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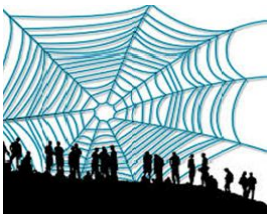

SPIDER

A Structured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch

A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients

PROTOCOL for the Feasibility and Cluster Randomized Controlled Trial in Elders Living with Polypharmacy

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Contents

TITLE

SPIDER: A research and QI collaboration supporting practices improving care for complex elderly patients: protocol for the feasibility and cluster randomized controlled trial in elders living with polypharmacy

1. TRIAL REGISTRATION

The study will be registered at ClinicalTrials.gov. The registration number will be updated here once done. <insert once we have Clinicaltrials.gov>

2. PROTOCOL VERSION

Sept 4, 2018

Version 6.3

3. FUNDING

The Canadian Institutes of Health Research (CIHR)

Matching financial support from collaborating partners including:

1. Quality and Innovation Program, the Department of Family and Community Medicine, University of Toronto
2. University of Toronto Practice Based Research Network
3. North York General Hospital
4. The College of Family Physicians of Canada
5. The Department of Family Medicine, Faculty of Medicine, University of Ottawa
6. The Department of Family Medicine, Faculty of Medicine & Dentistry, University of Alberta
7. The Department of Family Medicine, Faculty of Medicine, University of Calgary
8. Manitoba Primary Care Research Network, the Department of Family Medicine, University of Manitoba
9. The Department of Family Medicine, Max Rady College of Medicine, University of Manitoba
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16. The Department of Community Health & Epidemiology, Dalhousie University
17. Undergraduate Medical Education, Faculty of Medicine, Dalhousie University
18. Dalhousie Medical Research Foundation
19. Doctors Nova Scotia

4. ROLES AND RESPONSIBILITIES

4.1. PROTOCOL CONTRIBUTORS

This protocol is developed by the following contributors:

Name	Affiliations	Roles
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Sumeet Kalia	Department of Family and Community Medicine, University of Toronto	Collaborator, statistician
Jamie Wang	North York General Hospital	Project Manager
Stephanie Garies	Department of Family Medicine, University of Calgary	Co-I

4.2. TRIAL SPONSOR

This project is sponsored by the Canadian Institutes of health Research (CIHR):
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The sponsor will not be involved in nor have the ultimate authority over any of the following:
- Study design;
- Collection, management, analysis and interpretation of data;
- Writing of the report;
- Decision to submit the report for publication.

4.3. OVERSIGHT OF THE TRIAL

The conduct of the trial will be overseen by the steering committee composed of principle investigators and patient advisors. The steering committee will meet by teleconference on a bi-month basis to guide the trial conduct, update the trial progress and address emerging issues, if any. An operational group consists of members of the steering committee from each region will meeting bi-weekly or more often as needed to discuss the detail execution of the trial.

INTRODUCTION

5. BACKGROUND AND RATIONALE

5.1. HIGH COSTS

Half to two-thirds of healthcare costs in Canada and the U.S. are incurred by 5% of the population.[1-7] As an example, the average annual healthcare cost for Ontario residents in 2009–10 was approximately $3,600, while costs for the top 5% of users averaged $44,300.[8] Medical appointments may be relatively brief[9] and care can occur in multiple settings and through different health care providers. In this context, the management of complex patients may result in less than optimal care and patient experiences. Strategies to improve the care of these patients are needed.

5.2. OUR STUDY

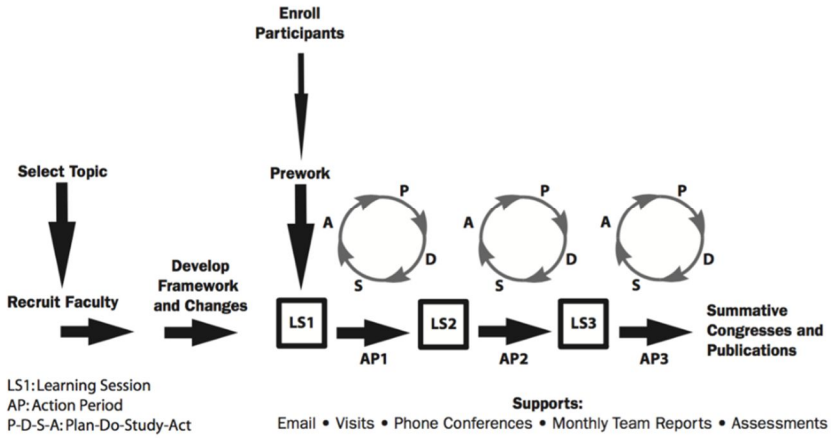
The intent of this study is to

- focus on patient managed in the community with chronically elevated costs, reflecting complexity and persistent unmet needs.[7,10,11]

- focus on primary health care, which is longitudinal and relationship based[12] as an ideal setting to improve the care of persistently complex patients living in the community.

5.3. THE IHI MODEL

Figure 2. Breakthrough Series Model



Improving patient care involves changing the way care is provided. We propose to address these challenges using Quality Improvement (QI) Collaboratives that build on the Institute for Healthcare Improvement (IHI) Breakthrough model.[13] The IHI model has four steps: (1) bringing together practices committed to QI to identify a care gap that they agree to be a priority; (2) engaging content experts and developing a learning information package that highlights the importance of the care gap and the opportunities for change; (3) conducting a learning session during which the practices learn about the challenges and select the change(s) best suited for their context; and (4) implementing the selected changes with ongoing Plan-Do-Study-Act (PDSA) cycles and regular communication.

Complex high cost patients are heterogeneous in their healthcare trajectory; only 15% of individuals incurring costs in the top 5% will remain in that category for three consecutive years.[7] Many have transient elevated costs related to end-of-life care.[14,15] Others, such as accident victims and transplant recipients, have an acute event requiring intensive resources for a limited time.[14] These groups represent different population segments and require approaches that focus on targeted needs.

A member of our team (SD) led the development and validation of an algorithm to allow community-dwelling individuals aged 65 years and older with "chronically complex needs" to be readily identified by their practice. Patients with chronically complex needs were defined as being at the top quartile of costs for *three or more* consecutive years. The study was population based and used Ontario health care data housed at the Institute for Clinical Evaluative Studies (ICES). The number of prescription medications proved to be the most reliable index of

persistent complexity.[16] The study showed a nearly linear relationship between number of medications and the likelihood of being identified as having "chronically complex needs". Establishing a cut-off of 10 or more medication for individuals 65 years of age and older would allow care providers to identify 23% of that population; virtually all (95.3%) of those identified in practice using this method fall into the "chronically complex needs" category. This is excellent specificity and would allow appropriate care to be directed to a primary care practice population based on overall complexity and costs rather than through targeting single health conditions.

5.4. POLYPHARMACY IS IN ITSELF A PROBLEM

While the relationship between a high number of prescribed medications and persistent complexity is not necessarily causal, polypharmacy itself is problematic. Polypharmacy in the elderly contributes to an elevated risk of adverse drug reactions,[17] falls,[18] drug-disease interactions[19], and drug interactions[20] and contributes to frailty and negative outcomes.[21] Polypharmacy also increases healthcare, drug, and hospitalization costs.[22-24]

While many medications that are beneficial and clinically indicated, some are unnecessary or can cause harm; these are termed Potentially Inappropriate Prescriptions (PIPs). The qualifier "potentially" is included to reflect the fact that the medication itself is not necessarily harmful to all patients, but can be under specific conditions or in prolonged usage. The Canadian Deprescribing Network (CaDeN)[25] and Choosing Wisely Canada[26] have identified the following classes as targets for decreased prescribing: proton pump inhibitors (PPInhs), sedative-hypnotics, medication associated with hypoglycemia in elders, and antipsychotics in elders.

Some PIPs may be appropriate during periods of time but continue to be prescribed because of clinical inertia.[27] For example PPInhs are often prescribed beyond the recommended short courses of treatment, with no defined benefit to patients and at significant cost and potential for harm (pneumonia, hip fractures, diarrhea), especially in elders.[28,29] Other medications are contra-indicated; these include benzodiazepines and other sedative-hypnotics, which increase the risk of falls, confusion, and hospital admissions,[30,31] and antipsychotics, which increase the risk of stroke and mortality in elders.[32,33]

Such medications need to be discontinued or "deprescribed." Deprescribing is gaining increasing importance in the management of complex patients: several trials and systematic reviews have shown that structured deprescribing is a promising approach to reducing PIPs, including PPInhs and benzodiazepines.[34] [35-37] Reviews have also reported some reductions in mortality[38] and improvement in quality of life.[39]

Deprescribing is a complex process that requires a multi-pronged approach.[30,35,40,41] Evidence based guidelines and tools are available.[28,42] Randomized controlled trials (RCTs) have shown that an interprofessional approach, including evaluation by a pharmacist, has improved the appropriateness of medications.[43,44] The use of benzodiazepines in elders has been reduced through direct education.[35] Patient involvement in a shared decision-making process is essential[40] and is likely to enhance the impact on survival.[38] Communication between clinicians and patients

should evolve from discussions about compliance to dialogues focusing on ensuring that risks and benefit are appropriately communicated and that the patient's decisions are aligned with their care goals.[45,46] Involving a pharmacist in the process improves effectiveness and increases patient empowerment and understanding.[47] Appropriately informed community-dwelling seniors in Canada have expressed a preference for reducing the number of medications they take.[48] Finally, ensuring appropriate communication with other prescribers will be important to ensure that patients do not get confusing or contradictory messages about their medications from different providers.[48]

We have therefore chosen to focus our efforts on the four classes of medications discussed above for elders with polypharmacy. They have been targeted as being appropriate for deprescribing discussions and evidence-based tools and guidelines on deprescribing have been published. Thus, evidence exists on "what to deprescribe" and "how to deprescribe".

5.5. SPIDER

We will enhance the Collaboratives through the use of validated EMR data provided by a national organization, the Canadian Primary Care Sentinel Surveillance Network (CPCSSN)[49] and by leveraging collaborations between primary care QI programs and Practice Based Research Networks (PBRNs)[50] in each region. QI programs will oversee QI activities and PBRNs will manage the analyses.

The **S**tructured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch (**SPIDER**) will help primary care practices to optimize their management of patients with complex needs by combining a number of proven methods and leveraging existing QI capacity, partnerships in primary care and EMR evaluation capacity. We will apply SPIDER to address polypharmacy.

6. OBJECTIVES

The main objective of the study is to assess the impact of SPIDER compared to usual care in reducing PIPs prescribed to patients aged 65 and older on ten or more medications

Secondary objectives include measuring the impact of SPIDER on patient health-related quality of life, on costs and on provider satisfaction.

7. TRIAL DESIGN

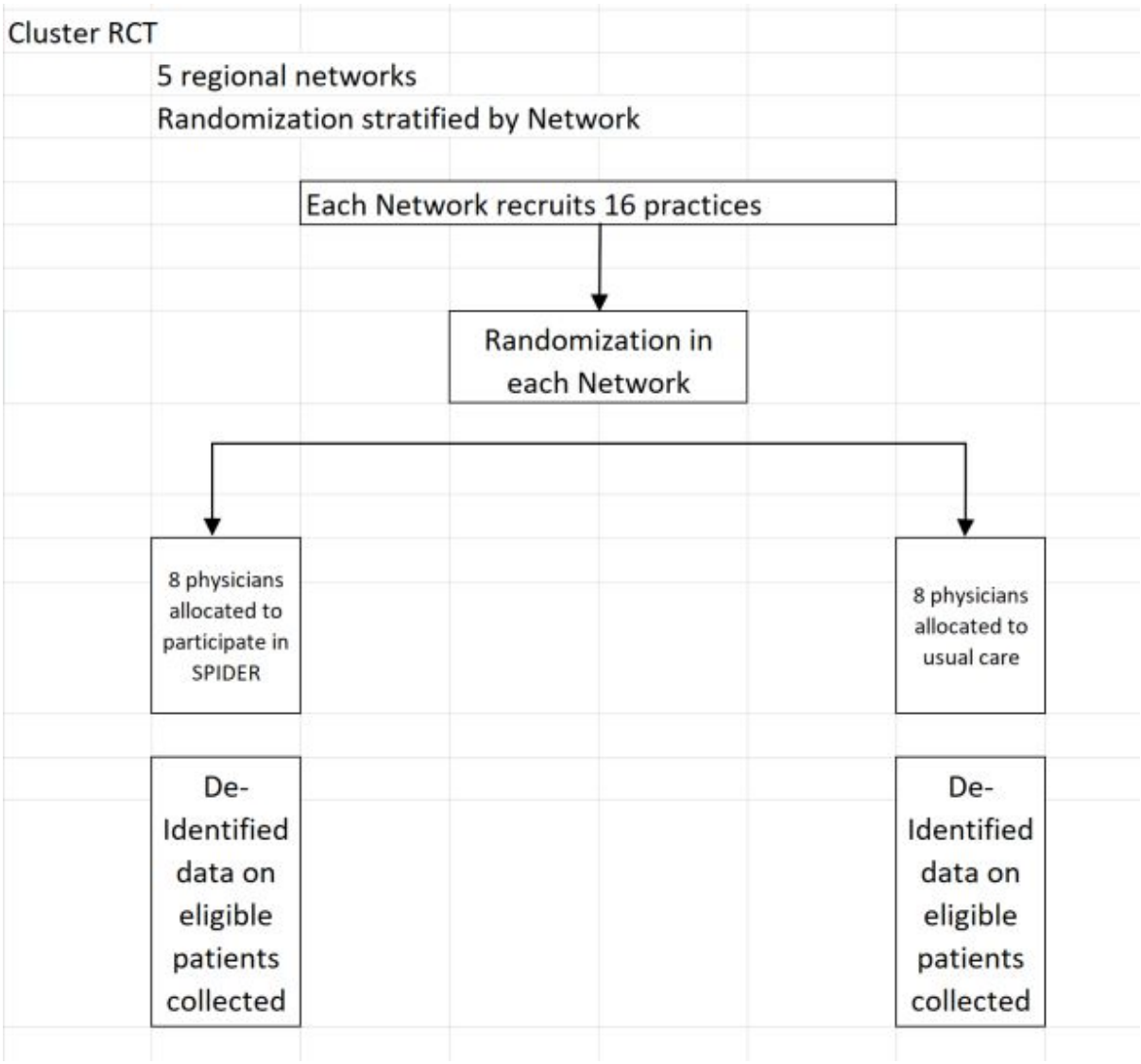
There are two phases to SPIDER:

1. Feasibility
2. Cluster randomized trial

The feasibility of SPIDER will be studied in three regions (Toronto, Edmonton, Montreal) using a single arm, prospective, explanatory mixed method approach.

We will then apply what we learn from the first phase to a pragmatic cluster RCT[51] with two parallel arms (usual care control, intervention) stratified by region and involving five regional networks (Winnipeg, Halifax, Calgary, Ottawa, Montreal). By pragmatic, we mean effectiveness in usual practice with broad criteria for eligibility to reflect usual care.[52,53] The pragmatic design (minimal patient selection criteria, use of existing primary care practices, and tailoring of the intervention to the setting) enhances generalizability to other patients in diverse primary care practices. As such, the study will investigate the "real world" impact of the intervention. That is to say, generalizability will be enhanced by tailoring the intervention to the variable circumstances in the practices[53,54].The clusters that will be randomized will be practices where several physicians may be co-located; this will avoid contamination where two physicians practicing in the same location are randomized to different arms. Each practice will have at least one physician participating. Patient-level data will be analyzed.

The trial will be reported using the CONSORT guidelines.[55,56] A senior statistician at the Department of Family Medicine, University of Toronto, will generate the allocation sequence. Randomization will be stratified by region. The allocation ratio will be 1 to 1. Analysis of covariance will be used to control for baseline imbalance. We will test for superiority of the SPIDER approach compared with usual care.



METHODS: STUDY SETTINGS, PARTICIPANTS AND OUTCOMES

8. STUDY SETTINGS

Seven Canadian regional networks across five provinces are involved in the study.

The Canadian healthcare system includes the following aspects:

- Universal coverage for all medically necessary procedures and visits provided by physicians or in hospital under the Canada Health Act.[57]

- Health care is largely managed within each province. This results in differences in primary care models including availability of interprofessional care and differences in physician remuneration

The study settings are primary care practices, either in the community or academic family practices affiliated with a hospital.

9. ELIGIBILITY CRITERIA

The study will be open to practices using any funding model, including fee for service, capitation or salaried; it will also be open to family physicians practicing in either interprofessional or non-interprofessional models. Eligible practices are required to provide comprehensive primary care, be a member of the network in their region and have at least one Primary Care Provider (PCP) in the practice who contributes data to the CPCSSN and consents to participate in this study. Consent will be obtained prior to randomization for centres participating in the cluster RCT. Each practice will select a practice champion among those physicians participating. The practice champion will build a team to participate in the Collaborative and support the initiative. They will be encouraged to invite a practice administrator/ staff, a nurse, and a pharmacist (where available in the practice) to participate in their practice team. Where the practice team does not include a pharmacist, they will be encouraged to engage at least one community pharmacist

All community-dwelling patients aged 65 years and older having had at least one visit in the past two years in the practice of a participating PCP and having had $\geq$10 medication prescriptions in the previous 12 months will have their de-identified EMR data included in the outcome measurement. A medication is defined as any unique prescription generated at least once in the EMR during the 12 months period preceding study initiation or in the 12 months following the study. Patients with at least one PIP at baseline may be invited to participate in the assessment of patient experience and self-reported outcomes.

10. INTERVENTION

As part of the SPIDER intervention, primary care practice teams, policy-makers, and patient partners will form a Collaborative group in each participating region. The PBRN in each region will supply the Collaborative with local EMR data cleaned by CPCSSN and will supply confidential reports identifying eligible patients to their practices. CPCSSN data are de-identified; a file allowing re-identification at the site of care is left at the practice site.

Audit and Feedback on their own patients and comparisons with other participants will be provided to family physicians and their teams, using best practices.[58] QI Programs in each region will manage the QI aspects of the project. All Collaborative group members will attend a one-day workshop (or equivalent, as locally appropriate) on polypharmacy and PIPs to discuss options to address this issue using their EMR data. Practice coaches will help each SPIDER Collaborative groups establish priorities for QI, choose practice changes, and set goals. With the support of practice coaches, each practice participating in SPIDER will then implement the

changes, adapting them according to the local context. A second workshop will be held at six months, and a summative congress will occur at one year. Monthly teleconferences will be available to participants.

Criteria for discontinuing the intervention include: practice no longer eligible (left practice, not practicing comprehensive care) or withdrawal of consent.

Comparator practices will continue with usual care. Routinely collected EMR data will be used to measure the primary outcome in both groups.

11.OUTCOMES

The primary outcome is the number of PIPs per patient. The PIPs are those identified by CaDeN[25] and by Choosing Wisely Canada[26] as appropriate for deprescribing: PPInhs, sedative-hypnotics, medication associated with hypoglycemia in elders, and antipsychotics.

11.1.FEASIBILITY EVALUATION

We will first evaluate the feasibility of SPIDER across seven dimensions: Acceptability to stakeholders, demand, implementation, adaptation, integration, practicality, and efficacy (see Table 1).

Table 1 evaluation of feasibility

	Tool and Approach
Acceptability	
Patients	Veterans Affairs multidimensional survey[59] capturing: five dimensions related to polypharmacy and deprescribing: "medication concerns," "provider knowledge," "interest in stopping medicines," "unimportance of medicines" and "patient involvement in decision-making."[59] Supplemented with interview questions (selected key informants) on experience with the process, symptoms (improvements/new), relationship with PCP, empowerment, and care coordination dimensions identified in previous qualitative research as pertinent.[40,59-61] These will be administered at twelve months
Providers	Semi-structured interviews with selected providers based on Theoretical Framework of Acceptability.[62] (Table 2); Focus group and survey based on Organizational Readiness to Change Assessment (ORCA)[90] and Data-Driven Quality Improvement in Primary Care (DQIP)[89]
Demand	Coordinator's log: Enrolment and retention of practices and providers
Implementation	Coordinator's log: Ability to apply the SPIDER elements as planned

	Project memorandums: Implementation facilitators and barriers; best practices
Adaptation	Coordinator's log: Fidelity to SPIDER process, and extent of change required to accommodate SPIDER to the context
Integration	Extent of effective collaboration across sectors (semi-structured interviews with selected practices)
Practicality	Ability to integrate the process into existing practice (semi-structured interview with selected practices)
Efficacy	Potential for approach to achieve desired outcomes: EMR data extraction: PIPs, survey: Patient health-related quality of life,[63] emergency room visits and hospitalization where available from Administrative data
Cost-Utility	Ratio of difference in quality of life measure to difference in estimated costs Health-related quality of life as measured by EuroQol-5D will be used to assess: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Estimate of costs of medication, delivering the enhanced QI program (materials, management costs for the program, EMR data extraction and analysis), and practice facilitation.

[1] We will adapt the multidimensional survey developed on 1547 Veterans Affairs patients prescribed five or more medications[59]

Table 2: Definitions of the component constructs in the Theoretical framework of acceptability[62]

Theoretical Framework of Acceptability (TFA)	**Definition**
Ethicality	The extent to which the intervention has good fit with an individual's value system
Affective Attitude	Anticipated Affective Attitude: How an individual feels about the intervention, prior to taking part Experienced Affective Attitude: How an individual feels about the intervention, after taking part
Burden	Anticipated burden: The perceived amount of effort that is required to participate in the intervention Experienced burden: the amount of effort that was required to participate in the intervention
Opportunity Costs	Anticipated opportunity cost : The extent to which benefits, profits, or values must be given up to engage in the intervention Experienced opportunity cost: the benefits, profits or values that were given up to engage in the intervention

Theoretical Framework of Acceptability (TFA)	Definition
Perceived Effectiveness	Anticipated effectiveness: the extent to which the intervention is perceived to be likely to achieve its purpose Experienced effectiveness: the extent to which the intervention is perceived to have achieved its intended purpose
Self-efficacy	The participant's confidence that they can perform the behaviour(s) required to participate in the intervention
Intervention Coherence	The extent to which the participant understands the intervention and how it works

11.2. CLUSTER RCT OUTCOMES

In the randomized controlled trial we will assess the cost-utility of SPIDER as the incremental gain in quality of life between the two arms in relation to intervention costs and by comparing the differences in investments and healthcare costs captured through EMR data and emergency room use and hospitalization.

We will capture the costs of medication, delivering the enhanced QI program (materials, management costs for the program, EMR data extraction and analysis), and practice facilitation. In Ontario, we will determine the annual healthcare costs using a person-centred costing methodology developed by Wodchis et al[65-67] that captures all costs covered by the provincial insurance plan, including costs incurred in acute, home, rehabilitation and complex care settings, and costs of physician outpatient visits, medical tests, and medication (for the subset of patients > 65 years). We will determine costs per provider in the year prior to the project and for the year following the project, and compare the change. We will adapt existing tools to assess all providers' experience in the Collaborative,[68] and their experience and confidence in deprescribing PIPs.[69] We will conduct PCP focus groups in each region to explore: experience in the Collaborative, appropriateness of guidelines provided, time required and burden, communication and shared decisions with patients and other providers, and confidence in deprescribing.

Table 3: surveys, interviews and administrative data for RCT

	Tools and Approaches	
Patients (10% sample)	EuroQOL-5D at 12 months Veterans Affairs Survey at 12 months Semi-structured interview about their experience with PIPs	Health related QOL
	Costs related to hospitalizations and admissions (Ontario, administrative data)	
Providers (1 focus group per region)	Providers' experience in the Collaborative,[68] and their experience and confidence in deprescribing PIPs.[69]	

12.PARTICIPANT TIMELINE

The **preparatory work** for SPIDER, including establishing the central research team and regional partnerships, developing the protocol for the process underpinning SPIDER, and seeking initial REB approvals, began in the third quarter of 2017. Dissemination of information about SPIDER to PCPs via the PBRNs and QI Programs and preparation for recruitment in the two feasibility sites has begun.

The 3-year demonstration project (reducing the prevalence of potentially inappropriate medication prescriptions) will be conducted from June 2018 to March 2020; final analysis of results and work to ensure the sustainability of the SPIDER approach and facilitate dissemination of the regional networks' successful interventions will continue through 2021.

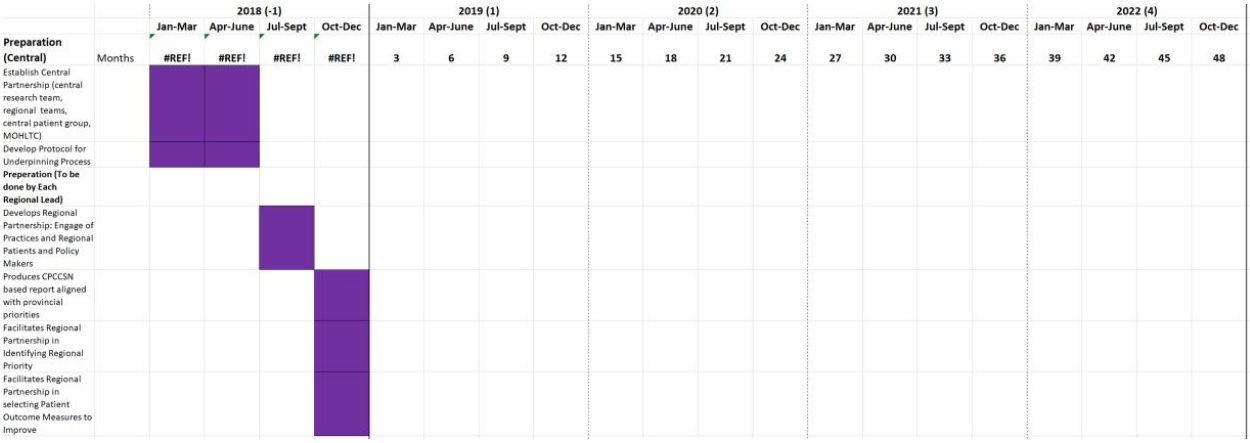
In the **feasibility phase** of the project, two of the regional networks will work with facilitators from September 2018 to September 2019 to establish their Collaboratives and select and implement QI interventions to reduce inappropriate prescribing. The networks' ability to maintain their Collaborative and QI interventions without the assistance of facilitators will then be monitored until the end of 2020.

Interviews, surveys and focus groups with patients, providers and policy makers will be conducted in 2018 and 2019; data collected in 2018 will be used to improve SPIDER in preparation for the RCT. REB approvals and Recruitment for the RCT phase will begin during the feasibility phase in 2018.

In the **RCT phase**, the remaining five regional networks will establish their Collaboratives and select and implement QI interventions with the help of facilitators from December 2018 to March 2020. Outcomes will be assessed for the year prior to each Collaborative and for the year after each Collaborative. Interviews, surveys and focus groups with patients, providers and policy makers will be conducted in 2019 and 2020.

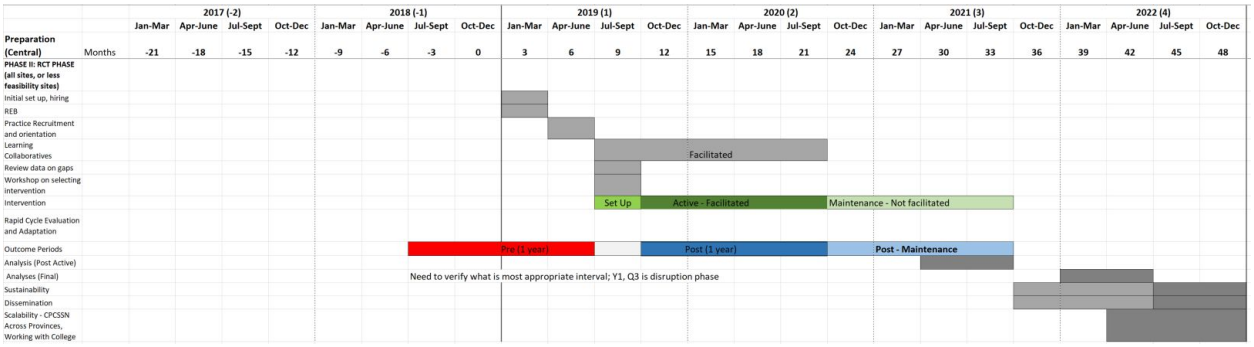
Qualitative analyses will be ongoing through the project as data are available. Quantitative analyses will be conducted in 2019 and 2020 for the feasibility phase and 2021 for the cluster RCT phase.

Preparation



Feasiblity

Cluster RCT



13.SAMPLE SIZE

Planning analyses conducted on 86 practice sites of the University of Toronto PBRN (UTOPIAN) involving 334 PCP showed the following: (1) an average of 24 patients per PCP had at least one PIP; (2) the prevalence of PIPs was PPInh: 58%, benzodiazepine: 33%, hypoglycemics: 1%, antipsychotics: 7%; (3) 73% of patients had at least one PIP (24% had two or more); (4) the mean number of PIPs was 0.987/ patient (standard deviation: 0.747); and (5) the intra cluster (practice) correlation (ICC) was 0.017.

13.1. DETAILS OF PLANNING ANALYSES

The ability to identify older patients on 10 or more medications was tested using the UTOPIAN (University of Toronto Practice-Based Research Network) database. Data were extracted as of 1 April 1 2017. Patients included in the cohort had at least one encounter in the two years before the date of extraction. Patients labeled as deceased were removed from the dataset. Complex patients were defined as those with 10 or more unique drugs prescribed at least once in the 12 months before the date of data extraction. All duplicate prescriptions were removed.

We identified prescriptions for the four drug classes of interest using the World Health Organization's ATC codes.[70] The UTOPIAN database collects information from 503,806 patients and 347 providers. We identified 8,121 patients who are 65 years of age or older (as of 31 March 2016) and had 10 or more drug prescriptions in the last 12 months (1 April 2016 to 31 March 2017). These 8,121 patients belonged to 334 family providers (clusters). On average, there are 24 patients for each family provider (mean = 24; median = 18; min = 1; max = 140 cluster size). We assessed the baseline prescription rates for four potentially inappropriate drugs (PIPs) in this cohort.

- Proton pump inhibitors: A02BC
- Benzodiazepines or Z drugs: N05BA or N05BE or N05CD or N05CF
- Hypoglycemic sulfonylureas: A10BB, exclude A10BB09
- Antipsychotics: N05A, exclude N05AN

- Proton pump inhibitors: baseline prescription rate: 4716/8121 = 58.1%
- Benzodiazepines or Z drugs: baseline prescription rate: 2677/8121 = 33.0%
- Hypoglycemics: baseline prescription rate: 99/8121 = 1.2%
- Antipsychotic drugs: baseline prescription rate: 576/8121= 6.9%

Estimating Intraclass correlation coefficient

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error	Z Value	Pr > Z
Intercept	**Site_ID**	0.05806	0.01887	3.08	0.0010

ICC = 0.05806/ (0.05806 + 3.29) = 0.0173

link: https://support.sas.com/resources/papers/proceedings15/3430-2015.pdf

We will recruit eight to twelve practices in each of the three PBRNs participating in the feasibility component of this study; allowing us to understand various facets of implementing the approach in three geographical regions, across at least 24 practices, including at least 24 PCPs, and over 400 patients. These numbers are sufficient to meet the six objectives that inform how

the approach might need to be tailored to optimize its implementation in the RCT phase. These will also allow us to estimate anticipated patient participation within 5% (assuming 50% participation [highest standard deviation]), 95% confidence intervals +/-5.2%) and determine with 99% confidence whether a 15% reduction in PIPs is possible.

For the RCT portion, assuming a conservative ICC of 0.05 and one participating provider per practice (24 patients), 35 practices in each arm are required to detect a mean difference of 15% (from 0.987-0.837) in PIPs, allowing for $\alpha = 0.05$ and $\beta = 20\%$. We will recruit 16 practices per region (total 80) to allow for attrition. The unit of randomization will be the primary care practice, and analyses will be conducted at the patient level.

14. RECRUITMENT

The Leads of the seven PBRNs participating in this study (each is a principal investigator on this study) will recruit the required number of practices for this study. As part of their infrastructure, PBRNs hold regular meetings and communicate with members.[71] The study will be promoted through email communications and at face-to-face meetings. Several practices have expressed an interest in participating. PBRN members have a strong history of engagement in innovations.[72 73]

For a practice to participate, at least one family physician from that practice must be willing to be involved participate. Each practice will select a practice champion among those physicians participating. The practice champion will build a team to participate in the Collaborative and support the initiative. They will be encouraged to invite a practice administrator/ staff, a nurse, and a pharmacist (where available in the practice) to participate in their practice team. Where the practice team does not include a pharmacist, they will be encouraged to engage at least one community pharmacist.

All CPSSN members have an existing ethics approval that allows de-identified patient data to be used for research. All patients identified to have 10 or more medication at baseline will be included as participants for assessing polypharmacy and PIPs.

Six months after study start, a PBRN practice facilitator will ask practices in both arms for permission to contact a randomly selected 10% sample of patients that were on PIPs at baseline. This method has been used successfully in previous PBRN studies.[74] After the family physicians have granted permission, patients will be contacted by a member of the research team and, after providing consent, will complete a questionnaire on experiences and self-reported outcomes.

METHODS: ASSIGNMENT OF INTERVENTIONS

15. ALLOCATION: SEQUENCE GENERATION AND CONCEALMENT MECHANISM

Treatment allocation (control or intervention) will occur in each region after recruitment is completed in that region. A computer-generated blocked (region) concealed randomization sequence will be used for practice treatment allocation. PBRN leads will send a list of participating practices, identified only by study codes, to the central statistician who will link the list to the appropriate randomization block to reveal the allocation for each practice.

16.BLINDING

Blinding of participants cannot be achieved in pragmatic trials of QI interventions in primary care.[75] The identification of PIPs and medication count (at baseline and end of study) will take place centrally by a data manager blinded to the arm attribution to avoid potential biases in cases where ambiguity about the presence of the drug requires their assessment of additional patient data. Similarly, data cleaning and imputation will be performed centrally by a staff member blinded to the arm attribution.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

17.DATA COLLECTION METHODS

All participating physicians in the RCT are required to be existing members of the CPCSSN initiative and would therefore have already contributed de-identified EMR data to regional network repositories. The method of EMR data extraction and the approach to processing the data (coding and standardizing) have been previously described.[49] CPCSSN has experience obtaining data elements required for this initiative[76-78] and generating lists of prescribed medication by time period, including attribution to the class of drug.[79 80 81]

A patient survey for patients with PIPs will be delivered to study participants in both arms by a research staff member at 12 months.

A short survey will be administered to both arms at baseline asking about PCPs and their staff about their practices. PCPs and staff of practices participating in each Collaborative will be asked to complete an online survey of their experience with the SPIDER process and its impact on their ability to care for patients with complex needs at 12 months and again at 24 months after baseline. Interviews of patients and focus groups with providers and policy-makers will be conducted only for the SPIDER arm at 12 months after baseline. These will be audiotaped and transcribed verbatim.

18.DATA MANAGEMENT

Data management will be as per secure CPCSSN processes.[49] Practices identified as participating in SPIDER will have de-identified data on prescribing collected and compared as

part of routine CPCSSN data collection. No data identifying patients or physicians will be released as part of study reports. Survey data for patient reported outcome and experience measures will be collected using study numbers, and will be entered in a secure, password-protected database at the University of Toronto.

Administrative data for hospital admissions, emergency department visits and system cost will be managed as per standard operating procedures at ICES. No information identifying patients or physicians will be released.

Centrally located data management and analytic staff will be overseen by the senior biostatistician at the University of Toronto's Department of Family and Community Medicine (DFCM), Dr Rahim Moineddin.

19. PROJECT COORDINATION AND MANAGEMENT

A central project manager will be hired at UTOPIAN. The manager will be tasked with overseeing resources and budgets as well as ensuring that appropriate actions and timelines are followed. This will include communication and liaison with each regional network and ongoing teleconferences as required. A steering committee composed of the principal investigators will be formed; committee members will meet by teleconference bimonthly. An operational group will meet by teleconference every two weeks or more often as needed.

19.1. PROJECT MANAGEMENT TASKS

- Actively manage the operations of the project for partners across Canada to ensure milestones and targets are met
- Guide decisions made by the steering committee and ensure decision outcomes are executed accordingly
- Acquire, analyze, and report information necessary for budgeting and assessment of project activities
- Respond to all enquires, collaborating as required with committees
- Troubleshoot problems at all stages, making modifications to address challenges
- Report on the activities and objectives set by the steering committee
- Articulate progress reports to the steering committee, demonstrating the status of the project

Finance

- Create financial projections and make adjustments to budgets throughout the life of the project
- Provide reports and analysis
- Create and maintain contracts and agreements between partners; negotiate contract terms with partner institutions/organizations
- Develop reports on milestones for funding purposes
- Monitor and maintain contractual obligations with stakeholders and partners

- Establish policies around fiscal management
- Collaborate with the Department of Family and Community Medicine at the University of Toronto to provide timely reporting to the Canadian Institutes of Health Research (CIHR) around financial status through regular reporting mechanisms as per CIHR

Partnerships/Collaborations/Communications

- Develop and lead the communication strategy, promoting the project to the research community, partners, patients, and the academic sector
- Engage in building the project profile with regular proactive communications by designing promotional strategies and related material for improved outcomes throughout written announcements, website, and other modes of communication

Staff Management

- Supervise, coordinate, and evaluate support staff (data management staff, research assistant, etc.)

20.STATISTICAL METHODS

Descriptive statistics will be used to provide information about physician and patient characteristics, participation rates, polypharmacy and PIPs. The analysis will be on an intention to treat basis; it will therefore include physicians who have agreed to participate but discontinue their engagement at any point during the study. Outcomes are at the patient level; we will use hierarchical modeling and generalized estimating equations with random effect variables to account for clustering; intracluster correlation coefficients will be reported. All patients of participating physicians who had been identified at baseline as eligible, regardless of whether they had or not a PIP at baseline will be included in the analysis. The number of PIPs prescribed per patient in the control and intervention arms over a 12-month period following the SPIDER intervention in each regional network will be compared. Analysis of covariance[82] will be used to adjust for potential confounders such as age, sex, comorbidity, and outcomes at baseline.

Qualitative methods will be used to explore and evaluate the processes associated with SPIDER, so that its effects can be better understood.[83] We will use purposeful sampling to invite participants (family physicians, interprofessional team members, staff members) in each centre to participate in interviews and focus groups. We will use a semi-structured guide based on the dimensions measured, asking about their experiences with SPIDER, acceptability of the process, ability to implement the changes and what barriers they encountered. Focus groups will also be conducted with policy makers. We will use grounded theory to code and analyze the data. The Consolidated Framework for Implementation research will be used to frame the results.[84]

Participating PCPs are required to agree to share information about the study with their patients. A randomly selected 10% sample of patients identified at baseline as having PIPs will receive a

study information sheet at six months asking for their permission to be contacted later by a member of the research team to participate in a study to understand their experience with medication. Individuals will be told that this will include a survey about their medication (both arms) and potentially an interview (intervention arm).

Interviews will be conducted with patients to explore satisfaction with care. The interviews will be audio-taped and transcribed verbatim. We will use the constant comparative method[85] to check and compare data to identify categories, key words and themes.[86]

ETHICS AND DISSEMINATION

21.RESEARCH ETHICS APPROVAL

We will obtain ethics approvals from the institution at each regional Network, followed by signed, informed consent from each participating physician. CPCSSN has received REB approval from each host university for all participating PBRNs. All participating primary care providers have provided written informed consent for the collection and analysis of their EMR data. Patients and primary care team members will provide informed consent prior to survey completion and/or interviews/focus groups.

22.DISSEMINATION POLICY AND KNOWLEDGE TRANSLATION

SPIDER is itself an approach to mobilization knowledge to action.[87] Within these activities that aim to encourage adoption of best practices in care delivery, we have adopted an integrated knowledge translation (IKT) strategy to inform implementation and to support the eventual scale up of the SPIDER approach. We have engaged several KUs as team members at the onset of the development of this proposal, including PCPs, other health professionals, health planners, and individuals with lived experience (5 covering 3 regions). All seven regions will have a full complement of these individuals as team members. We have also engaged health authorities from four regions (in addition to the PIHCI policy Leads), provincial Health Councils (2), and the CFPC. These members have contributed to identifying the health care priority being addressed, key issues to be considered during implementation (e.g. patient-provider communication, interprofessional collaboration, the feasibility of the approach across regions, scalability of the approach), the outcomes that should be evaluated, and other aspects of the proposed study. These members form an integral part of our research team, and we will ensure that their engagement is fostered throughout the study implementation phase. Their contribution will continue to inform the deployment of the intervention and its adaption across regions; this will ensure that the approach implemented in each region is best suited for that context, and that the analysis and interpretation of the data is appropriately informed by the various perspectives. All members of the team will also be involved in disseminating knowledge, throughout of the

study, as appropriate, and when the findings emerge. This IKT approach is a fundamental guiding principle of our work. This is especially important in this knowledge-to-action proposal because we are testing a promising process in a pragmatic manner and real-world settings. Evidence of effectiveness is now needed and is the final step before broader adoption and scale up of the innovation. Our approach to ensure authentic engagement is described with some details in the three-page addendum.

When PCPs/other health professionals and patient partners have had some experience working on this project, we will elicit their input in elaborating a more detailed study dissemination plan to reach various audiences. For now, we have made budgetary provisions for researchers, patients, health professionals and policy makers from each region to attend annual team meetings that will be held around scientific conferences. These will allow us to disseminate knowledge to researchers, and to some extent policy makers. We will rely on our health planner/policy makers partners and participating health providers to support the transfer of knowledge to their peers regionally, and across jurisdictions. PBRNs have set up infrastructure and models to promote increased participation in academic activities; one example is the UTOPIAN i2p (Insights to Proposals) course, which has provided training for 45 primary care clinicians in grant development.[88]

APPENDICES

23.INFORMED CONSENT MATERIALS

23.1. CONSENT FORM FOR FEASIBILITY STUDY: PROFESSIONALS

Informed Consent Form for Participation in a Research Study

TITLE:
SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Feasibility Phase

INVESTIGATORS:
• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:
The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:
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 QI-research study.

Please take your time in making your decision. You may find it helpful to discuss it with your colleagues. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect your current or future work or practices.

CONFLICT OF INTEREST:
There are no conflicts of interest to declare related to this study.

BACKGROUND:

Elderly patients living with multiple chronic conditions often take many medications (polypharmacy); some of them may not be beneficial. While many medications can be problematic, the following four classes of medications have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as targets for wiser uses in elders: proton pump inhibitors (PPInhs), benzodiazepines, antipsychotics and long-acting sulfonylureas. Polypharmacy is associated with poor patient health and reduced quality of life, high care costs and, often, care providers' frustration.

PURPOSE:
This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs by reducing potentially inappropriate prescriptions. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

NUMBER OF PARTICIPANTS:
The study will recruit a total of 104 – 156 family practices, including at least 104 family physicians and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax).

This consent pertains to the feasibility phase; we will recruit about ten practices in each region (Toronto, Montreal and Edmonton)

STUDY PROCEDURES AND INTERVENTIONS:
The study will first be tested for feasibility in Toronto, Montreal and Edmonton.

Here is what the intervention involves:

- Quality Improvement (QI)
    - For practice teams:
        - Select one physician as the practice champion and team up with other members of the practice (including, if feasible a nurse, a pharmacist and a front desk staff)
        - Participate in a Learning Collaborative with 3 - 4 workshops over a period of 12 months
        - Review data from your patients' electronic medical records (EMRs) with comparisons to colleagues, identify care gaps and possible ways to decrease those gaps
        - Work with a QI coach to implement practice changes and share best practices and challenges encountered via emails and occasional teleconferences
- Research
    - Provide some basic information about you and a survey about your practice team (half hour)
    - Complete an online survey (15 to 20 minutes)
    - You may be asked to participate in an interview at 6 to 12 months (30-40 minutes)
    - Participate in a focus group at about 12 months (1 hour)

Ten percent of your eligible patients will be invited to complete a paper-based survey and a short interview at 12 months. If you agree, these patients will be invited through your office by mail.

The focus group and interview will be audio recorded. The information collected from the surveys, the interview and the focus group are for research purposes only. There is no right or wrong answers. Some of the questions may be personal. You can choose not to answer any questions you may not be comfortable with. If you are a physician, we request your permission to identify your practice as participating in SPIDER in the EMR database of the research Network you are part of by assigning a study number in the database; this will not identify you or your patients.

What we learn from the feasibility study will then be used to guide a pragmatic randomized controlled trial (RCT) in 5 regions (Ottawa, Calgary, Winnipeg, Montreal and Halifax).

PARTICIPANTS' RESPONSIBILITIES:
If you choose to participate in this study, you will be expected to participate in activities described above, including the completion of an online survey, potentially participation in an interview and a focus group.

DURATION OF THE STUDY:
The entire project lasts for about 4 years. Your participation in the feasibility phase will be about 12 months.

WITHDRAWAL FROM THE STUDY:
You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your practice or the relationship with the research team or the institution. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the survey and focus group data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:
Taking part in this study has some risks. Reviewing information on patients may make you feel uncomfortable. Participating in a Learning Collaborative may mean making changes in practice and any change always involves risks and benefits. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions with others in the focus group. The research staff and focus group moderator will make every effort to minimize this.

POTENTIAL BENEFITS:
Taking part in this study has both direct and indirect benefits. Reducing potentially inappropriate drugs may improve patients' health and healthcare experience. This may improve your satisfaction with practice and contribute to a healthy society and reduced care system costs.

INFORMATION CONFIDENTIALITY:
Any information collected for this study will be kept strictly confidential. The EMR data provided to the practice teams is de-identified.

Only the researchers will have access to the information for the survey, interview or focus groups. No information that could identify you will be reported or released. During focus groups, all participants will be asked not to disclose anything said within the context of the discussion. By agreeing to

participate, you also agree to not disclose to others outside this event anything said within the context of the discussion. We may use quotes without identifying you.

All the information collected from the survey and the focus group will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

A copy of the recording will be forwarded to a contracted transcription service via a secure encrypted link. All transcriptionists will be required to sign confidentiality agreement prior to access the recordings. The research staff will clean the data to ensure no identifiable information will appear in the transcripts.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used in any case. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

STUDY INFORMATION:
A more detailed description of this clinical trial is available at http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search the website at any time.

COST AND COMPENSATION:
Participation in the research aspects of this study (e, focus groups) may incur some out of pocket expenses for transportation and parking. These will be reimbursed. You will not be compensated otherwise for your time in participating in the study.

RIGHTS AS A PARTICIPANT:
You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact our research staff to let us know if you would like this.

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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in the study.

QUESTIONS ABOUT THE STUDY:
If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE STUDY

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I agree to take part in the study.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

CONSENT TO PARTICIPATE IN THE FOCUS GROUP

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the focus group will be audio recorded and I agree to take part in the focus group.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining	Printed Name & Role	Date

Consent

CONSENT TO PARTICIPATE IN THE INTERVIEW
(For Selected Participants)

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the interview will be audio recorded and I agree to take part.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

23.2. CONSENT FORM FOR RCT: PROFESSIONALS

Informed Consent Form for Participation in a Research Study

TITLE:
SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Cluster Randomized Controlled Trial Phase

INVESTIGATORS:

• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:

The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:
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 QI-research study.

Please take your time in making your decision. You may find it helpful to discuss it with your colleagues. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect your current or future work or practices.

CONFLICT OF INTEREST:
There are no conflicts of interest to declare related to this study.

BACKGROUND:
Elderly patients living with multiple chronic conditions often take many medications (polypharmacy); some of them may not be beneficial. While many medications can be problematic, the following four classes of medications have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as targets for wiser uses in elders: proton pump inhibitors (PPInhs), benzodiazepines, antipsychotics and long-acting sulfonylureas. Polypharmacy is associated with poor patient health and reduced quality of life, high care costs and, often, care providers' frustration.

PURPOSE:
This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs by reducing potentially inappropriate prescriptions. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

NUMBER OF PARTICIPANTS:
The study will recruit a total of 104 – 156 family practices, including at least 104 family physicians and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax). There was an initial feasibility phase.

Five regions are participating in the Randomized controlled trial (RCT). This consent pertains to the RCT phase. About 16 practices in each region will be enrolled.

STUDY PROCEDURES AND INTERVENTIONS:
If you agree to participate, your practice will be randomly assigned to either the SPIDER intervention arm or the usual care arm. If you are a physician and are assigned to the intervention arm, we request your permission to identify your practice as participating in SPIDER in the EMR database of the research Network you are part of by assigning a study number in the database for research purposes; this will not identify you or your patients.

If your practice is randomly assigned to participate in the SPIDER intervention arm, here is what this involves:

- Quality Improvement (QI)
    - For practice teams:
        - Select one physician as the practice champion and team up with other members of the practice (including, if feasible a nurse, a pharmacist and a front desk staff)
        - Participate in a Learning Collaborative with 3 - 4 workshops over a period of 12 months
        - Review data from your patients' electronic medical records (EMRs) with comparisons to colleagues, identify care gaps and possible ways to decrease those gaps
        - Work with a QI coach to implement practice changes and share best practices and challenges encountered via emails and occasional teleconferences
- Research
    - Provide some basic information about you and a survey about your practice team (half hour)
    - Complete an online survey (15 to 20 minutes)
    - Participate in a focus group at about 12 months (1 hour)

If your practice is randomly picked for the control group, we are only asking you to complete some basic information and an online survey at 12 months.

We will ask your help to identify and invite about ten percent of your elderly patients on ten or more medications to complete a paper-based survey. If you are randomized to the SPIDER intervention, we will also ask for your help to invite about ten percent of these patients to a short interview.

The information collected from the surveys, the interview and the focus group will be used for research purposes only. There are no right or wrong answers. Some of the questions may be personal. You can choose not to answer any questions you are not comfortable with.

PARTICIPANTS' RESPONSIBILITIES:

If you choose to participate in this study, you will be expected to participate in the activities described above.

DURATION OF THE STUDY:

The entire project lasts for about 4 years. Your participation in the Learning Collaborative (if you are assigned to the intervention) will last 12 months.

WITHDRAWAL FROM THE STUDY:

You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your practice or the relationship with the research team or the institution. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the survey and focus group data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:

Taking part in this study has some risks. Reviewing information on patients may make you feel uncomfortable. Participating in a Learning Collaborative may mean making changes in practice and any change always involves risks and benefits. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions with others in a focus group. The research staff and focus group moderator will make every effort to minimize this.

POTENTIAL BENEFITS:

Taking part in this study has both direct and indirect benefits. Reducing potentially inappropriate drugs may improve patients' health and healthcare experience. This may improve your satisfaction with practice and contribute to a healthy society and reduced care system costs.

INFORMATION CONFIDENTIALITY:

Any information collected for this study will be kept strictly confidential. The EMR data provided to the practice teams is de-identified.

Only the researchers will have access to the information for the survey, interview or focus groups. No information that could identify you will be reported or released. During focus groups, all participants will be asked not to disclose anything said within the context of the discussion. By agreeing to participate, you also agree to not disclose to others outside this event anything said within the context of the discussion. We may use quotes without identifying you.

All the information collected from the survey and the focus group will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

A copy of the recording will be forwarded to a contracted transcription service via a secure encrypted link. All transcriptionists will be required to sign confidentiality agreement prior to access the recordings. The research staff will clean the data to ensure no identifiable information will appear in the transcripts.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used in any case. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

STUDY INFORMATION:

A more detailed description of this clinical trial will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

COST AND COMPENSATION:

Participation in the research aspects of this study (example, focus groups) may incur some out of pocket expenses for transportation and parking. These will be reimbursed. You will not be compensated otherwise for your time in participating in the study.

RIGHTS AS A PARTICIPANT:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact our research staff to let us know if you would like this.

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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in the study.

QUESTIONS ABOUT THE STUDY:

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE STUDY

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I agree to take part in the study.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

CONSENT TO PARTICIPATE IN THE FOCUS GROUP

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the focus group will be audio recorded and I agree to take part in the focus group.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

23.3. CONSENT FORM FOR POLICY MAKERS

Informed Consent Form for Participation in a Research Study

TITLE:
SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Feasibility Phase

INVESTIGATORS:

• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:

The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:
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 QI-research study.

Please take your time in making your decision. You may find it helpful to discuss it with your colleagues. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not result in any penalty or affect your current or future work or practices.

CONFLICT OF INTEREST:
There are no conflicts of interest to declare related to this study.

BACKGROUND:
Elderly patients living with multiple chronic conditions often take many medications (polypharmacy); some of them may not be beneficial. While many medications can be problematic, the following four classes of medications have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as targets for wiser uses in elders: proton pump inhibitors (PPInhs), benzodiazepines, antipsychotics and long-acting sulfonylureas. Polypharmacy is associated with poor patient health and reduced quality of life, high care costs and, often, care providers' frustration.

PURPOSE:
This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs by reducing potentially inappropriate prescriptions. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

NUMBER OF PARTICIPANTS:
The study will recruit a total of 104 – 156 family practices, including at least 104 family physicians and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax).

STUDY PROCEDURES AND INTERVENTIONS:
The study will first be tested for feasibility in Toronto, Montreal and Edmonton, followed by a cluster Randomized Controlled study.

Here is what the intervention involves for participating practices:

- Quality Improvement (QI)
    - For practice teams:
        - Select one physician as the practice champion and team up with other members of the practice (including, if feasible a nurse, a pharmacist and a front desk staff);
        - Participate in a Learning Collaborative with 3 - 4 workshops over a period of 12 months;
        - Review de-identified patients' electronic medical records (EMRs), identify care gaps and possible ways to decrease those gaps;
        - Work with a QI coach to implement practice changes and share best practices and challenges encountered via emails and occasional teleconferences.

- What we are requesting from you:
    - Participate in an interview regarding your views on this process (30-40 minutes)

The interview will be audio recorded. The information collected from the interview is for research purposes only. There are no right or wrong answers. Some of the questions may be personal. You can choose not to answer any questions you may not be comfortable with.

PARTICIPANTS' RESPONSIBILITIES:
If you choose to participate in this study, you will be expected to participate in the interview.

DURATION OF THE STUDY:
The entire project lasts for about 4 years. Your participation will be an interview.

WITHDRAWAL FROM THE STUDY:
You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your relationship with the research team or the institution. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the interview data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:
Taking part in this study has some risks. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions. We will make every effort to minimize this.

POTENTIAL BENEFITS:
Taking part in this study has both direct and indirect benefits. Reducing potentially inappropriate drugs may improve patients' health and healthcare experience and contribute to a healthy society and reduced care system costs.

INFORMATION CONFIDENTIALITY:
Any information collected for this study will be kept strictly confidential.

Only the researchers will have access to the information. No information that could identify you will be reported or released. We may use quotes without identifying you.

All the information collected will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

A copy of the recording will be forwarded to a contracted transcription service via a secure encrypted link. All transcriptionists will be required to sign confidentiality agreement prior to access the recordings. The research staff will clean the data to ensure no identifiable information will appear in the transcripts.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used in any case. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

STUDY INFORMATION:
A more detailed description of this clinical trial is available at http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search the website at any time.

COST AND COMPENSATION:
You will not be compensated for your time in participating in the study.

RIGHTS AS A PARTICIPANT:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact our research staff to let us know if you would like this.

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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in the study.

QUESTIONS ABOUT THE STUDY:
If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE INTERVIEW

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the interview will be audio recorded and I agree to take part.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

23.4. CONSENT FORM FOR FEASIBILITY STUDY: PATIENTS

Informed Consent Form for Participation in a Research Study

TITLE:
SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Feasibility Phase

INVESTIGATORS:

• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:

The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:
You are invited to participate in this study because you are 65 years or older and are taking 10 or more different drugs. 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. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not affect current or future health care.

CONFLICT OF INTEREST:
There are no conflicts of interest to declare related to this study.

BACKGROUND:
Elderly patients living with multiple chronic diseases often take many drugs (polypharmacy), some of which may not be helpful. While many drugs can be problematic, the following four groups of drugs have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as targets for wiser uses in elders: drugs that reduce stomach acid production; reduce anxiety and induce

sleep; treat agitation; and treat type 2 diabetes but have a high risk of low blood sugar. Polypharmacy often leads to poor patient health and poor quality of life, high care costs and doctor's frustration.

PURPOSE:
This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs by reducing potentially inappropriate prescriptions. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

ALTERNATIVE OPTIONS:
You do not have to take part in the study in order to receive care. Your family doctor will provide care as usual; this will not change whether you participate or not.

NUMBER OF PARTICIPANTS:
The study will enroll a total of 104 – 156 family practices, including at least 104 family doctors and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax).

STUDY PROCEDURES AND INTERVENTIONS:
• Your family doctor will team up with a nurse, a pharmacist and a front desk staff at the clinic to participate in a Learning Collaborative meant to work with patients and practices on care improvement;
• They will work with a Quality Improvement (QI) coach;
• Your family physician is participating in the study and has agreed for you to be contacted. We would like to ask you if you are interested and would agree to participate. It is completely your choice whether you participate or not.

We are asking you to:
1. Complete the survey (15 to 20 minutes)
2. Participate in an interview (about 30 minutes)

A research assistant will contact you to arrange a time and location that is convenient for you. The interview may be in person or over the phone and will take about 30 minutes and will be audio recorded. The information you provide in the survey and/or interview is for research purpose only. There will be no right or wrong answers. Some of the questions may be personal. You can choose to answer any questions you are comfortable with.

PARTICIPANTS' RESPONSIBILITIES:
If you choose to participate in this study, you will be asked to complete a survey and participate in an interview as described above.

DURATION OF THE STUDY:

The whole project lasts for about 4 years. You will only be asked to complete one survey and one interview.

WITHDRAWAL FROM THE STUDY:
You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your care. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the survey and interview data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:
Taking part in this study has some risks. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions with the research staff in the interview. We will make every effort to minimize any impact.

POTENTIAL BENEFITS:
If you have a better understanding of your medications you may be better able to make choices that you feel are right for you with your family doctor. This may lead to better health and better quality of life.

INFORMATION CONFIDENTIALITY:
Measures and protections are in place to ensure your information is treated confidentially. Your family doctor gave permission for you to be contacted to see if you might be interested in the study.

Only the researchers will have access to the information for the survey, interview or focus groups. No information that could identify you will be reported or released. During focus groups, all participants will be asked not to disclose anything said within the context of the discussion. By agreeing to participate, you also agree to not disclose to others outside this event anything said within the context of the discussion. We may use quotes without identifying you.

All the information collected from the survey and the focus group will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

A copy of the recording will be forwarded to a contracted transcription service via a secure encrypted link. All transcriptionists will be required to sign confidentiality agreement prior to access the recordings. The research staff will clean the data to ensure no identifiable information will appear in the transcripts.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used in any case. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

STUDY INFORMATION:

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

COST AND COMPENSATION:

Participation in this study will not involve any additional costs to you. The survey will be mailed to you with a paid return envelope attached. If you agree to be interviewed, the interview will be arranged at a time and location convenient for you. As a token of appreciation of your time, you will be offered a coffee card upon receiving your returned survey ($5) and/or completion of the interview ($25).

RIGHTS AS A PARTICIPANT:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact our research staff to let us know if you would like this.

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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in the study.

QUESTIONS ABOUT THE STUDY:

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE STUDY

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do

not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I agree to take part in the survey part of the study.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

CONSENT TO PARTICIPATE IN THE INTERVIEW

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the interview will be audio recorded and I agree to take part in the interview.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

23.5. CONSENT FORM FOR RCT: PATIENTS OF PHYSICIANS RANDOMIZED TO INTERVENTION

Informed Consent Form for Participation in a Research Study

TITLE:

SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Cluster Randomized Controlled Trial Phase

INVESTIGATORS:

• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:

The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:

You are invited to participate in this study because you are 65 years or older and are taking 10 or more different drugs. 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. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not affect your current or future health care.

CONFLICT OF INTEREST:

There are no conflicts of interest to declare related to this study.

BACKGROUND:

Elderly patients living with multiple chronic diseases often take many drugs (polypharmacy), some of which may not be helpful. While many drugs can be problematic, the following four groups of drugs have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as

targets for wiser uses in elders: drugs that reduce stomach acid production; reduce anxiety and induce sleep; treat agitation; and treat type 2 diabetes but have a high risk of low blood sugar. Polypharmacy often leads to poor patient health and poor quality of life, high care costs and doctor's frustration.

PURPOSE:

This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

ALTERNATIVE OPTIONS:

You do not have to take part in the study in order to receive care. Your family doctor will provide care as usual; this will not change whether you participate or not.

NUMBER OF PARTICIPANTS:

The study will enroll a total of 104 – 156 family practices, including at least 104 family doctors and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax).

STUDY PROCEDURES AND INTERVENTIONS:

• Your family doctor will team up with a nurse, a pharmacist and a front desk staff at the clinic to participate in a Learning Collaborative meant to work with patients and practices on care improvement;
• They will work with a Quality Improvement (QI) coach to implement the improvement plan;
• Your family physician is participating in the study and has agreed for you to be contacted. We would like to ask you if you are interested and would agree to participate. It is completely your choice whether you participate or not.

We are asking you to:

1. Complete the survey (15 to 20 minutes)
2. Participate in an interview (about 30 minutes)

A research assistant will contact you to arrange a time and location that is convenient for you. The interview may be in person or over the phone and will take about 30 minutes and will be audio recorded. The information you provide in the survey and/or interview is for research purposes only. There will be no right or wrong answers. Some of the questions may be personal. You can choose to answer any questions you are comfortable with.

PARTICIPANTS' RESPONSIBILITIES:

If you choose to participate in this study, you will be expected to complete a survey and likely an interview as described above.

DURATION OF THE STUDY:

The whole project last for about 4 years. You will only be asked to complete one survey and one interview as part of this project.

WITHDRAWAL FROM THE STUDY:

You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your care. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the survey and interview data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:

Taking part in this study has some risks. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions with the research staff in the interview. We will make every effort to minimize any impact.

POTENTIAL BENEFITS:

If you have a better understanding of your medications you may be better able to make choices that you feel are right for you with your family doctor. This may lead to better health and better quality of life.

INFORMATION CONFIDENTIALITY:

Measures and protections are in place to ensure your information is treated confidentially. Your family doctor gave permission for you to be contacted to see if you might be interested in the study.

Only the researchers will have access to the information for the survey, interview or focus groups. No information that could identify you will be reported or released. During focus groups, all participants will be asked not to disclose anything said within the context of the discussion. By agreeing to participate, you also agree to not disclose to others outside this event anything said within the context of the discussion. We may use quotes without identifying you.

All the information collected from the survey and the focus group will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

A copy of the recording will be forwarded to a contracted transcription service via a secure encrypted link. All transcriptionists will be required to sign confidentiality agreement prior to access the recordings. The research staff will clean the data to ensure no identifiable information will appear in the transcripts.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used in any case. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

STUDY INFORMATION:

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

COST AND COMPENSATION:

Participation in this study will not involve any additional costs to you. The survey will be mailed to you with a paid return envelope attached. If you agree to be interviewed, the interview will be arranged at a time and location convenient for you. As a token of appreciation of your time, you will be offered a coffee card upon receiving your returned survey ($5) and/or completion of the interview ($25).

RIGHTS AS A PARTICIPANT:

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact our research staff to let us know if you would like this.

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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in the study.

QUESTIONS ABOUT THE STUDY:

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE STUDY

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do

not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I agree to take part in the survey part of the study.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

CONSENT TO PARTICIPATE IN THE INTERVIEW

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I am aware that the interview will be audio recorded and I agree to take part in the interview.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

23.6. CONSENT FORM FOR RCT: PATIENTS OF PHYSICIANS RANDOMIZED TO USUAL CARE

Informed Consent Form for Participation in a Research Study

TITLE:

SPIDER: A Research and Quality Improvement Collaboration Supporting Practices in Improving Care for Complex Elderly Patients – Cluster Randomized Controlled Trial Phase

INVESTIGATORS:

• Dr. Michelle Greiver
  - Research Scientist, North York General Hospital; Acting Director, University of Toronto Practice Based Research Network; Associate Professor, Department of Family and Community Medicine (DFCM), University of Toronto;
  - michelle.greiver@nygh.on.ca; 416-756-6483; 416-978-5113;
• Patricia O'Brien
  - Program Manager, Quality and Innovation Program, Department of Family and Community Medicine, University of Toronto
  - patricia.obrien@utoronto.ca; 416-978-5112
• [Add regional PI's and Co-PI(s)' name, title, institution and contact information here]

SPONSOR/FUNDERS:

The Canadian Institutes of Health Research Operating Grant: Pan-Canadian Strategy for Patient-Oriented Research Network in Primary and Integrated Health Care Innovations Programmatic Grants

INTRODUCTION:

You are invited to participate in this study because you are 65 years or older and are taking 10 or more different drugs. 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. The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. Deciding not to take part or deciding to leave the study later will not affect your current or future health care.

CONFLICT OF INTEREST:

There are no conflicts of interest to declare related to this study.

BACKGROUND:

Elderly patients living with multiple chronic diseases often take many drugs (polypharmacy), some of which may not be helpful. While many drugs can be problematic, the following four groups of drugs have been recommended by Choosing Wisely Canada and the Canadian Deprescribing Network as

targets for wiser uses in elders: drugs that reduce stomach acid production; reduce anxiety and induce sleep; treat agitation; and treat type 2 diabetes but have a high risk of low blood sugar. Polypharmacy often leads to poor patient health and poor quality of life, high care costs and doctor's frustration.

PURPOSE:

This study aims to assess whether a Structured Process Informed by Data, Evidence and Research (SPIDER) will help family practices improve care for patients 65 years or older who are taking 10 or more different drugs. The study will also evaluate whether patients and their primary care teams are satisfied with the SPIDER process and whether SPIDER reduces care costs.

We are conducting a survey as part of the study to better understand what patients think and you are being invited to participate.

ALTERNATIVE OPTIONS:

You do not have to take part in the study in order to receive care. Your family doctor will provide care as usual; this will not change whether you participate or not.

NUMBER OF PARTICIPANTS:

The study will enroll a total of 104 – 156 family practices, including at least 104 family doctors and 250 patients, in 7 regions (Toronto, Ottawa, Montreal, Edmonton, Calgary, Winnipeg and Halifax).

STUDY PROCEDURES AND INTERVENTIONS:

Your family physician is participating in the study and has agreed for you to be contacted.

We are asking you to complete a survey to help us better understand care (15 to 20 minutes)

The information you provide in the survey is for research purpose only. There will be no right or wrong answers. You can choose to answer any questions you are comfortable with. It is completely your choice whether you participate or not.

WITHDRAWAL FROM THE STUDY:

You can withdraw from this research at any time without having to provide a reason. Your withdrawal will not have any negative impact on your care. If you decide to terminate participation, the study will stop collecting your data. However, previously collected data such as the survey data cannot be separated nor removed as these data are de-identified.

POTENTIAL RISKS:

Taking part in this study has some risks. You might feel uncomfortable, embarrassed or upset when sharing personal experiences and opinions with the research staff in the interview. We will make every effort to minimize any impact.

POTENTIAL BENEFITS:

If we gain a better understanding of what could help older patients taking many medications, this may help people make choices that they feel are better, together with their family doctor and their care teams. This may lead to better health and better quality of life.

INFORMATION CONFIDENTIALITY:

Measures and protections are in place to ensure your information is treated confidentially. Your family doctor gave permission for you to be contacted to see if you might be interested in the study survey.

Only the researchers will have access to the information. No information that could identify you will be reported or released.

All the information collected from the survey will be transferred into electronic files then encrypted and stored on a secure password-protected server. Access will be limited to authorized research personnel only.

The results of the study will be published and presented to the scientific community at conferences and in journals. Your identity will remain confidential. No names or identifiable information will be used. All data and documents will be kept for 7 years after the completion of the study then securely destroyed. Destruction of hard copy records will be through fine shredding or incineration. Destruction of electronic records (and other media) will be subject to current, approved institutional Information Technology (IT) processes which ensure that reconstruction of the information is not reasonably foreseeable in the circumstances (example, using wiping).

STUDY INFORMATION:

A description of this clinical trial will be available on http://www.clinicaltrials.gov. This website will not include information that can identify you. You can search this website at any time.

COST AND COMPENSATION:

Participation in this study will not involve any additional costs to you. The survey will be mailed to you with a paid return envelope attached. As a token of appreciation of your time, you will be offered a coffee card upon receiving your returned survey ($5)

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Authorized representatives of [Insert research site name] may have direct access to your original medical/clinical study records to check that the information collected for the study is correct and follows proper laws and guidelines.

RIGHTS AS A PARTICIPANT:

You will be told, in a timely manner, new information that may affect your willingness to stay in the study. You have the right to be informed of the study results once the entire study is completed. Please contact your family doctor to let us know your request. 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 investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

QUESTIONS ABOUT THE STUDY:

If you have any questions, concerns or would like to speak to the study team for any reason, please contact Dr. Michelle Greiver at michelle.greiver@nygh.on.ca [or your regional PI].

If you have any questions about your rights as a participant or any ethical issues related to the study that you wish to discuss with someone not directly involved with the study, you may contact Dr. W. L. Alan Fung, Chair of the North York General Hospital Research Ethics Board at alan.fung@nygh.on.ca, Tel: 416-756-6444 ext. 3483.

CONSENT TO PARTICIPATE IN THE STUDY

This study has been explained to me and any questions I had have been answered. I understand the information within this informed consent form. I know that I may leave the study at any time and I do not give up any of my legal rights by signing this consent form. I agree to the use of my information as described in this form. I agree to take part in the survey part of the study.

Signature of Participant	Printed Name	Date
Signature of Person Obtaining Consent	Printed Name & Role	Date

24. RESEARCH INSTRUMENTS

24.1. BASELINE PRACTICE INFORMATION AND SURVEY

Thank you for participating in the SPIDER Baseline Survey! This survey will help us understand background information about you and your practice and your team.

This survey should take about 5 - 10 minutes to complete. The first section asks about your practice. Please ask only **ONE** member of your team to complete this part. Please complete the remaining sections. All your answers will be kept confidential. We thank you in advance for your support and invaluable input!

Study ID number: _____

Regional Centre: _____

First, please let us know a bit more about your practice. Please ask only one member of your team to complete this section.

1. What area is your practice located?
   - ☐ Urban
   - ☐ Suburban
   - ☐ Rural

2. How large is your practice (number of family physicians in the office)?
   - ☐ Solo
   - ☐ 1 – 2 physicians
   - ☐ 3 – 5 physicians
   - ☐ 6 or more physicians

3. Does your practice have the following members, if so, please tell us how many does your practice have. Please check the options on the right and write down the number for yes option.

	No	Yes	Number
Front desk staff			
Office administrator			
Nurse			
Nurse practitioner			
Clinical pharmacist			
Social worker			
Dietitian			

Other, please specify _____			

4. How long has the practice been in existence? _____ years

5. Are there family medicine residents in the practice?
   - ☐ No
   - ☐ Yes

6. Are there medical students?
   - ☐ No
   - ☐ Yes

7. Are you part of an interdisciplinary model? (e.g., Family Health Team in Ontario)
   - ☐ No
   - ☐ Yes

8. Does the practice have regular office meetings?
   - ☐ No
   - ☐ Yes
     a. If yes, how often?
        - ☐ Weekly
        - ☐ Bi-weekly
        - ☐ Monthly
        - ☐ Bi-monthly
        - ☐ Other, please specify: _____

Next, please tell us a bit about yourself.

9. What is your age? _____

10. What is your gender?
    - ☐ Female
    - ☐ Male

11. What is your role in your primary care team?
    - ☐ Physician
    - ☐ Nurse
    - ☐ Pharmacist
    - ☐ Social worker
    - ☐ Front desk staff
    - ☐ Other, please specify: _____

12. How many hours a week do you work in your clinic setting? _____

13. How long have you been part of the practice team? _____ years

14. Have you participated in previous formal Quality Improvement (QI) efforts?
☐ No
☐ Yes
a. If yes, have you participated in a Learning Collaborative?
☐ No
☐ Yes
If yes, please specify: _____

b. Have you participated in other QI efforts?
☐ No
☐ Yes
If yes, please specify: _____

Last, we would like to know your opinions about team functioning.

15. To what extent do you agree or disagree with the following statements.

In this practice, we	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
reward clinical innovation and creativity to improve patient care					
solicit opinions of clinical and other staff regarding decisions about patient care					
seek ways to improve patient education and increase patient participation in treatment					

16. To what extent do you agree or disagree with the following statements.

In this practice, we	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
have a sense of personal responsibility for improving patient care and outcomes					
cooperate to maintain and improve effectiveness of patient care					
are willing to innovate and/or experiment to improve clinical procedures					
are receptive to change in clinical processes					

17. To what extent do you agree or disagree with the following statements.

In this practice, we	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
provide effective management for continuous improvement of patient care					
clearly define areas of responsibility for everyone					
promote team building to solve clinical care problems					

promote communication among all members of the team					
provide information on performance measures and guidelines					
establish clear goals for patient care processes and outcomes					
provide practice members with feedback/data on effects of clinical decisions					
hold members of the practice accountable for achieving results					

18. To what extent do you agree or disagree with the following statements.

Opinion leaders in my practice setting:	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
believe that the current practice patterns can be improved					
encourage and support changes in practice patterns to improve patient care					
are willing to try new clinical protocols					
work cooperatively with others to make appropriate changes					

(The End)

Thank you so much for your time and input! If you have any questions or comments or would like to request a report of SPIDER study results, please contact Jamie Wang (Jianmin.Wang@nygh.on.ca).

24.2. POST-INTERVENTION PATIENT SURVEY

SPIDER POST-INTERVENTION SURVEY – PATIENT VERSION

Thank you and welcome to the SPIDER Post-intervention Survey! This survey will help us understand how a **S**tructured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch, the SPIDER model, can potentially help improve quality of care. This survey should take about 15 - 20 minutes to complete. All your answers will be kept confidential. Please mail the completed survey back using the attached prepaid envelope.

First, we would like to know how you feel your overall health. Please select only one statement that describes you the best.

1. About my mobility:
   - ☐ I have no problems in walking about
   - ☐ I have slight problems in walking
   - ☐ I have moderate problems in walking about
   - ☐ I have severe problems in walking about
   - ☐ I am unable to walk about

2. About my self-care
   - ☐ I have no problems washing or dressing myself
   - ☐ I have slight problems washing or dressing myself
   - ☐ I have moderate problems washing or dressing myself
   - ☐ I have severe problems washing or dressing myself
   - ☐ I am unable to wash or dress myself

3. About my usual activities (e.g. work, study, housework, family or leisure activities)
   - ☐ I have no problems doing my usual activities
   - ☐ I have slight problems doing my usual activities
   - ☐ I have moderate problems doing my usual activities
   - ☐ I have severe problems doing my usual activities
   - ☐ I am unable to do my usual activities

4. About my pain/discomfort
   - ☐ I have no pain or discomfort
   - ☐ I have slight pain or discomfort
   - ☐ I have moderate pain or discomfort
   - ☐ I have severe pain or discomfort
   - ☐ I have extreme pain or discomfort

5. About my mood (e.g. anxiety or depression)
   - ☐ I am not anxious or depressed
   - ☐ I am slightly anxious or depressed
   - ☐ I am moderately anxious or depressed

☐ I am severely anxious or depressed
☐ I am extremely anxious or depressed

6. About my self-rated health:
   We would like to know how good or bad your health is **TODAY**. Please mark an "**X**" on the scale below and **write the number** you marked on the scale in the box. (100 means the best health you can image whereas 0 means the worst health you can image)

0 10 20 30 40 50 60 70 80 90 100

Your Health Today = ☐

Next, we would like to know a bit more about the medications you are taking. Please select <u>only one</u> statement that describes you the best.

7. How many different **prescription** medicines did you take **yesterday**? (Please include inhalers, eye drops and creams. If you take a medicine more than one time per day, only count it once.)
   ☐ 9 or less
   ☐ 10 – 12
   ☐ 13 – 15
   ☐ 16 or more

8. How many different **non-prescription** medicines, such as over-the-counter, vitamins or dietary supplements, did you take **yesterday**? (Please include inhalers, eye drops and creams. If you take a medicine more than one time per day, only count it once.)
   ☐ 0
   ☐ 1 – 5
   ☐ 6 – 10
   ☐ 10 or more

The following list of questions asks about concerns about medication and your attitudes toward stopping or reducing unnecessary and potentially inappropriate medications.

To what extent do you agree or disagree with the following statements. Please select **<u>only one</u>** option for each statement.

	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
9. My health in the future will depend on my medications.					
10. Medications do more harm than good.					
11. I feel that I am taking a large number of medications.					

	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
12. I am comfortable with the number of medications that I am taking.					
13. Having to take many medications disrupts my life.					
14. I am taking one or more medications that are not important for my health.					
15. I sometimes worry about long-term effects of my medications.					
16. I believe one or more medications is/are giving me side effects, unwanted reactions, or other problems.					
17. I feel that I may be taking one or more medications that I no longer need.					
18. I would like to reduce the number of medications that I am taking.					
19. If my family doctor said it was possible, I would be willing to stop one or more of my regular medications.					

The following list of questions asks about your opinions about shared decision making and how you feel about your relationship with your family doctor.

To what extent do you agree or disagree with the following statements. Please select **only one** option for each statement.

	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
20. The important medical decisions should be made by the family doctor, not by the patient.					
21. When different choices available, patients should have a say in which medication(s) they would like to take.					
22. If my family doctor had discussed with me about my medications, I would feel more confident that the decision made were in my best interest.					
23. I have a good understanding of the reasons I was prescribed each of my medications.					
24. My family doctor knows about all of my medical problems and my medications.					
25. I completely trust my family doctor's decisions about which medications are best for me.					
26. My family doctor keeps up with new medical information.					

The following list of questions asks about your experience with the care process in the past 12 months.

To what extent do you agree or disagree with the following statements. Please select **only one** option for each statement.

	Strongly agree	Agree	Neutral	Dis-agree	Strongly disagree
27. My family doctor has made me aware that options are available whether I should continue, reduce or stop using one or more medications.					
28. Every time there is a change in my life (i.e. onset a new symptom) my family doctor will go over my medications.					
29. My family doctor has kept a close eye on me and walked me through the process one step at a time when adjusting my medications.					
30. Sufficient amount of time has been given by my family doctor to go over my medications during my visit.					
31. My family doctor has discussed with me about medications prescribed by other providers.					
32. I feel my family doctor is reluctant to change the prescriptions ordered by other doctors.					
33. Sometimes my family doctor asks colleague's suggestions when making decisions about my medications.					

Think about the times in the past 12 months when you visited your family doctor and talked about your medications. How much effort do you feel that your family doctor has made

	No Effort	A Little Effort	Some Effort	A Lot of Effort	Every Effort
34. To help you understand pros and cons of medication choices?					
35. To listen to the things that matter most to you when it comes to taking medications?					
36. To include what matters most to you when choosing your medications?					

37. How many different medications per day would you consider to be a lot? _____

38. In the past 12 months, has any doctor **ever** told you to stop taking a medication? Please select **only one** choice that describes you the best.
☐ No
☐ Not sure or cannot remember
☐ Yes

If yes, who told you so? (Check all that apply)
☐ My family doctor
☐ A specialist, please specify which specialty: _____
☐ A pharmacist
☐ Other, please specify: _____

39. Have you ever asked your family doctor if you could stop taking a medication?
☐ No
☐ Yes

40. Have you ever tried to stop a regular medication (without your doctor's knowledge)?
☐ No
☐ Yes

41. Have you ever stopped taking a medicine (without your doctor's knowledge)?
☐ No, I am taking all of the medications I have been prescribed
☐ I am not sure or cannot remember
☐ Yes, I have stopped one or more medications

If yes, were you able to remain off the medication(s)?
☐ No, I had to restart the medication(s) or take a substitute
☐ Yes

42. Have you ever had one provider tells you one thing about a medication and another tells you something **different** about that medication?
☐ No
☐ Yes

If yes, for the most recent occurrence, which provider was involved? (Check all that apply.)
☐ My family doctor
☐ A specialist, please specify which specialty: _____
☐ A pharmacist
☐ Other, please specify: _____

45. Imagine that a **specialist** (like a heart doctor, kidney doctor or psychiatrist) prescribed a medicine for you. Would you be comfortable if your family doctor told you to stop taking it?
☐ No
☐ Yes

46. Imagine that your family doctor prescribed a medicine for you. Would you be comfortable if a **clinical pharmacist** told you to stop taking it? (This is a pharmacist that works in a clinic and has appointments to discuss medicines with patients, not a pharmacist who only dispenses your medicines at the pharmacy.)
☐ No
☐ Yes

Finally, we would like to know a bit more about you. Please select only one choice that describes you the best.

47. What is your gender?
☐ Female
☐ Male

48. How old are you?
- ☐ 65 – 69
- ☐ 70 – 74
- ☐ 75 – 79
- ☐ 80 or older

49. How do you identify yourself as?
- ☐ Caucasian
- ☐ Latino/Hispanic
- ☐ Middle Eastern
- ☐ Africa American
- ☐ East Asian
- ☐ South Asian
- ☐ Caribbean
- ☐ First Nations
- ☐ Other, please specify: _____

50. What language do you speak most often at home? If you live alone, indicate the language you feel most comfortable with.
- ☐ English
- ☐ French
- ☐ Other, please specify: _____

51. With whom have you been mainly living during the past 12 months?
- ☐ By myself
- ☐ With my spouse/common law partner
- ☐ With my children
- ☐ Nursing home or retirement home
- ☐ Other, please specify: _____

52. What is the highest level of formal education you have completed?
- ☐ No formal education
- ☐ Elementary school diploma
- ☐ High school diploma
- ☐ College diploma
- ☐ University diploma or degree
- ☐ Master's degree or higher
- ☐ Other, please specify: _____

(The End)

Thank you so much for your time and input! Please put the completed survey in the attached prepaid envelope and mail it back at your earliest convenience.

24.3. POST-INTERVENTION PROFESSIONAL SURVEY

SPIDER POST-INTERVENTION SURVEY – PROFESSIONAL VERSION

Thank you and welcome to the SPIDER Post-intervention Survey! This survey will help us understand how a **S**tructured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch, the SPIDER model was implemented in your setting.

This survey should take about 15 - 20 minutes to complete. Please click "Prev" and "Next" to navigate between pages. Your answers will be automatically saved. If you leave the survey without completing it, you will be directed to the page where you were left off the previous time. Once finished, please click "Submit" to complete the process.

Your participation is voluntary. All your answers will be kept confidential. We thank you in advance for your support and invaluable input!

First, we would like to know your overall experience with SPIDER.

1. How would you rate your satisfaction with the following SPIDER components?

	Very Satisfied	Satisfied	Neutral	Unsatisfied	Very Unsatisfied
The Learning collaborative					
The coaching experience					
The EMR feedback					

2. Were you able to make the changes you planned?
   - ☐ No
   - ☐ Yes

   a. If yes, what were the changes? _____

   _____

   _____

   _____

   b. What barriers did you encounter? _____

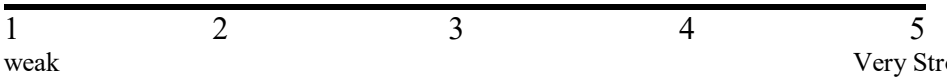
   _____

   _____

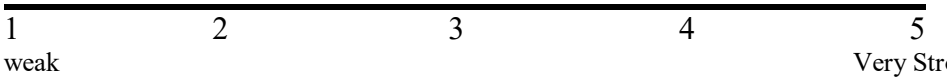
   _____

Next, we would like to know your opinions about <u>factors that could affect implementation.</u>

3. SPIDER's approach will result in fewer potentially inappropriate prescriptions for elderly patients on 10 or more medications. Based on your assessment of the evidence basis for the statement above, please rate the strength of the evidence, in your opinion, on a scale of 1 to 5 where 1 is very weak evidence and 5 is very strong evidence.



4. Now, please rate how you think respected clinical experts in your setting feel about the strength of the evidence, on a 1 to 5 scale similar to the one above.



5. To what extent do you agree or disagree with the following statements about the practice changes with regard to deprescribing.

The practice changes (deprescribing)	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
are supported by randomized controlled trials (RCTs) or other scientific evidence					
are supported by RCTs or other scientific evidence from other health care systems (hospital, specialist clinics)					
should be effective, based on current scientific knowledge					

6. To what extent do you agree or disagree with the following statements about the practice changes with regard to deprescribing.

The practice changes (deprescribing)	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
are supported by clinical experience with my patients or with patients like those in my practice					
are supported by clinical experience with patients in other health care systems (example, hospital, specialty clinics)					
conform to the opinions of clinical experts in this setting					

7. To what extent do you agree or disagree with the following statements about the practice changes with regard to deprescribing.

The practice changes (deprescribing)	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
have been well-accepted by patients in this study					
are consistent with clinical practices that have been accepted by patients in settings similar to ours					
take into consideration the needs and preferences of our patients					
appear to have more advantages than disadvantages for our patients					

Next, we would like to know your perceptions with respect to the adaptation, integration and implementation of the SPIDER approach at your practice over the past 12 months.

8. Is there collective agreement at our practice that deprescribing for elderly patients is important and worthwhile?
   ☐ Yes
   ☐ No
   ☐ Not sure

9. Have the strategies developed at the workshops been communicated to all staff at your practice?
   ☐ Yes
   ☐ No
   ☐ Not sure

10. Have the roles and responsibilities for Learning Collaborative members been assigned and clearly communicated?
    ☐ Yes
    ☐ No
    ☐ Not sure

11. Are there any periodic review and evaluation mechanism to help track progress and address any emerging issues at your practice?
    ☐ Yes
    ☐ No
    ☐ Not sure

12. How would you rate the level of support provided by the leadership of your practices?
    ☐ Very supportive
    ☐ Somewhat supportive
    ☐ Neutral
    ☐ Somewhat unsupportive
    ☐ Very unsupportive

13. Are there any additional comments or suggestions you would like to share?

_____

_____

_____

(The End)

Thank you so much for your time and input! If you have any questions or comments or would like to request a report of SPIDER study results, please contact Jamie Wang (Jianmin.Wang@nygh.on.ca).

24.4. POST-INTERVENTION PATIENT INTERVIEW GUIDE

SPIDER POST-INTERVENTION PATIENT INTERVIEW GUIDE

Opening:
Good morning/afternoon/evening and thank you for agreeing to take part in this interview. My name is _____. I'm a _[job title: (Research Assistant)]_ at _[Organization Name]_.

You have been invited because you are taking ten or more different drugs. Your family doctor is participating in the SPIDER initiative which aims to help reduce potentially inappropriate drugs you may take. SPIDER stands for the **S**tructured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch. We would like to know more about your feelings and experiences with the SPIDER process and the care you have received during the past 12 months.

The interview consists of about 12 open-ended questions and takes about 30 to 60 minutes to complete. There are no right or wrong answers; we are interested in how you feel and your personal opinions.

Before we get started, please take the time to look at the consent form which describes the study and your rights. [Go over the consent form with the patient and allow time for patient to read, contemplate and ask questions.]

As mentioned in the consent form, your participation is totally voluntary. You may withdraw at any point of time without any negative impact on your care or your relationship with your family doctor. You may choose to answer any questions you are comfortable with. As you may have noticed, the interview will be audio recorded for the study. Are there any question you would like to ask before we move on?

Interview:
First, we would like to know a bit more about your experience with the SPIDER process. Think about the visits you paid to your family doctor in the past 12 months.

1. Has your family doctor reviewed and discussed your medications with you?
   If **yes**, can you tell me a bit more about as:

   1.1. What triggered the review/discussion?
   [Prompt: Onset of a new symptom or adverse drug reaction; identifying new risk, ineffective or unnecessary medications; apparent non-adherence; change in treatment goals/priorities; hospital admission; or seeing a new doctor.]

   1.2. What and how did your family doctor discuss with you?
   [Prompt: Did your family doctor
   - Discuss that you need to stop or reduce one or more of your medications?
   - Make you aware that options for deprescribing exist?
   - Discuss the options available and their pros and cons (benefits or harms)?
   - Ask about your preferences and treatment goals?
   - Give you appropriate amount of information to help you digest?
   - Use a simple language and/or visual aids to help you understand?
   - Ensure you can give it a try and restart the medication if it does not work?]

1.3. How do you feel about the support your family doctor was giving during the deprescribing process?
[Prompt: Do you feel your family doctor has
- Allocated sufficient time to review and discuss with you during your visit(s)?
- Kept a close eye on you by asking you to come and visit more frequently during the process?
- Take actions and make suggestions whenever needed?]

1.4. How do you feel about your health? Do you feel any change(s) in your symptoms?
[Prompt: improvements; returning old symptoms; withdrawal reactions; or onset of new symptoms]

If **no**, do you think you need one? Why?

2. Have you experienced in a situation where your family doctor suggested that you stop or reduce the use of a medication that was prescribed by someone else, e.g., a heart or kidney specialist?
If yes, tell us a bit more about that case?
[Prompt:
- What triggered that?
- How did your family doctor do?
- Did you sense of any hesitation/reluctance or your family doctor was confident in doing so?
- Did you observe any sort of communication or cooperation between prescribing doctors?]

Next, we would like to know your attitudes towards multiple medication treatment.

3. How do you feel about taking a bunch of prescription medications every day?
[Prompt:
- Appropriate number or too many?
- Necessary/beneficial/effective or worried some of them cause problems and would like to stop/reduce?
- Benefits vs. harms?]

3.1. If it's possible to stop/reduce one or more medications you are currently taking, would you like a try? Why or why not?
[Prompt:
-If yes: dislike of medications, lack of effectiveness, fear of side effects past successful experience;
- If no, past failed experience; fear of returning conditions or withdrawal effects; displease my doctor]

The following questions concern your opinions about your family doctor and your decision making process.

4. Can you please tell us a bit more about how you and your family doctor make decisions whether to prescribe or reduce or stop a medication?
[Prompt:
- Who initiated the discussion?
- What was discussed?
- Who made the final call?]

4.1. Do you like such a decision making process? If yes, why? If no, why not?

4.2. To what extent do you agree or disagree that patients should be involved in making the treatment decisions? Why?
[Prompt:
- Patient autonomy, preference and engaged in managing their own health
- Patients' inadequate skills/knowledge]

5. How do you view your relationship with your family doctor?
[Prompt: trust or not]

5.1. Do you think your family doctor is knowledgeable enough to make right decisions about your medications? If yes, why? If no, why not?
[Prompt: Does your doctor
- Know about all your medical problems and medications?
- Know how to communicate with you about my medications?
- Keep up-to-date scientific evidence?
- Seek other doctors' advices?]

This is the end of the interview. Thank you again for your time and input.

24.5. POLICY-MAKER INTERVIEW GUIDE

Thank you for agreeing to take part in this interview. My name is ..... and I am a researcher from ..... I am part of a team conducting research on the SPIDER initiative which aims to help reduce potentially inappropriate drugs in elders on ten or more medications. SPIDER stands for the **S**tructured **P**rocess **I**nformed by **D**ata, **E**vidence and **R**esearch.

The interview takes about 30 minutes to complete.

Before we get started, please take the time to look at the consent form which describes the study and your rights. [Go over the consent form and allow time for the interviewee to read, contemplate and ask questions.]

As mentioned in the consent form, your participation is totally voluntary. You may withdraw at any point of time without any negative impact on your care or your relationship with your family doctor. You may choose to answer any questions you are comfortable with. As you may have noticed, the interview will be audio recorded for the study. Are there any question you would like to ask before we move on?

1. Could you please provide your views on polypharmacy?
2. What, in your opinion, might be policy levers that could address this?
3. What could be barriers? What might potentially be ways to address these?
4. What are your views on SPIDER to address polypharmacy in primary care? Was there anything else we should have considered?
5. What would make this more sustainable?

This is the end of the interview. Thank you again for your time and input.

24.6. POST-INTERVENTION FOCUS GROUP FOR PROVIDERS, MODERATOR GUIDE

SPIDER POST-INTERVENTION FOCUS GROUP MODERATOR GUIDE

[Consent form should be given prior to the focus group.]

Introduction (5 mins)

i. Welcome and explain the purpose of today's focus group:
   a. To help us understand your experience with the SPIDER process
   b. To evaluate the acceptability, implementation, adaptation, integration and practicality aspects of the SPIDER approach
ii. Housekeeping:
   a. Ground rules:
      - No right or wrong answers; everyone can speak
      - Be respectful and listen
      - Be open, honest and frank
      - Keep the discussion confidential and anonymous:
        - First name only and refrain from using identifying information
        - What's been discussed stays here
      - Speak one at a time
   b. Participants' rights:
      - Voluntary participation
      - Early withdrawal and related data handling
      - Right to request a report on study results
      - Ask to sign the consent form for those who have not yet done so
   c. Housekeeping:
      - Audio recording: purpose and confidentiality protection
      - Cellphone, bathroom and break (no break)
      - Gift cards: on way out, receipt signature required
   d. Any questions to ask
iii. Participant introductions:
   a. For the moderator: self-introduction and today's roles and responsibility
   b. For participants: first name, profession/title/role and organization/institute

[Turn on the recorder]

In-depth Group Discussion (50 mins)

[*General prompt questions for moderator:*

- *What exactly do you mean by …?*
- *Can you give me an example of …?*
- *Can you talk about that a bit more?*
- *Help me understand …*
- *How so?*
- *What else?*

- *Does anyone else feel the same way (or differently) about …?*
- *Did anyone else have a similar experience?]*

First, we would like to ask about your overall perception of SPIDER. Think about the workshops you've attended and the work you've been done with the help of the QI coach over the past 12 months. [~25 mins]

1. What is your opinion about deprescribing for elder patients with complex care needs?
2. What do you think of the SPIDER approach overall?
   [Probing/follow up questions:
   - How does SPIDER differ to other prescribing improvement work?
   - What do you like or not like about it?
   - Name one key features pertaining to the SPIDER initiative that you remember the most? Why do you nominate that?
   - How do you feel about the Learning Collaborative workshops, the use of EMR data, the work with the QI Coach and the networking with peer practice teams?
   - What do you think of SPIDER's team-based approach?]
3. What is your opinion about whether SPIDER fits with what you value the most in your practice?
   [Prompts: patient-centred care, patient outcome, quality of care, evidence-driven, necessity, sense of urgency, etc.]
4. How do you rate the amount of effort needed to participate in SPIDER? Please explain in detail.
   [Prompts: time, financial/human resources, etc.]
5. What has/have been given up (e.g., benefits, profits or values) in order to be engaged in SPIDER? Please give an example to illustrate.
   [Prompts: time, financial/human resources, work flow, etc.]
6. Compared to 12 months ago, how confident would you rate yourself when it comes to deprescribing for your elderly patients living with polypharmacy?
   [Prompts:
   - When to initiate the discussion/process?
   - How to weigh up benefits and harms?
   - How have you been communicating with patients to probe their preferences and engage them in the decision making process?
   - How have you explained medication deprescribing to your patients?
   - How to take a staged approach and keep a close eye on patients during the process?
   - How to deal with the medication that is prescribed by other clinicians?]

Move on to the next topic. Let's talk about how the SPIDER approach has been integrated into your existing practice flow and how different sectors collaborated with each other. [~20 mins]

7. Walk me through the process in terms of how your practice decided to join the SPIDER initiative.
   [Probing/follow up questions:
   - Were the aforementioned views/beliefs shared across the practice? Did the whole practice buy in?

- How did you communicate within your practice to make the decision collectively?]

8. How have you and your team done to ensure the SPIDER approach fit for your local context and be incorporated into your existing workflow?
   [Prompt:
   - How to prioritize and set the strategies?
   - Any adjustment or modification made?]
9. How have the team (physicians, nurses, pharmacists and admin staff) collaborated to get the work done?
   [Prompt:
   - Internal agreement reached at the early stage of implementation
   - Clear roles and responsibility assigned
   - Resources allocated
   - Regular communication and reviewing mechanism established]
10. In your opinion, what has facilitated the change implementation at your practice as a result of participating in SPIDER? And what has impeded? Please explain.

Last but not the least we would like to know your perceptions about the effectiveness of SPIDER. [~5 mins]

11. How do you think the SPIDER initiative has an impact on: patient outcomes; your practices; and on the healthcare system?
    [Prompts: patient health, quality of life, quality of care, provider satisfaction, and care costs, etc.]
12. In your opinion, will the SPIDER approach be sustainable and scalable in the long-run? Why or why not?

Closing (5 mins)

13. Are there any final comments or clarifications you would like to add?

Thank participants for their time and insights. Re-iterate that their input is invaluable to the success of SPIDER initiative; then turn off the recorder and close out.

24.7. EUROQOL-5D

Under each heading, please tick the **ONE** box that best describes your health **TODAY**

MOBILITY:

- ☐ I have no problems in walking about
- ☐ I have slight problems in walking
- ☐ I have moderate problems in walking about
- ☐ I have severe problems in walking about
- ☐ I am unable to walk about

SELF-CARE

- ☐ I have no problems washing or dressing myself
- ☐ I have slight problems washing or dressing myself
- ☐ I have moderate problems washing or dressing myself
- ☐ I have severe problems washing or dressing myself
- ☐ I am unable to wash or dress myself

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- ☐ I have no problems doing my usual activities
- ☐ I have slight problems doing my usual activities
- ☐ I have moderate problems doing my usual activities
- ☐ I have severe problems doing my usual activities
- ☐ I am unable to do my usual activities

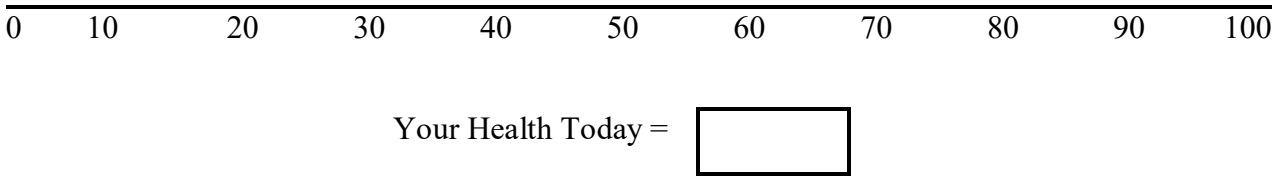
PAIN/DISCOMFORT

- ☐ I have no pain or discomfort
- ☐ I have slight pain or discomfort
- ☐ I have moderate pain or discomfort
- ☐ I have severe pain or discomfort
- ☐ I have extreme pain or discomfort

ANXIETY/DEPRESSION

- ☐ I am not anxious or depressed
- ☐ I am slightly anxious or depressed
- ☐ I am moderately anxious or depressed
- ☐ I am severely anxious or depressed
- ☐ I am extremely anxious or depressed

We would like to know how good or bad your health is **TODAY**. This scale below is numbered from **0** to **100**. **100** means the best health you can image. **0** means the worst health you can imaging. Mark an X on the scale to indicate how your health is **TODAY**. Then **write the number** you marked on the scale in the box below.


0 10 20 30 40 50 60 70 80 90 100
Your Health Today =

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