**CLINICAL DATA VISUALIZATIONS IN SERVICE OF POLYPHARMACY RISK REDUCTION**

**Project Acronym or Short Study Title: Polypharmacy Risk Reduction**

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# Protocol Synopsis

This research is concerned with the problem of overprescribing among the elderly. The study arises directly out of the BC Provincial Polypharmacy Risk Reduction (PPhRR) initiative, which has sponsored the development of a web-based tool (‘MedStopper’) to support de-prescribing drugs known to be overprescribed in older adult populations. The research targets well-known issues around uptake and use of electronic clinical decision support tools. As well, it targets issues that arise when information required to support de-prescribing sits in multiple locations within a potentially very large birth-to-death electronic health record (EHR). Specifically, the research seeks to develop a set of empirically validated clinical data visualizations that summarize the individual patient’s service system encounter history, highlight MedStopper-based recommendations, and summarize (at a cohort level) the risks/benefits related to those recommendations. The research design entails a randomized controlled trial to evaluate the impact of clinical data visualizations in de-prescribing processes. Propensity score matching methodologies will be employed to create visualizations of the benefits/risks associated with de-prescribing. Patients, family members, physicians and clinical pharmacists will be engaged directly to evaluate the usefulness and usability of the clinical data visualizations.

# Background & Rationale

**Need -** Polypharmacy, defined clinically as the use of more medications than are clinically indicated, is a growing problem in the elderly3-6 and is a known risk factor for a host of adverse outcomes in the frail elderly, including impaired adaptive functioning, increasing risk of falls, emergency visits and hospitalizations.7……………………………………………

**De-prescribing in older adult populations -** Medication optimization should be a primary goal in caring for seniors. Due to high rates of polypharmacy in older adult populations and associated higher rates of drug interactions, along with adverse drug reactions which may trigger prescribing cascades, medication optimization for older adults is likely to centre around de-prescribing drugs that are ineffective or may be causing side effects10………………………………….. .

**Challenges to de-prescribing** - While the case for medication de-prescribing is clear for older adults, there are multiple challenges to de-prescribing for this population:………………………………………………

# Objectives

This research is concerned broadly with the problem of older adults who are at significant risk for polypharmacy/ overprescribing. It focuses on patients coming from acute care into Residential Care (RC), as these patients may carry with them a medication profile associated with clinical episodes that preceded the acute care admission, as well as medications that were prescribed during the admission.1-2 The research responds directly to the challenges faced by prescribing practitioners or clinical pharmacists, who have limited time to evaluate what in many cases are complex medication profiles, and may not have the time to locate and review a potentially large number of documented service system encounters in the EHR in order to place medication orders in a clinical context. The research also seeks to respond to concerns that may be experienced by patients/family members at the prospect of de-prescribing medications. Working with encounter data extracted from the patient’s record in the EHR, and anchoring de-prescribing recommendations in algorithms that are embedded in the MedStopper decision support tool, the research seeks to develop and empirically validate two clinically relevant, concise and usable clinical data visualizations:

* Contextualized Medication Profile with Recommendations (“CMPR”) – a longitudinal visualization consisting of three superimposed components – (1) Patient’s medication profile; (2) Ordering providers and clinical services/ programs in which medications have been ordered; and (3) MedStopper-based de-prescribing recommendations.
* Clinical Risks & Benefits (“CRB”) – validating de-prescribing recommendation, and responding to potential concerns around impacts by depicting cohort-level clinical outcomes (sentinel clinical events, e.g., acute care readmissions) associated with de-prescribing *vs* continued use of the classes of drugs targeted by MedStopper.

These clinical data visualizations are intended to support patients, family members and prescribers in the development of a shared understanding of the patient’s medical history, along with potential risks and benefits associated with change/no change to the patient’s medication profile.

# Major Research Hypothesis and Associated Research Questions

1. Patients/families who face the question of de-prescribing are effectively informed by concise visualizations of the patient’s medication escalation profiles, and their engagement in decision-making will be effectively supported by graphical displays of health outcome rates for patients who taper or stop medications, compared to patients who do not.
2. Prescribers and other clinicians (e.g., clinical pharmacists) will find the two-part visualizations clinically pertinent and useful, and this will be reflected in de-prescribing rates for classes of drugs that are identified as likely targets for de-prescribing in older adult populations.
3. A given medication profile may reflect factors that extend beyond risks/benefits inherent in the prescribed drugs. Some portion of this array of clinical factors will be manifest in the history of patient encounters with clinical programs/services that target specific clinical issues at different levels of severity. Working ‘backwards’ from patient cohorts defined in terms of de-prescription profiles to encounters with key clinical services [i.e., decision-tree analysis or other partitioning algorithms] will highlight some of those historical factors that impact on clinical decision-making. For example, a history of engagement with psychogeriatric outpatient services may be shown to be associated with decision-making around ongoing use of antipsychotic medications.

# Study Approach, Design

**DESIGN**

The study is structured as a low-impact randomized controlled trial comparing Island Health’s 19 RC facilities (1954 beds) with respect to escalating/de-escalating medication regimens and their sequelae. Facilities will be paired on the basis of coarse characteristics (e.g., size, location, clinical specialization such as dedicated dementia care facilities). One member in each pair will be chosen randomly to be recipients of the two clinical data visualizations (CMPR, CRB) prior to a mandated full medication review (“Meaningful Medication Review”) that takes place after a “settling in” period in the RC facility.

The study will also seek to extract knowledge about RC patients who have/have not been de-prescribed drugs in the four categories targeted by MedStopper through the use of propensity score matching methodologies and decision tree analysis. This component of the study works from the same bodies of clinical encounter/service data used to generate the clinical data visualizations.

**ANALYSES**

* Clinical practice impact measures - controlled time series analyses of prescription/de-prescription rates within 90 days of admission (Day 0) – comparable methodologically to survival curves or epidemic curves – for all drugs prescribed at Day 0, and separately for each of the four classes of at-risk drugs targeted by MedStopper; propensity score matching methodology employed to introduce case mix (from acute care discharge diagnoses) and other clinical historical/risk factors based on encounter data as adjustments.
* Between randomized arms – differences in de-prescribing rates.
* Clinical outcomes - associations between medication maintenance/de-prescribing and sentinel service utilization events (e.g., acute care admissions; falls).
* Determinants - individual provider factors - between-provider analyses of medication de-prescribing practices, within and across facilities that are provided with clinical data visualizations.
* Financial impacts – differences in monthly cost of medications per patient after the 90 day intervention time period *vs* before; costs related to sentinel clinical events that have been treated as clinical outcome measures.

**METHODOLOGY**

**Sample size:** We are modeling our study on a randomized trial of using STOPP criteria in frail elderly inpatients that reduced significantly (p <0.013) the use of Potentially Inappropriate Medications (PIMs) by 40% in the intervention group (n = 74) versus 19% in the control group (n = 72).23 Our sample size calculations (1-sided test with 95% confidence and 80% power) show we need 50 (or 198) per group to detect a reduction of 2 (or 1) medications, based on the following assumptions: mean of 8.1 medications per patient in nursing homes (standard deviation, 4.1),24 increasing by 3.1 on hospitalization, and dropping by 1.4 on return.25 …………………………….

**Clinical Data Visualization – Contextualized Medication Profile with Recommendations (CMPR) –** See prototype, above. This within-person-over-time clinical data visualization consists of three components: (1) a within-person-over-time (longitudinal) depiction of the patient’s medication profile; (2) patient engagement with clinical services/programs, plotted on the same timeline as the medication profile; (3) MedStopper-based recommendations for select classes of medications ……………………….

**Clinical Data Visualization - Clinical Risks & Benefits (CRB) –** See prototype, above. This aggregate view is based on historical prescription and service encounter data located in the Island Health EDW. These data extend back to 2007, and the EDW repository contains information on roughly 9 million encounters, including approximately 30,000 RC admissions. Outcome data consists of sentinel clinical events, including service encounters and other coded events when available in the EDW (e.g,. falls ……………………. ).

**Outcomes associated with interventions -** Two classes of outcomes will be evaluated, within a time-frame of 90 days from admission to RC: (1) rates of de-prescribing drugs – across all drugs, as well as within the four categories of drugs targeted by MedStopper; (2) rates of sentinel clinical events for patients who are de-prescribed/maintained on medications targeted by MedStopper. Patients who experienced de-prescribing will be matched by clinical characteristics with patients who did not reduce their medications (matching by multivariate propensity scores.)28

**Cross-Continuum Location Coding and Compressing Scheme (CCCS) –** In order to render encounter data in an analysis-ready and clinically meaningful form, the research will employ a methodology that has been developed and implemented within Island Health Applied Clinical Research Unit18. This CCCS methodology consists of six pieces of meta-data attached to each of the 1500+ programs/service locations that collectively constitute Island Health. This scheme is used to perform three tasks: (1) render transparent the nature of programs that are referenced in the EHR and the data warehouse with idiosyncratic and non-transparent names; (2) enable large numbers of locations to be compressed down to a far smaller number of clinically/functionally homogeneous program classes, in order to create visualizations that are not overly detailed; (3) apply service intensity weights to ambulatory services, which can then be employed by propensity score matching methodologies or other weighting/stratifying schemes.

**Data Accessibility -**All of the data required to generate the visualizations currently reside in the Island Health Enterprise Data Warehouse (EDW), with records going back to 2007.

**Intervention Locations -** the research will be restricted to Island Health operated residential care facilities, as these all make use of the Island Health Cerner Millennium EHR, which is the source of the medication profile data and the longitudinal clinical encounter data.

**Usefulness, Usability Assessment –** usefulness and usability of the clinical data visualizations will be assessed through interviews with individual patients, family members and clinical providers- including prescribing physicians and clinical pharmacists. Providers will be accessed via the Divisions of Family Practice. Access to patients and family members will be facilitated by the Patient Voice Advisor to the PPhRR initiative.

**Study Limitations**

The study is subject to limitations at the level of data sources – a ‘complete’ visualization would incorporate prescription data from community pharmacies, as well as data that point to primary care physician engagement in host of different diagnostic and treatment activities (captured at least partially by MSP billing data). In order to warrant the substantial work involved in accessing and integrating these data feeds, the proposed research seeks to establish the clinical/empirical viability of the approach and the usability of the means employed to render typically large volumes of clinical information in a very condensed form.

# Data management

1. What are the technologies, sources of the data (e.g, X, Y and Z from the data warehouse; A, B & C supplied directly by subjects using web-based tools that store data in the Island Health instance of REDCap; etc)
2. Where will the data be housed – where researchers interact with the data, e.g, inside the Island Health Secure Research Environment; inside the Microsoft Azure Cloud environment; on a laptop (not likely to be viewed favourably!!)
3. Data flow diagram
4. Steps involved in preparing the data – who does what, in which environments
5. What are the activities that are performed to access the data, de-identify the data and locate the data in the environment where the data will be accessed
   1. Data flow diagram
   2. Steps involved in preparing the data – who does what, in which environments

# Consent, Protection of Privacy

1. Consent – [[development of models using large volumes of de-identified data – without consent; intervention arm of study- with patient consent]]
2. Protection of privacy at the level of researcher access to warehoused data will be ensured through the use of three sets of controls –
   1. Administrative – agreements between Island Health and all members of the research team – specifying permitted/proscribed activities that can be performed with the research data;
   2. Technical – to prevent unauthorized access to research data; to prevent unauthorized export of person-level data from the data disclosure environment; to prevent unauthorized import of person-level data from external data sources into the data disclosure environment.
   3. Data de-identification – to minimize risk for re-identification in the event of unauthorized access or in the event that researchers engaged in activities proscribed by Data Disclosure and Access Agreements; to enable the body of research data used to generate the models to be deemed to be free from Protected Health Information, or other personal information, in order to enable legislation and policy-compliant data access without consent.

For the Polypharmacy Risk Reduction Research, the Safe Harbor de-identification methodology will be employed as the reference standard for deeming the research data free from personal information.

# Data retention

The Researchers work only with a copy of data from the Island Health Enterprise Data Warehouse (EDW). The copy itself is housed within the DDAE. The source data in the EDW are subject to BC provincial and Island Health data retention policies, which require that the information be retained indefinitely. The Personal Identifiers are not included in the copy of the data made accessible to the Researcher. They are stored in the EDW and are retained indefinitely.

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| **Personal Identifiers will be retained for:** | Indefinitely in the EDW but not available at any time to Researchers |
| **Research Information will be retained for:** | The research data extract within the DDAE and the files created by the Researchers within the DDAE will be retained for a period of seven (7) years. |

# Publication of Results

# References