Child and Adolescent Mental Health Services and Interventions:

Improving Quality of Care Through Collaboration

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A thesis submitted in partial fulfillment of the requirements for the

Doctorate in Philosophy degree in Population Health

Interdisciplinary School of Health Sciences

Faculty of Health Sciences

University of Ottawa

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Acknowledgements

I would like to express my heartfelt gratitude to my family for their unwavering support and patience throughout my academic journey. Michelle and Charlie, your encouragement and understanding have been instrumental in helping me overcome the many challenges that I’ve faced throughout the last eight years. Despite the troubles and delays posed by the COVID-19 pandemic, their belief in me has been a constant source of motivation, and I am deeply thankful for their love and encouragement.

I am also immensely grateful to my supervisor, Dr. Philippe Robaey, for his invaluable guidance, expertise, and mentorship. Dr. Robaey’s insightful feedback, dedication, and belief in my work have played a pivotal role in shaping the direction of my research. His patience in answering my questions and his commitment to my growth as a researcher have been truly inspiring.

Furthermore, I would like to extend my appreciation to my thesis advisory committee for their valuable support throughout the research process. Their unyielding encouragement and understanding of the difficulties presented by the pandemic, and their flexibility in accommodating delays have been crucial in the success of my work. Dr. André Samson, our numerous projects together over the years have allowed me to grow both personally and professionally. Dr. Louise Bouchard has been my champion throughout this degree, fighting for me when the lines between academics and bureaucracy became blurred. Dr. Nick Gazzola has been a cheerful and steady presence throughout the many meetings, drafts, and other discussions we’ve had over the years.

In addition, I extend my overwhelming gratitude to Elizabeth Carreiro, research assistant at the CHEO Research Institute. Elizabeth has provided incredible assistance over the years, with hours spent together meticulously combing through participant transcripts, teasing out subtle nuances, and extracting meaningful insights. Her enthusiasm and passion for these projects has made this dissertation possible.

Lastly, I would like to acknowledge the individuals who participated in my study or provided assistance in various capacities. Without their willingness to contribute, this research would not have been possible. This work is a reflection of the combined efforts and support of many, and I am deeply thankful for every contribution, no matter how small. Your support has been an integral part of my academic journey, and for that, I am truly grateful.

Co-Authorships and Approvals

This dissertation comes as a result of regular collaboration with my thesis committee members: Dr. André Samson, Dr. Louise Bouchard, and Dr. Nick Gazzola, and thesis supervisor: Dr. Philippe Robaey. I also worked closely with researchers from the Peking University Institute of Mental Health, as well as research assistants affiliated with the Children's Hospital of Eastern Ontario Research Institute.

I received regular feedback from my thesis supervisor as well as Dr. Samson on drafts of Chapters 1, 2 and 3, while the entirety of the dissertation was edited and approved by Dr. Robaey. The article presented in Chapters 2 is a published work, therefore feedback from anonymous peer reviewers and editors affiliated with BMC Psychiatry was used for revisions. The article in Chapter 3 has been submitted for peer review and subsequent revisions will be based upon their feedback.

Approval to conduct this research was granted by the University of Ottawa on September 12th, 2020 with ethics approvals from affiliated institutions subsequently being obtained (General Appendix I). A final version of this dissertation will be submitted to the university in response to feedback from my thesis examiners following the oral defense.

General Abstract

Child and adolescent mental health conditions have gained increased attention in recent years, prompting the exploration of novel approaches for effective treatment and management. This work focuses on a comprehensive population health perspective in addressing these conditions, with a particular emphasis on Attention-Deficit/Hyperactivity Disorder (ADHD). The presented chapters encompass a diverse range of research studies aimed at identifying barriers and facilitators to mental health access, introducing clinical protocols, understanding decision-making strategies, and exploring the impact of internal and external factors on treatment outcomes, all while considering the critical lens of health equity. Chapters 2 and 3 examine the implementation of a shared-care approach to ADHD treatment in the unique context of China, delving into the identification of both barriers and facilitators that influence the adoption and effectiveness of such an approach across different metropolitan areas of the country, and within different pediatric healthcare settings. Socio-cultural factors, healthcare infrastructure, and the role of stigma are explored to shed light on the challenges and opportunities in expanding access to quality care for children and adolescents with ADHD. Presenting an innovative clinical protocol, Chapter 4 introduces a shared decision-making approach to stimulant titration for ADHD treatment. By involving patients, parents, and healthcare providers in the decision-making process, the protocol aims to enhance treatment outcomes and adherence. The significance of patient autonomy and tailored interventions is discussed, emphasizing the need to empower individuals in their healthcare journeys. Building upon the findings of Chapter 4, Chapter 5 explores the reasons behind the limited clinical adoption of placebo-controlled stimulant titration interventions for ADHD. Chapter 5 investigates the ethical, methodological, and practical considerations that have hindered, (or in some cases enabled) its use as a clinical

standard of care. Chapter 6 examines how different decision-making strategies employed in stimulant titration trials lead to varying recommended maintenance doses following the trials. Herein, a shared decision-making approach that emphasizes parental collaboration, an expert decision-making approach which mimics classical top-down medicine, and a computer-based approach using a ranked-choice voting algorithm are compared. Against the backdrop of the COVID-19 pandemic, Chapter 7 delves into the experiences of parents whose children have been diagnosed with mental health conditions. The study investigates challenges in accessing care, adapting to remote interventions, and addressing the exacerbated psychosocial stressors during the pandemic. Health equity is underscored as a central concern, as disparities in care access and support are magnified during times of crisis. Together, these works present a comprehensive exploration of child and adolescent mental health treatment from a population health perspective. The individual chapters collectively contribute to a deeper understanding of barriers, facilitators, protocols, decision-making strategies, and real-world challenges that healthcare users, practitioners, and organizational or system-level providers face, while emphasizing the critical role of health equity in shaping effective and inclusive interventions.

Chapter 1: General Introduction

This dissertation-by-article is comprised of a general introduction (Chapter 1), 6 standalone articles (Chapters 2-7) and a general conclusion (Chapter 8). Collectively, these address the research goal of reducing disparities in access, quality, and outcomes for children and adolescents with mental health needs. The general introduction provides an overview of the standalone articles, while situating them within the greater realm of population health research. Also included in the general introduction are a section on ethical considerations, and a reflexivity statement. Given the methodological differences of each article included within this dissertation, specifics related to study contexts, participants, procedures, data collection, and analysis are positioned within each individual article chapter. Included appendices contain information related to research ethics certificates (Appendix I), recruitment and consent documents (Appendix II), knowledge and dissemination activities (Appendix III), and other selected works published during my doctoral studies (Appendix IV).

Research Goals and Objectives

The goal of my doctoral dissertation is to examine a variety of situations involving the implementation or disorganization of child and youth mental health care, from the individual to the system-wide level. Contributing to population health research, the general theme is shared care in mental health between specialists and generalists, and between families and mental health professionals.

My overarching research question is as follows: how can disparities in access, quality, and outcomes for children and adolescents with ADHD and other mental health needs be reduced

from a system-level to an individual standpoint? This research question is answered through the following 6 sub-questions:

- What are the barriers and facilitators to the implementation of a nation-wide shared-care approach to ADHD treatment in a country with budding mental health care and limited resources? (Studies 1 and 2)?
- How can historical attempts at ADHD treatment inform current practices and clinical guidelines related to stimulant titration while promoting shared decision-making and patient-centered care? (Study 3)?
- Why do certain approaches to stimulant titration for the treatment of child and adolescent ADHD fail or succeed in clinical adoption? (Study 4)?
- How do different decision-making strategies compare with regards to a recommended stimulant dose for the treatment of child and adolescent ADHD (Study 5)?
- Given the dramatic changes in healthcare functioning, what are the experiences and coping strategies of parents of children with diagnosed mental health conditions during a world-wide traumatic event such as the COVID-19 pandemic (Study 6)?

A practical way of looking increasing health equity is though the use of collaborative care models and shared decision making (explored within the next section).

Theoretical Approach

Population Health and Health Inequity

Population health refers to the overall health status and wellbeing of a group of individuals within a defined population. It also encompasses the health outcomes of a group, including the distribution of such outcomes within that group. According to Kindig and Stoddart

(2003), the field of population health includes the study of health outcomes, patterns of health determinants, and the policies and interventions that link these two concepts. A population health approach addresses a variety of individual and collective factors that determine health and is intended to address whole groups or populations of people (1). Therefore, a population health approach has the goal of improving health while reducing health inequities among population groups (2). Health inequity arises from social, economic, environmental, and structural disparities that contribute to differences in health outcomes within and between a population (3). Essentially, they are system-level differences in the opportunities that groups have to achieve optimal health, leading to unfair and avoidable differences in health outcomes (4). Research into health inequity commonly stratifies its root causes into two clusters. The first, structural inequities, relates to intrapersonal, interpersonal, institutional, and systemic factors that dictate the variable distribution of power and resources across lines of group identity (sex, gender expression, sexual orientation, race, or class). Structural inequities refer to the systemic disadvantage of one social group relative to other groups with which it coexists, and the term encompasses politics, law, governance and culture and refers to race, ethnicity, gender or gender identity, class, sexual orientation and other domains (3). The second root cause, inequities related to the social determinants of health, pertains to the unequal allocation of power and resources which manifest in unequal social, economic, and environmental conditions (3). The social determinants of health are the conditions within the environments in which people live, learn, work, socialize, and age, and which affect a wide range of outcomes and risks to health, functioning and quality of life (3).

The factors that comprise the root causes of health inequity are diverse, complex, and changing. As they pertain to mental health and the overall goals of this dissertation, individual

factors related to education, stigma, vulnerability, socioeconomic status, employment, and geographic disparity are explored. Systemic factors related to education, training, resource allocation in mental health, and health systems and services are also discussed within the body of this work.

Situating Population Health, Health Equity, and Collaborative Mental Health Care

In Canada, shared mental health care is a crucial component of the broader collaborative care models that aim to blend the expertise of various health professionals to optimize patient outcomes. This approach is particularly relevant in the context of Canadian healthcare due to the country's diverse population and geographic disparities, which often affect access to mental health services. Shared mental health care in Canada typically involves a cooperative relationship between primary care providers (such as family physicians), mental health specialists (psychiatrists, psychologists, social workers), and often other health service providers like nurses and occupational therapists.

The Canadian model emphasizes the integration of services across different levels of the healthcare system. Primary care providers play a pivotal role as they often serve as the first point of contact for individuals experiencing mental health issues. These providers are not only tasked with initial assessments but also with ongoing management and coordination of care, supported by mental health specialists through a consultative model. This system allows for the development of comprehensive care plans that address both the mental and physical health needs of patients, facilitated by the shared use of health information systems that enhance communication among providers.

A commonality within the articles of my dissertation involves the use of collaborative health care models throughout a patient's health journey. Be it from the individual level, where the active participation, feedback, self-advocacy, and treatment adherence are required, to the organizational or systemic level where proactive environments are needed to support collaborative, patient-centered, and effective shared mental health care.

Collaborative care models stem from shared care, and are approaches to mental health treatment that involves a team of healthcare providers working together to support individuals with mental health concerns (5). This approach recognizes that mental health issues often have multiple contributing factors, and effective treatment may require expertise from various disciplines. Collaborative care is usually combined with stepped care, which aims to treat patients with an adequate treatment of the lowest possible intensity while continuously monitoring progress (6, 7). Finally, collaborative care models can include shared mental health care. Shared mental health care typically involves collaboration between a patient and their family, primary care providers, mental health specialists (such as psychiatrists or psychologists), and other relevant professionals (8). Shared mental health care aims to provide comprehensive and integrated care that addresses both physical and mental health needs, ensuring that individuals receive the appropriate and equitable treatment and support for their mental well-being. Sharing of care assumes collaboration between the specialist, GP, and patient, especially through shared decision making.

Health inequity significantly affects child mental health care, leading to disparities in access, quality, and outcomes for children and adolescents with mental health needs. These inequities arise from a combination of social, economic, and structural factors that disproportionately impact marginalized and vulnerable populations. Collaborative care models

can be a vessel by which the root factors that impact health inequity (mentioned in the previous section) could be addressed. Collaborative care and its role in reducing health inequities are explored within this dissertation. For example, Chapters 2 and 3 examine the sociocultural, structural, and external organizational environments that impact the implementation of a shared care pathway for the treatment of child and adolescent ADHD within country where such care is only just emerging, and resources are dramatically insufficient. Chapter 4 explores historical approaches to ADHD treatment within child and adolescent populations and argues for the widespread implementation of morally and socially responsible pharmacological treatment approaches that focus on shared decision-making and patient-centered care. Chapters 5 and 6 build upon the proposed shared decision-making stimulant titration protocol within Chapter 4, examining the uptake of innovative approaches to ADHD care and making direct comparisons between differing decision-making strategies for stimulant dosing. The concluding empirical research chapter within this dissertation (Chapter 7) takes a look at a specific population-wide traumatic event, the COVID-19 pandemic, exploring the experiences of parents of children with diagnosed mental health conditions across multiple points throughout the pandemic. Herein health disparities, social and economic implications, community resilience, and access to mental health care are examined.

Incorporating an understanding of ADHD care as well as general mental health care into population health considerations can lead to better-informed healthcare policies, improved access to appropriate treatments, reduced healthcare disparities, and ultimately better health outcomes for the community as a whole. This work is part of a broader effort to inform system-wide policies and tailor medical interventions to individual needs within the larger context of

population health improvement.

Philosophical, Theoretical, and Conceptual Frameworks

Choosing a methodology to address a research problem requires that a researcher uses an approach that acknowledges and aligns with their philosophical assumptions, the purposes of their study, the current state of knowledge relative to the area of research, and the ultimate goals of that research (9). Indeed, ontological and epistemological considerations are fundamental philosophical perspectives that shape how researchers understand, approach, and conduct their studies (10). These considerations provide the framework upon which research methods and approaches are built. Ontological considerations in population health include perspectives on the nature of health, well-being, and the determinants of health within a population (11). This thesis acknowledges the socially constructed nature of the participant's reality as well as the environmental and genetic determinants of their health. Given the heavily qualitative nature of this thesis, and the intention to describe the lived experiences of participants as is reported by those participants, this dissertation's philosophical foundation is based within hermeneutic phenomenology (12). Hermeneutic phenomenology is a philosophical and methodological approach to understanding human experience (13). The goal of phenomenological research is to explore the "essence or structure of an experience" (13) and was specifically developed for healthcare contexts (12).

Several theoretical and conceptual frameworks were used throughout this thesis, guiding the development of data collection tools, analysis, and reporting approaches. For example, Studies 1 and 2 used the Consolidated Framework for Implementing Research (CFIR) (14) to help develop the interview protocols used to explore the barriers and facilitators to implementing

a shared-care ADHD program in China. Used extensively in healthcare settings, the CFIR aids in the development of new interventions and allows for the creation of context-specific logic models and generalizable theories (14, 15). Similarly, Study 4 utilizes the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) Framework (16) which has primarily been used to identify barriers and facilitators to the adoption of a novel interventions. Often used within health implementation research (17-19), this framework guided interview questions and the presentation of results within the manuscript.

The Use of a Variety of Methods

There are a variety of differing methodological approaches incorporated within this dissertation that aid in addressing the research goals and questions. For example, the qualitative studies (1, 2, 4, and 6) primarily utilize adapted grounded theory or thematic analysis approaches, employ semi-structured interviews, or focus groups, and have theoretical frameworks guiding the protocol development. Study 3, which is quantitative in nature, proposes the use of triple-blind randomized placebo-controlled trials with daily questionnaires being used as data collection. The mixed method study, study 5, uses agreement statistics (or Kappas) as well as a thematic analysis approach. Here, surveys as well as semi-structured interviews are used. See Table 1 for an overview of the approaches used within this dissertation.

Table 1 – Overview of Methodological Approaches

Study	Design	Method	Data Collection	Framework	Participants
1	Qualitative	Adapted Grounded Theory	Focus Groups	CFIR	Mental Health Practitioners
2	Qualitative	Thematic Analysis	Focus Groups	CFIR	Pediatric Practitioners
3	Protocol Development/Quantitative	Triple-blind, Randomized Placebo-controlled Trial	Daily Questionnaires	-	Archival/Trial Participants
4	Scoping Review/Qualitative	Thematic Analysis	Semi-structured Interviews	NASSS	Titration Trial Investigators
5	Mixed Methods	Kappa/Thematic Analysis	Surveys/Semi-structured Interviews	-	Archival/MH Practitioners
6	Qualitative (Longitudinal)	Thematic Analysis	Semi-structured Interviews	-	Parents during COVID-19

The use of a variety of approaches in population health research offers unique advantages in comprehensively addressing complex health issues. For example, my mixing methods, you are offered the opportunity to receive a comprehensive understanding of health issues. Furthermore, mixed methods enhance the credibility and validity of research findings by using multiple data sources to investigate a topic. Mixed methods can uncover the complex factors contributing to health disparities, offering deeper insights into the interplay of cultural, socio-economic, and systemic influences. The adaptable nature of mixed methods is ideal for addressing the dynamic and evolving issues in population health, allowing researchers to adjust their studies in response to emerging findings. By integrating quantitative and qualitative data, mixed methods can better inform policy creation and program development, ensuring interventions are robust, culturally appropriate, and sustainable. Finally, mixed methods capture the interplay between individual

choices and external constraints, providing insights into why people behave in certain ways in relation to their health.

Reflexivity Statement

A reflexivity statement is a self-reflective piece of writing in which a researcher acknowledges and critically examines their own background, biases, assumptions, and personal experiences that may influence their research process, interpretations, and findings (20). As qualitative research is based on the subjective perception of experiences (both from participants and the researcher themselves), qualitative researchers must engage in reflexivity to account for *how* that subjectivity impacts their research goals (21).

My interest in qualitative health research began following my introduction and subsequent work with Dr. André Samson, a thesis committee member for this doctoral work. Prior to this, and stemming from the experience gained from my Master’s degree in Health: Science, Technology, and Policy, I was primarily a quantitative researcher who was much more comfortable in answering questions through statistical analysis. However, having worked on several qualitative works with Dr. Samson, and being forced to change thesis topics when my original topic was unrealizable due to the COVID-19 pandemic, my interest in such research methods began to flourish. Having little prior experience in such methods, I took several qualitative research methods courses, and under the guidance of my supervisor and thesis committee members, slowly became more comfortable with the various approaches, analyses, and inherent unique advantages that qualitative methods provide.

Researcher positionality allows for the examination of how researcher identities and biases shape a chosen research methodology (22). As a mental health researcher within a hospital setting, I am acutely aware of the complex interplay between personal identity and professional engagement. I recognize that my own background, experiences, and values can shape the way I approach research, which includes contexts related to child and adolescent mental health. Additionally, as a parent, I acknowledge the potential influence of my familial experiences on my research perspectives. These experiences have provided me with insights into the challenges families face when dealing with mental health issues. My own role as a parent ultimately results in empathy for the struggles that families face when seeking mental health care.

Given that my personal background could introduce certain biases into my work, several mitigation strategies were employed throughout the research process. In addition to continuously examining how my own identity and experiences might shape my assumptions, interpretations, and interactions with participants, each qualitative analysis was performed by myself and at least one other independent researcher. Such an approach allowed for each researcher to provide checks on potential biases and assumptions that the other could possibly be introduce to the work. Throughout the interview processes, I employed a neutral stance on the subject matter. Leading questions were not included within the interview protocols. All conclusions reached within this work were therefore based on the testimony of participants' lived experiences.

Ethical Considerations

Ethical clearance for the use of primary and/or secondary data was obtained for all studies. Studies 1 and 2 (Chapters 2 and 3) utilized semi-structured focus groups with healthcare providers in several major metropolitan regions in China. As this was a collaborative effort on

behalf of myself, the CHEO Research Institute's Mental Health Team, and the Peking University Institute of Mental Health, ethics clearance was obtained from all contributing institutions: University of Ottawa: H-02-23-9011; Children's Hospital of Eastern Ontario: 18/75X; and Peking University Sixth Hospital: (2020)伦审第(18)号.

Study 3 (Chapter 4) presents a novel protocol that employs a shared decision-making approach following stimulant titration trials for the treatment of child and adolescent ADHD. Data presented within this study is derived from past titrations done at CHEO and is archival in nature. As such, ethics clearance for the use of such data was sought by Dr. Robaey and granted in 2012 (REB clearance number: 12/84X).

Participants in Study 4 (Chapter 5) comprised of the principal investigators of research projects that used stimulant titration approaches for the clinical treatment of child and adolescent ADHD. University of Ottawa (H-02-23-8920) and CHEO Research Institute (21/79X) REB clearance was granted to perform the semi-structured interviews needed for this study. Using a mixed-methods approach, Study 5 (Chapter 6) compared three different approaches: Shared-Decision, Expert Decision, and Ranked Choice Vote Decision-making with respect to optimal recommended stimulant doses for ADHD patients following titration. University of Ottawa (H-02-23-9010) and CHEO Research Institute (21/30X) REB clearance was granted to use the quantitative data generated from physician reports, and qualitative data used to inform the study results.

As part of a larger project examining the effects of the COVID-19 pandemic on families, the final study within this work (Study 6/Chapter 7) interviewed parents of children with diagnosed mental health conditions. Research clearance was sought and granted to perform the

qualitative interviews associated with this study from both institutions in which I am affiliated: University of Ottawa (H-02-23-5707); CHEO Research Institute (21/30X).

All research activities were conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Informed, written consent was obtained from all participants with individual study consent forms available in General Appendix II.

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Chapter 2: Implementing a Canadian Shared-care ADHD Program in Beijing: Barriers and Facilitators to Consider Prior to Start-up

Citation: Maisonneuve, A.R., Bahraini, S., Liu, Y. et al. Implementing a Canadian shared-care ADHD program in Beijing: Barriers and facilitators to consider prior to start-up. BMC Psychiatry 22, 321 (2022). https://doi.org/10.1186/s12888-022-03955-7

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Abstract

Background: The shared care pathway for ADHD is a program developed in Canada with two main strategies: (a) implement a shared care pathway between general practitioners (GPs) and specialists, and (b) step up or down care so that the patient is treated at the most appropriate level of care, depending on the complexity or outcome of their illness. The current study aims to identify the challenges and facilitators of implementing this program in a Chinese mental health service setting.

Methods: Two focus groups were conducted using semi-structured interviews with a total of 7 health care providers in Beijing. An adapted grounded theory methodology using open-ended, axial, and selective coding was used for data analysis.

Results: We identified three main levels related to barriers and facilitators: (1) a sociocultural level of patients' and health care providers' perspectives; (2) a structural level related to internal and external organizational environments; (3) and the level of the intervention itself with its characteristics. The project is generally aligned with the mandates and goals of the health system, but two of the main obstacles are the varying qualifications of physicians in hospitals of different levels, implying different needs and flexible and adapted training programs, and the lack of appropriate patient referral systems between the different hospital levels.

Conclusion: Our study highlights the importance of consultation to obtain a "lay of the land" for deciding on the implementation steps of an a priori well accepted model of care.

Keywords: ADHD, Shared mental health care, Barriers and facilitators, Grounded theory, Context

Introduction

Attention Deficit Hyperactivity Disorder (ADHD) is one of the most common chronic childhood neurodevelopmental disorders. With an estimated prevalence of 5.7% of children in China (1), the number of children with ADHD in urban areas alone is around 7.1 million. ADHD is characterized by developmentally inappropriate inattention and/or hyperactivity/impulsivity and persists into adulthood in approximately 20% of those diagnosed in childhood (2). This disorder is often associated with academic underachievement (3), emotional lability (4), and behavioural problems (5). A diagnosis of ADHD increases the risk of death about twofold compared to people without ADHD, primarily due to unnatural death, especially accidents (6). ADHD that persists into adulthood can have negative consequences in an individual's personal (difficulty with relationships and an increased risk of substance abuse) and professional life (difficulty holding a job, absenteeism) (7). Although ADHD is chronic and often comorbid, it is also treatable. There is considerable evidence to support the efficacy and effectiveness of ADHD treatments (8). Although evidence for pharmacological treatments is somewhat stronger than that for non-pharmacological approaches (9), ADHD guidelines (10, 11), including Chinese guidelines (12), endorse a multi-modal approach combining medication, education and behavioural therapy. Optimal outcomes in ADHD treatment depend on adherence to guidelines and coordination of different interventions that must be planned according to patient needs.

In the Chinese urban setting, there are several challenges to the implementation of good-quality ADHD care, resulting in delayed initiation and/or poor follow-up care for most patients. In these settings, primary care is provided by general practitioners (GPs) who, for the

most part, do not consider themselves sufficiently competent to manage the diagnosis and treatment of children and adolescents with ADHD. One of the many possible reasons is that general practitioners receive only about 20h of training in general clinical psychiatry at the university level. As a consequence, patients often do not trust GPs and seek out a specialist directly. Patients predominantly consult specialists in upper-level hospitals without registering with and being referred by a GP. However, there is an extreme shortage of specialists who can manage ADHD patients. We estimated that there are in China about 500 ADHD-trained physicians for about 200 million children (ratio of 1:400,000). This shortage is exacerbated by the lack of a process to refer cases that require more complex care to specialists. As a result, patients have to wait a long time for their first or follow-up visits with a specialist. In fact, the vast majority of children with ADHD do not receive the care they need. In addition, those who are diagnosed and treated receive care in higher-level hospitals concentrated in urban areas.

These challenges must be seen in the context of major changes in the health care system since the economic reforms of the 1980s. Moving away from the rural Community Medical System and urban company-owned hospitals, China uses now a three-tiered system wherein each increasing tier is dependent on the severity of a patient's illness (13). The first tier of care, Level 1, refers to local hospitals that use basic equipment and offer basic care. District, municipal, or provincial hospitals, referred to as Level 2 hospitals, have more sophisticated equipment when compared to the former level. Finally, ministry-owned central hospitals, or Level 3 hospitals, offer a wide range of specialized cares, having the best available equipment in China. These hospitals are comparable to universities or research hospitals in North America. Just as there is a wide disparity in the level of care depending

on the type of hospital, the level of education of health care providers in China also varies widely. Currently, three levels of education are available, each level dictating where a physician can practice. Those holding a primary education level (1–3 years) are able to work as “village doctors” (13). Individuals with secondary education (2–3 years) are able to work at Level 1 and Level 2 hospitals. Physicians holding tertiary education (3–11 years) work in Level 2 or Level 3 hospitals (14). The level of care a patient receives, including the ability to prescribe medications, is highly dependent on a physician’s level of education. Some physicians still require additional training to meet the requirements of the hospital level in which they are currently employed.

To address the insufficient training for GPs and the shortage of specialists in Canada (although to a much lesser degree than in China), the Canadian Psychiatric Association and the College of Family Physicians of Canada have championed collaboration between psychiatrists and family physicians (15). This model of shared care can be generalized to other health care professionals such as pediatricians, nurses, etc. and effectively improve access to mental health care (8). GPs can play a crucial role in treating patients with uncomplicated ADHD, allowing specialists to treat patients with complicated ADHD instead, such as those with other developmental and psychiatric problems (16). With this in mind, the ADHD Shared Care Program was developed in Canada based on four essential components: care pathway, shared care, stepped care and standardization. A care pathway is an evidence-based, multidisciplinary organization of care for a defined group of patients (e.g., with a diagnosis of ADHD) over a defined period of time, in which different interventions are defined, sequenced, and documented in a way that facilitates communication and shared decision making. Stepped care allows for the most effective and

least resource-intensive treatment to be provided by primary caregivers first, and then to move to more intensive or specialized services, but only to the extent that the complexity or severity of the patient's needs requires. This ensures that care is provided by the right person, at the right time, to the right patient. This link between primary and specialty care, based on clear and agreed upon criteria, defines shared care. Finally, standardization of information enables effective and reliable communication within and between teams and with the family/patient, so that the patient moves smoothly through the various stages and levels of the care pathway. The project also includes a training program with an intensive online training core followed by weekly case discussion groups presented via videoconference by GPs with expert support over several months (e-clinic). In addition, we plan to implement a web-based intervention (Teacher Help, renamed ASSIST), which will allow teachers to learn about ADHD, and implement evidence-based strategies in their classrooms (17).

This model of care could address several challenges in the management of children with ADHD in urban China: scarcity of specialists but many more primary care providers, concentration of specialized skills, insufficient training, and lack of triage and referral system. In line with the Chinese guidelines for treating ADHD (12), the program also adopts a multimodal approach that combines educational, behavioural, and medical interventions. This paper is part of a large joint project between Canada and China with the goal of adapting and implementing the ADHD Shared Care Pathways program in the Chinese context. The current study aims to identify challenges and facilitators in adapting and implementing the ADHD Shared Care Program in a psychiatric care setting in Beijing, China.

Materials and Methods

Sample and study setting

A purposive sampling method was used to select participants who were able to make a valuable contribution in understanding facilitators and barriers to implementation of the Shared Care Pathways program in Beijing. The Primary Investigator in Beijing (L.Y) used her understanding of the local contexts to select individuals who would be the most likely to be involved in implementing the project. Two semi-structured focus group sessions were conducted, the first with three expert specialists in the field of ADHD from Beijing Sixth Hospital (FG# 1) and the second with 4 general practitioners in Hai Dian Qu Wan Shou Lu Community Health Services Center (FG#2). The first group was composed of ADHD specialists, while the second focus group was composed of physicians without any specialized training in ADHD (see Table 1 for characteristics of the research participants).

Table 1 Characteristics of the research participants

Role	Extra Training on ADHD Management	Work Experience in years (In General/The Current Care Setting)	Usual Work Setting	FG	Qualification
Child psychiatrist	Yes	50/41	Tertiary Hospital	1	As an expert to guide the whole process of ADHD treatment and nursing, and responsible for outpatient treatment
Child psychiatrist	Yes	21/18	Tertiary Hospital	1	As an expert to guide the whole process of ADHD treatment and nursing, and responsible for outpatient treatment
Child psychiatrist	Yes	18/15	Tertiary Hospital	1	As an expert to guide the whole process of ADHD treatment and nursing, and responsible for outpatient treatment
Child psychiatrist	No	32/10	Secondary Hospital	2	Clinical treatment (assessment and consultation of ADHD students)
Director of psychiatric hospital	No	32/5	Secondary Hospital	2	Registered psychiatrist in China responsible for the management and coordination of their medical center
Psychiatrist	No	24/13	Community Center	2	Clinical treatment
Director of Community Center	No	11/3	Community Center	2	Registered psychiatrist in China responsible for the management and coordination of their medical center

Data collection

Semi-structured focus groups were used to collect rich qualitative data for this research. Semi-structured interviews provide interviewers with the flexibility to explore themes that are particularly salient to participants. The Canadian researchers developed nine interview questions and specific probes to gather information on the current state of ADHD care as well as the facilitators and barriers to implement the Shared Care Pathways program in the local context (see the questions as supplemental material). The questions were developed based on the concepts of the Consolidated Framework for Implementation Research (CFIR) and were translated into Chinese. To ensure cross-cultural equivalence in translation, a 4-step translation process (forward translation, initial cross check, backward translation, and final crosscheck) was adapted from the WHO guidelines for translation (see the current study's translation guidelines as supplemental material). Because the data were collected prior to the implementation of the program in Beijing, the outline of the ADHD Shared Care Pathways program was sent to the research participants prior to the sessions. By means of sequential translation, the Canadian primary investigator (P.R) also explained the program in the beginning of the focus group sessions to ensure that everyone understand the program. Then, Chinese researchers (L.Y. & Q.Y.) asked the interview questions and facilitated discussions in the focus groups. Focus groups were done in person and were digitally recorded (audio recording only) and transcribed as a means of ensuring accurate records and analyses.

Data analysis

We analyzed the data according to the principles of Grounded Theory to identify barriers and facilitators for implementation of the project (Corbin and Strauss). The Grounded Theory is

a rigorous and well-established approach which could be used by both Canadian and Chinese researchers. It allowed us (1) to immerse ourselves in the data, (2) to follow systematic, precise and clear coding procedures for transcripts, (3) to ensure that the analysis procedure was consistent across teams, and (4) to minimize the risk of including personal biases. Each focus group transcript was coded via open, axial, and selective coding. Data was first assessed using line by line open coding, in which significant units were labeled using descriptive codes. These codes were synthesized into categories based on the units' common properties. Once we were satisfied with the open coding, researchers began the process of axial coding, whereby the relationships between the categories were determined through the researcher's interpretive lens. In completing axial coding, the research team depicted the various relations between the categories. Lastly, researchers engaged in selective coding of the data, whereby the categories and their relationships will be interpreted to describe newly emerging themes. Using a grounded theory methodology provided conceptual clarity in the identification of barriers and facilitators for project implementation. Data analysis was completed using the NVivo qualitative software package (version 12).

Data integrity

Several measures were utilized by the researcher to improve credibility and trustworthiness of the analysis, including: continuous comparative analysis, immersion in the topic of study, and persistent observation of the participants (18). Dependability was adhered to through the consistent execution of study procedures. Furthermore, transferability was increased through providing information on the context in which the research was carried out, research participants, and methods (18). To enhance confirmability, decisions made during the research

process and emergence of the findings were reviewed in joint meetings with Canadian and Chinese researchers. As our objective was to adapt and implement a Canadian model of care in China, which have two very different cultures and health care organizations, we used a multi-coder approach to ensure methodological rigor. Two coders (members of the Canadian team) independently analyzed the data and came to a consensus on the results of the analysis. An additional researcher from the Chinese team (trained by the Canadian team) independently coded the transcripts, and all three researchers reached an agreement on the barriers and facilitators they identified. This was an adapted grounded theory approach as a theory is never proposed at the end of the study. Instead, the methodology used incorporated a grounded theory approach.

Results

Several themes emerged from the data analysis of the interviews. These themes included: (1) Social level barriers and facilitators from the perspectives of clients and healthcare providers; (2) structural level barriers and facilitators related to both internal and external organizational environments; and (3) intervention related barriers and facilitators. The following sections describe these themes in detail and substantiate them using in-depth quotes taken verbatim from the participants within the study.

Social-level barriers and facilitators

Items were coded as social level if they assessed barriers/facilitators that represent the social context in which the organization is located. This theme emerged from two aspects: that of clients and that of the healthcare providers implementing the ADHD program. In what follows,

we will first explain barriers and facilitators on behalf of clients and then, barriers and facilitators on behalf of healthcare providers.

Social-level barriers on behalf of clients

Parents of children with ADHD seem to be unaccepting or distrustful of General Practitioners [GPs] working within basic level hospitals when seeking help in treating their child's mental health problems. This poor acceptance exists even when physicians within these hospitals are fully qualified and trained to treat such health problems. Instead, parents often actively seek the help of specialists within third level hospitals. As one of the participants said: *"…, if basic doctors [GPs] are trained, they may gain some knowledge about ADHD… But the question is whether the patient would like to see them…?"*. In addition, several participants indicated that there exists an overall inadequate parents' education on the importance of the psychological health of their children "*ADHD itself is a disease with unknown etiology, that is to say, it must have something to do with parents' education and family activities. … Therefore, it is necessary to provide education [for parents] in this area".* The research participants believed that this relatively low level of parental education also translates into a failure to screen for mental health problems in children. Finally, from a logistical standpoint, participants identified location and/or travel as a real barrier to accessing care. Some patients have to travel a long distance to see a specialist which is neither practical nor feasible for them. Whereas if the patients' treatment was stable, they would rather choose a place close to home to get the medication. The long queues that patients often face when seeking treatment were also seen as a barrier to accessing specialists: *"…there [at the basic level hospitals] is no need [for patients] to queue up [compared to a third level hospital] …*". Overall, with regards to social level barriers

that pertain to the Chinese clients, poor acceptance or distrust in the quality of physicians working at the basic level hospital, low parental education, and burdensome logistical barriers were chiefly identified.

Social-level facilitators on behalf of clients

In addition to the social level barriers identified by participants within the focus groups, several key facilitators were discussed to enable implementation of this project. To begin, participants indicated that the mandate and goals of the project are highly in line with the client demands within a Chinese healthcare context. Given that in the previous section, travel time and long wait times were identified barriers to accessing healthcare, participants indicated that this project would help address this issue. In particular, they believed that adopting a shared care approach would incentivize clients to visit their GPs at basic level hospitals, which would then result in lower costs and faster patient turnaround. Mentioned during one of the focus groups: "*It's quite easy to see a doctor in our hospital [basic level hospital] … there is a certain discount for taking medications from basic hospitals… and there is no need to queue up … So, the patients may go there*". Furthermore, participants believed this project would promote the education of parents, teachers, and classmates of children with ADHD, allowing for greater assistance for identification and management of children with ADHD. As one of the participants mentioned, *"… Especially in our country… the prevalence of children's problem is relatively high, their social functioning is dam aged obviously, their families, classmates, teachers will also have such needs [increased awareness about ADHD]… it is necessary to provide education in this area. One is education for parents and the other is education for teachers"*.

Developing a working partnership between GPs, specialists, teachers, and decision makers was recurrently mentioned as another facilitator during the focus groups. One of the research participants went so far as to indicate that: *"The biggest highlight of this project is integrating different parts together. Working together to get the task done instead of fighting alone individually. Personally, I think that is the biggest highlight"*.

A final facilitator to social level implementation involves assessing the acceptability of the project from the patients' perspective: "*This project includes some interview, and will also ask about patients' opinions, then … modifying the referral scheme [based on patients' feedback]. Incorporating patients' feedback can increase the chance of sustainability of the project"*.

To conclude, the client's social level facilitators comprise a mandate that matches their expectations, a belief that adopting a shared care approach would help with wait times and access to health services, promote education of parents and teachers of children with ADHD, develop a working partnership, and the ability to potentially assess of the acceptability of this project from the patients' perspective.

Social-level barriers on behalf of healthcare providers

In addition to the social level barriers regarding clients, we identified themes related to barriers faced by health care providers. For example, participants mentioned in China, specialists are often the ones in charge of training GPs. However, given an already heavy workload and the resulting time constraints, some of these specialists are often unable or unwilling to provide the necessary mental health training for GPs. As one of the participants mentioned, *"Doctors in*

Third Grade hospitals cannot frequently go to basic hospitals for training. Especially when it is very likely to be a long-term thing… So, we're … really intense with the time issue… How can I do it well, on the premise of not delaying my current work is a real challenge".

As mentioned by participants, not all physicians are authorized to prescribe stimulant medications for patients with ADHD. As such, participants indicated that there is a need for a streamlined certification process to prescribe stimulants medication. Related to this issue is the uncertainty about the legal scope of practice for different types of physicians. Several participants indicated that they had major concerns related to the risk of practicing beyond their scope of practice when treating patients with mental health challenges. For example: *"… For general practitioners, it is indeed a problem to practice beyond the scope, as a "specialist". So, in this part, I think we need to get it approved legally".*

Finally, the qualifications of physicians differ greatly from hospital to hospital, and from specialty to specialty. For example, as participants pointed out, a basic level hospital may be staffed only by undergraduates and GPs, while a third level hospital may house several specialists: "*The qualifications of doctors at different levels are quite different… some doctors at the basic hospitals are undergraduate, some are even not"*. As such, participants believed that an additional barrier to implementing the project is the heterogeneity of practitioners. Physicians who often come from different backgrounds raise a wide range of training needs in order to properly diagnose and manage patients. This situation makes the training of physicians in differing hospitals' levels complex.

In summary, the social level barriers faced by health care providers encompass issues related to training such as time constrain and heavy workload of specialists, barriers to proper

prescription certifications, and the varying qualifications held by physicians within Level 1 to 3 hospitals which cause a wide range of training needs.

Social-level facilitators on behalf of healthcare providers

Participants discussed at length the facilitators pertaining to healthcare providers in the implementation of this project. In general, they had a high degree of confidence and interest in the success of the project. For example, a participant indicated that: *"I give a score of 9* [out of 10 for success of the project*] ...I can even give 9.5, based on history, and the scientific nature of the project, as well as social needs".* Similarly, the project was seen to be highly in line with participants' own values and goals, which may facilitate its successful implementation and high sustainability. Participants often indicated that they had expectations and believed that the project would greatly *"make improvement of medical treatment"* within a Chinese context.

Structural-level barriers and facilitators

Items were coded as structural level if they assess barriers/facilitators that originate from the organizations in which the new ADHD program is being implemented (internal), or legal entities other than these organizations (external). In the following, we first explain the barriers and facilitators of the internal organization and then, the barriers and facilitators of the external organizations.

Internal organizational barriers

In speaking at length, participants identified several key barriers that they felt related to the internal organization of their respective hospitals and that could affect the implementation of the ADHD Shared Care Pathways program. Both GPs and specialists indicated that in order for this project to be successful, barriers related to an absence of support on behalf of leaders at hospitals from all levels would need to be addressed. For example, participants indicated that a lack of internal policies that would ultimately support this new program could be a barrier to implementation: *"…and, we also need their support… Whether the leaders of these hospitals support this kind of work also matters… To ensure we can do our work well, we must have policies … so that we can have full guarantee for other stuff"*.

On a related note, inadequate financial and human resources (technical and administrative staff) would greatly hinder implementation: *"we should have the resources from our hospital. Now in fact, your [referring to the tertiary level hospitals] burden is very heavy. If you do anything else, you have to make alternatives for the outpatient clinic. we should have the resources from our hospital… I don't know what the situation of the basic hospital is…Do they have enough personnel?" … "…we must have financial expenditures…"*.

Finally, participants indicated that a lack of an adequate referral system, which would allow patients to be referred from primary to specialized hospitals, and back to the primary hospital, was a definite barrier: *"The current referral system is still very imperfect…the problem is that the patients in Third Grade hospital are not transferred here [the basic level hospital] …"*. Therefore, it is necessary to design a proper referral system between the hospitals where the project will be implemented.

To conclude, internal organizational barriers identified by participants in both focus groups included insufficient organizational support, a lack of financial and human resources, and an unclear or nonexistent patient referral system.

Internal organizational facilitators

The compatibility of the project with the organizational culture present within many of the participating hospitals was mentioned as a major facilitator: "*According to the history, it [the designated hospital's culture and values] is matched [with the current project]".* One of the participants explained that the culture of their hospital supports innovation, and that is the reason for this compatibility. As was elaborated by another participant: *"... I think there should be no problem in the aspect of culture... In fact, in terms of our values and culture, we serve the general population and definitely can provide such services for children."*

Some of the hospitals that were represented by the focus group participants have ongoing connections within their communities, including their local school systems, which increases the chance of success in implementation of the project. Such connections were indicated by almost all participants: "*In fact, I think, especially in psychiatry, we have done some services in schools, including primary and secondary schools, and we also have certain communication with schools."*

External organizational barriers

External organizational barriers were identified in the form of an absence of support on behalf of municipal and state governments. Namely, participants indicated that inadequate

government level involvement would ultimately hinder the implementation of this project (or any others like it): *"Some of the slogans we have been spoken for 10 years did not solve the problem, and some of the medical staff have changed careers…That's why I emphasized that in this process, we should let the decisionmakers [at the governmental level] participate and let them have a look at the actual situation. Otherwise, doctors in the top hospitals are too burdened to think or study at all"*.

External organizational facilitators

Many external organization facilitators were discussed by the participants from both focus groups. For example, participants indicated that the mandate of the project was highly compatible with the needs of current medical triage practices and the current direction of medical care organization, particularly in Beijing. One of the participants mentioned the project was highly compatible with the *"management system of the Haidian district"*.

Participants named a hospital in Beijing that has been relatively successful in the grading diagnosis, and treatment of patients by expert medical teams: *"I know they have expert teams …such as for depression, ADHD,* etc.*… the number of outpatients of their attending doctors is relatively large… Top experts have to be recommended level by level…"*. Since an appropriate patient referral system was deemed necessary for the current project, the use of the aforementioned hospital's patient referral model was suggested as a possible facilitator.

Intervention-related barriers and facilitators

Items were coded as intervention level if they assess barriers/facilitators that were aspects of the proposed ADHD Shared Care Pathways program to be implemented. In the following, first the barriers and then the facilitators related to this theme have been explained.

Intervention-related barriers

The participants indicated the need for a detailed outline of the proposed program. Herein, participants wanted details on all internal procedures, especially as they pertain to the referral system. One of the participants asked: *"For example, this kid has been treated, but he has relapsed later. Under this situation… should we tell the child to go to the specialist directly or wait for the specialist to come over?"*. Another participant mentioned: *"But we should discuss what you [GPs] come to us [Specialist] [to receive training] for, and what tasks you [GPs] need to solve after you go back [to your hospital]"*.

Related to this aforementioned barrier, participants indicated that the program outline should consider the reality or context of China's current healthcare setting. For example, this program should take into account the limited availability of specialists who can provide training for GPs: "*I'm also thinking about the time issue if I'm going to do something really detailed. Because there are so many things in hand…"*.

The final barrier pertains to the current design of the training program. One of the participants felt that online training may not be sufficient for their needs: "*In the past, there was such [online] training because of the inconvenient transportation. But the effect of the training*

was not very good". The failure to provide additional in-person training could hinder the learning of those involved in the project.

Overall, intervention related barriers encompassed limited detail in the program outline, unavailability of specialists who can provide training, and the possibility that online training may be inadequate.

Intervention-related facilitators

A significant number of facilitators that were identified within this study pertain to the intervention. To begin, participants described the rigorous design of the project very acceptable for stakeholders in China. As was elucidated: *"the design of this research is very rigorous…there are very rigorous qualitative research methods… Through such a model, once established, it must be very scientific, effective, and generalizable".*

Participants indicated that a series of exams, designed for the online course, would increase the overall effectiveness of the training: *"We can add in exams. So online training plus exams, some tasks and so on. This will be better".* Further related to the training aspect of this intervention, they felt that adequate time should be allocated to specialists to prepare the courses (in cases where they train GPs), and that dividing the training tasks among differing specialists would reduce the overall burden associated with meeting training goals.

Another suggested facilitator to the project would be ensuring that the tools used to assess the project are short and/or simple and that the project is completed in small, adaptive parts; much like a pilot: "*But I still have some ideas. Don't do too much at one time, because I think starting from one point, then after you have accumulated enough experience and made some*

improvement, you can slowly move on". Participants mentioned having a clearly stated end goal for the project would also contribute to the sustainability and overall longevity of the project.

In conclusion, the intervention-related facilitators that were discussed by participants included the strong scientific foundations that make up this study, the allocation of adequate time to prepare training, the use of training tests, ensuring that the questionnaires/assessments used during the study do not overwhelm participants, and having a clearly stated end goal for the project.

Discussion

The purpose of this study was to assess the challenges and facilitators in adapting and implementing an ADHD Shared Care Pathways program developed in Canada in a Chinese context, specifically in a mental health setting in Beijing. In this study, we engaged healthcare providers (specialists and GPs) who work at designated hospitals where the project will be implemented in future. Understanding the challenges and facilitators from the viewpoint of those who are likely to be able to use the results of this research in their practice can enhance research uptake and project sustainability in a similar context (19). In the current study we identified three main themes: (1) Social-level barriers and facilitators faced by health care users and healthcare providers; (2) structural level barriers and facilitators related to both internal and external organizational environments; and (3) barriers and facilitators specifically related to our intervention. Understandably, these themes are a result of the differences between Chinese and Canadian approaches and therefore can both hinder or facilitate the implementation of the shared care approach to ADHD management.

Socio-cultural barriers

As a preface, our analysis of the sociocultural barriers in implementing a Canadian shared care approach to ADHD treatment in China included parental low level of education, mistrust in the Chinese primary healthcare system, long travel times due to the geographic layout of Beijing hospitals, and the low perceived competence of healthcare practitioners. These barriers may partly explain why ADHD is detected in some children and not in others in a timely manner. Low parental education about mental health issues, which in turn translated into a failure to engage in treatment seeking behaviours, was one of the main sociocultural barriers identified by our participants to program implementation. This issue is exacerbated by the patients' mistrust in the quality of GPs and their preference to consult specialists for most of their health needs. Given Beijing's geographic layout, many patients must travel long distances to visit these specialists who are in few numbers and only available in a few third level hospitals. The cumulative effect of this ultimately results in longer wait times as more and more patients opt for this option. On the other hand, our research participants mentioned that many GPs do not consider themselves competent enough to be in charge of the diagnosis and treatment of children with ADHD. As a result, they refer the patients to the third level hospitals which worsens the waiting time to access specialists. According to participants, the varying qualifications of GPs in China may account for this perceived poor competence, as not all of them receive the same level of medical education and are licensed to prescribe stimulant medication.

Clients' treatment seeking behaviours is highly important for timely recognition and quality management of ADHD (20). Results of our study attribute this failure to engage in care seeking to parents' insufficient knowledge about mental health issues and mistrust in health services provided by GPs at the first and second level hospitals. Such findings highlight the need

for community education regarding indicators, proper treatment, and available healthcare services for ADHD. To date, the source of parents' lack of trust has not been studied in China. However, it may be rooted in the lower level of education of physicians in first and second level hospitals. According to the China Health Statistics (13), 55.2% of licensed GPs in cities and 82.4% in rural areas did not hold a bachelor's degree from a medical university. Patients may expect physicians to be able to meet all of their health needs, but because this expectation is excessive for the capabilities of primary care physicians, it can cause dissatisfaction and mistrust when it is not met. Parents' distrust in health services has also been reported in Western countries as a barrier to ADHD treatment seeking behavior (21). However, the societal perception of ADHD can fuel this mistrust. For example, the claim that ADHD does not exist but is the manifestation of many different disorders that should be treated separately and that grouping them together under the single diagnosis of ADHD has triggered an unwarranted epidemic of stimulants is likely to contribute to the public's distrust of medical treatment for ADHD (22). Other parents perceive ADHD as a means of increasing profits for the pharmaceutical industry and its affiliates, and a series of class actions federal lawsuits were filled in the US alleging that the American Psychiatric Association was aiding and abetting an "inappropriate use" of stimulant medication (23, 24). While such actions may undermine parental confidence in the validity of ADHD diagnosis and treatment, the majority of pediatricians in the United States reported in both 2004 and 2013 that they lack confidence and training in the use of psychotropic medications (25). In the UK, as in many other Western countries, the general practitioner is the gatekeeper for referral to a specialist, and their inability or unwilling ness to identify ADHD is the main barrier to treatment (26). In conclusion, in both health systems, insufficient training of general practitioners thus contributes to delayed access to care, either

because wary parents bypass the general practitioner or because the general practitioner consulted is poorly trained to make a diagnosis or referral. To varying degrees, as we estimated a ratio of qualified specialists to the child population of 1:40,000 in Canada and 1:400,000 in China, the short age of specialists exacerbates difficulties in accessing care.

Socio-cultural facilitators

Our research participants believed adopting the Shared Care Pathways program would help overcome some of the aforementioned sociocultural barriers. Through this program, GPs will be trained to provide screening and initial ADHD treatment. Training GPs not only increases their own confidence in managing ADHD, but also enhances parents' trust in the services that GPs provide. Training ultimately promotes patients' access to health services and initiation of timely treatment as GPs are more accessible than specialists. However, if a patient's level of care exceeds that of routine care, the GP will be able to receive a consultation from a specialist and refer patients to that specialist if necessary, and thus ultimately facilitate access to more specialized care. Participants of our research also mentioned this program will facilitate community education by providing training programs for parents and teachers about ADHD through schools. On the other hand, they believed the Shared Care Pathways program is consistent with healthcare providers' own values and goals. Therefore, they would be very interested in implementing the program in their care settings. According to the Consolidated Framework for Implementing Research (CFIR) (27), effective implementation can be anticipated by the extent to which the project goal matches the needs and values of patients and care providers. The more alignment they perceive between the meaning they attach to the new

approach and their needs, the more readily they accept the proposed approach and subsequently contribute to its successful implementation (27).

Structural-level barriers

Our analysis revealed several organizational barriers that may hinder the implementation of a shared care approach to ADHD treatment in China. From a hospital specific standpoint, the absence of support from leaders, limited resources, and an inappropriate patient referral system were identified as chief concerns. An overarching and exacerbating component may be the limited support from municipal and state governments for mental healthcare in China. Therefore, our research participants believed that implementing the new approach requires internal and governmental policies, resource allocation, and technical support, especially to establish effective referral systems within the hospitals.

Leadership commitment in terms of interest and engagement in a new approach leads to a better implementation climate and subsequently implementation effectiveness (28, 29). High and middle level hospital leaders play a critical role in providing internal policies, negotiating resources, creating a climate to support employees' learning, and fostering collaboration across teams (30, 31). According to Gershon et al. (2004), the compatibility of the new intervention with the organization goal as well as the engagement of leaders in the decision-making process regarding implementation increase the likelihood of their support (31). Leadership support is crucial to develop capacities, especially those needed for the specific implementation of this project. The innovation-specific capacities should be expanded at the individual level (motivation and skills) and at the organizational level (human, technical, physical, and financial resources) (32, 33). Building specific capacities will allow the project to continue without further

dependence on external support. In the long run, a national support pol icy and guidelines are necessary to establish all the essential resources to improve the efficiency and sustainability of new implementations (27).

Structural-level facilitators

As in response to the concerns just described, research participants believed that the compatibility of the project with the culture of the designated hospitals (e.g., sup porting new and innovative approaches) and the current direction of local government can facilitate the dialogue with them to overcome the structural barriers just discussed. In 2016, Peking University Sixth Hospital signed an agreement with the Haidian Mental Health Hospital and associated community hospitals to develop a partnership to improve the management of mental health services in lower-level hospitals. Under this agreement, these hospitals will work together to provide logistic support (e.g., space, salary and training) and implement referral policies between primary and specialized ser vices. The shared care pathways program fits within this agreement as if it were arising from it, as it promotes a collaborative approach between different level hospitals. Research participants emphasized that the designated hospitals also have a good connection with schools, which facilitates the implementation of the program's web-based intervention in the schools. Cosmopolitanism is an important factor that impacts the success of implementation (27). Organizations that establish external networking are more prone to implement new practices quickly (34). In highly cosmopolitan organizations, peer pressure (i.e., emulation among organizations) has a positive association with implementation success, as demonstrated by the example of another hospital in Beijing that developed a referral system that could serve as a model in this project.

Intervention-level barriers

In general, two main related factors emerged that require special attention: the issue of accountability of the different stakeholders in the project, and the issue of stake holder competence development. These two factors are related as participants can be held accountable for their role only to the degree that they have the competencies to fulfill it.

To begin, the participants identified as a barrier the need for a more detailed description of the proposed program, particularly with respect to the referral system and the roles of different levels of physicians. In this con text, accountability means that everyone understands and accepts their assigned role and feels responsible for accomplishing their designated tasks (35). The detailed assignment of accountabilities (i.e., who does what and when) has been identified as extremely helpful for the research uptake (36). In keeping with this principle of accountability, a care pathway is a set of discrete but related interventions for which it is clear who is responsible for what (37). However, within a care pathway, how the care process is organized, and the respective responsibilities are defined, depends on the existing guidelines and the level of agreement between team members. Therefore, the different professionals involved in the care pathway need to reach a solid agreement on the details of the different steps, and on how to share responsibilities. This agreement can only be reached through a consensus process, and the details of responsibilities can only be defined after the adoption of an overall plan and initial training, which allows team members to define their more advanced training needs, and gain confidence that they are capable of fulfilling their assigned role. Above all, the Canadian team wanted to avoid the project being perceived as a "copy and paste" of a foreign model. On the other hand, identifying that we had given little detail about responsibilities as a barrier showed that

participants fully understood that the key to an effective care pathway is that responsibilities must be clear and transparent.

Another identified barrier was the possibility that our project would not sufficiently take into account the reality of the Chinese healthcare system, and in particular the limited number of specialists available in each hospital. Because of their heavy clinical responsibilities, specialists have very little time available to train GPs. No one disputes the need for training, however, as the suboptimal training of many primary care providers was clearly identified as a social barrier. Improving the quality of training was the first recommendation of a recent synthesis paper on the quality of primary care in China. This training should enable them to achieve an adequate level of clinical skills and prepare them to work in inter professional teams (38). While one way to address this limited availability is to use self-paced online trainings, this solution itself faces the identified barrier that such online trainings were felt to be inadequate for developing the skills and knowledge necessary for successful implementation of our intervention. It is true that the common 'gold standard' for training health care providers is in-person workshops, supplemented with manuals and clinical supervision (39). However, a metanalysis concluded that online methods may be as effective as alternative methods for training clinicians for the outcomes of knowledge and clinical behaviour (40). In China, a teacher-focused tradition created an expectation that the learner must acquire a legitimate knowledge directly from teachers rather than taking responsibility for their own training in a more interactive, self-paced, web-based pedagogy (41). While in-person training is certainly valued, there is also a desire for innovative alternative practices, which are further enhanced by restrictions on travel and meetings with the current COVID19 crisis.

Intervention level facilitators

In terms of intervention-specific facilitators, participants mentioned that the project had a strong scientific basis. Similarly, having a clearly defined endpoint and proposing clinical assessment tools that would not overwhelm participants were also seen as facilitators. Finally, allowing sufficient time for specialists to prepare materials for training GPs and evaluating the effectiveness of the training were also identified as factors facilitating the success of the training phase of the project.

In China, most of the research stops at publication, but the awareness is growing that the next step is to apply the research to solve real-life problems (42). The use of evidence is related to the level of scientific literacy of health care decision makers (43) and trust in the quality of research (44). Policymakers use information they can trust. A project with rigorous methodologies and scientific references, especially if supported by a trusted international organization, is more likely to be adopted (35). This international research project, conducted under the auspices of the Global Alliance for Chronic Diseases (GACD) and funded by China and Canada, met the conditions to be seen as scientifically sound. Along the same lines, having clear objectives and proposing well-structured research materials are also facilitators of successful implementation of the intervention (45). Three studies conducted in Australia, Canada, and Ireland which explore the factors influencing research utilization in each country highlighted the importance of clear articulation of the research with the knowledge users (46–48). Compatible with the results of our study, these three studies identified having clear goals and providing well-structured research materials as intervention-related facilitators to success of implementation.

As outlined by the CFIR (2009), the level of resources that are dedicated to implementing a project such as time, funds, and staff reveals the degree of the feasibility of the innovation (27). Along with the aforementioned factors, the stakeholders' willingness for change and to provide the conditions for the change (e.g., time for preparation, etc.) plays a crucial role in feasibility of innovation.

Identified barriers and facilitators in this study can, at their roots, be attributed to the differing sociopolitical and cultural contexts unique to the Chinese healthcare system. Although both Canada (the country that the program was originally developed in) and China have relatively strong and responsive healthcare systems, their core makeup can be very different. It was important to understand the healthcare landscape in China in order to properly situate our intervention within its greater context.

Limitations

Limitations of the study relate to the relatively low number of participants in this research which may reduce the variety of perspectives. The number of participants was dictated by the small number of ADHD specialists and the limited availability of specialists and general practitioners in tertiary, secondary, and community health settings.

Interviewing service users themselves would have been useful but proved impossible at this early stage. Our Chinese stakeholders felt that service users would not come and participate effectively in the focus group discussions because they do not yet trust general practitioners, but that they could be involved in the evaluation of the project once the referral system and training were in place.

Delimitations

Delimitations for this study include geographical restriction to Beijing, potentially limiting broader applicability. The study employs purposive sampling focused on healthcare professionals directly involved in the program, omitting other stakeholders like patients or policy makers. It is conducted through two semi-structured focus groups, one with ADHD specialists and the other with general practitioners, which could limit the diversity of medical perspectives and exclude non-medical viewpoints. The use of focus groups may not capture individual experiences comprehensively due to the group setting. These methodological and participant selection choices define the study's scope, influencing the interpretation and transferability of its findings.

Conclusion

We conducted a qualitative study to systematically examine the factors influencing the implementation of the ADHD Shared Care Pathways program in a Chinese context. We learned that there are a number of factors which could hinder or improve the uptake of the program in China, including issues relating to the program itself (intervention factors), aspects relating to clients and healthcare providers (sociocultural factors), and the context where the knowledge will be used (structural factors). The identified barriers and facilitators contribute to the adaptation of the program to fit local circumstances and eventually increase uptake and sustained use of the program. Two of the major barriers in China that may interfere with the implementation of the program are first, varying qualifications held by physicians within differing hospitals which suggest a wide range of training needs regarding ADHD management, and second, lack of appropriate patient referral systems between different levels of hospitals.

Our chosen approach allows us to slowly and dynamically implement a shared care approach within a very different context in which it was first developed. Instead of inserting ourselves within a vastly different medical system and dictating changes, our adaptive approach allows for the proper identification and allocation of resources and fosters investment in the goals of the project. We are continuing our collaboration with the local stakeholders to overcome other identified barriers in order to enhance the possibility of successful implementation. An effective implementation improves timely and quality ADHD management in children and adolescents and could also be a model for many other similar conditions in China or other developing countries.

Declarations

Acknowledgements

The authors would like to acknowledge and thank those who participated in the focus groups.

Authors' contributions

SB performed the data analysis and was a major contributor in writing the manuscript. AM performed the data analysis and was a major contributor in writing the manuscript. YL performed the data analysis and was a major contributor in writing the manuscript. AS aided in the literature review and data interpretation. QY aided in the literature review and data interpretation. FL developed the protocol and aided in data interpretation. LY developed the protocol and aided in data interpretation. PR developed the research design, supervised the

analyses, aided in the literature review and data interpretation and revised the manuscript. The authors read and approved the final manuscript.

Funding

This work was supported by the National Natural Science Foundation of China 8171101223 and Canadian Institutes of Health Research GAC154987.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

All work was conducted with the approval of relevant ethics committees (Children's Hospital of Eastern Ontario REB Protocol No: 18/75X; Peking University Sixth Hospital (2020)伦审第(18)号 and follows the principles of the Declaration of Helsinki. Informed consent was obtained from all participants prior to data collection.

Competing interests

The authors declare that they have no competing interests.

Appendix 1 - Focus Group Interview Questions

1. What is your perception of this new ADHD program with regard to evidence strength and scientific quality?
2. What kinds of changes do you think you will need to make to implement the new ADHD program, so it will work effectively in your setting? Do you think you will be able to make these changes in your setting?
3. How complex does the new ADHD program looks like for you, when it comes to duration, scope, number of steps, type of professionals and organizations involved?
4. What kind of training is needed to successfully implement the project?
5. How would you describe the culture (general beliefs, values, assumptions that people embrace) of your organization? Of your own setting or unit? How do you think your organization's culture will affect the implementation of the new ADHD program?
6. Is there a strong need for this new ADHD program?
7. Do you expect to have sufficient resources (including money, training, education, physical space, and time) to implement and administer the new ADHD program? [If Yes] What resources are you counting on?
8. How confident are you that you will be able to successfully provide changes or take actions to achieve the implementation goals of the new ADHD program? What gives you that level of confidence (or lack of confidence)?
9. What do you prefer about the new ADHD program?

Appendix 2 - Translation Guideline

Dear Translators,

The objective of the current study is to adapt a Canadian shared care model for Attention-Deficit/Hyperactivity Disorder (ADHD) to Chinese hospitals. To achieve this goal, we need to translate research materials such as questionnaires, interview questions, and codebooks.

Process of Translation of the Research Materials:

The aim of this process is to achieve Chinese or English research materials that are conceptually equivalent in each of the target countries/cultures. That is, the English and Chinese research materials such as a questionnaire should be equally natural and acceptable and should practically perform in the same way. The focus is on cross-cultural and conceptual, rather than on linguistic/literal equivalence. A well-established method to achieve this goal is to use forward-translations and back-translations. Implementation of this method includes the following steps:

- Forward-translation
- Initial Cross-check
- Back-translation
- Final Cross-check

1) Forward-translation

The translator should be knowledgeable of the second language culture, but his/her mother tongue should be the primary language of the target culture (i.e., a Chinese native speaker preferably translates English materials to Chinese)

We emphasize conceptual rather than literal translations and stress the need to use natural and acceptable language for the broadest audience. The following general guidelines should be considered in this process:

- Translators should always aim at the conceptual equivalent of a word or phrase, not a word-for-word translation, i.e. not a literal translation. The translator should consider the definition of the original term and attempt to translate it in the most relevant way.
- Translators should strive to be simple, clear and concise in formulating a question. Fewer words are better. Long sentences with many clauses should be avoided.
- The target language should aim for the most common audience. Translators should avoid addressing professional audiences such as those in medicine or any other professional group. They should consider the typical respondent for the instrument being translated and what the respondent will understand when she/he hears the question.

  Translators should avoid the use of any jargon. For example, they should not use technical terms that cannot be understood clearly; and colloquialism, idioms or vernacular terms that cannot be understood by common people in everyday life.
- Translators should consider issues of gender and age applicability and avoid any terms that might be considered offensive to the target population.

2) Initial Cross-Check

An expert in the mental health field (Preferably, bilingual in English and Chinese) will cross-check the forward translation. The goal in this step is to identify and resolve the inadequate expressions/concepts of the translation, as well as any discrepancies between the forward

translation and the existing or comparable previous versions of the questions if any. The expert may question some words or expressions and suggest alternatives. The principal investigator or the research advisor will provide the expert any materials that can help her/him to be consistent with previous translations. The expert will be in touch with the principal investigator and the forward translator.

The result of this process will produce a complete translated version of the research material.

3) Back-translation

Using the same approach as that outlined in the first step, the research material will then be translated back to the original language that it was initially developed by an independent translator, whose mother tongue is the target culture and who has no knowledge of the research material.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence and not linguistic equivalence.

4) Final Cross-check

The forward translator will compare the original research material, forward translation, and back translation. Discrepancies should be discussed with an expert in the mental health field and the back-translator. Further work should be iterated as many times as needed until a satisfactory version is reached. The forward translator will prepare the final version after resolving conflicts.

Translators’ role throughout the translation process:

Translators’ responsibilities include reading, thoroughly understanding, translating the given materials, and proofreading finished pieces of work. To be successful in this role, the translators should have a keen eye for detail. Ultimately, they will provide ready-to-use translated content that meets the internal needs of the project.

Readability of the document: Translators should ensure that the information is translated at a reading level appropriate for general population. We have determined a general grade 8 reading level using Flesch–Kincaid.

How to check readability of the document in Word

- Click the File tab, and then click Options.
- Click Proofing.
- Under When correcting spelling and grammar in Word, make sure the Check grammar with spelling check box is selected.
- Select Show readability statistics.

After you enable this feature, open a file that you want to check, and check the spelling by pressing F7 or going to Review > Spelling & Grammar. When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

Important: You must correct, or ignore, all spelling errors found in the document before the readability statistics will display. If there are still any red squiggles in the file, the readability statistics won't display.

Recommendations

- Translators should read the original versions very carefully to make sure if they fully understand the meanings. If the translator is not sure about the meaning of a work or sentence, they should contact the expert that research coordinator has introduced to her/him.
- After translation, please read the original version carefully and make sure that you don't miss some information.
- Read out loud and edit the translated version several times, until you feel that it is readable and is easy to be understood by a native speaker.

Using the same approach as that outlined in the first step, the research material will then be translated back to the original language that it was initially developed by an independent translator, whose mother tongue is the target culture and who has no knowledge of the research material.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence and not linguistic equivalence.

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Chapter 3: Barriers and Facilitators to Implementing a Canadian Shared-Care ADHD Program in Pediatric Settings in Shanghai: A Consolidated Framework for Implementation Research Approach

Submitted to: BMC Health Services Research

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Abstract

Objectives: The vast majority of children with attention deficit hyperactivity disorder (ADHD) do not have access to proper diagnosis and treatment in China. The goal of this project is to identify the challenges and facilitators in implementing a Canadian ADHD Shared Care Pathways program in pediatric settings in Shanghai region.

Methods: Purposive semi-structured focus groups were conducted on a total of 13 healthcare practitioners from the Shanghai Xinuha, Ninghai and Chongming hospitals. Two independent researchers conducted a thematic analysis of the data with themes emerging based on the Consolidated Framework for Implementation Research (CFIR).

Results: Notable barriers identified by participants included: 1) lack of knowledge in the management of ADHD, primarily among general practitioners; 2) lack of resources such as lack of staff, time, and medication for ADHD; 3) challenges in implementing an international multicentre intervention (such as communication difficulties between teams and integration of resources available in different hospitals); and 4) mental health stigma, difficulties in identifying ADHD patients, and logistical problems related to medication procurement rules put in place by provincial governments. Notable facilitators included: 1) the strong motivation of stakeholders and their confidence in their ability to learn and subsequently execute action plans to achieve the implementation goal; 2) the compatibility between the values and goals of the stakeholders and those of the program despite some cultural tension, a positive learning climate, strong tensions for change, and the high interest of organization leaders in engaging in the program 3) the perceived benefits of the program, such as standardization of the diagnostic and treatment process, and engaging primary care providers in ADHD management; and 4) the strong relationship between participating institutions and schools as well as provincial health initiatives

available to support collaborative models of care. Mixed factors to implementation were also explored.

Conclusions: Appropriate training of health care providers, cultural adaptation of the program, increase public awareness about ADHD to decrease stigma, as well as strong project management and guidelines that clearly describe the role and expectations of each team member appeared essential to successful implementation.

Key Words: ADHD, Shared care model, Barriers and Facilitators, Consolidated Framework for Implementation Research, Qualitative research

Introduction

Attention-Deficit Hyperactivity Disorder (ADHD) is one of the most common chronic childhood neurodevelopmental disorders, characterized by developmentally inappropriate inattention, hyperactivity and/or impulsiveness (21). Widely accepted as a disorder in the Western world, despite ongoing controversies about its nature and treatment, particularly with medications, ADHD is increasingly being diagnosed within East Asia. ADHD has an estimated prevalence of 6.3 percent of children in China (22) and is associated with academic underachievement (23), emotional liability (24), and behavioural problems (25). ADHD is highly heritable, with offspring having approximately a 34% chance of being diagnosed with ADHD when both parents are (26, 27). It is a chronic disorder with 50% of those individuals diagnosed in childhood continuing to meet DSM-IV criteria for ADHD as adults (28). In adults living with ADHD the condition often manifests as a sense of internal restlessness, deficits in higher-level executive functioning, and emotion control (29, 30). This can often result in challenges in maintaining relationships, increased risk of substance abuse, and occupational difficulties (31-33). North American, European, and Chinese ADHD treatment guidelines recommend a multimodal treatment approach which combines medication, education, and behavioural therapy (34-37). Although we well know how to treat ADHD effectively, it remains difficult to treat well, because the outcome depends on a multi-modal, multi-professional, inter-agency approach, monitoring and adherence to treatment, and the management of other associated developmental disorders (38).

There are several challenges in the implementation of good-quality ADHD care in China. Such challenges can be viewed from both historical and cultural perspectives. China has undergone major economic reforms since the 1980s. Whereas previously medical services were

accessed using rural community-led clinics and urban private hospitals, the Chinese medical system now comprises of different levels of hospitals, with varying levels of care spread around the country. Level 1 hospitals offer basic levels of care and are often located in rural communities. Level 2 hospitals offer increased care and make use of better equipment when compared to Level 1 hospitals, and are located in denser municipalities, districts, or provinces. Level 3 hospitals offer specialized care and are the best equipped health facilities within the country (39). The level of education a physician has achieved in China dictates the type of hospital in which they may be employed. “Village doctors” hold a primary education level (1-3 years) and may work within rural communities. Physicians that hold secondary education (2-3 years) are permitted to work at Level 1 and Level 2 hospitals. Physicians with tertiary education (3+ years) may work in Level 2 and Level 3 hospitals. That being said, many hospitals within China require additional physician training in order to meet the requirements for employment (39). The level of care that a patient receives is ultimately dependent on the treating physician’s level of education. These differences in education create problems with the diagnosis and treatment of children with ADHD within the country, resulting in delayed initiation and/or poor follow-up care for most patients. Primary care within Chinese urban settings is provided by General Practitioners (GPs) who are undertrained in general clinical psychiatry at the university level (40, 41). As a result, these GPs often consider themselves not sufficiently competent to manage the diagnosis and treatment of children and adolescents with ADHD. Conversely, patients seeking mental health treatment often opt for specialist treatment within Level 3 hospitals without first seeking referrals from GPs due to a lack of trust in the treating abilities of GPs. This treatment seeking behaviour, coupled with an extreme shortage of specialists trained in ADHD management (approximately 500 specialists for 200 million children) creates an

enormous burden in the mental health system within China. Patients are often faced with lengthy wait times for initial treatment and follow-up visits, must travel long distances to receive care (specialists are primarily located in dense urban areas) and in general, many do not receive the proper ADHD care that they require.

This shortage of specialists and inadequate training of general practitioners is not unique to China. In Canada, several systemic changes have been implemented to address these problems. For example, the Canadian Psychiatric Association and the College of Family Physicians of Canada have established strong collaborative bonds between family physicians and psychiatrists to promote timely evaluation and treatment for mental health conditions (42-44). Patients with uncomplicated mental health problems are treated by GPs while consultation-liaisons by specialists meet the needs of the most complex patients (45). Such a shared care approach can be generalized to other healthcare professionals such as pediatricians, nurses, therapists, and community resource managers to improve access to mental health care (46).

With this in mind the ADHD Shared Care Program focuses on four core principles: patient care pathway, shared care, stepped care, and standardization of information. Within the patient care pathway, treatment is based on relevant evidence and the work of a multidisciplinary team that focuses on a defined group of patients (those diagnosed with ADHD). Treatment takes place over a specified timeframe during which different intervention are defined within a pathway, implemented, and documented with the goal of facilitating communication and shared decision making. Stepped care defines how treatment is delivered according to the needs of the patient. This means that the most effective and least resource-intensive treatment is provided by PCPs, while more intensive and specialized services are more frequently used as the severity of the condition increases. Shared care relies on effective collaboration and communication based on

defined criteria between primary and specialized care caregivers. Finally, standardization ensures effective and reliable communication of information within and between care teams and the family/patient. This allows a patient to transition from one stage to another, and from one level of care to another in the most cost-effective and timely manner.

In China, the vast majority of children with ADHD do not have access to timely diagnosis and treatment in China. A shared-care approach could address several difficulties in the management of children with ADHD in China by addressing the scarcity of specialists, the complexity of a systematic approach to ADHD, and the lack of training of PCPs. In line with Chinese guidelines for diagnosis and treatment (37), the program also provides multimodal treatment combining educational, behavioral, and pharmacological approaches. This program promotes shared responsibilities between PCPs and specialists within a well-defined care pathway. Within this shared-care perspective, it is essential to define which specialists are best able to successfully collaborate with PCPs and in what setting. In China, despite progress over the last decades, there is an extreme dearth of child psychiatrists overall (47, 48). In a previous study, we examined the barriers and factors to implementing an ADHD treatment program in the Beijing psychiatric environment (49), where a level 3 psychiatric hospital (Sixth Hospital of Peking University) had entered into a partnership with Haidian Mental Health Hospital and associated community hospitals to improve the management of mental health services in lower-level hospitals. However, to address this shortage of specialist, pediatricians and some GPs also are a resource, as they are encouraged to train in the early diagnosis and basic treatment of the most common mental health disorders in childhood. Moreover, Developmental Behavioral Pediatrics is recognized as a pediatric subspecialty in China. Developmental behavioral pediatricians have specialized training and expertise in the assessment and care of children with a

broad range of developmental, learning, and behavioral difficulties, including ADHD, and may have an easier connection with GPs and pediatricians.

Therefore, we aimed in this study to identify the challenges and facilitators of implementing this program between a developmental behavioral pediatrics service in a Level 3 hospital (Xinhua Hospital affiliated to Shanghai Jiao Tong University School of Medicine) in Shanghai and a level 2 behavioral pediatrics services in Chongming Hospital (within the provincial-level municipality of Shanghai but two-hours' drive from downtown), and in Ninghai Maternity and Child Health Care Hospital (in Zhejiang province, 280 km away) which are in turn associated with regional community hospitals (Level 1 and 2).

Methods

A purposive sampling method was used to select participants who would provide valuable and informative perspectives on the implementation of a Shared Care Pathways program in Shanghai. The Investigator local to Xinua and Chongming Hospitals (F.L.) and the Investor local to Ninghai (M.H.) used their understanding of local contexts to select individuals who would be most likely to identify the barriers and facilitators involved in implementing this project. Three semi-structured focus groups (FG) were conducted with a total of 13 healthcare practitioners from the Shanghai Xinuha hospital (FG#1: n= 2 GPs & 3 specialists), Chongming hospital (FG #2: n= 2 GPs & 1 specialist), and Ninghai hospital (FG#3: n=3 GPs & 2 nurses): see Table 1 for characteristics of the research participants.

Table 1 Characteristics of the research participants

Role	Extra Training on ADHD Management	Work Experience in Years (In General/The Current Care Setting)	Usual Work Setting	FG	Qualification
GP	Yes	21	Secondary Hospitals/Dong Yang Maternal and Children Hospital	1	Bachelor's Degree/Chief Physician
GP	No	28	Secondary Hospitals/Chongming Branch of Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	1	Bachelor's Degree/Attending Physician
Specialist	Yes	16	Tertiary Hospitals/Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	1	Ph.D. Degree/Chief Physician
Specialist	Yes	22	Tertiary Hospitals/Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	1	Ph.D. Degree /Associate Director Physician
Specialist	Yes	15	Tertiary Hospitals/Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	1	Ph.D. Degree/ Associate Director Physician
GP	No	40	Secondary Hospitals/Chongming Branch of Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	2	Bachelor's Degree/Chief Physician

GP	No	28	Secondary Hospitals/Chongming Branch of Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	2	Bachelor's Degree/Attending Physician
Specialist	Yes	16	Tertiary Hospitals/Xinhua Hospital, School of Medicine, Shanghai Jiao Tong University	2	Ph.D. Degree/Chief Physician
GP	No	21	Ninghai Maternity and Child Health Care Hospital	3	Bachelor's Degree/Chief Physician
GP	No	21	Ninghai Maternity and Child Health Care Hospital	3	Bachelor's Degree/Chief Physician
GP	No	23	Ninghai Maternity and Child Health Care Hospital	3	Bachelor's Degree/Associate Physician
Nurse	No	12	Ninghai Maternity and Child Health Care Hospital	3	Bachelor's degree/Nurse
Nurse	No	3	Dong Yang Maternal and Children Hospital	3	Bachelor's degree/Therapist

Data Collection

In this study, qualitative data was collected through semi-structured focus group interviews. A semi-structured interview allows interviewers to explore themes that are particularly important to the participants, while allowing for a structured approach. Using nine interview questions and specific probes, the Canadian researchers collected information about the current state of ADHD care along with facilitators and barriers that may support or hinder the implementation of a Shared Care Pathway program locally. The interview questions were

translated into Chinese using the adapted WHO guidelines for cross-cultural translation (forward translation, initial cross check, backward translation, and final cross-check). Chinese researchers facilitated the focus groups in face-to-face or online sessions. We translated the transcripts into English and conducted the data analysis. Please see supplementary materials for interview questions and translation guidelines used.

Data Analysis

The Consolidated Framework for Implementation Research (CFIR)

The CFIR provides a variety of constructs arranged across five domains that can be used to systematically assess potential barriers and facilitators in the process of implementing a new intervention. This framework further allows for the development of context-specific logic models and generalizable theories (50). Such a framework has been used in hospitals, pharmacy, dentistry, primary care, and behavioural health agencies (13, 51). This framework has also been used in conjunction with the identification of barriers and facilitators in healthcare implementations in China (49). A complete list of CFIR constructs and domains used within the realm of this research can be found in the supplementary materials.

Qualitative Approach

A quasi-deductive approach comprising of both inductive and deductive approaches was used for data analysis (52). Such an approach has seen success in identifying barriers and facilitators in qualitative health research (see (53, 54)). Using CFIR constructs and definitions as a guide, transcripts were first deductively coded without inferences made from the data. Following this, a thematic inductive approach was applied to the codes previously generated,

identifying sub themes within the CFIR domains. An inductive thematic analysis (55) is an appropriate and powerful method to use when seeking to understand a set of experiences, thoughts, or behaviors across a data set (56). This allows researchers to search for themes of broader significance that was provided from the deductive coding, producing a rich description of the analysis. Data analysis was completed using the NVivo qualitative software package (version 12).

Data Integrity

Several measures were utilized by the researcher to improve credibility and trustworthiness of the analysis including continuous comparative analysis and immersion in the topic of study (57). Dependability was adhered to through the consistent execution of study procedures. Furthermore, transferability was increased through providing information on the context in which the research was carried out, research participants, and methods (57). To enhance confirmability, decisions made during the research process and emergence of the findings were reviewed in joint meetings with Canadian and Chinese researchers. We conducted member checking to increase credibility. As our objective was to adapt and implement a Canadian model of care in China, which have two very different cultures and health care organizations, we used a multi-coder approach to ensure methodological rigor. Two coders (members of the Canadian team) independently analyzed the data and came to a consensus on the results of the analysis. An additional researcher from the Chinese team (trained by the Canadian team) independently coded the transcripts, and all three researchers reached an agreement on the barriers and facilitators they identified. Conflicts regarding coding and themes were resolved in joint meetings between Canadian and Chinese researchers.

Results

Based on the CFIR, constructs pertaining to the following domains were identified: *Characteristics of the Individual*, *Inner Settings*, *Intervention Characteristics,* and *Outer Settings.* Table 1 summarizes the identified facilitators, barriers, and mixed factors related to each construct.

Table 1. Specific Barriers, Facilitators, and Mixed Factors that Contribute to the Implementation of a Shared Care Pathways Program in Shanghai

	Facilitators	Barriers	Mixed
Characteristics of the Individual			
-Knowledge and beliefs about the intervention		• Lack of physicians' knowledge in ADHD management.	
- **Self-efficacy**			• Confidence in their own capacity to execute courses of action to achieve the project's goals. However, they need related support and training to do so.
- Other personal attributes	• Stakeholders' high motivation to help their patients and contribute to their field and organization. • Roleplaying, online training and educational videos were identified as individuals' preferred learning methods		
Inner Setting			
- Implementation Climate			
a- Compatibility	• Physician values and aims were in alignment with project goals.	The philosophy underling the treatment of ADHD children are different in Canada and China	Despite differences, physicians in China are willing to learn from the Canadian approach.
b- ***Organizational Incentives***	• The opportunity to participate in scientific research.		

	• Increase salary and bonus. • Allocating more trained staff to help with assessment and screening for ADHD. • Receiving promotions. • Receiving certifications.	
c- Learning Climate	• Potential leaders express their own fallibility and need for learning and collaboration with colleagues.	
a- Tension of change	• strong urge for improving the situation.	
-Readiness for Implementation		
a- Leadership engagement	• Leaders are willing train others in the health system. • Leaders are willing to manage and coordinate an interdisciplinary team.	
b- Available Resources	• Determining the level of understanding of GPs with regards to ADHD can facilitate providing appropriate resources.	• Only a basic level of care is currently offered in community hospitals. • Heavy workload and insufficient specialized medical personnel. • Lack of qualified support staff. • Lack of training for general physicians. • Lack of standardized procedures to ADHD treatment. • Lack of availability of medication to treat ADHD in primary and secondary level hospitals. • Not havening licenses for certain ADHD medication.
Intervention Characteristics		
-Complexity		• Time limitation for implementing the program. • Communication and cooperation between different teams in an international, multi-centered project. • Meeting the varying needs of different settings and hospitals. • Integration of resources

		at different levels of care.	
-Intervention Source	• Stakeholders are willing to learn Canadian approach This	• Program is externally developed (foreign);	• This program is externally developed (foreign); however, stakeholders are willing to learn Canadian approaches and implement it.
-Relative Advantage	• The introduction of a systematic approach to ADHD management. • Standardized treatment. • Increased training of physicians. • Increased participation of general physicians.		
Outer Setting			
-Cosmopolitanism	• The number of schools within the reach of hospital education networks is high in Shanghai and Chongming. • There exist good working relationships between physicians and schools in Shanghai and Chongming. • Implementation settings have a strong relationship with other levels of hospitals in the area.	• Ninghai stakeholders do not have a strong relationship with schools.	
-Patients' needs and Resources		• Lack of public awareness about ADHD. • Many individuals do not know that ADHD is treatable. • Metal health stigma.	
-External Policies and Incentives	• Governmental policies are in place to increase overall training of GPs.		

Characteristics of Individuals

Knowledge and Beliefs

The majority of participants pointed to lack of knowledge of GPs regarding ADHD, and their unfamiliarity with accepted procedures and principles of ADHD management which resulted in the immediate referral of potential cases to specialists: *"I think GPs are not familiar*

with this disorder [referring to ADHD] and will not accept any cases. They will tell you to go to XX hospital [a third level hospital] instead of thinking how they can help [manage the case]". Relatedly, the majority of participants believed that they need training as well as support from specialist in other fields for complex ADHD cases: *"…However, some patients may have other comorbidities. In those cases, we need to work with paediatric psychologists… for consultation, discussion, or even referral. We need to encounter more cases to be able to handle complicated situations*".

Self-efficacy

Participants showed moderate to high levels of confidence in their capability to implement the project. However, participants indicated that they required support from various team members, as well as their administration in order to do so: "*We are confident since we are at this level. However, we need help from the upper level of administration in a lot of areas such as technical support. In other words, we need appropriate coordination*". Participants expressed the desire for additional training on non-medical treatment approaches and the details of the Shared Care model.

Other Personal Attributes

Participants expressed a genuine desire to implement the project and help their patients: *"Well, I think, ADHD patients show various problems in behaviour and study. Any improvement they show will greatly encourage you. That is where my motivation comes from".* Other sources of motivation for participants in implementing the program were: enhancing their level of diagnostic and treatment skills, upgrading their academic level by being involved in the project,

standardizing the management of care, and eventually improving the economic benefits to their hospitals.

Participants placed a high value in enhancing knowledge in their field by allocating time to research and sharing new knowledge with other team members: "*My team members' eagerness and devotion to science has made me more confident. They are using their spare time to do this project …motivation is essential*". Another participant mentioned: "*Even though we are so used to what we have been doing in the out-patient clinics, every time we learned a new concept, we talked about it in our department".* In terms of learning style, participants mentioned that their main preferred method of learning was through role-playing, followed by online training sessions, and educational videos.

Inner Setting

Implementation Climate

Compatibility: Participants felt that the goals of the project were generally congruent with their own values. They believed that the project would significantly improve treatment of ADHD patients, which is consistent with the goals and values of health care providers: "... *whatever the trainers talked about was highly practical and compatible with our work. Some of them [the training content] are already in our practice. Some of them are things we need to pay attention to*". In addition, a participant who identified themselves as a leader in their health care setting was receptive and supportive to the project, citing the need to learn and develop: "*I am sure that the whole community in our Chongming area lack knowledge about the disorder because we got little training. I will support this project. It is a great opportunity for us to learn and get*

trained…". Although participants believed that there is a great compatibility between their own values and the project's goal, they noted that the philosophy underling ADHD treatment is different between Canada and China. Specifically, participants mentioned that the current care approach in China emphasizes supporting children's abilities to meet strict expectations. Participants perceive the Canadian approach as being comparatively more focused on trying to understand the limitations that are driving children's behaviour and adjusting accordingly. However, the majority of participants expressed that a more empathetic approach could be beneficial in mental health treatment: "*I think we need to make some changes in our philosophy. Different educational concepts have led to different values and beliefs. We will become more open after learning. I think we need to put ourselves in the child's shoes and try harder to understand the child. That will be more helpful to the child…*".

Organizational Incentives: Although salary increases and bonuses were mentioned, participants placed more of an emphasis on increasing respect through obtaining certification for completing ADHD training sessions through the project, as well as participating in scientific research and writing articles: "*People from the Psychology Department always clamour that you cannot run such programs because you don't have the license… can you give us some certificates for promotion, to prove that we can run its program after training… Yes, give us some certificates so that we can put them on the wall."* In addition, participants mentioned the training in new research methods as an additional incentive: *"Personally, I am quite interested in qualitative research… but I have no idea where to start. It would be a great experience if I can learn something like that in this project"*. Other incentives included allocating more trained staff (regular and skilled employees) to help with ADHD assessment and screening, and receiving financial promotions.

Learning Climate: Regarding this sub-construct, participants who were recognized as leaders within their organization spoke of their own need to learn and collaborate with colleagues: *"Even though we are psychiatrists … even though you recognized their conditions [ADHD children] and planned to treat them, you will be frustrated at the outcome… I need further training in what to do to help them"*. From a more logistical standpoint, participants discussed different training opportunities that promoted a positive learning environment for them. One of the leaders mentioned: *"…We were the first group to get the training. We have also got online training from Professor [Name]. Through this training, we have enhanced our level of professional skills and we have a better idea about care management in our county level hospital"*. Although leaders demonstrated their desire to learn from other team members, there was an implication that participants were more willing to learn from colleagues who have equal or more senior positions than themselves, and not junior colleagues.

Tension for Change: In our study, participants showed a strong urge for change and subsequent desire to implement this project as it contributes to parents, doctors, and teachers' knowledge in ADHD recognition and management: *"As doctors in the communities, we have to enhance our ability to make correct diagnoses. We have to be able to tell what is mild, what is serious, what is complicated or with comorbidities"*.

Given the patient age ranges that Chongming community hospitals usually serve (which is younger than the age that most ADHD diagnoses are made) this project would also address issues related to ADHD diagnoses in older children but locally. As one participant pointed out: *"Currently township hospitals are dealing with the population from 0 to 6-year-old and that is also related to their level of skills."* Instead of being treated locally, older patients must travel to Shanghai every two weeks to be treated by institutions that treat patients over the age of seven,

and subsequently patients who eventually receive an ADHD diagnosis. Ultimately, participants felt that the implementation of a Shared Care approach to ADHD management would enable them to treat their patients locally, rather than referring them elsewhere, which could lead to a *"reduction of burden to the economy"*.

Readiness for Implementation

Leadership Engagement: Regarding this sub-construct, many of the participants (who are considered leaders in their respective occupational settings) indicated their interest in engaging in the project to train community doctors: "We are now talking about forming collaborations to help each other. Doctors in the communities are not skillful enough to deal with the disorder, right? I can teach and train them with the practical ways". Similarly, one of the leaders in Xinhua Hospital [Third Level Hospital] indicated their team's willingness to coordinate and manage the interdisciplinary team in other designated hospitals: "We will coordinate the interdisciplinary team to provide excellent services. I talked to X [name of one of the potential leaders in Shanghai] yesterday. I said we are not the focus in this project, but the two regions we serve are [pointing to Chongming and Ninghai]".

Available Resources: To begin, participants indicated that the level of healthcare provided in the communities of Chongming and Ninghai are usually very basic and is often limited to growth monitoring and immunization. One participant mentioned that: "*Although they also have primary childcare in the community, the service is relatively simple… it is only limited to height and weight measurements"*. Another participant mentioned that: "My job is basically doing the assessments… The rest of my job is communicating with the doctors."

Participants spoke about the insufficient resources needed to treat paediatric ADHD, particularly with regards to qualified personnel: “*No pediatricians are specialized for ADHD in this hospital [referring to a secondary level hospital]. No one is specialized in overall developmental behavior”.* In addition to lack of specialists, participants indicated a lack of “regular and qualified staff” to assist with assessment. Specifically, more staff with appropriate training could conduct routine assessments and therefore reduce the workload of specialists. For example, one participant indicated that: “*Only I and [Name of the doctor] are doing the assessments. Nobody else is qualified, has a certificate.”* It was further mentioned that: *“Because we use Wechsler Intelligence Scale and SNAP-IV for screening, it takes long time to finish one assessment, and the community nurses don’t know how to do it. They need training, and the training takes time too.”* Because of this lack of trained GPs and nurses, many of the hospitals surrounding Shanghai shift the focus to ADHD management: *“Basically, this is the reality. Personally, I think it is somewhat difficult for us to reach out to the communities to do assessments. It would be better if we focus on promotion and education. This way is better for them too.”* For the project to be successful, participants indicated that it would be necessary to determine the level of expertise of GPs regarding ADHD and find new ways to increase their interest in the topic.

The heavy workload and lack of time for pediatric specialists in third-level hospitals were also reported as challenges for project implementation and generalist training. One of the specialists said, "*Honestly, I feel almost exhausted from the clinical work. I have to see over 30 new patients in one morning...*"

A lack of standardized procedures to ADHD diagnosis and treatment was identified by participants as another barrier. Participants repeatedly spoke of a piecemeal approach to ADHD

that often varied from hospital to hospital and from physician to physician: *"Because this specialty, ADHD assessment, belonged to the neurology or psychology department in the past. It was not in the primary child health care system until recently. In addition, the number of ADHD patients is relatively small. Doctors are actively developing [their own practices]... The care management for those children is not systematic, and the number of those children going to the hospital pediatric department is also relatively small."*

Participants expressed the need for clear guidelines on ADHD treatment throughout China*"… Actually, we have made some referrals. However, without a guideline, all the decisions were made based on an individual doctor's judgment. Therefore, we need to make the procedures standardized*". To mitigate these barriers somewhat, participants felt that the materials that would be available through the implementation of our proposed program would support standardization: "*Given the resources available now, including the educational models* [referring to the program], *I think it is quite easy for us to achieve that goal* [standardizing the procedures]".

Finally, participants identified the unavailability of ADHD medication at primary and secondary level hospitals as a barrier: "*At the level of county hospitals… not all the hospitals can purchase the medications and keep them in inventory*". Similarly, another participant mentioned, "*If the patient needs pharmaceutical treatment he goes to (a third level) hospital to get the medication*..." For hospitals that do have the capacity to obtain ADHD medication the logistical barriers to maintaining an adequate supply are substantial: "*If they want to use this medication, they can apply for the interim license… you can submit a report when you want to use this medication..."* These provisional licenses are only valid for limited periods and quantities: "*The application process lasts for one month. But how long they can use one depends on how much*

medication they will use. For example, they can't stock up a lot of medications in their hospital in one application".

Intervention Characteristics

Complexity

The participants felt that collaborating and communicating between the teams of different countries, and different hospitals, integrating the resources available in the different hospitals, and meeting the needs of these different hospitals was a real challenge in finalizing this project within five years: *"However, how to better implement and carry on for 5 years remains a challenge…This is an international project. We are going to transplant a new system from a foreign country. Cooperation and communication will be a huge challenge."*

Intervention Source

On a related note, our research participants acknowledged that the intervention itself was international in nature and therefore "*foreign*" and may need some adjustment to become appropriate to the Chinese context. However, some participants had confidence in a project developed in Canada: "*The program has been developed in Canada …. I am confident about that system".* Despite the foreign source of the intervention, all participants indicated that they were willing to engage in its implementation: "*I like that this is an international project. Through this project we can learn from the foreign advanced experience and apply it to our practice*." When discussing the benefits of the training that was provided as part of the implementation of this project, participants said: "*From what we learned yesterday and the other days [from researchers in Canada], not only did I learn more about the knowledge network in psychiatry, but also about project management."*

Relative Advantage

Participants indicated that our project had the potential to help not only with the standardization of ADHD treatment, but also with the administrative management of working with these patients: *"…this project is very good because there is already something similar in place [in Ninghai], which is a good foundation. The new project [current project] can optimize the flow of the procedures which are already working, making them more efficient."* In addition, participants felt that the involvement of GPs was a strength of the project: "*The pediatric department is responsible for training the general physicians. So, they have the advantage. They can take that opportunity to further train their GPs"*.

Outer Setting

Cosmopolitanism

Several participants from secondary/tertiary hospitals reported well-established working relationships with other hospitals in the region, and with university teaching hospitals in Shanghai. Participants also reported strong working relations with schools in the area: "*Generally have very good relationships with elementary schools"* which could help promote the program. Expanding on this, another participant indicated that health promotion through schools was effective *"We have over 100 elementary schools and high schools… it may also be done [health promotion] through the parents in the schools"*. Leaders from local hospitals also often used their personal connections to promote knowledge of ADHD in schools*: "…. Currently our Director [name] is using his personal network to do promotions. For example, some of his classmates/friends are working in schools, and they invited him to the schools [for educating*

teachers about ADHD]". Therefore, building a formal connection with schools in Ninghai has been considered as an area that needs to be improved for implementation of the project.

In addition, participants indicated that they could invite senior physicians from teaching hospitals to train junior physicians: *"In terms of knowledge network, … another resource available is the teaching hospitals. Teachers in hospitals affiliated to the university will come for this project".* It was indicated that some hospitals could share best practices between their respective institutions, allowing for optimal training levels and treatment approaches: "*Shared information. There is a lot of information about how to enhance attention [in kids with ADHD], I know there are materials specific on this subject. I wonder if we can share related information from big hospitals."* Finally, participants from Ninghai Hospital indicated that they had an excellent working relationship with other community hospitals: "*We have a very close relationship with the 17 township hospitals around us... Whenever we have new or special cases we will communicate within the group. It is very convenient".*

Patient Needs and Resources

Most participants indicated that there is a significant lack of public awareness of ADHD in Chongming and Ninghai: "*Education to raise people's awareness is needed, and relatively we are falling behind in this area.… I think generally parents, doctors, and teachers are not updated, and that is where we need to make some improvement*". This lack of awareness has been mentioned as one of the main obstacles in identifying and treating patients with ADHD in Chongming and Ninghai: *"There are approximately 2000 children with ADHD in Chongming* [estimation based on the prevalence of ADHD in paediatric populations] *…, but it is challenging to identify them all… where are these 2000 patients?"* Participants indicated that a significant

number of social resources, spanning all levels of society, would be needed to implement the program. Furthermore, even among those who know about ADHD, many do not know that treatments exist and are available: *"Despite the large-scale publicity campaign, there are still a lot of people that don't know that ADHD is treatable. They don't know treatment is available in their community hospitals either."*

This lack of awareness was attributed to limitations in Chinese primary health care for children: "This hospital is the only hospital with a primary childcare department on this island [Chongming], and the primary childcare department focuses mainly on the kids under three years old. So, we can see that people on this island lack education [on ADHD]." Socio-economic factors were also shown as a limiting factor: "The differences here compared with Shanghai are that the economy here is backward and the parents here are less educated. The parents' consciousness is still different from that of Shanghai people… the educational level of the teachers is pretty good in Shanghai and Chongming island is relatively behind. Its social economic status is pretty low."

Finally, participants reported that their patients were often wary of the stigma associated with mental health in China, including for pediatric ADHD. For example, participants reported that parents often chose to go to pediatricians in a primary care setting rather than to a mental health specialist: "*if the children have the ADHD problem, they are willing to go to the pediatrician, and they are more willing to go to the primary childcare department, because the primary childcare department could see all kinds of patients. But, if the kids go to the mental health hospital, they have to be documented."* From the same perspective, people living in Chongming would prefer to go to Shanghai to reduce the risk of their child's ADHD diagnosis becoming known in the community: "*Even if they feel something wrong, they will rather not say*

it; … rather not come here for treatments; but they might go to see doctors in Shanghai city secretly. Because this is a relatively small place, it will be spreading among people soon".

External Policies

Policies at various levels of government to increase general practitioner training within the pediatric departments of Chongming hospitals was identified as a facilitating factor: "*The Shanghai government has given the order that GPs on this island have to get some training in the pediatric department*." Related to this, and with the growing demand of medical services within Chongming, the municipal government of Shanghai took additional measures: *"as we are far away from downtown Shanghai, and at a special geographical location, people's demands for both medical services and the general services provided by our hospital are still growing. Therefore, in 2009, Shanghai municipal government authorized Shanghai Jiao Tong University and Xinhua Hospital to take full charge of the management."*

Discussion

The purpose of the current study was to determine barriers and facilitators of implementing a Canadian ADHD Shared Care Pathway program in pediatric settings in Shanghai. We collected the data from healthcare providers who work at the hospitals where the project will be implemented in the future. Using the CFIR, a variety of domains and constructs were identified that would support or hinder the implementation of this project. Regarding the domain of characteristics of the individual, knowledge and believe about the intervention, self-efficacy and other personal attributes were explored by participants. Related to Inner Setting, the

implementation climate was spoken of at length. Specific to Readiness for Implementation, one of the most significant talking points was leadership engagement and a lack of available resources. Specific to intervention characteristics, complexity, the source of the intervention, and the relative advantage were explored. Rounding off the domains covered by the CFIR, the Outer Setting was highlighted insofar as it pertained to cosmopolitanism, patients' need and resources, and external policies. The mental health stigma and lack of public awareness about ADHD were spoken of at length by focus group participants as the main barriers in this domain. Key factors under each domain will be further discussed.

Characteristics of individual

GPs' limited knowledge about ADHD management in Shanghai has been identified as one of the key barriers in implementation of the ADHD Shared Care Pathway program. This gap may be attributed to GPs' insufficient education about ADHD and developmental behavioral pediatrics in universities, lack of experience with pediatric population, and limitations in prescribing medications. Similarly, in a systematic review conducted by Tatlow-Golden and colleagues (58) lack of ADHD knowledge has also been reported by GPs in Australia, UK, Canada, and Iran. Results of this study revealed that almost all participating GPs in the aforementioned countries had low confidence in ADHD diagnostic ability and believed the overview of specialists was required for ADHD management. In line with the result of the current study, GPs cited lack of training and uncertainty regarding ADHD principles as main reasons for their limited knowledge. Despite and perhaps because of the participating physicians' inadequate knowledge of ADHD, our results revealed their strong desire to learn. Developing a training program that is designed based on the different physician's level of knowledge can improve their understanding and practice toward ADHD management (59). As Chinese

physicians' heavy workload can be a significant barrier for attending in training programs, a combination of on-line and web-based ADHD training programs can offer easily accessible training at the time and place of physicians' convenience.

Inner setting

Compatibility of the Shared Care Pathway program with stakeholders' values and beliefs has been identified as a great facilitator for implementation of this project in Shanghai. According to the CFIR (50), the more knowledge users perceive compatibility between the innovation and their own values has a strong impact on likelihood of their acceptance of the innovation. This factor has been considered as an important predictor of a successful implementation. However, clear cultural differences have also emerged, particularly in non-pharmacological approaches to ADHD. In the West, and specifically in Canada (60), individualized educational plans are offered to children with neurodevelopmental disorders ("exceptionalities"), with curriculum adaptations or different expectations to help students acquire skills that are not included in the curriculum, or that are consistent with the child's actual learning level. The concept of individualization acknowledges the child's limitations, for example in attention or motor control, and considers behavioral problems as a response to the mismatch between the child's abilities and adult expectations. From this perspective, the role of the adult (parent or teacher) is to adapt their expectations so that the child can be successful again. In the Chinese society, shaped by Confucianism despite Western influences, the role of parents is to transmit to their children a sense of responsibility for academic success, obedience and maintenance of harmony in the home and classroom (61, 62). Problems of inattention, hyperactivity or misbehavior are primarily perceived as a failure on the part of parents or teachers to transmit this sense of responsibility and self-control. The more adults blame

themselves for their children's failings, the harder it is for them to match their expectations to their children's abilities, because that's precisely what they blame themselves for: failing to instill these expectations in their children. Conversely, in the West, the main resistance to accepting individualized education plans often comes from the children themselves, who resent the fact that expectations are different for them as compared to their peers, because they want to be like everyone else. In this perspective, pharmacological approaches did not elicit the same feedback from participants, since the blame lies on a cerebral dysfunction in the child, which the treatment aims to correct to enable the child to meet expectations. These cultural differences are reflected in the current lack of accommodation for children with ADHD, particularly in the school environment. The implementation of a shared model of care therefore has to cope with significant cultural differences, especially around the issue of accommodation. Encouragingly, however, participants recognized the benefits of taking the child's perspective ("putting yourself in the child's shoes"). The enthusiasm of participants to learn and apply Western approaches to the diagnosis and treatment of ADHD is an important facilitator of successful implementation. Nevertheless, the research team became acutely aware of the need to culturally adapt the program so that it would be acceptable in the Chinese context. In the next phase of the project, we decided to use a cultural adaptation framework for all the different components of the Shared Care Pathway program. This cultural adaptation framework will permeate all training activities. For example, we started to culturally adapt an ADHD diagnostic interview during training. At each step of the training program, feedback is obtained on cultural adaptation, and provided to a steering committee formed of Chinese knowledge-users that ultimately decide which to include.

Adaptation of the program will also address some of the other identified barriers such as lack of resources due to modification of the program to consider hospitals' supplies and

capacities. Other identified facilitators in the inner setting, such as positive learning climate and strong leadership engagement in participating hospitals are also considered as factors that will increase success of the implementation.

Intervention characteristics

The key barrier identified under this domain was complexity of conducting an international implementation project. There is a negative relationship between knowledge users' perception of complexity of the interventions and success of implementation (50, 63, 64). Therefore, determining complexity of the project and applying strategies that contribute to successful implementations is of a great importance. An international project is always complex to organize, and participants placed particular emphasis on the need for communication and cooperation. The main challenges are geographical distance, which limits opportunities for face-to-face contact; language barriers (difficulties with English as a working language, lack of knowledge of Mandarin, need for simultaneous translation, captioning of audiovisual documents), particularly with services delivered from outside university centers; and time differences, which limit the time and duration of videoconferences. Added to these linguistic difficulties is the perception of the program as foreign, and the need to adapt it so that users can make it their own. Suggested by CFIR (50), having simple, clear, and detailed implementation plans, schedules, and task assignment are some of the strategies that facilitate the process of implementing a complicated project. In the present project, limiting its size to a collaboration between a Level 3 center and two regional Level 2 centers, a clear definition of shared care and the care pathway are key success factors. If the international aspect of the project was perceived as a difficulty, it was also felt to be a facilitator, because the stakeholders had confidence in a

program developed in Canada and were willing to learn from a foreign experience and apply it in their own practice.

Outer setting

Stigma and lack of public awareness of ADHD were also identified as key challenges for the project's implementation in Shanghai. Stigma is one of the factors limiting access to and use of mental health services (65). The stigma towards mental health problems can be felt all over the world. A recent systematic review of attitudes towards ADHD in community samples from Australia, Sweden, Germany, Finland, Korea, Indonesia and the USA found that attitudes are generally negative (66). ADHD is considered to be overdiagnosed, the acceptability of ADHD drug treatment is questioned, and people with ADHD are thought to be more likely to exhibit inappropriate behaviours, and best kept at a distance.

In China, the disruptive behaviors often associated with ADHD clash with the expectation of harmony in the classroom, necessary for the concentration of other students. Disruptive children are often rejected and sometimes excluded from the school environment. The stigma and rejection are all the stronger when ADHD is not recognized or treated, and when adaptation efforts are lacking. The project to implement the Shared Care Pathway model in the pediatric setting may help to reduce stigma. China is one of the few countries where Developmental Behavioral Pediatrics is recognized as a subspecialty. The Academy Section on Developmental and Behavioral Pediatrics in China was only founded in October 2011. Parents who feel too embarrassed to consult a mental health center for fear of the stigma attached may more comfortably seek care in a pediatric service.

The hospitals in our study have already established close links with schools and are running neurodevelopmental health promotion workshops on ADHD with parents and teachers in the school setting. Improving the level of mental health literacy is supposed to reduce stigma and discrimination against people with mental health problems (67). In the West, non-professionals, particularly teachers and parents, generally have a poor understanding of ADHD, and tend to endorse biological, rather than psychosocial, factors to account for ADHD (68). A priori, this explanation allows the blame to be placed on the brain, and at the same time absolves parents, and teachers, for the child's disruptive behaviors (69). But for illnesses such as adult psychosis, anti-stigma campaigns that present mental illness as an illness like any other have actually increased the perception of dangerousness and the desire to keep patients at arm's length (70). This paradoxical effect appears to be linked to stereotypes such as dangerousness associated with mental illness, which are more linked to biological than psychosocial explanations (71). Although no studies have been conducted on the effects of anti-stigma campaigns for ADHD, and a fortiori in the context of Chinese culture, we will jointly develop with our Chinese partners a literacy program that is as balanced as possible in the causal explanations of ADHD and its treatments.

Strength and Limitations

We used CFIR as a theoretical framework to systematically capture the complexity of implementation of the project. We engaged the perspective of different clinicians (i.e., pediatricians, GPs, and nurses) from different level of hospitals to strengthen the trustworthiness of results and research uptake at the designated settings. The research team used the member check approach after writing the result section to ensure research participants confirm the

outcome of the focus groups and therefore increase credibility of the findings. Coding was conducted by two researchers to enhance dependability of the findings of the study. Discrepancies identified between these coders were resolved in team meeting with other researchers.

Limitations of the study include the relatively small number of participants, which may reduce the range of perspectives. However, we recruited all stakeholders from the different sites. Above all, the small number of specialist physicians, general practitioners and nurses qualified in the field of ADHD dictated the number of participants. Because of their expertise, however, focus group participants were ideal for assessing the factors surrounding the barriers and facilitators to implementation of the ADHD Share Care Pathway program. The other limitation is the lack of direct involvement of patients and families. This study focused on stakeholders' perceptions of the challenges and facilitators associated with implementing the intervention. It was the stakeholders who reported the "Patients' Needs" in the "Outer Setting" domain. In general, CIFR does not make extensive use of patient perspectives or experience (51). But the results of the study showed that the patient perspective will be essential in defining and evaluating mental health literacy programs, and the implementation of accommodation measures. Due to the specific nature of the study context, the results are not transferable and generalizable to other care contexts, which would require specific projects. What is generalizable, however, is the application of CFIR in the specific perspective of a particular mental disorder (ADHD), in a distinctive medical setting (Developmental Behavioral Pediatric) and in a well-defined cultural and geographical context (Xinhua Hospital in Shanghai and behavioral pediatric services in Chongming and Ninghai).

Conclusions

This study provides findings of factors that facilitate and restrain the successful implementation of the Canadian ADHD Shared Care program in China. The key factors that contribute to the success of this program include strong leadership engagement, learning climate, cosmopolitanism, and alignment of the project's goal with the knowledge users' and governmental policies. The reported barriers can be used to inform knowledge users on how to improve implementation of the program. Key barriers include lack of physicians' knowledge on ADHD principles, complexity of conduction of an international project, lack of public awareness and stigma toward ADHD, cultural differences between Canada and China, and lack of resources. Appropriate training of health care providers, adapting the program for the Chinese context, increasing public awareness about ADHD through social media platforms and schools as well as providing strong project management and guidelines that clearly describe the role and expectations of each team member are essential to successful implementation. In comparison with findings from a psychiatric setting in Beijing, the most striking differences were that cultural adaptations and stigma were more readily addressed in a paediatric setting. This may be related to the fact that pediatricians are integrating the physical and mental aspects of development into their practice, and that in this more normative medical context, patients are more likely to express concerns about the marginalization of their children. These differences in attitude will be reflected in the implementation of services, and whether they will result in differences in the success of implementation is an important question for the future of ADHD care in China.

Delimitations

In this qualitative study examining the implementation of the Shared Care Pathways program in Shanghai, the delimitations are defined by several key choices. The study is geographically limited to Shanghai and specifically to Xinuha, Chongming, and Ninghai hospitals, which may not represent other regions or healthcare contexts. A purposive sampling method was employed, selecting healthcare practitioners deemed most knowledgeable about program implementation barriers and facilitators based on the local investigators' judgment, potentially excluding less directly involved stakeholders such as patients or administrative staff. Data collection was confined to three semi-structured focus groups, a format that prioritizes certain types of interactive discussion but might not capture the full depth of individual experiences. The study focuses exclusively on healthcare practitioners, including GPs, specialists, and nurses, thereby limiting the perspective to that of medical professionals. These methodological and participant selection decisions delineate the study's boundaries and influence the generalizability and applicability of its findings.

Declarations

Acknowledgements

The authors would like to acknowledge and thank those who participated in the focus groups.

Authors' contributions

SB performed the data analysis and was a major contributor in writing the manuscript. AM performed the data analysis and was a major contributor in writing the manuscript. DW performed the data analysis and was a major contributor in writing the manuscript. MH performed the data analysis and was a major contributor in writing the manuscript. MX aided in the literature review and data interpretation. LY developed the protocol and aided in data interpretation. AS aided in the literature review, protocol development and data interpretation. FL developed the protocol and aided in data interpretation. PR developed the research design, data collection, supervised the analyses, aided in the literature review and data interpretation, and revised the manuscript. All authors reviewed and approved the final manuscript.

Funding

This work was supported by the National Natural Science Foundation of China 8171101223 and Canadian Institutes of Health Research GAC154987.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

All work was conducted with the approval of relevant ethics committees (Children's Hospital of Eastern Ontario REB Protocol No: 18/75X; Peking University Sixth Hospital (2020)伦审第(18)号 and follows the principles of the Declaration of Helsinki. Informed consent was obtained from all participants prior to data collection.

Competing interests

The authors declare that they have no competing interests.

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Appendix 1 - Focus Group Interview Questions

10. What is your perception of this new ADHD program with regard to evidence strength and scientific quality?
11. What kinds of changes do you think you will need to make to implement the new ADHD program, so it will work effectively in your setting? Do you think you will be able to make these changes in your setting?
12. How complex does the new ADHD program looks like for you, when it comes to duration, scope, number of steps, type of professionals and organizations involved?
13. What kind of training is needed to successfully implement the project?
14. How would you describe the culture (general beliefs, values, assumptions that people embrace) of your organization? Of your own setting or unit? How do you think your organization's culture will affect the implementation of the new ADHD program?
15. Is there a strong need for this new ADHD program?
16. Do you expect to have sufficient resources (including money, training, education, physical space, and time) to implement and administer the new ADHD program? [If Yes] What resources are you counting on?
17. How confident are you that you will be able to successfully provide changes or take actions to achieve the implementation goals of the new ADHD program? What gives you that level of confidence (or lack of confidence)?
18. What do you prefer about the new ADHD program?

Appendix 2 - Translation Guideline

Dear Translators,

The objective of the current study is to adapt a Canadian shared care model for Attention-Deficit/Hyperactivity Disorder (ADHD) to Chinese hospitals. To achieve this goal, we need to translate research materials such as questionnaires, interview questions, and codebooks.

Process of Translation of the Research Materials:

The aim of this process is to achieve Chinese or English research materials that are conceptually equivalent in each of the target countries/cultures. That is, the English and Chinese research materials such as a questionnaire should be equally natural and acceptable and should practically perform in the same way. The focus is on cross-cultural and conceptual, rather than on linguistic/literal equivalence. A well-established method to achieve this goal is to use forward-translations and back-translations. Implementation of this method includes the following steps:

- Forward-translation
- Initial Cross-check
- Back-translation
- Final Cross-check

1) Forward-translation

The translator should be knowledgeable of the second language culture, but his/her mother tongue should be the primary language of the target culture (i.e., a Chinese native speaker preferably translates English materials to Chinese)

We emphasize conceptual rather than literal translations and stress the need to use natural and acceptable language for the broadest audience. The following general guidelines should be considered in this process:

- Translators should always aim at the conceptual equivalent of a word or phrase, not a word-for-word translation, i.e. not a literal translation. The translator should consider the definition of the original term and attempt to translate it in the most relevant way.
- Translators should strive to be simple, clear and concise in formulating a question. Fewer words are better. Long sentences with many clauses should be avoided.
- The target language should aim for the most common audience. Translators should avoid addressing professional audiences such as those in medicine or any other professional group. They should consider the typical respondent for the instrument being translated and what the respondent will understand when she/he hears the question.

  Translators should avoid the use of any jargon. For example, they should not use technical terms that cannot be understood clearly; and colloquialism, idioms or vernacular terms that cannot be understood by common people in everyday life.
- Translators should consider issues of gender and age applicability and avoid any terms that might be considered offensive to the target population.

2) Initial Cross-Check

An expert in the mental health field (Preferably, bilingual in English and Chinese) will cross-check the forward translation. The goal in this step is to identify and resolve the inadequate expressions/concepts of the translation, as well as any discrepancies between the forward

translation and the existing or comparable previous versions of the questions if any. The expert may question some words or expressions and suggest alternatives. The principal investigator or the research advisor will provide the expert any materials that can help her/him to be consistent with previous translations. The expert will be in touch with the principal investigator and the forward translator.

The result of this process will produce a complete translated version of the research material.

3) Back-translation

Using the same approach as that outlined in the first step, the research material will then be translated back to the original language that it was initially developed by an independent translator, whose mother tongue is the target culture and who has no knowledge of the research material.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence and not linguistic equivalence.

4) Final Cross-check

The forward translator will compare the original research material, forward translation, and back translation. Discrepancies should be discussed with an expert in the mental health field and the back-translator. Further work should be iterated as many times as needed until a satisfactory version is reached. The forward translator will prepare the final version after resolving conflicts.

Translators’ role throughout the translation process:

Translators’ responsibilities include reading, thoroughly understanding, translating the given materials, and proofreading finished pieces of work. To be successful in this role, the translators should have a keen eye for detail. Ultimately, they will provide ready-to-use translated content that meets the internal needs of the project.

Readability of the document: Translators should ensure that the information is translated at a reading level appropriate for general population. We have determined a general grade 8 reading level using Flesch–Kincaid.

How to check readability of the document in Word

- Click the File tab, and then click Options.
- Click Proofing.
- Under When correcting spelling and grammar in Word, make sure the Check grammar with spelling check box is selected.
- Select Show readability statistics.

After you enable this feature, open a file that you want to check, and check the spelling by pressing F7 or going to Review > Spelling & Grammar. When Word finishes checking the spelling and grammar, it displays information about the reading level of the document.

Important: You must correct, or ignore, all spelling errors found in the document before the readability statistics will display. If there are still any red squiggles in the file, the readability statistics won't display.

Recommendations

- Translators should read the original versions very carefully to make sure if they fully understand the meanings. If the translator is not sure about the meaning of a work or sentence, they should contact the expert that research coordinator has introduced to her/him.
- After translation, please read the original version carefully and make sure that you don't miss some information.
- Read out loud and edit the translated version several times, until you feel that it is readable and is easy to be understood by a native speaker.

Using the same approach as that outlined in the first step, the research material will then be translated back to the original language that it was initially developed by an independent translator, whose mother tongue is the target culture and who has no knowledge of the research material.

As in the initial translation, emphasis in the back-translation should be on conceptual and cultural equivalence and not linguistic equivalence.

Appendix 3 - CFIR Constructs

Characteristics of Individuals

According to the CFIR, organizations are made up of individuals who are responsible for the implementation of an intervention, and thus, influence the success of the implementation. Within this Domain of the CFIR, we identified the constructs of Knowledge and Beliefs, Self-efficacy, and Other Personal Attributes, specifically, high stakeholder motivation.

Knowledge and Beliefs: This construct refers to individuals' familiarity with the underlying principles of the intervention.

Self efficacy: Self-efficacy refers to individual's belief in their own capability to complete course of action to achieve implementation goals.

Other personal attributes: This construct refers to broader personal attributes such as motivation, values, and learning style which can impact a successful implementation.

Inner Setting

This domain focuses on the dynamic interactions between the "working parts" within an organization which may influence implementation. The CFIR constructs relevant to the inner setting in our study were the Implementation Climate and Readiness for Implementation.

Implementation Climate: This construct is related to the absorptive capacity for change in engaged individuals, and the extent to which an organisation supports and rewards the use of a new intervention. Related to the CFIR's Implementation Climate construct, we identified the sub-constructs of compatibility, organizational incentives, learning climate, and tension for change.

Compatibility: refers to the degree of fit between the value attributed to the intervention and stakeholders' values and needs, as well as existing systems within the organisation.

Organisational incentives: are related to the extrinsic rewards for reinforcing behaviors in order to gain desirable results and consequently, success in implementation.

Learning climates: refers to leaders' expression of their own fallibility and need for getting assistance and input from team members.

Tension for Change: relates to the degree to which stakeholders perceive that the current situation needs to be changed.

Readiness for implementation: This construct relates to indicators of organizational commitment to implement an intervention. We identified the sub-constructs of leadership engagement and available resources.

Leadership engagement: relates to commitment and involvement of leaders with the implementation.

Available resources: refer to the level of resources dedicated for implementation.

Intervention Characteristics

This domain pertains solely to the key attributes that make up an intervention. The CFIR constructs relevant to this domain in our study were the complexity of the intervention, the source of an intervention, and its relative advantage.

Complexity: This construct relates to the perceived difficulty of the implementation of this project.

Intervention source: Intervention source relates to the opinion of stakeholders about whether the intervention is externally or internally developed.

Relative advantages: This construct refers to stakeholders' opinion on the benefits of implementing an intervention versus an altered or current solution.

Outer Setting

This domain refers to the outer setting's network of support for implementation of an intervention including the social and political context. Pertain to this domain, we identified the constructs of cosmopolitanism, patient needs and resources, and external policies.

Cosmopolitanism: Within CFIR, cosmopolitanism is the degree to which an organization is networked with other external organizations.

Patients need and resources: This construct reflects patient-related factors of implementation of the intervention.

External polices: This construct encompasses external strategies to spread innovation.

Chapter 4: N=1 Stimulant Titration in Clinical Practice for the Treatment of Attention Deficit Hyperactivity Disorder: Feasibility Study of a Shared Decision-Making Protocol

Tentative Journal: BMC Public Health

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Funding details:

No funding details to declare.

Abstract

Background: Attempts to evaluate leading treatments for ADHD and therefore determine an optimal treatment approach were spearheaded in the 1990s by the Multimodal Treatment of ADHD study. The recommended approach provided by the MTA study had several shortcomings with regards to clinical utility and cost.

Methods: CHEO has developed a stimulant titration trial approach in the treatment of ADHD based on that of the original MTA protocol. This approach automates much of the complexities associated with MTA-derived titration trials, using a triple-blind, crossover, placebo-controlled design with a lead-in phase. Patient baseline ADHD symptoms and side effects are measured using a strength-based questionnaire combining therapeutic and side effects (Strength-based ADHD Monitoring, or SAM). Titration utilizes 4 randomized weeks with placebo, low, medium and high doses. Patients receive randomized dispill stimulant medication from a local pharmacy. Doses/weeks are blinded (parent/patient/teacher/clinician) until the end of the trial. Parents and the patient's teachers complete daily online SAM questionnaires online (REDCap) to assess patient ADHD symptoms and side effects. A determination of a final maintenance dose of stimulant medication is made using a shared decision-making approach wherein parents use patient decision aids to select a preferred week while still blinded to the dose.

Results: Feasibility of the CHEO titration approach show a clear effect of dose of medication. The dose-effect was stronger in teacher's than in parent's ratings: $F\ (2.12, 40.276) = 4.050$; $\varepsilon = .707$, $p=.023$). There was no order effect. Completion rates of the daily SAM questionnaires were high, with parents averaging 5 days and teachers averaging between 3 and 5 days. Only 4% of the teachers, and 15% of parents found providing scores difficult (from moderately to

extremely), and 11% of the parents and 17% of the teachers had some difficulty using the system. Moderately dissatisfied represented more than 85% of the "difficult" responses.

Conclusion: The placebo-controlled stimulant titration trial for the treatment of child ADHD at CHEO builds upon the original MTA study, introducing a shared decision-making process and providing modern solutions to patient-centred clinical standards of care. Feasibility measures support the use of such titration as a standard of care approach in clinical practice.

Key Words: ADHD; Shared Decision Making; Clinical Practice; Stimulant Titration; Methylphenidate; Protocol.

Introduction

ADHD Definition and Prevalence

Attention Deficit-Hyperactivity Disorder (ADHD) is the most common neurodevelopmental disorder among children (1), with a worldwide prevalence estimated at between 2.8% (2) and 5.3% (3). ADHD prevalence is generally lower in adults than in children (4). Findings from recent a meta-analysis suggest a worldwide prevalence of ADHD in children and adolescents at 3.4% (5). Within the United States and Canada, the estimated prevalence is somewhat higher, with 10.2% (6) and 8.6% (7) of children being diagnosed with ADHD respectively. A diagnosis of ADHD is three to four times more common in boys than in girls (8).

Impacts of ADHD

Given the absence of biomarkers associated with the disease, an ADHD diagnosis is made based on the severity of its associated symptoms. ADHD is characterized by inattention, hyperactivity, impulsivity, or a combination of these symptoms which in turn have an impact on everyday life (9). An ADHD diagnosis has been associated with academic underachievement (10, 11), lack of employment (12, 13), difficulties in maintaining relationships with family and romantic partners (14, 15), increased criminality (16), a higher risk of accidents and premature death (17), and the development of comorbid psychiatric symptoms (17, 18).

Use of Titration/MTA approach

Attempts to evaluate the leading treatments for ADHD and therefore determine the optimal treatment approach were spearheaded in the 1990s by the NIMH sponsored Multimodal Treatment of ADHD (MTA) study. Using a national and diversified sample of approximately 600 children, four treatment groups were compared: intensive medication management alone;

intensive behavioral treatment alone; a combination of both; and routine community care (the control group). Up until that point, studies exploring the safety and efficacy of medication and behaviour therapy were conducted relatively short term compared to now, however the MTA study enrolled participants for up to 14 months, with follow-ups to 8 years. The MTA study generated over 70 peer-reviewed articles related to ADHD treatment in children (19), and the study offered a novel and intricate titration protocol for determining optimal stimulant doses for children with ADHD.

One of the main challenges in the medication treatment is its initiation, as the optimal dose can vary largely from one child to another and as there are no predictors of the optimal dosing. According to the AACAP recommendations, a clinician chooses the initial dose of the medication (methylphenidate or amphetamine salts), then increases the dose every 1 to 3 weeks until either the maximum stimulant dose is reached, ADHD symptoms disappear, or side effects prevent further titration, whichever comes first. The recommendations also point out that it is useful to obtain rating scales from the teacher and parents after the patient has been observed on a selected dose for at least a week. Parents and patient should be asked about side effects (20). In the MTA study these recommendations were implemented in a rigorous and systematic way.

Stimulant Titration Protocol

The stimulation titration protocol within the MTA study consisted of a 4 to 11 day lead-in phase followed by a 28-day, double-blind daily-switch titration of methylphenidate hydrochloride, using 5 randomly ordered repeats each of placebo, 5 mg, 10 mg, and 15 or 20 mg (higher doses for patients >25 kg) (21). According to the protocol, each dose was administered three times a day with cross-site teams of clinicians blindly reviewing reports of parent and teacher ratings of a participant's responses to the four doses of medication. These reports

assessed symptomatology, impairment, and side effects. ADHD symptoms were assessed using the Conners, Loney, and Milich (CLAM) scale that incorporated the IOWA Conners scales (Loney and Milich, 1982; Pel-ham er al., 1989); impairment was assessed using McBurnett, Swanson, Kotkin, Agler, Flynn, and Pelham's (McSKAMP) scale (Swanson, 1990); and side effects were monitored using a modified version of the Pittsburgh Side Effect Scale (Pelham, 1993). The CLAM and McSKAMP scales were summarized into mean dose-response line graphs (one for each parent and teacher), and side effect ratings were averaged and listed. Clinicians would examine these reports and come to a consensus on a participant's best dose, which would ultimately become the maintenance dose moving forward for that participant (21).

Shortcomings (time, expense, no placebo, model of care)

The MTA study definitively examined the safety and effectiveness of the leading treatments for ADHD in children and adolescents at the time. However, several shortcomings have been highlighted, specifically with regards to its clinical utility and cost (22). Gaining the cooperation of parents and teachers throughout a month-long trial, gathering and compiling the data from daily questionnaires, employing and training a multi-site panel of clinicians, seeing to the logistics involved with delivering random repeats of daily dosages of medication, and clinical follow-ups with patients makes such an approach extremely difficult in everyday practice, where personnel, funding, and quick treatment turnaround are expected (23). Additionally, with focus moving away from traditional authoritarian models of treatment and towards more patient-centered approaches, the care model employed by the MTA group for treatment of ADHD may not be appropriate today.

The authors of the MTA study emphasize that although the intervention groups with medication protocols showed the greatest improvements in ADHD symptoms and side effects,

they acknowledge that there is no single best treatment for all children with ADHD. Instead, first-line treatments for ADHD should be evidence-based (whether medication, behavior therapy, or a combination of both), and guided by family and medical considerations (24). A child's needs, personal and medical history, and other relevant considerations must be made when tailoring a suitable treatment for a child's ADHD (25).

Current Methods of ADHD Treatment

As ADHD is a chronic condition, The Canadian Pediatric Society (CPS) recommends a multimodal, shared care approach to ADHD treatment in children and adolescents. Such an approach combines non-pharmacological behaviour management and pharmacological interventions (26). Non-pharmacological approaches commonly include psychoeducation, shared decision making, parental behaviour training, social skills training, cognitive therapies, diet modification, and exercise. Pharmacological interventions include extended-release (ER) or immediate-release (IR) stimulants, or non-stimulant medication. Given lower treatment response rates (27-29) and effect size (28, 30), non-stimulant medication is considered a second-line medication management strategy in the treatment of ADHD when compared to stimulant medication. Psychostimulants, including methylphenidate (MPH), are widely accepted as a form of ADHD treatment (31, 32) with many guidelines recommending a tailored MPH dosage relative to a patient's needs (33, 34).

Goals of Study

Given the identified difficulties in adopting an MTA-style medication management protocol within clinical settings (see Chapter 5), as well as the multimodal CPS-recommendations, a clinically relevant option is needed to appropriately treat patients who opt for a medication strategy for treating their ADHD. The titration protocol used at the Children's Hospital of Eastern Ontario (CHEO) builds upon that of the original MTA study, adapting it to fit modern treatment standards. This approach is novel in its medical decision-making approach and ease-of-use in clinical settings. As such, the goal of this article is to disseminate the protocol used at CHEO, with the hope that its clinical adoption becomes mainstream for the medication treatment of ADHD. Given improvements in terms of automation and streamlining of services, the CHEO approach to stimulant titration for the treatment of ADHD is one that has the potential to positively impact the current standard of care.

Methods/Design

Shared Decision-Making

A major adaptation of the titration protocol used at CHEO, when compared to the MTA protocol, is the use of a Shared Decision-Making model of care, rather than adopting a traditional medical expert model of care. Built upon the foundations of personal well-being and self-determination, Shared Decision-Making (SDM) is the process in which both a treating physician and patient collaborate on the medical decision-making process and contribute equally to treatment decisions (35, 36). SDM is a useful tool when there is a close trade-off between the benefits and harms of a certain treatment decision (such as when administering a stimulant medication) which could shift depending on individual patient preferences and values (37). Such

a model of care has been associated with an increase in patient knowledge and risk perception accuracy; improvements in patient-clinician communication; a reduction in decisional conflict; a reduction in patients feelings of being uninformed; and patients being more assertive about their treatment choices (38).

Literature also shows that SDM has had a positive impact on patient's satisfaction and adherence to treatments, as well as improvements to feelings of empowerment and quality of life (39). The achievement of quality SDM in clinical practice depends on building a good relationship within a clinical encounter, fostering an environment where information is shared and patients and their families are supported in the expression of their preferences and views during the process (40). SDM is increasingly being recognized as the gold standard for patient-centred care (41, 42).

Strength-based ADHD Monitoring (SAM) system

ADHD Assessment

The Strength-based ADHD Monitoring (SAM) system (see Appendix 1) used in this protocol is based on the Strengths and Weaknesses of ADHD Symptoms and Normal Behaviors (SWAN) rating scale. The SWAN itself was developed as a result of increasing concerns that the existing standardized scales used truncated summary scores based on normal population behavior patterns (43-45). As such, scales focus primarily on psychopathology and extreme ADHD symptoms, which have the potential to result in evaluation errors, causing over or under-diagnosis of ADHD (45).

In addition to changes that include more accessible language, the SAM builds upon the SWAN by monitoring the most relevant associated behaviours, mainly described in the literature as ADHD comorbid conditions or side effects of stimulant medications. The SAM considers each ADHD symptom as the extreme of a behavioral trait for which is it possible to define the opposing strength. For example, "makes careless mistakes", which is a symptom of inattentive ADHD, can be contrasted with the corresponding strength in the SAM, which is the ability to self-monitor our actions in line with the objective at hand “pays attention to details and avoid careless mistakes”. The SAM questionnaire uses a 7-point rating system: a score of 0 is assigned for normal behaviors, negative scores reflect weaknesses (far below average = -3, below average = -2, slightly below average = -1) and positives scores reflect strengths (slightly above average = 1, above average = 2, and far above average = 3). Finally, the presence of interfering life events (emotionally disturbing events, illness, etc.) is documented daily in a separate section in the questionnaire, where participants are encouraged to provide comments. With 9 ADHD inattentive, 9 ADHD hyperactive impulsive symptoms and 8 ODD symptoms, the SAM counts 26 therapeutic items divided into 3 dimensions and 2 global scores (ADHD and ODD).

Assessment of comorbid conditions

We included the symptoms of Oppositional Defiant Disorder (ODD) that are often comorbid with ADHD in our assessment, as ODD symptoms are very frequent in children with ADHD and about a third of them meet all the diagnostic criteria for ODD. These questions were always formulated on a strength base, e.g., “stays cool-headed or cool off on their own when upset” rather than “often loses temper”.

Assessment of medication side effects

Using the SAM, we adapted the Stimulant drug Side effect Rating Scale (SERS) (46) which lists 17 side effects. We define 28 questions related to side effects that can be grouped according to 5 dimensions: Neurovegetative (sleep, appetite, physical pain), Psychomotor Activation (tic, nervous movement) and Retardation (sluggishness, daydreaming), Interactiveness (lack of emotional connection, participation in conversation), and Mood/Anxiety (prone to cry, fearful). These items were also strength-based, for example "maintain a normal appetite over time" rather than "decrease appetite".

Other information

In addition to identifying the responder, date, and time, we asked the parents to provide the time of the medication in the morning and the afternoon (noon capsule is given at school). Parents were also given the option to respond with free text to the question: *"Was there any event TODAY that could have affected this student's behavior? Report all relevant problems, including conduct problems with overt or covert aggression/destruction."*

Titration process

The proposed triple-blind clinical trial is based upon the protocol of the Multimodal Treatment Study of Children with ADHD (MTA). It includes an optional lead-in phase followed by a 4-week trial during which clinical measures are obtained to evaluate treatment efficacy. The titration process is proposed for children ranging from 6 to 16 years of age. It is a standard clinical procedure within the ADHD team of the Mental Health Outpatient Clinic at the Children Hospital of Eastern Ontario (CHEO).

Lead-in Phase

A 3-day lead-in phase is performed to ensure that the patient does not display prohibitive side effects. This lead-in phase may not be necessary if the patient has already been on psychostimulants for some time. The lead-in phase exposes patients to increasing methylphenidate (MPH) daily doses (see dosages) in an open trial. Strength-based ADHD monitoring (SAM) scales are completed on a daily basis by a parent and a teacher(s) to assess severity of symptoms and side effects. Patients with major side effects are given 2 to 5 additional days to adjust. However, if side effects persist at the end of the lead-in phase, the titration process is abandoned and treatment with a medication other than MPH is proposed. The only medication used in the titration process is short acting MPH.

For children who initially are unable to swallow pills, we use a manual-based program of swallowing progressively larger cake decorations to improve their swallowing ability. As an alternative, the capsule can be opened, and its contents sprinkled on a spoon with soft foods such as peanut butter or applesauce.

Medication Protocol

During the trial period, patients will take either a placebo, low dose, medium dose, or high dose of MPH daily (refer to Table1 for weight-related dosages). To prevent unwanted side effects in small children, the protocol limits the highest MPH dose to 35 mg/day (≅ 0.8 mg/kg per dose) for children weighing 25 kg or less and to 45 mg for children weighing 40 kg or less.

Table 1. Weigh-Dose Medication Protocol

MPH mg/capsule	Weight ≤ 25kg	Weight ≤ 40kg	Weight > 40kg
Placebo	N/A	N/A	N/A
Low dose	5-5-5	5-5-5	5-5-5
Medium dose	10-10-5	10-10-10	10-10-10
High dose	15-15-5	15-15-15	20-20-20

To optimize the time-course of MPH action, the total daily intake will be given in three IR doses: between 7:00-8:00, 11:00-12:00 and 15:00-16:00 hrs. Immediate release capsules are used as the placebo capsule is currently unavailable in extended-release forms. White methylphenidate powder is repackaged into similar-appearing opaque capsules containing 5, 10, 15 or 20 mg MPH by local compounding pharmacies. The capsules are dispensed in weekly Dispills with the day and hour indicated on each pocket. Capsules containing the placebo are also prepared so that they are indistinguishable, in order to ensure "blinding" of dose and content. See Appendix 2 for an example of the Dispills delivered to the patient.

Rating process

At the end of each day, the patient's behavior and side effects are rated by a parent (7-days/week) and their teacher(s) (5-days/week) using an online version of the SAM scale. One parent and the patient's main teacher are assigned to complete the questionnaires. If the child is in a French Immersion program or a high school program, two teachers may be asked to take part in the trial, to ensure that the patient's behavior is accurately represented throughout the school day. A third version of the questionnaire has been developed for the youth if she/she wants to participate.

Titration step by step

Discussion with the referring physician

At the Children's Hospital of Eastern Ontario, participants are normally selected based on date of referral, but a discussion with a referring clinician to determine appropriateness of the referral may also take place. Given that the titration process requires a great deal of effort from a patient's family, in certain circumstances it may not be the optimal time to approach a family about taking part in titration. If there is any doubt, a nurse will call potential families to confirm their willingness and ability to participate in the trial.

Meeting the Parents and youth.

At least one week prior to the start of the titration trial, a patient's parents are invited to a meeting with the treating physician who is in charge of the titration program. Since COVID, this meeting is most often done online. During this time the entire process is explained, and the parents are invited to ask any questions or voice concerns that they may have. The inclusion of the child in this preliminary discussion is decided on a case-by-case basis considering factors such as their age, maturity, and parental wishes. If the parents decide to proceed with the titration trial, they are provided with an information letter that they give to their child's teacher and they inform the teacher that a nurse will contact them.

The nurse provides the parents with all technical information about the trial. For example, the nurse explains the items of the daily questionnaire, how to complete the questionnaire online, the time involved in completing the questionnaire, and determines which parent will complete

the questionnaire (if they jointly complete the questionnaire, a determination as to who will decide the final rating will be made in case of disagreement), which teacher(s) are the most reliable to rate the child's behavior, and the best dates to start the titration given school schedules. If the parents choose to use paper form of the SAM, they are given written instructions and a set of questionnaires for the baseline week. If parents choose to use the online version, they are provided with a login, a password, and written instructions. Following the end of the trial, a nurse schedules an appointment for a post-titration consultation with the clinician who recommended the trial.

In most instances, the same parent is asked complete all questionnaires throughout the trial. This could be either the mother or the father or jointly (although joint completion is more time consuming). Case by case decisions of which parent should complete the questionnaires will need to be made if there is shared custody, with the child alternating their place of residence every second week, or if the week is split between the parents. If the parents did not agree about symptomatology (e.g., vast differences in the rating profiles completed as a component of the clinical investigations) the decision may be made not to have the questionnaires completed by the parents at all. In these rare cases, the titration procedure could rely exclusively on the teacher ratings, but this was seldom done. Such an approach should only be used if unavoidable. Given the potential difference between raters, parents generally agreed that the decision will be made primarily based on teacher ratings.

Meeting with school personnel.

First the parents contact the teacher and asked if they would agree to participate in the titration trial. If the teacher agrees, which is almost always the case, a nurse obtains the contact

information of a patient's school from their parents. The nurse then contacts the school administration and teacher to propose a meeting to explain the teacher's role in the procedure, emphasizing the time needed to complete the titration process. Again, since COVID, this meeting is most often done online. The school's authorization for providing the medication is picked up or faxed, and the timing and mode of administering the medication to the child at noon is discussed with the teacher. If the child has multiple teachers, the nurse determines who is going to fill in the questionnaire, as only one teacher should do it. If the child is in a French Immersion program or a high school program, and their time is split between multiple teachers every day, then two teachers can be asked to take part in the trial. If the teacher chooses to complete the questionnaires online, a password and a login are provided, together with instructions to access the SAM. Teachers are encouraged to use the online questionnaires, but a paper option is also available. If the teacher chooses to use the paper version, the instructions for completion and 5 copies of the paper questionnaires are mailed, one week at a time, to avoid confusion if the teacher forgets to add the date to the questionnaires. The initiation of the 4-week period of the titration is then selected in order to not coincide with a period in which the placebo week could negatively affect the child, such as the timing of an important test. The teacher also completes the baseline SAM questionnaires for one week in order to ensure that they are fully aware of the behaviours that they will be asked to rate and to provide them with an early opportunity to ask any questions they might have about the rating scale.

Contact with pharmacist.

When the timing of the trial has been formalized, the four-week period is randomized (via REDCap), and the week-to-dose assignment is sent through an automatic email to a local

compounding pharmacy. The participating pharmacy has previous relations with the trial physician and agrees to create Dispills for a small fee. The specific pharmacy used for CHEO titration trials requires 48 working hours advance warning to prepare the placebo and medication, thus the medication request is made on Wednesday for delivery on the following Monday. When a week of medication has been delivered, notification is automatically sent to the prescribing physician and the nurse. This email contains the dates of the start and end of the titration trial, but not the order of randomization (to ensure blinding). A specific titration prescription is created by the REDCap database, printed, signed by the prescribing physician, and faxed to the participating pharmacy.

Scheduling titration.

All titration trials begin on a Monday. The first medication Dispill and the set of questionnaires (if a paper option was chosen) for the first week are delivered to the patients' home on the previous Friday. The parents start giving the medication and filling out the questionnaire on the following Monday morning until the following Sunday evening. On the next Friday, the second medication Dispill and the set of questionnaires for the second week are delivered. Parents continue administering medication and completing questionnaires for the first week until Sunday evening. Upon delivering the third Dispill and the third set of questionnaires for the third week, the questionnaires and the used Dispill packaging of the first week are picked up. The same process applies if the parents use on-line questionnaires, as parents always have the possibility to fill in a paper form should they be unable to access the online format. Upon delivery of the fourth Dispill with the set of questionnaires for the fourth week, the questionnaires and the used Dispill of the second week are picked up. This process continues for

the remaining weeks in the titration. A final pick-up is done the Monday following the last Sunday (of week 4) to collect the questionnaires and the used Dispill packaging of the third and fourth weeks. If a lead-in phase is required, the first delivery is on Thursday and the three following days are used for the lead-in phase, before starting the first trial week on Monday. Please see Appendix 3 for a Gantt Chart of recommended trial timelines.

A baseline is completed one to three weeks before the titration process; the questionnaires are checked by the nurse, under the supervision of the trial physician. If there are any concerns with regard to the completion of the questionnaires, the family is contacted to review the instructions and confirm their comprehension of the procedure.

If the titration has to be interrupted because of side effects or difficult behavior, the parents are told to administer the medication the child was taking before the titration process was started. If the child was not treated before the titration, the prescribing physician may give the parents a prescription to cover the remaining days of that week.

Monitoring titration.

The patient's parents are provided with a contact number to call should they have any questions about procedures or the completion of the questionnaires. A nurse returns these calls. If no call has been received, the nurse initiates contact with the parents and teachers at least once a week to ask if they have any questions and to review if any pills have been missed. A nurse reports these calls and any missed pills on a specific phone log form, so that there is an overview of the missing doses, and any unusual events. This telephone log can be printed and reviewed during the feedback session with parents. One of the physicians on the hospital ADHD team is

on call (i.e., available by telephone) at all times. When necessary (e.g., negative side effects reported by the parent), the nurse contacts the on-call ADHD physician to inform them of the concern and provides them with contact information for the family. A nurse may also ask the parents to call the on-call team member through the hospital switchboard. Usual coverage on leaves of absence is used to ensure that a physician is always available.

For those families/teachers that opt to use the online forms, the nurse verifies that the online forms have been completed on a daily basis contacts the parents if there is a problem. The nurse is also responsible for examining the contents of each Dispill returned to the pharmacy and recording the number of pills taken/not taken. At the end of the titration period, the nurse automatically compiles the data and runs a scoring program using a short script, which produces the clinical reports of the trail and forwards them to the clinician who recommended the titration trial. The clinician and the nurse meet the parents to review the results of the titration procedure.

The feedback consultations between the treating clinician and the teacher, and then with the patient's parents are completed within three weeks following the completion of the trial. This means that the full procedure, including one week of baseline measurement, is completed in less than two months.

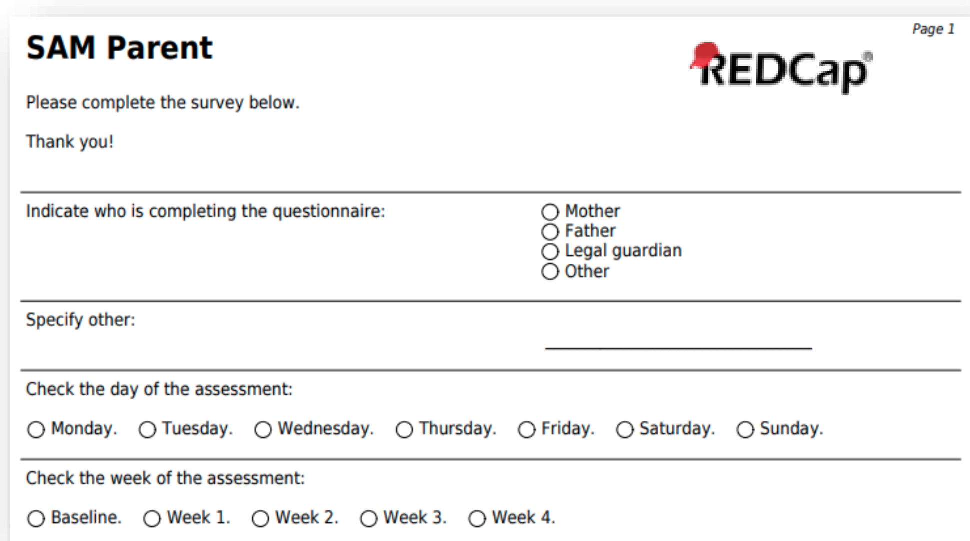
Web-based application

REDCap application

An initial application was developed using an Oracle database with support from the former Ontario Centre of Excellence for Child and Youth Mental Health (now the Knowledge Institute on Child and Youth Mental Health and Addictions). When CHEO's Research Institute set up a

REDCap database to support clinical research, the application was redesigned and is available to parents/teachers online. Parents and teachers enter their scores directly, which are then saved on a secure server.

Figure 1. An example of the online system used by parents and teachers.



The questions are presented one by one with a total of 5 “not applicable” responses that are allowed. It is possible to navigate back and forth between questions. Definitions of the ratings are available to the user by placing the cursor above each number on the scale from -3 to +3.

Clinical tools

Parent report

The results of the titration are summarized in automatically generated clinical reports. These graphs have been developed in collaboration with the CHEO Patient Decision Support Group. The clinical reports contain graphs showing the severity of ADHD symptoms and side effects for each day of the trial, critical items related to the patient's appetite, sleep, and emotional regulation, and the number of missing answers within the questionnaire (see Appendix 4). One version has been developed for parents and one version for children and adolescents.

If there is no difference observed in the graphs of behavioural symptoms across doses, a result of "no condition" is determined, reflecting that no condition was clearly better than another. If a difference is observed, the most effective dose, defined as the lowest dose for which there was a meaningful clinical change, is assigned as the "best dose condition". Finally, side effect scores are examined to ensure that the "best dose" is not associated with significant side effects. Children who show no response (placebo) or no-condition are considered non-responders. If the best condition chosen is not the placebo, the child is considered to be a responder. Classification as responder or non-responder is regarded as the prime indicator of the response (or not) to treatment.

During the feedback consultation the results of the trial are discussed, and with support from the treating clinician, parents are asked to rank the titration weeks according to their interpretations of improvements of ADHD symptoms and reduction of side effects. As side effects are given equal credence in the decision of a "preferred" recommended week, that week may not be the one associated with the most reduction in side effects. For example, should a

child respond best to a given week in terms of ADHD symptoms, but that week is associated with poor sleep quality and a reduction in appetite, that particular week ultimately may not be the preferred week. The ranking of weeks is based on what parents hold as most important for consideration for their child and not the treating physician's clinical recommendation, making this a shared decision-making approach. Once a preferred week is decided upon, the blinding of the weeks are removed, and both the parents and the treating physician are able to see the corresponding recommended dosage. This dosage becomes the child's maintenance dose moving forward.

If the parents decide to use a long-acting medication (Concerta, Biphentin), instead of short acting medication, the results of the titration trial are used to compute the corresponding long-acting maintenance dosage. In these situations, the same parent and the teacher may complete the SAM questionnaire for an additional week of the new treatment, in order to ensure patient acceptance and tolerability of the new medication.

In the MTA protocol, there is "room for improvement" (RFI) condition if the final recommended dosage of medication does not reduce ADHD symptoms to almost normal levels. In addition, if that dose shows a "meaningful clinical change" (MCC), but there is still RFI and tolerable adverse effects, the medication can be tried at a higher dose. In the CHEO titration, shifting from the best to the preferred dose needs to consider additional specific outcomes (i.e., opposition/defiance) for a "room for improvement" condition to be applied. In addition, a RFI condition needs to consider "room against worsening" (RAW), a buffer that protects the patient against potential adverse effects. For our protocol, there is RFI or RAW only if the effect is clearly dependent on the dose. Therefore, it can be predicted that a higher dose would produce a MMC. With these more stringent criteria, the need to try a higher dose than those scheduled in

the trial is rare. However, the strength-based rating clearly often suggests that there is a "room for progress" (RFP), (i.e., as some ratings are still not in the normal zone). Acknowledging this, RFI allows for the discussion of evidenced-based non-pharmacological approaches in the treatment of a particular patient's ADHD, such as behavioral parent training, behavioral management, as well as school adaptation.

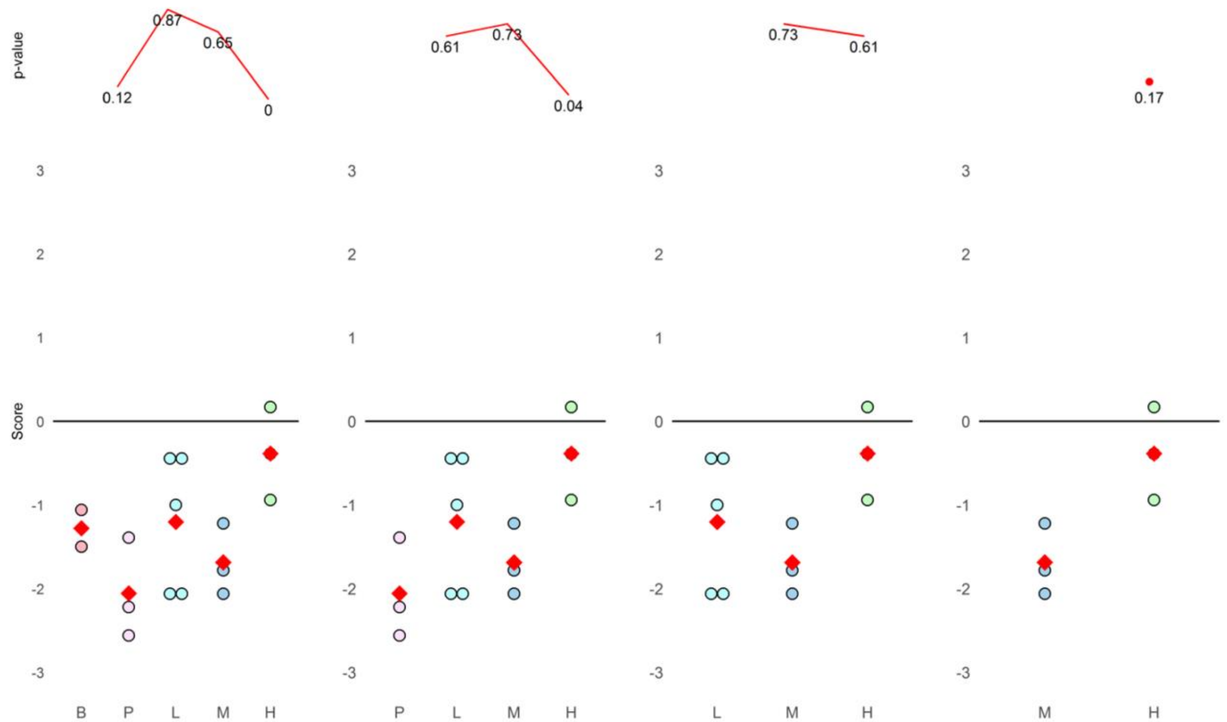
In the MTA study, if there is a RFI and no MCC, the child is a non-responder and was given an open trial of dextroamphetamine. The same strategy is used in the CHEO titration, except that the shift from the best to the preferred dose leads to judge the MCC along multiple dimensions for both positive and adverse effect. Before taking any decision to try another stimulant (dextroamphetamine), parents are informed that among non-responders to methylphenidate, only 43.5% would respond to it the new medication as the two medications have shown approximately 90% overlap in efficacy. Finally, a report is sent to the referring physician with the clinical reports, the preferred dose and any key points of the shared decision meeting with the parents.

Other decision supports

In order to support the comparison between weeks, a statistical procedure has been developed in conjunction with the generation of clinical reports. First, we randomized days across the four weeks of trials, so that any difference related to systematic change between weeks (dosage) is lost. Second, we computed over 1000 bootstrapped sets of data and the probability of obtaining the observed difference between two weeks. In order to take autocorrelation into

account, the mean for contiguous days is computed, and these means are used in bootstrapping, not the individual days. A graphic output is automatically generated (see Figure 2).

Figure 2. Statistical Reports used to Corroborate Comparisons Between Weeks.



Clinical sample

Feasibility of the CHEO approach to stimulant titration has been assessed using the data obtained from patients' trials. The sample is composed of 23 patients (age range 7-15 years; mean age: 10.7 ± 2.3 years); 16 males and 7 females, who were consecutively referred for titration. They all had a diagnosis of ADHD, as per their medical chart: 14 combined type, 4 inattentive, 1 hyperactive-impulsive and 1 not otherwise specified. The majority had comorbid conditions (N=16, 70%) with 6 learning disorder, 4 Oppositional Defiant Disorder, 4 Parent-

Child Relational Problem, 3 Developmental Coordination Disorder, 2 Autism Spectrum disorder and 3 other problems.

Results

Descriptive analyses of the scores

The results on the feasibility sample showed a clear effect of dose of medication (see Figures 3 & 4). When examining this effect on the global ADHD score, this dose effect was stronger in teacher's than in parent's ratings: $F(2.12, 40.276) = 4.050$; $\varepsilon = .707$, $p=.023$). A remarkable aspect of using strength-based instrument is that the ratings are no longer confined by a ceiling of zero (no symptom) as in symptom-based tools. This translated into a linear within-subject contrast that was stronger in teacher's than in parent's ratings: $F(2.12, 19) = 6.821$; $p=.017$). Similarly, "side-effects" decreased with increasing doses, and this effect was also stronger in teacher's than in parent's ratings: $F(3, 57) = 5.998$; $p=.001$). This linear within-subject contrast was also stronger in teacher's than in parent's ratings: $F(1, 19) = 10.741$; $p=.004$). The only side-effect that appeared to increase with dose was neurovegetative which includes sleep problems and loss of appetite, and only in parent's rating.

Figure 3. SAM scores by parents as a function of the stimulant dose.

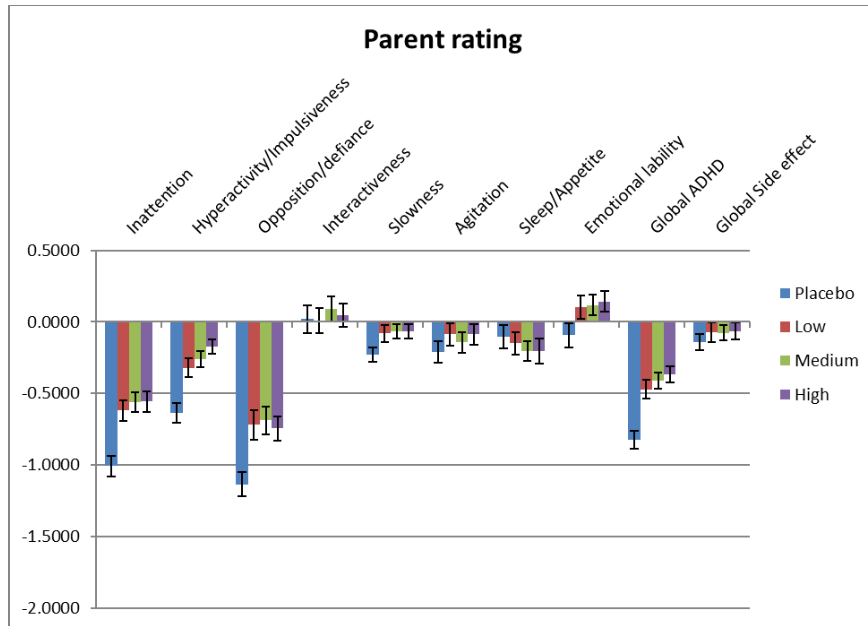
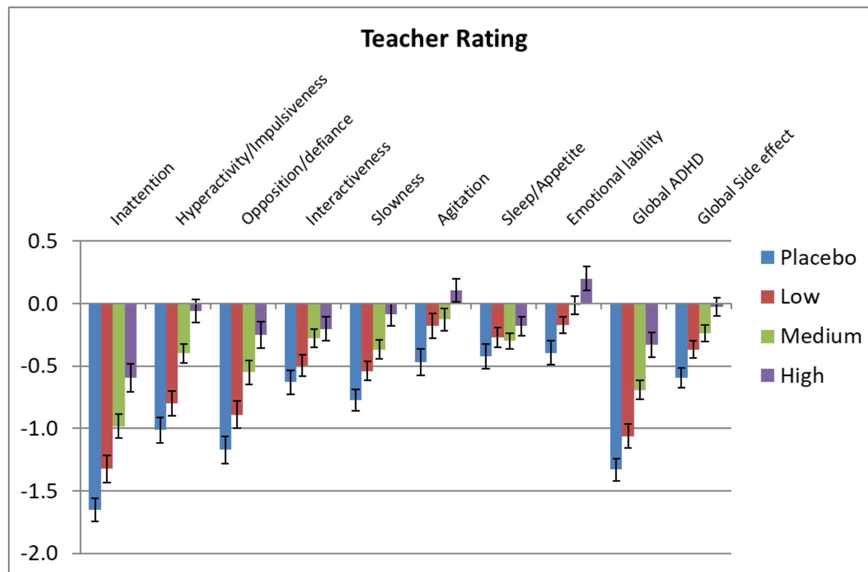


Figure 4. SAM score by teachers as a function of the stimulant dose.



We also wanted to test that the differences between weeks were mostly due to the differences in dose and not to the order of the weeks. First, as most children had a baseline week before the titration, we present the graphs of the scores from the baseline to the last week of titration (Figures 5 & 6). Clearly the scores do not reflect an order effect during the titration, but the ratings were worse during the base line as compared to the titration weeks, especially for the ADHD symptoms in parent's ratings. There was a very significant difference between all 5 weeks when comparing the total ADHD scores by the parents: $F(4, 80) = 10.757$; $p < .001$.

Figure 5. SAM scores by parents as a function of the order of the weeks.

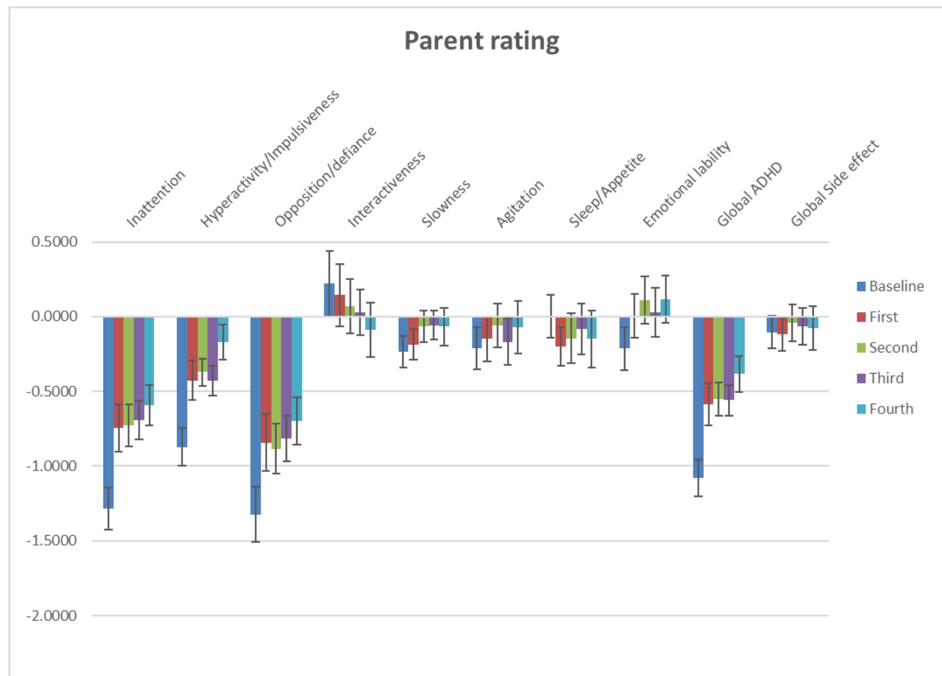
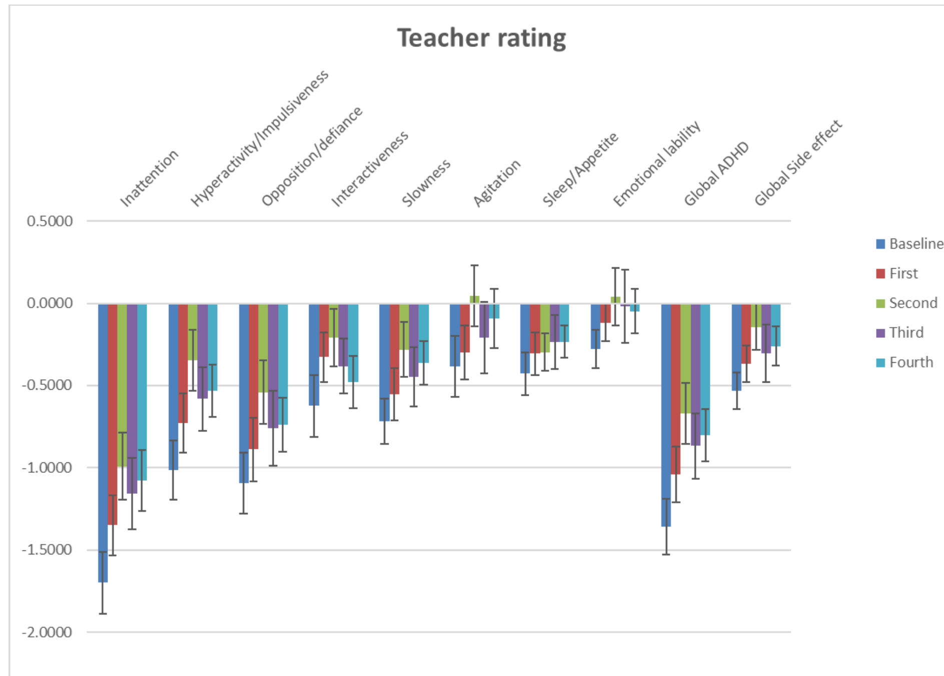


Figure 6. SAM score by teachers as a function of the order of the weeks.



When examining pairwise comparison (t-test with Bonferonni correction), the ratings for the baseline week were significantly more negative than any other week ($p \leq .001$), a difference that was never significant when comparing the other weeks between them (Table 2).

Table 2. Pairwise comparisons of parent ADHD scores and week

(I) Week	(J) Week	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b] Lower Bound	Upper Bound
1	2	-.517*	.100	<.001	-.834	-.200
	3	-.561*	.110	<.001	-.907	-.215
	4	-.546*	.113	.001	-.902	-.190
	5	-.707*	.112	<.001	-1.061	-.352
2	1	.517*	.100	<.001	.200	.834
	3	-.044	.117	1.000	-.412	.324
	4	-.029	.125	1.000	-.423	.365
	5	-.190	.122	1.000	-.576	.196
3	1	.561*	.110	<.001	.215	.907
	2	.044	.117	1.000	-.324	.412
	4	.015	.130	1.000	-.394	.425
	5	-.146	.117	1.000	-.513	.222
4	1	.546*	.113	.001	.190	.902
	2	.029	.125	1.000	-.365	.423
	3	-.015	.130	1.000	-.425	.394
	5	-.161	.119	1.000	-.535	.213
5	1	.707*	.112	<.001	.352	1.061
	2	.190	.122	1.000	-.196	.576
	3	.146	.117	1.000	-.222	.513
	4	.161	.119	1.000	-.213	.535

Based on estimated marginal means

*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.

By contrast, no significant difference emerged between all 5 weeks when comparing the total side effect scores by the parents: $F(4, 80) = 0.707$; ns. There was also significant differences between all 5 weeks when comparing the total ADHD scores of the teachers: $F(4, 76) = 3.865$; $p = .007$, but the differences between weeks were less systematic. The baseline week was involved

in every difference that was significant. In teacher's ratings of side effects, the differences between all 5 weeks was barely significant: $F(2.431, 14.645) = 2.865$; $p=0.057$. Pairwise comparisons did not yield any significant effects.

Table 3. Pairwise comparisons of teacher ADHD scores and week

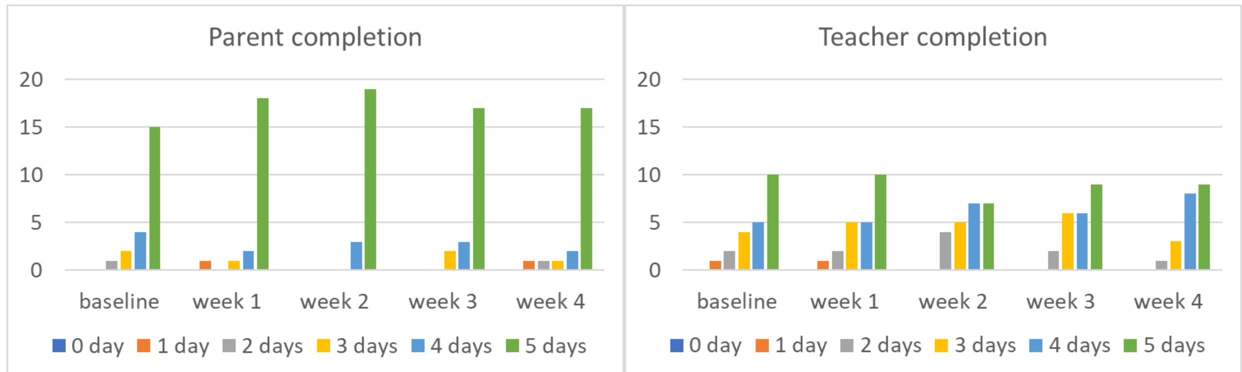
(I) Week	(J) Week	Mean Difference (I-J)	Std. Error	Sig.[b]	95% Confidence Interval for Difference[b]	
					Lower Bound	Upper Bound
1	2	-.339	.164	.520	-.858	.180
	3	-.762*	.197	.010	-1.386	-.138
	4	-.471	.232	.571	-1.208	.267
	5	-.558	.177	.053	-1.119	.004
2	1	.339	.164	.520	-.180	.858
	3	-.423	.225	.753	-1.136	.290
	4	-.132	.229	1.000	-.859	.596
	5	-.219	.203	1.000	-.863	.426
3	1	.762*	.197	.010	.138	1.386
	2	.423	.225	.753	-.290	1.136
	4	.291	.207	1.000	-.364	.947
	5	.204	.192	1.000	-.405	.813
4	1	.471	.232	.571	-.267	1.208
	2	.132	.229	1.000	-.596	.859
	3	-.291	.207	1.000	-.947	.364
	5	-.087	.203	1.000	-.731	.557
5	1	.558	.177	.053	-.004	1.119
	2	.219	.203	1.000	-.426	.863
	3	-.204	.192	1.000	-.813	.405
	4	.087	.203	1.000	-.557	.731

Data completion

To assess the completion rate, we calculated the number of days over which the various questionnaire factors (SAM) could be calculated, knowing that at least half of the items must be completed to do so. This is a relevant index as it enables us to assess the number of days

contributing to the weekly graphs of the clinical report. The results show that the completion rate is higher for parents than for teachers, which is expected (Figure 7). Among parents, it is most often at 5 days, and occasionally lower. Among teachers, it is most often between 3 and 5 days.

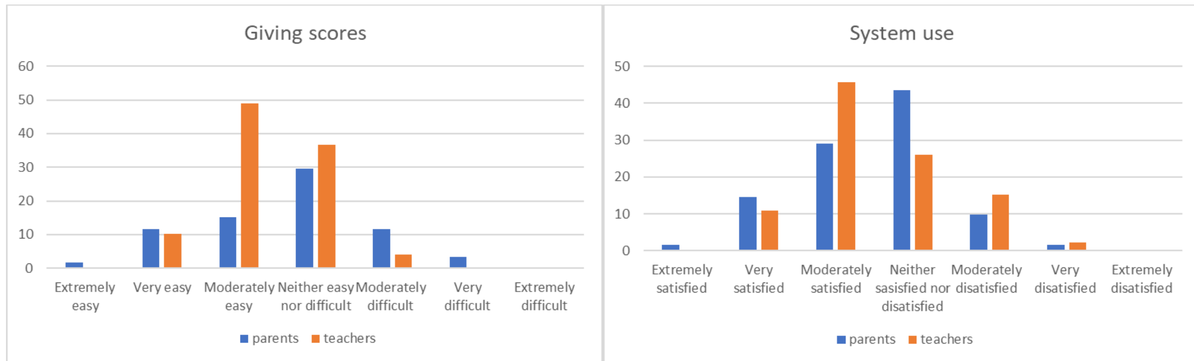
Figure 7. Parent and teacher survey completion rates.



Easiness of scoring and system usability

The usability of the online questionnaires was assessed by asking 2 questions at the end of the tool: (1) *How easy or difficult was to give scores to the questions today? Leave us a comment if you want* and (2) *How satisfied are you with the system you are working with today? By satisfied we mean the ease and functionality of the system itself*. Responses were provided by 6 parents and 4 teachers. More than 40% of teachers found it moderately easy to rate the behavior and were satisfied when using the system, while parents were more neutral with the scoring and the system (Figure 8).

Figure 8. Parent and teacher ease of scoring and system usability.



Discussion

Therapeutic response and side effects

We observed a discordance between side effects such as loss of appetite or sleep difficulties and other side effects (psychomotor, mood and anxiety, social interaction, etc.), the former being worsened with an increased dose of stimulant, while the latter were improved. This is not the first observation along these same lines. As early as 1990, Barkley (47) reported a significant worsening of side effects such as loss of appetite and insomnia when comparing parents' scores for a placebo with low or high doses of methylphenidate, while teachers reported a significant improvement in side effects for anxiety, sadness, and lack of interaction (staring). In another study (48), insomnia, loss of appetite, headaches, stomach aches and somnolence increased in frequency with higher doses of methylphenidate, while waking reverie, irritability, anxiety and nail biting decreased in frequency compared with placebo. Similarly, parents reported a greater average number and higher average severity of side effects before a drug trial than during the period when children were taking methylphenidate (49). In another double-blind,

placebo-controlled trial (50), side effects were present with both placebo and low- or high-dose stimulants, except for sleep disturbance, reduced appetite and nail biting. In addition, according to the parents, the total side-effect score was significantly correlated with the Abbreviated Conners Rating Scale for ADHD symptoms, both with placebo and with low- and high-dose methylphenidate. In an open-label study, after 15 days of treatment with methylphenidate (18±5 mg/day), "loss of appetite" scores worsened significantly, but "irritability", "ready to cry", "anxiety", "nail biting" and "euphoria" scores improved (51). In a double-blind crossover trial in which 157 children diagnosed with ADHD (aged 6-12) received placebo and methylphenidate (0.5 mg/kg b.i.d. divided dose), each for one week, the side effects of decreased appetite, insomnia and headaches worsened under treatment, but other side effects did not (52). These somatic side effects were not correlated with response to methylphenidate as assessed by the Conners' Global Index (CGI) for parents, whereas mood and anxiety side effects (irritability, proneness to cry, anxiety) were. However, they were not correlated with medication-related changes in CGI scores by teachers. The authors conclude that mood and anxiety symptoms could influence how parents score their child's behavior. One interpretation of why these symptoms have been interpreted as side effects of stimulants is that they respond significantly less well to treatment than the primary symptoms of ADHD (inattention, hyperactivity/impulsivity). As ADHD symptoms diminish, these secondary symptoms become relatively more evident and may be considered to emerge with treatment. But the extent to which they share a common biological basis with ADHD is still a matter of unresolved research.

Another aspect of these data is the presence of a clear placebo effect in parents' ADHD scores, but not in those of side effects. For teachers, this placebo effect was much less dramatic, and can be considered non-significant for both ADHD symptoms and side effects. In the MTA

study (53), 32 children (12.5% of 256) responded equally well to placebo and methylphenidate, with no room for improvement, and were considered placebo responders. But during the 14-month follow-up period (54), only 3 remained medication-free (9% of 32, or 1.2% of the 256 who had completed titration) following a significant relapse of ADHD symptoms. This placebo effect was robust enough to reduce the stimulant dose by 50% in a sample of 26 subjects (27% girls, age range 7-15), with no reduction in parent and teacher ADHD scores (IOWA Conners parent and teacher rating scales) when combined with a "dose extender", even though the parents, child and doctor were fully aware that the extender was a placebo ("a pill containing no active drug or medication") identifiable by a visually distinguishable capsule (55). Not all that surprisingly, given our previous discussion, the side effects rated by parents were no lower in the 100% dose condition, compared with 50% with a placebo.

Finally, the use of strength-based scales allows us to explore the full range of drug effects on the various symptoms of ADHD and side effects, making it possible to distinguish responders with greater precision and sensitivity. In conclusion, the pharmacological response in a blind, placebo-controlled, crossover trial is sufficiently clear after one week to assess it and make a treatment recommendation.

Shared decision making

Although stimulants are a first-line treatment approach for ADHD (56, 57), it can often be difficult for parents to come to terms with the idea of medicating their child (58, 59). The decision to use stimulant medication for a child’s ADHD is rife with decisional conflicts. Parents may attribute their child’s behaviour to emotional problems rather than as ADHD symptoms, or see their actions as instigated by a third party, commonly the child’s school. Finally, some

parents may not perceive their child's *behavior* as problematic and therefore do not endorse a medication strategy. Among parents who do decide to treat their children's ADHD with medication, differences in perception can persist (59). For example, some parents may delay treatment with medication for as long as possible, with their sense of parental self-efficacy or emotional support being the driving force behind this delay (60). When a child's negative behavior continues unabated, and parents become exhausted or feel a sense helplessness, medication treatment strategies are often viewed as a last resort (61).

Labelling a child's condition as ADHD may validate and legitimize a parent's difficult experiences. As such, initial treatment negotiations are a crucial step that can help resolve decision-making conflicts, and thus reduce the likelihood of a parent delaying their decision, change their mind about the chosen treatment, regret their decision and blame the treating physician in the face of poor results (62). A shared decision approach significantly aids in the initial treatment negotiations, certifying that parents are equal and active participants in the treatment of their child's ADHD with stimulant medication. Recent meta-analyses have showed significant improvements in patient-clinician communication, reduced decisional conflict, and fewer participants remaining undecided regarding treatment options when using an SDM approach (63, 64).

In a shared decision-making process, the clinician engages the patient (here the parents/guardians and child) in a deliberative decision-making process, exploring and clarifying their preferences. The key elements of a shared decision-making process are to explain the decision-making process in detail, to clearly present the benefits and risks of the different options, to communicate clearly about the probabilities of the different possible outcomes, to clarify the values on which the parents want to base their decision, i.e. the outcomes that matter

most to them or the problems they absolutely want to avoid, and to present the data in a balanced way (65). Most often, this approach involves the use of decision aids. According to the International Patient Decision Aids Standards (IPDAS) Collaboration (66), “Patient decision aids are tools designed to help people participate in decision making about health care options. They provide information on the options and help patients clarify and communicate the personal value they associate with different features of the options.” In addition to increasing patient knowledge and awareness of treatment options, engaging in the decision-making process, improving in risk perception, and reducing decisional conflict(62), PDAs have been shown to reduce racial and minority health inequities (67, 68) and introduce significant cost savings (69). There are few specific examples of decision aids in the initial treatment of ADHD, but one study evaluated the effect of using ADHD medication choice cards on shared decision-making. The cards covered important aspects of medication, namely "Improvement," "Side Effects," "Duration," "Daily Routine," and "Cost". Compared to controls, intervention group parents were more involved in shared decision-making, more knowledgeable, and less conflicted about treatment options (70). We have developed a report template that displays parent and teacher scores in an intuitive yet deliberative manner, with parent and teacher scores in columns and weeks on rows, using the same scores that parents reported throughout the titration (see Appendix 4). This reporting format applied to the different components of the SAM scale enables parents to readily compare different aspects of their decision, to clarify what is important to them, and to prioritize certain components according to their values, since there are always differences in dose-dependent changes between different symptoms and side effects, at school or at home. With practice, we also added a page showing the evolution of scores over the 4 weeks of titration for critical items, which are issues that often carry a lot of weight in the final decision: maintain a normal appetite

over time (parent); go to bed, get to sleep and remain asleep (parent); hold back from being excessively tearful, prone to cry, looking excessively said (teacher and parent). However, the final decision is always weighted by personal factor unique to each parent and child.

In addition to decision aids, we took advantage of the blinding process to further reinforce shared decision-making. Blind design originates in pharmacology and enables placebo effects to be controlled. In usual practice, the blind is lifted at the end of the titration and the clinician communicates the results to the parents with full knowledge of the doses assigned to each week, which enables them to demonstrate the effects of the medication by comparing weeks. We made a deliberate decision to keep the results discussion on a blind basis. In this meeting, the doctor cannot explain the results in terms of the drug's effect (without taking an unwise risk), but the parents can explain without resistance why they prefer one week over another, according to their priorities. This voluntary de-balancing of the relationship in fact enables a re-balancing of the relationship in which the parents are the experts on their child's behavior, and the clinician is the experienced guide who enables them to grasp the available information easily and completely. Once the decision has been made, the clinician once again becomes the expert in implementing the decision, for example, by discussing the pros and cons of different stimulant long-acting forms. This enhanced shared decision-making process is made possible by the nature of the drugs discussed, in particular their short half-life and rapid elimination, but could be extended to other examples.

Statistical support

In the present titration process, the responder definition follows a logical approach based on the algorithm developed for the MTA study, in particular the concepts of meaningful clinical

change and room for improvement (71), but is not based on a statistical index. But in the titration developed by Vertessen (72), the definition of responder was based on the reliable change index (RCI)(73). The RCI is defined as a change in score divided by the standard error of the difference for the test used. It is therefore a standardized difference representing a change in a score that is below a probability threshold if no extrinsic factors modify its distribution. While its statistical validity is evident, its validity as a clinical decision-making tool is less certain. It obviously depends on the difference considered, and there are many differences to be considered that will have different RCIs. But this index also leads to the rejection of differences that parents might consider clinically significant, even if the attribution of this difference to the effect of the drug does not reach a pre-established threshold. We have also developed a statistic approach to dose differences. In this approach, we calculate differences in mean scores or proportions of scores less than or equal to -2 (defined as a symptomatic score) between two weeks, for all pairs of weeks, and then use a bootstrap approach to assess the probability of obtaining a difference at least equal to that observed. The statistical report is not intended for discussion with families and is only available after the shared decision-making process has been completed. But it does give the clinician an idea of the probability linked with the difference related to the preferred dose.

Logistical considerations

As we have shown with the completion rates, getting parents and teachers to complete the questionnaires is a challenge. One way of reducing the demand on parents and teachers is to ask them to complete only one questionnaire at the end of each week, instead of one each day. Due to its retrospective nature, the scoring process can be influenced by significant incidents during the week and can bias the assessment. With a single questionnaire per week, the risk of having

no information on that week is also automatically increased. We should also consider that the task of filling in daily questionnaires for the duration of the titration is an adaptive one, enabling parents to participate in decision-making based on their own assessment, to learn about symptoms and side-effects, to feel supported in this decision by a team that monitors the process daily, and thus contributes overall to the necessary adaptation of parents to the reality of raising a child with a neurodevelopmental disorder such as ADHD. The same reasoning can be applied to teachers in their more demanding educational effort than for other children without difficulties in their class. Finally, parent and teacher satisfaction with an online system is acceptable, and the questionnaire completion rate is very good for parents and acceptable for teachers. Since we implemented a systematic meeting with the teacher and principal, now done online, teacher participation is further encouraged. But it is always important to make a preliminary assessment of the feasibility of titration, especially in very complex situations (parental disputes over custody, teenagers living in foster homes, etc.).

The SDM stimulant titration protocol for the treatment of ADHD in children and adolescents used at the Children's Hospital of Eastern Ontario has several logistical considerations that need to be addressed in order to be implemented properly. For example, this titration approach relies largely on a compounding pharmacy that is willing to make dispills (that include placebos), as well as ship them to participating patients. The treating physicians within the hospital have personal community ties to local compounding pharmacies, enabling us to use their services within our trials.

The generation of clinical reports from the trials also requires the implementation of an online questionnaire system and related computer scripts that compile the titration data. These automated reports summarize the severity of ADHD symptoms and side effects from each week

into easily digestible and user-friendly graphs. The ease in which these graphs are generated allow for quick follow-up appointments with a patient's family to determine a best recommended week (and therefore dose) for the patient. Our hospital's Clinical Research Unit aided in the programming of automation scripts, allowing for the easy generation of reports.

Conclusions

According to the one of the principal authors of the original MTA study, a major goal of the project was to "bridge the gap between research and clinical settings" and to "provide a protocol whose findings could be translated into practice" (21). By building upon the original medication management protocol in the MTA, automating the randomization and delivery of medication, offering the questionnaires online, limiting the number of clinicians evaluating the results of the trials, automatic generation of clinical reports, and introducing a Shared Decision-Making approach we hope to change the way in which clinicians approach stimulant titration for the treatment of child and adolescent ADHD.

Acknowledgements: we want to thank Marina Lifshin for her contribution to the previous Oracle version of the titration database.

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Appendix 1. SAM Rating Scale

Given the size of the SAM Rating Scale, the survey in its entirety has been hosted on the University of Ottawa's One-Drive server. Please click here to access the scale.

Appendix 2. Example of the Dispill distributed to patients each week.

Test Patient, Nursing Home
Test Home
ON

13-Dec-2007
Card 1

Qty	Form	Generic	Description	Mfr	DIN	Instructions	Rx	Doctor
21	CAP	MPH Study, Child <25kg		GLB	00000000	1 CAPSULE BETWEEN 7-8A(?), 1 BETWEEN 11A...	499476	Dr

Printed on: 13-Dec-2007 (for 1 weeks starting 13-Dec-2007)

Page 1 of 1

Test Patient, Nursing H... 19-Dec-2007 Glebe Pharmasave Apot... Wed 0700-0800 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 19-Dec-2007 Glebe Pharmasave Apot... Wed 1100-1200 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 19-Dec-2007 Glebe Pharmasave Apot... Wed 1500-1600 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 19-Dec-2007 Glebe Pharmasave Apot... Wed
Test Patient, Nursing H... 18-Dec-2007 Glebe Pharmasave Apot... Tue 0700-0800 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 18-Dec-2007 Glebe Pharmasave Apot... Tue 1100-1200 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 18-Dec-2007 Glebe Pharmasave Apot... Tue 1500-1600 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 18-Dec-2007 Glebe Pharmasave Apot... Tue
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Test Patient, Nursing H... 14-Dec-2007 Glebe Pharmasave Apot... Fri 0700-0800 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 14-Dec-2007 Glebe Pharmasave Apot... Fri 1100-1200 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 14-Dec-2007 Glebe Pharmasave Apot... Fri 1500-1600 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 14-Dec-200 Glebe Pharmasave Apot... Fri
Test Patient, Nursing H... 13-Dec-20 Glebe Pharmasave Apot... Thu 0700-080 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 13-Dec-2007 Glebe Pharmasave Apot... Thu 1100-1200 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 13-Dec-2007 Glebe Pharmasave Apot... Thu 1500-1600 1 CAP MPH Study, Child <25kg	Test Patient, Nursing H... 13-Dec-200 Glebe Pharmasave Apot... Thu

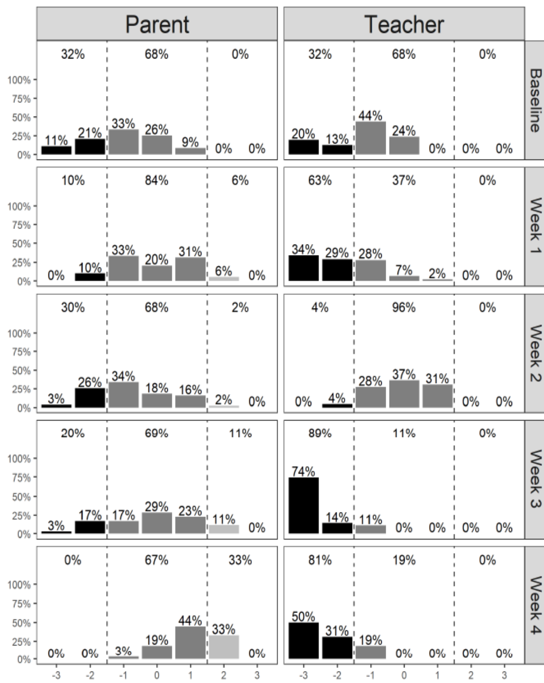
Appendix 3. Gantt Chart of Recommended Trial Timelines

Lead-in Week				Week 1							Week 2						
Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Dispill and questionnaires for **lead-in** are delivered																	
	Parents administer medication and complete questionnaires for **lead-in**			Parents administer medication and complete questionnaires for **week 1**							Parents administer medication and complete questionnaires for **week 2**						
	Dispill and questionnaires for **week 1** are delivered							Dispill and questionnaires for **week 2** are delivered							Dispill and questionnaires for **week 3** are delivered		
															Dispill packaging and questionnaires for **week 1** are recovered		

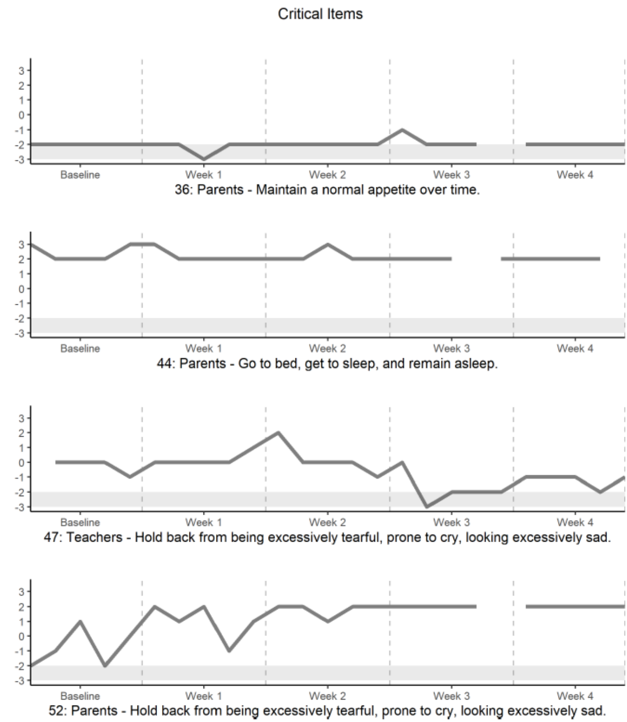
Week 3							Week 4							Recovery Week			
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Monday	Tuesday	Wednesday	Thursday
Parents administer medication and complete questionnaires for **week 3**							Parents administer medication and complete questionnaires for **week 4**										
				Dispill and questionnaires for **week 4** are delivered													
				Dispill packaging and questionnaires for **week 2** are recovered										Dispill packaging and questionnaires for **weeks 3 and 4** are recovered			

Appendix 4. Example of Items within the Clinical Reports Generated from the Titration Trials

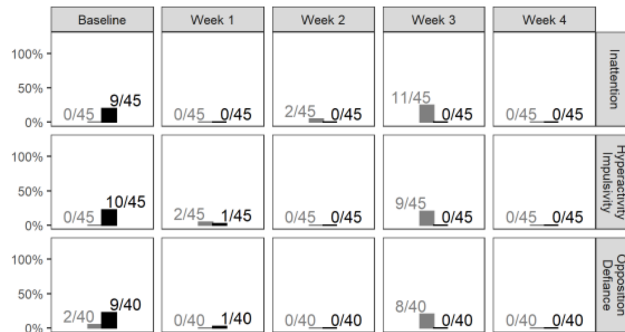
Global ADHD



Critical Items



Answers Missing



Chapter 5: The Uptake of Innovation and the Adoption of New Approaches to ADHD Treatment: An Examination of the Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study Offshoots

Tentative Journal: Journal of Child and Adolescent Psychopharmacology

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Funding details:

No funding details to declare.

Abstract

Objectives: The purpose of this study was to examine differing approaches to ADHD stimulant titration treatment as they relate to the original MTA study. In addition, to compare and contrast the protocols, measurement plans, management plans, and decision processes used in each of these approaches. The final goal of this study was to qualitatively examine the MTA approach and its "offshoot approaches" to ADHD treatment as a means to situate the adoption of this approach as it relates to clinical healthcare settings.

Methods: A literature review of studies/protocols that have used an MTA approach or a similar approach to ADHD treatment was done, resulting in 10 identified studies. Of these 10 studies, six investigators were recruited for a series of semi-structured interviews. The interview protocol used was based on the NASSS framework. Questions aimed to gain information from the participants about key features of their chosen approach, their thoughts on the sustainability of their project, and the factors leading to the ultimate success or failure of their approach.

Results: Identified protocols were compared and contrasted based on their country of origin, blinding, stimulant used, randomization schedule, delivery of questionnaires, delivery of medication, supports used, and dosage decision process. Qualitative analysis revealed 12 facilitators, 9 barriers, and 4 mixed factors related to uptake and adoption of an MTA style approach to ADHD treatment according to the NASSS domains.

Conclusions: The identified implementation barriers, facilitators, and mixed factors for each domain of technological innovation within the NASSS provide valuable insight for policy makers, hospital administration, and clinicians in implementing MTA-style approaches. For successful implementation of these sorts of approaches, we recommend addressing or mitigating

organizational, policy/legislative, or funding-related barriers and promoting the streamlining of MTA-style protocols and innovation champions within healthcare settings.

Key Words

ADHD; Shared Decision Making; Clinical Practice; Stimulant Titration; Methylphenidate.

Introduction

Attention Deficit-Hyperactivity Disorder (ADHD) is the most common neurodevelopmental disorder among children and adolescents. A recent systematic review and PRISMA-based meta-analysis suggests that the global prevalence of ADHD in children and teenagers is 7.6% (95% confidence interval: 6.1–9.4%) and 5.6% (95% confidence interval: 4.8-7%) respectively (1). Characterized by persistent patterns of inattention and/or hyperactivity and impulsivity (2), ADHD is more commonly diagnosed in male children (3). Children diagnosed with ADHD can exhibit difficulties in learning, disruptive behaviours, and poor social skills (4). The social ramifications of ADHD can persist well into adulthood, resulting in unemployment, criminal behaviour, social and interpersonal problems, and unhealthy lifestyles and physical injury (5-7).

Publications on ADHD and its treatment have increased exponentially within the last 40 years (8, 9) with one of the most notable studies on the subject being the National Institute of Mental Health (NIMH)-funded Multimodal Treatment Study of ADHD (MTA) (10). The first study of its kind, the authors (MTA Cooperative Group) sought to evaluate the leading treatments for child and adolescent ADHD in order to determine an optimal treatment approach. This 14-month study comprised of a sample of 579 children with Combined Type ADHD that were assigned to either a medication management group (titration followed by monthly visits); an intensive behavioral treatment group (parent, school, and child components, with therapist involvement gradually reduced over time); a combined group; or a standard community care group (treatments by community providers). Although all four groups showed reductions in ADHD symptoms over time, the medication management treatment group was superior to behavioral treatment and to routine community care.

The MTA Medication Management Protocol

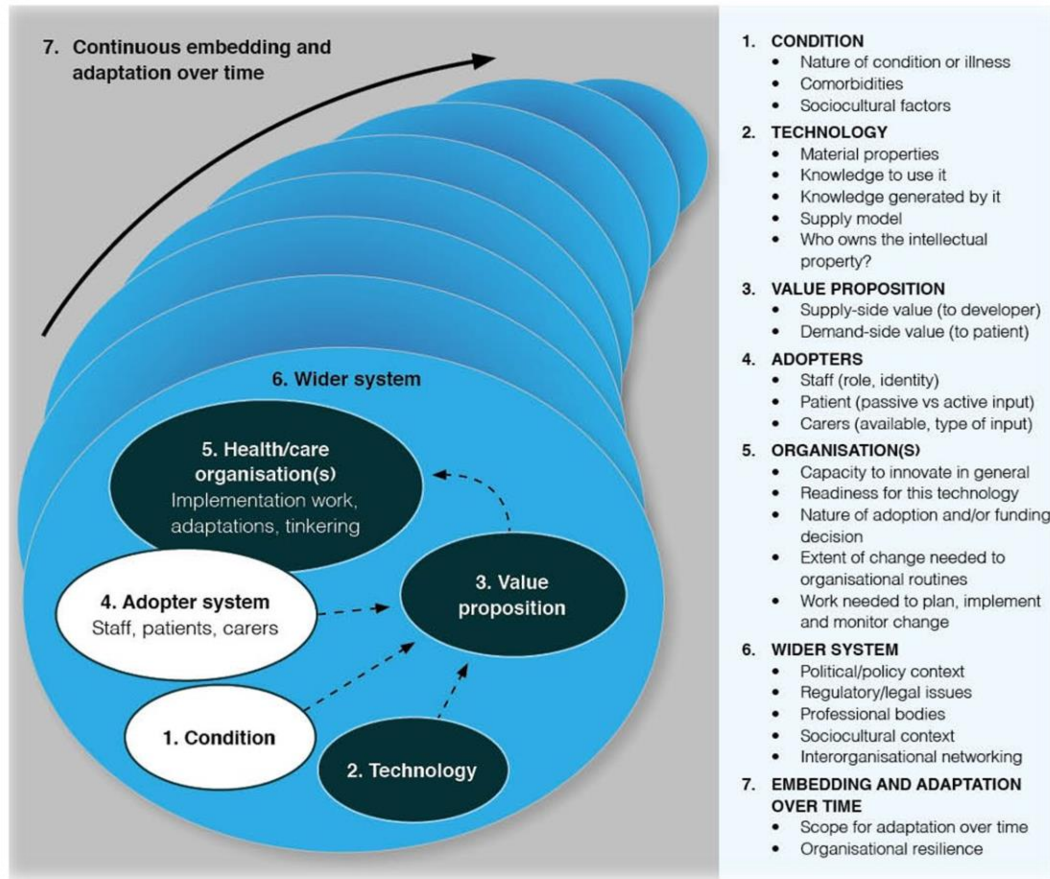
The Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study (MTA) stimulation titration protocol was part of an optimal ADHD medication treatment strategy (11-14). In short, the titration process was a 28-day trial that administered three doses of methylphenidate and placebo in a randomized crossover, daily switching, triple-blind protocol. The MTA titration rating scales for parents and teachers addressed ADHD symptoms and adverse events. A titration trial dose selection algorithm was used by experts to blindly rate the graphs and side effect tables that summarized the results. As a result, the *"best"* dose to start maintenance was recommended. Prior to the MTA study, standard treatment approaches to ADHD included a process of trial and error, where clinicians would start treatment with a low dose of stimulant medication and slowly increase the dose over time until symptoms remit, or side effects became intolerable. Despite showing evidence that the MTA medication management approach held many benefits for the treatment of ADHD, especially in terms of the identification of an acceptable starting dose for an ADHD patient, it has struggled with widespread clinical adoption. From the start, it was recognized that the MTA titration trial's design was complex (11) and unlikely to be used in standard office practice (15). However, different attempts have been made to transfer the key aspects of the MTA titration design into clinical practice.

The Uptake of Innovation

Since the early 2000s, research into the uptake of technological innovation has gained momentum, with level of uptake now being viewed as a significant potential contributor to health (16). That being said, programs that require major changes in organizations or the wider care system have seen a general lack of uptake due to problems of non-adoption and abandonment from practitioners and difficulties with scale-up (17). According to Greenhalgh et al (2017), the poor uptake of technological innovations can often be explained in terms of barriers and facilitators (18). For example, studies examining telehealth, electronic patient record systems, electronic prescribing, and surgical safety checklists have used barrier-and-facilitator approaches to examining intervention uptake. However, barrier-and-facilitator approaches do not always have the underlying theoretical foundations as to why a program or intervention fails to be adopted, scaled, spread, or sustained (18). Herein, the Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework can be useful.

The evaluation of health technology programs should be theoretically informed, interdisciplinary, and generate in-depth explanations. The NASSS framework was developed to study unfolding health programs in real time and to identify and manage their emergent uncertainties and interdependencies. The NASSS framework comprises questions in seven differing domains (see Figure 1): (1) the condition or illness, (2) the technology, (3) the value proposition, (4) the adopter system (comprising professional staff, patient, and lay caregivers), (5) the organization(s), (6) the wider (institutional and societal) context, and (7) the interaction and mutual adaptation between all these domains over time.

Figure 1. The Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) Framework.



*Reproduced with permission from Greenhalgh et al.

When examining an innovation through the lens of the NASSS framework, the *Condition* domain refers to the clinical nature, comorbidities, and sociocultural aspects associated with a medical condition being addressed. *Technology* refers to the material and technical features of a technology being used. The *Value Proposition* relates to whether a new technology or approach is worth developing in the first place, while the *Adopter System* explores the adoption (and continued) of an approach by staff and participants. The *Organization* domain addresses an organization’s capacity and readiness to embrace an innovation. The *Wider Context* relates to the

wider institutional and sociocultural contexts in which an innovation is being implemented. Finally, *Embedding and Adaptation over Time* refers to the feasibility in continuing to adapt an innovation, and an organization resilience (19).

Methods

Participants

A literature review of studies/protocols that have used an MTA approach or a similar approach to ADHD treatment was done. A search of relevant terms (N=1; Stimulant Titration; Protocol; Titration Trial, etc.) within PubMed, SCOPUS, Web of Science, and Google Scholar was performed. After the elimination of irrelevant articles, we identified 10 studies/protocols that fit the inclusion criteria (see Table 1 in Results section). Efforts were made to identify studies that utilized MTA-style treatment approaches in clinical settings. Each of the principal investigators (PIs) of the studies were contacted by email or phone for participation in a qualitative interview with n = 6 investigators agreeing. Full citations for identified articles can be found in Appendix 2.

Data collection

Qualitative data were collected through a series of semi-structured one-on-one interviews. Such an interview approach allows researchers to employ a guiding framework in which data collection can be recorded, challenged, and reinforced (20). A total of six semi-structured interviews were conducted with PIs who had used an MTA-style approach to stimulant titration in the treatment of ADHD, and who could be contacted. One investigator from the list of identified studies/protocols declined to participate while two investigators were unable to be traced. Each interview was conducted over Zoom and lasted approximately one hour.

Interviews were recorded and transcribed allowing for a systematic exploration of the themes and ideas presented by the participants. Twenty-one interview questions and relevant probes were developed based on the NASSS framework (see Appendix 1). Questions aimed to gain information from the participants about key features of their chosen approach, their thoughts on the sustainability of their project, and the factors leading to the ultimate success or failure of their approach.

Research Objective

The purpose of this research project is to examine differing approaches to ADHD stimulant titration treatment as they relate to the original MTA study. In addition, to compare and contrast the protocols, measurement plans, management plans, and decision processes used in each of these approaches. The final goal of this project is to qualitatively examine the MTA approach and its "offshoot approaches" to ADHD treatment using the NASSS framework as a means to situate the adoption of this approach as it relates to clinical healthcare settings. Herein, the MTA approach to ADHD treatment will be examined based on the condition (ADHD), the technology used, the value proposition offered by the approach, the adopter system in place (professional staff, patient, and lay caregivers available), the organization(s) involved, the wider (institutional and societal) context, and the interaction and mutual adaptation between these domains over time. Ultimately, we seek to explore why MTA-style approaches to ADHD treatment may have difficulty with clinical adoption.

Data Analysis

Non-adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework.

When attempting to understand the implementation process and determinants of a new intervention or innovation, it is often useful to employ a guiding theoretical framework (21). Consisting of condition, technology, value, adopters, organization, wider system, and adaptation domains, the NASSS framework has been used extensively in healthcare settings to assess new innovations. For example, the NASSS framework has been used to assess the utility of Cognitive Behavioural Therapy in psychiatric healthcare (22); cardiovascular risk programs (23); fetal monitoring (24), and the use of artificial intelligence in healthcare (25).

Although not predictive of the success of new innovations, the NASSS framework aids in generating "a rich and situated narrative of the multiple influences on a complex project; to identify parts of the project where complexity might be reduced; and to consider how individuals and organizations might be supported to handle the remaining complexities better" (19).

Qualitative Approach

As a guiding framework was used to qualitatively assess the use of participants' individual protocols to ADHD treatment, we used a quasi-deductive approach to data analysis. Such an approach uses both a combination of induction (data-based analysis) and deduction (theory-based analysis) (26). To begin, each transcript was read several times to ensure familiarity with the participant responses. The domains within the NASSS framework were then used as an analytical framework wherein codes were deductively categorized into barriers and facilitators. Following this, Braun and Clarke's (2006) thematic inductive approach was applied to the deductive codes, identifying sub-themes within the NASSS domains (27). Such an approach has been used to identify barriers and facilitators in qualitative health research (see

Chapters 2 & 3). Methodological rigor was maintained by having each transcript read and coded by two independent authors who came to a consensus on the results of the analysis. Conflicts regarding coding and themes were resolved by all authors (28). Coding for this portion of the research was completed using Nvivo qualitative software package (Version 12).

Results

The identified MTA-style protocols included in this research occurred in the United States, Canada, Australia, Israel, and the Netherlands and were performed between 1999 and 2023. Each protocol focused on child and adolescent populations and included either double or triple-blind placebo-controlled trials. All but one protocol used immediate release capsules. All protocols deviated from the original MTA study by using weekly (instead of daily) randomizations. No information about questionnaire delivery was available for 4 protocols, however those that did report on their methods mentioned either delivering their questionnaires through the mail or online. Most medication was either delivered or made available through local pharmacies to trial participants. Healthcare and non-healthcare support varied. All protocols except one used an expert decision process or an automated algorithm for determining the starting dose for participants. A summary of each protocol identified within the literature review can be found in Table 1.

Table 1 – Comparison of different approaches to ADHD treatment.

Authors	Date	Location	Age Range	Research Design	Administration	Randomization	Dosage	Measurements	Delivery of Questionnaire	Medication delivery	Non-healthcare Support	Healthcare Support	Decision Process
1. Greenhill, et al.* (MTA)	1999	USA, various clinics	7-9 years	Triple blind randomized placebo controlled	3 MPH IR capsules per day	Daily randomization	Placebo Low Medium High	Daily questionnaires (parent & teacher): CLAM, SKAMP, MTA Side Effect Rating Scale	Questionnaires mailed daily	New blister pack delivered to parents, used ones recovered during clinic visits	Meeting with teacher: participation essential	Weekly visits with pharmaco-therapist	Expert-based selection of best dose using CLAM/SKAMP graphs and side effect table
2. Robaey P, et al.*	TBD	Children's Hospital of Eastern Ontario	5-16 years	Triple blind randomized placebo controlled	3 MPH IR capsules per day or 1 ER capsule	Randomized week starting Monday	Placebo Low Medium High	Daily questionnaires (Parent & Teacher) SAM	Daily online application (REDCap)	Weekly delivery of new dosette, recovery of used dosette at home/work	Meeting with school principal and teacher, participation essential	Weekly phone calls by clinical assistant; emergency call available 24/7	Shared decision still blinded using patient decision aids clarifying and considering parental values; report to treating physician
3. Epstein JN, et al.*	2007	Cincinnati Children's Hospital	1st -5th grades	Double blind placebo controlled fixed order	1 Concerta® ER tablet re-encapsulated	Fixed week order	Placebo Low Medium High	Weekly questionnaires (parent & teacher) : Conners Global Index, Side effect questionnaire	Questionnaires mailed weekly	Packaged medications available through local pharmacies	No information	No information	Expert decision and report faxed back to pediatrician
4. Grizenko N, et al.* **5. Joober R, et al.***	2006 2007	Douglas Hospital	6-12 years	Double blind randomized placebo controlled	2 MPH IR capsules	Randomized week	Placebo Medium	Weekly questionnaires (parent & teacher): Conners Global Index, Side effect Rating Scale	No information	Blister pack given to parents on first day and collected at the end of study	No information	No information	Expert decision provided to the parents
Nikles CJ, et al.† **Nikles CJ, et al.**	2006 2007	Mater Misericordiae Children's Hospital	5-16 years	Triple blind placebo controlled randomized	IR MPH capsules (amount unclear)	For 3 weeks, 2 treatment periods in a school week (Mon/Tues and Thurs/Friday): Dexedrine/Ritalin, placebo/	Individualized dosing	Pre- and post-questionnaires (parent & teacher): Conners Rating Scale short-form, ADHD du Paul Rating scale IV, Adverse effects and preference. (Children > 12 years): Conners-Wells Adolescent Scales	Questionnaires mailed weekly	Medication and questionnaires mailed to doctor's office	Teacher participation essential	Phone calls	Expert decision and report faxed or emailed to treating physician
Kent MA, et al.‡	1999	IWK Grace Health Center	4-14 years	Double blind randomized placebo controlled	2 MPH IR capsules	Randomized 7-day block starting Saturday	Placebo Low Medium	Baseline and weekly questionnaires (parent & teacher): Conners Rating Scale, Description of child's activities, behavior, mood, attention span and possible side effects	No information	No information	Teacher participation essential, 2 teachers max.	No information	Expert decision and report to treating physician by phone
Taragin D, et al.‡	2013	Bnai Zion Medical Center	6-13 years	Double blind randomized placebo controlled	1 MPH IR capsules	Randomized week	Placebo Low	Pre- and post-weekly questionnaires (parent & teacher): Conners Rating Scale, Abbreviated Acceptability Rating Profile.	No information	No information	No information	No information	Expert decision
6. Vertessen et al.*	2023	Netherlands, various clinics	5-13 years	Double blind randomized placebo controlled	2 MPH IR capsules	Semi-randomized	Placebo Low Medium High	Weekly questionnaires (parent & teacher): SWAN; MTA Side Effect Rating Scale (adapted)	No information	Packaged medications available through local pharmacies	Teacher participation essential	Dedicated nurse to oversee trial	Quasi-shared decision

*Authors interviewed for qualitative portion of the study; †declined; ‡could not be traced

Following the qualitative analysis, 12 facilitators and 9 barriers were identified. Four mixed factors were also identified depending on context. Each identified factor, categorized by NASSS domains are summarized in Table 2. Specific themes and supporting quotes follow.

Table 2. Identified factors, categorized by NASSS domains as they relate to MTA-style Titrations conducted.

Domain	Sub Domain	Barrier	Facilitator	Mixed Factor
1. Condition	1A. Nature of ADHD.	• Sometimes difficult to differentiate between comorbid disorders.	• Nature of ADHD is well understood.	
2. Technology	2A. Key Features.		• Switch from daily dose changes to weekly dose changes. • Online delivery of questionnaires.	
	2C. Knowledge Needed.		• Titration process is relatively simple.	• Training of new staff to conduct the titrations
3. Value Proposition	3A. Clinician Value.		• Builds confidence in treatment.	
	3B. Patient Value.		• Desirability is high in patients. • Can aid families who have decisional conflicts. • Builds confidence in treatment.	
4. Adopters	4C. Expectations of Carers.			• Having teachers and parents complete the questionnaires. • Clarifying expectations.
5. Organization	5A. Capacity to Innovate.	• Use of placebos makes adoption difficult. • Use of REBs is an obstacle to clinical adoption.	• Most organizations had capacity to innovate.	
	5E. Work needed to implement change	• Infrastructure needed to support innovation. • Involvement of IT services • Specific development to build automated tools. • Pharmacy and pharmaceutical company engagement.		
6. Wider System	6A. Policy Factors	• When research funding ends, the clinical application ends.		
	6B. Regulatory Factors	• Prescription duration (USA). • Laws restricting titration packages to certain pharmacies (EU).	• Compounding pharmacies are able to dispense both medication and placebos (CAN). • Drug plans make running titration trials inexpensive.	
7. Embedding and Adaptation over Time	7B. Organizational Resilience		• Titration trial champions.	• Whether sustained funding was secured.

Domain 1 – The Condition

In general, participants agreed that the *condition, or nature of ADHD* was well understood clinically: *"I think it's a reasonably well understood condition with quite clear criteria for diagnosis and for treatment decisions"* [1]. However, it was also acknowledged that ADHD has many comorbidities and therefore could be sometimes difficult to diagnose: *"I think the hardest part of making a diagnosis is identifying the difference between ADHD and whether there something else that could explain the symptoms. I think that's the hardest part of the diagnostical work"* [2].

Domain 2 – The Technology

Several subthemes related to the technology domain arose during the analysis. Regarding *Key Features,* all but one participant indicated that their chosen approach employed weekly dose changes: *"I think the difference with the MTA study is that we used weekly switches of doses and not the daily switches"* [2]. This acted as one of the greatest simplifications when compared to the MTA protocol: *"these weeks are randomized by week and not by days like in the MTA, cause it's easier. And there is no up and down* (differences in doses) *from one day to another"* [1]. An additional key feature of the participants' chosen approaches was the incorporation of online, automated delivery of questionnaires: *"during these four-week trials, the parents and the teachers complete the questionnaires online. The questionnaires always have the same format"* [1] and reporting: *"Well we, we have this ROM[1] system in which we can see the scores of the questionnaires. And then we show them week one, week two, week three, week four"* [2].

[1] Routine Outcome Measure (ROM) system. See: Sytema, S., & van der Krieke, L. (2013). Routine outcome monitoring: A tool to improve the quality of mental health care? In *Improving Mental Health Care* (pp. 246-263)

Some participants indicated that they required additional support or knowledge in order to sustain their approach to ADHD treatment: *"what we usually do is we have a specialized nurse here and she sends out the questionnaires like by hand… but she sends them out and she has telephone contact weekly with the parents"* [2]. Another participant similarly stated: *"You need to train the people to administer the questionnaires. And we had a very specific protocol using the RA, which takes some training"* [3]. Although protocols varied in their complexity, participants acknowledged that the way in which a titration was administered was relatively simple: *"I think the titration, uh, clinically done is something that is… once people have the experience, they know what they're doing"* [4]. Building on this, a general sense of having the willingness to perform titrations was needed on behalf of treating clinicians*: "The clinician has to accept it, which is not part of the current practice. For the titration itself, there is no big learning curve"* [1].

Domain 3 – The Value Proposition

The desirability of MTA-style approaches to ADHD treatment within patients was deemed high according to participants. For example*: "I think they're also happy with it. And most like if you have a discussion between parents, that's something we have a lot as well"* [2].

Participants also acknowledged that titration trials for ADHD can be very useful for parents who are reluctant to medicate their children with ADHD: *"…. A titration, or a double-blind titration with medication could be very helpful for parents who are reluctant to give medication to their children… And you let them… basically see the results of the pharmacological trial by themselves. So they feel empowered once they see the results and they can, they can accept the medication where they were extremely reluctant before"* [4].

In a similar vein, participants found that the titration trials for ADHD treatment for children could build confidence within both parents and clinicians themselves: *"You also build confidence in yourself because when you prescribe medication for years, it's so much easier when you are convinced that it is effective and that you tested it. So, it's not only for the parents, it's also for the clinician"* [1].

Finally, with regards to *return on investments (ROI)*, participant responses were varied. Some participants simply stated that they didn't have any conversations about ROI when implementing an MTA-style approach to ADHD treatment [2, 4, 5, 6]. This is often attributed to simply not building a business case for the approach as their respective titration systems were developed for research purposes.

Domain 4 – The Adopters

When asked about the expectations of the caregivers or patients, participant responses varied according to their individual protocols. For example, several participants mentioned the importance of requiring participants and teachers to complete the questionnaires, and the difficulties associated with this requirement: *"...getting the information in from parents. They are usually quite motivated to fill in the questionnaires… But we also want the teachers and getting the teachers involved and having them fill in a weekly questionnaire. It's quite a hurdle."* [2]. Other participants discussed having to manage parent's expectations during and following the trials: *"... doing a clinical titration with the patient and the family and giving them the guidance and the psychoeducation regarding that, and what is expected, what are the side effects? And mostly, you know, clarifying what are the expectations, because I think that's a very*

important point." [4]. Depending on the titration process, demands on staff can vary from one organization to another.

Regarding staff adoption, several participants mentioned hiring, or having dedicated personnel managing the titration process: *"She's actually doing the one doing all those phone calls and making sure all those questionnaires are sent out… before she was here, I was doing it myself and that was taking a lot of my time"* [2]. Another participant mentioned the learning curve that staff needed to overcome in order to manage the titration trials, but that the training needed wasn't significant: "*So, they to learn different aspects of the process, but it is not more difficult to learn that any other clinical process. Everyone involved in clinical work must learn new approaches, new techniques all the time"* [1]. In each case, the adoption by staff was relatively manageable, but this was mostly attributed to it being their dedicated vocation.

Domain 5 – The Organization

Questions were asked relating to participants' organizations capacity to innovate. Despite many participants mentioning that they had ceased using titration trials in their ADHD treatment, most participants indicated that their respective organization fostered innovation: *"there is certainly the possibility of innovation… Innovation often goes through research, because it's much easier to innovate in a research setting than in a clinical setting"* [1]. In a similar vein, when performing their work within a research setting another participant mentioned: *"It's all under the big umbrella of innovation. All of our grants have been funded, and all of the projects are peer-reviewed, innovative"* [4]. One participant did mention, however, that innovation was difficult within their respective organization: "We have no capacity innovate. It's all run by administrators right now that are, uh, you know, would-be counters" [3].

Although participants felt that their organizations emphasized their support for innovation, the required use of a placebo within the titration trials made some organizations reluctant to adopt the practice into standard clinical care: *"...If you say to a hospital manager that you want to use a placebo, they stop listening generally. Because 'placebo is research and it's not my business.' And then you have to explain why it should be their business"* [1]. Compounding the issue is the requirement for a lot of organizations to include their respective ethics committees when using such an approach: *"... in clinical practice that will pose a number of challenges. If you are going to do it, clinically, you need to give a placebo, but giving placebo requires to go through ethics committees and all that business"* [4].

A final subtheme associated with this domain related to the work involved in implementing the participants' approaches. Preparatory work was required by most participants in order to ensure that their titration trials went smoothly. For example, one participant mentioned: *"We needed infrastructure that we had to get in place to get the rating scales out to parents and teachers, where we really did all the work to do that data collection for doctors in order to be able to provide them back those rating scale information across those weeks"* [6]. To support automation processes participants also mentioned having to involve various IT specialists within their organizations: *"We had statisticians who did some coding… it was a team group that built the system in a matter of a few months"* [1]. Several participants also mentioned difficulties in securing medication that was conducive to randomized control trials. American participants in particular spoke of difficulties associated with acquiring proper stimulant medication: *"The obstacles were many… I had to talk to pharmacies until I got one that was willing to make those drugs, to, to dispense them in the way we wanted"* [6].

Domain 6 – The Wider System

Similar to the difficulties in getting pharmaceutical companies to create medications suitable for a titration trial, American participants spoke of regulatory issues they faced in dispensing medications: *"…You can't write subscriptions for a week prescription* here [United States]. *You have to write them for a month. And so, we were already deviating from the MTA"* [6]. Comparatively, the Canadian participants did not consider medication and placebo acquisition troublesome*: "I just called the pharmacy and asked them…if they are able to do that… it's the same prescription that you do … it's simply done in a, in a special setting instead. So, there are no special rules or authorizations"* [1]. European participants highlighted some of the barriers they faced with acquiring the medication for their trials, noting differences between countries that they had previously worked in*:* [2] "… *then they changed the law and then they couldn't do that anymore…. It had to be a specialized pharmacy who prepared these kinds of packages. In Belgium they can all do it. That's the difference with the Netherlands; they restrict it"* [2].

Funding was discussed at length by all participants. Unfortunately, implementation of titration approaches within clinical practice was widely viewed as unsustainable without continuation of the original research funding. This was especially felt by American participants: *"… all of those obstacles made it that when the grant ended… there really wasn't anything to support this sort of thing. And it, wasn't the sort of thing that the American healthcare system and insurance companies were going to start reimbursing anytime soon*" [6], as well as Canadian participants: *"We had funding for it for over 20 years. So, it was very, very easy. We had money rolling in, it was easy to run, but now unfortunately it was not"* [3]. That being said, one Canadian participant was able to incorporate the costs of their titration process into their

organizations budget in order to continue it in a clinical capacity, despite there being no budget for drugs in their outpatient clinic: *It was something that was developed within a research setting and was after that accepted as a clinical process, which is relatively marginal within the system"* [1]. One European participant disclosed that with their national insurance health care plan, the cost of the titration is relatively minimal, making their approach much more accessible to patients: *"people pay themselves for the preparation. And I think that's around 30 euros depending on the pharmacy that makes it. People don't complain about that. I must say I've never had anyone complain about this being too expensive"* [2].

Domain 7 – Embedding and Adaptation Over Time

Although funding was discussed in relation to the wider context in the previous section, participant testimony repeatedly linked adequate and sustained funding to the success of MTA-style titration approaches being implemented in clinical practice over time. For this reason, funding is discussed in both sections. Related to organizational resilience, when asked specifically about whether their chosen approach was ultimately successful, participants indicated yes, and it would have continued to be provided an adequate funding scheme was implemented: "Extremely. Chalking it up to the funding running out, it would be still going to this day, and it would still be very useful and valid" [3]. In fact, the majority of clinical use of MTA-style titration approaches to ADHD treatment employed by the participants stemmed from related research projects. As such, most relied on grant funding in order to continue operations. Once that funding terminated, many stopped utilizing the titration trials outlined in their respective research papers: *"I mean, it really wasn't sustainable without NIH funding."* [6]. Once funding had ended, other participants mentioned that their organization was unwilling to absorb

the costs associated with blinded trials: *"We just don't have the infrastructure and we can't get the placebo because we have to pay for them and we, the hospital will not pay for it"* [3]. Still others leverage research funds to support clinical use of MTA-style trials, one participant mentioning that if they did not do so, the titration would *"not work without that*" [PR][1].

For the two participants who have been able to secure ongoing funding for their clinical use of titration trials, either through their organizations willingness to pay for the trials in a clinical capacity or as a result of their countries' drug care plan, an interesting theme emerged. The two participants both believed that continued use of their approach was dependent on their own willingness to champion it within their current organization*: "Yes, it's a unique situation. I think that if, if it were not for me, it [the titration trial process] would not occur"* [1]. This also varied according to the relative freedom participants had within their own organization: *"I can do what I think is a good idea as long as our head agrees that I'm doing things that are okay…"* [2].

Discussion

The aim of this study was to examine MTA offshoots using the NASSS framework in order to determine what led to the adoption or non-adoption of titration, more than 25 years after the initial publication in 1996. To begin, two observations are in order. First, the original MTA model has been emulating clinical applications for all that time. Second, none of these models have shown widespread adoption in a clinical setting as most have stopped due to lack of funding, and they remain highly dependant on a few tenacious champions. This begs the question: what are the reasons for this non-adoption? Using various elements of the non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) model and the systematic comparison of our results with the literature, this discussion will attempt to address this question.

In this discussion, we will use the term MTA-style titration to refer to these randomized placebo-controlled double/triple-blind offshoots.

As far as the condition to be treated is concerned, the reasons for lack of uptake do not seem to be linked to ADHD itself as the efficacy of stimulant treatment is supported by strong evidence, and despite the emergence of drug alternatives with non-stimulants (atomoxetine), the advantage remains clear for stimulants. The advantage is also clear when we compare the effect of stimulants with non-pharmacological approaches such as neurofeedback or psychoeducational interventions, even if multimodal approaches are still recommended, as the authors of the MTA study first imagined and demonstrated. In addition, the arrival of extended-release stimulant forms has made them easier to use and accept, which has helped to increase their use. Despite this extensive use of stimulants, the titration process that enables their more rigorous prescription has not really been adopted in the clinic (29).

Over the past 25 years, technology has also evolved, and it is now possible to gather the necessary information much more easily from parents and teachers, using on-line questionnaires, e-mail invitations, videoconferencing to meet teachers, automated reporting, etc. Even if these developments have a significant initial cost, their use in routine clinical practice is easy and inexpensive. However, despite these technical advances, MTA-style titration has not yet made its way into clinical practice.

The value of the proposition is considered high by all participants. A priori, parents, teachers and clinicians are very positive about the concept of MTA-style titration. The alternative proposal is open-label, non-placebo-controlled titration (titration as usual). According to the AACAP recommendations, the clinician chooses the initial dose of the medication (methylphenidate or amphetamine salts), then increases the dose every 1 to 3 weeks until either

the maximum stimulant dose is reached, ADHD symptoms disappear, or side effects prevent further titration, whichever comes first. The recommendations also point out that it is useful to obtain rating scales from the teacher and parents after the patient has been observed on a selected dose for at least a week. Parents and patient should be asked about side effects (30). Studies have shown that adherence to titration as usual, according to recommendations, is low in routine clinical practice. Using the Delphi method, clinicians judged certain recommendations for medication management in ADHD to be important but difficult to implement in routine practice. This contrast between importance and feasibility was particularly pronounced for obtaining weekly information on clinical improvements or side effects, or having questionnaires completed by teachers at the beginning or end of the titration phase (31). A feasibility study with psychiatrists (who are expected to take up more time than primary care physicians) illustrates these challenges. Herein participants were asked to perform a titration in which 4 fixed doses of stimulant were to be tested systematically. But they only used 3 or 4 doses for just over half the titrations (54.5%). If the family saw an improvement in the child's behavior after the first dose, they were often unwilling to try a higher dose. Parents completed just over half the questionnaires (61.9%), while teachers completed very few. This was far short of what was needed for a reliable assessment of a medication effect (32). In this context, a study of stimulant dosage profiles in children treated for ADHD using data from managed care plans showed that in the community the dose ranges used were notably lower than those reported in the MTA study (33). This was already the case in the MTA study, when comparing the treatment group as usual with the medication management group. Logically, medication management (which included titration) was associated with greater improvement in most ADHD symptoms (29). Not only are titrations often incomplete, they are also often overlooked. In the Olfon et al. study, the

percentage of children who had a medication titration at the start of treatment ranged from 52% to 62%, depending on the stimulant formulation (33). This pattern of routine clinical practice may partly explain why attitudes towards medication use are generally not positive in the general population. In Australia (Queensland), roughly the same proportion of respondents found medication acceptable (42%) and unacceptable (38%) in the treatment of ADHD (34). In Germany, while 90% of respondents to a telephone interview had heard of ADHD, the majority (66%) were opposed to stimulant treatment (35). The great difficulty of following the recommendations for ADHD treatment in routine practice, particularly initial titration, and the poor reputation of stimulant treatments should logically have contributed to further increasing the relative value of the MTA-style titration proposal, which again did not happen.

Implementing MTA-style titration more than 25 years after the initial study must without doubt also take into account what we have since learned about families' expectations on the path towards managing their child's ADHD. Once parents have recognized an ADHD-type problem in their child, seeking professional help is difficult, not least because it is too often synonymous with medicating their child (36). Many parents will delay medication for as long as possible, so long as they feel effective and emotionally supported (37). But when these parents become exhausted and start to feel powerless, medication appears to them as a last resort (38). Even if they resign themselves to doing what helps the most, their ambivalence does not vanish. The initial negotiation of treatment is therefore a crucial stage that generates a great deal of decision-making conflict. Parents with a high level of decisional conflict are more likely to delay their decision, or change their mind about the treatment option, or regret their decision and blame the doctor if the outcome is not what they expect. A shared decision-making process is the best approach to address this decision-making conflict. The key elements of a shared decision-making

process are to explain the decision-making process in detail, to clearly present the benefits and risks of the different options, to communicate clearly about the probabilities of the different possible outcomes, to clarify the values on which the parents want to base their decision (i.e. the outcomes that matter most to them or the problems they absolutely want to avoid), and to present the data in a balanced way (39). But clearly, parents are no longer prepared to accept arguments from authority (doctor's orders), as shown by their posts on ADHD blogsites (40).

Yet almost all offshoots of MTA-style titration have used an expert model, as in the reference study. For example, in Vertessen's study, teachers and parents completed a questionnaire each week and an algorithm decided whether the score during the placebo week or at each active dose of MPH was above a threshold to classify participants as non-responders, placebo responders or active dose responders, and determined the optimal dose. A report was sent to the treating physician to discuss the findings with the families and children to decide on treatment and dosage. Although the doctor was encouraged to follow a shared decision-making process and could deviate from the recommended dose (which they did in half the cases), the recommendation did come from an expert who had designed the decision algorithm. The only exception to the expert model is the approach developed at CHEO, where a triple-blind randomization process was used to enforce a shared-decision approach rather than an expert one. During the discussion of results, both clinicians and parents are always blinded, without knowing the doses assigned to the different weeks. The clinician would be taking a great deal of risk if they tried to explain the differences in the child's behavior between weeks on the basis of his or her knowledge of the effects of the medication (which, in any case, is not the purpose of the meeting), and the parents are placed in the role of experts in their child's behavior in order to choose not the best dose, but the week they prefer. The clinician then presents the results of the

questionnaires filled in by parents and teachers for the different weeks, using graphs that have been developed to be easily understood, and which present with equal emphasis the therapeutic and adverse effects, according to different dimensions. Then, with the clinician's support, the parents compare the weeks to rank them from the one they like best to the one they like least. At this point, both clinician and parents are still blind to the doses assigned to the weeks. Once the parents have made their choice based on their own values, their ranking is entered into the computer system and the doses associated with the weeks are disclosed. If the difference between the weeks is decisive for the parents, they have the choice of continuing treatment with the preferred dose, discussing with the clinician how to implement it in the daily routine. The value of the MTA-style titration proposal can therefore vary greatly depending on the model adopted, expert decision or shared decision-making, beyond its value as an objective pharmacological test. But much more research is needed to document the value of the decision mode proposition. So far, many proponents of MTA-style titration have used it as a means of addressing other research questions and have not paid much attention to the clinical value of the proposition or to the decision-making process. A retrosptective qualitative study of titration with shared decision-making (see Chapter 6) showed that parents' experience, several years after titration, was marked by positive interactions with treating clinicians, discussions related to treatment, desire to give a child a proper dose, experiences of parents who are reluctant to give their children medication, and confidence in treatment.

From an organizational point of view, all the participants agreed that placing titration solely in a research context is clearly an obstacle to its adoption in clinical settings. Titration can be associated with research, but more in the context of improving the quality of care, or in the secondary use of clinical data in research when possible. There are major differences between

REBs in different institutions, and these are discussions that need to take place at local level, but which can be helped by external examples. However, certain reticence needs to be overcome, such as the idea that a placebo, randomization, or blinding belongs solely to the research domain. In fact, protocols used in research can be used in the clinic for clinical purposes, such as controlling a placebo effect in drug prescribing or facilitating a shared decision-making process. To answer the question of titration costs, cost-effectiveness studies should be carried out to show how the MTA-type titration model compares with the usual model, both in terms of cost and effectiveness. The involvement of IT departments can be costly at the outset, but existing infrastructures can be used to mitigate these costs. For example, the availability of routine outcome monitoring to support clinicians in the clinical decision-making process provided the basis for the development of questionnaires used in one of the titration approaches in examined in this study (Sytema & van der Krieke, 2013). At CHEO, the titration process has been developed in a database widely used around the world (REDCap), enabling the model to be exported at minimal cost if the infrastructure already exists elsewhere.

At a broader system level, it is necessary to address certain limitations linked to the prescription of stimulants where they exist, and to develop partnerships with pharmacies equipped to produce drugs for titration, e.g. in Dispill form, and in particular to ensure that the different doses cannot be distinguished on the outside of the capsules. It is also important to obtain reimbursement for titration drugs in accordance with local regulations. The attitude of pharmaceutical companies could also be a decisive factor in the adoption of MTA-style titration. So far, efforts to interest pharmaceutical companies in producing placebos have been unsuccessful. But, if these companies could put on the market titration kits that would allow treatment for a few weeks of testing, using their long-acting preparation and the different

dosages required, and with an identifier to code randomization, this would be a strong incentive to set up titrations with those forms of stimulant that are most widely used clinically. Clinicians would better understand the usefulness of titration if it could be done with the drugs they prescribe long-term, without having to resort to local pharmacies to prepare immediate-release capsules with different doses and having to resort to equivalences between immediate and long-term formulations; although solutions do exist to establish these equivalences (41). In this sense, pharmaceutical companies also bear their share of responsibility for the non-adoption of MTA-style titration in clinical practice.

Of all the participants interviewed, only two have managed to maintain their MTA-style titration approach in clinical practice over the years. Both participants indicated that they were tenacious in their belief that stimulant titrations were the most ethical and methodical in the treatment of ADHD in children and adolescents, and that they spearheaded their approaches within their respective organizations. Health champions, or individuals committed to supporting and commercializing a health innovation at all stages of its development and implementation, are widely recognized as key factors in the successful implementation of quality improvement initiatives in healthcare settings (42-44). Often, these "torchbearers" or "champions" perform multiple functions, including advocacy, clinical consultation and interdisciplinary team coordination (45). These individuals facilitate implementation outcomes and ultimately influence clinical adoption. The results of our study suggest that the future of individualized MTA-style titrations as standard clinical care for the treatment of ADHD are largely determined by these individuals who champion these approaches in healthcare settings.

Conclusion

This study shares the experiences of clinicians who have used stimulant titration trials for the treatment of child and adolescent ADHD in clinical settings. The identified implementation barriers, facilitators, and mixed factors for each domain of technological innovation within the NASSS provide valuable insight for policy makers, hospital administration, and clinicians in implementing MTA-style approaches. As clinical research is increasingly shifting focus toward the assessment of health intervention effectiveness under the conditions of routine clinical practice (46, 47), research such as this is invaluable in helping others in their own innovative endeavors. For successful implementation of these sorts of approaches, we recommend addressing or mitigating organizational, policy/legislative, or funding-related barriers and promoting the streamlining of MTA-style protocols and innovation champions within healthcare settings.

Limitations

It should be noted that we had a marked difficulty in identifying published articles of clinicians using MTA-style approaches in clinical practice, and even greater difficulty in having participants agree to be interviewed about their experiences. As such, our sample of participants was relatively small. We believe that this lack of published literature itself contributes to the difficulties in having widespread adoption of stimulant titration approaches in the clinical treatment of ADHD in general. Literature suggests that documenting and publicizing early positive outcomes of innovative healthcare strategies contributes to maintaining internal support for new programs (45). We encourage further publication of literature related to MTA-style approaches to ADHD treatment in hopes that a growing body of research contributes to the widespread adoption of these treatment strategies within clinical standards of care.

Delimitations

In this qualitative study focusing on the implementation of MTA-style approaches to ADHD treatment, the delimitations are prominently shaped by the scope of the literature review and the participant selection process. The literature review was confined to articles found in specific databases (PubMed, SCOPUS, Web of Science, and Google Scholar) using a narrow set of search terms related to stimulant titration and ADHD treatment protocols. This may have excluded relevant studies indexed in other databases or using different terminology. From the literature, only 10 studies met the inclusion criteria, further narrowing the scope of research considered. Additionally, the participant pool for qualitative interviews was limited to the principal investigators of these studies, and only 6 out of the 9 reachable PIs agreed to participate, which could limit the diversity and representativeness of the insights gathered. The interviews were conducted using Zoom, which, while facilitating access to participants, may influence the dynamics of the interaction compared to face-to-face interviews. These methodological choices define the boundaries of the study's inquiry and impact the breadth of evidence and perspectives included in the research.

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Appendix 1. Interview Protocol

The following protocol will be used during the Zoom calls with participants. Although all questions related to the NASSS framework are included within this protocol, not all questions may be asked (depending on how much of the NASSS framework can be completed using the information provided in the participants' respective publication related to the MTA study.

As part of a study on the uptake of an MTA-style approach to the treatment of ADHD, I would like to ask you about your experiences. Please describe your experiences with as much detail as possible and to the best of your ability. There are no 'wrong' answers and no judgment will be placed. If a question makes you feel uncomfortable, please let me know and that question will be skipped. I would like to remind you that you are free to quit the study at any point during the interview with no repercussions from your doctors or the researchers. Would you like us to clarify anything before I begin?

Close-ended Question

1. Are you using an MTA-style (stimulant titration) approach to ADHD treatment within your clinical practice?

Open-ended Questions

Domain 1: The condition or illness

1A. In your opinion, how would you characterize the nature or condition of ADHD?

- Is it well understood and/or predictable in terms of diagnosis and treatment?

1B. What sociocultural factors would you say are relevant when discussing and/or treating ADHD?

- Can you comment on relevant comorbidities?
- How likely are these sociocultural factors/comorbidities to affect care planning and service provision?

Domain 2: The technology

2A. Can you describe the key features of your chosen approach to ADHD treatment?

- Would you say that the approach is completely developed/interoperable?
- How dependable is this approach in treating ADHD?

2B. In terms of measuring the quantifiable outcomes associated with your chosen approach, how would you describe the link between data generated and the condition?

- How do you measure changes in the condition?

2C. What knowledge and/or support do you think is required in order to support your current approach to ADHD treatment?

- Are detailed instructions/training and/or helpdesk support needed for this approach?

2D. Given your chosen approach, was there much in terms of organizational reconfiguration that was needed in order to incorporate this sort of approach?

Domain 3: The value proposition

3A. When implementing this approach within your clinical setting, were there any discussions in terms of value propositions/return on investments?

- Has your practice benefitted financially from your approach?
- What is the benefit, what is the cost (cost/benefit ratio).
- Could this approach be done in a way that is economically viable?
- Was a commercial application to your approach developed?

3B. Would you say that your chosen approach is desirable for patients?

- Is it effective, safe, and cost-effective?
- Do you have a budget associated with continuing the services associated with your approach?

Domain 4: The adopter system

4A. Have there been many changes in terms of staff roles or practices associated in using your chosen approach to ADHD management?

- Do your staff need to learn new skills and/or are more staff needed to be hired to support this approach?

4B. What is expected of the patient/caregivers in undergoing treatment using your approach?

- Are patients required to perform routine tasks? Are these tasks relatively complicated or require changes in therapies?

4C. What does your current treatment approach assume in terms of extended network of caregivers (ie. Are a network of caregivers required to coordinate among themselves)?

Domain 5: The organization

5A. How would you describe your organization's capacity to innovate?

- Do you have a well-led organization with many resources and good managerial relations?
- Is risk taking encourage at your organization?

5B. How ready would you say your organization was in supporting your chosen approach to ADHD treatment?

- Were there high tensions for change?

5C. How would you describe the funding and adoption change?

- Was there a single or multiple organizations with partnership relations?
- Was the cost-benefit balance favourable or neutral?
- Can you comment on infrastructure or recurrent costs associated with the adoption of your approach?

5D. What changes in terms of team interactions were needed in order for this approach to ADHD management to work?

- Were there new team routines or care pathways that needed to be established?

5E. What work is involved in implementing this approach and who performed this work?

- How much work was needed in order to build a shared vision/engaged staff and enact new practices and monitor impact?

Domain 6: The wider context

6A. Can you comment on the political, economic, regulatory, professional (e.g., medico-legal), and sociocultural context that was present during the program rollout?

Domain 7: Embedding and adaptation over time

7A. In your opinion, what is the potential for adapting or coevolving your chosen approach over time? Will this program/service be easily adapted to other standards of care?

7B. Have you experienced any critical events or unforeseen events during your use of this approach to ADHD treatment?

- How resilient was your organization in handling/adapting to these events?

Final Question

1. In your opinion, why do you think that your approach was ultimately successful/unsuccessful in your clinical setting?

Appendix 2 - List of projects utilizing an MTA-style approach to ADHD treatment.

The MTA Cooperative Group (Greenhill, L). A 14-Month Randomized Clinical Trial of Treatment Strategies for Attention-Deficit/Hyperactivity *Disorder. Arch Gen Psychiatry.* 1999;56(12):1073–1086. doi:10.1001/archpsyc.56.12.1073

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Chapter 6: Who knows best? A study of different decision-making strategies in stimulant titration for the treatment of child and adolescent ADHD.

Tentative Journal: Journal of Child and Adolescent Psychopharmacology

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Funding details:

No funding details to declare.

Abstract

Objectives: The purpose of this research was to compare and contrast the recommended stimulant dose provided by three different decision-making approaches in the treatment of ADHD following a stimulant titration trial. This objective was achieved by first exploring the level of agreement between a shared decision-making (SDM) process with parents, with clinicians (Experts), and an automated ranked-choice voting (RCV) algorithm when it comes to recommended dose. Given the disagreements that can result from different decision-making processes, our second objective was to retrospectively explore the experience of parents who benefited from shared-decision stimulant titration.

Methods: Data from 26 stimulant titrations performed at CHEO was used for each experimental arm of this study. Reports describing the therapeutic effects (Inattention, Hyperactivity/Impulsiveness, Opposition/Defiance) and adverse effects (Interactiveness, Sleep/Appetite, Psychomotor Agitation/Slowness, and Emotionality) were created for each titration. For the SDM group, the archival data of parents' chosen dose was used. For the expert group, selection of the best dose was made by a clinician (expert) rather than in collaboration with parents. As an additional comparison group, a computer-based algorithm was developed to automatically select the "best dose" using a Ranked Choice Voting (RCV) algorithm.

Results: Agreement between the doses selected by the Experts and SDM was poor (<0.20) while agreement between the Experts themselves ranged from .25 to .55. Agreement between RCV and individual Experts varied from poor (0.19) to moderate (0.47). There was fair agreement (.36) between the RCV and SDM groups. Agreement between SDM and RCV varied with dosage. Qualitative analysis revealed positive interactions with treating clinicians, discussions related to

treatment, desire to give a child a proper dose, experiences of parents who are reluctant to give their children medication, and confidence in treatment as themes.

Conclusions: Significant differences in experimental groups make it difficult to determine what strategy is best when determining an optimal dose of stimulant medication following an ADHD titration trial. A shared decision-making approach enables parents to make a sound, regret-free decision, enabling easier life adjustments following an ADHD diagnosis.

Key Words

ADHD; Shared Decision-Making; Clinical Practice; Stimulant Titration; Dose Comparison; Ranked Choice

Introduction

Attention Deficit Hyperactivity Disorder (ADHD) is a common neurodevelopmental condition that is diagnosed in childhood and can persist into adulthood (1). Prevalence is estimated at approximately 5.3% of children and adolescents and 2.5% of adults when it persists into adulthood (2-4). Clinical presentation of ADHD includes either hyperactivity/impulsivity (e.g., difficulty controlling excess movement) and/or inattention (e.g., difficulty keeping focus) (5). Child and adolescent ADHD can often result in familial and peer relationship impairment, poor academic performance, and behavioural challenges (6). Adolescents with ADHD are found to engage in more risky behaviours (7), substance use (8), and depression (9) when compared to neurotypical children. Adult ADHD shows significant correlations with lower educational attainment, higher unemployment, romantic problems, criminality, and vehicular accidents (10-14)

Evidence-based treatments for ADHD usually involve psychosocial and/or pharmacological treatments (15, 16). Psychosocial treatments include behaviour modification interventions or organization and communication skills training (17). Pharmacological treatments primarily utilize stimulants such as methylphenidate or amphetamines, and non-stimulants including serotonin and norepinephrine reuptake inhibitors (16, 18). Methylphenidate is the most effective and safest short-term drug treatment for children and adolescents with ADHD and is recommended as a first line treatment in many clinical care guidelines around the world (19, 20).

Stimulant Titration at the Children's Hospital of Eastern Ontario

As a child's response to stimulants can be variable and unpredictable (dosing calculated with height or weight), the American Academy for Pediatrics (AAP) recommends that clinicians

titrate stimulant doses to achieve a maximum, optimal effect in controlling symptoms without adverse effects (21, 22). A formal randomized placebo-controlled stimulant titration protocol for the treatment of child and adolescent ADHD was first put forth by the National Institute of Mental Health (NIMH) sponsored Multimodal Treatment of ADHD (MTA) study. The goal of this study was to provide recommendations on an optimal treatment strategy for the treatment of ADHD (23-26). Herein, a 28-day titration trail that administered three doses (low, medium, and high) of short-acting methylphenidate and a placebo in a randomized crossover, daily switching, triple-blind protocol was used. ADHD symptoms and side effects were measured by both parents and teachers. A titration trial dose selection algorithm was used by a panel of experts to blindly rate summary results of symptoms and side effects. As a result, the "best" dose was recommended as a maintenance dose for patients following the trial. Unfortunately, the MTA stimulant titration protocol design has been characterized as complex (23), unlikely to be used in standard office practice (22) and has seen relatively little uptake (27, 28).

The Children's Hospital of Eastern Ontario (CHEO), has introduced several innovations that improve upon the original MTA protocol, making it easier for parents, teachers, pharmacists, and physicians to engage in stimulant titration. The titration process itself still involves the blind administration of a placebo, low, medium, and high dose of simulants but streamlines the original MTA protocol by incorporating weekly (rather than daily) switches of medication and online (rather than paper-based) tools and measures. The use of an online survey and database manager (REDCap) allows pharmacists to automatically randomize and deliver medication doses while keeping parents, teachers, and the treating physician blinded to the dose. REDCap also enables parents and teachers to complete an online standardized questionnaire called the Strength-based ADHD Monitoring (SAM), which evaluates three clinical dimensions:

(hyperactivity/impulsiveness, inattention, opposition/defiance) as well as five side-effects (interactiveness, psychomotor slowness, agitation, sleep/appetite, emotionality). In-house statistical software synthesizes and summarizes the parent and teacher data into general and easy to interpret clinical reports in which optimal dosing can be determined.

The decision-making process at CHEO also differs from that of the MTA protocol in that parents and physicians collaborate used a Shared Decision-Making (SDM) approach in the determination of a best recommended dose, rather than a panel of experts determining the best dose once the trial terminates. An SDM approach is defined as “an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, and to achieve informed preferences” (29). The CHEO SDM titration process allows practitioners to work alongside parents of children with ADHD to both subjectively and objectively find the best treatment dose. Following the four weeks of titration, parents and the child’s physician examine and compare the results of weekly clinical reports specifically designed to support parent’s decision (see Appendix I for an example report). In order to ensure an equal partnership between parties, dose blinding is maintained during this consultation so that the clinician can provide methodological expertise while parents provide their unique knowledge and understanding of their child’s circumstances. Both parents and physicians discuss their preferred titration week according to improvement in symptoms and side effects, but without knowing the dose assigned to each week. Maintaining blinding balances the physician-patient relationship by removing the physician's power to explain the child's behavior by the dose of medication (no one knows the dose for each week), and by giving room to the parent to choose the week they prefer based on what they value or prioritize in the report, with the physician's coaching. After a preferred week has been selected, blinding is removed, and

the dose associated with the preferred week is used as a maintenance stimulant dose. The titration process uses short-acting stimulant medication, but the results can be translated into long-acting medication using a computational strategy with up-to date pharmacokinetic data that we developed independently (30).

This decision-making process has been associated with increase in patient autonomy; improvements in patient-clinician communication; less decisional conflict; and increases in patient confidence (37). A shared decision approach also contributes to patient satisfaction and adherence to treatments (31), and is essential for patient-centered care (32, 33).

Research Objective

Differences are expected between clinician- and parent-selected doses due to discrepancies between parent and teacher ratings, and between different dimensions of therapeutic or side effects. A potential drawback of the shared decision-making approach could therefore be that parents prefer a medication dose that would not be optimal with regard to ADHD symptom control. Therefore, the first objective of this study was to explore the level of agreement between the shared decision-making process with parents, the decision by experts based on the same anonymized reports, and from an automated choice algorithm (based on Ranked Choice Voting) as a point of comparison. Given the disagreements that can result from different decision-making processes, our second objective was to retrospectively explore the experience of parents who benefited from shared-decision stimulant titration, so that their insights could shed light on how to deal with the question: who knows best?

Methods

Quantitative Procedure

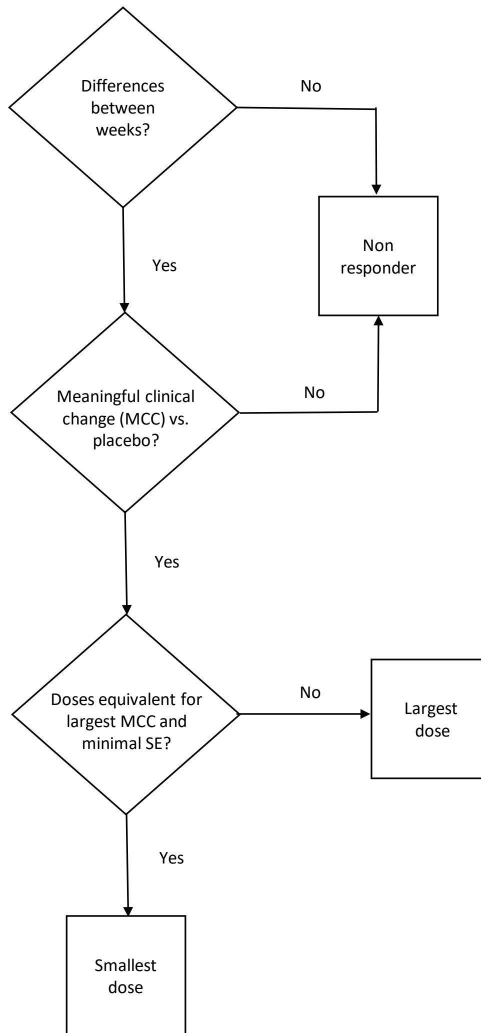
Shared Decision-Making Experimental Group

The experimental group is comprised of data from 26 stimulant titrations performed at CHEO, each using a shared decision-making (SDM) approach for a final recommended maintenance dose. In this approach we used a report describing the therapeutic effects (Inattention, Hyperactivity/Impulsiveness, Opposition/Defiance) and adverse effects (Interactiveness, Sleep/Appetite, Psychomotor Agitation/Slowness, and Emotionality). The doses selected by parents and the treating physician for each trial were used for analysis. For a thorough description of the shared decision-making titration process see Chapter 4.

Expert Decision-Making Experimental Group

The expert decision-making (EDM) process was similar as in the MTA study. Herein, a selection of the best dose was made by a clinician (expert) rather than in collaboration with parents. Clinicians at CHEO who regularly prescribe stimulants for the treatment of ADHD were asked to examine the clinical reports generated by the titration trials. These are the same reports used in the SDM group, but without inclusion of the recommended doses determined by parents and the treating clinician. This effectively isolates an "expert" recommendation from one based on an SDM approach (which uses parental collaboration). Instead, these experts separately made a determination using an algorithm similar to that used in the MTA study (34) (see Figure 1).

Figure 1. Decision Process for Expert Dose Recommendation.



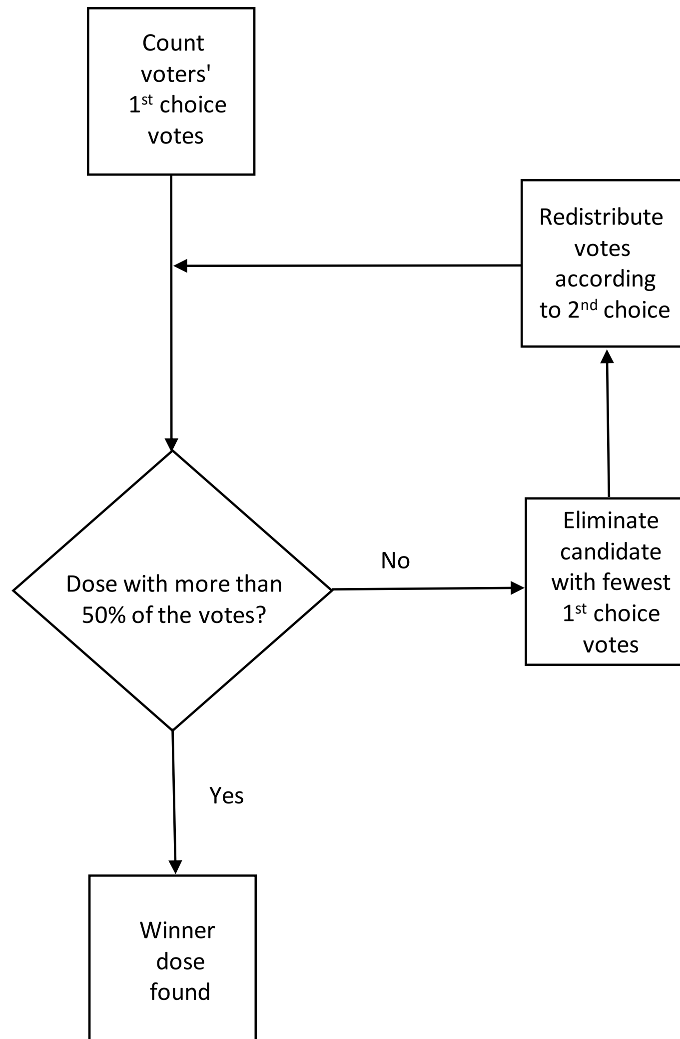
Experts determine whether a) there are differences across scales from week to week; b) decide if there is a meaningful clinical change (MCC) between each pair of conditions; c) if there is, rank-order the weeks; d) decide if any of the doses are equivalent for MCC; e) if doses are not equivalent for MCC, select the highest dose without meaningful adverse effect; if doses are equivalent, select the smallest dose without meaningful adverse effect. Finally, each expert was asked to write their recommended week based on symptom improvement and side effect

reduction. This recommended week was then unblinded and the associated dose accepted for data analysis.

Ranked Choice Voting Decision-Making Experimental Group

As an additional comparison group, a computer-based algorithm was developed to automatically select the "best dose" using a Ranked Choice Voting (RCV) algorithm. RCV, sometimes called instant run-off voting, is an electoral selection technique in which voters are provided with the option to rank candidates based upon personal preferences: 1st, 2nd, 3rd, and so on, rather than indicating support for only one candidate. Following a vote, the candidate with more than 50% of first-choice of votes is selected. If no candidate receives more than 50% of first-choice votes, the candidate with the fewest number of first choice votes is eliminated. Votes for the eliminated candidate are then redistributed among remaining candidates according to their second-choice for an additional round of voting. If again no candidate receives more than 50% of the second first-choice votes, this process is repeated a until a majority vote is achieved. The voting algorithm is illustrated in Figure 2.

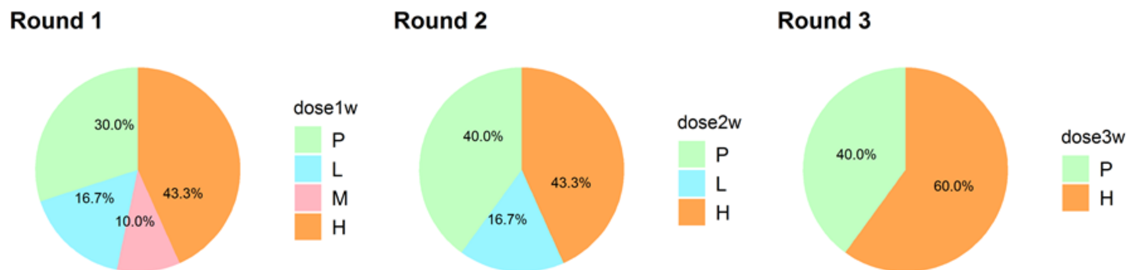
Figure 2. Ranked Choice Voting process.



In the RCV decision-making process, the candidates were represented by the different doses (placebo, low, medium, and high doses) used within the titration and the voters are the clinical rating subscales for the therapeutic (hyperactivity, inattention, and opposition/defiance) and adverse (interactiveness, psychomotor retardation, psychomotor agitation, sleep/appetite, emotionality) effects. As there are more scales (i.e., voters) for negative than positive effects, the votes are weighted so that the therapeutic (weight of 0.165 for each of the 3 subscales) and

adverse effects (weight of 0.1 for each of the 5 subscales) have an equal final influence (0.5) on the outcome. The RCV process can be based on the parent's ratings, the teacher's ratings, or both. ADHD scores derived from the clinical reports will be inputted into a vote-based ranking algorithm to produce a computer-generated optimal stimulant dose for each patient for which the clinical reports are based. An example in which three rounds of ranked choice voting are needed to determine an optimal recommended dose for a given titration using the weighted clinical subscales of the SAM questionnaire can be found in Figure 2.

Figure 2. Example of a three-round ranked choice voting for a recommended dose of stimulant titration.



P = Placebo; L = Low Dose; M = Medium Dose; H = High Dose

Participants

A purposive sample of clinicians from the Children's Hospital of Eastern Ontario was used as experts. To be eligible to participate as an expert in this study, participants must either be pediatricians with mental health experience or psychiatrists employed at CHEO with expertise in the treatment of children with ADHD using stimulant medication. Three experts evaluated the reports and provided a complete recommended week/dose for each of the 26 titrations.

Data Analysis

Cohen's Kappa and Fleiss' Kappa were used to determine the level of agreement between the SDM, EDM, and RCV raters on their ranking (first, second, third and fourth ranked dose). Kappa (κ) statistics are useful for either interrater reliability testing and can range from −1 to +1, where 0 represents the amount of agreement that can be expected from random chance, and 1 represents perfect agreement between the raters (35). Quantitative data analysis was performed in SPSS v29.

Qualitative Procedure:

Participants

A qualitative component to this study was included in order to provide context into the experience of parents who have undergone the SDM titration protocol with their children at CHEO. The participants (n=9) comprised of a purposive sample of parents of children who had undergone the stimulant titration process at the Children's Hospital of Eastern Ontario. Participants were selected due to their unique experience in contributing to their child's medical treatment using the CHEO SDM protocol.

Data collection

Participants recruited for the purposes of this study had undergone the stimulant titration process, involving the SDM model with the CHEO outpatient clinic between 2009 and 2019. In order to obtain an in-depth understanding of parents' experiences, a series of semi-structured interviews were conducted. This interview approach was selected as it allows researchers to

collect exploratory data related to a research topic and when using mixed methods, allows the provision of context to the data collected i.e., from a quantitative phase of a study (36, 37). The interviews occurred over Zoom teleconferencing software or telephone with audio being recorded. Audio files were anonymized and transcribed using an electronic service (REV.com). Transcriptions were then verified by two researchers for accuracy. Interviewed lasted approximately one hour.

Measures - Interview Protocol/Questions

An exploratory interview protocol was developed with the lead physician conducting the titrations, through consultation with relevant literature and medical professionals experienced with ADHD patients, families, and titrations (See Appendix 2 for interview protocol). The 10-question interview protocol explored participants' overall experiences with the process, their experiences prior to the treatment of their child, their views on ADHD medication prior to and following the titration, their experiences working in conjunction with the treating physician, and their views on the outcome of the titration process. Interview questions were organized to facilitate rapport between the researcher and the participant with the aim of promoting participants' introspection and examination of their experiences (38).

Data Analysis

Due to the exploratory goal of this phase of the study, an inductive thematic analysis approach was selected. Using the methodology outlined by Braun and Clarke (2006), such an approach entails deriving meaning and the identification of themes solely from participant

testimony with emphasis placed on eliminating any bias or preconceptions from the researcher (39). First, researchers familiarized themselves with the data in order to gain a general understanding of participant experiences before identifying themes. This was followed by a series of open code work, where a set of initial codes to represent the patterns and meanings in the data were made. Codes were then collated with supporting data across transcripts. From then codes were then clustered into groups of major themes or subthemes before being finalized for dissemination. Data analysis for the qualitative phase of this study was completed using the NVivo qualitative software package (Version 12).

Data Integrity

Qualitative research is increasingly being recognized and valued within scientific health research. As its prominence increases, it is important that qualitative researchers conduct their work in a rigorous and methodological manner. This allows potential readers of this research to determine for themselves whether the research has been done in an a precise, consistent, and exhaustive manner (40). To ensure credibility and trustworthiness of this analysis, several measures were taken including the use of several independent coders who identified themes separately, then worked together to collaboratively to agree upon the final results. Differences in coding themes or analytical methods were settled through reflexive discussion. Dependability and transferability of results was ensured through the methodical execution of the interview protocol and the disclosure of research context, participants, and methods (41). Participant recruitment continued until a saturation of themes occurred.

Results

Quantitative Results

Agreement between the doses selected by the *Experts* and *SDM* was poor (<0.20) while agreement between the *Experts* themselves ranged from .25 to .55, with just approximately 50% complete agreement. When comparing *RCV* to the individual *Experts* within the study, agreement varied from poor (0.19) to moderate (0.47). *RCV* in comparison with *SDM* resulted in fair agreement (0.36) in recommended doses. A summary of the agreement between decision-making groups including standard error, z scores, significance, and confidence intervals can be seen in Table 1.

Table 1. Agreement between decision-makers (Cohen's weighted Kappa)

Ratings	Weighted Kappa	Asymptotic			95% Asymptotic Confidence Interval	
		Std. Error	z	Sig.	Lower Bound	Upper Bound
SDM - Expert 1	0.190	0.129	1.566	0.117	-0.064	0.443
SDM - Expert 2	0.115	0.146	0.786	0.432	-0.171	0.400
SDM - Expert 3	0.146	0.142	1.040	0.298	-0.132	0.424
RCV - SDM	0.364*	0.157	2.548	0.01	0.057	0.671
RCV - Expert 1	0.480**	0.130	3.744	< 0.01	0.226	0.734
RCV - Expert 2	0.471**	0.148	3.200	< 0.01	0.182	0.760
RCV - Expert 3	0.192	0.159	1.332	0.183	-0.119	0.503
Expert 1 - Expert 2	0.409**	0.138	3.217	< 0.01	0.139	0.679
Expert 1 - Expert 3	0.546**	0.148	4.231	< 0.01	0.257	0.836

Expert 2 - Expert 3	0.253*	0.147	1.716	0.086	-0.035	0.541

As can be seen in Tables 2 and 3, the overall agreement between the *Experts* and the *RCV* Group was moderate (0.41), but increased with dose, from .18 (placebo) to .26 (low), .34 (medium), and .41 (high).

Table 2. Overall agreement between *Experts* and *RCV* (Fleiss' Multirater Kappa)

	Fleiss Kappa	Asymptotic			Asymptotic 95% Confidence Interval	
		Standard Error	z	Sig.	Lower Bound	Upper Bound
Overall Agreement	0.409**	0.05	8.208	<.001	0.311	0.506

Table 3. Agreement between *Experts* and *RCV* by dose (Fleiss Multirater Kappa)

Dose	Conditional Probability	Kappa	Asymptotic			Asymptotic 95% Confidence Interval	
			Standard Error	z	Sig.	Lower Bound	Upper Bound
Placebo	0.222	0.175	0.080	2.181	0.029	0.018	0.332
Low	0.413	0.264*	0.080	3.299	0.001	0.107	0.421
Medium	0.533	0.344*	0.080	4.298	0.000	0.187	0.501
High	0.667	0.412**	0.080	5.151	0.000	0.256	0.569

The overall agreement between *SDM* and *RCV* was fair (0.33) (Table 4) while the agreement between *SDM* and *RCV* varied with dosage, from 0.06, 0.60, 0.34 and 0.46 going from placebo to low, medium, and high doses respectively (Table 5). It should be noted that the agreement between these groups did not show a regular increase with dose as seen for the *Expert* group.

Table 4. Overall agreement between *SDM* and *RCV* (Fleiss' Multirater Kappa)

	Fleiss Kappa	Asymptotic			Asymptotic 95% Confidence Interval	
		Standard Error	z	Sig.	Lower Bound	Upper Bound
Overall Agreement	0.326*	0.051	6.454	<.001	0.277	0.425

Table 5. Agreement between *SDM* and *RCV* by dose (Fleiss Multirater Kappa)

MPH dose	Conditional Probability	Kappa	Asymptotic			Asymptotic 95% Confidence Interval	
			Standard Error	z	Sig.	Lower Bound	Upper Bound
Placebo	0.000	-0.061	0.196	-0.312	0.755	-0.446	0.323
Low	0.667	0.597**	0.196	3.044	0.002	0.213	0.981
Medium	0.533	0.344*	0.196	1.755	0.079	-0.040	0.729
High	0.720	0.461**	0.196	2.349	0.019	0.076	0.845

For Tables 1-5, the strength of agreement can be considered poor for a kappa < 0.20, fair* for a kappa in the 0.21-0.40 range, moderate** for a kappa in the 0.41-0.60 range, substantial*** for a kappa in the 0.61-0.80 range and near perfect **** for a kappa in the 0.81-0.99 range.

Qualitative Results

Major themes that arose from the qualitative analysis of participants past experiences include *Positive Interactions with Treating Clinicians, Discussions Related to Treatment, Desire to Give a Child a Proper Dose, Experiences of Parents who are Reluctant to Give their Children Medication*, and *Confidence in Treatment.*

Positive Interactions with Treating Clinicians

Participants spoke at length about the positive interactions that they had with the treating clinician and the titration trial team: “[Physician] *explained it to us very well. We had an understanding of it, but with the titration, it gave us an even more in-depth way of thinking about things. So, yes, it was very helpful, and so was he. He was very patient with us”* (Participant 2). Participants also felt that the treating clinicians took their time in describing the titration process and results: *“… and he just listens to us both about how things are going and what kinds of concerns we have… he's just much more attuned to what we're saying and listening… He's very good at thinking through what we're saying, and not sort of jumping to conclusions or rushing through things”* (Participant 5).

Direct comparisons were made between the clinicians treating their child's ADHD, and other experiences with physicians in the past. Participants indicated that the clinicians involved

with the SDM titration trials were much more thorough than other GPs that they had worked with in the past: *"... if I go see* [Physician]... [its] *almost an hour that we get to speak and talk. When you go to your general practitioner, you're there for forty minutes and then you're out"* (Participant 4). Similarly, one participant mentioned that their child was more comfortable in talking with the treating physician during the trial: "*And like I said,* [Physician] *with* [Child] *was amazing because* [child] *wasn't very comfortable talking to physicians and stuff like that, but he was comfortable talking to* [physician] *and he wasn't afraid to ask questions or say 'well this is happening- why?*" (Participant 2).

Discussions Related to Treatment

All participants that went through the SDM titration trials with their children spoke of their experience with in being involved with the decision-making process, and ultimately the final maintenance dose that their child would take: *"I felt everybody kind of was party to discussing the results. So, there was an objective measure that helped us evaluate, like, was this actually working and at that dose?"* (Participant 1). Participants felt personal satisfaction at being involved with their child's treatment: *"I think we did a good thing personally. I think we did a good thing, and we were happy of the result, and we were able more to communicate with her"* (Participant 7) as well as the collaboration with the clinician on dosages: *"I felt a good level of collaboration. Like, I didn't feel like I was in the dark"* (Participant 6). When speaking specifically about the physician-patient power dynamic, participants felt as though both parties contributed equally to the decision-making process: "*I knew it was ultimately my decision to make which dose we decided to go with, but at that point we'd established a relationship… The*

graphs were clear, so the decision made itself, but it was based on his recommendation. I also got to see the research, the proof that we were making the right choice" (Participant 8).

Desire to Give a Child a Proper Medication

Having the goals of the stimulant trial thoroughly explained in addition to being involved with the decision-making process, participants spoke about the considerations involved with ensuring their child receives the proper dose of medication: *"...I was actually happy about it, it was just feeling good that something was finally being done, and it kind of felt like this is right way to proceed in terms of figuring out what he needed and what was working"* (Participant 5). Having the proper dose allowed participants and their children to avoid and alleviate any potential side effects with stimulant medication: "*We felt that* [Child]'*s medication, and even* [Child] *felt that his medication, was too strong for his schooling because became a zombie in the morning, if you can use that term. And in the afternoon, he would, he was still extremely hyper"* (Participant 2). Providing their child with the proper dose of medication also allowed both parents and their child to cope with their daily functioning*: "... I saw the changes immediately. It wasn't just for my benefit, but it was for my son's as well. The medication really helped him with the day to day after that"* (Participant 9). Finally, when speaking about past experiences in seeking treatment for their children, participants spoke of their wanting to ensure that their chosen treatment was necessary. For example, many of the participants children were, in the participants' opinions, arbitrarily prescribed medication without proper rationale: *"No one was offering anything else other than drugs, and I remember having discussions with the initial doctor we saw, saying that we should put him on antipsychotics, and I said 'no'"* (Participant 5).

Experiences of Parents who are Reluctant to Give their Children Medication

Several participants described the potential for the SDM titration trials to act as a decision aid for parents who may be reluctant to use medication to treat their child's ADHD: *"...I would say that it's definitely worth doing… it would give you some piece of mind afterwards that you're doing the right thing. Especially for kids who are recently diagnosed… it's the first time that they're prescribing medication"* (Participant 5). Even after agreeing to participate in the trial, participants spoke of how it enabled some of their spouses to better accept the outcomes: "*I think for my husband, it may have brought him on board a little more… because he had no experience with ADHD or ADHD medication before that trial, but I know that he thought it was a positive experience as well"* (Participant 1).

Confidence in Treatment

The last major theme from the qualitative analysis was that of the confidence that participants gained in the treatment and in their dosage decision: "*I think it's important for ensuring that we are using the right medication and the right doses. Different kids respond differently and by going through that process, I felt confident that we were doing the right thing and that we had figured out what the best dose was"* (Participant 5). Participants also mentioned that their children gained confidence in themselves, and in the treatment approach: *"… It gave him, it gave us an awareness of what the real* [Child] *looks like, and it also gave* [child] *the confidence to know the difference"* (Participant 2). Finally, participants felt that their SDM decision was more reliable when compared to their prior experiences with ADHD treatment: *"I found the whole titration process a little more, um, reliable… Whereas with the titration study, I felt confident that, um, there was a difference between like the placebo or whatever and the*

actual medication" (Participant 1).

Discussion

The purpose of this research was to compare three different decision-making approaches in the determination of the optimal dose of stimulant medication for the treatment of child and adolescent ADHD following a titration trial. Additionally, we sought to use the testimony of participants who had undergone a titration trial using our shared decision-making approach to provide insight and context to what this process is like for parents and their thoughts about the experience.

The first finding of note lies in the little agreement between expert-based decision-making and shared decision-making with families. For practitioners who have used shared decision-making from the outset of their clinical practice, this observation is surprising as the decision-making process seems clear and well supported for each titration. But this low level of agreement seems more to be expected on further reflection. We derived the expert decision-making process from the MTA study. In this study (34), experts blindly and independently evaluated clinical graphs, following a well-defined decision algorithm. If there was disagreement between evaluators, the graphs were faxed to all participating sites and discussed twice weekly in a Cross-Site Psychopharmacology Panel (CSPP) teleconference. The final decision to select the best dose was taken by majority vote, with priority being given to consensus-building beforehand. This process clearly shows that there were disagreements, but to the best of our knowledge the degree of initial agreement, or within the CSPP, has never been published. These discrepancies between the experts' decisions and those reached in shared decision-making with parents immediately raise the question: who knows best?

In the present study, the experts did something that never happens in clinical practice: they made a decision without even meeting or talking to the patient and their family. In real life, a clinician's decision on medication would certainly be influenced by their interactions with a patient and their families. Additionally, if the shared decision process is only poorly in agreement with the experts' decision, agreement with the Ranked Choice Voting process can be considered fair. Agreement between the decision of two experts and the RCV was slightly better, but poor for the third. Overall RCV agreement with SDMs was 0.326 and only slightly better (0.409) with experts, so a relatively small difference. The RCV is not considered here as a gold standard, but only as a point of comparison. A limitation of RCV is that it is based solely on rank and does not take into account the size of the score differences between ranks. But its advantages are that all information is taken into account in the final choice, and that all decision criteria are controlled. The same importance is given to evaluation by parents and teachers, and to therapeutic and adverse effects. As symptoms of Oppositional Defiant Disorder were included in the daily assessments, they carry the same weight as those for hyperactivity/impulsivity or inattention in the RCV decision. The different side-effect components also have the same weight in the decision, though obviously not the same impact in everyday life. Nevertheless, the fact that the agreement between RCV and experts or SDM is stronger with an active drug than with a placebo shows that both parents and experts were able to interpret the graphs correctly and similarly able to detect changes linked to pharmacological effects. Overall, the fairly good to moderate agreement between RCV and experts and SDM, respectively, suggests that these two approaches considered all available information, but did not give equal weight to each factor contributing to the decision.

As the study of agreement between different decision-making approaches does not allow us to conclude who knows best, we retrospectively analyzed medical notes during shared-decision consultations and expert notes. In 8 of the titrations (30%), the data was unequivocal, and all approaches readily converged on the same dose. For a further 5 titrations (20%), the discrepancies concerned only one dose level (e.g. low vs. medium), but for the remaining 13 (50%), the differences concerned more than one dose level (e.g. low vs. high) in at least one comparison between decision processes. As might be expected, these discrepancies occurred when there were differences between weeks in teacher and parent ratings, and/or between therapeutic and adverse effects. Experts might have given more weight to parents' assessments than to teachers', but they did not always do so. Parents might give more weight to teachers' assessments, as long as the side effects that are important to them remained acceptable. But sometimes parents gave more weight to their own evaluation for effects they valued, such as an improvement in oppositional behavior. Overall, it seems that since there are no common principles to account for specific experts and shared decision-making, and that all decisions were unique.

These differences in dose selection are not particular to our titration process. For example, in another MTA-style titration process in the Netherlands (1), a decision algorithm used the Reliable Change Index (RCI) to determine whether a child was a non-responder or a placebo responder, then ranked the doses in order of efficacy and selected the recommended dose as the one that most reduced symptoms without intolerable side effects. The "expert" report advised the treating physician to use the recommended dose or to find alternatives in case of non-response or placebo response. The treating physicians were encouraged to use the results as part of a shared decision-making process. After discussion with families, they prescribed the

recommended dose in only 55% of cases. There was no clear factor to explain non-adherence to the recommendations, but when they were different, doses were on average lower. But clearly, a rigorous placebo-controlled, randomized process is not enough to win over not only parents, but also physicians.

We have therefore turned to what parents reported about their experience to shed further light on the issue. Parents remembered the titration very clearly, even several years later. They expressed their desire to give an appropriate dose and appreciated the opportunity to observe the effect of the drug directly with their own eyes, without having to consent to its long-term use, since it was a trial. Parents learn the effects of treatment directly by observing and inputting information specifically about their child, rather than through statistics such as averages from which their child may deviate considerably. Conversely, a lack of patient understanding of medical treatments and other related healthcare information has long been associated with decreased adherence to treatment outcomes, and negative experiences with clinicians (42). The shared-decision titration process was particularly helpful when there was a high level of decisional conflict, or a high level of disagreement between the parents. However, it must be clear that shared-decision titration is not a means of tricking parents into accepting the medication, but a genuine trial, and that the outcome must remain open until the parents make their final decision as part of the shared decision-making process. This is the only way for parents to express their confidence in the process, both in terms of finding the best dose, and in terms of respecting their decision. Parents also report a truly collaborative and supportive relationship with the clinician. This opinion is based not only on the clinician's expertise, but also on the particular circumstances of the encounter. Blinding the assignment of doses to weeks until a decision is reached removes the clinician's ability to explain differences between weeks in

terms of pharmacological effects. The clinician must then only adopt a coaching role in reviewing the report and focus solely on behavioral changes from week to week, an area where parents are clearly the experts. Maintaining the blind at a time when all the data has been collected and processed might seem unnecessary, or even problematic for data interpretation. However, clinical expertise can unbalance the physician-patient relationship and give power to the one who knows best vis-à-vis the one who receives knowledge about a child on a daily basis (the parent). Often times when power is depicted in the physician-patient encounter, it is portrayed as something that physicians inherently own and yield to their own advantage, with little conscious awareness of that power (43). But in the shared decision-making process, the pharmacological interpretation of differences between weeks is not the objective of the clinical consult at the end of the titration trial. Instead, removing it by design allows for the expression of parents' preferences and values. Parents of children who had gone through the SDM titration process indicated that they felt equal to the physician in the decision-making process with no perceived power dynamics being present during the titration. This is in line with the role of clinician in a shared decision-making process, which is to provide guidance without being overly directive (44).

In conclusion, the question of who knows best is probably the wrong one. Parents appreciate the objectivity of the MTA-style titration process, the support of the titration team and the interaction with treating physicians in the context of a drug trial, at a time when decisional conflicts are high. Due to the amount of information gathered during the trial on various behavioral variables both at home and at school, the dose decision is a unique one on every occasion. The most important point is to base this decision on objective data in a bona fide trial. The question, then, is not so much who knows best, but rather what is the best decision-making

process that enables parents to make a sound, regret-free decision, and thus contribute to the child's and family's adjustment to the life change that an ADHD diagnosis and its treatment always entails.

Limitations

The expert group comprised of three members and more participants would have validated more strongly the comparison with other decision-making approaches. Using a larger number of titrations would also strengthen our conclusion. Interviewing parents sometimes several years after titration does not provide the same depth of information as a prospective study during and after titration, which should be done in the future. Future studies should also examine the decision-making process in greater detail, in order to standardize the shared decision-making process as well as possible.

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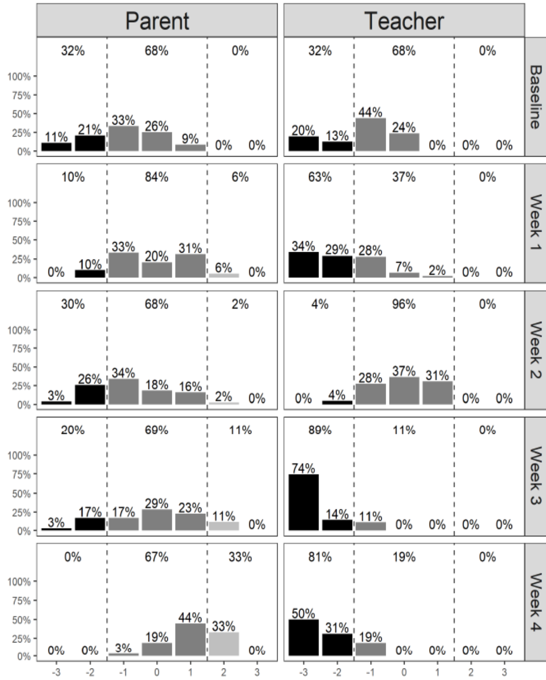
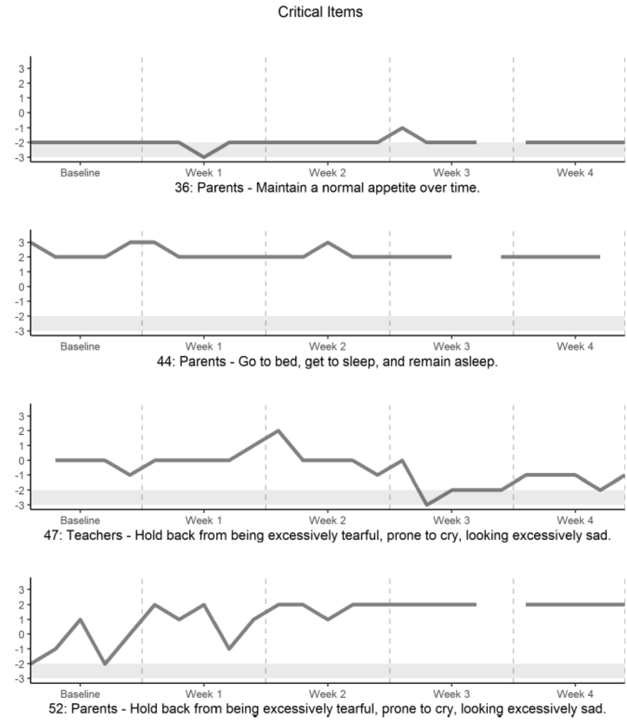
Appendix 1. Example of Items within the Clinical Reports Generated from the Titration Trials

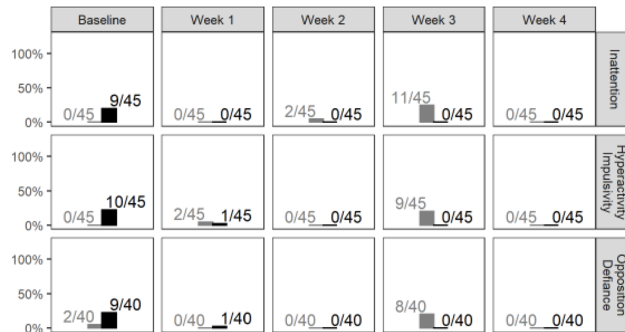
Global ADHD



Critical Items



Answers Missing



Appendix 2. Interview Protocol for Participants

To be verbalized to participant by interviewer. As part of a study on the experiences of parents of children with ADHD diagnoses, I would like to ask you about your experiences. Please describe your experiences with as much detail as possible and to the best of your ability. There are no 'wrong' answers and no judgment will be placed. If a question makes you feel uncomfortable, please let me know and that question will be skipped. I would like to remind you that you are free to quit the study at any point during the interview with no repercussions from your doctors or the researchers. Would you like us to clarify anything before I begin?

Participant's overall experience of titration process

1. You participated in an ADHD medication titration process with your child. Could you please tell me what you remember about that experience?
   Follow up questions/prompts (if not mentioned spontaneously):

   a. What sticks out most in your mind about that process?
   b. What do you think about the fact that you and the teacher did not know the dosage (blinding) when completing the questionnaires?
   c. Tell me about your child's "best" week during the titration process.
   d. Tell me about your child's "worst" week during the titration process.
   e. Were there any obstacles for you or your child during the titration process?
   f. How did the experience affect you on an emotional level?
   g. How did you react when you discussed the results of the titration with the doctor? Were you surprised?

Participant's experiences prior to titration experience

2. Please describe for me the experiences that brought you to the titration process.
   Follow up questions/prompts (if not mentioned spontaneously):

   a. Why did you consider medication for your child's ADHD?
   b. Why did you think titration was a good idea? Please describe for me any expectations you had for the titration process.
   c. What was your level of confidence in the titration process? Explain why?

Participant's views on use of ADHD medication prior to titration process

3. Amongst the secondary effects of ADHD medication, please describe for me any hesitation or fears you may have had/ or have regarding your child's use of the medication.
   Follow up questions/prompts (if not mentioned spontaneously):

   a. Did you worry about side-effects ("zombie effect")? About the efficacy of the treatment? About stigma/embarrassment for you, for your child? About the way

diagnosis and treatment were done? About the public image of medication in children? About long-term effects (growth, dependence, any other)?

b. Did you feel you knew enough about medication? How did your doctor explain it? Did you try to have other information? How?
c. How long did you take to accept the idea of giving medication? What did you go through to accept it?
d. How consistent were you in providing your child with his/her medication doses?
e. How did your child respond when given the doses of medication?

Participant's experience of working with physician during titration process

4. Please describe to me your experience in interacting with your child's physician during the titration process.
    a. What did you find most helpful in your interactions with the physician during the titration process?
    b. What, if anything, did you feel was lacking from your interactions with the physician during the titration process?
    c. How did you feel, as a parent, speaking to your child's physician during the titration process? Was it different from a regular visit to a physician? If yes ask: What was different? Please describe for me the level of power you felt during these interactions.
    d. How do you think the fact that the physician did not know your child's medication dosages affected your discussion with him about the results?

Participant's views on use of ADHD medication after titration process

5. Please tell me about your experiences of comparing the different medication dosages and placebo.
6. How did the titration process influence your views and feelings about your child and their use of medication to help manage their ADHD symptoms?
7. How did any changes in your child's behaviour during the titration process affect your parenting experience?
8. Do you think that the medication can solve the problem alone? Did the titration affect your view of other things that can be done, at school, at home, etc. (behavioral intervention, parenting)?

Outcome of participation in titration process/Concluding remarks

9. What do you feel you have taken or learned from this titration experience?
10. What advice would you give other parents of children undertaking the titration process?

Interviewer will summarize the answers of the participant.

11. Have I summarized your experiences well?

12. What would you have liked me to ask, that I did not ask?
13. Would you like to add anything?

Chapter 7: A Qualitative Study of the Experience of Parents of Children Treated in a Mental Health Outpatient Clinic During the First Year of the COVID-19 Pandemic

Tentative Journal: Child & Adolescent Psychiatry in Mental Health

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Funding details: This work was supported by the CHEO Research Institute's COVID-19 Grant. The authors have no competing interests to declare that are relevant to the content of this article.

Abstract

Objectives: Using a longitudinal exploratory thematic analysis approach, this study examined the experiences and coping strategies of parents of children with mental health conditions during the first year of the COVID-19 pandemic.

Methods: Parents of children aged 4 to 18 (M = 13.30, SD = 3.43) receiving outpatient mental health treatment at a pediatric tertiary care centre were eligible to participate. Participants were identified through their child's electronic medical record and contacted for participation. Two semi-structured interviews were conducted. The first interview was completed in May and June of 2020, three months after the declaration of emergency in Ontario. A second, follow-up interview was conducted in March of 2021, one year after the declaration. Interview 1 consisted of N = 15 participants while Interview 2 consisted of N = 11 participants. The initial interview used 14 questions that explored parenting experiences, specifically as they related to information gathering, sources of support, family functioning and routines, sources of stress, and coping strategies during the pandemic. The 3-question follow-up interview served as a member-check, summarizing the main topic of discussion from the initial interview, in addition to questions related to changes in thoughts and feelings toward the pandemic, views on the vaccine, and whether any positives aspects emerged from the COVID-19 pandemic. Data were analyzed and presented using a Thematic Analysis Approach.

Results: Time 1 analysis revealed relative stress prior to the pandemic, children's mental health, pandemic impacts on children, family functioning, financial uncertainty, health anxiety, parenting during the pandemic, and parental coping as the major themes. Time 2 analysis revealed reflections since time 1, child's mental health, family functioning, parental coping, thoughts on the vaccine, and looking to the future in a COVID-19 era as major themes.

Conclusions: The COVID-19 pandemic had a profound impact on not just our participants, but society as a whole. Participants were burdened by financial insecurity and the reduction of mental health resources. The impact of the pandemic on the health system as a whole and balancing the physical effects of the virus in light of its mental health impacts need to be considered when implementing risk-mitigation strategies in the future.

Key Words

COVID-19 Pandemic; Longitudinal; Qualitative; Parental Mental Health; Parental Experiences; Thematic Analysis

Introduction

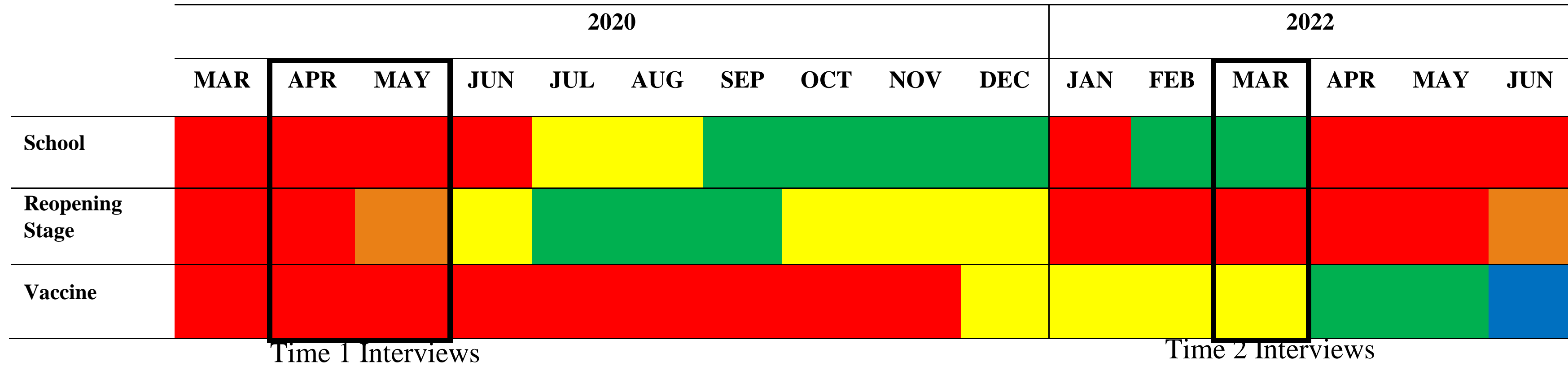
Caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the coronavirus disease (COVID-19) has resulted in widespread social, economic, political, and health impacts across the world. First identified from outbreaks in the Chinese city of Wuhan in December 2019, The World Health Organization (WHO) declared a Public Health Emergency of International Concern in January 2019 and then declared the coronavirus disease as a pandemic on March 11, 2020. Since its declaration as a worldwide pandemic, COVID-19 has resulted in approximately 642 million infections and 6.6 million deaths globally (1).

Background: Breakdown of the pandemic and timelines in Ontario

Following the declaration of COVID-19 as a pandemic and with rising local cases, the premier of Ontario declared a provincial state of emergency on March 17, 2020 (2). This marked the beginning of closures of all recreation facilities, libraries, schools, daycares, places of faith, bars/restaurants, and provincial parks. Non-residents to the country were banned entry, and Canadians who were out of the country were strongly urged to return home due to imminent border closures. By March 23rd, 2020, the closure of all non-essential businesses across the province was ordered and self-isolation orders were put in place for recent travelers. All outdoor recreational amenities such as parks were closed to the public by the end of March. Residents of Ontario were required to stay in their home and only permitted to leave for essential purposes such as purchasing food or receiving healthcare. Close contact with others was limited to those living within the same household, and people were required to maintain a distance of at least 2 metres between each other when in public. In October 2020, the Ontario government enacted province-wide mask mandates within all public areas. In response to the multiple waves of

COVID-19 infections within the province, Ontario has gone through several periods of lockdowns and staged reopenings during the last three years (3) (see Figure 1).

Figure 1. Timeline of School Status, Reopening Stage, and Vaccine Eligibility during the COVID-19 pandemic in Ontario.



School
Closed
Summer
Open

Reopening Stage
Emergency Stay-at-Home Order
Stage 1
Stage 2
End of Mandates/Regulatory Requirements

Vaccine Rollout
Not Available
For high-risk individuals
At risk, working in-person, and in high-risk communities
All Remaining Eligible

COVID-19 Burden on Families

At a national level, non-pharmaceutical interventions such as limiting movement between countries have shown promise in reducing the spread of COVID-19 infections (4). At a local level, regionally-targeted lockdowns have been implemented worldwide (5-7) with restrictions limiting contact among individuals being successful in curbing the spread of COVID-19 (8, 9). Although studies have shown that limiting inter-regional travel and imposing social restrictions is associated with lower incidence and prevalence of COVID-19 cases and death rates (10, 11), there is growing literature that suggests such measures have had major indirect social, economic, and health impacts.

Social isolation, school and childcare closures, employment instability, and inaccessible recreation facilities and healthcare services during the first wave of the COVID-19 pandemic has placed unique burdens on families raising children at home (12-14). Growing mental health impacts, especially with regards to the family context are of particular concern (14, 15). There have been several studies examining the association between the COVID-19 pandemic and family mental health status (16). In a study by Gadermann et al (2021) on a nationally representative sample of Canadians, authors found that a significant proportion of parents (44.3%) reported deteriorated mental health when compared to participants without children (35.6%) since the onset of the COVID-19 pandemic. Among parents with children at home, women, parents under 35, parents with pre-existing mental health conditions, parents with a disability, parents with younger children, and parents with financial stress reported significantly worse mental health. Deteriorations in family mental health are being seen world-wide (16), with international studies showing increasing rates of anxiety and depressive symptoms, and psychological distress (17). Parents of school-aged children are disproportionally affected by

worsening mental health due to the COVID-19 Pandemic. Difficulty coping, increased alcohol use, increased suicidal ideation, and increases in negative parent-child interactions have been reported within this population (15, 16, 18). In addition to balancing their own career workloads, parents have been required to provide full-time supervision while also attending to the educational needs of their children.

Research suggests that 24.8% of parents reported that their children's mental health had deteriorated (12) during the pandemic. Indeed, a globally-representative meta-analysis indicates that lockdown measures are associated with worsening mental health in children (19). Daily routines provided by school and extra-curricular activities are known protective factors in children and adolescent mental health. These routines provide children and adolescents with physical activity, sleep regulation, and social interaction. Unfortunately, and similar to parents, school and childcare closures, the cessation of after-school activities, summer camps, and recreational sports and general social isolation has resulted in severe detrimental effects to mental health (20-22). Within Ontario, the impact of this emerging mental health crisis in families with children and youth in the general population has been documented with increasing rates of depression and anxiety/irritability and stress being seen across the province (23). During the early months of the pandemic, frontline agencies such as Kids Help Phone, a national telephone help line, saw a 28% increase in calls about physical abuse, 42% increase in calls about anxiety or stress and a 48% increase in calls about isolation (24). It has been argued that the disruptions to daily routines and reduction or cessation of community support services, coupled with the negative effects associated with social isolation has exponentially increased the risk of child mental health problems. It has been suggested that children from marginalized or socioeconomically disadvantaged families (25), with chronic disorders (26), or with pre-existing

mental health conditions (27) are at the highest risk of developing pandemic-related mental health problems.

Present Research

There has been an abundance of research examining the psychological effects of the COVID-19 pandemic within the general population. However, less literature exists on the mental health of children and their families (see: Wang et al., 2020; Xie et al., 2020)(28, 29), and even less on children with pre-existing mental health conditions (see: Magklara et al., 2022; Fischer et al., 2022) (30, 31). Additionally, qualitative approaches that examine participant experiences are under-represented within the literature. As such more research, specifically longitudinal qualitative research, is needed to gain a better understanding of the experiences of families as they navigate the widespread changes brought on by the COVID-19 pandemic.

As part of a larger project examining the effects of the COVID-19 pandemic on families, the purpose of this research is to describe the lived experience of parents of children with preexisting mental health conditions during the COVID-19 pandemic. Using a longitudinal exploratory thematic analysis approach, we sought to explore parents' main sources of stress during the pandemic, their ways of coping with stress, especially in parenting children with mental health problems (confinement at home, routine, support, continuity of care, mental health changes).

Methods

The decision to conduct this study using qualitative methodologies was made with objective of capturing the lived experiences of parents of children receiving tertiary mental

health care at the height of the onset of COVID-19 pandemic in ways that might otherwise be missed through quantitative methods. The longitudinal nature of this study allows the researchers to build upon initial rapport made with the participants and conduct semi-structured interviews to see how the changing landscape of lockdown restrictions have impacted parents, children, and their families especially as it relates to mental health. The use of qualitative methods allows researchers to see themes and patterns within the experience of parents as they recounted in real time their experience throughout the first year of the pandemic.

Participants/Recruitment

Data were collected from the parents of children aged who were receiving outpatient mental health treatment at a pediatric tertiary care center. A summary of participant characteristics can be found in Table 1. This study was approved by the University of Ottawa's Research Ethics Board (H-02-23-5707) and the Children's Hospital of Eastern Ontario Research Ethics Board (CHEOREB# 20/36X).

Table 1. Participant characteristics at the onset of the study

Characteristic	Value
Average age	44.9 years
Gender	
Male	14.0%
Female	86.0%
Marital status	
Married	40.0%
Separated	26.7%
Divorced	20.0%
Widowed	13.3%
Custody arrangement	
Parental	40%
Joint custody	20%
Sole custody	40%
Mental health condition	
Yes	46.7%
No	53.3%
Chronic physical health condition	
Yes	20%
No	80%
Average age of child in outpatient clinic	11.6 years

Procedure

Participants were identified through their child's electronic medical record and contacted for participation by a clinical care coordinator following hospital protocol. As part of a larger study examining the effects of COVID-19 on families, hospital administrative staff initially contacted 637 parents by phone. Parents who expressed further interest in a qualitative study

exploring their parenting experiences during the pandemic were recruited for the present study. Participants completed an electronic consent form and general demographic questionnaire using a secure online survey platform (RedCap). Participants were then contacted by the Principal Investigator to schedule interview times. Interview 1 consisted of N = 15 participants while Interview 2 consisted of N = 11 participants.

Data Collection

In-depth, semi-structured interviews were conducted at two time points. The first interview was completed in May and June of 2020, three months after the declaration of emergency in Ontario. The second interview was conducted on the same participants in March of 2021, one year after the declaration of emergency in Ontario and at the onset of the COVID-19 vaccine roll-out within the province. With data collection taking place over the course of the first year of the pandemic, interviews were conducted at a time when participants were experiencing the most restrictive provincially-mandated requirements related to movement and socialization. This allowed researchers to obtain richly detailed and accurate information on the experiences of parents and their families during the onset and progression of the pandemic. With the exception of one participant who preferred answering questions over email during the second interview, interviews occurred over videoconferencing software or telephone and interview audio was recorded. Audio files were anonymized and transcribed using an electronic service. Transcriptions were then verified by two researchers for accuracy.

Measures - Interview Protocol/Questions

An exploratory interview protocol was developed by the Principal Investigator with input from the co-authors (see Appendix 1 for the initial interview protocol) for Time 1. This was chosen as the impacts of the pandemic on our sample population were unclear at the time of study development and data collection. An exploratory approach allowed researchers the opportunity to explore the experiences of participants without a-priori expectations on emergent themes. The initial interview consisted of 14 questions that explored parenting experiences, specifically as they related to main concerns, information gathering, family functioning and routines, sources of support, child health and crises, and coping strategies during the pandemic at that time.

The Time 2 interview protocol was developed following the analysis of the Time 1 transcripts (Appendix 2). This allowed researchers to reflect on the themes and subthemes found in Time 1 and assess how the findings, along with the changing pandemic landscape (the nearby emergence of the first round of COVID-19 vaccines), could inform our Time 2 interview questions. The second interview served as a member-check, summarizing the main topics of discussion from the initial interview, and asked additional questions related to changes in participants' thoughts and feelings toward the pandemic, views on the upcoming vaccine, and whether any positives aspects emerged from the COVID-19 pandemic.

Data Analysis

The data were analyzed using an inductive approach to thematic analysis, based on Braun & Clarke's (2006) framework for thematic analysis (32). Such an approach requires recognizing similarities and differences within the data, in this case parental and family experiences, and

categorizing them according to their relevance to the participants and the data set as a whole. This is done by first familiarizing oneself with the data, generating initial codes based on notable facets of the data across the sample, looking for themes within these codes, reviewing themes as they relate to both the individual data extracts and the whole data set, followed by naming/defining each of theme, and finally producing results and finding key descriptive data extracts for use in reporting. An inductive approach to analysis allowed the researchers to examine the data without trying to code and categorize the data using pre-existing frameworks or expectations. Given the open-ended goal of our research, having an iterative bottom-up approach was the best fit for this data set. Data analysis was completed using the NVivo qualitative software package (Version 12).

Data Integrity

Several measures were utilized by the researcher to improve credibility and trustworthiness of the analysis including continuous comparative analysis and immersion in the topic of study (33). Analyses for both time points were conducted collaboratively between the Principal Investigator and the Second Author. Taking an iterative approach, the researchers made constant revisions while coding the interviews, identifying themes, expanding and narrowing the definitions of these themes as the analysis progressed, and recognizing and naming sub-themes within the themes. Dependability of study results was adhered to through consistent execution of study materials while transferability was ameliorated through thorough disclosure of the research context, participants, and methods (33). When differences in coding themes or analytical methods emerged, disagreements were settled through reflexive discussion. Such an approach to qualitative analysis ensures greater methodological rigor. Participant recruitment for the Time 1

interviews continued until a saturation of themes was achieved. Time 2 interview served as a member-check for the Time 1 interviews.

Results

Time 1 Results

Relative stress prior to the pandemic, children's mental health, pandemic impacts on children, family functioning, financial uncertainty, health anxiety, parenting during the pandemic, and parental coping were the major themes identified during the initial interview with participants. Each theme comprised several subthemes (Table 2).

Table 2. A summary of themes and subthemes identified during Time 1 of the analysis.

Theme	Subtheme(s)
Relative stress prior to the pandemic	• Child' mental health problem and high stress • Stress as a part of everyday life • Improvements in stress • Uncertainty about the duration of the restriction
Children's mental health	• Changes in mental health status • Improvements vs. deteriorations
Children's coping	• Settings and behaviour changes • Amount of screen time • Behavioral crises
Family functioning	• Managing stress • Changes in family routines • Difficulty finding activities for children. • Family growth and slowing down of life
Financial uncertainty	• Changes in spending • Financial security or not • Empathy for people in financial hardship • Paying out of pocket for therapies
Parenting during the pandemic	• Keeping family safe from illness • Emerging concerns about mental health • Parenting around children's mental health concerns - Decrease in support - Isolation and lack of socialization, especially through school - Lack of physical contact • Parenting around restrictions - Confining children at home with one parent - Explaining restrictions to their children - Parental modeling
Parental coping	• Restriction-related stress: shopping, family visit • Work-life balance • Schooling from home • Parental distress • Acceptance and self-distraction • Social support: friends, family • Therapeutic resources accessed by parents

Relative stress prior to the pandemic

When asked about stressors related to living during the pandemic, participants often spoke of their relative stress levels prior to the pandemic, frequently drawing comparisons between these times. In general participants indicated that managing their children's mental health was a main contributor to their high stress levels before the pandemic occurred. For example, one participant noted: *"I will tell you three years into this battle, it's at least three years, it might even be longer than that at this point, on any given day, I'm flying by the seat of my pants"* (2). That same participant went on to describe how their child requires constant attention, contributing to their overall stress: "*So I said to the therapist on Saturday night, I'm like, "Here's the thing that's insidious about all of this. I only have to slip up once." That's the reality. That's what I face every single day. I only have to turn my back once"* (2). Similarly, another participant noted: *"Yeah. I guess what I find hard is not having a break because he's always here. So depends. Like the last two nights my son didn't let me sleep well. So it makes harder in those times to apply anything. I always feel overwhelmed… That's not even with the pandemic"* (3).

Although participants indicated that their stress going into the pandemic was relatively high, they also mentioned how this high stress wasn't out of the ordinary in terms of their daily lives: *"I'm not going to say it's easy, because it's complicated by all the legal things that have been going on. To be honest, nothing's really changed for me because of this pandemic. That's the interesting thing. I've been in chaos since I separated my ex"* (5). Other participants mentioned that their stress has improved since the onset of the pandemic: *"COVID allowed us to stop. It allowed us to slow down. It allowed us to remove her from the environment that was causing her chaos and it allowed our family to take a step back because I am a single mom"* (6).

Participants often spoke of their general uncertainty about what the future entailed in light pandemic restrictions. Participants worried about the potential for mandated restrictions and lockdowns being part of daily life: *"And I'm worried though, now with this COVID-19 that we've now created a situation it'll be like that forever"* (12). The eventual duration of the pandemic was often spoken of with many participants being unsure of school arrangements: *"I don't know. Yeah. And how long it's going to last for and are they going back to school?"* (10). Participants were unsure how long it would take to return to normal, which was another source anxiety: "*So it's going to be around for a long time. So, I guess I'll ... Should I say fears? I worry. I have anxieties about society's situation in general getting worse, not returning to the normal and people not dealing with that well. Not returning to pre-COVID normal and people are not dealing with that well in general*" (15).

Child's Mental Health

Parents identified managing their children's mental health as a main concern prior to the pandemic. Similarly, their children's mental health throughout the pandemic was also a main theme that arose. However, a polarity emerged within this theme as parents indicated that their children's mental health would either deteriorate or improve up to that point in the pandemic. For example: *"We are well entrenched in* [Hospital], *my kid and I. This is a three year because their stuff, and in fact there was a* [Hospital] *visit on Saturday night because her mental health has taken a dive"* (2). This deterioration in mental health was exacerbated by pre-existing health conditions: *"Oh yeah. They most certainly are. Like I said more so for my one son because he's normally anxious about things like dying and being in a wheelchair. He has some anxiety normally. So, this just stepped it up to the next level, I think for him"* (13). Mainly attributed to a general slowing down of life, several parents mentioned that their child's mental health improved

following the pandemic lockdowns: *"…And for whatever reason, whatever blessing has occurred, whatever thank you God, my child is now pretty self-sufficiently, mentally stable. So that's why I say there's this strange sort of trajectory that occurred for us that I think is incredibly atypical but happened, thankfully… I hate saying this because it's affected so many people but for my family, it was the best thing that could have happened at the right time. I'm convinced it saved her life."* (6). Similarly, Participant 11 indicated that: *"…the seven-year-old, we haven't seen anything. We used to see him in breakdowns almost daily or every second day. And since the pandemic, we might've seen two or three… For him, yeah. And I think it's all the (lack of) outside stimuli."*

Children's coping

Although primarily concerning their children, when speaking of their parenting experiences participants spoke at length about how their children were coping when faced with the impacts of the COVID-19 pandemic. Main topics that arose within this theme included (a) changes in settings and the subsequent effects on their children's behaviour, (b) socialization and the amount of screen time their children were consuming, (c) changes in behavioral crises, (d) parental explanation of the pandemic to their children.

In terms of the subtheme of (a) <u>settings and behaviour changes</u>, parents emphasized that increased time at home and subsequent changes in expectations improved their child's behaviour. For example, Participant 4 said: *"…And then it was just an explosion of tantrum basically. So, in reality, his behavior at home has been phenomenal compared to when he's going to school……I think a lot of it is the expectations at home is different than the expectations at school"*. In a similar way, participants explained that their children often showed good adaptability to remaining at home: *"Youngest one, very good reaction. He is very adaptable, and*

he goes with the flow. Recently, he's been talking about missing his friends much more" (9); *"But when it comes to putting everything together, my kids have handled this like little rock stars. I'm super proud of them. They have done such a good job of adjusting and now"* (5). However, many parents expressed that the routines and structure offered by a school environment helped with their child's behaviour: *"And after the first month, she just kept dropping everything, because she didn't have the understanding, the motivation, she was lazy. So, for her as well, it was not a good situation for learning. If she's in class it's great where she has someone teaching her, showing her examples, it's fine. The self-learning, I thought even as an adult, that's hard for a lot of people to do, and they expect it from children?"* (4).

As it was difficult to engage in in-person socializing, participants indicated an increase in the (b) <u>amount of screen time</u> that their children were consuming during the pandemic. Interestingly, this socialization seemed to be gendered in that male children opted for playing video games as a means of socializing with friends while female children preferred Messenger or FaceTime: *"I find the girl, my oldest, I don't want to generalize it, but she has a very much easier time having a Facetime chat with her friends and just chat away while she's doing something. Boys, they don't just chat. They need something else to do together so unfortunately, and fortunately too, online gaming's very, very helpful so they have something common to do while they talking. They not talking about gaming, they're talking about something else, but they're also doing the gaming together"* (1). Participant 4 echoed this sentiment: *"Yeah. They enjoyed that aspect of it, but they really missed the social ness with their friends and playing their friends. The girls were lucky because they were able to FaceTime their friends and text and chat. That kind of a thing. Johnny, this is younger one, it was harder for him because boys don't do it the same way, but my son is a very social person. So that was tough for him"* (4). Although participants were generally happy

that their children found a way to mitigate the effects the pandemic had on their child's social life, they expressed concerns as to the amount of screen time their children were now consuming: *"But I also, I think it's really good to have these social connections and I feel that I'm worried that I'm going to lose or they're going to lose all of themselves to electronics and not have that connection anymore. I mean, that's aside from like getting sick and dying from COVID-19, that's my big worry of the world we're going to go into after"* (12).

The (c) children's behavioral crises that participants reported managing varied greatly with some reporting no change: "*I wouldn't say anything major happened. I wouldn't say any major crisis that is not part of his normal tantrum"* (14); others reporting intermittent or acute crises: *"So twice during the earlier phase that was more negative. It was kind of highlighted by two different occasions when the police were called. And the second one, we ended up going to CHEO with him in an ambulance"* (15), while still others reported ongoing crises: *"So I'd say it's like a constant, like almost in crisis, like really, really upset. Yeah. And he's not ... like he's a horrible sleeper"* (12).

Family functioning

Participants spoke about the various aspects of family functioning that effected their household during the pandemic, and the subsequent changes that were required in in order to adapt to a new normal. Namely, management, routines, family growth, activities, and a general slowing down of life were discussed as subthemes.

When asked if they were managing stress on a day-to-day basis during the pandemic, participants were varied in their responses. Some indicated that little had changed: *"Not much. I don't feel stressed by the pandemic at all. I'm in a good situation. My job is guaranteed. Financially, I'm doing well"* (9). Acknowledging that their life situations had changed, some

parents indicate that they were still doing well: *"So I guess basically, all that to say I think I'm finding it okay, the day-to-day, but it's just accepting that things are not the same and not be hard on myself that somethings are going to go. And that's going to be okay"* (8). Still other parents indicated that they were feeling overwhelmed: *"I don't know. I think I kind of take it hour by hour. Some days, I never think a whole day goes well... I would say though that throughout the day, there's times where I'm struggling and when it's okay and it's ... But I find, I just, I get so exhausted"* (12).

One of the major changes effecting participants were <u>changes to their family routines</u>, especially during the onset of the pandemic: *"I guess it's hard to have a set routine and I still find it hard to get everything done, make sure my work gets done and I take care of my son. I'm lucky because I've been allowed to work part-time. But even part time I still find it hard to get everything done because I make sure my son still does his homework"* (3). A common occurrence for participants was a lack of set-routines. For example, Participant 1 expressed: *"But routine-wise, yeah, we didn't have a set routine. We didn't have a solid set routine; we had a kind of vague routine"* while Participant 10 said: *"Not really. When we get up, they have breakfast or [Child' name] will either bike to his dad's or help do some stuff around the house".* These changes in routines often encompassed basic coordination within the family such as using a laptop: *"I think the biggest thing that we use that for was within the first month trying to work out the routine, because we have one computer and one laptop, and I need the computer to do my work while my children are using a laptop"* (4) or the family vehicle: *"And for my husband, I told him this morning, he's going to have to start riding his bike to work because we only have one car and I'm like, so we could drive to different splash paths and stuff like that because we only have the one vehicle"* (12). Some participants indicated that their change in routines meant a

change in the medication timing for their children: *"Usually I was timing the medications with school to make sure he's medicated all through his school hours. Right now, we ended up changing it up with talking about it with the educator from school. So, what I do is I give it to him first thing in the morning, and I'll go according to that. If he gets up early, he might get another dose when he's about to do his homework. If not, usually I'll wait until lunchtime"* (3). Participants also described the difficulties trying to find activities for their children during lockdowns: "He can't do jujitsu. He can't do the things that would help him with that kind of body control. I just can't leave him unsupervised. He could kill his brother" (5); "I don't even know how I'm going to have them be able to have a resemblance of summer, to really just be able to run outside, do activities. I don't have the time. So that's also another concern" (14).

Although the COVID-19 pandemic was associated with many negative changes, it also provided the opportunity for family growth within our participants. For example: *"I have a lot of games. It just depends a lot of just having fun, just playing a lot of board games, a lot of games, going outside, playing. I bought them a hockey net this year, so playing hockey, going biking. All those things that we really never had time to do as a family"* (14). Participants found that their children benefited from the opportunity to be closer with them: "*So, I think that's an interesting trend that gets emphasized in him because I think he needs more of our time. A, in the absence of these other peers or friends; and B always it's a connection, right?"* (15). Similarly, when speaking about parental accessibility Participant 7 stated: "*When she's having a rough minute, she will come and sit on there with her iPad while I'm doing stuff and just be close. Just be physically within that few feet of each other and she knows that I'm here and I'll push my chair back and grab her toes for 10 seconds between doing something. Just a physicality. A rub on the back".* A common appreciation for the restrictions being mandated was a general slowing down

of life, which enabled participants to be together: *"When I say it's a blessing for my family, I am not kidding. It has changed us so deeply and most people would say, for the worst, this has been terrible. And I hear them. I understand them and those statements are completely valid. But for us, it's just been really, truly, like the biggest, best thing that could have happened, was forcing us to stop and stay home together"* (6).

Financial uncertainty

Lengthy discussions pertaining to finances were brought up by most participants. Topics within this theme covered the economy and a general awareness or prices, relative level of worry about finances, empathizing with others in worse financial situations, and being required to pay for their child's therapies.

Participants deplored the increases in prices: *"All those, I say might be first world problems, because financially, we are still here, we're still safe. We still have the means to do what we need to do. It might be a little more difficult to get those products, or get those things to be done, because everything's closed, but you figure it out and you adapt"* (14). The increases in everyday prices were somewhat offset by savings in other areas of the participants' lives: *"If anything, we're not spending as much money because things have been canceled, activities, tutors, that sort of thing"* (8). Participant 12 noted: *"So all the money we spend on daycare, normally, I've taken that money and I put it into savings right away. So, the one really good thing about COVID is for the first time since having children, we actually have money in a savings account"*.

Within Ontario, treatment from psychiatrists or general practitioners is covered by public health insurance. The children of our participants also often received mental health support within their school settings. With school shutdowns and significant limitations in publicly funded

mental health access, some parents reported having to pay out-of-pocket for private therapies: *"So with all of these kids regressing, which mine has, we've been doing the therapy, that's all out of pocket. There has been no extra assistance, either financially or through any additional type of support, and I mean anything for kids with special needs, from the either Autism Ontario, government officials,* [Hospital] *or any of those natures, they really haven't done anything to help these kids"* (14).

Although discussions relating to costs were made by all participants, the financial strain that participants experienced was varied. Some participants reported feeling no financial hardship. This was usually attributed to the job security afforded by working for the Federal or Provincial governments: *"A blessing. My work has paid me all the way through. I have no financial worries... Because luckily enough if I'm stuck with some of what people are going through right now post-COVID, my employer has an incredible health plan"* (7); *"Well, I guess I should say, we work for the federal government so we're not in impacted financially or job-wise. So, that's not a stress"* (8). Participants that worked for the private industry were more likely to report financial hardship: *"I should say my husband's job, they all went down to 80% salary almost right away. So financial concerns although interestingly they've recently gone back up to a hundred percent. So, they were concerned about cashflow issues, and they proactively went down and now they've been able to come back up"* (15). Unfortunately, those participants that self-reported living in poverty were taking drastic measures to stave off food insecurity: *"I've got a garden that I'm growing for a whole year for food. Because I already know that I can't afford food. I already know that I will not be able to afford... so yeah keeping an eye on food security"* (5). Those participants who reported physical or mental disabilities, or were single parents were the most disproportionately affected by financial strain within our sample population: *"Because*

of my situation, I'm on disability… Oh God. There's so much to do. That's the thing, the house is old. That's the thing too, repairs need to be done. I have no money; I have to do it myself. I'm really going to have to climb on my roof, but it's okay" (5). An interesting subtheme emerged in that those with financial security often empathized with those who were experiencing difficulties: *"A hundred percent. And I definitely feel for those families who have lost their job and who are now on the CERB. $2,000 a month, as great as it is that the government is doing it, doesn't even pale in comparison to what you should be making, and then what do you do? Especially having a special need child at home, what do you do when you're the, I'm the only breadwinner in the house. And I'm going to have a mortgage to pay, bills to pay, mouths to feed, and therapy to pay for, and nothing is coming in, what the hell do I do? It's only so much that you can drain from a rock"* (14).

Parenting during the pandemic

Given the uncertain prognosis of COVID-19 at the time of the initial interview, participants harbored a fair amount of health anxiety, and wanted to protect their families from the disease: "*Health. The physical health that they (family) might catch COVID. We might catch COVID, one of our family members or loved ones in extended family may catch it"* (1). Participants spoke of the methods in which they kept their families safe: "*Top concerns are obviously keeping ourselves and the children healthy. So, we've been keeping our circle pretty tight"* (13).

Although physical safety was of primary concern, some parents discussed how mental health was emerging as a concern as well: *"So I guess my top concern was health. But now after a couple of months, I find that that's shifting more to… I'm still concerned about health, but now I'm getting a bit concerned about mental health"* (8). As all of the participants within this study

had children with some underlying mental health condition, the onset of the pandemic made it difficult to address crises: *"There have been a million other situations throughout her life, where there's at least a response of some kind that we can ... there's an action. There's a, 'Okay, we can do this in response to this,' around her mental health stuff. 'We'll get you a therapist. We'll get meds,' all of the things we've done all the way through, but I can't fix this one. None of us can."* (2). Participant 15 echoed this sentiment: *"So the whole COVID restriction, the self-isolation restriction generated the acute events that triggered that, so then he reacted poorly to us saying, 'Well, no. And you got to think of other people and the whole world is in self-isolation, so can you not do it also please'... Anyway, and he ultimately ended up in a worst place himself*". Within the realm of mental health of their children many participants worried about the socialization of their children: *"Well, I mean, the top concern for me, from a parent's perspective, has been the socialization of my girls"* (6). Similarly: *"Yeah. I was noticing I worry about his... and it's not there yet, or anything, but that he could get a bit depressed or a bit down by not socializing, because he is very social and he's really sporty and stuff. And all his activities have been canceled and everything. But other than that, no"* (8). Parents were worried about the lack of physical contact: *"I know COVID-19 is unhealthy and very serious, but also that impact of like never hugging someone again or like the kids playing with them and that their life becomes online for the most part."* (12). The participants felt that not going to school in person considerably diminished their opportunities for socialization, and longed for when their children would be allowed to return to school: *"I don't care what else they do come September. You lock down the rest of the world and make us all stay home; I'm cool with that. You need to get our kids back to school, a hundred percent. I think that my kid would echo that in school"* (2).

In addition to the health-related concerns that participants had, participants discussed their experiences of parenting around restrictions, especially confining children home with one parent while limiting outings to the essentials, and explaining restriction to their children, including by modeling.

In general, participants limited the number of outings from their home: *"So my husband is the only one who does the grocery shopping. He goes once a week. The reason he goes grocery shopping is well, he usually does the grocery shopping, but also right now being a healthcare worker, he gets to the front of the line"* (12). When leaving the house, most participants indicated that it was for essential purposes only: *"But just basically obviously to leave the house and go to Walmart or grocery shopping. In and out. We don't wait"* (13); *I do grocery shopping. Yeah. I just do shopping, but other than that, not really. No… Just the essentials"* (4). Most parents indicated that they limited the amount of time that their children spent in public places: "*We still haven't brought the kids into a store, but we're out and about in the neighborhood*" (13) with some parents employing certain strategies to limit their children's exposure: *"Couple of months ago it was a real struggle. It was like, okay, well, we don't want the kids to go into the stores at all. But having three kids it's... So we would load up. We would go as an entire family and then my husband would drop me off at Walmart and he would drive around… then when I was ready, they'd come and pick me up"* (4). Participants mentioned that it was especially difficult to find activities to do with their children given the restrictions at the time: *"because when they started talking about closing the beaches, I thought, 'Boy, I better find something.' Because a summer with no swimming and these kids is going to be tough."* (10).

How to explain the COVID-19 pandemic situation to their children were often triggered by the need to explain to their children why some people in the community were not following

mandated restrictions (playing at parks, not maintaining social distancing rules): *"I just explained mainly that every family is different and that we're doing everything to protect him, and he doesn't need to worry. And that's why, and I also explained to him like we're washing our hands and we're keeping our distance. But if he was to get sick or catch it, I explained like he'd be okay because we keep taking care of him. And then he was very focused from that on blaming these people for getting it"* (12). Participants report to have to manage their child's frustration when they saw other families breaking mandated restrictions was troublesome for participants: "*And the only other is that a lot of the parents are letting their kids go on the play structures. So, I did try and figure out while I was at the park if the play structures were open or not, but they're not. And that was hard because you're like, if all the parents weren't doing it, it'd be so much easier*" (12); "*But the odd time that they would, my oldest son would be, he's like, that's not fair, they're allowed to play. I'm like that's just to keep us safe*" (13).

Other parents opted to provide their children with a simplified version of events, likening a COVID-19 infection to the flu: *"We'd put it in very simple terms, just that there was a flu, and the flu was... Basically, people were dying because of the flu so that's... And that's why we can't go to school. And that's why mommy and daddy couldn't go to work" (13).* This simplification was done in relation to participants' children relative capacity to understand the situation: *"Right? So, tell them a little bit, don't tell them the whole extent because they're only seven and five, but tell them enough that's going to make them realize that it's not a vacation, it's not all rosy, there is a problem in the world* (14). Participants with older children tended to be understanding of restrictions but were still negatively affected by them: "*The advantage I have is that she is old enough to read the news and see the media and connect the dots on her own. So, that helps some, but I mean, the ongoing statement in my house over the last four months is, it's*

not fair. She's not wrong" (2). Several participants mentioned that their children would model their level of concern off of the participants themselves, and that the participants had to subdue their overt reactions to the pandemic in order to alleviate stress in their children: *"To be honest, I think at the start he was very concerned about it. And I think that played a big part because of how I was reacting to it. And he could see that it was worrying me and stressing me… So, he was rather worried at the start. And now it's a little bit more relaxed"* (4). One participant in our sample relied on their Christian faith to explain the pandemic and its possible repercussions to their children: *"Faith is also uplifting and fulfilling in that way, but for me, it's this is what this is. We will do our best to avoid it. We may end up with it. If we do, we'll do our best to deal with it and if we die, well, then that's because that was supposed to happen. But we're not going to be foolish and run into it"* (7).

Parental coping

By far the most substantial theme to emerge from our analysis of participant transcripts is related to experiences with parental coping. The subthemes were restriction-related stress, work-life balance, schooling from home, parental distress, and coping strategies as acceptance, self-distraction, and social support and therapeutic resources.

Given the government mandates during the initial waves of the pandemic, and the subsequent social restrictions, participants often spoke of their restriction-related stress: *"So what do I think about this new normal? It's hard to say. At the beginning I found it very stressful because there were so many restrictions, especially when they did the 'no park play, don't touch this, don't touch that, don't go out'"* (1). When speaking of having to deal with the restrictions Participant 13 said: *"It's still a big change for us trying to juggle kids and grocery shopping, and who can go into stores and limits on family members and things like that. "*. The onset of the

pandemic resulted in medication dispensation restrictions where prescriptions were only filled one month at a time, adding to the stress of our participants: *"What happens when wave two hits, and I actually can't go to the pharmacy four months from now? These are things that…, it keeps me up at night. Because I used to be able to pick up three months at a time for her script, and often did"* (2). Participants also found it difficult to cope with the travel restrictions between provinces: *"The rules are different, and it's hard for a child with ADHD to understand provincial differences and things like that. Also, they used to see [Father] every day too, so that's really hard too"* (5) and out of the country: *"So that is emotionally and mentally exhausting for all of us. We miss our family, but it is what it is, and we understand it and the border will remain closed for as long as it remains closed. We just have to work through that"* (6).

Given school and childcare closures and work-from-home orders, all participants discussed work-life balance. Participants lamented having to balance their parenting schedules while simultaneously caring for their kids: "*I'm home with the kids pretty much all the time doing all that plus on top of that, I have to work at night and the evenings… So, when my husband comes home from work on like Mondays, he gets home between 12:00 and 1:00. And then I go to work at 1:00 and I work till like 10:00 or 11:00 at night with no breaks*" (12). Having children at home also made it much more difficult to address their workload: *"I'm in meetings almost all day, like I have a high position at the company I work in, so it's like I just can't take three hours to go play Pokémon cards with him, because I'm on calls all the time"* (14). Participants acknowledged that the difficulty that they experienced in managing their work-life balance was unsustainable: *"My biggest challenge as a mom, especially as a single mom, is this work-load is untenable for the long term. And a lot of my mom friends are at home on the couch all day or hanging out with their kids and they've been off work for months and months…"* (6).

A related aspect of managing participants' work-life balance involved coping with their children being <u>schooled from home</u>, and the teaching role parents were expected to adopt. A pervasive thought throughout the interviews was that "all of the teaching fell to me" meaning that parents felt that they were required to assume the role as teacher for their children: *"And it's not like they do a lot of schooling. They do like a half an hour a day. I mean, sorry with the teachers, the teachers kind of just do like a check-in, but all the teaching fell to me"* (12). Many felt inadequate in the role of teacher: *"Although I don't know if they learned anything. I don't know. I taught them the way I learned how to do math. So, they're screwed for next year. Yeah. Yeah. Like I cannot do fractions. I couldn't back then, I still can't"* (12). Having to teach their children during the pandemic, the participants often felt frustration at their situation: *"But there were definitely times when I was getting frustrated with doing the schoolwork with my youngest, the two girls were pretty good at basically doing their own. But yeah, I could. There were times when I was like, "Could somebody just step in and teach? Because I need to walk away"* (4). Participants felt alleviated when the summer started and the schools had ended, meaning that they weren't required to teach their children anymore: *"So I can get more work done, because I'm still working from home full time, and my wife is working full time, so I think it really has just kind of calmed down a little bit now the past week where there's not as many stressors that are demanding my attention"* (14). In addition, many of the participants' children received mental health support from their respective schools. With school closures, participants found it difficult to cope with a reduction in those resources: "*The public schools are closed, so the therapists are not there. Most of the private schools, I would say 99% of them, are closed. But then there's really nowhere else for these kids to go. A lot of them are getting the free services from the public school, they're not around, and then what do the parents do in these situations?*" (14).

Most participants felt that they were required to put their kids needs before their own: *"The second you have a baby, a child, you're going to sacrifice. There's nothing that you won't do. There is nothing… Oh yeah, you talk about sacrifice. I would do it all over again for my babies"* (5). Many of the participants had their own mental health conditions but focused on their children's treatment rather than their own: *"My concern all along has been, I'm all about getting Emma the help she needs, so I fall last on that list. Everybody's like, "Are you getting therapy?" I'm like, "In what time? When would that happen?"* (2). Although experiencing great deals of stress, participants felt that they needed to put on a strong front for their children in order to alleviate any concerns that their children may have had during the onset of the pandemic: *"We're going to get through this. And just don't try it, because if I start freaking out, then the kids are going to freak out and that's not good because then we're never going to get out of this perpetual cycle"* (14). Given this mindset of putting their children's needs first, participants were beginning to feel overwhelmed and mentally exhausted: *"Obviously we have mental health issues. We have autism. We have a lot on our plate, and we need a break. We could use a break. Definitely"* (13). A few months into the pandemic, some participants were starting to feel a sense of hopelessness: *"but in the beginning it was sort of like this is new and you're trying to figure it out… And now it's like, it's been going on, oh God, like three months. And I have to say for myself, like I'm exhausted. And you kind of lose hope because it feels like it's never going to end"* (12).

Participants also talked about their ways to cope with the restriction-related stress. In terms of acceptance, some parents believed that the pandemic was temporary, and by accepting the changes brought on by the situation that they'd have an easier time in coping: *"So it concerns me a bit but I'm hoping it's just temporary in the situation. So, I guess basically, all that to say I*

think I'm finding it okay, the day-to-day, but it's just accepting that things are not the same and not be hard on myself that somethings are going to go. And that's going to be okay" (8). Other participants used the mindset that since COVID-19 was out of their control, there was no use in letting it affect their mental health. For example, Participant 14 stated: *"I don't get stressed out about these things because I know knowledge is power, and really, at the end of the day it's not worth it to get stressed out over this. There's nothing you can do about it. If it was something that you caused, then okay, but literally there's nothing you can do about this. You can get stressed out as you want but at the end of the day it's still going to be here, and you're the only person who's going to suffer"* (14). Viewing pandemic life as somewhat of a threat, some participants chose to adapt by <u>learning survival skills</u>: *"And now I find myself thinking of things like I need to take self-defense classes, and I need to go and learn how to shoot a gun. And this is the sort of stuff that I find myself thinking about. And I get that it's a little bit extreme, but I think it's less extreme than it was a year ago"* (2). Other participants opted for <u>becoming more self-sufficient</u>: *"I'm gardening. I'm doing a lot of practical things. I'm doing a lot of what people would actually do in a pandemic. They start to fix things and garden. Think about getting creative with the materials you have"* (5).

In addition, many participants turned to a variety of <u>social supports, especially close friends</u>: *"I haven't seen her in person. It's just all texting, but yeah, I have very, very good friend support that I can rely on and there's another friend-circle, family friends that know I can always talk to"* (1). Similarly, Participant 4 mentioned: *"But I did start doing morning walks with a friend of mine, the six feet away, but we started going for walks and then we started running. So that was a big help just mentally for myself"*. Other participants saw <u>family as a form of social support</u>: *"But you do what you have to do and we talk, almost every day, with my mom and*

sisters and cousins and aunts and uncles and everybody else we can, just to try and stay connected. So, we do our best" (6).

Having their own diagnosed mental health conditions, many participants spoke of the therapeutic resources that they were currently engaged with: *"Yeah. We get a fair bit of help. Oh, I'm totally skipping that we get a fair bit of professional help. So long before COVID and continuing through COVID my son meets psychologists and so do I. Meet with the different psychologist in the same group and it's all about helping us parent him* (15). Participants mentioned that the skills they learned through their personal therapy helped cope with parenting during the pandemic: "Are we using the skills? I'm using some of the skills that I've learned through my own therapy, I guess… So I would say the only skill that I'm trying to use now is to not get upset… Like to not let it affect me, to just be calm" (8).

Time 2 Results

Participants were interviewed again, approximately one year after the initial interview. Reflections since Time 1, child's mental health, family functioning, parental coping, thoughts on the vaccine, and looking to the future in a COVID-19 era were the major themes identified during the second interview with participants. Each theme comprised of several subthemes (Refer to Table 3).

Table 3. A summary of themes and subthemes identified during Time 2 of the analysis.

Theme	Subtheme(s)
Reflections since Time 1	• Government communication • Confronting COVID-19 • Balancing physical vs mental health
Child's mental health	• Deterioration of mental health • Child' coping mechanisms, mostly avoiding
Family functioning	• Routines and adaptation • Co-parenting challenges
Parental coping	• In-person school and community support • Difficulty accessing hospital mental health resources • Social responsibility • Social support: friends, family, community
Thoughts on the vaccine	• Concerns for safety, long term effects • Vaccines as a means of returning to normalcy
Looking to the future in a COVID-19 era	• Mental health impacts and generational trauma • The "new normal" • General pessimism

Reflections since Time 1

As these interviews were performed approximately a year following the initial interview and the start of the pandemic, it was natural for participants to reflect on their experiences during this time. Discussions related to government communication, confronting COVID-19, and balancing physical vs. mental health are explored.

Several participants spoke of the provincial government's poor communication of pandemic-related information, and how it compared to one year prior: *"So I find that you're right. 100%, it's the miscommunication. It is the total miscommunication. And also, the total, I find right now, the lack of transparency right now. I think at the beginning they were giving daily conferences."* (14). Relatedly, participants were often confused as to what restrictions were in place at a given time during repeated lockdowns: *"We had just been allowed to start going to parks again, but the schools, they weren't allowed to move out of zones and their gym was closed. But if your child played hockey, that was open, or dance, right, that was open"* (12). They were frustrated at the rationale between allowing some activities and restricting others: *"So I was like, how can that not be politically motivated as to what you opened for your supporters? So let me get this straight, your kid can go to hockey, five times a week and power skating and he's nine or 10, and my kid can't go play in a park. So, I guess that's my whole thing with Corona is a lot of it are politically motivated decisions"* (12). At the federal government level, participants believed that there was political motivation in the distribution of the vaccine: *"I firmly believe that Trudeau is, at the federal level, giving Toronto and Montreal more vaccines because those are the swing provinces for the upcoming October election, right? Montreal has enough vaccines for everyone. Yet Ottawa, BC, and Alberta don't have enough"* (14).

Some participants spoke of their experiences and concerns in avoiding the COVID-19, given how prolific it was in the community: *"We remain in the background concerned about COVID. Everybody has, are we going to get it? Are we going to suffer long term effects? No one in my group's family got COVID, so that's good. We're all still doing the painful masking, distancing, not really seeing our"* (15). Several participants had chronic health conditions that made it especially important for their families to remain safe and virus-free: *"Stuff like that, I struggle with it, because the reality is stuff like that puts me in direct jeopardy, I am high risk now. I am considered high risk. Your bad behavior that spikes numbers means I could die"* (2). Single-parent participants worried about the consequences of them contracting the virus, and what that would mean for their families: *"I am immunocompromised. So, me getting COVID would be detrimental to our family as I am a single mom. I'm the only parent in this family. So, me getting COVID as an immunocompromised individual would be incredibly bad, incredibly bad"* (6). At the time of the second interview, only one participant mentioned a family member getting a COVID-19 infection: *"My daughter did get COVID in November. We don't know where she got it… Yeah, it was just out of the blue, she is one of the most cautious ones and paranoid in a way, so I don't know how she got it, where she got it"* (1).

Most participants discussed an element of balancing their physical health against their mental health needs. As the pandemic went on, participants questioned the utility of mandated restrictions when it came at the expense of their mental wellbeing: *"I think that everybody needs to do what works within the boundaries of their own family and mental health is health. If I'm going to keep myself physically safe at the expense of my mental health, then what's the point? Then it doesn't matter if I'm alive, if I'm not enjoying it"* (2). In light of many community member shirking restriction mandates, some participants questioned whether they should

continue following mandates themselves: *"You start to question the cost and benefit personally of whether or not the measures we've taken are positive for your certain situation, especially considering there so many people that are a lot more lax"* (12).

Child's mental health

As with the Time 1 analysis, participants spoke of their children's mental health when speaking of their parenting experiences during the COVID-19 pandemic. Main topics that arose within this theme included changes their children's coping, crises, and resources accessed.

In terms of mental health and coping, with the exception of two participants whose children's had improved (with caveats), participants' children's mental health had generally deteriorated since the first interview. Many of the children of the participants had deteriorating mental health, directly related to the pandemic restrictions: *"She has a terror of humans. She is terrified to be around someone else because she doesn't know if they have COVID or not. And she can't revert back to being able to see her friends because they don't want to be friends anymore because they think she's a prune. When all she's trying to do is follow the guidelines to keep people safe. Those guidelines have hurt my child"* (6). One participant had indicated that their daughter had developed a stress-related tick, while her son's mental health and coping was slowly improving: *"But yeah, my daughter's ticking in and my son is going upwards very slow, like a windy way, going up and down, but going slowly going upwards"* (1). Another participant indicated that their child was improving but attributed their progress to a newly-formed romantic relationship: *"Has matured a lot in the last, I'm going to say late fall. I'm going to guess for all the money we pour into psychological supports for him, I think it was the girlfriend"* (15). The vast majority of participants indicated that their children weren't coping well, nearly one year

into the pandemic: *"Mental health wise, she's not great. Having said that, there are verbal outbursts. She's angry and sad a lot, but she tows the line"* (2). Some participants indicated that their children's aggression had gotten worse: *"My eldest, who is autistic, has regressed even further in some ways and gotten better in others. His aggression has gotten worse"* (14). Participants who had previously mentioned that their children were improving or showing no signs of mental detriment indicated severe changes in their child's mental health status. For example, one participant's child started self-harming and expressing suicidal ideation: *"Anyways, so we took him to [Hospital Name] obviously and it took hours, hours to get him to calm down and stop trying to hurt himself. And this was in [Hospital Name] and stop trying to harm himself and keep talking about killing himself… But I mean, no one saw that coming"* (12). Another participant, who explained in Interview 1 that their child had never been in a better mental state, reported a new eating disorder: *"It's just, she's developed a severe eating disorder. She's lost 35% of her body weight. So, her way to maintain control over anything was to control her food intake"* (6), symptoms of dissociation: *"Then I started to notice that she was disassociating herself with the situation. So, she wasn't actually able at that point to come to reality, that that was a safe thing to do"* (6) and suicidal tendencies: *"... I have to look at that from a wide lens, but no, I mean, if I wasn't home, my child, she would have killed herself already"* (6).

Specific coping methods that their children used during Time 2 that were mentioned by the participants included separating themselves from sources of stress: *"he just wants to go to school, and he doesn't want to talk about it and we're just giving him a space, but he doesn't want to talk about anything. He doesn't want to talk to us and it's scary"* (12). For participants with older children, the main methods of coping included video games and substance use: *"Her*

go to, to handle her problems and feelings is to play video games and smoke pot, which is a pretty standard 16-year-old thing, let's face it. That's not entirely abnormal" (2).

Family functioning

In terms of family functioning, participants discussed their family routines and experiences in co-parenting one year into the pandemic.

In general participants reported a relatively easier time in maintaining a routine when compared to the start of the pandemic: *"We're into that regular routine where he is getting up at the time he has to get up, like 7, 7:30, and going to bed earlier. Because he was going to bed later at the time too. It was getting up later, going to bed later. So yeah, that hasn't really been an issue"* (8). Given the differences in the multiple lockdown phases experienced around the Time 2 interviews, participants had learned to adapt their routines accordingly: *"So, yeah. So I guess what happened with respect to the unpredictability is that I developed a pattern of what to do if it was lockdown, what my expectation were, versus, and then if I had to homeschool what my expectations were and then everything else would have to change in our lives. So cleaning went down, I had to accept that. And more TV went up but..."* (5).

As was the case during Time 1, participants had to balance their working days with their partners in order to care for their children. Participants who either themselves or their partners worked in a front-line healthcare role found it difficult to coordinate their schedules: *"So it's just... My husband and I, and then of course in January he would come home from work after being in the hospital and I would be at work until 10 or 11 and then every weekend I had to go in and there was just no help"* (12). Difficulties in family functioning were experienced by

participants in occupations other than healthcare as well: *"I deployed in September, so what I can tell you is that this has added to the challenges of managing COVID-19 for my family. Without me there, this has increased the demands on my husband with regards to juggling work schedule and home life, while managing to keep the kids safe from the virus…"* (13). Participants who were single parents were more likely to report difficulties in family functioning: *"So I'd study from 3:30 in the morning until 8:00 in the morning and then I have to homeschool them all day when it was lockdown. And the father wasn't even doing homeschooling with my son. And that created a lot of chaos and the school had to intervene"* (5). This disparity was exacerbated when the participant's child had severe mental health issues: *"I can't function in my job, which needs me desperately. I can't function for my other child because 100% has to be with my child in crisis. And that's due to the lack of capacity in a system that doesn't even understand itself. So it's very, very, frustrating"* (6).

Parental coping

Similar to the Time 1 analysis, the theme of parental coping was the most substantial in terms of participant experiences. Subthemes included their children going back to school, parenting around mental health concerns, social responsibility, and social support.

A major change since the Time 1 interviews was the fact that, for the most part, participants' children were back to in-person schooling. This alleviated much of the stress that parents were experiencing: *"…and that's just some of the things that you've mentioned in terms of routine and in terms of the mental health, our mental health, and the stress on us as parents. Him being in school in person has certainly helped that situation"* (8). Having children attend in-person schooling made it easier for them to receive community support: *"So, just that is much*

easier. There's been some breaks when there is cases of COVID at school, but at least in those times he's doing school from home, but school was pretty good in offering a good support" (3). There was widespread belief that in-person schooling was critical in supporting children's mental health: *"I'm so thrilled for them; it makes me so happy. It's been an enormously challenging year for her, and her mental health is not great, but the program is what keeps her... It's the one good thing, it's the silver lining"* (2) and that the physical health risks were outweighed by the mental health benefits: *"I really feel like children with ADHD and kids with special needs should be, I think that the benefits outweigh the risk in terms of having face to face in a pandemic. They need to go to school"* (5). Although happy that their children were back to school, participants had concerns regarding the physical restrictions in place that would hinder the socialization of their children: *"he was saying the other day that he can't wait till COVID is over because he wants to play tag, but not just in their little square at school. They want to play tag across the whole school yard. And I thought that was the saddest thing in the world because I hadn't thought of that"* (12). Some participants also had concerns about the disparity in what child was allowed to attend in-person schooling: "*And then what's even worse, in his class, there's five kids in his class. Three were allowed to go, two weren't. So, three were in class, two were on Zoom. So why is it fair for that kid to go, and I can't? How do you explain to him that this child is more special needs than you?"* (14).

Participants coping was affected by their ability to parent around their children's mental health conditions. Participants overwhelmingly spoke of their <u>difficulties in accessing mental health resources for their children</u>. This difficulty spanned not being able to attend physician visits because of COVI-19 related healthcare restrictions: *"And because of those guidelines with COVID only one parent can be in there with him. So, I couldn't leave my baby. So, my husband*

sat in the parking lot at [Hospital] *for six hours while I went in the room with him"* (12) and difficulties in actually meeting with a practitioner: *"And I can even see the psychiatrist who's dealing with us, she's canceled four or five appointments in a row with us. Not her fault at all. And I asked her what's going on? She goes, '*[Participant Name]*, you wouldn't even imagine the amount of people coming into psychiatry right now at* [Hospital]. *It's just unimaginable how many kids are coming in.'"* (14). Due to the overwhelming need for child mental health care during the pandemic, wait times for treatment were exceedingly long: *"I realize that if and when my kid is ready for therapy again, we're going to wait a fucking year for her to see somebody"* (2). Participants also spoke about their children's inability to adapt to telemedicine, furthering their difficulties in receiving mental health treatment: *"The downside of that is that she definitely qualifies for and needs long term therapy for any number of issues. But at this point, that Zoom is not working for her"* (2). Many participants say their difficulties in accessing mental health care for their children as a societal problem: *"But something's got to give, and it's got to give soon, we owe our children. I know my child's specifically, but our collective Ontario children don't have the luxury of time in mental health crises. And that's where we're stuck right now. We're stuck in the hurry up and wait"* (6)

Our participants placed heavy emphasis on the importance of <u>social responsibility</u>. This concept, and their views on its adherence within their community subsequently affected participants' ability to cope with the COVID-19 pandemic. When seeking activities to do as a family, most participants chose ones that allowed for social distancing: *"Oh no, I don't know about that, but anyways, I mean, but we're not perfect. Don't get me wrong. We went to Lansdowne to go tobogganing and there was a lot of people there, but we kept the kids to keep their distance"* (12). Even if participants found the mandates restrictive, they still adhered to

them in order to keep themselves and their community safe: *"We're all still doing the painful masking, distancing, not really seeing our friends"* (15). Acknowledging the interconnection between people within the community, some participants who worked closely with others chose to forgo some of their own personal activities: *"The gym did reopen but I am not going back because I run a home daycare, and we have bubbles that are much bigger than in regular families. So, I don't want to go out somewhere and then take a chance"* (1). Participants also expressed frustration toward those who skirted COVID-19 restrictions: *"I feel like until everyone is affected nothing's going to change because those people who don't follow the rules are never going to follow the rules and people who follow the rules, they're going to follow the rules and we're going to keep suffering for other people"* (12). A commonly held sentiment within our sample was that single parents: *"When people go out and behave badly, it's people like me, it's single moms that they're putting in harm's way"* (2) and families with members with mental health conditions were disproportionately affected by those who did not follow COVID-19 mandates: *"So as per public health orders, we maintained close contact to our household only. And that started affecting her in mid-January where just her friends were all still living their lives, even during a stay-at-home order"* (6).

Participants turned to <u>friends, family and community support</u> to cope with the stress. When speaking of friends, participants would often meet up in-person: *"we'll do a walk in the streets, we'll bring masks and six feet apart and get some exercise together which is often the way we meet up with them"* (15). Given social restrictions, some participants opted to use the phone while maintaining their normal social activities: *"And so, yeah. We can spend an hour or two hours with a phone, with a friend, and still talk the same, and then they can have their glass of wine, I'll have mine"* (9). Participants indicated that family members were trustworthy in

terms of adhering to social restrictions, and they felt comfortable socializing and receiving support from them: *"And my sister is eight minutes away, walking… Yeah. It does change things. It makes it so much easier. Even if it's just a little higher, just a little help with a little something. It's good to have people I trust around"* (3). Similar to findings in the Time 1 analysis, participants would enroll in community parenting groups that revolved around their children's mental health: *"We convinced him to tap into an adopted kids' online community… Adopt4Life, which is the basis of our parent support group. There's actually now a kids group as well and he's actually, as I say, he's gone three times or something now, it's monthly. He went back the second and third time rather than the court"* (15).

Thoughts on the vaccine

During the Time 2 interviews the COVID-19 vaccine had just been made available to frontline healthcare workers and high-risk individuals. As such, it was a relevant topic of conversation for our participants. Subthemes included thoughts on the vaccine's safety, and the potential for the vaccine to ensure that the COVID-19 pandemic comes to an end.

In terms of safety, some participants were hesitant to get the COVID-19 vaccine. This hesitancy stemmed from concerns participant perceptions on how quickly the vaccine was made available to the public: *"I don't feel it's safe a hundred percent. It's going way too fast. I've never seen any pharmaceuticals going so fast to administrate it to humans so fast"* (1). Participant hesitancy to get vaccinated against COVID-19 was also attributed to the unknown long-term consequences of the vaccine: *"I am still on the fence about the vaccine. History has shown that when we rush things, this does not fare well for future generations. I don't believe we know all the risks involved and long-term repercussions there may be. I do feel it is necessary however,*

but I don't feel comfortable with the fact that it was developed so quickly" (13). Other participants felt reassured that other populations would be receiving the vaccine first, acting as a pilot or trial against adverse effects: *"And I'm not opposed to vaccines at all. But because it's an entirely new vaccine and it's a new technology I'm in a way happy that the older people are going first. I know that sounds..."* (5). The one participant indicated that they did not think they would vaccinate, citing their good family health as the primary reason: *"I'm a bit, not fully reassured. But our health is good. We are not like, when I say we as family unit, like close family unit, kids and I are in good health"* (9).

The majority of participants believed the COVID-19 vaccine was safe, and that they had faith in our regulatory health care bodies: *"I am pro vaccine, 100%... Yeah, absolutely. I will be getting vaccinated as soon as it's offered. For me, presumably, that is phase two, because I am a chronic condition"* (2). Most participants believed that in addition to the COVID-19 vaccine being safe, they thought it necessary for society: *"Yes, I think it's safe, and yes, I think it's necessary and I can't wait for, hopefully, most people will get vaccinated"* (8). Several participants expressed their disdain for those that here hesitant of the vaccine, labelling them conspiracy theorists: *"If I was able to get it right now, I would take it. So at the end of the day, I still have to have faith in our medical professionals, that if they say it's safe, I will take it. I'm not the type of conspiracy theorist who goes around saying, "I'm not putting something into my arm"* (14).

For many participants the COVID-19 vaccine provided some hope in returning to a sense of normalcy. From a specific standpoint, participants acknowledged that widespread use of the vaccine would open up the school system, allowing for the socialization of their children: *"But that's also doing a disservice to our children because the longer it takes to vaccinate, the longer*

it takes to re-socialize, the deeper that our children will get into mental health crises. So, I'm all over the board on this one" (6). There was a general sense within our participants that vaccines, in addition to other public health initiatives, would allow for pandemic recovery: *"And it's going to be longer if people are people and can't deal with the ongoing frustration of masking and distancing. I guess that's my general thinking. I'm sort of putting my faith in the vaccines"* (15). Related to this, many participants acknowledged that the vaccine wouldn't be a guaranteed way to return to normal: *"Agreed. I think we still need to behave accordingly. I agree with that. I don't think the vaccine is an immediate, oh, life can resume now. I think people probably need to be careful about that, about it's easy to get an idea that everything's fine now"* (2). On the whole, most participants believed that vaccines were the primary way in which we would achieve global recovery from the COVID-19 pandemic*: "And I keep telling her that the vaccine, I explained polio, I explained smallpox vaccine save lives and vaccines allow us to give back to our lives"* (6). Interestingly, some participants that were hesitant to get the vaccine echoed this sentiment: *"I do want the country to globally to recover from it, and if the vaccine seems like the only tools at the moment that we have, then we should go for it"* (1).

Looking to the future in a COVID-19 era

The final theme explored within this analysis was that of participants' musings on what the future holds while living in a pandemic era. The subthemes identified included future mental health impacts and the possibility of <u>generational trauma</u>, <u>living in a "new normal"</u>, and <u>general pessimism</u> on the future.

Participants were <u>extremely concerned about the future mental health impacts</u> of the COVID-19 pandemic on both them and their children. There was a widely held belief within our

participant pool that the mental health impact on children was, and continues to be, underestimated: *"But I think the mental health impact on children is going to be greater than I ever anticipated as a lay person and as a parent who thought they were helping their kids cope with this really well, if that makes sense"* (12). There were worries that all children, regardless of mental health status, would be affected mentally by the COVID-19 pandemic: *"I think post-medical pandemic, there's going to be massive mental health pandemic. Those kids who were suffering before, but even more so those kids who weren't suffering before who will be suffering now… there definitely is going to be ripple effects for years and years to come on this"* (14). Relatedly, participants held the belief that the impact of the COVID-19 pandemic would cause generational trauma in the years to come: *"That is an irreversible damage that I can't see how we're going to get those generational kids in these crises out of. I hope that studies and things assist us to do that"* (6) with one participant drawing parallels from what she had seen elsewhere in the world: *"That's just too much for kids. I just can't believe that children have to go through this so young… And in Japan, again, those kids are called the lost generation or iceberg generation, that's what we call them. And I don't want to not have known my kids, but not have kids, a certain generation have to still be stuck labeled on it and carried on to the end of their life"* (1).

Participants described what they saw as the "new normal" when looking to the future in a COVID-19 era. This included expectations for economic downturns and job insecurity: *"The stuff that we see getting more expensive, I think that stuff's going to continue to get more expensive. I worry about what challenges that may lead to in the next little bit. Yeah, I worry about getting laid off"* (2). Unsurprisingly, participants harbored sincere hopes that there would be no more global, life-altering emergencies following this pandemic: *"Like once COVID is*

done, I really, really, really hope we get a couple of years of just a reprieve. My feeling is that I think we're into a new norm where these are going to be happening a lot more possibly often" (14). Acknowledging that the future would not return to a pre-pandemic way of life, some participants held some hope for the future: *"I feel like, okay, there may be some reason this year for some cautious optimism around returning to normal, or whatever the... I don't think normal is ever going to be normal again. But a return to something approaching that maybe"* (2).

Although some participants were hopeful for what the future entailed, most held pessimistic positions on the future, given the societal impacts of the pandemic thus far. Several participants mentioned that the positive health behaviors that society had adopted were going to lessen: *"I think the hygiene thing is not going to stay unfortunately. it depends on how good it is and how it wouldn't be a bad thing to keep it, but I don't think human nature is going to sustain that. Maybe a few people but I think the majority will go back"* (15). Many participants expressed frustration at the lack of people following the pandemic mandates (masking, social distancing), believing that COVID-19 will be with us for the foreseeable future: *"Anyways, I feel like until everyone is affected nothing's going to change because those people who don't follow the rules are never going to follow the rules and people who follow the rules, they're going to follow the rules and we're going to keep suffering for other people"* (12). Drawing upon historical trends, one participant believed that the lessons learned from the pandemic will be unfortunately forgotten: *"I think history has proven that we will forget in five years. So, after this, we're going to have nice talk, nice report about what went wrong, what could have been done better, what needs to be done for the future. And then in 15 years, it's going to be, those books going to be all dusty, and immediate needs are going to supersede the prevention, the readiness needs. And in a hundred years, we're going to have another one"* (9).

Discussion

The purpose of this research was to explore the lived experiences of parents of children with preexisting mental health conditions during the COVID-19 pandemic. Using a longitudinal exploratory thematic analysis approach, we found that the participants said almost nothing about the COVID-19 itself, which was rarely present in their experience. The first interview reflects the initial impact of pandemic-related restrictions on their children's mental health, their family functioning, their financial situation, and the struggles of parenting children with a mental health problem in this crisis, while facing their own challenges in coping with this stress. A year later, the children's mental health had generally deteriorated, but the families had adapted to the restrictions and sought ways to cope with the stress through the support of schools, friends, family, community, and a sense of social responsibility. Access to mental health care remains difficult. Vaccination appears to offer hope of a return to normalcy, but for some it raises questions about its safety, and there is widespread concern about the future. This research not only highlights what participants were experiencing during a given time in the pandemic but allows the opportunity to explore the changes in these experiences over time. This discussion will focus both on the major findings across and between interview times, situating the findings within the greater literature related to the pandemic. Namely, we will discuss the effects of the pandemic on financial insecurity, on the reduction of mental health resources, its impact on the health system as a whole, how participants viewed the physical effects of the virus in light of its mental health impacts, and how the COVID-19 vaccine could act as a source of hope.

The pandemic and financial insecurity

The issue of financial insecurity and outcomes from the pandemic are multi-faceted. In general, our participants worried about their finances. Unexpected events, such as the COVID-19 pandemic, can increase the frequency of financial concerns and financial stress (34, 35). According to our participants, the COVID-19 pandemic amplified the effects of their financial insecurity. In a financial report published by Deloitte (2022), the COVID-19 pandemic was found to be associated with changes in cash savings, with the majority of people seeing a reduction in their savings. Consistent with our findings, a minority of people experienced no changes in savings, or slight increases in savings (36, 37). Participants also reported having to pay out-of-pocket for mental healthcare due to the closure of community mental health resources during the pandemic.

An indication of deprivation and impoverishment, food insecurity is an important social determinant of health in Canada (37, 38). Participants that self-identified as impoverished were more likely to speak about their financial concerns in light of the economic effects of the pandemic. Consistent with relevant literature, these participants reported living with food insecurity and difficult living situations. As was the case with our population, those most vulnerable to food insecurity include people who lost employment, those who were job-insecure, and households with children (37). Additionally, food insecurity can create or exacerbate mental health conditions, with research suggesting significantly higher risks of anxiety and depression in households experiencing food insecurity (39-41). Food insecurity can also elicit feelings of shame, guilt, worry, and irritability, causing additional psychological problems(42, 43).

An interesting finding within our research was that those participants who did not experience financial insecurity almost universally felt empathy towards individuals who were

impacted financially. Growing evidence suggests that empathy is a positive psychological trait used to help cope with the challenges imposed by the COVID-19 pandemic (44). Links between empathic ability and positive stress responses during the pandemic have been made (45), with specific empathic abilities like acknowledging other points of view and feeling compassion or concerns with others being linked to better coping with pandemic restrictions (46-48).

Reduction of community mental health resources

Prior to the COVID-19 pandemic, there was a documented need for mental health services in Canada. In 2018, 17.8% of Canadians reporting needing help for their mental health in the previous year (49). Of these Canadians in need of help, the need for counselling services was the most likely to be unmet (49). Participants in this study. reported a significant reduction in access to community mental health services after the onset of the pandemic. In order to keep servicing community members, schools and community mental health centers had to adapt with the myriad of social restrictions put in place to curb the spread of the COVID-19. This exacerbated an already weakened facet of mental health system (50).

The COVID-19 pandemic has disrupted or halted critical mental health services in most countries around the world, with most of these disruptions effecting vulnerable people including children and adolescents (51). According to the Canadian Mental Health Association of Ontario (2023) most Ontario schools offer mental health and addictions counselling and special education services for students who have atypical behaviors, communication, intellect, physical abilities, or other exceptionalities (52). Many participants indicated that their children received had mental health resources within their respective schools' systems. Having schools closed during the pandemic effectively eliminated these resources for their children.

The healthcare system

During the pandemic, hospital-based outpatient services were closed and switched from in-person to virtual care using home-based videoconferencing and mental health care providers had to quickly improvise, adapt, and problem-solve. As verbal information and non-verbal communication (primary through visual cues) are the primary component of mental health care, most aspects of usual in-person care may be translated across a virtual medium. A growing body of evidence suggests that the use of virtual health care for psychotherapy and other mental services improves patient satisfaction, acceptance, improvement in symptomology, improvements in quality of life, and reduces the costs of care (53, 54). This marked growth during the COVID-19 pandemic of telemental health use has been observed worldwide, and it will likely remain in use for the foreseeable future (55). However, participants of this study spoke of the troubles their children experienced with home-based videoconferencing. Little has been published in terms of child and adolescent attitudes towards telemedicine (56, 57). However, there is a clear need to develop an hybrid model and ways to decide what is the best approach for an specific child/family (57).

Hospital wait times were increasing with many forms of care being delayed, cancelled, or otherwise effected by the pandemic (58). Nearly all of our participants spoke of these difficulties, citing drastic changes in their personal and/or child's health care. Furthermore, several participants mentioned having to use emergency medical services for their children, especially in times of crisis. The wait times to see specialists, even in times of crisis, were exceedingly long. The pandemic has caused an increase in overtime work (59), exhaustion, personal risk of infection, fear of transmission to family members and the loss of patients and colleagues (60) within the health workforce; contributing to unmet needs in the Canadian population.

Participants expressed concerns about the sustainability of healthcare during the pandemic, and the inability for the system to meet their needs or the needs of their children. Globally, Canadians highly trusted scientist and physicians during the pandemic while trust toward politicians and employers was waning (61). However, this specific group felt that their very high needs had not been met one year after the start of the pandemic.

Overall, the experience of restrictions during the pandemic has shown that for children with special mental health needs, community services, particularly in schools, play a crucial role in stabilizing their mental health. The disappearance of these services during school closures, combined with the primacy given to emergency departments in specialist services, to the detriment of outpatient services in hospital services, contributed to overloading emergency departments and increased the sense of lack of access to services, particularly for those who needed them most.

Balancing physical vs mental health

COVID-19 and its aftermath exposed families to stressful situations, with fear of contracting the disease, frustration, boredom, information overload, family financial loss and radical changes in daily activity patterns (62). When they did respect the restrictions in place, particularly for access to public spaces and social activities, participants lamented having to explain to their children why some families chose not to adhere to the same rules. For example, after seeing other children playing in parks (which were closed) or socializing with friends (which was prohibited under the social distancing mandates), participants found it difficult to manage their child's expectations. These difficulties were compounded by the often contradictory or difficult-to-understand, and hard-to-explain, messages from the health authorities. These

restrictions were also difficult to convey to children who suffered all the more from this isolation the longer it lasted, in addition to the difficulties associated with their own mental health problems.

Although most participants reiterated that they continued to follow public health guidelines, they began to question the usefulness of seclusion measures in light of the harm done to their children's mental health. These concerns are not unfounded. In the same population, we showed that parents who reported a greater impact of restrictive measures also reported more behavioural difficulties in their children, and that this relationship was mediated by parental mental health and parental stress. During previous pandemics (H1N1 in Arizona, California, Florida, New York, and Texas, USA, or SARS in Toronto, Canada), parents had already reported a negative effect of quarantine/isolation on their children, in particular post-traumatic stress symptoms (63). A meta-analysis confirmed that lockdown measures during the COVID-19 pandemic were associated with a deterioration in children's mental health (64). While the effects are small in the general population, they vary with the pre-existing mental health condition. For example, two months after the onset of the pandemic, almost 60% of the children diagnosed with Autism Spectrum Disorder showed a worsening of their symptoms or the emergence of new symptoms (65).

The question may legitimately be asked whether the restrictions should have applied equally to all, and whether the balance between mental and physical health should have taken into account the difficulty for the most vulnerable groups (such as children and young people already being treated for health problems) to cope effectively with this additional stress.

The vaccine as a source of hope

Public perceptions of COVID-19 vaccines are invaluable in achieving protective levels of herd immunity (66). An important finding within this research lay in how participants viewed the COVID-19 vaccine as a source of hope, allowing society the opportunity to return to a situation close to normalcy. Consistent with relevant literature (67, 68) a minority of participants expressed some reluctance related to receiving the vaccine, citing concerns about its rapid development and unknown long-term side effects. The majority of participants however viewed the upcoming vaccine in a positive light, believing in its safety and adopting a hopeful attitude towards its utility in society. With widespread administration of the COVID-19 vaccine being available to the participants shortly after our second interview, and claims on its impacts on society (see Dr. Anthony Fauci's widely publicized interview (69)), participants naturally held hope for the future. To these participants, the COVID-19 vaccine enabled them to engage a certain level of post traumatic growth. Post traumatic growth is a positive change in values and major life goals that is experienced as a result of the struggle with a highly challenging life circumstance (70, 71). Post traumatic growth can by influenced by positive psychological traits such as hope (72, 73). Hope in and of itself has been associated with a variety of mental health benefits such as coping with severe mental illness, suicidal ideation, depression, anxiety and trauma-related disorders (74-76). Remarkably, this hope did not prevent a certain pessimism among these parents, who believed that the lessons of the pandemic would soon be forgotten. Our hope is that they will be proved wrong.

Limitations

This study made use of semi-structured interviews of participants with children with pre-existing mental health conditions about their experiences during the COVID-19 pandemic. As such, the data gathered relies on the participants accounts of their own lived experiences. Given that some of the questions and concepts discussed can be construed as sensitive, it is possible that response bias could have affected answers to certain questions, despite efforts made to ensure that confidentiality would be maintained and that all answers are acceptable. In addition, the nature of qualitative research requires that investigators interpret participant responses. Herein, the research is dependent not only on the individual skills of the researchers, but their personal biases and idiosyncrasies. Several methods were made in order to reduce or eliminate potential bias when analyzing the results of this research.

Delimitations

In this qualitative study on the experiences of parents whose children received mental health care in Ontario during the COVID-19 pandemic, the research is delimited by its geographic focus on a specific pediatric tertiary care center, limiting its generalizability. Employing qualitative methods through longitudinal semi-structured interviews during key pandemic milestones, the study captures detailed personal narratives but excludes quantitative data that could provide broader statistical insights. Interviews were conducted via videoconferencing, telephone, and email due to pandemic restrictions, which could affect the depth of emotional expression compared to in-person interactions. Participants were selected from hospital records, focusing on parents engaged with the healthcare system and willing to participate, potentially omitting perspectives from less integrated or non-responsive families.

These methodological and participant selection decisions delineate the study’s scope and influence the applicability of its findings.

Acknowledgments: The authors would like to acknowledge Mina Salamatmanesh, Deepti Reddy, and Nick Barrowman who assisted with the data collection process.

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Appendix 1. Initial Interview Protocol

To be verbalized to participant by interviewer. As part of a study on the experience of parents of children treated in a mental health outpatient clinic during the first year of the COVID-19 pandemic I would like to ask you about your experiences. Please describe your experiences with as much detail as possible and to the best of your ability. There are no 'wrong' answers and no judgment will be placed. If a question makes you feel uncomfortable, please let me know and that question will be skipped. I would like to remind you that you are free to quit the study at any point during the interview with no repercussions from your doctors or the researchers. Would you like me to clarify anything before I begin?

1. How are finding things now that COVID-19 has become a part of daily life?
2. What are your top concerns regarding this COVID-19 pandemic and quarantine?
3. How are you getting information about the pandemic? How much time do you spend on getting the information?
    a. Prompt: if online, how reliable is the internet? How reliable is the information?
4. Are you leaving your home at all during this quarantine?
    a. Prompt: How do you spend your time away from home?
5. Do you have some contact and support from family members, neighbours, friends or associations? What kind of support is it?
6. What activities do you do yourself with your child, inside or outside of the home? Are there other adults at home doing activities with your child?
7. How have your children generally reacted to staying at home? What activities does your child do alone?
    a. What activities does your child with peers, in-person or online?
8. Have you established some routines at home? Can you describe them?
    a. How does your child comply with these routines?
9. What programs have you accessed through CHEO in the past? Are you using any skills from these programs to help you manage the current situation?
10. How much do you think your child worries about the disease? How did you explain the situation to them?
    a. How do you think she/he understands the situation?
11. How does your child cope with the stress of the changes from the pandemic?
12. Have you had any crises or incidents with your child during this pandemic?
    a. How did they resolve?
13. What are you doing personally to cope with the stress of the changes from the pandemic?
14. Do you feel as though you're managing with the day-to-day during this pandemic?
    a. Prompt: do you feel as though you could use some extra help?

Appendix 2. Follow-up Interview Protocol

To be spoken verbatim to participants:

Good morning/afternoon [Participant name]. I hope that you and your family are doing well and staying safe during this additional, but hopefully short lockdown. I would like to thank you once again for taking the time to respond to this follow-up on the previous interview we had a few months ago.

The purpose of this second interview is to perform a member check and to give you the opportunity to further expand on your initial responses. The member check entails a summary of the previous interview including major themes, allowing you to verify if our interpretation of your responses were accurate. You will also be given the opportunity to let us know if your thoughts and feelings toward COVID-19 have changed and whether you had any thoughts on the vaccine.

Your participation in this interview is completely voluntary and you can choose to not answer any of the questions that may come up. The interview should take about 20 minutes in total.

- - -

During our last interview we spoke at length about [summary of the interview]. *In general, we found that* [list of major themes] *entailed the major themes within that interview. Would you agree with this summary and identification of themes? Please feel free to expand on anything that we had talked about.*

- - -

Thank you. To finish off the interview, I would like to ask you a few short questions on your thoughts and experiences related to COVID-19 since we last spoke:

1) First, how have your thoughts and feelings towards COVID-19 changed?
2) Second, what thoughts, if any, do you have regarding the vaccine?
    a. Prompt: do you think its safe? Necessary?
3) Finally, do you think that there are any positives that have come from the COVID-19 crisis?
    a. Prompt: Are there some behaviours that you will carry forward or not go back to once the pandemic is over?

- - -

That concludes our follow up interview. Thank you once again for participating and all of us at CHEO wish you and your family well in 2021.

Chapter 8: General Discussion

This thesis explores several public health interventions related to shared care in the field of child and adolescent mental health. This is done through an analysis of barriers and facilitators to service implementation at the national or systemic level, where mental health resources are relatively scarce; at the institutional level, where new interventions help promote individualized care and a shared decision-making approach; and at the individual level, where health policies in times of health crisis hinder access to mental health services. This concluding chapter will present the major findings of each article represented within this dissertation and highlight their importance in relation to health equity and their contribution to the field of population health.

Summary of Major Findings

Article 1 assessed the challenges and facilitators in adapting and implementing a Canadian ADHD Shared Care Pathways program in mental health settings in Beijing, China. Three main themes that arose from the study were (1) social-level barriers and facilitators faced by healthcare users and healthcare providers; (2) structural-level barriers and facilitators related to both internal and external organizational environments; and (3) barriers and facilitators specifically related to the program. This study highlights the need for an adaptive approach to the proper identification and allocation of resources in order to foster proper implementation of a shared mental health care system in Beijing.

While the first article assessed the challenges and facilitators in implementing a Canadian ADHD Shared Care Pathways program in mental health settings in Beijing, Article 2 focused on the same issue but in pediatric settings in Shanghai, China. Focusing on a different healthcare setting between the two cities revealed several different aspects relevant to the implementation of a shared-care approach to ADHD treatment. Results of the analysis suggested that in order to

successfully implement a shared-care approach within this context, efforts must be made to improve the training of health care providers, culturally adapt the program to Chinese contexts, increase public awareness about ADHD to decrease stigma, and clearly define the role and expectations of healthcare providers.

Article 3 explored the difficulties in adopting an MTA-style medication titration protocol for the treatment of ADHD within clinical settings. This article addresses the feasibility of the CHEO approach and suggested modernized improvements to clinical stimulant titration strategies. These included automating the randomization and delivery of medication, offering questionnaires online, reducing the number of clinicians evaluating the results of the trials, automatic generation of clinical reports, and the use of Shared Decision-Making when making a decision about medication dosing.

Article 4 examined the uptake of MTA-style stimulant titration strategies using the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework. This article highlighted that although efforts to use such strategies have been ongoing since the original MTA study in 1996, widespread adoption had not taken place. Results of the qualitative analysis indicate that the technology has advanced since the initial study, making it easier for patients and their families to engage in the titration process. That being said, adherence to the process still remains low for both practitioners and patients. Conflicts related to the decision-making process may also hinder a parent's choice to medicate their child with stimulants. Concurrently, organizational obstacles related to the distinction between research and clinical practice inhibit widespread uptake. Across the systems level, limitations related to the distribution of prescription stimulants make it difficult for some organizations to implement titration approaches in clinical practice. Finally, the use of health champions within an

organization was identified as a driving factor in the continued use of clinical stimulant titration for the treatment of child and adolescent ADHD.

Article 5 compared three different decision-making strategies in the determination of an optimal dose of stimulant medication for the treatment of child and adolescent ADHD following a titration trial. Qualitative analysis of participants who had undergone the titration process at CHEO was also used to provide insight and context into their experiences. Results suggest that the agreement between expert and Shared Decision Making (SDM) groups was poor, while agreement between the SDM group and a computer-based algorithm (Ranked Choice Vote – RCV) group was fair. Agreement between the expert and the RCV decision making varied between poor and fair. As such, the question of which is the best dosage has no unambiguous answer, so we have to ask which is best for whom. By including parental experiences regarding their involvement in an SDM approach, we established that parents appreciate the support of the titration team and the interaction with treating physicians in the context of a drug trial, especially when decisional conflicts are high. The SDM approach to stimulant titration enables parents to make sound, informed, and regret-free decisions which allow them to adjust to daily life.

Using a qualitative longitudinal design, Article 6 explored the lived experiences of parents of children with preexisting mental health conditions during the COVID-19 pandemic. This study highlighted the impacts that the pandemic had on financial insecurity, the reduction of mental health resources, the impact on the health system as a whole, the balance between physical and mental health in light of social restrictions, and the role of the COVID-19 vaccine as a source of hope.

Revisiting Population Health and Health Equity

This dissertation explored a variety of situations related to the organization or disorganization of child and youth mental health care at differing levels of the healthcare system. The summation of this work emphasizes collaboration in mental health between specialists and generalists, and between families and mental health professionals. This is accomplished by the use of population health interventions related to the reorganization of mental health care, the advocacy of shared decision-making approaches when treating mental health conditions, and the examination of the unintended consequences of reducing mental health access and care (in favour of other inpatient procedures) during a worldwide emergency.

Shared mental health care and health equity are both critical aspects related to improving the overall wellbeing and mental health of a population. Health inequities are the systematic differences in the opportunities that certain groups have to achieve optimal health, leading to unfair but avoidable disparities in overall health outcomes. As was discussed in the introduction of this dissertation, the root causes of health inequity are commonly stratified into either structural inequities, or inequities related to the social determinants of health (1).

Structural Inequities

Structural inequities are the personal, interpersonal, institutional, and systemic drivers that disadvantage one social group compared to other groups within a society (2). Structural inequities often encompass policies or laws, governance, and culture that ultimately lead to inequitable experiences within the social determinants of health. As was seen in several of the articles presented within this dissertation, barriers to the implementation of mental health

interventions and mental health treatment were present at the policy, legislative and governance level.

Mental Health Training

Participants in Articles 1 and 2 cited a lack of training of mental healthcare providers as a barrier to the implementation a shared care approach to ADHD treatment in China. This was attributed to overwork or individual hospital training policies that hindered the proper recruitment and training of mental health professionals. Training mental health professionals and addressing health equity are two critical aspects of improving mental healthcare access and outcomes. The impact of poor training for mental health professionals exacerbates the issue of health equity. As many of the essential skills that a practitioner would otherwise cultivate may be lacking given an improper educational foundation. For example, mental health practitioners are expected to be culturally competent, understanding the diverse backgrounds, beliefs, and values of patients with this skill being associated with a reduction in racial or ethnic disparities in health and healthcare (5). Undertraining in these areas can result in lessened provider knowledge, attitudes, skills, and a reduction in patient satisfaction (6). Article 2 further emphasized the importance of adapting healthcare interventions to cultural and social contexts. Okoniewski et al's (2022) systematic review of culturally sensitive interventions in pediatric primary care settings (7) found that culturally sensitive health interventions were associated with a reduction in tobacco use (8), a decrease in child behaviour problems and a reduction in parenting stress (9), and an increase in childhood immunization rates (10). Although it can be argued that the overwhelming majority of patients seen in relatively large cities like Shanghai or Beijing do not constitute non-Han minorities and therefore the cultural competence of a practitioner may not be as important in such settings, the Canadian shared-care approach to ADHD treatment emphasizes

such characteristics in medical interventions. The main factor in cultural inadequacy is obviously that diagnostic tools have been developed in a radically different cultural context, and that a concept like ADHD has emerged in very different societies. One can argue that a problem like ADHD can be found in all societies and cultures, because it is the result of a neurodevelopmental disorder that is largely genetic in origin. But we should not overlook the fact that its development, expression, and treatment are dependent on societal and cultural context. Given the differences between China and other Western countries in terms of ethnolinguistic language and culture, systems of health, and resources available to treat mental health disorders, cultural adaptation is warranted when implementing new interventions (11, 12). Failure to take this into account contributes to inequalities in mental health, insofar as the approach to diagnosis and care will only be adapted to a minority who have largely adopted a Western lifestyle. But for everyone else, both assessment and treatment can become inadequate, creating misunderstanding and mistrust, and ultimately contributing to the failure to help and care for those who need it. Community engagement also suffers when a healthcare practitioner is undertrained. Rapidly evolving healthcare landscapes that place ever-increasing demands on physicians has been attributed to a reduction in the public role and community advocacy of physicians (13-15).

Health Policies

The potential for misuse, dependence and abuse of stimulants is high (16). As such, the regulation and control of stimulant medication through laws and policies is often done as a means of harm reduction (17). As an example, following the US opioid crisis, which came as a result of the influence of pharmaceutical companies, inadequate regulation, and overprescribing of opiate pain medication by medical professionals (18), an agreement was reached between

major pharmaceutical distributors and the attorneys general of 46 states. This agreement resulted in stricter limits on the supply of drugs to individual pharmacies and the close monitoring of their distribution activities. The agreement also imposed limits and additional oversight on other controlled and potentially addictive substances, such as those used to treat ADHD. To this day, Americans still have difficulty in obtaining medication to treat their ADHD.

Although such actions are meant to increase public safety, they can sometimes impede the proper use of medication for therapeutic purposes. Policy and legislative barriers can have a profound impact on mental health equity by either exacerbating or alleviating existing disparities in access to mental healthcare and the quality of mental health services. Additional structural inequities were highlighted in Articles 1 and 4, where practitioners discussed difficulties in dispensing stimulant medication for the treatment of ADHD. The participants in Article 1 were often barred from prescribing many stimulants due to legislative and/or organizational policy barriers. Comparatively, participants in Article 4 cited insurance pricing schemes, availability of placebo medication, and distinctions between clinical and research practices as the main reasons for the difficulties in prescribing medication for ADHD titration trials. In each case, participants believed that systemic barriers impeded their ability to properly treat their patients' mental health conditions. Given the complexity of the healthcare system, patients can sometimes experience harm from the healthcare process itself (19, 20). For example, although general drug use for the treatment of health disorders has raised in the last decades, literature has found that under-prescription of medication ranges between 22% and 70% depending on the study setting (21-23). Specifically with regards to ADHD, there exists controversy as to whether the condition is over, or under diagnosed and, by extension, whether it is over or under treated with medication (24). Indeed, individuals with untreated ADHD may be faced with serious negative outcomes. For

example, Ruiz-Goikoetxea et al (2018) found a significantly higher risk of injuries in children and adolescents with ADHD compared to children without the condition (25). Similarly, the risk of automobile-related accidents and mortality is higher in those with ADHD than for those without (26, 27). In sum, it is evident that discussions related to the availability of stimulant medication must centre on balancing public health risks (such as risk of addiction) with the risk of non-treatment of ADHD by limiting access to medication.

Technical Innovation

Achieving mental health equity through modernized health interventions involves leveraging innovative approaches, technologies, and strategies to address disparities in mental healthcare access, quality, and outcomes. Articles 1-5 heavily emphasized the importance of collaborative care and patient-centered approaches to healthcare interventions that focus on shared decision-making. Herein, modernized mental health interventions and decision-making strategies were shown to aid in the equitable access and treatment of ADHD in children and adolescents. As was covered within the mentioned articles, interventions that use digital formats have shown improvements in patient access and treatment related to mental health disorders (28, 29). Similarly, shared decision-making strategies hold promise for improving health equity by better engaging patients within their own health care (30). Highlighted by Article 5, shared-decision making approaches are preferred by parents, especially when decisional conflicts are high. Shared decision-making is a patient-centered approach that empowers individuals to actively participate in their mental health care decisions by promoting autonomy (31), cultural sensitivity (32), and reducing disparities (33).

Inequities Related to the Social Determinants of Health

While structural inequities are produced on the basis of the identities of certain vulnerable groups, the social determinants of health are the vectors by which health inequities are derived. Individual-level behavioural factors (example: physical activity, healthy eating, alcohol or drug use) are traditionally cited as the factors that determine health outcomes (1). However, in reality the factors that contribute to individual and population health are much more nuanced. Population health researchers often refer to nine social determinants: Education, income and wealth, employment, health systems and services, housing, the physical environment, transportation, the social environment, and public safety that affect the overall health of populations. Pertinent to this dissertation, education, income, health systems, physical and social environments, and public safety contributed to issues related to the health and health equity of the participants sampled.

Health Literacy

Articles 1 and 2 discussed the implementation of a shared care approach to the treatment of child and Adolescent ADHD in China. Participants indicated that there was a general lack of public awareness about ADHD, and that contributed to a lack of education about the condition and a general distrust of general practitioners within the country. China has undergone rapid changes to their healthcare landscape within the last several decades. As such, the fragmentation of organized medicine and a general public perception of self-interest within the medical profession can lead to mistrust in healthcare providers (13, 34). Combined with relatively low health literacy (35), issues related to mental health access and care persist. Health literacy is an important social determinant of health, and predictor of a person’s health outcomes. Low health

literacy has been linked with risky behaviours, higher rates of hospital readmission, poorer general health management, and undue financial strain on the health system (36). Increasing health literacy, and awareness of mental health services and treatment has been associated with a reduction in stigma and barriers to care (37). A lack of education and general distrust of GPs within China also can be associated with barriers to healthcare access as limited education has been linked with lower socioeconomic status and therefore financial means to pay for treatment (38). Education provides individuals with the tools to seek out and understand health information independently. Patients with lower educational attainment can be limited in their access to information (39) and may struggle to advocate for their health (40), which can affect the quality of care they receive. Policies and practices that aid in reducing education disparities are an important step health disparities (37, 41).

Health system

Healthcare is arguably the most well-known determinant of health (42). While Articles 1 and 2 discussed the barriers and facilitators related to implementing a novel intervention within a budding mental health system, Article 6 illustrated the outcomes and consequences of an established mental health system challenged by a global pandemic. Chiefly, Article 6 demonstrated the impact that a reduction of mental health resources and access had on a sample of parents with children with pre-existing mental health conditions. The COVID-19 pandemic resulted in a significant impact on mental health equity, exacerbating existing disparities and highlighting the importance of addressing mental health as a public health priority. Those with pre-existing mental health conditions were disproportionately affected by the stress, health anxiety, economic instability, and social isolation brought on by COVID-19 related sickness and

policies (43). Measures used to limit the spread of the disease disrupted access to mental health services during pandemic lockdowns. Participants in Article 6 repeatedly lamented their inability to balance their child's mental health needs with the isolation measures imposed by government restrictions. The social environment, or the interconnections between individuals, families, and communities, is often measured in relation to health outcomes (1). Social connections between families and communities are protective against negative physical and mental health outcomes (44). Consistent with relevant literature, the public safety restrictions enforced on our participants precipitated feelings of fear, anger, anxiety, boredom, loneliness, and guilt about not being available for family members (45). In essence, the social and physical environments in which the participants found themselves exacerbated pre-existing mental health issues within their children. Community mental health resources on which these participants often relied were either reduced or eliminated. Income inequality was illustrated within this work. During the pandemic, parents with the financial means were able to continue paying for private therapies, while others were forced to cope with reduced access to mental health care for their children. Access to stable financial resources from income or accumulated wealth affects health by acting as a safety net against financial threats (such as was presented by the pandemic) while also facilitating access to health-promoting resources (46). One of the most salient and real-world conclusions that we can make regarding the results of this work lies in the healthcare management approach during the pandemic. In an effort to mitigate the impact on the health system, it can be argued that a focus on acute patient care was made to the exclusion of other "less visible" ailments. The participants of this research felt that their kids were left behind when compared to patients who accessed medical services for physical ailments. When it came to the

mental health system in general, the decision to focus resources on acute, inpatient health was not made collaboratively between healthcare provider and patient.

Linking Shared Mental Health Care and Health Equity

Each of the articles presented within this dissertation utilizes or discusses the role of shared care in mental health. In their own respect, these articles explore the impact of shared care models on relevant systems of care. A system of care in the context of mental health care refers to a coordinated and comprehensive approach to delivering services and support to individuals with mental health needs (47). In this respect, a system of care uses a set of guiding principles and core values to promote collaboration among various service providers, agencies, and organizations to ensure that people receive the right care, at the right time, in the right place (48). Particularly salient to this are the findings from Articles 1 & 2, where the proposed intervention specifically seeks to establish proper and efficient collaboration between appropriate levels of care and increase health equity, and Article 6 which shows the breakdown of a system of care during an emergency, providing examples of a loss in health system equity. The remaining articles discuss the importance and utility of using a shared decision making approach between patient/family and care provider in aiding in the proper dosing of stimulant medication for the treatment of ADHD, increasing patient confidence and trust in the health system. Shared or collaborative mental health care models such as the ones covered in this dissertation relate to health equity in a myriad of ways. For patients, such approaches enhance the quality or mental health care received, improve access to psychiatric consultations, and improve access to psychiatric services when needed. For physicians, shared care approaches can result in better training and skills when managing mental health problems, increased effectiveness when acting as consultants and supports for families, and mutual support when managing complex or

comorbid mental health conditions. Finally, with regards to the health care system, benefits include greater and more efficient use of available resources, the increased provision of mental health care for vulnerable patients, the elimination of barriers that prevent integrated mental health care, and increased opportunities for collaboration on projects aimed at prevention or early detection of mental health problems (49). Taken as a whole, shared care approaches such as those discussed in this dissertation contribute to increased mental health equity by aiming to reduce disparities in mental health care and outcomes that can lead to significant social and health injustices. The integration of shared mental health care in standards of practice requires multifaceted approaches that involve policy changes, improved access to care, awareness and education, and ongoing efforts to address the social determinants that influence mental health disparities.

Overall Conclusion

As was seen within this dissertation, policies at all levels, from those that effect individuals to overall systems, are the main drivers of structural inequities. These structural inequities cover the personal, organizational, and systemic drivers that affect the fair distribution of health opportunities and outcomes. By extension, the social determinants of health are the vessel by which structural inequities result in health inequities (1). Throughout this dissertation I have explored the relationship between health equity, population health approaches, and shared mental health in a modern healthcare landscape. The relationship between health equity and shared mental health care is not only pivotal in transforming our healthcare systems, but also holds a great deal of promise for individual patients. By prioritizing health equity through shared mental health care, we can reduce systemic barriers and ensure that mental health services are

accessible, culturally sensitive, and responsive to the diverse needs of populations. Shared mental health care interventions, characterized by collaborative approaches and integrated care models, become the conduit through which these principles can be realized. Through my dissertation's inductive exploration of health system needs, individual patient needs, and the development of novel shared decision-making interventions, we have the opportunity to lay the groundwork for a healthcare landscape where every individual, regardless of their background or circumstances, has equitable access to mental health care. Such work not only reshapes our healthcare systems but also has the potential to profoundly impact the lives of patients across the globe, fostering a future where mental health equity is not an aspiration but instead an attainable reality.

Contributions to Knowledge

Study 1

This study contributes significantly to the understanding of how sociocultural and systemic differences influence the adaptation and implementation of a Canadian-developed ADHD Shared Care Pathways program in a Chinese setting. By identifying specific socio-cultural barriers such as mistrust in primary healthcare and structural challenges like inadequate specialist availability, this research outlines critical factors that need addressing for successful international healthcare program transfers. Additionally, it emphasizes the necessity of local capacity building through GP training and community education to enhance program uptake and sustainability in diverse settings.

Study 2

The study expands knowledge on the challenges of implementing a mental health care model across different cultural and administrative frameworks within China. It delves into the varying perceptions of ADHD treatment between Canadian and Chinese healthcare systems, highlighting the need for culturally adapted approaches that respect local values and educational methods. This work provides a foundation for developing international collaborative programs in pediatric mental healthcare, addressing both universal and culturally specific barriers.

Study 3

This study significantly advances ADHD treatment methodologies by adapting the Multimodal Treatment Study of Children with ADHD (MTA) protocol for stimulant titration at the Children's Hospital of Eastern Ontario (CHEO), incorporating a patient-centered Shared Decision-Making (SDM) model. This approach enhances treatment adherence and satisfaction by better aligning medical decisions with individual patient preferences. Additionally, the introduction of the Strength-based ADHD Monitoring (SAM) system, developed from the SWAN scale, shifts focus from deficits to strengths in tracking treatment effects, promoting a more positive therapeutic outlook. By automating the titration process and utilizing user-friendly online tools, this protocol simplifies the clinical implementation of ADHD treatment, bridging the gap between research and practice. These innovations could markedly improve the standard of care for ADHD, emphasizing patient empowerment and tailored medication management.

Study 4

The study reviews the adoption of MTA-style titration in clinical practice, offering a critical examination of why, despite proven efficacy, this method has not seen widespread clinical adoption. It highlights technological, systemic, and practical barriers to implementation

and underscores the potential of shared decision-making processes in enhancing patient-clinician dynamics and treatment outcomes. This adds to the literature on clinical practice innovations and their challenges in real-world settings.

Study 5

By comparing three different decision-making models in the dosing of ADHD medication, this study enriches the discourse on patient-centered care approaches. It challenges traditional expert-driven models by demonstrating that shared decision-making can lead to outcomes that are more aligned with patient and family preferences, thus contributing to improved satisfaction and potentially better adherence to treatment.

Study 6

This longitudinal study provides crucial insights into the impacts of the COVID-19 pandemic on children with preexisting mental health conditions and their families. By documenting the evolving challenges and adaptations over the course of the pandemic, the research contributes to a deeper understanding of the interplay between public health crises and mental health, emphasizing the need for resilient and flexible mental health service provisions in times of crisis.

Each study offers distinct and valuable contributions to various facets of healthcare and treatment approaches, enhancing the body of knowledge in fields ranging from international health program implementation to individualized patient care in mental health.

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General Appendix 1 – Ethics Certifications

Studies 1 & 2

CHEO

CHEO Research Ethics Board Approval - Delegated Review

Principal Investigator: Dr. Philippe Robaey

REB Protocol No: 18/75X

Romeo File No: 20180327

Project Title: CHEOREB# 18/75X Shared Care for ADHD in Children and Youth: Merging the Canadian and Chinese Experiences ADHD.

Primary Affiliation: Mental Health\Psychiatry

Protocol Status: Active

Approval Date*: July 09, 2018

Approval Expiry Date:** June 15, 2019

Documents Reviewed & Approved:

Document Name	Comments	Version Date
Protocol	Protocol	4/10/2017
Other Document	Cover letter	5/21/2018

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed within the delegated stream, which is reserved for projects that involve no more than minimal risk to human participants.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

1. **The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.**
2. **The investigator is responsible for complying with all applicable guidelines and regulations regarding the ethical conduct of research with humans, as applicable to the research project.**
3. **Approval for studies that include an investigational device(s) is contingent upon the investigator securing an Investigational Testing Authorization notice from Health Canada.**
4. **Investigators must obtain annual renewal approval prior to the expiration date stated above.**
5. **The investigator must not implement any deviation from, or changes to, the protocol, consents or assents without the approval of the REB except where necessary to eliminate hazard to the research subject, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff). As soon as possible, however, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted to the Board for review and approval.**
6. **The investigator must, prior to use, obtain approval from the Board for changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.**
7. **Investigators must obtain approval from the Board of French version(s) of the consent/assent form(s), unless a waiver has been granted. An interpreter should be offered to participants as required or at the request of the participant throughout the course of research.**
8. **The investigator must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).**
9. **Investigators must notify the REB of any changes in study status (closed to accrual, temporary, premature or permanent).**
10. **Investigators must submit a study closure event form at the conclusion of the study.**

Should you have any questions or concerns, please do not hesitate to contact the Research Ethics Board Office at 613-737-7600 ext. 3350 or 2128.

Regards,

Richard Carpentier, PhD
Chair, Research Ethics Board
Président, Comité d'éthique de la recherche

* The final approval date for initial delegated study applications approved with or without modifications will be the date the REB has determined that the conditions of approval have been satisfied.

** The expiry date of REB approval for initial study applications will be as follows:

- If the date of approval was **on or before** the 15th of the month, the expiry date will be the 15th of the month prior to the date of review and approval by the Chair and/or delegate *in the following year,*
- If the date of review and approval was **after** the 15th of the month, the expiry date will be the 15th of the month in which the date of review and approval by the REB *in the following year.*

uOttawa

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

CERTIFICAT D'APPROBATION ÉTHIQUE | CERTIFICATE OF ETHICS APPROVAL

Numéro du dossier / Ethics File Number	H-02-23-9011
Titre du projet / Project Title	Implementing a Canadian shared-care ADHD program in Beijing: Barriers and facilitators to consider prior to start-up.
Type de projet / Project Type	Thèse de doctorat / Doctoral thesis
Statut du projet / Project Status	Approuvé / Approved
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	06/03/2023
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	15/05/2023

Équipe de recherche / Research Team

Chercheur / Researcher	Affiliation	Role
Alexander MAISONNEUVE	École interdisciplinaire des sciences de la santé / Interdisciplinary School of Health Sciences	Chercheur Principal / Principal Investigator
Philippe ROBAEY	Département de psychiatrie / Department of Psychiatry	Superviseur / Supervisor

Conditions spéciales ou commentaires / Special conditions or comments

CHEO REB Protocol No: 18/75X

Study 3
CHEO

Children's Hospital of Eastern Ontario
Centre hospitalier pour enfants de l'est de l'Ontario

CHEO RESEARCH ETHICS BOARD APPROVAL – DELEGATED REVIEW

Principal Investigator:	Dr. Philippe Robaey
Proposal Number:	#12/84X
Protocol Title:	Data Analysis of the Titration Process
Department or PSU:	Mental Health PSU
Approval date:	September 17, 2012
Valid Until:	September 15, 2013
Documents reviewed and approved:	• Protocol version (Appendix One), submitted July 2012 • Consent version (Appendix Two), submitted July 2012 • Strength-based ADHD Monitoring (SAM) questionnaire Parent Titration version (English and French) • Strength-based ADHD Monitoring (SAM) questionnaire Teacher Titration version (English and French)

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed under the delegated review stream, which is reserved for projects that involve no more than minimal risk to human subjects.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

- The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.
- The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff).
- The investigator must, prior to use, submit to the Board changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.
- For all other research studies, investigators must promptly report to the REB all unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches).
- Investigators must submit an annual renewal report to the REB 30 days prior to the expiration date stated above.
- Investigators must submit a final report at the conclusion of the study.
- Investigators must provide the Board with French versions of the consent form, unless a waiver has been granted.

For complete procedures relating to REB procedures, please refer to the REB website at http://www.cheori.org/en/researchet t Sharon Haig, Ethics Coordinator at shaig@cheo.on.ca or 613-737-7600 ext. 2128.

Regards,

Dr. Carole Gentile, C.Psych.
Chair, Research Ethics Board

CG/smeh 17/09/2012
c.c. CHEO RI Administration
Jennifer Munroe, Research Coordinator

401 Smyth Road, Ottawa, ON K1H 8L1, Canada
Tel: (613) 737-7600 www.cheo.on.ca

401, chemin Smyth, Ottawa (ON) K1H 8L1, Canada
Tél.: (613) 737-7600 www.cheo.on.ca

Making a difference in the lives of children and youth

Faire une différence dans la vie des enfants et des adolescents

Study 4
CHEO

CHEO REB
Letter of Approval

REB Protocol No: 21/79X

ROMEO File No: 20210242

Principal Investigator: Dr. Philippe Robaey

Protocol Title: CHEOREB# 21/79X - The uptake of innovation and adoption of new approaches to ADHD treatment: An examination of the Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study and its offshoots

Protocol Status: Active

Approval Date: June 14, 2021

Approval Expiry Date: May 15, 2022

The CHEO REB has conducted a delegated review and determined that the conditions of approval have been satisfied for the above-named study. Approval is valid for the period indicated above. This research study is to be conducted by the investigator noted above. Annual renewals or study closures must be completed before the expiry date noted above.

REB members involved in the study do not participate in the review, deliberations, or decision.

Documents Approved:

Document Name	Comments	Version Date
Recruitment Materials	Appendix II - Recruitment Phone Call_Clean	2021/06/11
Recruitment Materials	Appendix I - Recruitment Email_Clean	2021/06/11
Consent Form	Appendix III - Consent Form_Clean	2021/06/11
Questionnaire/Survey	Interview Protocol - 2021-05-28	2021/05/28
Protocol	Protocol_Clean - 2021-06-14	2021/06/14

Any modifications made to the study must be reviewed and approved by the REB prior to implementation, except when necessary to eliminate immediate danger or hazard(s) to study participants or when the change(s) involves administrative aspects of the study. Investigators must promptly alert the REB of any changes that increase the risk to participants or affect the safety of participants, all unanticipated and harmful events that occur, and new information that significantly impact the conduct of the study.

The CHEO REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS 2); the International Conference on Harmonization Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; and Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The CHEO REB is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research

Protection

Please do not hesitate to contact the Research Ethics Office if you have any

Best wishes for the successful conduct of your

Cécile Bensimon, MA, PhD

Chair, Research Ethics Board

uOttawa

Université d'Ottawa | University of Ottawa

Bureau d'éthique et d'intégrité de la recherche | Office of Research Ethics and Integrity

Lettre d'approbation administrative | Letter of administrative approval

Numéro de dossier / Ethics File Number	H-02-23-8920
Titre du projet / Project Title	The uptake of innovation and adoption of new approaches to ADHD treatment: An examination of the Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study and its offshoots
Type de projet / Project Type	Thèse de doctorat / Doctoral thesis
CÉR primaire / Primary REB	CHEO / CHEO
Statut du projet / Project Status	Approuvé / Approved
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	06/03/2023
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	15/05/2023

Équipe de recherche / Research Team

Chercheur / Researcher	Affiliation	Role
Alexander MAISONNEUVE	École interdisciplinaire des sciences de la santé / Interdisciplinary School of Health Sciences	Chercheur Principal / Principal Investigator
Philippe ROBAEY	Département de psychiatrie / Department of Psychiatry	Superviseur / Supervisor

Conditions spéciales ou commentaires / Special conditions or comments:

CHEO REB Protocol No: 21/79X

Study 5
CHEO

CHEO Research Ethics Board Approval - Delegated Review

REB Protocol No: 21/30X

ROMEO File No: 20210115

Principal Investigator: Dr. Philippe Robaey

Project Title: CHEOREB# 21/30X - Comparison of recommendations between different decision-making strategies in stimulant titration

Protocol Status: Active

Approval Date*: April 20, 2021
Approval Expiry Date: April 15, 2022**

Documents Reviewed & Approved:

Document Name	Comments	Version Date
Questionnaire/Survey	Participant Information Form	2021/04/01
Questionnaire/Survey	Titration Trial Rating Form	2021/04/01
Consent Form	Consent Form	2021/04/01
Protocol	Protocol	2021/04/15
Recruitment Materials	Recruitment Email	2021/04/01

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed within the delegated stream, which is reserved for projects that involve no more than minimal risk to human participants.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

1. **The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.**
2. **The investigator is responsible for complying with all applicable guidelines and regulations regarding the ethical conduct of research with humans, as applicable to the research project.**
3. **Investigators must obtain annual renewal approval prior to the expiry date stated above.**
4. **The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB except where necessary to eliminate an immediate hazard to the research subject, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff). As soon as possible, however, the implemented deviation or change, the reasons for it and, if appropriate, the proposed protocol amendment(s) should be submitted to the Board for review and approval.**
5. **The investigator must, prior to use, obtain approval from the Board for changes to the study documentation, e.g., changes to the informed consent letters, recruitment materials.**
6. **Investigators must obtain approval from the Board of French version(s) of the consent/assent form(s), unless a waiver has been granted. An interpreter should be offered to participants as required or at the request of the participant throughout the course of research.**
7. **For clinical drug or device trials, investigators must promptly report to the REB all adverse events that are both serious and unexpected (SAEs) or unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches.**
8. **For SAE reports on clinical drug trials, the investigator must also comply with the hospital-wide Policy regarding, Procedures for Considering Medical Error in the Differential Diagnosis of Severe Adverse Events (SAE) Associated with the Drugs Administered in a Clinical Trial.**
9. **Investigators must promptly report to the REB any new information regarding the safety of research subjects (e.g., changes to the product monograph or investigator's brochure of drug trials). Where available, any reports produced by the Data Safety Monitoring Board should also be promptly submitted to the REB for acknowledgement.**
10. **Investigators must notify the REB of any change in study status (closed to accrual, temporary, premature or permanent).**
11. **Investigators must submit a study closure event form at the conclusion of the study.**

The CHEO REB operates in compliance with, and is constituted in accordance with, the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonization Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; and Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The

CHEO REB is registered with the U.S. Department of Health and Human Services (DHHS) Office for Human Research Protection (OHRP).

If you have any questions, pertaining to this letter, please contact the Research Ethics Board Office.

Regards,

Cécile Bensimon, MA, PhD
Chair, Research Ethics Board
Président, Comité d'éthique de la recherche

* The final approval date for initial delegated study applications approved with or without modifications will be the date the REB has determined that the conditions of approval have been satisfied.

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- If the date of approval was **on or before** the 15th of the month, the expiry date will be the 15th of the month prior to the date of review and approval by the Chair and/or delegate *in the following year*;
- If the date of review and approval was **after** the 15th of the month, the expiry date will be the 15th of the month in which the date of review and approval by the REB *in the following year*.

uOttawa

Université d'Ottawa — University of Ottawa

Bureau d'éthique et d'intégrité de la recherche — Office of Research Ethics and Integrity

Lettre d'approbation administrative | Letter of administrative approval

Numéro de dossier / Ethics File Number	H-02-23-9010
Titre du projet / Project Title	Comparison of recommendations between different decision-making strategies in stimulant titration for the treatment of ADHD.
Type de projet / Project Type	Thèse de doctorat / Doctoral thesis
CÉR primaire / Primary REB	CHEO / CHEO
Statut du projet / Project Status	Approuvé / Approved
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	06/03/2023
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	15/04/2023

Équipe de recherche / Research Team

Chercheur / Researcher	**Affiliation**	**Role**
Alexander MAISONNEUVE	École interdisciplinaire des sciences de la santé / Interdisciplinary School of Health Sciences	Chercheur Principal / Principal Investigator
Philippe ROBAEY	Département de psychiatrie / Department of Psychiatry	Superviseur / Supervisor

Conditions spéciales ou commentaires / Special conditions or comments:

CHEO REB Protocol No: 21/30X

Study 6
CHEO

CHEO Research Ethics Board
Approval - Delegated Review

REB Protocol No: 20/36X

ROMEO File No: 20200173

Principal Investigator: Dr. Philippe Robaey

Project Title: CHEOREB# 20/36X - Parenting Children with Mental Health Problems During the COVID-19 Outbreak

Protocol Status: Active

Approval Date*: May 07, 2020
Approval Expiry Date: April 15, 2021**

Documents Approved:

Document Name	Comments	Version Date
Questionnaire/Survey	Interview Guide version 1, April 6, 2020.	2020/04/06
Case Report Form	Case report form	2020/04/29
Questionnaire/Survey	Parental Environment Questionnaire-Parent-Child Conflict	2020/04/28
Questionnaire/Survey	General questionnaire with date	2020/04/28
Questionnaire/Survey	COVID-19 FI questionnaire with date	2020/04/28
Other Document	General educational intervention email	2020/04/29
Other Document	ADDENDUM: Incidental Findings Management Plan v3	2020/04/23
Other Document	Letter to REB forParenting Children with Mental Health Problems During the COVID-19 Outbreak, version 1, April 7, 2020	2020/04/07
Protocol	Protocol Version 3 & 4/24/2020	2020/04/24
Investigator Response	Itemized response letter signed by the local principal investigator	2020/04/29
Consent Form	Consent Form - Intervention study	2020/04/29
Consent Form	Consent form-qualitative study	2020/04/28
Consent Form	Consent form - Quantitative study	2020/04/28

This is to notify you that the Children's Hospital of Eastern Ontario Research Ethics Board has granted approval to the above named research study on the date noted above. Your project was reviewed within the delegated stream, which is reserved for projects that involve no more than minimal risk to human participants.

Final approval is granted for the above noted study, with the understanding that the investigator agrees to comply with the following requirements:

1. **The investigator must conduct the study in compliance with the protocol and any additional conditions set out by the Board.**
2. **The investigator is responsible for complying with all applicable guidelines and regulations regarding the ethical conduct of research with humans, as applicable to the research project.**
3. **Investigators must obtain annual renewal approval prior to the expiry date stated above.**
4. **The investigator must not implement any deviation from, or changes to, the protocol without the approval of the REB except where necessary to eliminate an immediate hazard to the research subject, or when the change involves only logistical or administrative aspects of the study (e.g., change of telephone number or research staff). As soon as possible, however, the implemented deviation or change, the reasons for it and, if appropriate, the proposed protocol amendment(s) should be submitted to the Board for review and approval.**
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6. **Investigators must obtain approval from the Board of French version(s) of the consent/assent form(s), unless a waiver has been granted. An interpreter should be offered to participants as required or at the request of the participant throughout the course of research.**
7. **For clinical drug or device trials, investigators must promptly report to the REB all adverse events that are both serious and unexpected (SAEs) or unexpected and untoward occurrences (including the loss or theft of study data and other such privacy breaches.**
8. **For SAE reports on clinical drug trials, the investigator must also comply with the hospital-wide Policy regarding, Procedures for Considering Medical Error in the Differential Diagnosis of Severe Adverse Events (SAE) Associated with the Drugs Administered in a Clinical**

Trial.

9. **Investigators must promptly report to the REB any new information regarding the safety of research subjects (e.g., changes to the product monograph or investigator's brochure of drug trials). Where available, any reports produced by the Data Safety Monitoring Board should also be promptly submitted to the REB for acknowledgement.**
10. **Investigators must notify the REB of any change in study status (closed to accrual, temporary, premature or permanent).**
11. **Investigators must submit a study closure event form at the conclusion of the study.**

If you have any questions, pertaining to this letter, please contact the Research Ethics Board Office at (613) 737-7600, ext. 3350 or 2128.

Regards,

Richard Carpentier, PhD

Chair, Research Ethics Board

Président, Comité d'éthique de la recherche

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** The expiry date of REB approval for initial study applications will be as follows:

- If the date of approval was **on or before** the 15th of the month, the expiry date will be the 15th of the month prior to the date of review and approval by the Chair and/or delegate *in the following year;*
- If the date of review and approval was **after** the 15th of the month, the expiry date will be the 15th of the month in which the date of review and approval by the REB *in the following year.*

uOttawa

Université d'Ottawa — Bureau d'éthique et d'intégrité de la recherche

University of Ottawa — Office of Research Ethics and Integrity

Lettre d'approbation administrative | Letter of administrative approval

Numéro de dossier / Ethics File Number	H-02-23-5707
Titre du projet / Project Title	A Qualitative Study of the Experience of Parents of Children Treated in a Mental Health Outpatient Clinic During the First Year of the COVID-19 Pandemic.
Type de projet / Project Type	Thèse de doctorat / Doctoral thesis
CÉR primaire / Primary REB	CHEO / CHEO
Statut du projet / Project Status	Approuvé / Approved
Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)	06/03/2023
Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)	17/04/2023

Équipe de recherche / Research Team

Chercheur / Researcher	**Affiliation**	**Role**
Alexander MAISONNEUVE	École interdisciplinaire des sciences de la santé / Interdisciplinary School of Health Sciences	Chercheur Principal / Principal Investigator
Philippe ROBAEY	Département de psychiatrie / Department of Psychiatry	Superviseur / Supervisor

Conditions spéciales ou commentaires / Special conditions or comments:

CHEO REB Protocol No: 20/36X

General Appendix 2 – Consent Documents

Studies 1 & 2

Not Applicable – Consent documents created and distributed internally by Peking University Sixth Hospital: (2020)伦审第(18)号

Study 3

Not Applicable – Archival Data

Study 4

Informed Consent Form for Participation in a Research Study

Study Title: Comparison of recommendations between different decision-making strategies in stimulant titration.

Sponsor's Study ID: Not Applicable

Principal Investigators:

Dr. Philippe Robaey,
Professor of Psychiatry, University of Ottawa
Children's Hospital of Eastern Ontario
401 Smyth Road
Ottawa, ON K1H 8L1
Tel: [REDACTED]
Fax: [REDACTED]

Alexander Maisonneuve
Interdisciplinary School of Health Sciences, University of Ottawa
Thompson Hall - THN 136
25 University Private
Ottawa, K1N 7K4
Tel: [REDACTED]

Sponsor/Funder(s): Not Applicable

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you have been identified as the Principal Investigator in a publication related to the treatment of ADHD using an approach similar to The Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study (MTA Study). This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this research project is to examine the differing approaches to ADHD stimulant titration treatment as they relate to the original MTA study. In addition, we seek to compare and contrast protocols used, measurement plans, management plans, and decision processes. The final goal of this project is to examine the participants' approach to ADHD treatment using the NASSS framework as a means to situate the adoption of this approach as it relates to the healthcare setting. Herein, your approach to ADHD treatment will be examined based on the condition (ADHD), the technology used, the value proposition offered by the approach, the adopter system in place (professional staff, patient, and lay caregivers available), the organization(s) involved, the wider (institutional and societal) context, and the interaction and mutual adaptation between these domains over time.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that approximately 8 participants will take part in this study.

The interview associated with this study should take approximately one hour to complete, and the results should be known in about 1-1.5 years.

WHAT WILL HAPPEN DURING THIS STUDY?

After the MTA titration trial design was published it received criticism for its complexity and lack of uptake. That being said, there have been several efforts to implement this type of approach to ADHD in a clinical setting. Given this, a concerted effort will be made to identify literature in which an MTA (or similar) approach to ADHD treatment has been used, and to determine whether this approach is still being used in a given clinical setting.

The principal investigators of these studies (the participants) will be recruited and questions based on their continued use of their chosen MTA approach in their clinical setting, and questions based on the NASSS framework will be asked. Comparisons and contrasts between the differing approaches, as well as inferences related to adoption, abandonment, scalability, spread, and sustainability of their approach will be made.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

Upon receipt of the consent forms, semi-structured interviews will be scheduled with participants over Zoom. Participants will be required to answer open-ended questions based on their continued use of their chosen MTA approach in their clinical setting, and questions based on the NASSS framework.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The interview will take approximately one hour to complete.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Participants can choose to end their participation in this research (called withdrawal) at any time without having to provide a reason. If participants choose to withdraw from the study, they are encouraged to contact the research team.

Participants may withdraw their permission to use information that was collected about them for this study at any time by letting the research team know. However, this would also mean that they withdraw from the study. If participants decide to leave the study, they can ask that the information that was collected about them not be used for the study. Let the research team know if you choose this.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no risks associated with participation in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no benefits to you for taking part in this study.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this Centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Children's Hospital of Eastern Ontario research ethics board who oversees the ethical conduct of this study.
- The Children's Hospital of Eastern Ontario – Ottawa Children's Treatment Centre and the Research Institute, to oversee the conduct of the research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your disclose identifiers e.g., name, initials, participant code, age, sex, place of clinical practice and email address.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Data collected for this research may be used in future related research projects that are either an extension of the original project or in the same general area of research (secondary use of data). Any personal identifying information will be removed from the data and cannot be linked back to you. Researchers outside of this specific study may request access to the data for new research purposes. You will not be asked to provide additional informed consent for the use of your de-identified data for future research.

The use of virtual platforms, like any internet communication or storage and retention of information, involve privacy risks around access and disclosure of information, however, there are safeguards in place to reduce these risks, (e.g., account registration, meeting passwords, disposal of records or devices on which information is stored).

Study records will be retained for 7 years after the study closure.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researchers, or involved institutions for compensation, nor does this form relieve the researchers, or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

Alexander Maisonneuve	[REDACTED]
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

The CHEO Research Ethics Board 613-737-7600 x 3272

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form.
- I allow access to personal health information as explained in this consent form.
- I agree that my data collected for this research may be used in future research. Your data could be used in future studies examining expert dosage recommendations following stimulant titration.

  ☐ Please check this box if you do not wish to have your study data included in future research.
- I understand that the reconciliation sessions that may arise will be conducted using Zoom. which has privacy risks associated with its use.
- I agree that my participation in the Zoom meetings will be recorded for research purposes.
- I do not give up any of my legal rights by signing this consent form.
- I agree to take part in this study.

______________________	______________________	______________________
Signature of Participant	PRINTED NAME	Date

______________________	______________________	______________________
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

____________________________	____________________	_________________
PRINT NAME of Interpreter	Signature	Date

____

Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

____________________________	____________________	_________________
PRINT NAME of witness	Signature	Date

____

Relationship to Participant

Study 5

Informed Consent Form for Participation in a Research Study

Study Title: A comparison of recommended stimulant medication dosage between different decision-making strategies in stimulant titration.

Sponsor's Study ID: Not Applicable

Principal Investigators:

Dr. Philippe Robaey,
Professor of Psychiatry, University of Ottawa
Children's Hospital of Eastern Ontario
401 Smyth Road
Ottawa, ON K1H 8L1
Tel: [REDACTED]
Fax: [REDACTED]

Alexander Maisonneuve
Interdisciplinary School of Health Sciences, University of Ottawa
Thompson Hall - THN 136
25 University Private
Ottawa, K1N 7K4
Tel: [REDACTED]

Sponsor/Funder(s): Not Applicable

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you have been identified as the Principal Investigator in a publication related to the treatment of ADHD using an approach similar to The Multimodal Treatment of Attention Deficit Hyperactivity Disorder Study (MTA Study). This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this research project is to examine the differing approaches to ADHD stimulant titration treatment as they relate to the original MTA study. In addition, we seek to compare and contrast protocols used, measurement plans, management plans, and decision processes. The final goal of this project is to examine the participants' approach to ADHD treatment using the NASSS framework as a means to situate the adoption of this approach as it relates to the healthcare setting. Herein, the your approach to ADHD treatment will be examined based on the condition (ADHD), the technology used, the value proposition offered by the approach, the adopter system in place (professional staff, patient, and lay caregivers available), the organization(s) involved, the wider (institutional and societal) context, and the interaction and mutual adaptation between these domains over time.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that approximately 8 participants will take part in this study.

The interview associated with this study should take approximately one hour to complete, and the results should be known in about 1-1.5 years. Participants will be informed of the major findings/conclusions of this study via an end of study letter.

WHAT WILL HAPPEN DURING THIS STUDY?

After the MTA titration trial design was published it received criticism for its complexity and lack of uptake. That being said, there have been several efforts to implement this type of approach to ADHD in a clinical setting. Given this, a concerted effort will be made to identify literature in which an MTA (or similar) approach to ADHD treatment has been used, and to determine whether this approach is still being used in a given clinical setting.

The principal investigators of these studies (the participants) will be recruited and questions based on their continued use of their chosen MTA approach in their clinical setting, and questions based on the NASSS framework will be asked. Comparisons and contrasts between the differing approaches, as well as inferences related to adoption, abandonment, scalability, spread, and sustainability of their approach will be made.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

Upon receipt of the consent forms, semi-structured interviews will be scheduled with participants over Zoom. Participants will be required to answer open-ended questions based on their continued use of their chosen MTA approach in their clinical setting, and questions based on the NASSS framework.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The interview will take approximately one hour to complete.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

Participants can choose to end their participation in this research (called withdrawal) at any time without having to provide a reason. If participants choose to withdraw from the study, they are encouraged to contact the research team.

Participants may withdraw their permission to use information that was collected about them for this study at any time by letting the research team know. However, this would also mean that they withdraw from the study. If participants decide to leave the study, they can ask that the information that was collected about them not be used for the study. Let the research team know if you choose this.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no risks associated with participation in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no benefits to you for taking part in this study.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this Centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Children's Hospital of Eastern Ontario research ethics board who oversees the ethical conduct of this study.
- The Children's Hospital of Eastern Ontario – Ottawa Children's Treatment Centre and the Research Institute, to oversee the conduct of the research at this location.

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, email, or other information that may directly identify you will not be used. The records received by these organizations may contain your disclose identifiers e.g., name, initials, participant code, age, sex, place of clinical practice and email address.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

Data collected for this research may be used in future related research projects that are either an extension of the original project or in the same general area of research (secondary use of data). Any personal identifying information will be removed from the data and cannot be linked back to you. Researchers outside of this specific study may request access to the data for new research purposes. You will not be asked to provide additional informed consent for the use of your de-identified data for future research.

The use of virtual platforms, like any internet communication or storage and retention of information, involve privacy risks around access and disclosure of information, however, there are safeguards in place to reduce these risks, (e.g., account registration, meeting passwords, disposal of records or devices on which information is stored).

Study records will be retained for 7 years after the study closure.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the research team.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researchers, or involved institutions for compensation, nor does this form relieve the researchers, or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution. That person is:

Alexander Maisonneuve	[REDACTED]
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

The CHEO Research Ethics Board 613-737-7600 x 3272

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form.
- I allow access to personal health information as explained in this consent form.
- I agree that my data collected for this research may be used in future research. Your data could be used in future studies examining expert dosage recommendations following stimulant titration.

  ☐ Please check this box if you do not wish to have your study data included in future research.
- I understand that the reconciliation sessions that may arise will be conducted using Zoom. which has privacy risks associated with its use.
- I agree that my participation in the Zoom meetings will be recorded for research purposes.
- I do not give up any of my legal rights by signing this consent form.
- I agree to take part in this study.

______________________	______________________	______________________
Signature of Participant	PRINTED NAME	Date

______________________	______________________	______________________
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

______________________________	______________________	__________________
PRINT NAME of Interpreter	Signature	Date

____
Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

______________________________	______________________	__________________
PRINT NAME of witness	Signature	Date

____
Relationship to Participant

Study 6

Informed Consent Form for Participation in a Research Study

Study Title: Parenting Children with Mental Health Problems during the COVID-19 Outbreak - Quantitative Study

Principal Investigator: Dr. Philippe Robaey
Children's Hospital of Eastern Ontario
Phone: [REDACTED]

INTRODUCTION

You are being invited to participate in a research study. You are invited to participate in this study because you are the parent or caregiver of a child who is being seen for mental health at the Children's Hospital of Eastern Ontario (CHEO). This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that your child receives outside the study.

IS THERE A CONFLICT OF INTEREST?

There are no conflicts of interest to declare related to this study.

WHY IS THIS STUDY BEING DONE?

In this study, we primarily try to understand the factors that impact parenting and the mental health of parents and their children with a mental health problem during the COVID 19 pandemic. The second objective is to select the families who will be offered to participate in a one-week online parenting intervention.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 1000 participants will take part in this survey study.

This study should take 2 to 3 months to complete depending on the duration of the confinement, and the

results should be known in about 6 months to 1 year after the end of the study.

WHAT WILL HAPPEN DURING THIS STUDY?

You will be asked to complete an online questionnaire. The purpose of the questionnaire is to understand the different problems that can affect parenting and mental health of parents and their children with a mental health problem during the COVID 19 pandemic. The questionnaire will take about 80 minutes to complete.

We will ask you questions about your health status, financial situation, work, housing, family status, especially with regard to the COVID-19 situation. Then we will ask questions about your fears and the impact of the COVID-19 situation, your level of parenting stress, the functioning of your family, your type of parenting and your sense of competence in parenting, the ways you are coping with stress, and your mental health (specifically anxiety and depression), as well as the mental health of your child. We will also collect some information in the electronic health record of your child about his/her mental health (diagnoses/problems and level of functioning).

The information you provide is for research purposes but some information will be used to select the parents who will be offered to participate in the one-week online parenting training. Some of the questions are personal. You can choose not to answer questions if you wish. By responding to some questions you may experience some emotional distress. You may stop responding and return to the questionnaire later.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this phase of the study will last for 80 minutes.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the research team.

You may withdraw your permission to use information that was collected about you for this study at any time by letting the research team know. However, this would also mean that you withdraw from the study.

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the research team know if you choose this.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation in the study may be stopped early, and without your consent, for reasons such as:

- The research team decides to stop the study.
- The CHEO research ethics board withdraws permission for this study to continue.

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no medical risks to you from participating in this study. But a potential discomfort may include you feeling uncomfortable with some of the questions being asked if they are sensitive or evocative. If you feel uncomfortable, you may choose not to answer a question.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may not receive direct benefit from participating in this phase of the study. We hope the information

learned from this study will help other parents/caregivers of youth with mental health in the future. The results from this questionnaire will be used to select the parents who will be offered to participate in the one-week online parenting training.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Children's Hospital of Eastern Ontario – Ottawa Children's Treatment Centre and the Research Institute, to oversee the conduct of the research at this location
- The CHEO research ethics board who oversees the ethical conduct of this study

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published/ presented to the scientific community at meetings and in journals.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about the new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please let the research team know.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights against the researcher, nor does this form relieve the researcher or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to the research team, or the person who is in charge of the study at this institution.

That person is: Dr. Phillippe Robaey Telephone: [REDACTED]

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

The CHEO Research Ethics Board 613-737-7600 x 3272

Future Phases of this Research Study:

Some participants in this study may be eligible to take part in:

1. An in-depth interview (20 parents/caregivers);
2. An intensive short-tem (one week) online intervention to support parenting (20 parents will participate every week)

Please indicate by selecting from the options below if you would be interested in participating in the previously mentioned future phases of the study. Even if you indicate you are interested in participating now, you can change your mind later. You would be asked to complete a separate consent form(s) for this other phases of the study.

☐ Yes, I am interested in taking part in the **in-depth interview** phase of the study

☐ Yes, I am interested in taking part in the **online intervention** phase of the study

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to my child's medical records and related personal health information as explained in this consent form,
- I do not give up any of my legal rights by signing this consent form,
- I agree to take part in this study.

______________________	______________________	______________________
Signature of Participant	PRINTED NAME	Date
______________________	______________________	______________________
Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

General Appendix 3 – Knowledge Dissemination Activities

Conference Proceedings

- **9th World Congress on ADHD (Poster) –** Maisonneuve AR., Carreiro, E., Alharti, S., Boafo, A., O'Kelly, F., Barrowman, N., Bijelic, V., & Robaey, P. *Choosing the best dose in stimulant titration for ADHD treatment: agreement between a shared decision process with parents, expert decision and an instant-runoff voting algorithm (IRV).* May 18-21, 2023; Amsterdam, Netherlands.
- **9th World Congress on ADHD (Poster) –** Maisonneuve, AR., Carreiro, E., & Robaey, P. *Offshoots of from the titration process of the Multimodal Treatment of Attention Deficit Hyperactivity Disorder (MTA) study: a qualitative inquiry into the reasons for failure/success in clinical uptake.* May 18-21, 2023; Amsterdam, Netherlands.
- **AACAP/CACAP 2022 Annual Meeting (Poster)** – Maisonneuve, AR., Carreiro, E., Samson, A., Erbach, M., Watanbe, L., Logan, D., & Robaey, P. *A Qualitative Study of the Changes in the Stress and Coping Experience of Parents of Children Treated in a Mental Health Outpatient Clinic During the First Year of the COVID-19 Pandemic.* October 19-21, 2022; Toronto, Canada.
- **AACAP/CACAP 2022 Annual Meeting (Poster)-** Robaey, P., Erbach, M., Watanabe, L., Carreiro, E., Logan, D., & Maisonneuve, AR. *Parental Stress as a Mediator of the Impact of the COVID-19 Crisis on Parent-Child Conflicts in Families with a Child in Treatment at a Mental Health Outpatient Clinic.* October 19-21, 2022; Toronto, Canada.
- **AACAP/CACAP 2022 Annual Meeting (Poster) -** Bahraini, S., Maisonneuve, AR., Liu, Y., Samson, A., Ying, Q., Li, F., Yang, L., & Robaey P. *Barriers and Facilitators to Implementing a Canadian Shared-Care ADHD Program in a Behavioral Pediatric*

Setting in Shanghai: A Consolidated Framework for an Implementation Research Approach. October 19-21, 2022; Toronto, Canada.

- **8th World Congress on ADHD (Poster) –** Bahraini, S., Maisonneuve, AR., Liu, Y., Samson, A., Yang, L., Li, F., & Robaey, P. *Barriers and facilitators to Implementing a Canadian shared-care ADHD program in Beijing.* May 6-9; Virtual presentation.
- **CANNEXUS (Presenter) –** Samson, A., & Maisonneuve, AR. *Non-Cognitive Factors as Predictors of the College Adaptation Process*. January 27-29, 2020; Ottawa, Canada.
- **7th World Congress on ADHD (Poster) –** Fletcher, E., Samson, A., Maisonneuve, AR., & Robaey, P. *Parents' Adaptive Tasks and Coping Skills with Stimulant Titration and Shared Decision-Making Process Within the Context of a Child Living with an ADHD Diagnosis.* April 25-28, 2019; Lisbon, Portugal.

General Appendix 4 - Selected Works Published During my Doctoral Studies

Robaey, P., Erbach, M., Watanabe, L., Carreiro, E., Logan, D., & Maisonneuve, AR. (TBD). The impact of COVID-19 restrictions on parent-child conflict and mental health among children in tertiary mental health care. *Scientific Reports*. In press.

Abstract:

This study focused on children treated for mental health problems during the pandemic. We examined how parent's difficulties in managing COVID-19 restrictions increased children's behavioral problems (internalizing and externalizing) and parent-child conflict through parental mental health and parental stress. Family functioning, particularly problem-solving ability, was tested as a resilience factor. Data were collected using online surveys from 337 parents with a child between the ages of 4 and 18 years who was receiving active outpatient mental health treatment at a pediatric tertiary care center. Parents who reported a greater impact of COVID-19 reported more behavioral difficulties in their children. This relationship was significantly mediated by parental mental health (general stress, anxiety, and depression) and parental stress. Similar indirect pathways were observed when examining internalizing and externalizing problems in children, where the most significant pathway had parental stress as the sole mediator. Furthermore, the effect of COVID-19 impact on parent-child conflict through parental stress was significantly moderated by problem-solving skills within the family. Parental stress mediates the impact of COVID-19 on parent-child conflict. Interventions that improve family problem solving-skills may decrease the effect of parental stress on parent-child conflict.

Samson A., Maisonneuve AR., Achille, K., Spicer, K., Haddad, A., Chénier-Ayotte, N., Negura, L., & Robaey, P. (2023). The Contribution of Vocational Preparation in the Context of the Psychosocial Adaptation Process to University Studies. *International Journal for Educational and Vocational Guidance.* In press.

Abstract:

This research aims to analyze the experiences of first-year students during their process of adaptation to university. Ten participants were interviewed at two points in time: (1) during the transition from high school (grade 12) to university, and (2) at the end of their undergraduate studies. A phenomenological qualitative analysis of interviews was conducted. Results highlighted that participants had to adapt to unknowns such as a new social environment and academic requirements that could result in unexpected psychological challenges. Furthermore, the adaptation process to university studies is facilitated by the sufficient development of vocational preparation during high school years.

Samson A., Too, A., Maisonneuve, AR., Moreau K, Tomiak E, Barkley JL. (2021). Meaningful relationships as a driving force in the experience of parents of a child living with polyposis conditions. *Psychol Health Med, 27*(9):1951-1962. doi: 10.1080/13548506.2021.1990361.

Abstract:

While much research has been conducted on the experiences of individuals with inflammatory bowel diseases, there remains a dearth of research conducted on those affected by polyposis conditions. As a result, little is known about the lived experiences of those with polyposis

conditions, especially in the cases of parents of pediatric patients with these conditions. Using a hermeneutical phenomenological qualitative research approach, this study sought to explore the lived experiences of parents of children with polyposis conditions, with specific attention paid to the processes in which parents engage in order to adapt to their realities. In total, three major themes were revealed from the experiences of seven participants. Parents discussed the importance of building collaborative relationships with family physicians, building reassuring relationships with other parents, and building educative relationships with their child. These findings demonstrate the need for family-centered care practices by physicians, and role of relevant relationships as a driving force in helping parents in the management of their child's illness.

Bouchard, L., Nyqvist, F., Marí Mayans, I., van Kemenade, S., & Maisonneuve, AR. (2021). Public policy and citizen-based practices that support social and health services for official and co-official language minority communities. An international perspective: What has really been achieved and what are the gaps? *Linguistic Minorities and Society, 15-16*, p. 6–38. doi: https://doi.org/10.7202/1078475

Abstract:

By late 2017, there were 55 countries considered to be bilingual, trilingual, or multilingual (Leclerc, 2017). This reality has led researchers to examine the legal frameworks and policies governing the use of languages in these countries and their challenges and outcomes regarding their use within the health system.

Samson, A., Maisonneuve, AR., & Saint-Georges, Z. (2021). Ethnolinguistic Identity and Vocational Readiness as Non-Cognitive Factors Related to College Adaptation and Satisfaction with Life Among Franco-Ontarian Post-Secondary Students Living in an Anglo-Dominant Context. *Canadian Journal of Career Development, 20*(1), 17–27.

Abstract:

The purpose of this research was to determine how Francophone Ethnolinguistic Identity and Vocational Readiness facilitate College Adaptation and predict students' Satisfaction with Life. Using a sample of 179 first-year students, the development of a novel scale used to measure Vocational Readiness, or the degree to which a student is ready to make a post-secondary program choice and be engaged in the transition to post-secondary studies, was done and validated. Correlational analyses showed that all aspects of Vocational Readiness are consistently associated with better overall Adaptation in College and overall Vocational Readiness is associated with all subscales of College Adaptation. Regression analyses showed that Vocational Readiness was a significant predictor of College Adaptation and Satisfaction with Life Francophone Ethnolinguistic Identity was also a significant predictor of Satisfaction with Life. The interaction between Vocational Readiness and Francophone Ethnolinguistic Identity (Model F) was a significant, negative predictor of Satisfaction with Life. Post-hoc regression analyses indicated that both Vocational Readiness and Francophone Ethnolinguistic Identity are significant predictors of Social Adaptation.

Buchanan, D., D'Angiulli, A., Maisonneuve, AR., Samson, A., & Robaey, P. (2020). Acceptability of transcranial direct current stimulation in children and adolescents with ADHD: The point of view of parents. *Journal of Health Psychology, 27*(1):36-46. doi: 10.1177/1359105320937059.

Abstract:

Transcranial direct current stimulation (tDCS) is a novel treatment option for attention deficit hyperactivity disorder. To facilitate translation into clinical practice, we interviewed parents of children who have experienced experimental tDCS. A grounded theory approach using open, axial, and selective coding provided seven emergent themes for acceptability: tDCS provides hope for parents, safety tolerability and side effects of tDCS versus medication, burden of treatment, education and trust with care providers, cost and coverage, unestablished tDCS efficacy versus established medication effectiveness, perceived compliance of tDCS versus medication. Results suggest tDCS is acceptable but depends on evidence of effectiveness and regular availability.

Maisonneuve, AR., Witteman, HO., Brehaut, J., Dubé, E., & Wilson, K. (2018). Educating children and adolescents about vaccines: a review of current literature, *Expert Review of Vaccines*, *17*:4, 311-321, DOI: 10.1080/14760584.2018.1456921.

Abstract:

Introduction: Until recently, research on vaccine hesitancy has focused primarily on parent populations. Although adolescent knowledge and views are gaining momentum within the literature, particularly with regards to the human papillomavirus and influenza, children remain a

virtually unstudied population with regards to vaccine hesitancy. **Areas covered:** This review focuses on the lack of literature in this area and argues for more vaccine hesitancy research involving child and adolescent populations. It also outlines special issues to consider when framing health promotion messages for children and adolescents. Finally, we explore the use of new and existing technologies as delivery mechanisms for education on vaccines and immunizations in populations of children and adolescents. **Expert commentary:** Children undergo cognitive development and experiences with vaccines (e.g. pain or education) have the potential to create future attitudes toward vaccines. This can influence future vaccine behaviour, including their participation in decision-making around adolescent vaccines, their decisions to vaccinate themselves when they are adults, and their decisions to vaccinate their own children. Interventions aimed at children, such as education, can create positive attitudes toward vaccines. These can also potentially influence parental attitudes toward vaccines as children convey this knowledge to them. Both of these impacts require further study.