.2 Privacy and Security of Data

Privacy and security of data was another issue raised by participants. Privacy and security of data issues must be addressed before biobanks would be able to grow in scale and scope. Concerns surrounding participants' privacy may interfere with their retention and recruitment for biobank research and ultimately deter the willingness of people to participate and donate samples for the biobank. Participant 10 stated:

"My biggest concern is probably privacy: you know that if I'm going to be providing this information that it's used for the purpose as intended."

Participant 10 continued:

"So, I wouldn't want that data to be with, let's say with insurance companies, for example, or health insurance companies or life insurance companies. So, I think privacy to me is a big one that I want to see taken care of first as my biggest concern."

Participant 11 provided recommendations about the security of data:

"I am very supportive (of research), but as always, it has to be very well designed and protected, so that patient rights and privacy comes first."

The biobank must ensure the security and protection of data and samples. Expressly, it must protect research participants to the greatest extent that is practically possible in order to address the privacy concerns of donors. Participant 6 mentioned:

"My first thought would be to make sure that it's going to be kept secure. I would personally just be concerned about its security, that it's kept in a secure facility. It's being stored correctly, and then if it's going to be destroyed to be done properly."

Regarding the importance of privacy, security, and confidentiality of samples and donor information during the course of scientific research, Participant 6 stated:

"I think it's important and to make sure that all your information is secure."

Participant 6 further added:

"I would hope there wouldn't be a breach, but you know, I think sometimes it does happen."

Participant 9 suggested that storage and sharing of samples, test results, and other health information should be done only with anonymized data to protect privacy and ensure security:

"I think I prefer in that way. That way, you could probably feel a little safer knowing that it was unidentifiable, making sure that my information, my contact information, who I am, where I'm from, my medical history is not known to other people other than the people who are doing the research and what they're researching for. So, other information that is not pertaining to the specific research is not known to anybody."

Participant 8 provided perspective on any future breach of data and what needed to be done to ensure security:

"Well, I know it definitely could happen. I mean, there are all sorts of breaches that happen in this world. So I think it would be something that it would definitely have to go through to the police or law, so there definitely need to be charges laid if somebody reached that. Because I think it is important to make sure it is kept secure. Because it's not that everybody needs to know it. There is always a chance that it could happen. I mean, they would just hope that they have proper safety protocols in place."

Participant 15 mentioned:

"Well, I would trust the researchers and research project to keep the information as safe as possible. But I understand there's hackers out there that can get into anything if they want to so… As long as, you know, reasonable precautions were taken, I wouldn't call the researcher or research company accountable for a hacker."

4.3.3 Factor

Participants discussed the various factors or reasons that influence them to participate in biobank research or to donate samples. This theme emerged as another main theme through a total of 88 occurrences in the interview data over six subthemes: lack of trust in research organization (n = 8), lack of information about biobank research (n=12), details about research (n = 21), financial benefit (n=13), return of research results (n=27), and fear of pain (n=7).

4.3.3.1 Lack of Trust in the Research Organization

Trust in research bodies plays a central role in participant and research relationships and is an essential contributor to positive participant engagement, recruitment and retention. Factors such as distrust or negative views of the type of research organization (private, public, university, commercial, drug companies, etc.), may influence participants to participate in biobank research

or to donate samples for research. There are a variety of mechanisms and reasons which could contribute to a development of such distrust. Participant 6 trusted research conducted in universities over drug company-led research:

> *"I guess I wouldn't necessarily feel comfortable sharing it with the drug companies because I guess maybe they are for-profit to me. I would be worried about them, and how they might interpret things. Where you know like a university, where they're using it for studying and learning and finding out more about particular things, I would definitely be okay with it."*

Participant 4 had faith in the conduct of public or not for profit research:

> *"So public research: absolutely I feel secure and fine. Commercial: I'd say probably not."*

Participant 3 trusted organizations who had established credibility:

> *"It depends, I guess, on the organization. It has to be reputable……. reputable organization."*

Participant 2 favored public research entities over the potential risk of exploitation associated with for profit, private entities:

> *"A public research organization would be the best in terms of assisting individuals, as opposed to private, which is to again get back to the strong profit motive for a private corporation."*

Participant 12 trusted the government research bodies but was concerned about future changes in policies and political landscapes:

"*I would say yes, I trust them, but that doesn't mean the trust is going to be universally applied across time. You know, and that may be one of the risks, is that once politics get involved, privacy is not necessarily the top of their priorities."*

Later in the interview, Participant 12 expressed doubt about the precarious nature of government research entities:

"I do just feel like a big brother government knowing everything kind of thing; I'd be worried about the track here trace there all that type of thing."

Participant 6 had trust in research undertaken in educational institutions:

"I would want to make sure that it's for one being done with accredited school or lab; as long as it's a major university or college or that type of thing. If there were no information, I would hesitate because for me; personally, I need to know this information. For me, I need to know is it for the University of Toronto? Is it for the University of Calgary? Is it for Cornell in the states? Is it for Oxford in England? That's my personal opinion; that I would need to know what it's about."

4.3.3.2 Lack of Information about Biobank Research

Public awareness and engagement are among the main prerequisites for the successful and sustainable recruitment of participants for biobank research. The willingness to participate in biobanking among the public depends on a high awareness of biobank research. Still, there is a lack of information on biobank research among members of the public. In response to the question of whether lack of information or little information about biobank research (where, how, and when to donate samples) is a deciding factor in research participation, Participant 11 stated:

"*Yes, I would say that's true. You need to be very interested in it and proactive just to seek out either activities for, or research, or to be part of the research."*

Participant 12 stated:

"I suppose I haven't heard of it before."

Participant 9 mentioned:

"*There may not be a lot of information about it. Or is it just me because I never heard of it? Like I said it was only because I went online to see what it actually was, but other than that, I'd never heard of it before. So maybe there is a lack of information out there about it. If there was more information about it, maybe more people would do it."*

Participant 3 had a similar experience:

"I don't have a lot of information about it, and I don't think the general public does either."

Participant 14 expressed a similar sentiment:

"This is the first time that I encountered this research. So yeah, I don't really have much information yet."

Participant 15 mentioned:

"I knew little or nothing about it. I'm moderately well read on this stuff so I don't think there's a multitude of information out there, no. You can't participate if you don't know anything about it."

Participant 7 mentioned her personal experience:

"As a scientist, I was able to look for studies and to reach out to researchers on a professional level, but because of my science background, I was able to do that, and I was able to understand what the particular studies are about. But I think for the general

public, there is a huge gap in knowledge, and there doesn't seem to be a lot of connections made through typical websites."

Participant 4 believed that biobank research information is not easily accessed:

"I don't think it's very well advertised, or I don't think the information is out there."

While Participant 5 self-identified as proactive and has sought out opportunities to participate in research, he has found inadequate supporting information about the research:

"Yes, I think there's a real lack of information. I'm very aware, and I keep up to date with what's going on with transplants. And I've lectured, I presented a program on the impact of transplants as a transplant recipient. I've spoken to many different groups, including dental nurses, different charity groups, about the need for organ donation. So, I consider myself probably above normal awareness, and I still have not heard anything of this before."

Participant 6 agreed that there is little or no information regarding biobank research participation:

"There's no information out there unless you're already experiencing an issue or have a chronic condition or have a medical issue then you might know. But for the general public, they are not going to know. Because there's nothing out there, there's no information out there about 'hey donate, see if you can help science,' it's like I said: it's not out there I only know because of the different issues personally I have."

4.3.3.3 Details about Research

Some participants consider knowledge of the research details to be a vital factor when considering whether they will take part in the biobank research. Participants discussed that

knowledge of the following details about research influences them to participate: the objectives or purpose of research, the type of research, the negative or positive impact on participations, the researcher, the research organization, etc. Participant 11 mentioned that knowledge of the aim of the research as well as the identity of the principal investigator (PI) before participating in a research project are important factors:

> *"I like to know the information on what the purpose is, and things like who the PI (principal investigator) would be a vital piece of information for me to know*."

Participant 11 further stated:

> "*Those people who are solicited to participate in research like to know what the end goal or at least prospect of the end goal. So, without having any kind of tangible information on what the tissue or specimen is being collected for, I may be more reticent to participate."*

Participant 8 liked to know the research objective before participating in research:

> *"I guess it sort of depends on what? But, yeah, I would say if me not knowing what the research is for would probably impact my choices*."

Participant 1 was unwilling to participate if he was unaware of the intended use of samples in biobank research:

> *"I think the right thing to do… if you want to harvest some of my tissue, then you are going to tell me who is going to use it. Do you know what it is for? So, what I am saying maybe for future usage, I would probably be a little more reluctant to give it to you. I mean, if there is a specific reason somebody wants it for, or just maybe use it later for the purpose. I do not know, I can be a little more reluctant to give it up."*

> Knowing the aim of the research was also a crucial consideration for Participant 12:

"If I knew what it was for, that would be fine. If they're trying to find a cure for kidney disease or for cancer something like that; but if it's just for kind of weird stuff, they want to do, I don't know. Yeah, would depend on if it's for good or evil I guess."

Participant 5 identified knowledge of the research objective as well as the identities of the researcher and the research bodies as contributing factors to consider prior to donation of samples for biobank:

"I think it influences in that I'm not able to make that commitment without that information. There needs to be more awareness of this whole part of what's going on. I just need to know that it's for a good cause and that the person who is doing the research is doing it for the university or some kind of a public benefit. I wouldn't do it if it were for a drug company that was looking to build a drug, and if it was as proprietary, and I'd have second thoughts."

A similar opinion was stated by Participant 4;

"Yeah, I think that would matter. Well, I mean, I think it's kind of important to know what the person is like; if the researcher is ethical. But, you know, coming from an established university or hospital or something like that. , I mean I think the researcher has to have some kind of credibility that the patient or the person volunteering their samples with, you know, would feel like it's not just some nefarious or private company that's not, you know, using it for maybe the right reason, so I think, yeah, you have to be informed (as) the donor for sure."

Participant 14 would want to know the identity of the researcher before committing to research:

"It would be nice if I get information on his (researcher) background and what he's doing. But going ahead blindly, I think I'll have to have a second thought. I would prefer if I know a little bit more about the researcher."

Participant 15 stated:

Well, it'd be important to know if he's (researcher) a medical doctor or if he's a plumber or if he's a garbage collector. You need to know some professional qualifications and their reason why they want you to participate."

With regard to research objectives, Participant 15 further added:

"I want to make sure it's for an ethical reason and one that you can relate to and understand how your participation is going to help the researchers or another person's situation down the road."

Participant 16 stated the decision to participate in research is dependent upon research topics:

"It depends on what the research is. If I knew what the research was, I would be more, you know, understanding or suitable for my decision."

Participant 3 believed knowing the research entities along with detailed information about privacy and confidentiality were also contributing factors:

"If there's not enough information on the privacy and the *confidentiality or if it comes from a credible source I guess or center like from a university where there is a lot of rules and regulation and how strict it is, but sometimes you have to wonder that never heard of that organization before so that can be scary."*

Participant 10 stated:

"It depends on what they are asking you to do as part of the research, I guess. If it was more of an interview like this… yeah, I'd probably yeah just great. If it were biobanking

where they're taking samples; I'd say probably not if I don't know the answers to some of those questions. I'm probably much more hesitant to be part of it. It just depends on the type of research what they are asking to do as part of that."

For Participant 10, knowing the fate of donated bio samples was an important factor in considering biobank research participation:

"To be perfectly honest, I think either a bit more information prior to the collection of samples is probably a good thing. A bit more detail to individuals: what would happen to that sample? Or what's the projected use of that sample beyond that initial purpose? I think would be useful just so that yeah if it is stored for how long."

Participant 17 will not participate in a research study if the researchers and research objective are unknown:

"I would say 'no' because I would expect to have an introduction to the researcher. And even with an introduction, it's not the researcher that would be the issue for me. It would be the grounds on what type of research is done or is going to be done. I would not volunteer myself without knowing what type of research is going to be done. Because I would want to know freely what I'm partaking in. I am a type of person that wants all my questions answered. I want full voluntary transparency from the researcher or research team."

4.3.3.4 Financial Benefit

Monetary incentives are often used to help motivate participants well as to facilitate, and improve research recruitment and retention. Reimbursements or financial incentives are provided to research participants, and are intended to cover minor incidental expenses (such as

transportation, parking, etc.) incurred through their participation in research. This practice is acceptable from an ethical perspective. Participants argued whether the financial benefit in return for their contribution to the biobank would influence their decisions to participate in biobank research. Participant 12 said they would accept any compensation in return for donating samples:

> *"If I got compensated, I'd be fine with it. If that's what the question was if I'd want to be compensated or not, I don't mind. But, if the government can give money to the art gallery, they probably should give it to people who donate parts of their bodies for research; seems fair."*

Participant 3 agreed that receipt of any monetary benefit would influence their decision to take part in research;

> *"Well, it helps*. So, *I would, yeah, and I would say it does a little bit."*

Participant 1 wanted to be compensated if his sample was atypical:

> *"Well, I say that's the kind of crux of the thing I mean if I was somehow unique: like it is a unique property and you know by this uniqueness a production line made out of it, then yes. And if it was not unique, and thousand people got the same thing then no I would not expect to get the compensation……no*."

Participant 5 believed that people should be compensated when they donated samples and subsequently needed to offset the costs related to recovery time:

> "*I do support people that are willing to donate kidneys and receive financial support to get them through that recovery period. So if there is an anticipated recovery for supplying these samples, then I think you would see more participation if those costs ……real out of pocket costs were covered."*

Participant 7 stated that although she would not require monetary incentives, she understood how compensation could be motivating and helpful for some people:

> *"As a scientist, I'm happy to share whatever helps further the understanding of this condition. But I'm also fortunate in that you know, especially in the context of COVID, I'm employed, and you know I'm not impacted financially. So, I think for some people, if there was a financial incentive to participate, participation might be greater*."

Participant 11 did not seek any financial benefit for participation:

> *"As a scientist myself, I feel that the advancement of science as a whole is benefit enough. So, I don't need or expect a direct windfall from participating in a research project."*

Participant 10 felt the same way:

> *"I think it's better to help the broader PKD community. I think there's a lot of people who feel that way. I know this by other members of my family that would contribute as well without any sort of financial incentive"*.

Participant 6 agreed:

> "*Personally, for me, finance isn't a reason I would do it or not do it. Money has no say in the matter is it nice to get a little stipend, sure, but it's not the be-all end all for me personally."*

4.3.3.5 Return of Research Results

The return of research results is another factor that influences participants to donate samples. Biobank research participants want to receive the results from the research studies they have participated in and to which they have donated samples. Research data or results may be of

great utility to study participants. In addition, the information can provide their clinicians with insight into how to manage the health of patients who participate in research. While the return of research results is a motivating factor for participants, results are rarely returned to people who have participated in the research. Participants discussed receiving or learning the results of general or individualized research , and whether knowledge of such results would have a positive or negative influence on their decision to participate in biobank research or to donate samples. Participant 2 stated returning research results is important not only for what they would gain in knowledge, but also for understanding what the sample used for and what was achieved through the research;

> *"Yeah, I think that would be very useful from a knowledge perspective, and it was benefiting whether the results were conclusively favorable or not. Besides the point what the results were, and what specifically at the end of the day, the samples were used for. It will provide us a feeling in my case of comfort in terms of what was accomplished by doing research*."

The same participant further added:

> *"I would think it would encourage more, yes. I think it would reinforce the source of the benefit of my providing the samples."*

Participant 10 added:

> *"I would think knowing the overall experiment results would be a positive thing because it gives you a sense of okay; this is what you contributed to."*

Participant 9 would be interested in knowing the research results:

> *"I think it would be nice to know the results."*

Participant 3 shared the same opinion:

"Yes, I would probably prefer knowing. But I won't say no, but I would prefer to know the result if possible. Well, because it's something that does interest me research and well, especially when it comes to something like what's the purpose of it and what will be the outcome of it to me, I'm just a curious person I guess in general, so whenever I participate in something I like to know the result."

Participant 6 identified the return of research results as an influencing factor for her to decide to participate in research:

"I think for me it would be interesting to know cause I'm the type of person that I like to learn about different things, so I'd like to know what they found out. So, I think I might be influenced by it, and it would be good to know the end results. It is kind of an incentive to know that oh okay, I'll do this, but then, in the end, I will get a little bit more information which is great; so for me it would be nice to have that little bit extra incentive to know."

Participant 12 was also influenced by the prospect of receiving research results:

"Yeah, that it would be fine to know whether it's cure cancer, whether it's found a cure for this disease is going on now that COVID or who knows it's just nice to know why I suppose."

Participant 11 mentioned that return of results is not a contributing factor, as they would participate for the sake of advancing research:

"Sharing of information may not be possible, or you know information or actual results may not come until very much further down the line. But, for me, it is still important to be able to participate in these research projects for the sake of advancing the research and not only just to get personal data or feedback on my samples."

Participant 17 added*:*

"I would like to see…. So, if there was ground… you know, education being made, discoveries being done, yeah, I would like to know that."

4.3.3.6 Fear of Pain

Fear of pain can significantly limit the recruitment of biobank research participants. Pain or discomfort can be associated with the needles and biopsy procedures utilized in the retrieval of sample donations. Fear of pain can discourage people who might otherwise agree to provide samples for biobank research. Despite altruistic intentions, the experience of pain discourages participants/donors from donating, might lead to higher dropout rates, and might affect donor retention. Participant 12 even despised providing blood for laboratory tests:

"I have to get blood tests all the time, and I just despise it. Yeah, I don't like that at all; I'm a total wimp. I don't like even getting a needle in me, so anything else if they're going to start prodding and poking and taking parts of my body away, I kind of want to keep it."

Participant 7 explained a previous traumatic experience:

"It would depend on the type of sample, to be honest. I have been asked to undergo another kidney biopsy just to clarify the exact nature of my disease, and I have declined because it doesn't change the treatment. And I had my first kidney biopsy; was going very poorly and was very detrimental to my health. So, I don't think I would donate certain tissue samples that I wouldn't be comfortable for donating."

Participant 3 agreed to donate samples so long as they would not experience discomfort:

"As long as it doesn't hurt. As long as there's no pain like a small needle in the arm, I don't mind because it's for research; but a major biopsy no."

Participant 1 declined to donate samples if the procedure would induce pain;

"It is something excruciating painful thing that has to give it up by biopsy…….kidney biopsy: no thank you. But if you are doing some sort of surgery or it is a by-product of that surgery, no…. not a problem."

Participant 1 had the same opinion:

"As long as it was not excruciating pain factor came into that. It was part of the kidney; if I had to have a biopsy, then no. I have had a kidney biopsy, and there no fun, I tell you."

Participant 16 stated:

"*Well, it depends on what it is, you know, what kind of sample and how much of a procedure that's needed for that sample. You know, if it's just blood then it's no problem, you know. if it's a piece of skin, it's not really a problem. But if it's a piece of, you know, tissue in organ, you know, that's a problem. Pain is a major issue,.One doesn't like to be in pain."*

4.3.4 Ownership of Samples

Another major theme that arises from the analysis is ownership of samples. Participants wondered whether ownership lies with the biobank or the donor once a sample is donated. This theme emerged as another main theme in the data through a total of 27 occurrences in the interview data over three subthemes: ownership to the donor (n = 10); ownership to biobank (n=13); and ownership to both donors and biobank (n = 4). The ownership of biological specimens is a very complex and unresolved topic that presents ethical and legal issues. Several possibilities are suggested: ownership to the biobank, ownership to the donor, or ownership to both biobank and donor.

4.3.4.1 Ownership to Donor

Repositories of human biological samples (including tissues, organs, biofluids such as blood and their derivatives) and clinical data are vital resources for biomedical research. The ownership of these biological samples and data has been a subject of much debate and confusion for some time amongst the donors/volunteers from whom it is harvested, the researcher performs studies on it, the university or institution that provides research facilities, and the funding or oversight bodies enabling clinical care and research. Participant 11 preferred that ownership belong to the donor to keep the option open for any future withdrawal:

> "*I don't think that there are many situations where the donor can carry over ownership of samples once donated depending on the context, but I think that in any case that it would be possible. I believe that the donor should keep ownership of the sample in case intent to withdraw from the research if possible."*

On the question of whether donors should have the right to claim their samples after donation, withdraw their samples at any time, or retain the right to have them destroyed whenever they want, Participant 11 stated:

> "*I believe that is preferable. I know, and again in some cases, I know that that's not possible in experimental design; however, when possible, I believe that it's preferable to have control over samples from a legal perspective."*

Participant 3 stated having the ownership of samples is a way to prevent biobank from using samples for malicious purposes:

> *"I would say the donor so the biobank wouldn't be able to sell it to, let's say, foreign countries or things like that. But being the owners like you would decide what can be done. Just in case if they decide to sell that sample to a third party or something like that*

could be scary, so for the donor to be its owner of it, then that could prevent something like that. I wouldn't need them; it's just it's still having control over that sample just in case something happens."

Participant 10 believed ownership belongs to the donor and biobank should ask the participant for consent for any future use of the samples:

"Well, I think yeah, if you donated for a specific purpose, any additional experiments not related to that purpose that you donated for should have to seek your consent to use your donation for other experiments."

In addition, Participant 10 stated:

"I think if you ask people most of the time, they say yeah go ahead and use it. I don't think people necessarily deny that, but I think you need to be asking for that consent. I think if you donate for a purpose that is going to be used for something else, then you deserve the right to be asked for consent before that takes place."

4.3.4.2 Ownership to Biobank

Participant 9 believed once someone donated samples, then he or she no longer has ownership of the sample:

"If I were to give my sample, I've agreed to donate it. I don't believe that it should be mine anymore. I know what I'm giving the sample for. I'm not giving the samples so that I can have it back or that it belongs to me. I'm giving the sample to research."

Participant 9 mentioned the donor should not have the right to claim their samples after donation; nor should they have right to withdraw the samples or to have them destroyed whenever they want:

"*Once I would donate samples, I don't believe it's my right to say I want them back or destroyed."*

On the question of whether biobank should have the authority to distribute and manage the samples, decide what tests are run on samples, or determine what type of future research can be conducted with samples, Participant 9 replied;

"I think so. I think they should have the right to do whatever they feel necessary. I think that once I give them, it's theirs. They should be able to decide if they research one thing or another, and that should be their decision, not mine. So, they should have the right to do with them what they feel necessary."

Participant 10 had a similar opinion:

"Well, I think once you've decided to donate, I think it belongs to the biobank."

Participant 14 stated:

"I would say biobank. Well, once I donate it to the biobank then I guess it's up to biobank"

Participant 15 mentioned:

"Well, by the word donation that means you're giving it to somebody, so I guess the biobank."

Participant 16 stated:

"I give it to the lab, right, it's their responsibility and they do what they need to do. I hand it over, once I give approval of the specimen from myself, I relinquish my authority. That's the way I look at it."

Participant 6 was adamant that sample ownership belongs to the biobank:

"I would assume it's the biobank. To me, I would assume that I'm donating it and that there would be paperwork that would give them legal rights to it. I would be notified if they were going to be destroying it for some reason or anything like that, but in the beyond all, you're donating it to a lab or for the biobank, so I would assume it's theirs."

Participant 5 reiterated the donated bio samples are considered a gift;

"I gave it is a gift, and I consider the provision of these samples to be research gifts. They should be allowed to use them in any way they want to. I don't have any reason to want possession of them."

Participant 4 thought it would create a problem and delay the research process if donors retained ownership of samples: ;

"No, I think it should be the biobank. Well, I think you know as long as you're an informed donor, then what the biobank decides to do with it, I mean, I think it would hold up the research unnecessarily and create possible legal issues. I think it could be detrimental. I think if you have enough trust to be a donor, then you should be okay. You made the decision, you donate whatever your DNA, yourselves, your tissue, whatever it is, and then you know you've made that informed decision. Then I think you should have enough trust with the biobank what they do with it."

4.3.4.3 Ownership to Both Biobank and Donor

An argument was made in favor of dual ownership of biological material. Participants stated dual ownership or custodianship should be considered. Participant 8 stated:

"I don't think you should have the right to destroy them whenever you want, but you should have a little bit of a say potentially. Because I guess that's how it is. I don't think

you should have 100 per cent right away of what should happen with your samples, but I do think you should have a say in what happens."

Participant 8 continued:

"I think it should be equal where you should still have some power about it. However, it should still be limited, but it would be yeah you should have limited power, and what you say with that."

Participant 12 mentioned dual ownership and stated:

"Maybe both. I guess I don't see it has to be one person or the other."

Participant 12 further added:

"I don't know if I lend you my lawnmower well, (it's) kind of like your lawnmower cause you're using it; still my lawnmower."

4.4 Summary

The findings of data analysis of patients' views, knowledge, and engagement on PM are summarized in this paragraph. Four major themes emerged from data, including (1) benefits, (2) concern, (3) perceived barriers to implementing PM, and (4) informed consent model. Participants mentioned one of the benefits of PM is improved treatment and diagnosis. PM will enhance the understanding of disease causes, enable accurate diagnosis and effective treatment. According to participants, PM will be more targeted/tailored as it will use patients' detailed information to create individualised treatment plans. Another benefit mentioned by participants is increased effectiveness. Since PM is tailored to the needs of the individual, participants felt it would be more effective than a traditional medicine approach.

The second theme that emerged from data analysis is concern, and several concerns were expressed by participants. Participants expected the initial costs of integrating PM into the

current healthcare system could be high. Privacy and security of the data is another concern. Participants worried privacy and security could be breached, or data could be stolen, could fall into the hands of a third party, and ultimately used against them. Another concern is undue stress. Genetic test results used in PM could reveal predisposition to disease or other unwanted information, which could be stressful for some people. Insurance and employment discrimination were additional concerns noted by participants. The potential for breach of trust was the final concern raised by participants. Participants were fearful that their personal data could be shared with a third party without their consent, or that it could be used for purposes outside of those for which they had provided consent.

Barriers emerged as a third theme in the analysis of data. Some of the barriers listed by participants include: lack of knowledge of PM among the general population, lack of knowledge of PM among physicians, and the readiness of the Canadian healthcare system. The fourth theme that emerged from data analysis is the form of informed consent model used, such as categorical, broad, and study-by-study. They provide reasonings for their model preferences.

The findings of the second research question (knowledge, perceptions, and experience of CKD Patients about biobanks) are discussed in the following paragraph. Four major themes emerged from data analysis, including (1) benefits, (2) concerns about biobank research or donated samples, (3) factors that influence participation in biobank research and (4) ownership of donated samples. Advancements in future medical research and finding a treatment emerged as two of the sub-themes of benefit. Participants imagined biobank would advance medical and biomedical research by way of an increase in understanding of diseases and aiding in the development of new diagnostics and therapies. One of the benefits of donating samples for biobank is to help (help community, society, future generations, humanity, etc.). Concern

emerged as the second theme. Breach of trust as well as privacy and security of data were two concerns raised by participants. Breach of trust could occur if donated samples and data for biobank research ended up being used for purposes other than those for which they were originally intended. Regarding privacy and the security of data, patients feared data related to donated samples could be breached and reveal their identity. Factors emerged as the third theme and these factors have a significant effect on participants' willingness to participate in biobank research or to donate samples. Such factors include lack of trust in the healthcare system, lack of information about biobank research, details about the research, financial benefit and fera of pain. The last theme that emerged from data is ownership of donated samples. Participants discussed in length and mentioned their preferences and reasoning of ownership (ownership to the donor, ownership to biobank, or both).

CHAPTER 5: DISCUSSION

A discussion of the study results described in Chapter Four are presented in the chapter that follows. The first research objective of this study was to explore the knowledge, perceptions, and experience of CKD patients about PM. This study identified four major themes regarding question one: (1) benefits, (2) concern, (3) informed consent model, and (4) perceived barriers to implementing PM. Participants (CKD patients) identified some benefits or sub-themes of PM including: PM will improve treatment and diagnosis, PM will offer patients targeted or tailored treatment, PM will be less expensive, PM will improve on the outcome and effectiveness of conventional medicine. In addition, participants felt positive about the future and overall prospects of PM. Participants also identified a number of concerns (sub-themes) of PM including: PM's potential high costs, privacy and security of patients' data, undue patient stress, insurance and employment discrimination, and breach of trust. Data analysis also revealed additional perceived barriers (sub-themes) to the successful implementation and integration of PM in the current healthcare system such as lack of knowledge of PM amongst both physicians and the general population, as well as the readiness of the Canadian healthcare system. Participants also discussed their preferences for the best method by which consent could be obtained (i.e., their preferred informed consent model).

The second research objective of this study was to explore the knowledge, perceptions, and experience of CKD patients about biobank. There are four major themes regarding research question two: (1) benefits, (2) concern, (3) factors, and (4) ownership of samples. Participants (CKD patients) identified the benefits, or sub-themes, of biobanking: biobank medical research will advance future medical research and aid in the development of cures or treatments of diseases, participation in biobank research is a way to help fellow community members and

future generations. Furthermore, participants detailed their concerns (sub-themes) of biobanking: including breach of trust as well as the privacy and security of data. Participants identified additional factors (sub-themes) that influenced their willingness to donate samples for biobank research including lack of trust in a research organization, lack of information about biobank research, knowledge of research details, the presence of financial incentives, return of research results, and fear of pain. Moreover, participants also stated their preference (sub-themes) regarding the ownership of samples: donor ownership, biobank ownership or joint ownership.

Finally, the implications of the research, potential future directions, and the strengths and limitations of the study will be discussed. This study is the first study to employ a qualitative approach to explore the knowledge, perception, and experience of PM amongst CKD patients.

5.1 Knowledge, Perceptions, and Experience of CKD Patients About PM (Research Question 1)

Four major themes regarding knowledge, perceptions, and experience of CKD patients were identified in this study. The first theme benefit emerged from data analysis. The participants identified four main benefits or sub-themes. The first such benefit is improvements in treatment and diagnosis. Participants believe healthcare will be transformed with the implementation of PM. Participants also envisioned scientific breakthroughs and advancements related to PM. They stated that these advancements could enhance the understanding of disease pathogenesis and transform disease diagnosis and treatment. Ultimately the conventional symptom-driven practice of medicine would be improved. PM offers a tremendous opportunity to improve treatment because it provides clinicians with a deeper understanding and a corresponding ability to better identify disease risk factors. In addition, PM considers genetic, demographic, and environmental factors, making diagnosis more precise thus sparing patients of

unnecessary diagnostic procedures. This is supported by previously published literature (Kopp & Winkler, 2018; Sun et al., 2017; Witasp et al., 2014).

According to participants, another benefit of PM is more targeted or tailored treatment (sub-theme). Literature published earlier also supported this (Rhee et al, 2018; Sun et al., 2017). Sun et al. (2017) suggested that PM is based on accurate diagnosis, therefore, treatment will be tailored. Rhee et al. (2018) discussed in their review that PM has the potential for paradigm shifts and improvements in dialysis and management of ESKD patients. Rhee et al. (2018) discussed that the traditional paradigm has been to commence incident hemodialysis patients on a treatment regimen of three times per week, based on adequacy targets. On the other hand, alternative treatment regimens such as incremental hemodialysis can be applied among certain subpopulations while taking into consideration some factors (patients' residual kidney function, volume status fluctuations, symptoms, and preferences). This new approach of incremental dialysis therapy is a dynamic and patient-centric approach that is tailored to patients' unique characteristics which will improve the health, well-being, and survival of the population. PM allows physicians to treat patients for disease using personalized plans. PM offers a far more accurate, holistic picture of the patient by using detailed information to create (or tailor) a treatment plan for a disease that contrasts with the one-size-fits-all approach of traditional medicine. The PM approach relies on recent scientific advances specifically in understanding patient susceptibility to a particular disease based on that patient's unique molecular and genetic profile. So, PM offers a detailed picture of patients subtyped and grouped to find the most effective targeted treatment regime. PM tailors medicine or therapy to one's biological needs.

The PM is less expensive emerged as a sub-theme under theme benefit. Participants believed PM would be less costly as it utilizes a more effective treatment that does not employ

trial-and-error; therefore, it likely reduces long-term hospitalization costs, follow-up costs, unnecessary medications and treatments, and results in fewer adverse effects, etc. In addition, individuals will react differently to treatments due to genetic differences; therefore, a tailored treatment plan could improve treatment outcomes and reduce treatment costs. Thus, PM offers cost-effective medical solutions. Many studies concluded that the PM intervention is at least cost-effective compared to traditional care (Kasztura et al., 2019). A scoping review by Kasztura et al. (2019) concluded that PM intervention is cost-effective compared to traditional care. This broad scoping review included 83 studies that were relevant to economic evaluations and cost-effectiveness of a broad range of PM interventions. Kasztura et al. (2019) suggested some major factors that influence cost-effectiveness such as the prevalence of the genetic condition in the target population, costs of genetic testing and companion treatment and the probability of complications or mortality. Some other studies, however, did not have similar findings (Almarsdóttir et al., 2005; Budin-Ljøsne & Harris, 2016). A qualitative study by Budin-Ljøsne and Harris (2016) stated that representatives of patient interest organizations (PIO) believed that PM might be too expensive for many health care systems. They experienced that patient access to conventional treatment is increasingly restrained due to cost issues and observed that new targeted drugs will be so highly priced that patients would be unable to afford them. Focus group participants in Almarsdóttir et al. (2005) study believed that tailored medication according to individual's genetic predisposition would be costly compared to the use of conventional drugs.

Another benefit of PM is that it is more effective (sub-theme) and it is significantly manifested in the data. Participants suggested PM would be more effective because it is tailored and does not apply a trial-and-error treatment that treats everyone in the same way to find the best possible solution. In addition, PM allows physicians to use patients' genetic and other

molecular information as part of routine health care, which increases their ability to understand the underlying mechanism of diseases. With PM, physicians can thus increase their ability to predict the best treatment for a particular patient. This is in agreement with Moradi and Kalantar-Zadeh (2018) where authors suggested PM approach takes into account patients' details which are unique to each particular patient. The author also suggested that PM identifies and recognizes the complexity and diversity of different mechanisms that can be present in individuals with the same condition. This targeted approach enables PM to better predict the most effective treatment in each particular case (Moradi & Kalantar-Zadeh, 2018).

It is apparent through the emergent themes present in the data, that the participants expressed some concerns (theme). One concern is that PM is more expensive (sub-theme). Disadvantages of traditional medicine are repeated efforts, readmission, etc. While PM can eliminate these problems, implementation of PM requires a significant financial investment. Initial higher costs arise from building capacity for collecting, curating, storing, and sharing data, as well as from creating the security infrastructure for the data. These findings are in agreement with previous publications (EPFL IRGC, 2018). The high initial costs of PM implementation could prove to be a burden for healthcare. In addition, there are additional costs associated with PM, including those associated with stratification, genetic sequencing, intervention, treatments, and drug development and tailoring, which include new approaches to treatment (dosage, formula, protocols), new targeted drugs for individuals with identified biomarkers, and new drugs for those who are not responsive to existing ones (EPFL IRGC, 2018).

Privacy and security of data (sub-theme) emerged as a concern for participants for PM. The participant felt the key challenge of the PM initiative is its ability to provide data privacy and security. Participants mentioned many aspects of data privacy and security, including the

necessity of confidentiality and protection of data, the potential that data could be revealed to a third party (insurer, employers, etc.), the capacity of the health care system to protect data, potential security breaches, etc. These data privacy and security concerns are well documented and in agreement with previously published papers (Issa et al., 2009; Rogith et al., 2014). In Rogith et al. (2014) study though participants in the study recognize the significance of sharing genomic data with researchers, they expressed concern regarding privacy of genomic data. A representative survey of 4,659 American adults was conducted in Issa et al. (2009) study, and 90 percent of respondents would be concerned about the protection and privacy of their genomic data.

Genetic/DNA testing on patients could identify inherited genetic mutations which could lead to precision therapies that profoundly improve the practice of medicine. Genetic/DNA testing could aid in diagnosis and could predict genetic traits or rule out genetic disorders. This ability to predict for a specific disease or condition will provide personalized insights to customize therapy based on individual makeup. However, sometimes knowing genetic test results causes undue stress to patients, which affects their phycological health, such as anxiety and depression. Furthermore, the genetic test result is not conclusive and cannot tell whether an individual will or will not get a particular disease. For example, having a predisposition or genetic trait for CKD does not necessarily mean a person will have CKD in the future. As a result, sharing these results and any additional unexpected information can be stressful or upsetting to an individual and adversely affect health and family relationships. These findings are supported by previously published papers (Genetic Alliance, 2010). It is suggested in this paper that understanding the unique aspects of genetic information can help guide a course of action to minimize distress and maximize benefit for both the patient and family, but it can affect the

psychological and social well-being of the patient and family (Genetic Alliance, 2010). Knowing genetic information could lead to a range of emotions including guilt, fear, and helplessness.

Insurance discrimination (sub-theme) emerged from data analysis as another concern. Participants discussed in length the possibility of insurance discrimination. The fear of possible insurance discrimination looms large in the minds of participants. Participants fear that the unwanted disclosure of genetic information and other health information to insurance companies could lead to discrimination. The insurer may use genetic or health information to determine an individual's eligibility for insurance or to make coverage, underwriting, or premium setting decisions. These findings are in agreement with Stiles and Appelbaum (2019) in which the authors suggested that patients have concerns about the privacy and confidentiality of genetic test results and whether they could negatively affect insurance coverage. The Genetic Information Non-discrimination Act protects against discrimination in both the workplace and in health insurance coverage based on genetic information. This law, however, does not apply to life, disability, or long-term care insurance or any other insurance product (Stiles & Appelbaum, 2019). Bélisle-Pipon et al. (2019) also shared similar findings. Many people are concerned about the high risk that genetic information could be used for potential insurance discriminatory purposes that will affect the insurance options available both to the underwritten individuals and to their family members. Consequently, there is a fear of unwanted disclosure, and possible genetic discrimination looms large in the public imagination (Bélisle-Pipon et al., 2019).
The Genetic Information Non-discrimination Act prohibits health insurers from using genetic information to analyse eligibility or adjust premiums, to require applicants to undergo genetic testing or to impose pre-existing condition exclusions (Bélisle-Pipon et al., 2019).

Employment discrimination (sub-theme) surfaced as a concern for participants. Employment discrimination is a significant worry for participants regarding PM. There is a possibility that employers might use an individual's detailed information retrieved for PM (genomic, lifestyle, and environment). Chapman et al. (2020) and Bélisle-Pipon et al. (2019) also had similar opinion. Employment discrimination might occur if an employer wants to use genetic information to select, advance, not advance, or terminate employees based on predictions of traits, such as intelligence, athleticism, or empathy, among other phenotypes influenced by genetic factors (Chapman et al., 2020). Knowing genetic information and implementing it beyond employee efficiency or even the safety of employee; the employer may simply want to reduce healthcare expenses for employees and their dependents (Chapman et al., 2020). Bélisle-Pipon et al. (2019) discussed that knowing a prospective or current employees' risk for diseases or conditions (whether the chances of future illness and the prospect of productivity, direct and indirect healthcare cost) could greatly impact employers in the processes of recruitment and promotion. The Canadian Genetic Information Non-discrimination Act prohibits employers from requiring an individual to undergo a genetic test or disclose the results of a genetic test, and the law forbids them from making any use of these results even if the results are made available to them (Bélisle-Pipon et al., 2019).

In PM, collecting, linking, and reusing large amounts of molecular, clinical, phenotypic, and lifestyle data are essential and are the foundation of efforts toward PM. Participants stated their concern about the breach of trust (sub-theme) and the intended use of data without their consent. There was widespread concern over potential breaches of trust by sharing these data with commercial organizations, insurance companies, pharmaceutical companies (for profit), unfair monetization, cloning, and the risk that data could be stolen and used against them. These

findings are in agreement with other studies (De Marco et al., 2010; Haddy et al., 2010; Issa et al. 2009). Participants in the Haddy et al. (2010) study expressed their anxiety and doubts about the intended use of their data as well as whom their data could be shared with. They distrust the pharmaceutical company; that they could use genetic information and utilize this opportunity to profit (Haddy et al., 2010). Issa et al. (2009) revealed that participants in the study were concerned about disclosure, privacy, and confidentiality of genetic test results, as well as the potential that these data would be shared with insurers and employers. Participants raised concerns about the intended use of data by insurers and employers (Issa et al. 2009). Participants of De Marco et al. (2010) study also expressed similar concern about the privacy of their genetic data, and they believed that results data could be exploited, and privacy would be compromised.

There are few (sub-theme) barriers (theme) that emerged from data; these are perceived barriers of PM implementation and integration of PM into the current health care system. Multiple barriers must be addressed for PM to reach its full potential. Lack of knowledge of PM among the population is one of them. There is a need for PM integration across medical specialties and healthcare in general, but a significant proportion of the public remains unknowledgeable and unaware of PM. Previous studies reported similar findings (Budin-Ljøsne & Harris, 2016). In Budin-Ljøsne and Harris (2016) study, several patient interest organization representatives expressed skepticism regarding the patient's ability to understand and endorse PM strategies. The authors of this study discussed that PM is a new and challenging topic, for patients to understand as they are lacking in general health literacy (Budin-Ljøsne & Harris, 2016). In addition, lack of knowledge influences patient attitudes and interests. Participants of this study considered this a barrier, as lack of knowledge brings negative attitudes and may cause

them to express skepticism, lower interest, etc. Canedo et al. (2020) stated, “the continued diffusion of PM innovations into healthcare practice is influenced by many factors, including the willingness of patients to adopt new PM approaches” (p. 3). But lack of awareness could influence patient acceptance of PM.

Another barrier evident in the data is the lack of knowledge of PM among physicians. Similar findings are well documented in a previous publication (Baars et al., 2005; Bonter et al., 2011; Caroll et al., 2016). The ability for physicians to understand the evidence that supports the clinical and analytical validity of the genetic test related to PM are paramount for the adoption of PM in the healthcare system (Bonter et al., 2011). However, the current state of knowledge of PM among physicians is insufficient or inadequate for adoption (Bonter et al., 2011). Bonter et al. (2011) suggested “a need for better physician education or a need for additional supporting evidence for PM implementation” (p. 6) . The Baars et al. (2005) study revealed that there is a lack of knowledge of genetics among health care providers. The authors of this study argued that health care providers are not equipped to answer any questions posed by patients about genetics and genetic tests (Baars et al., 2005). Carroll et al. (2016) study revealed primary care providers’ understanding of PM was vague, and that they had little or no knowledge of recent developments in PM.

Participants also questioned the preparedness of the Canadian healthcare system (sub-theme) to adopt PM. In addition, some participants expressed their concern regarding potential obstacles to the integration of PM into the healthcare system. Several obstacles were cited by participants: a conservative, slow and rigid system, a lack of advocacy within the system, and a low availability of financial resources. This topic is also discussed in previous studies as well (Bombard et al., 2013; Bonter et al., 2011; Budin-Ljøsne & Harris, 2016). In Canada, physicians

lacked formal education about PM and had limited time and resources available to study this subject (Bonter et al., 2011). In Budin-Ljøsne and Harris (2016) study, patient interest organizations believed that inadequate mechanisms and infrastructure delay the integration of PM into healthcare. In the Bombard et al. (2013) study, the citizens' panel was skeptical about the readiness of the health care system to incorporate PM. The panel members in the study suggested some strategies which will facilitate PM integration: increase public awareness, restructure laboratory facilities, and prepare and train health care providers (Bombard et al., 2013). In Bonter et al. (2011) study, physicians suggested some barriers to adopting PM into health care systems such as unavailability of genetic test in their practice setting, the length of time it takes to obtain results, lack of practice guidelines, limited provider knowledge, and lack of evidence-based clinical information. The authors concluded that Canada is trailing behind other countries with more resources in place to support PM (Bonter et al., 2011). Many barriers were cited regarding PM implementation in Canada, specifically in Alberta -

> performing robust multi-omics phenotyping on defined patient cohorts to reclassify diseases at the molecular level is a significant undertaking. The data and analytics demands are substantial, and intimate engagement among fundamental and clinical researchers is required. Other challenges include performing appropriate clinical research and development on new products, establishing suitable reimbursement models, evaluating new Precision Health technologies and processes in practice, and educating health care professionals on the appropriate use of Precision Health strategies. (Eagle & Dubyk, 2019, p. 8).

From thematic framework analysis, the informed consent model emerged as a theme. Informed consent is the fundamental requirement for PM research. Informed consent is the

process of informing participants of research intelligible and tailored information and confirming participants/consumers understand the information, ensuring information needs have been met, and requesting informed consent (Bunnik et al., 2013). Informed consent provides the participant/consumer with self-determination, autonomous decision-making, the right to choose, information, and comprehension (Bunnik et al., 2013). A few informed consent models, such as broad, categorical, and study-by-study (sub-theme) were discussed. Participants stated their preferences for an informed consent model for genetic and health data sharing for PM research. The reasons for choosing broad consent included the freedom to not be required to give consent for every new stage of research, to help the researcher do multiple types of research, to allow the researcher to perform any future studies, and to recognize future studies that are subject to ethical review. In the case of study-by-study consent, participants felt they had an element of control and authority. Categorical consent also provides participants with a sense of control over the types of research studies they will engage in. Similar findings are also prevalent in previous studies (Kaufman et al., 2009; Platt et al., 2014; Simon et al., 2011). Kaufman et al. (2009) surveyed veterans' affairs patients in the USA about their preferred consent models. The findings showed that preferences for different types of consent were mixed. Some participants preferred blanket consent, whereas others preferred separate consent for each research study (Kaufman et al., 2009). The online survey of US adults by Platt et al. (2014) revealed their choice of consent of research; their preferences are the broad and study-by-study consent models.

5.2 Knowledge, Perceptions, and Experience of CKD Patients About Biobank (Research Question 2)

Benefit is one of four major themes that emerged about knowledge, perceptions, and experience of CKD patients about biobanking. The participants of this study identified three

main benefits or sub-themes. One of the benefits of biobanking is that it will advance future medical research. Participants believed biobank is an excellent platform for medical and biomedical research. The use of biospecimen will contribute to improved understanding of the disease and aid in the development of new diagnostics and new therapies. Overall, the biobank will provide an essential contribution to scientific progress and the advancement of future medical research. These expectations are in agreement with previously published literature. As Kinkorová et al. (2021) stated "it (biobank) is a well-developed and structured multidisciplinary field that reflects developments and advances of biomedical research based on principles of predictive, preventive and personalized medicine" (p. 1).

Hummel and Specht (2019) also stated "biobanks provide an essential contribution to the accelerated development in the context of precision medicine" (p. 5). According to participants, a benefit of biobank research is its ability to aid in the discovery of new therapies or treatments (sub-theme). Many participants wished biobank research could generate new knowledge and further the development of new therapies or treatments of diseases and illnesses. They stated that biobanks could play a pivotal role in improving healthcare outcomes through basic and clinical research. In many areas of biomedical research, biobanks contribute to understanding the causes or mechanisms of diseases, thus help in the development of novel treatment or therapies for the disease. In addition, studies utilizing biobank samples help develop targeted therapeutics (Kinkorová, 2016). However, there are few benefits of biobanking stated by participants in this study. One of the benefits is altruistic; participants said they found altruistic reasons to participate in biobank research or to donate samples for research. Participants feel biobank research is a way to help in many ways: to help find a cure for a disease, to help to understand or find the cause of a disease or illness, to help in medical science, to help to advance medical

research, to help others/people/ patients, to help society, to help future generations, to help humanity, etc. This result aligns well with literature published earlier (Braun et al., 2014; Heredia et al., 2017; Kettis-Lindblad et al., 2006; Overby et al., 2015; Porteri et al., 2014; Sanderson et al., 2017). In Kettis-Lindblad et al. (2006) study, the most common motives for donating a sample were for the benefit of future patients and for the benefit of family. In Porteri et al. (2014) study, participants who expressed the willingness to provide biological materials for the constitution of a biobank were motivated by different factors; one of which was altruism. Similar findings were also revealed in Braun et al. (2014) study. A desire to help others was cited as one reason for participants to donate samples (Braun et al., 2014). In Sanderson et al. (2017) study, one of the perceived benefits of participating in biobank research is helping future generations.

Participants mentioned concerns (theme) about biobanking One concern is potential breach of trust (sub-theme) which has a significant effect on their willingness to participate in biobank research. Breach of trust by researchers/research organizations is a possibility; samples, or biospecimens and data retrieved from those specimens collected could be used for purposes other than initially intended, in situations wherein consent was not granted, or for potentially harmful purposes. In addition, a third party could play a role in breach of trust. According to participants, there are many ways breach of trust can occur: sharing research participants' data or health information with law enforcement, insurance companies and employment authorities and using data or health information for profit or unethical research, etc. Similar concerns were also cited in other studies (Heredia et al., 2017; Rychnovská, 2021). These studies cited participant concerns related to the risk of secondary application or the use of biobank data for discriminatory purposes (misuse of profiling, especially medical or genetic profiling) or other harmful purposes

by the state or third party (Rychnovská, 2021). Many additional concerns had been cited by Heredia et al. (2017), such as "biospecimens sale for the personal benefit of the researcher, unethical research such as cloning, and no control over the biospecimen use in the long-term" (p. 7). It is necessary to establish rapport and trust between research participants and the researcher and is paramount for successful research (Guillemin et al., 2018). In this case, the researcher and biobank research organizations should ensure (i) transparency, (ii) that professional values are aligned with an ethical standard, (iii) they follow regulations and guidelines, etc.

Privacy and security of data is another concern (subtheme) for participants of this study. Biobank collects and gathers an unprecedented amount of data for the research process, including medical and health data (specimens coupled with health records and lifestyle information). The most prevalent notion of future challenges in biobanking relates to those data privacy and security. When asked about what issues concern them most in biobanking, many participants responded that data privacy and security are significant concerns. These findings are aligned with previously published articles (Kaufman et al., 2009; Oberby et al., 2015; Sanderson et al., 2017). In Sanderson et al. (2017) study, participants worried about their privacy of data, that someone or drug companies might make money using their health information and that the researcher might misuse the health information in the biobank. Respondents in Oberby et al. (2015) study expressed their concern related to confidentiality and potential for misuse of information (information stored in the biobank might be used against them). There is widespread concern about privacy and the intended use of data among participants of Kaufman et al. (2009) study. As a robust platform for biomedical research infrastructure, biobanks should provide data privacy and security to participants; a philosophy considered by many to be an ethical and scientific imperative. A participant's willingness to donate biospecimens for biobank research

depends on the biobank's ability to provide data privacy and security. Some participants expressed a desire for their health information to remain anonymous or de-identified to the extent that not even the researcher would be able identify the donor. Many participants stated that security breaches could occur and expose donor identity, health data could fall into the possession of someone outside the research study, and that information could be used against them.

Moodley and Singh (2016) stated "biobanking has become a core resource for medical researchers as it has enormous transformative potential"(p. 2). A diversity of public participation is needed in biobank research for its success. To increase public involvement in biobanking, it is crucial to determine the factors that influence the decision-making to participate (Ahram et al., 2014). Participants had discussed few factors (subtheme) that influence them to participate in biobank research or to donate samples. Lack of trust in the research organization (sub-theme) is one of them. Generally public expect biobank to protect their interest. Participants of this study are cautious and expressed lack of trust could be a defining factor in their decision to participate. A study by Moodley and Singh (2016) and Heredia et al. (2017) also outlined similar findings. This lack of trust in research bodies posed a significant challenge to engage participants in biobank research (Moodley & Singh, 2016). This trust issue is fuelled by experience and a history of exploitation in medical research (Moodley & Singh, 2016). Participants of the focus groups in the Heredia et al. (2017) study described a number of factors that could impact their decision to donate biospecimens; one such factor is a lack of trust in healthcare system or healthcare. There are many reasons for this lack of trust cited by participants such as sale of biospecimens for the personal benefit of the researcher, unethical research such as cloning or illegal trafficking, having little control over the biospecimen’s use in the long-term (Heredia et

al., 2017). Lack of trust was also stated as a factor in Hagiwara et al. (2014) study. Participants feared exploitation or were concerned that they would be treated as a 'guinea pig' in medical research (Hagiwara et al., 2014).

Lack of information about biobank research (subtheme) is another factor that influences participation. Participants mentioned a widespread lack of information that resulted from limited familiarity in biobank research, lack of awareness, misconception, and confusion. Additional findings supporting this factor were documented in the previous publication (Heredia et al., 2017). There is a necessity to educate the community about biobank research, what it means, biobank research participation opportunities, more advertisement, the benefits that can emerge from scientific discoveries made through biobanking (Heredia et al., 2017).

Details about research emerged as a factor (subtheme) influencing participation in research. Similar findings were documented in the previous publications (Ahram et al., 2014; Heredia et al., 2017). Participants of Heredia et al. (2017) study noted that there exists a lack of detailed information or lack of specifics of biobank research influencing them not to donate biospecimens: lack of information with regards to what participation entails, how biospecimens will be used, or the impact on one's health. If this information is missing, then people are not willing to participate. The inability to know the type of research, the researcher's identity, and research objectives had an impact on participation. There are uncertainties surrounding information about biobanking, including what the biospecimens will be used for, the location of biospecimen storage, participation details (e.g., time commitment, type of specimen, and information collected), and potential impacts on health (Heredia et al., 2017). Any potential participants should be provided with valid information about the risks, potential benefits, procedures, and alternatives of the biomedical research in which they are going to participate.

Therefore, the necessity of detailed and complex informed consent forms is paramount in biobank research (Karbwang et al., 2018). The inability to know the type of research, storage time of samples, and researchers' identities impacted the participants' decision to donate biospecimen in biobanking (Ahram et al., 2014).

Very few participants stated that a lack of financial benefit (subtheme) in return for their participation could affect their decision to participate. Though most respondents were not influenced by the lack of monetary compensation for their biobank donations. These findings are in line with the previous study (Ahram et al., 2014). Almost three quarters of respondents in Ahram et al. (2014) study did not think that lack of health or monetary benefit in return for contributions to the biobank would impact their decision to participate. The payment to research participants comes in the two forms of compensation and reimbursement. Payment to research participants enhances recruitment and provides an incentive to participate, or enables subjects to participate without financial sacrifice. The practice of paying participants is a regular yet uneven and contentious practice in medical research (Grady, 2005). However, several ethical dilemmas are presented to researchers regarding the payment of research participants (Grady, 2005).

Return of research results (subtheme) is another influencing factor for participants to donate samples. Respondents of this study appeared eager to learn both general and individual research results. They mentioned that not receiving such results would negatively influence their decision to participate in biobank research. These findings are in line with earlier literature (Ahram et al., 2013; Heredia et al., 2017). Biomedical research involving biospecimens leads to identifying and causative factors of disease or illness and discovering new diagnostic and treatment modalities. These findings are essential for donors, as knowing this information could be of clinical significance and give them a chance for earlier intervention (Alahmad et al., 2020).

From a biobank perspective, certain ethical challenges exist when informing donors of research results. One of them is whether the results are limited to research goals or include incidental findings (Alahmad et al., 2020). Other challenges include the ethical responsibility of the researcher and research bodies to inform donors of the research results, the donor's right to know or not to know the results, and whether consent should be taken from or provided by donors before the research in terms of the possibility of returning any results (Alahmad et al., 2020). From a logistics point of view, returning research results requires considerable resources and time from biobank and deviates from the primary goal of research (Peterson & Van Ness, 2015). It is also critical to consider the moral argument, as donors donate their time, accept possible health risks and welfare, donate biospecimens, and share their health care and other information. Participants in the Heredia et al. (2017) study expressed that a lack of communication from researchers about both the results of the studies that used their biospecimens, as well as their individual personal results, was a barrier to participation. Some of the participants wanted information about the overall findings of the research after donating their biospecimens, if they helped others, or whether their donation had resulted in any benefit to the population's health (Heredia et al., 2017).

Some participants mentioned fear of pain or harm (sub-theme) due to donating biospecimens for biobanking as a factor influencing participation. These fears including bodily injury, fear of needles, contracting disease, medical error, etc. Such phobias limit an individual's ability, motivation, and tendency to avoid donating biospecimen for research. Previous research also found similar results (Hagiwara et al., 2014; Heredia et al., 2017). In Heredia et al. (2017) study, the fear of experiencing pain or harm as a result of donating a specimen for biobanking was a commonly identified barrier to participation. There are many fears listed by participants

such as being afraid of needles, contracting diseases, or medical errors. Some expressed fears of blood draws, needles, and having samples taken from places other than veins such as palms, eyes, or bone (Heredia et al., 2017). Participants in Hagiwara et al. (2014) study expressed their fear of bodily harm due to research participation; they suggested that medical researchers might use contaminated equipment to collect biospecimens.

The last theme that emerged from data is ownership of samples. Three subthemes emerged from data analysis: ownership to donor, ownership to the biobank, and ownership to both donor and biobank. This topic was also discussed in previous literature (Coppola et al., 2019). Participants in Coppola et al. (2019) study shared a common view that their samples are valuable, however they did not have a set of shared perceptions about specimen ownership, retention, and oversight. Instead, they display widely divergent views on ownership of retained specimens, often identifying more than one owner. Huge quantities of human biological samples are collected and stored for research purposes. Questions remain as to who owns and controls these biological materials since they must be stored for long periods of time, sometimes indefinitely (Cadigan et al., 2011). There is an uncertainty and lack of consensus about ownership, and the ethical, legal, and social landscape of human specimen ownership is still evolving (Cadigan et al., 2011). The ownership of biospecimen has been analyzed for many years and debated as an issue of 'guardianship' versus 'ownership'. It is pivotal for a biobank to strive for transparency and to clearly outline stewardship or ownership expectations in the consent form to avoid lawsuits and destruction of valuable human biospecimen.

5.3 Key Findings

The key findings of this study regarding PM are the benefits of PM. Participants widely expect that the health care system will benefit from PM by increasing the general understanding

of disease mechanisms, enabling accurate diagnosis and offering targeted and effective treatment. Although participants recognized the benefits of PM, they also raised concerns about the approach. One major finding here is the concern regarding privacy and security of the data; participants are worried their data could be breached, stolen, or fall into the possession of a third party. In the worst-case scenario, they raise concerns that data could be used against them. Another concern is undue stress. Participants felt that some people may be mentally unprepared for the stress which might arise from genetic test results used in PM, should these results reveal a predisposition to disease or other unwanted information. Another key concern is discrimination such as insurance and employment discrimination. PM has the potential to draw ever-finer distinctions among individuals and could contribute to discrimination based on genetics (i.e., genetic profile). Additionally, PM could indicate not only that a person is likely to develop a certain disease in the future, but also that the person would not be receptive and susceptible to certain drugs and might therefore be prone to increased morbidity and mortality risk. Therefore, participants were concerned these factors might influence insurance companies to raise premiums or not to provide insurance for those individuals. The potential for employment discrimination was another concern for participants. Participants fear an individual might be treated unfairly at work or in society based on his or her genetic predisposition or susceptibility to any disease/condition. Employers might use a potential employee's genomic data to select, advance, not advance, or terminate employees based on predictions of traits and other factors influenced by genetic factors. Another key finding, breach of trust, was a concern for participants. Participants were fearful that their private data could be shared with a third party without their consent or could be used for a purpose to which they not provided consent.

The major findings of the second research question regarding knowledge, perceptions, and experience of CKD patients about biobanks are: benefits, concern about biobank research or to donate samples and factors that influence participation in biobank research. According to participants, the benefits of biobank research include the likelihood that biobank would advance medical and biomedical research, increase understanding of diseases and help in the development of new diagnostic and therapies. Another major finding is concern surrounding breach of trust as well as privacy and security of data. Participants anticipated breach of trust could occur if donated samples and data for biobank research were used for unintended purposes. Regarding privacy and security of data, participants worried donated samples and related data could be breached and subsequently reveal their identities. Another major finding included factors which would have significant effect on a participant's willingness to contribute to biobank research or donate samples: lack of trust in the healthcare system, lack of information about biobank research, knowledge of details about the research, and financial benefit.

5.4 Study Strengths and Limitation

This section combines a discussion of the strengths and limitations related to this study. Several strengths were demonstrated by this study. These strengths included the qualitative study design and its execution, in-depth understanding, and rich insight into CKD patients' knowledge, attitude, and perceptions about PM and biobanking. A significant strength of this study is the fact that it is the first to apply qualitative study, to our knowledge, to the exploration of CKD patients' knowledge, attitude, and perception about PM and biobanking. Some findings of this study, specifically those regarding biobanking but also those results pertaining to PM, would add unique value and essential information to the literature. Participants in this study represented varied age groups and were recruited from across Canada providing additional strengths to this

study. Semi-structured, open-ended questions allowed participants to more deeply explore the subject. Due to the strict nature of confidentiality, participants could speak freely, free from fear of repercussion. Moreover, several steps were taken to enhance the rigor of the study, including (i) appropriateness of research design, data collection, and data analysis, and clear and accurate description of these steps, (ii) clear interpretation and reporting of results, participants' viewpoints, opinions, thoughts, and experiences, (iii) repeated visiting of audio recordings were done to check emerging themes and remain true to participants' accounts, and (iv) a three member team (MH, PR, and SP) reviewed and discussed the coding process lent credibility.

Despite its many strengths, this study also has some limitations. Although recruitment and obtaining consent for participation were not problematic, finding an agreeable and convenient time to conduct the interviews was challenging. As a result, researcher bias might have occurred based on assumptions surrounding scheduling of the interviews. An effort was made to control biases from the researcher by taking field notes, keeping an interview journal, and performing comparisons of the interview data and coding process. Convenience sampling for this study had some limitations, including that the sample was chosen because of its accessibility resulting in non-random selection of participants. In other words, the researcher might have been subjective and biased in selecting the study subjects. In addition, the generalizability of convenience samples is unclear, impedes the researcher's ability to draw inferences about a population, and is often biased. Due to the small number of samples, the views and opinions derived from this study could not represent an overall representation of CKD patients in Canada. In this study, recruitment relied on volunteers who responded to emails or advertisements and recruits were consequently included only those people who were enthusiastic or interested in participating in the study. The CKD patients interested in participating may differ from (or not be

representative of) all CKD patients in Canada. Participants of this study were from Canada, and the context of this study cannot be applied to other countries, explicitly to developing nations. Another limitation of this study is member checking; due to the limited availability or unavailability of participants, participants were not contacted for feedback or for discussions about the study's results and findings.

5.5 Implications and Direction for Future Research

This study might help a range of biobank and PM research stakeholders understand the perspectives of research participants and the specific opinions of CKD patients. This is the first study which investigates CKD patients' understandings of PM and biobanking. Diagnosis of CKD is not accurate, current treatment can not cure CKD and cannot reverse the loss of renal function in CKD. Dialysis has many side effects and may or may not result in an improvement in the patient's quality of life and functional status. There are many causative factors, practices, and conditions that lead to the development of CKD and which are not completely understood and curable. The complexity of the molecular nature of CKD, along with its co-morbidities, curtailed the development of ideal therapeutic targets. Thus, there is demand for greater knowledge of pathology, advanced risk identification, and determination of prognosis of CKD. Current advances and emerging knowledge in the field of PM has opened the possibility that physicians could better identify specific biomarkers or have access to accurate diagnostic modalities and thus develop targeted therapy for patients with CKD. To achieve the implementation of PM in the diagnosis and treatment of CKD, PM requires the involvement of various crucial stakeholders such as CKD patients. CKD patients can play an important part in the implementation of PM regarding governance, priority setting, conducting research, and knowledge translation. CKD patients can share their genetic profiles and risk dispositions to

health care providers and can help outline tailor-made treatments. As found in this study, information about patients regarding their understanding as well as their distinctive experiences obtained through living with CKD, will help health care providers implement PM in the treatment of CKD. In addition, this research may heighten awareness about the importance of recognizing the challenges faced by participants of biobanking and PM research and determine how to best overcome those challenges. The following paragraphs discuss these challenges. In addition, suggestions for how to resolve these challenges are outlined.

Essential issues raised in this study could be used for future research. One key issue in PM and biobanking is the privacy and security of data. Researchers and healthcare workers should provide sound informed consent to the research participants. Sound informed consent that clearly outlines privacy and security of data would provide confidence and reassurance to participants and as a result they would be encouraged to participate. Another issue raised is undue stress caused by knowing genetic test results. Healthcare providers and policy makers should implement plans for physicians to develop an adequate understanding of genetics and genomics to counsel their patients appropriately. Physicians would then avoid revealing unwanted information about genetic test results to patients, and refer their patients to appropriate experts to interpret and further evaluate test results to ensure their patients receive the best care possible and avoid distress. Discrimination, in the areas of insurance coverage and employment was yet another key issue. Healthcare providers and policy makers should implement knowledge translation activities, either in the form of printed media, digital media or social media to inform research participants or patients about the Genetic Non-Discrimination Act (GNDA), or Bill S-201. The bill, along with amendments in the Canadian Labour code and the Canadian Human Rights Acts prohibits companies and employers from requiring genetic testing or the results of

genetic tests. The GNDA also prevents companies from denying services based the results of genetic tests. Moreover, the act forbids the use and disclosure of an individual's genetic test results without their written consent.

Factors arose in the study which have major impact on participants willingness to participate in biobank research or donate samples. These factors include lack of trust in the healthcare system, lack of information about biobank research, and knowledge of details about the research. Once again healthcare workers and policy makers must inform participants of these issues via social media platforms as well as by way of digital and print media. Healthcare workers, with their proximity to patients, are also in an excellent position to inform research participants about ongoing research projects and research details. When a patient enters a healthcare facility for treatment, healthcare workers could inform them about ongoing research projects and their details which could in turn encourage patients to participate in research.

Trust is often considered paramount to successful research. Trust is considered crucial in the relationships between research participants and researchers. Communicating effectively and engaging with participants from the earliest opportunity is one way to build trust. Researchers and research organizations should ask questions and listen to participants, rather than making assumptions especially when exploring the fears and feelings surrounding the research. Some participants can be motivated to engage in the research study if they feel their responses will make a difference. To attract these participants, researchers and research organizations should include the benefits of the study, or outline the impact of participants' responses, in the study invitation and welcome screen or script. Return of research results is another important step to building the trust of participants. When possible, and if it makes sense, offer to share the results of the findings with respondents, which in turn increases participant confidence in the research

projects. Some participants trust research organizations, their reputations and value. Researchers can take advantage of that as Guillemin et al. (2018) suggested "researchers can foster and take advantage of participants' institutional trust by ensuring that their professional values are aligned with those of their institution, and by transparently following the guidelines and regulations set out for them by their governing body" (p. 7-8). In addition, research institutions, "… should uphold their systems of research ethics and integrity because it is this that participants are putting their trust in" (Guillemin et al., 2018, p. 8). Guillemin et al. (2018) mentioned: "participants' trust is closely linked to the reputation of the institution. If the institution suffers a loss of reputation, or its systems for research integrity are not upheld, this has the potential of heavily compromising the ability of researchers to do their research" (p. 8). Research participants also put their trust in the objectives of research projects and goals of research organizations. Research participants or patients feel confident if they see research organizations conducting research for common good, and not for profit.

In the end, additional inquiries examining participants/patients points of view on benefits and concerns of PM and biobanking would contribute to a deeper and broader understanding. Though participants of this study were recruited from across Canada, it cannot be stated that participants' perspectives can be generalized, as it is a qualitative study that included small number of samples. Thus, further research involving more extensive samples of CKD patients is warranted.

5.6 Conclusion

This novel research study explored the knowledge, attitude, and perception of CKD patients about PM and biobanking and, specifically PM, an unexplored area in the literature. Regarding PM, the study identified CKD patients' perceived benefits and concerns of PM, the

perceived barriers to implement PM in the current Canadian healthcare system, and their preferred choice of informed consent model. This study also found participants' in-depth understanding of the benefits and concerns of donating samples for biobanking, factors that influence them to participate or donate samples for biobank research, and their opinions and views on ownership of samples.

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Appendices

Appendix A: Email Recruitment Template

Email template

Subject Line: Participants being sought for interview in a research study

Dear Members,

Researchers at the University of Calgary are seeking patients with chronic kidney disease from across Canada to take part in research interviews. The intent of the research is to understand patients' knowledge, perception and experiences of precision medicine and biobanking. The findings of this research may help to enhance patient engagement in, and awareness of, precision medicine and biobanking.

To be able to take part in this study, individuals must have a diagnosis of chronic kidney disease, be at least 18 years old or older, and English speaking.

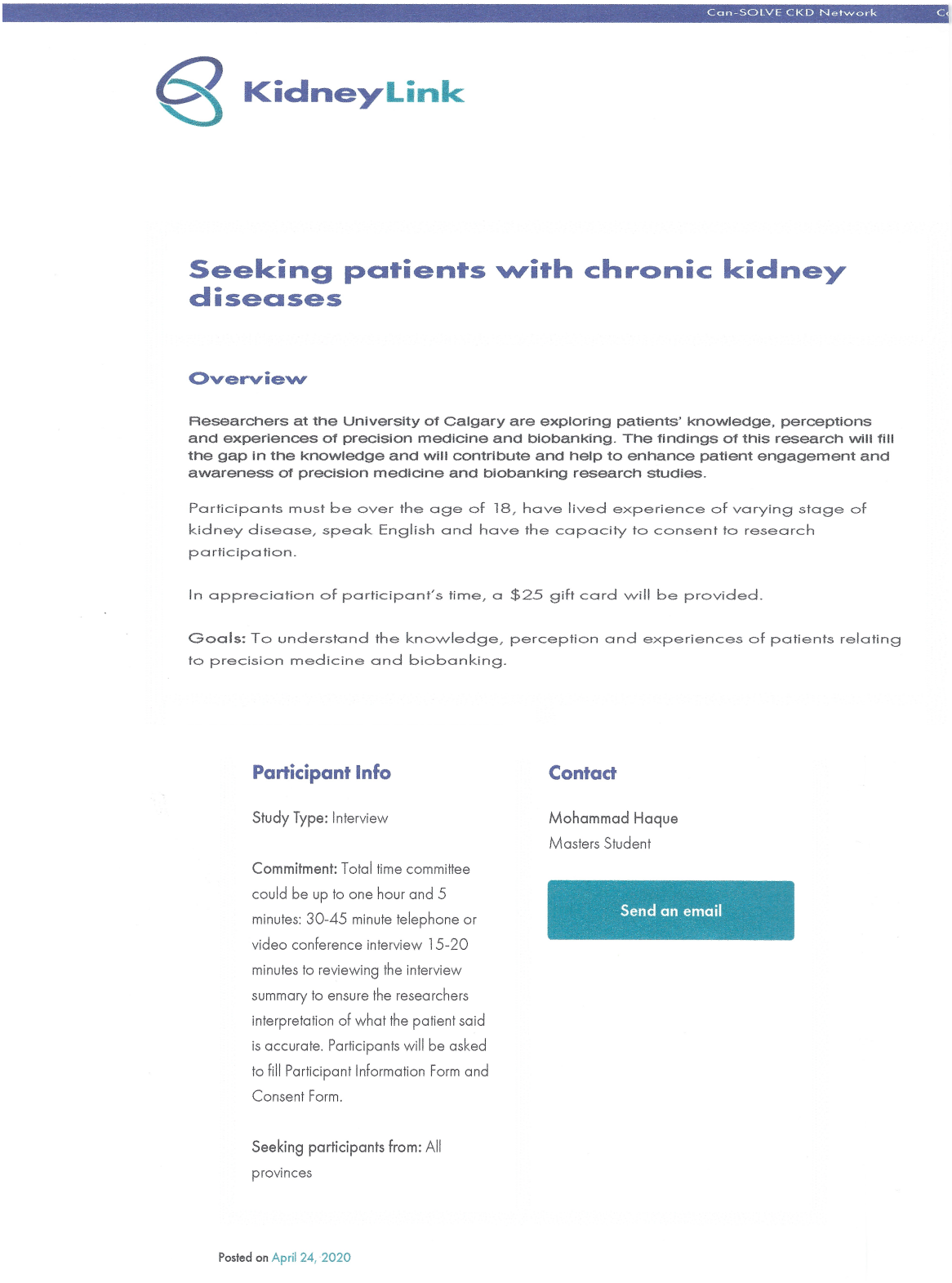
The interviews will be conducted either by phone or by skype or Zoom or Google Hangouts and will take approximately 30-45 minutes. Participant's responses will be kept confidential, no personally identifiable information will be associated with responses.

In appreciation for participant time, a $25 gift card will be provided. This study has been approved by the University of Calgary Conjoint Health Research Ethics Board (REB20-0036)

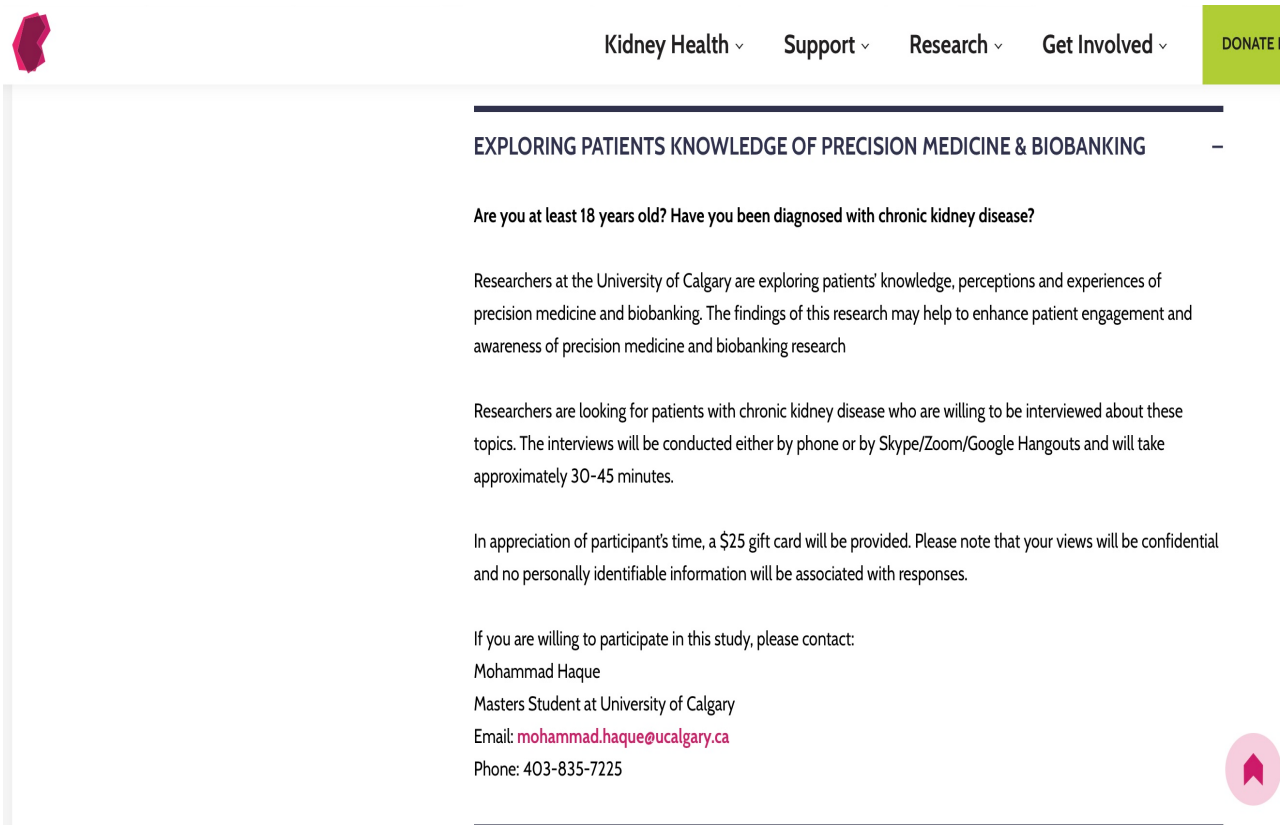
If you are interested in participating or have any questions about the study, please contact:

Mohammad Haque
Masters Student at University of Calgary
Email: mohammad.haque@ucalgary.ca
Phone: 403-835-7225

Appendix B: Can-SOLVE CKD Network Website Advertisement



Appendix C: Kidney Foundation Website Advertisement



Appendix D: Consent Form

CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Understanding the knowledge, perception and experiences of patients about precision medicine and biobanking

SPONSOR: University of Calgary

FUNDER: Canadian Institutes of Health Research (CIHR)

INVESTIGATORS: Mohammad Haque (Study Coordinator)
Contact: 1-403-835-7225 or mohammad.haque@ucalgary.ca

Dr. Stacey Page (Principal Investigator)
Contact: 1-403-220-2763 or sapage@ucalgary.ca

Mr. Mohammad Haque (Study Coordinator) is undertaking this study under the supervision of Dr. Stacey Page (Principal Investigator) as a research project for his graduate thesis in the Department of Community Health Sciences at the University of Calgary.

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve if you decide to participate. Before deciding to take part, please take as much time as you need to ask any questions you have. You are encouraged to discuss with family, friends, your personal physician or other health professional, or any members of your community that you trust if that is helpful to you. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

Participation in this research study is voluntary (you do not have to participate if you don't want to). To participate in this study, the person must be *a patient with varying stages of kidney*

disease, 18 years of age or older, can speak English, and have capacity to consent to research participation.

INTRODUCTION

Precision medicine seeks to customize health care by taking into account factors that are unique to individual people, such as their genes, environment and lifestyle. Central to precision medicine is a person's genetic make-up. Therefore, to understand a person's genetic make-up and to study and offer precision medicine approaches, sample of biological material is often taken from individuals and stored. This is called biobanking. This study will employ qualitative research methodology to explore understanding of patients' knowledge, perception and experiences of precision medicine and biobanking.

Little is known about people's perspectives on precision medicine and biobanking. The findings of this research will fill the gap in the knowledge and will contribute and help to enhance patient engagement and awareness of precision medicine and biobanking research studies. Moreover, by gaining the insight of patients view on biobanking and precision medicine, knowledge translation activities may develop to overcome misinformation and misunderstanding that may impede the biobank research and practice of precision medicine clinically. The findings of the study will also be valuable to contribute in future precision medicine and biobank research initiative.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to learn more about what patient's like you think about precision medicine and biobanking. The information that you and others provide will impart new knowledge in this context and contribute in further precision medicine and biobank research process.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 15 participants will take part in this study.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you volunteer to participate in this study, you will be asked to take part in an interview (either by phone or by Zoom/Skype/Google Hangouts) at a date and time convenient to you. You will be asked to fill participant information form (name, age, gender, phone, email, education, English proficiency, stage of kidney disease you are diagnosed with) and some questions about your knowledge, perception and experiences of precision medicine and biobanking. The interviews will be conducted by Mr. Mohammad Haque and will be recorded and transcribed. The information will be summarized with that of the other people who take part. You may be asked to review the summary to ensure the researcher's interpretation of what you have said is accurate. Mr. Haque will call you within a few weeks of the interview if this review is needed.

HOW LONG WILL I BE IN THIS STUDY?
The interview (either by phone or by Zoom/Skype/Google Hangouts) will take approximately 30-45 minutes of your time. Reviewing the summary should take no more than 15-20 minutes.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT I CAN EXPECT FROM THIS STUDY?
There are no anticipated risks from your participation in this study. The interview includes questions to find out your knowledge, perception and experiences about precision medicine and biobanking. But if you feel stress or do not want to participate any more, the interview will be stopped, and you may withdraw participation at any time without any consequences. Please be aware that you can choose not to answer questions that cause you distress or are not comfortable with. When you feel some discomfort at responding some questions, please feel free to ask to skip the questions.

ARE THERE ANY POTENTIAL BENEFITS IF I PARTICIPATE?
There are no direct benefits to you as a participant in this study. Your participation may contribute to the body of knowledge about this topic.

WHAT OTHER CHOICES DO I HAVE IF I CHOOSE NOT TO PARTICIPATE?
Participation in this study is your choice. If you decide not to take part in this study, there will be no penalty to you. Your decision will not affect the standard medical care you receive.

CAN I STOP BEING IN THE STUDY?
If you choose to participate, you are free to withdraw your consent at any time. You can stop by letting Mr. Haque know during the interview. If you change your mind before or after the interview, you can let the researchers know by calling the number at the beginning of this form to have your data removed from the study.

WITHDRAWAL OF STUDY DATA
You can ask for your data be withdrawn for up to 2 weeks after the interview.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?
For the participation in the interview you will be provided incentive as compensation for your time. You will receive a $25.00 gift card in recognition of your time and contribution to this study. You will not have to pay anything to participate.

WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but there is always the potential for an unintended breach of privacy.

When the audio recording is transcribed all names and personal identifiers will be removed to maintain confidentiality therefore, your name will not be associated with the information that is transcribed from the interview. No identifiable information about you will be kept with your research data and identifiable information about you will be replaced with a code or number. A master list linking the code or number and your identifiable information will be kept separate from the research data. All of the research data will be maintained in a secure location at the University of Calgary. Only authorized individuals will have access to it. All digital audio files and coded research files of the session will be kept on a password protected laptop computer and an external hard drive in a locked cabinet.

The study results will be published or discussed in conference without disclosing any individually identifying information and no information will be included that would reveal your identity.

HOW LONG WILL INFORMATION FROM THE STUDY BE KEPT?
As required by the University of Calgary data retention policy, research data will be kept for 5 years after the study is complete, and then the data will be destroyed.

WHOM MAY I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Mr. Haque at 1-403-835-7225 or Dr. Stacey Page at 1-403-220-2763 with any questions or concerns about the research or your participation in this study.

Conjoint Health Research Ethics Board (CHREB):
If you have any questions concerning your rights as a possible participant in this research, please contact the Vice Chair, Dr. Kathy Oberle, Conjoint Health Research Ethics Board, University of Calgary at 1-403-220-7990.

HOW CAN I FIND OUT ABOUT THE STUDY RESULTS?
You will receive a summary of the study results. You will be asked to fill participant Information Form which include a phone number and an email address so that this information can be provided to you.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the standard medical care you receive
- If you decide to take part, you may leave the study at any time

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to take part in the study. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities.

SIGNATURE OF STUDY PARTICIPANT

_____

Name of Participant

_____ _____

Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____

Name of Person Obtaining Consent Contact Number

_____ _____

Signature of Person Obtaining Consent Date

A signed copy of this consent form has been given to you to keep for your records and reference.

Appendix E: Interview Guide

Interview Guide

Title: Understanding the knowledge, perception and experiences of patients about precision medicine and biobanking; a qualitative study

Preamble:
At first, I would like to introduce myself and discuss the objective of this study. My name is Mohammad Haque and I am a Master of Community Health Sciences student at the University of Calgary. I am conducting this interview for my thesis project.

The objective of this interview is to investigate patients' knowledge, perceptions and experiences of precision medicine and biobanking. Few studies had explored this topic but very little is known about kidney patients' knowledge, perceptions and experiences in this regard. Therefore, this interview includes a series of questions to find out your knowledge, perception and experiences about precision medicine and biobanking. I hope that the findings of this study will impart new knowledge in this context and contribute and help to enhance patient engagement and awareness of future precision medicine and the biobank research process.

I would like to thank you for taking time to participate in this study, by undertaking this interview. The duration of this interview will be approximately 30-45 minutes. Reviewing the summary should take no more than 15-20 minutes. This interview will be recorded in order to capture everything you say and to transcribe accurately afterwards, so while talking, please make sure you speak in a clear and loud voice for a clearer recording.

When the audio recording is transcribed all names and personal identifiers will be removed to maintain confidentiality; therefore, your name will not be associated with the information that is transcribed from the interview. All data collected for this study will be confidential, meaning that this information will not be shared with anyone outside the research team. While information or quotations from this interview may be used in publications or presentations, your identity will never be revealed to anyone outside the research team. Only me (Study Coordinator) and my supervisory committee (including Drs. Stacey Page, Maria Santana, Pamela Roach and Alexander Sandy-Dubyk) will have access to the written documentation of this interview for analysis. I want to reiterate that your participation is completely voluntary. You

can decline to answer any questions without having to provide a reason. You may withdraw from this study simply at any point during the interview, by stating to me that you wish to withdraw. If you wish to withdraw from the study after today's interview, please email or call me. You may request your data to be removed from study within 2 weeks after the interview. Should you opt either to participate or to withdraw from this study, there will be neither any benefits nor repercussions of standard medical care you receive. Do you have any questions or concerns about the study, the interview, or your participation?

1. Can you tell me what your understanding of biobanking is?

   If cannot answer, then

   Read the following description:

   Biobank –

   - Store human biological samples/biospecimens (such as human tissue, blood, urine or DNA)
   - Store patients' medical records or associated data along with samples
   - Provide access to samples and medical records to scientists or researchers to conduct medical research
   - Keep or store samples and medical records or associated data for many years so research can be done in the future

   So, a biobank is a type of storage place that accepts, processes, stores and distributes human biological samples/biospecimens (such as human tissue, blood, urine or DNA) and associated data or information for use in current and future medical research and clinical care.

2. Based on this information, what initial questions and thoughts do you have about a biobank? (Probe: What makes you say that? What are some reasons for that?)

3. Have you ever given or donated blood or other human tissue for future medical research purposes?

   Clarify: The sample of blood or other human tissue was not taken by your doctor during a routine visit but was stored to use in future medical research projects.

4. Tell me about your opinion of people donating their blood and other body tissues that is stored for future medical research.

Or

How do you feel about people having their blood and other body tissue collected and stored for research? And why?

If necessary, probe for attitudes: Ethical/Moral/Religious beliefs

5. Tell me about your concern or what things worry you having your blood or other tissue collected and stored for research?

   Or

   Tell me about what make you less willing to have your blood or other body tissue collected or stored for future research?

   a. Probe: If the participant refers to fear…Why are you fearful about donating blood or other body tissues?

   If necessary, probe for potential barriers: Lack of information, No direct benefit

   If necessary, probe for potential concerns: Fear, Misuse of blood/tissue, Loss of privacy, Mistrust of biobanks, Potential for future discrimination, Security of the data

6. Tell me about what make you more willing to have your blood or body tissue collected and stored for future research?

   Or

   What would be some good things about having your blood and other tissue collected and stored for research?

   Or

   Tell me about some benefits having your blood and other tissue collected and stored for research?

   Probe: What things would make you think it is a good idea?

   If necessary, probe for potential facilitators: Provider recommendation, Word-of-mouth, Materials/information in language you understand, Bilingual staff, Staff from same racial/ethnic group, Financial incentives, Location and time of blood collection, Control over how blood is used and by whom

   If necessary, probe for potential benefits: Helping other people, Scientific progress, Receiving results from blood tests

7. Do you like to add anything that we didn't discuss about biobanking that you would like to tell us or think we should know?

8. Can you tell me what your understanding of Precision Medicine is?
   If can't answer, then -
   Precision medicine has the potential to customize healthcare to the individual patient by using their genetic information to guide treatment choices.
   - Precision medicine uses genetic information to identify biomarkers that can be used to understand the nature of one's disease.
   - Biomarkers can be prognostic, providing information about overall treatment outcomes, or predictive, providing information about the likelihood of response to treatment which in turn help your doctor personalize your treatment.
   - For example, using Precision Medicine can help nephrologists select the most effective treatment and avoid ineffective treatments with harmful side effects

   Therefore, Precision Medicine refer to "customizing medical treatment to the individual characteristics of each patient".
   And the purpose of Precision medicine is -
   (a) to identify the optimal treatment for each individual patient;
   (b) to maximize treatment benefit;
   (c) to minimize adverse effects

9. Tell me about your experiences with Precision Medicine.

10. Tell me about benefits you perceive of using Precision medicine?
    If necessary, provide probe; Cost effectiveness/reduce cost, Best clinical outcome, Effective treatment, Public trust

11. Is there anything else that worries you about Precision Medicine?
    Or
    What are some barriers of implementing Precision Medicine?

If necessary, provide probe; Cost of Precision Medicine, Lack of knowledge of Precision medicine among patients and healthcare providers, Inadequate healthcare structure/system to support Precision Medicine, Lack of economic resources of government, Ethical Legal and Social issues surrounding Precision Medicine (patient's data privacy & confidentiality, preferences for data sharing, informed consent, non-incidental/incidental findings, stigma, equity (at both the individual and population levels), disparities/discrimination in treatment and outcomes across gender, ethnicity/race, socioeconomic status, educational background, disability status, sexual orientation, and other patient characteristics, etc.)

12. Is there anything else you would like to say about Precision Medicine that we haven't discussed yet?

Appendix F: Participant Information Form

Department of Community Health Sciences

Participant Information Form

Study Title: Understanding the knowledge, perception and experiences of patients' about precision medicine and biobanking; a qualitative study

1. Name of the participant: _____
2. Age: _____ (years)
3. Phone Number: _____
4. Email: _____
5. What is your biological sex?
   - ☐ Male
   - ☐ Female
   - ☐ Other (Please specify) _____
6. What gender do you identify as?
   - ☐ Male
   - ☐ Female
   - ☐ Other (Please specify) _____
7. What is highest level of education you have completed?
   - ☐ Less than high school
   - ☐ High school diploma or equivalent
   - ☐ Trades or apprenticeship certificate or diploma
   - ☐ College or other non-university certificate or diploma
   - ☐ University degree, certificate, or diploma below bachelor level
   - ☐ Bachelor's degree
   - ☐ Master's degree or diploma/certificate above bachelor level
   - ☐ Doctorate

8. If English is your first language/mother tongue? ☐ Yes ☐ No
    a. If "no," please describe your English proficiency (competence);
        i. ☐ elementary or limited, working proficiency
        ii. ☐ full/professional proficiency
        iii. ☐ native or bilingual proficiency

9. What stages of kidney disease you are diagnosed with?

    ☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4 ☐ Stage 5

10. How long you have been seeing a kidney specialist?

    ☐ First visit ☐ <1 year ☐ 1- 5 years ☐ 6 -10 years ☐ >10 years

11. Have you participated in research before? ☐ Yes ☐ No