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The Impact of Patient Attachments to Nurse Practitioners in a Primary Care Clinic

Integrating Prescribed Physical Activity as a Primary Care Intervention in Routine Practice

Examining the Incidence of Type 2 Diabetes in the Canadian Newcomer Population

A Client Perspective on Virtual Appointments with Their Primary Health Care Nurse Practitioner during the COVID-19 Pandemic

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The Impact of Patient Attachments to Nurse Practitioners in a Primary Care Clinic: A Comparative Analysis of Acute Care Utilization

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ABSTRACT

Background: The rising demand for accessible primary care services in the face of an aging population and increasing chronic conditions underscores the need to optimize healthcare delivery models. This study investigates the efficacy of patient attachments to Nurse Practitioners (NPs) in reducing acute care utilization in an urban primary care clinic in British Columbia.

Method: Through a comparative analysis of patient panels managed by NPs, including before and after attachment data, significant reductions in emergency department visits, in-patient admissions, and readmissions within 30 days of discharge were observed post-attachment.

Analysis: Statistical analyses confirmed the effectiveness of NP attachments across all providers. Economic analysis revealed substantial cost savings associated with reduced acute care utilization.

Conclusion: These findings underscore the pivotal role of NPs in delivering comprehensive, proactive care, and highlight the economic benefits of investing in patient attachment programs. Moreover, beyond healthcare system benefits, patient attachments to NPs offer direct benefits to patients, enhancing overall well-being and quality of life. Further research into the long-term implications of NP-led primary care and patient attachment programs is warranted to inform healthcare policies and practices, advancing patient-centred, sustainable healthcare delivery models.

Introduction

As the global population ages and individuals live longer with an increasing prevalence of chronic conditions, the demand for accessible and comprehensive primary care services has become more pronounced than ever (Heale et al., 2018). Primary care, often regarded as the cornerstone of healthcare delivery, encompasses a broad range of preventive, promotive, and curative services to address the diverse healthcare needs of individuals and communities (Government of Canada, 2012). However, amidst the growing need for primary care, the scarcity of access to primary care has contributed to a concerning trend towards frequent use of emergency departments and acute care services (Assadpour, 2021; van den Berg, van Loenen & Westert, 2016). In this context, the imperative to foster strong patient-provider relationships within primary care settings has garnered heightened attention. This highlights the critical importance of bolstering primary care resources and optimizing healthcare delivery models to better meet patients' evolving needs. Among these models, patient attachments to nurse practitioners (NPs) in primary care clinics has been established as a successful approach to improving healthcare outcomes while optimizing resource utilization (Assadpour, 2021; DiCenso et al., 2010; Government of Canada, 2007; Stewart, 2018). Establishing a consistent and trusting relationship between patients and their healthcare providers is paramount in primary care settings, where patient needs span a spectrum of acute and chronic conditions (Bonner et al., 2019; Canadian Nurses Association, 2023; Grembowski et al., 2014). With their holistic approach to care and emphasis on preventive measures, NPs are uniquely positioned to cultivate such relationships (Heale et al., 2018; Maier, Aiken & Busse, 2017). By promoting continuity of care and personalized interventions, patient attachments to NPs is successful in mitigating the need for frequent reliance on acute care services, thereby alleviating strain on healthcare systems and improving overall patient outcomes (van den Berg et al., 2016).

This paper will delve into the existing empirical evidence that supports the efficacy of patient attachments to NPs in reducing acute care utilization at a primary care

clinic in urban British Columbia. Through a comparative analysis of relevant statistics collected before and after the implementation of patient attachment programs in NP clinics, we aim to elucidate the tangible impacts of these initiatives on healthcare utilization patterns. By examining indicators such as emergency department visits, hospital admissions, and urgent care utilization, we quantify how patient attachments to NPs contribute to a more efficient and sustainable healthcare delivery model. In synthesizing these findings and presenting insights from our analysis, this paper aims to underscore the pivotal role of patient attachments to NPs in British Columbian healthcare. By illuminating the benefits of these relationships, we hope to inform policymakers, healthcare administrators, and providers of the value of investing in initiatives that promote continuity and collaboration in patient care.

"By examining indicators such as emergency department visits, hospital admissions, and urgent care utilization, we quantify how patient attachments to NPs contribute to a more efficient and sustainable healthcare delivery model."

Patient Attachment

Patient attachment to a primary care provider requires establishing a designated relationship to support care longitudinally. This phenomenon is distinguished by the consistent engagement of patients with the same primary care provider over an extended period, with the hope of facilitating continuity of care and engendering confidence (Bonner et al., 2019; DiCenso et al., 2010; Grembowski et al., 2014; Hayes, 2007; Heale et al., 2018). Central to patient attachment is continuity, wherein patients recurrently seek healthcare services from a familiar provider, fostering a deep understanding of the patient's medical history, preferences, and values. This sustained relationship enables primary care providers to deliver personalized care tailored to meet each patient's individualized needs and circumstances, recognizing the changing needs over time. Moreover, attached primary care providers are pivotal in comprehensive care coordination, serving as the linchpin for integrating various healthcare services and specialties; through proactive engagement and emphasis on preventive care strategies, patient attachment endeavours to mitigate the onset of chronic conditions and promote overall wellness. Furthermore, patient attachment empowers individuals by fostering collaborative decision-making and active participation in their healthcare journey, enhancing treatment adherence and patient outcomes. Cumulatively, patient attachment to a primary care provider embodies a collaborative, patient-centred approach to healthcare delivery, characterized by trust, communication, and continuity of care, which has been shown to yield improved health outcomes and greater patient satisfaction while mitigating healthcare costs through judicious utilization of resources.

Data Collection

Our analysis included comparing the patient panels of four NPs working in an urban primary care clinic in British Columbia in October 2020. These four NPs provide primary care for both attached and unattached patients, who had been identified through community services of hospital-based services as requiring a primary care provider. Many of these patients had multiple chronic conditions, and many were homebound. We aimed to understand patients' utilization of acute care services, including emergency department visits and in-patient hospital admissions, before and after attachment to an NP. Aggregate patient data was collected from the NP's electronic medical record system (Profile aEMR) and the regional health authority electronic medical record system (Meditech) utilized in the surrounding hospitals for two years before and after attachment. No specific identifiable patient-level data were collected.

Findings

At the time of data collection, the clinic provided care primarily to unattached patients who were awaiting permanent attachment. Through this initiative 409 unattached complex patients were permanently attached to four NP primary care providers at the clinic, accounting for 4913 clinic appointments. The average age of the patients who were attached to the NPs was 59.3 years, and most sought appointments related to chronic disease management (e.g. hypertension, diabetes, and prescription renewal). Table 1 provides an overview of the attached patients by provider with a summary of the most frequent international classification of disease version 9 codes (ICD-9).

Acute care usage, including emergency department (ED) visits, in-patient admissions and readmissions to the hospital within 30 days of initial discharge, was reduced from 835 total visits to 349 following patient attachment to a regular primary care NP provider, demonstrating a profound decrease in acute care service utilization. Table 2 provides a summary by provider comparing before and after attachment visits.

Using the Wilcoxon signed-rank test (α level 0.05), a non-parametric equivalent of a paired t-test, comparing the *median* differences before and after an intervention (patient attachment), found a statistically significant difference across all four NP providers ($p < 0.05$). Table 3 summarizes mean visits per patient, including ED visits, acute care admissions, average length of stay, and the associated Wilcoxon signed-rank significance results.

Table 1. Attached Patients per Nurse Practitioner (NP)

NP	Attached Patients (N)	Gender (n)	Average Age (in Years)	Overall Number of Appointments	Most Common Documented ICD-9 Codes
1	74	Female 38% (28) Male 62% (46)	56.7 57.3	378	Hypertension General Physical Exam Prescription Renewal
2	140	Female 59% (82) Male 41% (58)	58.4 57.8	2786	Hypertension Diabetes Chronic Pain
3	128	Female 50% (64) Male 50% (64)	59.5 60.7	1298	Prescription Renewal Hypertension Diabetes
4	67	Female 45% (30) Male 55% (37)	63.2 60.5	451	Prophylactic Influenza Vaccination Anticoagulant Management Chronic Pain

Table 2. Acute Care Visits, including Emergency Department Visits and In-Patient Admissions Before and After NP Attachment

NP	Before Attachment			Post Attachment		
	ED Visits (n)	Acute Admission (n)	Readmission to Hospital (within 30 days of discharge)	Ed Visits (n)	Acute Admission (n)	Readmission to Hospital (within 30 days of discharge)
1	161	36	2	27	3	0
2	162	45	23	152	31	7
3	223	38	2	63	14	0
4	108	32	3	43	9	0
Total	**654**	**151**	**30**	**285**	**57**	**7**

Table 3. Acute Care Usage Means and Significance Before and After NP Attachment

NP	Annual ED Visits per Patient			Acute Care Admissions per Patient			Acute Care Admission Length of Stay (days) per Patient		
	Before Attachment (M)	After Attachment (M)	P (Mdn)	Before Attachment (M)	After Attachment (M)	P (Mdn)	Before Attachment (M)	After Attachment (M)	P (Mdn)
1	3.72	0.51	<0.05	1.62	0.08	<0.05	10.27	1.38	<0.05
2	2.23	1.97	0.08	1.42	0.68	<0.05	8	8.75	<0.05
3	2.94	0.85	<0.05	1.41	0.33	<0.05	21.79	2.97	<0.05
4	2.55	0.95	<0.05	1.72	0.20	<0.05	28.12	2.52	<0.05

Discussion

This project investigated the impact of patient attachment to NPs on acute care utilization in an urban primary care clinic in British Columbia. Through analysis of patient panels managed by four NPs, the project found that attachment to NPs substantially reduced acute care service utilization, including emergency department visits, in-patient admissions, and readmissions within 30 days of discharge. Statistical analyses demonstrated significant differences before and after attachment across all NPs, highlighting the effectiveness of attachments to NPs as a successful approach to reducing patient in hospital visits. The reduction in acute care utilization suggests that NPs play a crucial role in managing chronic conditions within primary care settings, potentially leading to improved health outcomes and cost savings. The findings underscore the importance of strengthening primary care systems and the role of NPs in delivering comprehensive, proactive care to address patients' needs and minimize reliance on emergency services and hospital admissions. These findings are consistent with other research recognizing the benefit of accessibility and continuity of primary care (Heale et al., 2018; van den Berg et al., 2016).

Further research could explore the long-term implications of NPs in primary care on healthcare resource utilization and patient outcomes.

In examining the economic impact of this work, the project yielded a reduction of 369 emergency department visits in the 2 years post-NP attachment, compared to the pre-intervention period. With each emergency department visit estimated at $304, the total cost savings amount to approximately $112,176 (CIHI, 2020). This substantial reduction in emergency department visits underscores the effectiveness of the project in mitigating unnecessary healthcare utilization and associated expenses, highlighting the economic benefits of optimizing primary care services and reducing reliance on acute care facilities. The project also significantly reduced hospital admissions, with a total reduction of 94 admissions compared to the pre-intervention period. Given the average daily cost of hospital admission estimated at $8,103, this reduction translates to potential cost savings of approximately $761,682 (CIHI, 2023) over a 2-year period. This substantial decrease in hospital admissions highlights the effectiveness of the project in minimizing the need for acute care services and the associated financial burden. The overall cost savings estimated in the 2 years post NP attachment was $873,858, or $2,136 per patient. Projecting these cost savings over 10 years, we estimate that secure attachment to an NP could save the health system $10,682 per patient. These cost savings underscore the economic benefits of enhancing primary care services and reducing reliance on hospital admissions, contributing to healthcare delivery systems' overall efficiency and sustainability. Similar work has promoted the impact of NP primary care providers on long-term care residents' acute care usage (Assadpour, 2021; Mileski et al., 2020).

"Projecting these cost savings over 10 years, we estimate that secure attachment to an NP could save the health system $10,682 per patient."

Furthermore, beyond the advantages evident within healthcare systems, patient attachments to NPs offer myriad direct benefits to patients themselves. One notable benefit lies in enhancing patients' overall well-being and quality of life, stemming from improved management of chronic conditions (Bonner et al., 2019; Grembowski et al., 2014). While this project primarily focused on quantifiable metrics such as acute care utilization, it is essential to acknowledge the impact on patients' health outcomes and daily lives, as underscored by previous research (Grembowski et al., 2014; Hayes, 2007). Effective management of chronic conditions alleviates symptoms, enhances physical health, and fosters emotional and psychological well-being, enabling patients to lead more fulfilling lives (Smyth et al., 2022). These unmeasured benefits contribute to a more comprehensive understanding of the value of patient attachments to NPs and their potential to drive positive healthcare outcomes beyond the confines of conventional health system metrics. Moreover, by addressing underlying health concerns and promoting preventive measures, patient attachments have the potential to mitigate the progression of chronic conditions, ultimately reducing the burden on healthcare systems and improving overall healthcare utilization and efficiency.

Conclusion

This study has shed light on the significant impact of patient attachments to NPs in primary care settings, particularly in an urban clinic in British Columbia. Through analysis of patient panels managed by NPs, the research has demonstrated a significant reduction in acute care service utilization, including emergency department visits, in-patient admissions, and readmissions within 30 days of discharge. The findings underscore the pivotal role of NPs in managing chronic conditions within primary care settings, leading to improved health outcomes and cost savings. By fostering strong patient-provider relationships and emphasizing continuity of care, patient attachments to NPs have emerged as a promising strategy to optimize healthcare delivery, minimize reliance on acute care facilities, and enhance overall patient satisfaction. The economic benefits of these interventions are evident through the considerable reduction in emergency department visits and hospital admissions, resulting in significant cost savings for healthcare systems. Moreover, while this study primarily focused on healthcare system benefits, it is essential to acknowledge the potential impacts on patients' overall well-being and quality of life through provider attachment, which could further influence healthcare costs and utilization. Continuing research into the long-term implications of NP-led primary care and patient attachment programs is crucial for informing healthcare policies and practices, ultimately advancing patient-centred, sustainable healthcare delivery models.

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2. Data on file, Eisai Limited.

* Comparative clinical significance unknown.

† A 12-month multicentre, randomized, double-blind, Phase III study in 959 patients, 18 years and older with insomnia disorder, using patient sleep diaries, comprising a 6-month placebo-controlled treatment period followed by 6 months of active treatment. *Primary efficacy endpoint:* mean change from baseline in sSOL at the end of month 6. *Key secondary efficacy endpoints:* mean changes from baseline in sSE and sWASO during 12 month treatment period.

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Integrating Prescribed Physical Activity as a Primary Care Intervention in Routine Practice

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ABSTRACT

Most Canadian adults do not achieve recommended levels of physical activity (PA). Prevalence of physical inactivity has detrimental impacts on health, chronic disease management and healthcare expenditure. Primary care providers are ideally positioned to provide PA counselling. Prescribed PA is an effective method that increases client adherence, combats the barrier of providers' time limitation and improves perceived quality of care. An approach is outlined which identifies PA as a 'vital sign', addresses eligibility for safe activity engagement, develops an individualized prescription that promotes compliance, and establishes routine follow-up. This approach aims to translate effective PA counselling into routine primary care.

Keywords: Physical activity, exercise, prescribed physical activity, physical activity counselling, preventative healthcare, primary care.

Background

There is common understanding and agreement in health literature that routine physical activity (PA) results in many health benefits. To ensure patients are meeting the minimum recommended target, nurse practitioners (NPs) are encouraged to promote 150 minutes of moderate-to-vigorous PA per week.[1-3] Performing PA at this recommendation results in a profound impact on reducing all-cause mortality and decreasing the risk of noncommunicable and chronic disease (Table 1).[4,5] Several epidemiologic and longitudinal studies have demonstrated that meeting the established PA target significantly reduces the prevalence and severity of cardiovascular disease, hypertension, diabetes mellitus type 2, obesity-related infertility, cancers, dementia, osteoporosis, anxiety, depression, and frailty.[4-6] However, a disparity exists between patients who would benefit from PA counselling and those who effectively receive it. Despite knowledge that routine PA is a pillar of health and a paramount component of healthy behaviour modification, only one third of patients report receiving PA counselling from their primary care provider.[5] On the last recorded consensus of 2020, only 49.2% of Canadian adults met the recommended PA target.[7] The high prevalence of physical inactivity amongst Canadian adults has significant economic effects on the healthcare system. However, as little as a 10% reduction in physical inactivity has the potential to reduce healthcare expenditure by $150 million dollars annually.[6] With sufficient understanding regarding the impact of sedentary living for both the individual and the healthcare system, primary care providers should prioritize PA as a 'vital sign' of health and effective PA counselling should be integrated into routine practice.

Table 1. Health Benefits Associated with Routine Physical Activity

Improved:	Cognition
	Quality of life
	Sleep
	Weight loss
	Bone health
	Physical function
Reduced:	All-cause mortality
	Cardiovascular disease
	Hypertension
	Diabetes Mellitus Type 2
	Altered blood lipid profile
	Cancers of bladder, breast, colon, endometrium, kidney, lung, and stomach
	Dementia including Alzheimer's disease
	Anxiety and depression
	Falls and fall-related injuries

Nurse practitioners are in an ideal position to facilitate change through health promotion. Over 80% of Canadians visit their primary care provider annually and express a preference to receive health information directly from their

provider,[8] but studies have shown that most primary care providers do not regularly assess or promote PA as part of routine care.[3] Determining how PA counselling is most often conducted is difficult as the task is poorly completed within primary care settings. Several studies and meta-analyses recognize PA prescriptions as an effective method in approaching PA counselling that provokes sustained behavioural change.[1,3,5,8,9]

Current Barriers to Initiating Physical Activity Counselling

Several barriers to engaging in effective PA counselling exist from both the patient and provider perspective. Patient specific barriers include lack of time, motivation, physical limitation, resources, and guidance.[5] Providers have identified time limitations, lack of resources and lack of knowledge as barriers towards engaging in PA counselling.[5] Of the listed barriers for providers, time limitation is the most significant. This corresponds with the strain placed on providers to address multiple or complex medical concerns, while simultaneously educating on health promotion and lifestyle modifications.[5]

Motivational interviewing is a common approach that has been encouraged to providers as an effective method to stimulate change and behavioural intervention adherence.[3] This approach tends to require time in practice which is a clear limitation to providers. An alternative and effective method toward PA counselling is providing a PA prescription, which requires only two to four minutes for the intervention to be complete in the primary care setting.[3] This process will be discussed in detail later in this article. Providers need to adapt a mindset that this is 'time well spent'. The number needed to treat (NNT) for PA counselling to convert one sedentary individual to a physically active individual meeting the target recommendation at a one-year follow-up is 12.[3,10] As a comparison, the NNT for effective smoking cessation is 50 to 120.[3] Therefore, PA counselling is at least four-fold more effective and requires less clinical effort than smoking cessation counselling which is more routinely implemented in primary care practice.

Amongst providers, there is a reduced awareness of systematic approaches and resources that aid in the efficient creation of individualized PA prescriptions that promote patient safety. Steps that have been integrated into the approach discussed in this article come from one example of such a resource, titled the *Health Care Providers' Action Guide*, which facilitates prescription development tailored to the individual.[1] Creating an individualized PA prescription is essential towards effective PA counselling and behavioural modification adherence.[8,9] Additionally, an accessible resource is the American College of Sports Medicine (ACSM) *Rx for Health Series*[11] website, which outlines a comprehensive list of PA recommendations for over 30 chronic diseases such as aneurysms, atrial fibrillation, chronic kidney disease, osteoarthritis, peripheral arterial disease and many more. These resources are valuable tools to demystify establishing appropriate type and intensity of PA for certain comorbidities for providers who may have hesitation or uncertainty related to PA recommendations. To overcome current barriers to effective PA counselling, providers should utilize systematic approaches to PA prescription development, acknowledge the importance and efficacy of individualized PA counselling, and utilize available resources to overcome knowledge gaps for patient-specific comorbidities.

"Motivational interviewing is a common approach that has been encouraged to providers as an effective method to stimulate change and behavioural intervention adherence.[3]"

Understanding the Goal

As mentioned, the goal is to achieve a weekly minimum of 150 minutes of moderate-to-vigorous PA.[1,3] The total minutes should be dispersed over a minimum of 3 days per week to promote daily PA efforts, ultimately leading to the development of a physically active lifestyle.[2] To provide context and definition, moderate intensity activity is an intensity where individuals are still able to talk, but not sing.[5,10] Vigorous intensity makes it difficult for an individual to speak more than a few words.[5,10] Intensity may also be defined by metabolic equivalent task (MET) units with moderate activity defined as 3.0 to 6.0 METs and vigorous activity defined as greater than 6.0 METs.[5] As a baseline, resting metabolic energy expenditure is equal to 1.0 MET.[5] Examples of exercises for moderate and vigorous intensity categories are listed in Table 2.

The aim should be for a client to engage in sustained recommended activity for at least 12 months to ensure that effective PA counselling was achieved, resulting in adherence to the behavioural modification.[3] As a patient progresses towards a consistent physically active lifestyle, resistance exercises should be introduced at least two times per week to reap further health benefits.[10,12]

Patients may express a hesitancy towards engaging in PA or about meeting 150 minutes per week based on time limitation. In this circumstance, the patient should be educated that PA below the weekly target of 150 minutes still results in remarkable health benefits. As an example, smaller increments of PA, such as 15 minutes of brisk walking per day, led to a 14% reduction in all-cause mortality and averaged an additional 3 years of life expectancy.[5] The mentality that "some is better than none" should be instilled in patients when creating specific, achievable, and realistic goals.[5,10] By tailoring the

Table 2. Types of Exercise Considered Moderate and Vigorous Intensity Activity[1,2,5,13]	
Moderate Intensity Activity (3.0-6.0 METs)	Brisk walking 3 – 4 mph on level terrain
	Bicycling 5 – 9 mph on level terrain
	Water aerobics
	Walking a round of golf
	Badminton
	Pickleball
	Cricket
	Raking leaves
	Dancing
	Continuous swimming
Vigorous Intensity Activity (>6.0 METs)	Jogging or running
	Brisk walking up a hill
	Bicycling >10 mph or on steep terrain
	High impact step aerobics
	Skating
	Skiing
	Soccer
	Tennis
	Snowshoeing
	Hockey

goal to the individual while addressing their perceived barriers, the likelihood of behavioural modification adherence rises.[9]

An Approach

Determine Current Physical Activity Engagement – Physical Activity as a 'Vital Sign'

Prioritizing PA assessments as a 'vital sign' of health will facilitate effective counselling. The approach begins by understanding the patient's current PA engagement. This value is achieved with two questions: 1) On average, how many days per week do you engage in moderate or greater activity such as a brisk walk? 2) On those days, how many minutes do you engage in activity at this level?[1,3] Providers then simply multiply Answer 1 by Answer 2 to obtain the total minutes of moderate-to-vigorous PA per week.

Determining Readiness for Change

Understanding the patient's readiness for change and resolving ambivalence towards change is a core aspect of motivational interviewing and PA prescription development. It is recommended that motivational interviewing be used in conjunction with PA prescription development to facilitate individualized and sustained behavioural modification.[8] Providers must assess a patient's willingness to change and then proceed based on this with a personalized PA prescription. A commonly referenced way to determine the present stage of change a client is in is by using The Transtheoretical Model of Health Behavior Change:[14] precontemplation, contemplation, preparation, action, and maintenance.

"Understanding the patient's readiness for change and resolving ambivalence towards change is a core aspect of motivational interviewing and PA prescription development."

If the patient is in the preparation stage, expressing an openness to change in the near future, it is appropriate for the provider to progress towards PA prescription development.[1] Alternatively, if the patient expresses disinterest or lack of motivation the provider should inquire towards identifying barriers, facilitate strategies to overcoming them, and revisit the topic of PA during future visits.[1,8] Regardless of the patient's current stage of change, health benefits that may be realized related to PA as they pertain to the current health status or comorbidities of the individual should be shared routinely during primary care visits with the goal of advancing the client further in motivation to change in future.[1]

Determine Eligibility to Safely Engage in Physical Activity

Cardiovascular, metabolic, and renal disease have the potential to cause risk to individuals who are initiating or progressing PA intensity.[1] Healthy adults with no past medical history or comorbidities can safely begin routine PA at a moderate intensity with progression to vigorous intensity gradually. However, those with known or suspected cardiovascular, metabolic, or renal disease are encouraged to have medical clearance prior to pursuing routine PA of any intensity.[1] Medical clearance should involve standard measurements of height and weight for BMI, vital signs, a personal history of symptoms experienced during exertional efforts, and medical tests pertinent to prevention screening and cardiopulmonary function.[15] If there are concerns related to cardiopulmonary function or symptoms such as those listed in Table 3, an exercise stress test is recommended.[15,16]

This step should not deter providers from using PA prescriptions for those with comorbidities. Adverse events related to PA engagement are rare and create unnecessary barriers for patients who will benefit from light-to-moderate PA introduction.[1,13] Those who would benefit from decreasing their blood pressure, improving serum lipid profiles, glycemic control, and decreasing insulin resistance should pursue PA as a first-line therapeutic approach.[13,17] It is concluded by

Table 3. Criteria Warranting an Exercise Stress Test Prior to PA Initiation[16]	
Concerning Symptom Complaints Warranting Exercise Stress Test Prior to PA Initiation	Angina pectoris or feature of cardiac ischemia without chest discomfort either at rest or with exertional effort
	Dyspnea at rest or on exertion
	Paroxysmal nocturnal dyspnea and/or orthopnea
	Syncope or presyncope sensations
	Arrythmia or palpitations
	Cardiac murmur

the ACSM[1] that pre-exercise screening protocols have not been shown to reduce the risk of cardiac events during exercise and instead create barriers for patients where benefits would outweigh risk. PA decreases the risk of cardiovascular disease by 21% and further decreased the risk of cardiovascular mortality by 36%.[17] To illustrate its effect, one meta-analysis compared PA to other lifestyle modifications including weight loss, dietary modifications, smoking cessation, and alcohol moderation. It was concluded that aerobic PA demonstrated greater impact on blood pressure reduction than weight loss, Mediterranean diet, smoking cessation, and alcohol moderation interventions.[17] In addition, aerobic PA showed greater effect on improvements of serum cholesterol and triglyceride levels than dietary modifications and alcohol moderation.[17] Primary care providers should recognize clear indications of cardiopulmonary concern related to engaging in PA; however, in these circumstances a supervised PA alternative such as cardiac rehabilitation programs should be offered to individualize the approach instead of omitting PA engagement.[1]

The Physical Activity Prescription

A typical PA prescription is created using the FITT model: frequency, intensity, time, and type.[2] Frequency is the number of days per week, intensity is the level of PA, time is the number of minutes per session, and type is the activity of choice.[2] As a guideline, the ideal frequency is at least three days per week for a minimum of 30 minutes per session at a moderate or greater intensity, with an activity that promotes individual choice and preference.[2] A consistent physically active lifestyle is attainable for all individuals regardless of socioeconomic status and individualized recommendations that overcome perceived financial barriers towards engaging in routine PA should be encouraged, such as outdoor walking or bicycling.

A PA prescription template is available from the ACSM Exercise is Medicine[12] website that is structured using the FITT model, including examples of each intensity, as well as a recommended step goal of 7,000-9,000 steps per day. Alternatively, RxFiles Academic Detailing[18] has a PA prescription tool titled "Exercise Prescription Pad" available for free on their website by accessing the clinical tools page. This prescription contains the FITT model, goals of therapy, reductions in sedentary activities, comorbidity specific parameters (ie. checking blood sugar before and after exercise), a follow up timeframe, and cautionary symptoms. Both are conveniently structured as 'select all that apply' options for providers to tailor the prescription to the individual efficiently.

Below is an example of an introduction to PA prescription tailored towards a sedentary patient with no medical concerns (Table 4).

Table 4. Example of PA Prescription Using FITT Model[2,12,18]	
	Example PA Prescription for Healthy Sedentary Beginner Adult
Frequency	3+ days per week
Intensity	Moderate
Time	20-30 minutes per session
Type	Brisk walking at 3 – 4 mph

Follow-up

A guideline for PA prescription follow-up is at 3-, 6-, and 12-month intervals to meet the recommended follow-up range of one to four times annually.[9] Follow-up appointments strengthen PA prescription efficacy by providing an opportunity to reassess patient barriers, set continued goals, progress PA towards the target recommendation, and address medical concerns impeding progression.[3] Clinically effective follow-up visits can be accomplished in person or over the phone.[9] Follow-up appointments also allow the provider to ensure a tailored approach to the PA prescription that acknowledges individual preference, choice, and experience.[9] Motivational interviewing techniques should be used throughout patient interactions to increase adherence to behavioural modifications and maintain an individualized approach towards goal setting.[8]

Conclusion

It is crucial for providers to understand and value PA as a 'vital sign' of health. Improving the number of physically active Canadian adults will drastically decrease healthcare expenditure, improve overall quality of life, and positively impact chronic disease and health outcomes. An effective approach towards PA counselling is achieved with using motivational interviewing along with tailored, individualized PA prescriptions and intentional follow-up to facilitate purposeful behavioural modification that has sustained outcomes. Following this systematic approach allows providers to prescribe PA safely and efficiently in the primary care setting while overcoming perceived barriers related to time limitations, lack of resources

and lack of knowledge. Enforcing the message that "some is better than none" is a great start for all patients who express hesitancy towards PA engagement. Given the vast health benefits, increased awareness and priority need to be placed on effective PA counselling using PA prescription in the primary care setting as an attempt to improve the overall health and quality of life of Canadian adults.

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NEXTSTELLIS offers the convenience of a **24/4 dosing regimen.**[1‡]

Please refer to the NEXTSTELLIS Product Monograph for complete dosing and administration information.

* Comparative clinical significance has not been established.

† According to pooled data from two pivotal phase 3, open-label, single-arm, multicenter studies: Study 302 conducted at 77 sites across the United States and Canada and Study 301 conducted across 69 sites in Europe and Russia. In both studies, NEXTSTELLIS was supplied via oral administration, once daily as 24 active tablets followed by 4 inert tablets (4-day hormone-free interval) for 13 consecutive cycles. The primary efficacy endpoint was the number of on-treatment pregnancies assessed by the Pearl Index PI in the ITT Population of women aged 16 to 35 years (n=1864) in Study 302 and 18 to 35 years (n=1553) in Study 301.

‡ Clinical significance is unknown.

§ Studies conducted in healthy pre-menopausal women (16-50 years of age) with a duration of study at least three 28-day cycles and included the dosage and regimen of NEXTSTELLIS (E4/DRSP 15/3 mg, 24/4). The safety analysis included safety data from 3,790 subjects, of which a total of 3,575 subjects was confirmed treated. The safety population (N=3,790) also included 215 subjects who were dispensed study medication, but for whom the actual intake of study medication was not confirmed.

ITT: intent-to-treat; B/S: bleeding and/or spotting.

NEXTSTELLIS SAFETY INFORMATION[1]

Clinical use:

- Safety and efficacy have been studied in women between 16 and 50 years old. No data in women under 16 are available. Use of this product before menarche is not indicated.
- No geriatric data are available. Not authorized for use in women over 50 years of age. NEXTSTELLIS is not indicated for use in postmenopausal women.

Contraindications:

- NEXTSTELLIS is contraindicated in patients
  - who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container
  - who have a history of or actual thrombophlebitis or thromboembolic disorders
  - who have severe or multiple risk factor(s) for arterial or venous or thrombosis, such as hypertension, hereditary or acquired predisposition for venous or arterial thrombosis, such as Factor V Leiden mutation and activated protein C (APC-) resistance, antithrombin-III-deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinemia and antiphospholipid-antibodies (anticardiolipin antibodies, lupus anticoagulant) and prothrombin mutation G20210A, severe dyslipoproteinemia, diabetes mellitus with vascular involvement, increasing age, particularly above 50 years, obesity, other medical conditions associated with venous thromboembolism (VTE) or other adverse vascular events, positive family history (arterial thromboembolism [ATE] in a sibling or parent especially at relatively early age, e.g., below 50), prolonged immobilization, major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma, and smoking, particularly in women who are over 35 years of age
  - who have a history of or actual cerebrovascular disorders
  - who have a history of or actual myocardial infarction or coronary artery disease and valvular heart disease with complications
  - who have a history of or actual prodromi of a thrombosis (e.g., transient ischaemic attack, angina pectoris)
  - who have active liver disease, hepatic dysfunction or history of or actual benign or malignant liver tumours
  - who have known or suspected carcinoma of the breast, carcinoma of the endometrium or other known or suspected estrogen-dependent neoplasia
  - who have undiagnosed abnormal vaginal bleeding
  - who have steroid-dependent jaundice, cholestatic jaundice, history of jaundice of pregnancy
  - who have any ocular lesion arising from ophthalmic vascular disease, such as partial or complete loss of vision or defect in visual fields
  - with known or suspected pregnancy
  - with current or history of migraine with focal aura
  - with a history of or actual pancreatitis if associated with severe hypertriglyceridaemia
  - who have renal or adrenal insufficiency

Most serious warnings and precautions:

Cardiovascular: Cigarette smoking increases the risk of serious cardiovascular events associated with the use of hormonal contraceptives. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, NEXTSTELLIS should not be used by women who are over 35 years of age and smoke.

Sexually transmitted infections (STIs): Patients should be counselled that birth control pills do not protect against STIs including HIV/AIDS. For protection against STIs, it is advisable to use latex or polyurethane condoms in combination with birth control pills.

Other relevant warnings and precautions:

- **Patients should discontinue NEXTSTELLIS at the earliest manifestation of:**
  - **thromboembolic and cardiovascular disorders**
  - **conditions which predispose to venous stasis and to vascular thrombosis**
  - **visual defects- partial or complete**
  - **papilledema or ophthalmic vascular lesions**
  - **severe headache of unknown etiology or worsening of pre-existing migraine headache**
  - **increase in epileptic seizures**
- Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium level checked during the first treatment cycle.
- NEXTSTELLIS should not be used in patients with conditions that predispose to hyperkalemia (e.g., renal insufficiency, hepatic dysfunction, and adrenal insufficiency).
- Consider monitoring serum potassium concentration in high-risk patients who take a strong CYP3A4 inhibitor long-term and concomitantly.
- Women who currently have or have had breast cancer should not use NEXTSTELLIS because breast cancer is a hormonally-sensitive tumour.
- Increased risk for arterial thromboembolism (myocardial infarction) or for cerebrovascular accident (e.g.,transient ischaemic attack, stroke). Arterial thromboembolic events may be fatal.
- The use of any COC carries an increased risk of VTE compared with no use – this risk is highest during the first year a woman ever uses a COC or restarts the same or a different COC.
- For women with multiple risk factors for VTE and ATE: If a woman has more than one risk factor, it is possible that the increase in risk is greater than the sum of the individual factors – in this case her total risk should be considered.
- Diabetic patients, or those with a family history of diabetes, should be observed closely to detect any worsening of carbohydrate metabolism.
- Alternative contraception should be used in women with severe dyslipoproteinemia.
- Worsening of Crohn's disease and ulcerative colitis has been reported during combined oral contraceptive (COC) use.
- Persistent irregular vaginal bleeding requires assessment to exclude underlying pathology.
- Patients with fibroids (leiomyomata) should be carefully observed.
- Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal.
- Risk of oral contraceptive-related cholestasis. NEXTSTELLIS should be discontinued if jaundice develops.
- Caution is warranted when starting therapy with the Hepatitis C virus (HCV) combination drug regimen ombitasvir, paritaprevir, ritonavir, with or without dasabuvir.
- Patients taking oral contraceptives have a greater risk of developing gallbladder disease requiring surgery within the first year of use. The risk may double after four or five years.
- In women with hereditary angioedema, exogenous estrogens may induce or exacerbate symptoms.
- Before oral contraceptives are used, a thorough history and physical examination should be performed, including a blood pressure determination and the family case history carefully noted. Disturbances of the clotting system must be ruled out if any members of the family have suffered from thromboembolic diseases (e.g., deep vein thrombosis, stroke, myocardial infarction) at a young age and breasts, liver, extremities, and pelvic organs should be examined and a Papanicolaou (PAP) smear should be taken if the patient has been sexually active. The first follow-up visit should be done 3 months after oral contraceptives are prescribed, and at least once a year, or more frequently if indicated thereafter. Follow-up visit examinations should include those procedures that were done at the initial visit as outlined above or per recommendations of the Canadian Task Force on the Periodic Health Examination. Serum potassium concentration should be monitored in high-risk patients who take a strong CYP3A4 inhibitor long-term and concomitantly.
- The onset or exacerbation of migraine or the development of headache of a new pattern that is recurrent, persistent, or severe, requires discontinuation of COCs and evaluation of the cause.
- With use of COCs, there have been reports of retinal vascular thrombosis which may lead to partial or complete loss of vision.
- There is an increased risk of thromboembolic complications in COC users after major surgery.
- Patients with a history of emotional disturbances, especially the depressive type, may be more prone to have a recurrence of depression while taking oral contraceptives.
- Hormonal contraceptives may cause some degree of fluid retention.
- During the first months of use, irregular spotting or bleeding may occur.
- Chloasma may occasionally occur in women who take COCs, especially in women with a history of chloasma gravidarum.
- If pregnancy occurs while taking NEXTSTELLIS, further intake must be stopped.
- The use of COCs should not be recommended until the breast-feeding mother has completely weaned her child and an alternative contraceptive method should be advised to women wishing to breastfeed.
- The safety and efficacy of NEXTSTELLIS in women with a body mass index (BMI) >35 kg/m^2 has not been evaluated.

For more information:

Please consult the Product Monograph at pdf.hres.ca/dpd_pm/00060352.PDF for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-855-331-0830.

References: 1. NEXTSTELLIS Product Monograph, Searchlight Pharma Inc. March 5, 2021. **2.** Searchlight Pharma Inc. Data on File. 2024.

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Examining the Incidence of Type 2 Diabetes in the Canadian Newcomer Population

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ABSTRACT

Newcomers from certain ethnic backgrounds are underdiagnosed with type 2 diabetes mellitus (T2DM) by Canadian primary care providers. Newcomers to Canada also tend to have poorer health outcomes when compared to Canadian-born individuals, and account for a disproportionate percentage of the T2DM population in Canada. Newcomers' health is affected by acculturation to the Western diet/lifestyle and genetic predispositions. Several barriers to care, including poor English, lack of social supports, lower income, and lack of culturally sensitive care, contribute to lower healthcare utilization rates in this population. As the Canadian newcomer population continues to grow, healthcare providers must take an increasingly proactive, collaborative, and culturally sensitive approach to reduce the incidence of diabetes in this population. Since certain high-risk ethnic groups are more likely to progress from prediabetes to T2DM when compared to non-migrant Canadians, early screening and intervention among newcomers is critical. The purpose of this article is to identify the unique challenges and risk factors affecting Canadian newcomers, and prompt healthcare providers to provide early screening and culturally relevant information for this growing population.

Keywords: Prediabetes, diabetes mellitus, Canadian, newcomer, refugee, immigrant

Introduction

Type 2 diabetes mellitus (T2DM) is a growing concern in Canada, and has been classified as a public health priority.[1] As of 2019, there were 2.5 million Canadian residents living with T2DM.[1] The immigrant and refugee populations account for a disproportionate percentage of people living with this chronic illness.[2] It is important to examine the effects of developed nations' increasingly sedentary lifestyles on the incidence of T2DM in immigrant and refugee populations. Canadian immigrants and refugees who have been diagnosed with prediabetes are at an increased risk of converting to T2DM when compared to their non-migrant counterparts.[3] This article examines the risk factors (both genetic and lifestyle) and barriers to treatment for immigrant and refugee patients with prediabetes, and outlines recommendations for healthcare providers working with this population.

Background

The terms "refugee" and "immigrant" are distinct; the former involves involuntary displacement from a home country with poor living conditions, while the latter involves voluntary migration to a new country. For the purposes of this paper, these two distinct populations have been amalgamated under the umbrella term "newcomer." This term is also used by the Government of Canada, which only distinguishes the two groups when significant differences are present.

Canadian newcomer rates reached an all-time high in 2022. The high influx of newcomers to Canada has underscored the importance of tailoring T2DM prevention, screening, and treatment to meet the unique needs of this population.[7] In 2022, Canada welcomed 431,645 immigrants and refugees, who accounted for 75% of Canada's population growth that year.[7]

Type 2 diabetes mellitus is a chronic illness that affects a large proportion of the Canadian population. Initially, Canadian immigrants tend to be healthier than non-immigrants due to immigration policies that favour healthier candidates.[4] In addition, immigrants tend to have healthier diets and lifestyles in their countries of origin.[4] This is known as the "healthy immigrant effect," which persists for approximately five years before it begins to decline.[4] According to the 2022 *Health Inequalities Data Tool* developed by the Government of Canada, the diabetes prevalence rates among newcomers aged 18 to 79 years were as follows: 4.4% for those who have lived in Canada for less than or equal to 10 years and 13.19% for those living in Canada for more than 10 years.[5] In contrast, the prevalence of diabetes among non-immigrant Canadians was 7.13% during the same time period.[5] The prevalence of T2DM is particularly high (12-15%)

among certain ethnic groups, such as South Asians and Arabs, in the western world.[6] In some high-risk regions, including the Western Pacific, Middle East, North Africa, and Central America, the prevalence of T2DM is higher than 20%.[3]

Newcomers from certain ethnic backgrounds, such as those from South Asia, Southeast Asia, West Asia, Arab countries, Sub-Saharan Africa, and Caribbean nations, are up to 60% more likely to convert to T2DM when compared to their non-migrant Canadian counterparts, aged 35 years or older.[3] On average, 5 to 15% of those living with prediabetes will convert to T2DM each year, with newcomers constituting the higher end of this range.[3,6] Limiting the conversion of prediabetes to T2DM can effectively reduce the proportion of Canadians at risk of T2DM-related adverse health effects and other chronic illnesses, including cardiovascular disease.[8] Therefore, delaying or preventing the onset of diabetes could allow many Canadians to enjoy a higher quality of life for a greater proportion of their lives.

Literature Search

Three databases (Pubmed, CINAHL, and Embase) were utilized to search for the following keywords and MeSH headings: ("prediabetes OR impaired glucose tolerance OR impaired fasting glucose OR A1C OR fasting glucose OR plasma glucose") OR ([MH "prediabetic state"] OR [MH "glucose intolerance"]) AND ("immigra* OR newcomer* OR migra*) OR ([MH "refugee"] OR [MH "Immigrant"] OR [MH "emigration and immigration"]) AND ("second-generation immigrants or children of immigrants" OR west* OR Canad*) OR (MH "Canad*") AND ("type 2 diabet* OR hyperglyc* OR NIDDM") OR ([MH "diabetes mellitus"] OR [MH "hyperglyc*"]). The search retrieved a total of 77 articles. Filters were applied to the final search results to show only those articles published in the previous 10 years, which were also available in English and as full text through the University of Manitoba libraries. Duplicate articles were removed. Saturation was believed to have occurred, as repetition of the same articles appeared in all three databases. The final search yielded eleven articles on CINAHL, four articles on Pubmed, and nine articles on Embase. Given the breadth of the search terms used and the limited number of articles retrieved, this literature review highlighted the paucity of relevant research on this topic.

Risk Factors

Although there is a lack of research examining the higher prevalence rates of prediabetes and diabetes among newcomers in Canada, several risk factors have been identified in the literature. These risk factors include acculturation to the Canadian diet and lifestyle, which increases newcomers' risk of developing diabetes.[9] In certain immigrant populations, such as South Asians, the hemoglobin A1C levels of young adults are roughly equivalent to those of non-immigrant Canadians who are 15 years older.[10] In Canada, the average age of conversion from prediabetes to T2DM is up to 4.6 years earlier for non-European newcomers than for Western European immigrants.[3] Early screening and treatment are critical for the newcomer population due to their higher hemoglobin A1C levels and tendency to convert to diabetes at a younger age. Furthermore, since newcomers tend to have lower income jobs and live in lower income neighbourhoods than their Canadian-born counterparts, they have limited resources for healthier, and more expensive, food choices.[8,10]

"Early screening and treatment are critical for the newcomer population due to their higher hemoglobin A1C levels and tendency to convert to diabetes at a younger age."

Genetic Factors

It is not well understood why certain ethnic groups tend to be more susceptible to T2DM when compared to Western Europeans. For instance, newcomers from sub-Saharan Africa, Latin America, and South Asia are two to four times more likely to develop diabetes than Western Europeans.[4] Newcomers from high-risk ethnic backgrounds tend to have a greater genetic predisposition for developing diabetes; for example, those from South Asia and China tend to have higher insulin resistance when compared to Western Europeans.[10] The TCF7L2 transcription factor is believed to contribute to this susceptibility by increasing insulin resistance and causing adipocyte hypertrophy.[11] These genetic predispositions are compounded by the increasingly sedentary lifestyles and processed diets that have become commonplace in developed nations, and serve to further increase newcomers' risk of developing T2DM.

Lifestyle Factors

Somalian refugees have been the largest refugee population in the United States for the past two decades.[12] One study found higher rates of prediabetes among Somalian refugees when compared to non-foreign-born residents of the United States, even when controlling for rates of overweight and obesity.[12] This study on Somalian refugees highlighted the need for earlier screening and treatment for prediabetes regardless of BMI, which is normally a significant risk factor for diabetes.[12] Newcomers who resettle in Western nations were generally more physically active in their countries of origin.[12] After resettling, newcomers tend to spend a lower

proportion of time in physical activities due to a multitude of factors, including: sedentary workplaces, increased distance to exercise facilities, and insufficient expendable income to pay for exercise facilities.[12] Newcomers' risk of diabetes is further compounded by their acculturation to the Canadian lifestyle; as they become acculturated, they become less active, and more similar to their Canadian adult counterparts, who are sedentary for approximately ten waking hours each day.[13]

One qualitative study examined the perspectives of T2DM among sub-Saharan Africans who migrated to Australia. The migrants placed little value on T2DM prevention, as they did not know of many locals with the disease and thought this disease affected only wealthy individuals, who had an unhealthy diet/lifestyle.[14] These factors may play a role in Canadian newcomers' perceptions of T2DM, since many come from developing nations. Residents of developing nations tend to have active lifestyles and consume less processed foods.[9,12] It is well understood that diet and lifestyle are the cornerstones of diabetes management; therefore, a deterioration in these factors increases the incidence of T2DM among newcomers, as they acculturate to the Canadian lifestyle. As a result, NPs need to provide diabetes education to newcomers in order to limit the negative effects of acculturation on their overall health.

Dietary Factors

As a result of lower income and the acculturation process, newcomers to Canada often consume a lower quality diet, which contributes to the development or worsening of prediabetes.[9] Newcomers must adapt to a new diet that is generally more processed and less nutritious when compared to their native diet.[12] Heavily processed foods from the grocery store or fast food restaurants are generally less expensive than healthier alternatives and, thus, may be more appealing to lower income newcomers.[12] Diet-related education provided by healthcare providers to newcomer patients must be tailored in a culturally competent manner so these patients can maintain a healthy, culturally appropriate diet.[4] Culturally competent dietary advice has been shown to have greater effects on glucose control when compared to non-culturally competent care.[4]

Barriers to Healthcare Access and Utilization

Data obtained from various Canadian health databases, such as the *Canadian Community Health Survey*; *Longitudinal Immigrant Databases*; and *Immigration, Refugees, Citizenship, Canada*, have demonstrated that newcomers have lower incomes, lower rates of prescription drug coverage, and are less likely to seek specialist care when compared to non-migrants.[16]

Woodgate and colleagues[15] conducted a qualitative study that examined African newcomers' experiences of accessing primary care in Manitoba, Canada. The researchers identified the following main barriers to healthcare access in this population: poor communication due to language barriers, limited time to discuss health concerns with primary care providers (PCPs), lack of culturally sensitive care, inadequate referrals to specialists, insufficient social support, and differences in expectations.[15] This study also noted that newcomers were concerned about the high cost of non-essential treatment and medications.[15] These concerns were further compounded by the fact that newcomers could not afford private health insurance and had difficulty finding full-time work with group-funded health insurance.[15] Additionally, they discussed the challenges associated with taking time off work for appointments and arranging transportation to health clinics. The study participants and researchers posited that culturally appropriate support networks may be a viable solution for improving newcomers' social determinants of health. Woodgate and colleagues' analysis of newcomers' lived experiences provided valuable insight into the barriers to care for this population, and how to circumvent these barriers.[15]

A secondary analysis by Corscadden et al.[17] examined patients' engagement with PCPs in 11 different Western nations. In this study, on average 21% of a country's population reported multiple barriers even before seeking primary care, while 16% reported two or more barriers after they had already engaged with PCPs.[17] The most common barriers to healthcare included: the overall costs of care, limited office hours of PCPs, long wait times to see PCPs, poor affiliation with PCPs, and language or cultural differences.[17] The populations that experienced the most barriers to care were those with mental health conditions, migrants, and those with lower incomes[17]; therefore, it can be postulated that newcomers would experience a higher degree of barriers to healthcare as they generally fit into all three of these categories.

Organizational innovations and policy changes are required to facilitate diabetes screening and treatment for newcomers, and to provide the newcomer population with equitable access to healthcare. It is critical that newcomer populations have access to healthcare services that are culturally competent, trauma-informed, and tailored to meet the specific needs of the local population.[18] Healthcare policy changes need to be aimed at decreasing the level of discrimination, unconscious bias, and organizational barriers to care, thereby improving the confidence and involvement of vulnerable populations in the healthcare system. Such changes to the healthcare system must address structural and organizational barriers and biases, such as approachability, affordability, and culturally competent care, which collectively result in lower utilization rates and lower perceived effectiveness of interventions among vulnerable populations.[19]

Role of the NP

Nurse practitioners play a vital role in improving glycemic control and preventing the progression of prediabetes to diabetes in the newcomer population. Nurse practitioners can reduce the risk of conversion among newcomers by addressing the common barriers to care, providing culturally competent care, and screening patients earlier than in standard practice. Since newcomers are known to have a higher degree of susceptibility and earlier onset of T2DM, NPs should screen for T2DM in newcomer patients approximately five to ten years sooner than they would in Western European patients.[3] In addition, due to the healthy immigrant effect, NPs should re-screen newcomer patients for T2DM every five years after their arrival to Canada.

It is imperative that NPs conduct a thorough meet and greet with each newcomer patient to become aware of their unique background, including their past medical history, social history, socioeconomic status, and reasons for leaving their country of origin. As part of this assessment, NPs need to become familiar with the patient's cultural diet, which includes learning about various ethnic grocery stores in the local neighbourhood. This knowledge will empower NPs to provide culturally competent dietary recommendations that can actually be implemented into their patient's normal diet.[4] In addition, when newcomers have access to ingredients from their country of origin, they are more likely to retain their cultural diet, thereby limiting their acculturation to the less healthy North American diet.[2,3] This level of cultural competence and awareness will support a greater proportion of patients to successfully implement the NPs' dietary advice.

Nurse practitioners are well-positioned to be leaders in their communities, and can improve patients' health outcomes by integrating evidence-based knowledge with their patients' own preferences for care. Effective communication is the key to building rapport and working collaboratively with patients to meet their unique needs. However, many newcomers experience some level of difficulty engaging in dialogue outside their native tongue.[4] The use of medical jargon, along with new and unfamiliar terminology, can result in lower levels of patient understanding and may become a barrier to seeking further care.[15] In addition, patients and PCPs have reported poor communication as a significant barrier to healthcare.[15] Communication barriers can make it very challenging for NPs to fully understand their patients' concerns and to obtain the information required for their care. Newcomer patients are less likely to form therapeutic relationships with their PCPs when they feel like their voice and concerns are not being heard or understood; therefore, it is critical that NPs utilize a translator, whenever possible, to improve the quantity and quality of information transferred .[15] Many healthcare facilities and health regions offer translation services for this reason. In addition, NPs can improve patients' understanding of their illness, medications, and treatment plan by providing written handouts translated into the patients' native language. For example, documents approved by the Winnipeg Regional Health Authority can easily be translated into numerous languages to improve patient understanding.

Nurse practitioners can facilitate newcomers' access to healthcare by expanding their clinic hours to include evenings and weekends, and by involving social workers or other community resources to connect newcomers to financial and cultural support. The expansion of clinic hours beyond the typical "nine to five" workday allows newcomers, and Canadians in general, to visit their PCP without having to take time off work and suffering financial consequences. Since newcomers tend to be employed in low income jobs, they often delay seeking care because they view financial stability as a higher priority.[15] In addition, many female newcomers are stay-at-home mothers who care for young children and face several logistical barriers to seeking healthcare, including: finding a babysitter, navigating a new city, and utilizing public transport with their children if they cannot make alternative arrangements for child care.[15]

Lastly, NPs need to find opportunities to engage with their colleagues, such as through clinical practice, conferences, and professional associations, to increase awareness of the need for earlier T2DM screening in newcomer populations as well as to promote culturally competent care that will maintain or improve newcomers' baseline health. Engaging other providers in dialogue about newcomers' health can allow NPs to effect change in current policies and practices. Nurse practitioners are often well-trusted by the public and their patients, and are uniquely positioned to engage in knowledge translation activities. Given these facts, a well-informed NP can disseminate valuable, although infrequently discussed, information to newcomers who may not otherwise have access to knowledgeable or reliable sources.

Limitations

Research related to the conversion of prediabetes to T2DM in the newcomer population is limited. The literature search conducted in this study produced only 26 relevant articles, and demonstrated a need for greater awareness on this topic. The available studies were mostly retrospective and did not account for various confounding factors, including body mass index, levels of activity, medication use, health beliefs, and family history.[3] More rigorous studies are needed in order to isolate the modifiable and non-modifiable risk factors affecting this group. Of note, most of the research articles that informed this paper were published within the previous five years, so there appears to be a growing interest in this topic.

Conclusion

Canadian newcomers from certain ethnic backgrounds are at higher risk of converting from prediabetes to T2DM when compared to their Canadian-born counterparts. The reasons for these disproportionate rates of T2DM among newcomers are not well understood at this time. It is believed that a combination of genetic factors, acculturation to the Canadian lifestyle, lower socioeconomic status, sedentary jobs, organizational barriers and biases, and differing expectations of the delivery of healthcare services play a role in newcomers' higher susceptibility and earlier onset of T2DM. As a result, there is a need for earlier screening for T2DM among newcomers when compared to non-migrant Canadians to limit the adverse T2DM-related health effects, including cardiovascular disease. A search of the available literature on this topic produced limited results, suggesting that T2DM has not been thoroughly researched in the newcomer population. Newcomers may believe that T2DM is a disease of the rich and inactive. The Nurse Practitioner should be mindful of the healthy immigrant effect, which typically lasts ~5 years, as it is an ideal time to implement culturally competent diet and lifestyle interventions. Additionally, NPs should incorporate members of the interdisciplinary team, such as social workers, to connect newcomers to financial and cultural supports. Nurse Practitioners can improve knowledge translation in the topic of early T2DM screening and management in newcomer populations by utilizing translators and by providing patient handouts in the patient's native language. As NPs become more aware of newcomers' elevated risk of developing T2DM, they can more effectively engage in prevention, screening, and treatment interventions to limit the conversion of prediabetes to T2DM in the newcomer population.

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A Client Perspective on Virtual Appointments with Their Primary Health Care Nurse Practitioner during the COVID-19 Pandemic

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ABSTRACT

Background: A systematic review was conducted using Covidence to examine the current literature on the transition to virtual care from a primary health care perspective during the pandemic. A total of 23 studies were extracted and further organized into a literature review table (Appendix A).

Methods: A cross-sectional study was then conducted using a multimodal survey design with a total of six questions to assess clients' perspectives of virtual care during the COVID-19 pandemic. Participants were recruited via telephone call from a generated list of clients who were marked as having had a virtual appointment through the NBNPLC during the pandemic. The interviews were conducted in October 2021.

Results: Overall, majority of participants were satisfied with their virtual appointment and would like an option in the future between virtual and in-person appointments.

Interpretation: Primary health care (PHC) within Ontario during the COVID-19 pandemic resulted in a transition from in-person visits to virtual appointments. Based on this quantitative and qualitative data, there is potential for sustainability with virtual care in the PHC setting. However, future client-centered research is needed to analyze client barriers to virtual care from an equitable standpoint, to understand if video calls rather than phone calls would be preferred as an alternative to face-to-face appointments, and to identify criteria to determine when virtual appointments rather than face-to-face appointments are warranted.

Keywords/Concepts: Virtual appointments, Primary Health Care (PHC), COVID-19, client perspective, nurse practitioner

Introduction

Purpose

The purpose of this study was to understand the current literature around the increased use of virtual care modalities in primary health care (PHC) during the COVID-19 pandemic and to assess client satisfaction with their virtual appointments with their Nurse Practitioner at the North Bay Nurse Practitioner-Led Clinic (NBNPLC) over the past 18 months.

Background Research

Background research on virtual care was collected through a systemic review conducted using Covidence. Three databases were reviewed – Scopus, PubMed, and Medline (OVID) within the last five years. The syntax included "Nurse practitioner" OR "NP" AND "virtual care" OR "telehealth" AND "primary health care". A total of 752 studies were imported, 285 duplicates removed, 440 studies screened, and 379 studies deemed not relevant to this study. A total of 61 full-text studies were assessed for eligibility and further narrowed down to 23 studies for the literature review table (Appendix A).

Virtual Care During the Pandemic

Telehealth is defined as the use of information and communication technologies to perform synchronous or asynchronous consultations at a distance between the healthcare practitioner and client. (Deldar et al., 2016). Telehealth is an umbrella term that encompasses a wide range of technology or tools to facilitate care using methods such as video conference, telephone, or secure messaging (Canadian Medical Association, 2020). Telehealth has existed for decades, however, before

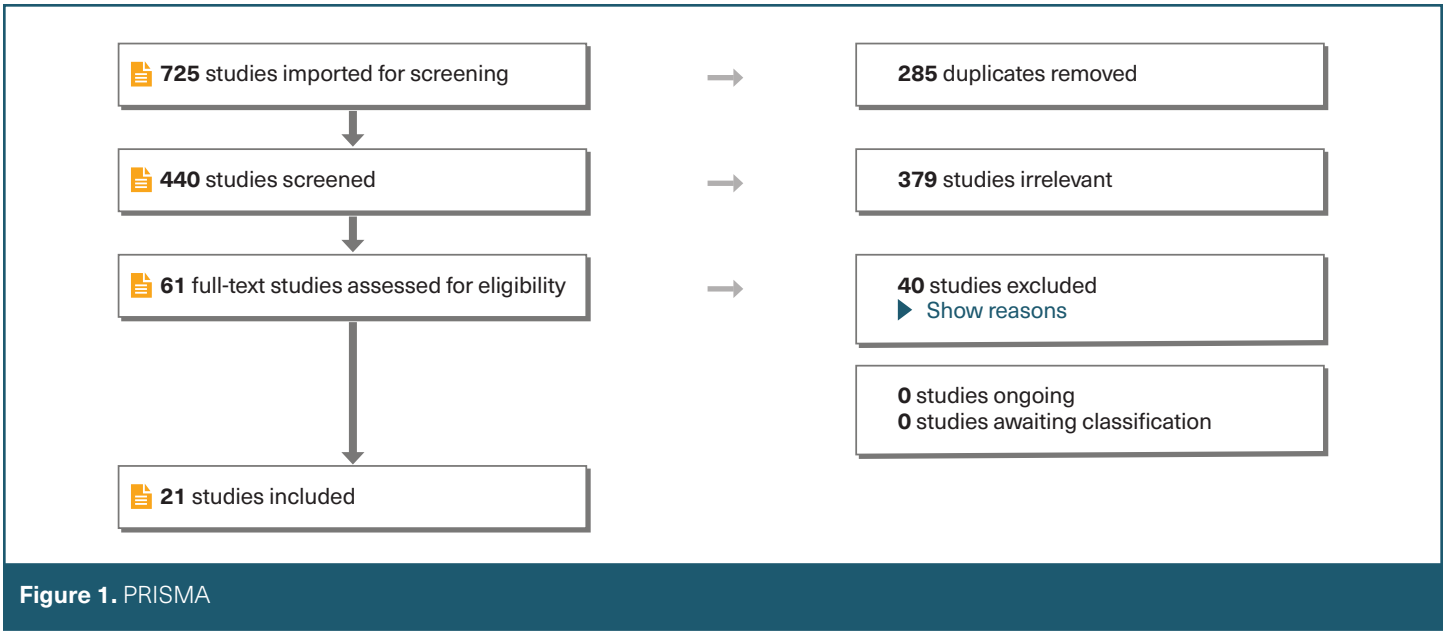

Figure 1. PRISMA

the pandemic the uptake had been slow, particularly among PHC providers (Cheung et al., 2021). During the COVID-19 pandemic, governments at the national level introduced temporary measures to remove barriers to utilizing telehealth (Breton et al., 2021). The increased prevalence of telehealth during the pandemic has assisted PHC practitioners to continue to provide care to patients while continuing to maintain necessary public health measures (Al-Busaidi et al., 2020). Healthcare practitioners and clients were put in a position that required rapid adaptability with little to no experience with virtual methods, presenting an opportunity for integration of regular telehealth use into PHC providers' practice (Breton et al., 2021).

Advantages of Virtual Care

The potential advantages that virtual care offers holds merit and should continue to be further understood to improve aspects of the PHC system. The advantages of virtual care noted in current literature include improved care access (Breton et al., 2021; Haldane et al., 2020; Leblanc et al., 2020), cost-effectiveness (James et al., 2021; Leblanc et al., 2020), increased flexibility (Breton et al., 2021), a great option for routine follow up care where face-to-face isn't necessary (Breton et al., 2021; Goldberg et al., 2021; Haldane et al., 2021), and for the diagnosis and patient care when problems are classified as relatively minor (Breton et al., 2021).

Virtual Care Barriers

To understand the potential of sustainability post-pandemic, barriers to equitable access need to be further examined to preserve the universality of the healthcare system (Breton et al., 2021). Client-related barriers noted in the literature included poor competence with the chosen technology (Connolly et al., 2021; Breton et al., 2021; Franzosa et al., 2021), minimal digital literacy (Cheng et al., 2021; Dhaliwal et al., 2021; Franzosa et al., 2021), a lack of urban-rural coordination (Leblanc et al., 2020, Liaw et al., 2019), the inability to perform a physical exam (Breton et al., 2021), the potential to miss important information leading to less effective care (Franzosa et al., 2021; Vosburg et al., 2022), and maintaining privacy (James et al., 2021). A large barrier noted was the inequality between certain demographics. Examples of these populations include the elderly, new patients, those who have visual, audio, or cognitive impairments, and vulnerable populations that may not have proper access to digital tools (Breton et al., 2021; Franzosa et al., 2021; Kaplan, 2021).

Considerations with Virtual Care

Although virtual care in certain circumstances can be a better alternative, a few considerations should be noted. Virtual care is best utilized with established clients rather than treating new clients (Connolly et al., 2021; Mozes et al., 2022), the appropriateness of the case should be dependent on the severity of the situation or problem (Breton et al., 2021; Mozes et al., 2022), and virtual care should be individualized based on the clients' demographic and if it is a feasible option. It is significant to note that the benefits that accompany virtual care must be considered alongside the potential limitations. Franzosa et al. (2021), discuss that virtual care may expand the capability to increase the number of visits, but it is not valuable or beneficial to the client if vital information is missed or if the time spent to travel to an appointment is now used to assist a patient to log onto the virtual care platform. The implementation of a framework for successful electronic outreach and the internet should be considered for virtual care to be successfully integrated into the healthcare system (Leblanc et al., 2020). Sustaining the use of virtual care beyond the COVID-19

pandemic will involve collaboration, openness to change, and flexibility (Kaplan, 2021), to identify a balance between the use of virtual care and face-to-face visits (Johnson et al., 2021).

Method

Study Design and Setting

A cross-sectional study was conducted using a multimodal survey design with a total of six questions to assess clients' perspectives of virtual care during the COVID-19 pandemic. This study involved the use of the Canadian Institutes of Health Research (CIHR) Strategy for Patient-Oriented Research (SPOR) with an understanding that patient involvement is an aspiration that recognizes shared leadership and decision-making professions to become collaborators in research to ensure a multi-way capacity building and mobilization of patient's experiential knowledge to be valued as evidence (SPOR, 2019). The data collected is beneficial to gaining a client-orientated perspective around the barriers, facilitators, and overall satisfaction of virtual care to further understand the sustainability of virtual care post-pandemic.

Ethical considerations: All participants provided informed consent. Clients who agreed to take the survey were informed by a telephone call that the survey was conducted on behalf of the North Bay Nurse Practitioner-Led Clinic, and the information would be shared within the clinic and that generalizations would be shared at a regional, provincial, or national level. Clients were notified that their answers were anonymous, the survey was voluntary, and that they could stop at any time should they choose to. Telephone dialogue and voicemail dialogue were synchronous to ensure each conversation and the information shared was standardized.

Procedure: Participants were recruited via telephone from a generated list of clients who were marked as having had a virtual care appointment through the NBNPLC during the COVID-19 pandemic. To avoid any bias, the researchers were in no way related to or involved in the care of participants. The list was broken up into three packages and four students enrolled in the Bachelor of Science in Nursing (BScN) program at Nipissing University called clients using the phone numbers provided by the NBNPLC administrative staff. Phone calls were made during clinic hours at the clinic, client information did not leave the clinic and confidentially was maintained. If the client did not answer their phone, a voicemail was left to return the call voluntarily and at their convenience.

Materials: A multimodal survey comprised of six questions (Appendix B) was utilized. The survey contained single-answer questions and included the use of a Likert scale with the following options: strongly disagree, disagree, neutral, agree, and strongly agree. The end of the survey included a comment section that disclosed qualitative feedback regarding the client experience.

Results

Participant demographic: The survey was conducted in October of 2021. A total of 264 telephone calls were made and a total of 84 surveys completed. A total of 19 clients declined, including 7 that stated they did not have or recall a telephone appointment and a total of 161 voicemails were left. The age demographic included ages (0-20) = 5, (21-40) = 23, (41-60) = 23, (61-80) = 24, (81+) = 5, and (no age identified) = 4.

Quantitative Data Analysis

This secondary data analysis is based on the 84 surveys that were completed and will identify the two components of the Likert scale that were of majority for each question. Appointments were classified into three categories: a chronic health concern (57%), an acute health concern (38%), and an unknown (5%). Out of the 84 participants, 100% stated that their appointment was conducted by telephone and that they had proper access to a telephone at the time of their appointment, with 96% stating that they did not need assistance from a family member or friend to attend their appointment. When asked if clients felt their appointment time and date were easy to recall 49% of clients stated that they agreed and 36% strongly agreed. On average clients enjoyed not travelling to their appointments as 42% agreed and 25% strongly agreed with this statement. Clients did make time for their virtual appointments noting that 60% agreed with this statement, and 32% strongly agreed, however, it was identified that there were times it was difficult regarding scheduling appointments during their work hours. The majority of clients were able to access a quiet and confidential space for their appointment, as 55% of participants agreed, and 33% strongly agreed. When asked if clients felt they were able to focus within the virtual environment for their appointment 62% agreed and 27% strongly agreed. Considering that a large concern of virtual appointments is the risk of a privacy breach, it is important to note that 58% of patients agreed, and 40% strongly agreed that their privacy was protected during their appointment. Clients felt comfortable voicing their health concerns during the appointment with 45% of participants agreeing, another 45% strongly agreeing, and 48% of participants strongly agreed, with another 44% agreeing that their concerns were listened to and addressed during the appointment. A total of 70% of clients interviewed stated that their health concern was addressed during the appointment, with only 29% needing to come into the clinic for follow-up. Overall, 51% of clients that participated strongly agreed they were satisfied with their virtual appointment, and another 44% agreed. When asked if clients would like the option for a virtual appointment in the future, 44% agreed, and 33% strongly agreed.

Qualitative Data Analysis

A secondary analysis was completed of the associated qualitative data using the six-step Braun and Clarkes (2006) thematic analysis approach. Thematic analysis of qualitative responses was used to identify common themes reported by respondents. The process is initiated by becoming familiar with the data, then coding the data resulting in an initial set of themes. Inductively the data was tagged and coded using the Delve Qualitative Analysis tool software. Once all data had been tagged, the final list of themes was identified, and a visual thematic map was created to display the associated themes and subthemes (Appendix C). A total of four final themes were identified: Client experience with a virtual appointment, client barriers to a virtual appointment, feedback for nurse practitioners, and the use of virtual care in the future.

Client experience with a virtual appointment

Although clients felt that a virtual appointment was convenient ("Convenient", "Saves me from making a trip to the clinic", "Felt convenient for both patient and practitioner", "Convenient based on the times we are living in", "was comfortable in my own home"), and accessible ("Easier for mobility", "Short and sweet. Easily accessible", "I'm glad the clinic was able to keep up with my appointments during the pandemic"), it was noted that the choice between in-person and virtual was appreciated ("Clinic offered options, it's nice to have a choice", "Like that the option is there", "I enjoyed having the option for phone appointments"), and the overall majority preferred face-to-face appointments with their NP ("Prefer to see a face and talk to someone", "Feels better to see the NP in person, not quite the same over the phone", "Don't like phone appointments, rather face-to-face", "Not as a good as personal visit", "Do like physical appointments better").

Clients felt virtual appointments were sufficient for simple and minor health concerns ("Not necessary to come in for some things", "I would like to have the option for phone visits but would like to go into the clinic for the bigger ones", "I enjoyed having the option for phone appointments, especially for simple/quick concerns"), however, felt it was only appropriate for specific circumstances such as those when a complex diagnosis is not discussed ("Only if appropriate, no major diagnosis", "Found out I had breast cancer over the phone, not appropriate", "Further appointments = follow up in person", "No action was taken to address health concern").

Client barriers to a virtual appointment

Qualitative data did not identify many barriers that were noted in the background. Barriers identified in the thematic analysis include difficulty addressing health concerns over the telephone ("Better understood in person rather than on the phone", "Hard to describe on the phone"), feeling unprepared ("Has to remember to write everything down", "felt unprepared, states they should have made a list, advises patients to make a list"), scheduling concerns ("Needed to book appointment 2 weeks ahead, tried to 3 weeks ahead and was refused. Running out of antidepressants, unable to make an appointment for 2 to 3 days, went off meds"), and the inability to focus ("I wasn't able to focus on the appointment").

Feedback for Nurse Practitioners

Overall clients within the NP-Led clinic felt that their NP exhibited good communication ("Good listeners, they always have the answer", "No loss in communication or effectiveness", "good communication and efficient", "NP is great and listens to concerns", "Good communication over the phone", "NP easy to talk to on the phone"), was attentive ("Staff pleasant and helpful", "NPs have taken care of me", "inviting", "You can talk to her about anything", "the clinic was attentive to my needs, accommodating, kind", "takes time to service patient even if behind schedule"), and thorough ("NP fast, thorough", "They're thorough includes the client in care", "NP is assertive. NP gets to the point but is very nice", "Always get looked after well and treated well. Makes appropriate referrals") during their virtual appointment. This demonstrated a positive correlation between a good NP and client satisfaction during a virtual care appointment.

Virtual care in the future

When clients discussed their overall experiences, the majority of patients stated that they would prefer face-to-face appointments in the future ("I hope for future face-to-face appointment", "I would rather in person but would like virtual appointments in the future for quick visits", "Prefer in-person appointments", "Rather come into the clinic but don't mind doing appointments over the phone", "Seeing the NP in person is preferred"), however, would like to have the option between face-to-face and virtual appointments ("I enjoyed having the option for phone appointments", "Sometimes more convenient virtually", "Likes that the option is there"). Specifying that it is dependent on the health concern ("In person wasn't necessary". "There are some issues that I would prefer to speak with someone in person", "Felt as it was an appropriate context for the situation", "Simple issues are easily addressed", "depends on what it is for") and accessibility ("doesn't have a vehicle/depends on the bus, so phone appointments can make it easier", "when roads are bad, doesn't mind telephone call", "I am happy to go in any time that I feel I need to or to have a phone appointment, whatever makes their life easier makes my life easier!", "If it can be dealt with over the telephone it is easier and I know that if I need to go in, I can", "Easy with kids to be able to attend virtually", "Phone appointments are easier for me because I'm not able to get to my appointments").

Discussion

Many clients appreciated their NP and the staff within the clinic for the care they had received and continued to during the pandemic, being grateful to have continued receiving care during the pandemic. The time the NPs had spent with clients, the trust built, and the holistic care received had helped to form therapeutic relationships that assisted with carrying client satisfaction throughout the difficult times of the pandemic. Even though this study revealed that clients prefer face-to-face appointments from the thematic analysis, the survey demonstrated that clients were still satisfied with the virtual appointment model during the COVID-19 pandemic and would like the option between virtual and in-person. With 70% of clients not requiring in-office follow-up for their virtual appointments, there is merit in the sustainability of virtual appointments with further research and the incorporation of a video interface. Consideration of incorporating telehealth and virtual care competencies within the NP curriculums would be a beneficial measure to ensure NPs are comfortable with providing care with these technologies (Dhaliwal et al., 2021). Significantly, it is important that health care practitioners become familiar with the regulatory aspects involved with telehealth, standards of care, ethics, fraud prevention, and economic aspects (Solari-Twadell et al., 2022). The addition of change management support to increase technical training, in-house organizational support, and administration support are valuable resources that should be impletion to support further integration of virtual care in PHC settings (Mohammed et al., 2021).

Limitations

Strengths of this study include recent preliminary data with a client-centered perspective of the rapid transition to virtual primary care from their NP during the COVID-19 pandemic. The use of a multimodal survey was cost-effective, and the results demonstrate generalizability and reliability. The thematic analysis allowed for interpretation, highlighting of key features, and summary of qualitative data sets. There are several limitations. COVID-19 has disproportionally affected marginalized communities, and the lack of data collection around this specific demographic makes it difficult to generalize data to these populations. There were only 84 respondents out of the 264 called, demonstrating a survey response rate of 32%. This small sample size can affect the reliability of results, as it can lead to a higher variability with the potential to result in voluntary response bias. As BScN students at Nipissing University conducted the interviews for their community placement, this could have resulted in time constraints as clients who did not answer were left voicemails to return the call voluntarily. Clients may have returned the call but were unable to complete the interview as the students were no longer in placement. This could have contributed to the smaller sample size. In the qualitative analysis, clients noted their appreciation and the positive impact their NP has had on them; this could result in biased answers regarding their perspective on virtual care aside from their relationship with their NP. All 84 participants noted their appointment was conducted by telephone call; the lack of video calls makes it difficult to know if patients prefer in-person face-to-face rather than the opportunity of face-to-face via video call. While thematic analysis is flexible, it results in a less rigorous method of analysis and can be applied broadly.

Future Research

Additional research is required to further analyze client barriers from an equitable standpoint, understand the preferred digital tool to use as an alternative to face-to-face, and the identification of standardized criteria to determine when a virtual appointment is warranted and when it should be considered on an individualized case-by-case basis. Further health equity impact assessments of virtual care during the pandemic demonstrate merit to determine if this model is adequately serving all populations along with specific initiatives that could be put into place to sustain an equitable virtual care framework, so it is accessible for all client demographics.

Conclusion

The NBNPLC reports preliminary data on patients' perspectives on transitioning to virtual care during the COVID-19 pandemic. It was noted that the majority of patients prefer face-to-face appointments, however, they remained satisfied with their virtual care appointment. Clients would appreciate the choice between virtual appointments and face-to-face appointments in the future depending on the reason for the appointment and accessibility. The convenience of virtual appointments was noted, and the thematic analysis further revealed client barriers to virtual appointments. Future research is needed to identify if virtual care can remain sustainable post-pandemic, and to make it an equitable means of healthcare delivery.

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† The starting and recommended dose of TRINTELLIX is 10 mg once daily for adults <65 years. See Product Monograph for complete dosing and administration information.

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DSM-IV-TR=*Diagnostic and Statistical Manual of Mental Disorders*, 4th edition, text revision; MADRS=Montgomery-Åsberg Depression Rating Scale; MDD=major depressive disorder; MDE=major depressive episode; SDS=Sheehan Disability Scale

* See guidelines for complete recommendations.

‡ Double-blind, fixed-dose, placebo-controlled study of 608 patients aged 18-75 years with a primary diagnosis of recurrent MDD according to DSM-IV-TR criteria, a current MDE >3 months' duration and a MADRS total score ≥26. Patients were randomized to TRINTELLIX 15 mg, 20 mg (10 mg/day during Weeks 1 and 15 or 20 mg/day from Weeks 2 to 8) or placebo for 8 weeks. Mean baseline MADRS total scores were 31.5 for placebo, 31.8 for TRINTELLIX 15 mg and 31.2 for TRINTELLIX 20 mg. Mean baseline SDS total scores were 19.8 for placebo, 20.6 for TRINTELLIX 15 mg and 20.7 for TRINTELLIX 20 mg. Mean baseline SDS work scores were 6.3 for placebo, 6.8 for TRINTELLIX 15 mg and 6.9 for TRINTELLIX 20 mg. Mean baseline SDS social scores were 6.8 for placebo, 6.9 for TRINTELLIX 15 mg and 6.8 for TRINTELLIX 20 mg. Mean baseline SDS family scores were 6.9 for placebo, 6.7 for TRINTELLIX 15 mg and 7.0 for TRINTELLIX 20 mg.

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