***PROTOCOL TITLE***

**Project Acronym or Short Study Title: FASD: Clinical Profiles and Service Utilization**

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# Protocol Synopsis

A retrospective longitudinal study on individuals diagnosed with fetal alcohol syndrome with health information collected from VIHA’s EHR will be conducted to explore the basic characteristics of their MHSU clinical profiles and service usage patterns. Further analyses will examine the associations between MHSU clinical profile make-up and service access and if different groups of individuals with FAS can be categorized based on these findings.

# Background & Rationale

First described in the late 1960s, Fetal Alcohol Spectrum Disorder (FASD) is a term that describes the range of detrimental effects that can occur when someone is prenatally exposed to alcohol. The effects of FASD are chronic and include physical, psychological, behavioural, and learning impairments (CanFASD, 2014). Despite the fact there are currently no confirmed statistics on the number of people in Canada who have FASD, it is widely considered to be a leading known cause of developmental disability in Canada with estimates ranging as high as 9 out of every 1000 babies born with a form of FASD (FASD-CMC, 2008). Furthermore, the estimated indirect and direct costs of FASD are calculated to range from $1.3 – 4 billion per year in Canada (CanFASD, 2014; Popova et al., 2015). Beyond economic the cost, FASD exacts a substantial toll on families, caseworkers, and communities as a whole. Individuals with FASD face complex life challenges and often require extensive support in order to lead fulfilling lives.

There is no cure for FASD and the condition can only be managed via environmental supports (e.g. supported housing) and behavioural interventions (e.g. skills training). Individuals with FASD frequently come into contact with various aspects of the healthcare system; those who have been diagnosed with Fetal Alcohol Syndrome (FAS), the most severe type of FASD, often carry multiple co-morbid diagnoses at rates much higher than the general population that necessitate multiple forms of treatment and intervention (Popova et al., 2016). This high rate of co-morbidity across a variety of physical and psychological domains likely leads to a frequent use of healthcare services across their lifespan. Given the relative lack of research on healthcare usage and related healthcare outcomes for individuals with FASD, it is imperative that research focus on the patterns of healthcare access for those with this lifelong condition in order to improve the delivery of services to these individuals and to improve our understanding of individuals who live with this diagnosis.

# Objectives

* Establish a basic clinical profile for the average individual with FAS that accesses services with VIHA
* Establish a basic service access profile for the average individual with FAS
* Determine which services have the most impact in reducing health, behavioural, and other issues
* Determine the timing of services that provide the most impact in reducing health, behavioural, and other issues

# Major Research Hypothesis and Associated Research Questions

* What services / interventions lead to reductions in behavioural / psychological concerns in the clinical profiles of those diagnosed with FAS?
* Does the timing of these services change how effective they are?
* Do specific clinical profile observations predict the type of services accessed by those with FAS?
* Are there different classes of individuals with FAS that are differentially affected by service access?

# Study Approach, Design

## Cohort selection criteria will be for all those within the VIHA Electronic Health Record that have been diagnosed with FAS (ICD Code: Q86.0). All ages and genders will be included in this group. MHSU clinical profile data (including any cognitive or functional assessment data) for these individuals will be required, as will their full service access data. The study will be conducted in 2 phases:

Phase 1:

1. Conduct an exploration and determination of the average clinical profile of an individual with FAS that accesses services with VIHA
2. Conduct an exploration and determination of the average service access profile of an individual with FAS
3. Observe any general trends/changes over time

Phase 2:

1. Use structural equation modeling to determine what clinical services lead to reductions in observed behavioural, functional, emotional, and other concerns found in the MHSU clinical profiles.
2. Determine whether the timing or sequence of service access plays a role in outcomes.
3. Ascertain whether distinguishable classes of individuals with FAS that respond differentially to service access can be observed.

The results of this study will help inform healthcare providers with a more clear idea of needs of individuals with FAS. Furthermore, it would hopefully lead to a streamlining and tailoring of services provided to these individuals based on their needs. Finally, it will lead to a deeper understanding of the constellation of symptoms that make up FAS and how these symptoms progress over time.

# Data management

All data will be drawn from the VIHA healthcare encounter data warehouse and the MHSU clinical profile data. The data will be housed in a 256-bit AES encrypted USB drive only to be accessed by the primary and supporting researchers via a password-protected laptop. Due to issues of practicality, acquiring consent of enough individuals diagnosed with FAS would likely prove impossible so all data must be de-identified by a data specialist within VIHA before a transfer is made to the primary researcher. The Safe Harbor De-identification methodology should be used.

# Consent, Protection of Privacy

Issues of consent are addressed in the previous section. All efforts will be made to de-identify the data and the data will not be linked to any other datasets to prevent indirect re-identification of the subjects.

# Data Retention

In compliance with the University of Victoria, Victoria Island Health Authority, and TCP-2 guidelines for data retention, data will be held for the longest possible period dictated by the three governing bodies following completion of the study.

# Publication of Results

The study will be published in the most appropriate medical journals as deemed by the research team. A report will also be provided to VIHA for the purposes of knowledge dissemination.

# References

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