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1.0 RESEARCH OBJECTIVES OF THE LIVING WITH HIV (LHIV) INNOVATION TEAM

HIV is an increasingly complex chronic condition and disproportionately affects marginalized populations, requiring a new paradigm of HIV care delivery. Sixty-five thousand Canadians live with HIV(1) and this prevalence is increasing as people being treated live full life spans. In response, we propose a multi-centre, multi-jurisdictional program of linked research-to-action projects that will advance an innovative integrated care model for HIV, with transferable potential to improve care for other complex chronic conditions.

In Canada, HIV has been managed largely by specialists and providers in HIV-focused practice rather than by general primary care providers(1). This disease- rather than population-based approach has led to substantive care gaps that leave the majority of people with HIV without comprehensive care, despite our universal healthcare system (Figure 1)(2). We do not have a way to reach people diagnosed with HIV who have not yet linked to HIV care (Gap 1). In Ontario, only 70% of people diagnosed with HIV between 1997 and 2004 had a first viral load (VL) test within six months of diagnosis(3). We also do not know whether these individuals ever enter care (Gap 2) or whether those who receive VL testing go on to have sustained, comprehensive care including combination antiretroviral therapy (cART)(3). We do know that frequency of care is often inadequate (Gap 3)(4), which may result in delayed cART, viral load rebound, lower CD4 counts, drug resistance, and ultimately increased transmission and mortality(5–11). Receipt of cART is currently our most important indicator of quality of HIV care, but cART alone is not an adequate measure of the health and well-being of this population, much less the quality of care. We must establish a more meaningful and comprehensive set of indicators, including patient experience (Gap 4), and ensure that this performance measurement leads to actionable information for key stakeholders (patients, providers and policymakers) (Gap 5)(12).


Figure 1. Continuum of HIV Care
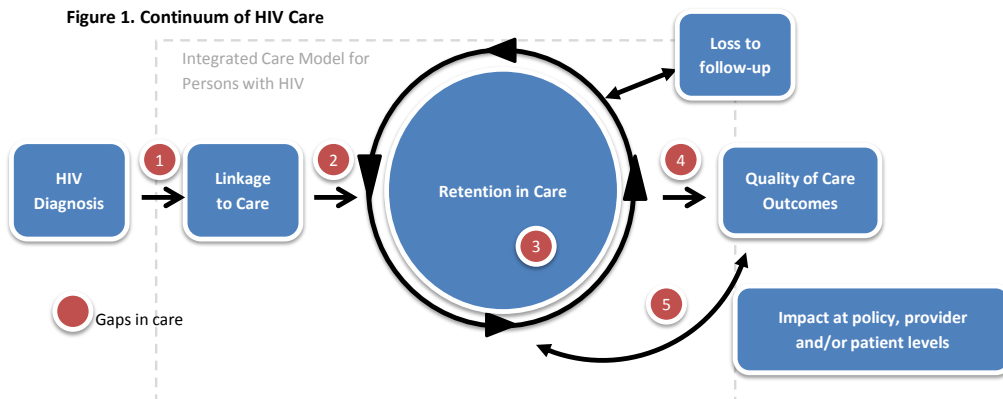
We propose that shifting the routine management of people living with HIV from specialized clinics to the community-based primary healthcare setting will make the most effective use of the skills and resources within our healthcare systems and lead to improved quality of care. We adopt the Expanded Chronic Care Model (E-CCM) as a framework for understanding how the principles of chronic disease management and prevention can be applied to this vulnerable population (Figure 2). We hypothesize that an approach to care grounded in the key aspects of the E-CCM (a population-based, patient-centred, integrated team approach with decision support) will improve the health of this population, improve the patient experience of care, and reduce costs(13).

WE HAVE FOUR MAIN OBJECTIVES:
1) To create a better understanding of the health, healthcare utilization, and quality of care of persons living with HIV.
2) To implement and evaluate an integrated care model for HIV care delivery in our affiliated clinics.
3) To examine the patient's perspectives of receiving care through a primary healthcare approach.
4) To build the Living with HIV (LHIV) Innovation Team (Appendix 1): a new, highly skilled, interdisciplinary HIV primary healthcare team including researchers in primary and HIV care delivery, clinicians, community-based agencies, people with lived experience, and policymakers.

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Figure 2. Living with HIV (LHIV) Innovation Team projects mapped to the Expanded Chronic Care Model
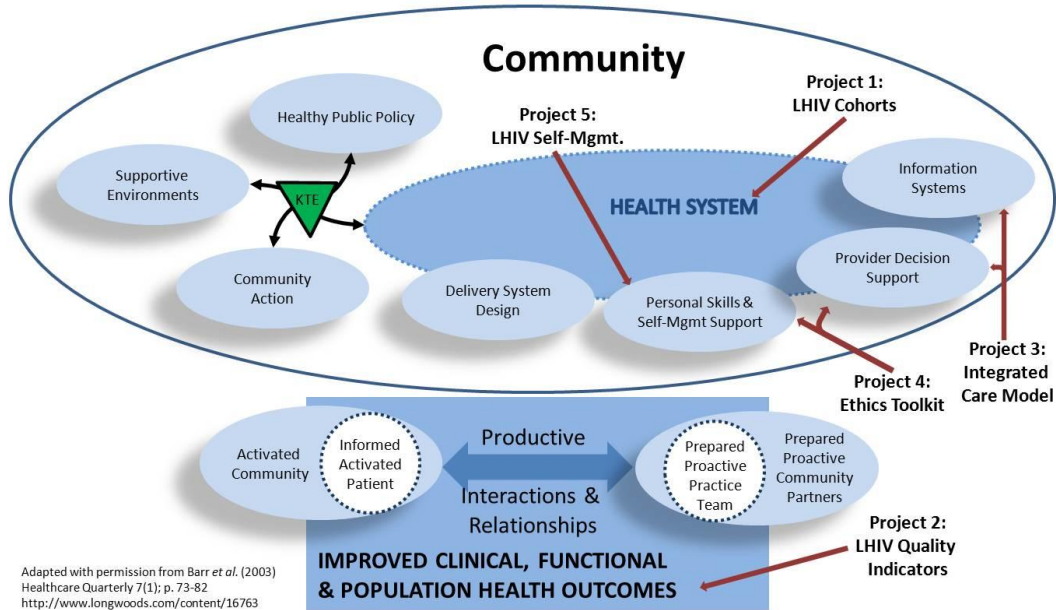
To meet these objectives, we will start with the creation of comprehensive population cohorts of people living with HIV (Living with HIV (LHIV) Cohorts). Our team has unique access to and experience with cohort and provincial health administrative data that we will use to explore HIV-related disease burden, including mental health comorbidities and addictions that compound barriers to care, across three provinces (Ontario, Manitoba, and Newfoundland and Labrador). These cohorts will allow us to make important comparisons about regional variations in health and healthcare use based on actual utilization patterns (Gaps 2&3) and to identify times and places for engaging with people diagnosed but not in comprehensive care earlier in the course of their disease trajectory (Gap 1). Through these cohorts, we will better understand the population from a patient, provider, and system perspective, and will evaluate key organizational attributes of quality of HIV care in our affiliated practices, each with varied existing models of care delivery (Gap 4). These findings will strengthen policy recommendations related to optimal models of care delivery (Gap 5). To inform this work, we will develop the first Canadian quality indicators for comprehensive HIV care, using emerging capacity in performance measurement for HIV care. This work makes a fundamental contribution to CIHR's Joint Technical Steering Committee by establishing a common set of outcome measures for those living with HIV. By collaborating across traditional silos, this work will be at the forefront of chronic disease management and will hold important lessons for the management of many chronic conditions. (**Objective 1; Projects 1&2**)

Second, we will support an integrated care delivery model for HIV through the establishment of an electronic consultation service between specialists and primary care providers. Greater attention to service coordination and continuity of care will be fundamental to shifting care from the specialist HIV provider to the primary care settings(14). Kodner describes integrated care as "a holistic, person-centred approach to addressing multiple needs of individuals with complex conditions"(14). An innovative electronic consultation platform that links primary and specialist care will support transitions in care and ultimately improve the patient experience and quality of care. We will leverage our partnerships with our community providers in the implementation of the service as well as the development and dissemination of best-practice guidelines and decision-support education tools. (**Objective 2; Project 3&5 & KTE activities**)

Third, we will improve our understanding of the patient's perspective so that we can be responsive to barriers to accessing and utilizing care as they arise. We will use rich qualitative methods to provide new insights into the ethical concerns raised in HIV care from the perspectives of primary care providers, specialists, and people living with HIV. These findings will inform the **development of a framework and**

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provider toolkit to guide decision-making in the context of ethical challenges related to treating persons with HIV. We will also gain insight into how people living with HIV can manage their chronic conditions so that providers and policymakers can incorporate **self-management support** into HIV care. (**Objective 3; Projects 4&5**)

Fourth, we are a national, multi-centre interdisciplinary team led by primary and specialist care clinicians and researchers with demonstrated, internationally recognized expertise in the fields of chronic disease management and HIV care. We are uniquely positioned to build the research capacity to champion this effort and the requisite data, support and infrastructure to meet our objectives. We will implement interventions through our several affiliated clinics and networks and through connections with collaborating community-based agencies. Our three provinces represent the Canadian breadth of challenges in the delivery of care for HIV and other complex chronic conditions, including delivery in remote and rural regions, care of specific marginalized populations such as Aboriginal groups, and the impact of social determinants on health inequities.

Relevance to funding opportunity objectives: Our program is designed to directly respond to the needs of the CIHR priority population of **people living with HIV/AIDS** as we will optimize outcomes related to **HIV and aging**. We meet both targeted research areas of this CBPHC funding opportunity through our focus on **improving chronic disease prevention and management** and **improving access to appropriate care for vulnerable populations**. The populations most affected by HIV face inequities related to stigmatization, gender, ethnicity, mental health issues, substance use, and the broader social determinants of health (e.g., poverty, unstable housing). In addition, the issues addressed in our program are highly relevant to other complex chronic conditions and to the broader Canadian population where multi-morbidity is increasingly the norm and consumes large primary care resources(15).

2.0 LITERATURE SUMMARY
As people with HIV age, their healthcare becomes increasingly complex; they face co-morbidities associated with aging, such as cardiovascular disease, diabetes, cancer, and liver disease, as well as neurocognitive disorders related to HIV and cART treatment(16–19). When HIV was still considered a terminal illness, studies showed that HIV specialists (vs. general care providers) and those with higher HIV caseloads provided a higher quality of care as measured by disease-specific indicators(20–25). Today, however, it is increasingly recognized that HIV specialists are less comfortable and less proficient in preventive care(26–28) and in managing the co-morbidities commonly associated with chronic HIV, such as diabetes and hyperlipidemia(26,29–33). **Shifting HIV care into the primary healthcare community will more effectively meet the needs of these patients. (Objective 1; Project 1&2)**

Primary care, with its core values of first point of access, continuity, comprehensiveness and coordination of care, is the foundation of strong health systems. Populations with access to good primary care are born healthier, live longer, have lower usage of emergency departments, fewer hospital admissions, lower all-cause and cause-specific mortality, and better self-reported health, even after adjustment for socioeconomic and lifestyle risk factors(34–36). Access to primary care is also associated with improved prevention and management of chronic disease by reducing inefficiencies and mitigating inequities(36). Although primary care forms the backbone of healthcare in Canada, **we know little about how HIV is managed in community settings and how to integrate HIV-specific expertise with the benefits of primary care for this aging and increasingly diverse population**(12)**. (Objective 2, Project 3)**

The Chronic Care Model developed by Wagner et al.(1) identifies six essential elements for appropriate care of people with chronic diseases: community linkages, healthcare organization, delivery system redesign, clinical information systems, decision support, and self-management support. Taken collectively, these six elements are intended to produce effective interactions between *proactive prepared* practice teams and *informed activated* patients who take an active part in their care. The end result is better functional and clinical outcomes, greater provider and patient satisfaction, and increased cost-savings(19-22). In Canada,

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many jurisdictions have adopted an Expanded Chronic Care Model (E-CCM, Figure 2) [developed by Barr et al.](23), in which chronic disease prevention and management strategies target both the health system and community elements to improve care and to reduce the burden of disease on individuals, communities, and the health system(23). Through the lens of the E-CCM, Canadian provinces have invested intensive resources in developing new models of primary care. Their organizational characteristics are generally reflected in components of the E-CCM (e.g., population approach, delivery system design, clinical information systems), but these models vary substantively(37). Measuring the specific organizational features associated with improved care is essential to understanding quality of chronic care delivery(38). A limited literature describes that certain E-CCM components such as delivery system redesign(39) and decision support and clinical information systems(40) (Appendix 2) improve some aspects of HIV care, and that self-management strategies are similar to those for other conditions(41). However, these studies were heterogeneous, often population-specific and lacked sufficient detail to direct policy. **While the E-CCM provides a guiding framework for the work required to shift HIV care from a specialist to a primary chronic care approach, research is required to understand the association of each element of the E-CCM in improving care for persons with HIV. (Objective 1, 2&3, Project 1, 3&5)**

A handful of studies have explored how best to support a primary care approach to HIV care that allows timely, continuous access to specialist expertise. The interprofessional provision of care by new types of allied health professionals(42), co-management(28), community-based versus hospital-based practices(43), and telephone consultants(44) have all shown promise. However, these strategies, which rely chiefly on co-location and synchronous communication between physicians and other allied care providers, are impeded in many parts of Canada by small numbers of HIV specialists, long wait times, geographic barriers, lack of specialized equipment (e.g., for telemedicine), and outstanding privacy concerns. **To shift HIV care to community-based primary healthcare, interventions that facilitate simple, prompt and regular communication between HIV specialists and primary care providers must be implemented and evaluated**(44). **(Objective 2, Project 3)**

Chronic disease self-management (CDSM) is a key component of the E-CCM. The goal is to ensure that people with HIV are partners with their primary care providers in their own care. Characterizing HIV as a chronic disease to be managed within primary care – and supporting self-management effectively – will require patients and healthcare professionals to navigate ethical issues common to other chronic diseases, such as non-adherence to treatment, duty of care, and access issues. In addition, HIV gives rise to specific ethical challenges related to stigmatization, criminalization, and marginalization(45,46). **Understanding the patient's perspective and the complexity of such ethical challenges in the practice of integrated care is vital to anticipate and respond to areas where patient-centeredness may be at risk and to identify potential for resolution as we implement our interventions**(47). **(Objective 3, Projects 4&5)**

3.0 PROGRAMMATIC RESEARCH APPROACH AND SCHEDULE OF WORK:

PROJECT 1. Creating comprehensive provincial population-based cohorts of persons living with HIV (LHIV Cohorts) to compare health, utilization and quality of care across jurisdictions (Gaps 1,2&3 (linkage to, entry into and retention in care))
Lead investigators: Rourke, Kendall, Manuel, Bayoumi, Glazier, Becker, Yu, Caetano, Ashghari
Research objectives: (a) To describe and compare the burden of disease for persons living with HIV, including morbidity, mortality, and self-reported health across different jurisdictions; (b) To develop a care typology representing different ways in which care is provided and compare rates of healthcare utilization by care typology; (c) To study differences in quality of care (process measures and health outcomes) by care typology; (d) To identify patient, provider and organizational characteristics that are associated with improved quality of care; (e) To describe the costs of care for people living with HIV by care typology; (f) To identify opportunities for better and earlier linkage to care for those not accessing regular HIV care.

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Data sources: Appendix 3 identifies the data sources that will be linked to develop comprehensive provincial cohorts. Types include health administrative, public health lab, clinical (from existing cohort studies or development of cohorts from chart abstractions) and prescription drug (where available). Appendix 4 contains a separate list of data source acronyms. Appendix 5 provides a detailed description of the Ontario Cohort Study.

Patient demographic and clinical variables: Relevant variables from all provincial data sources are listed in Appendix 6. Not all will be used in our primary analyses but will be explored as hypotheses emerge.

Provider and practice/organizational characteristics (Appendix 6)**:** Some organizational features of care can be extrapolated or derived from health administrative data. In addition, a member of our team (Hogg) working with the Canadian Institute for Health Information has coordinated the development of a community-based primary care organizational survey which is ideal for determining the characteristics of practices that may be associated with better outcomes(48). For practices in our defined linked cohorts (Appendix 3), we will use this survey to delineate organizational features of care such as EHR use, team composition, and after-hours access. The survey is designed to be completed by an office manager rather than a provider, and due to our relationship with these clinics we anticipate a very high completion rate.

Outcomes: *Health care utilization* outcomes are outlined in Appendix 8. Project 1 will guide us in the selection of *quality indicators* (preliminary outcomes list in Appendix 9) that are relevant for HIV PHC care. Many of these indicators have already been operationalized into health administrative databases(49) and will be otherwise further explored through the cohort data.

Case ascertainment of persons living with HIV: In Ontario, we will apply a previously validated algorithm (developed by members of our team) to the health administrative data of people 18 years of age and older and living in Ontario on April 1, 2008. Briefly, this algorithm uses 3 physician claims over a 3-year period and has a sensitivity and specificity of 96.2% (95% CI 95.2–97.9%) and 99.6% (95% CI 99.1–99.8%) respectively for identifying people living with HIV and receiving HIV care (Appendix 10)(50). This algorithm estimated there were 12,179 HIV-positive Ontarians were in care between April 1, 2007 and March 31, 2009 (44.4% of the 27,420 individuals estimated to be living with HIV in Ontario in December 2009(51). As all of our settings have low population prevalence of HIV, it is feasible that this algorithm will identify several people who are not, in fact, HIV positive, thus we will use positive HIV tests and VL tests from public health to further increase specificity in each province (see below). This algorithm will be applied to and further validated in the MHIS (MB) and NLCHI (NL) databases, recognizing that in current form the algorithm will not capture NCCHC data (no physician billing) or the ~30% of NL physicians who do not bill fee-for-service.

Generation of the LHIV Cohorts: Comprehensive provincial cohorts of people living with HIV (Appendix 11)**:** For each province, we will generate a comprehensive population cohort of people living with HIV who are alive and in the province on April 1, 2009. Records will be extracted from each data source and anonymously linked by provincial identifier. Individuals will be assigned to the cohort hierarchically (+HIV test, +VL test, in existing cohort, meets HIV algorithm) with duplicates excluded.

Data analysis (outlined by objective):

(a)Describe and compare burden of disease. This analysis will be performed on all individuals in our LHIV cohorts. We will present demographic and clinical characteristics of persons with HIV in the three jurisdictions using descriptive statistics (mean+ SD for continuous variables with symmetrical distribution or median +IQR if skewed, frequencies and proportions for categorical variables). To describe the burden of disease for persons living with HIV, we will present estimated rates of morbidity and mortality, together with 95% confidence intervals (outcomes in Appendix 9). Comparisons across the three jurisdictions will be presented using chi-squared tests for categorical variables and ANOVA for continuous variables.

(b)Characterize patterns of care. This analysis will be performed on all individuals in our LHIV cohorts. To develop a care typology for people living with HIV, we will first determine 4 rates for each patient: primary care visits for HIV, primary care visits for other diagnoses, specialist visits for HIV, and specialist visits for other diagnoses. Observed distributions for these rates will be investigated to determine possible cut-points for high or low visit rates, and these will then be used to create mutually exclusive categories

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corresponding to our underlying hypotheses. We anticipate that the typology will approximate the following 5 categories: (i) care mostly by an infectious disease specialist, (ii) care mostly by a focused generalist/family physician, (iii) care mostly by a comprehensive family physician, (iv) shared care by a comprehensive family physician and specialist physician, and (v) sporadic receipt of healthcare services. The distribution of care typologies will be described and compared across jurisdiction using chi-squared tests. We will describe the demographic and clinical characteristics of persons in each care typology. We will use Poisson regression analyses to compare rates of healthcare utilization (ambulatory visits, emergency department visits, hospitalizations) among care typologies, with log-patient follow-up time specified as an offset term, and typologies specified as a categorical variable. Secondary analyses will investigate adjustment for patient demographic and clinical characteristics (e.g., age, sex, years since immigration, ethnicity, rurality index, marginalization index, residence in low-income neighborhood, number comorbidities, ACG score, time since first +HIV test) that may be potential confounders.

(c)Evaluate differences in quality of care and health outcomes. We will describe quality indicators using proportions, with 95% confidence intervals (see Appendix 9 for specific process and outcome indicators that will be investigated and then refined in Project 2). Results will be compared across jurisdictions and care typologies using chi-squared tests. Secondary logistic regression analyses will be conducted to adjust for patient demographic and clinical characteristics (as above). We will first conduct the analysis using only covariates and outcomes available from the health administrative data; thereafter, further associations will be explored using cohort data.

(d)Identify patient, provider and organizational characteristics associated with quality of care. We will conduct a series of multi-level logistic regression analyses to identify patient, provider and organizational characteristics associated with improved quality of care (process and outcome quality indicators). To conduct the multi-level analyses, each patient will first be associated with a most responsible provider (MRP). The quality indicators will be considered as dependent variables for these analyses. Provider and practice characteristics, (as identified in Appendix 7) will be entered as independent variables in the models, including features such as specialty, volume of HIV care, primary care model (if relevant), use of EHR, availability of after-hours access. Provider and practice will be specified as random effects to account for intra-practice correlations. This analysis will be performed on all individuals in our 15 clinical cohort sites (Appendix 3). We will first conduct the analysis using only covariates and outcomes available from the health administrative data and survey instruments; further associations will then be explored using cohort data, which has a richer set of variables, but may be subject to selection biases.

(e)Describe the costs of care for people in different types of models. This work will first be done in ON due to this team's expertise in working with data housed at the Institute for Clinical Evaluative Sciences (ICES) for cost analysis, and will be extended to other jurisdictions once the methodology and measures are refined. The economic evaluation will assume a single government payer and focus on direct costs, as the largest proportion is government funded, and the costs of different models are of most interest to policymakers and government. We will ascertain the costs of physician billings, hospitalizations, and emergency department visits from April 1, 2009, to March 31, 2010, using standard methods (Ontario Case Costing Initiative, www.occp.com). Data will be adjusted to standard dollars for that year. Inflation and cost-of-living will be used to adjust prices.

(f) Identify earlier opportunities for linkage to care. We will pay special attention to the healthcare utilization patterns of people identified as diagnosed with HIV who are not engaged in HIV care (typology v) to determine possible missed opportunities for linkage to care, such as repeat emergency department visits, ambulatory care visit without HIV diagnoses from multiple providers, or other STI diagnoses.

PROJECT 2. Delineating cross-cutting (HIV/PHC) quality indicators to create a Canadian LHIV Performance Framework that will drive system improvement (Gaps 4 (outcomes) and 5 (impact))
Lead investigators: Johnston, Burchell, Loutfy
Research questions: (a) What measures of quality of primary health care are of greatest importance to different stakeholders (people living with HIV, specialist HIV care providers, primary HIV care providers,

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regional and provincial policy-makers and administrators, and community organizations and advocacy groups), and which are common across stakeholder groups?; (b) How can HIV and PHC performance data be used by different stakeholders to improve HIV care and outcomes?; (c)What is the best way to report this information back to stakeholders to facilitate collaboration in improving HIV care?

Methodological approach: We will use qualitative methods including a narrative literature review and semi-structured interviews with a diversity of stakeholders to explore the importance and potential use of the many performance indicators emerging from growing research in the fields of PHC performance measurement and HIV care as a complex adaptive system(52).

Performance Framework development: We will perform a literature search for HIV-specific performance indicators and performance frameworks in developed settings(4,53,54) and will map these to a Canadian PHC organization performance framework(55) (Appendix 12). This will enable us to develop a Canadian LHIV Performance Framework and indicators grounded in PHC service delivery yet which include the crucial connections with specialty care. We will assess each of the indicators according to established criteria(56), based on published reports of testing, our interviews with key stakeholders, and our work in Project 1 to develop Canadian data sources and data collection methods, to promote those most likely to be effective in measuring and improving care. Given the evolving nature of HIV PHC and the need to learn with multiple stakeholders in the field, we anticipate an iterative cycle of using and revising the framework based on two-way knowledge exchange with stakeholders, particularly in identifying methods of influencing HIV care across stakeholders and important performance dimensions(57,58). This framework will guide the quality of care measurement in the LHIV cohorts (Project 1) and the evaluation of e-consultations services (Project 3).

Sampling and recruitment: We will use a snowball sampling strategy to recruit interview participants starting with our team's extensive network of stakeholders. Given our extensive contacts and the leadership reputation of team members, we will recruit potential participants with an initial introductory email from our research team. We will seek to capture perspectives from a wide array of experiences and expertise by aiming for diversity of region, practice type, community representation, and policy role and level and anticipate several stakeholder groups (including persons living with HIV, specialist HIV care providers, primary HIV care providers, regional and provincial policy-makers and administrators, and community organizations and advocacy groups).

Data collection: A research assistant will perform semi-structured interviews with consenting stakeholders. We will use an adapted Stakeholder Engagement Framework (Appendix 13)(59) to capture and organize key information such as performance indicators of greatest importance to specific stakeholders and mechanisms of influence on HIV PHC delivery. We will use the Canadian LHIV Performance Framework with interviewees to identify relevant performance domains as well as to assess the comprehensiveness and validity of the framework to Canadian stakeholders. We will aim for a minimum of 5-10 interviews per stakeholder group and will interview within stakeholder groups until theme saturation is achieved, or 10 interviews are completed, ensuring significant input by that group.

Data analysis: Interviews will be recorded and transcribed. Analysis will adopt an initial template organizing style(60) using the Stakeholder Engagement Framework to derive an initial coding manual. Transcripts will be coded by two research assistants initially double coding and comparing results to discuss interpretation of codes until similar coding is achieved, then single coding will take place(61). Retrieved segments for each code will be subsequently analyzed using an immersion/crystallization approach(62) to explore common themes. We will identify which indicators are most important to given stakeholders, which are common between groups, and the potential ways performance indicators can influence collaboration between stakeholders. Additionally, we will explore how these indicators can be measured through our other projects. To promote the rigor of analysis in this project, we will present our findings back to stakeholders and interview participants to seek validation or additional feedback.

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PROJECT 3. Implementing an integrated care model through electronic consultation (Gap 3 (retention in care))

Lead investigators: Liddy, Becker, Farrell

The objective of this project is to scale up a successfully designed and implemented e-consult pilot(63)(Appendix 14) into a multi-site project in three provinces (NL, MB, ON) to specifically improve access to care for persons with HIV. Using a pre-existing secure web-based collaboration space, primary care providers (PCP) submit a patient-specific clinical question to a regional specialist using a standardized electronic form that permits the addition of supplementary attachments (e.g., laboratory results, digital images). The specialist responds within 1 week by either directly answering the question (negating the need for referral), asking for additional patient information, or requesting an in-person referral (Appendix 15). We have processed over 500 e-consultations with an overwhelmingly positive response from both PCPs and specialists. In 43% of cases, a face-to-face consultation would have been necessary had our e-consult system not been available (Appendix 16).

Research questions: (a) What is the impact of an e-consultation service on specialist HIV care (access to care, timeliness of specialist service, proportion of visits avoided, potential cost savings)?; (b) Can an e-consultation service be used to provide subsequent follow-up consultations from specialists to subspecialists (e.g., HIV specialist to dermatology subspecialist)?; (c) How is communication between PCPs, specialists, and subspecialists affected by e-consultation?; (d) What is the patient's perspective of accessing specialist care electronically?; (e) Can evaluation of e-consults identify opportunities for community-based educational sessions for PCPs?

Methodological approach(63):

Step 1. Stakeholder engagement: In each partner province, we have already identified and engaged local partners from the primary care and specialist communities as well as e-health implementation partners. All regions have confirmed that the collaboration space (Sharepoint) is available via secure networks to host the platform and will be supported locally. This will enable us to transfer existing workflows, e-forms and training modules to each region (see letters of support).

Step 2. Adaptation and development: We will expand on the current e-consultation service through the adaptation and development of workflows and new e-forms in two ways. First, we will build on the current service to include an HIV speciality service as one of the available PCP selections. Second, we will expand the service to enable specialist-to-specialist consultation to enable HIV specialists who need to access sub-specialists such as cardiology, endocrinology and dermatology; this service would also permit the PCP to remain connected to the care that their patients are receiving (with patient consent) by being 'linked in' to the conversation between the specialists, ensuring a tight circle of care.

Step 3. Training of users: We will train specialty physicians/services and primary care providers to use the e-consult service.

Step 4. Launch of services: Along with ongoing support including physician engagement, we will stagger the launch of the e-consultation services – ON and MB in the first phase and NL in the second phase – with adjustments made from lessons learned.

Step 5. Integrated and ongoing evaluation: We will use a mixed-methods evaluation approach to examine the implementation of e-consultation, with a focus on the usability and utility aspects of this system with a specific focus on provider communication and patient safety(64). Quantitative analysis: We will collect information on all referrals made during the implementation phase from the e-consultation database in order to understand patterns of usage, the capacity to reduce avoidable referrals, the potential for identification of community-based learning opportunities for providers, the ability of an e-consultation system to improve physician-to-physician communication, and potential system cost-savings of these avoided referrals. For a preliminary list of the quantitative metrics, see Appendix 17.

Qualitative analysis: Attitudinal information regarding the efficiency of the consultation process and communication between the relevant parties will be measured using semi-structured interviews with PCPs, specialists, administrative staff, and patients to obtain feedback on the value and shortcomings of the e-consult system and on the feasibility of using this automated system to replace current approaches for

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specialty referrals. Data will be evaluated using a constant comparative approach with a combination of inductively and deductively determined codes. Initial coding will be developed by an experienced qualitative researcher and refined with the assistance of other team members. Anticipated metrics for the semi-structured interviews are outlined in Appendix 18. Qualitative data will be evaluated using NVIVO™10 software.

PROJECT 4. Developing a toolkit for providers navigating ethical issues arising in practice (Gap 3 (retention in care))
Lead investigators: Kaposy, Allison, Marshall
Phase 1: Using Institutional Ethnography to examine complex relationships in settings where people with HIV seek medical care
Research questions: (a) What are the key ethical concerns raised in interactions between clinicians and patients in the context of HIV care?; (b) How do primary care clinicians, specialists, and people living with HIV navigate these ethical dilemmas?; (c) How do stigmatization, criminalization, and racialization complicate the management of ethical concerns?; (d) Do these ethical challenges differ depending on setting (primary care, specialist, community-based program), province (ON, MB, NL), location (urban, suburban, rural) or population (e.g., intravenous drug users [IDU], men who have sex with men [MSM]); (e) What tensions arise where the person living with HIV is expected to be engaged in the "treatment as prevention" paradigm"?; (f) What practical strategies are recommended for PCPs in order to better manage ethical challenges in providing HIV care?;

Methodological approach: Institutional ethnography (IE) is a qualitative method of critical inquiry that has been used to successfully explore the interactions between physicians and people living with HIV as well as broader organizational and community structures(65,66). IE provides rich data on the importance of interactions, relations of power, and the role of texts in organizing social relationships(47,67). Through overlapping analytical approaches, IE looks critically at work processes(68,69) and explores *how* things happen (how social relations unfold) rather than *why*(68).

Settings and populations: We will collaborate with seven clinics already participating in our team in order to reflect maximum variation in terms of type of clinic (community- or hospital-based), clinical service focus (specialist or primary health care), populations served (e.g., IDU, MSM, women, Aboriginal), and the size and geographic location of the community (urban, rural, remote).

Data collection: A postdoctoral fellow with experience in IE will collect data from three sources of IE discourse: non-participant observation, semi-structured interviews, and textual analysis (Appendix 19).

Data analysis: We will use discourse analysis from these data sources to unveil ethical dilemmas in practice(70). Discourse analysis will examine the processes by which language and authority might overlap and how the very social conditions of being HIV positive are shaped by discourse(71,72). Interviews will be captured in detail using a process of naturalized transcription in which verbal and nonverbal communication are recognized as conveying information on relations of power and the meanings associated with the interaction(73). Researchers will then identify analytic themes and discursive patterns, using NVIVO™10 software to manage the data. From these themes, an emerging analysis will be developed and will be triangulated with data from the textual analysis and observation field notes.

Phase 2: Developing the ethics toolkit
Research question: What decision-making model(s) in the clinician-patient relationship will enable providers and patients to resolve ethical issues that emerge in primary care for people with HIV?

Methodological approach: We will conduct a conceptual analysis of the ethical concerns identified in Phase 1 and propose solutions grounded in well-supported ethical norms. We refer to this as a "discursive" process because we will arrive at solutions through discussion, structured dialogue, and consultation with experts and stakeholders. We will move through the four steps commonly employed in decision-procedures for solving ethical dilemmas in healthcare(74,75) (Appendix 20).

Toolkit development: We will use the data from this process to develop a framework and corresponding toolkit for providers describing common ethical issues arising in the care of people living with HIV in

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CBPHC settings and concrete step-by-step decision-making strategies for practitioners and teams to resolve these issues in care(76). In consultation with our stakeholders, we will develop workshops and webinars for healthcare providers. These educational sessions will be case based and enable participants to become familiar with applying the tools to ethical issues that commonly arise in clinical HIV practice.

PROJECT 5. Seed project: Implementing and evaluating LHIV self-management tools and supports (Gap 3 (retention in care))
*Lead investigators: Liddy, Johnston*
In years 4 and 5, we will seek additional funding to address the issues related to self-management support for persons with HIV. We are well positioned as our current team includes nationally recognized chronic disease self-management experts (Liddy&Johnston)(Appendices 21&22)(77–79). We have identified partners (Wellness Institute, Seven Oakes General Hospital, MB; Living Healthy Champlain, ON;) who are interested in further development and evaluation of self-management support group programs derived from the Stanford Patient Education Research Centre (Positive Self-Management Program for HIV, or PSMP)(80,81). In addition, OHTN is developing a series of online self-management tools (PHA Tools) that can be accessed by computer or smartphone to help people organize their health information (lab results, medications, diagnoses), link to trusted sources to empower them with knowledge about their health, and facilitate their conversations with healthcare providers.

In this project, we initiate the implementation and evaluation of these self-management support strategies using two approaches. First, working with identified partners who both hold a license to run the PSMP, we will evaluate the program's reach and overall effectiveness. Based on the team's previous experience in evaluating CDSM programs(77,78), we will develop an evaluation strategy tailored for participants. Participants will be asked to complete surveys that evaluate the suitability and effectiveness of the PSMP to support their self-management at baseline and 6 weeks. The evaluation, surveys and additional qualitative data from interviews and/or focus groups with participants and health care providers, will be examined using qualitative analysis techniques. Second, we will pilot the use of PHA Tools with persons with HIV and their primary care providers in the greater Toronto area. Are they an effective self-management support? Do people using PHA Tools feel more knowledgeable and more confident about managing their health? Are they better able to adhere to medications and do they experience better health outcomes? From the provider perspective, do patients seem better able to manage their health? Does the information lead to better conversations about their care and treatment? This pilot will form the foundation of subsequent randomized controlled trials and will also be ideal for a graduate student to lead.

SCHEDULE OF WORK FOR OUR PROGRAM OF RESEARCH:

Figure 3. Schedule of Work
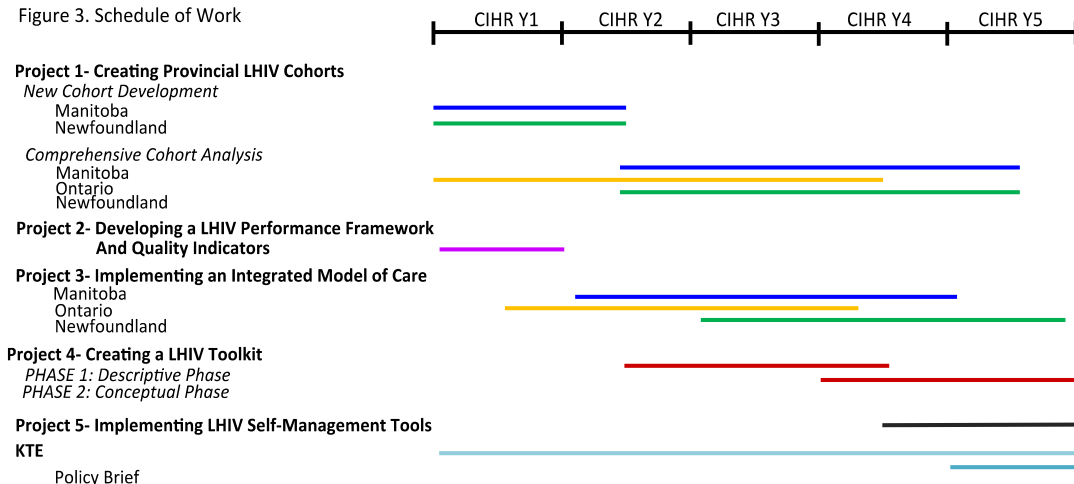
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4. 0 NATURE OF OUR LIVING WITH HIV (LHIV) INNOVATION TEAM AND TEAM ENVIRONMENTS
Our LHIV Innovation Team is comprised of regional networks of highly-accomplished researchers, methodologists, health professionals in primary and HIV care, policymakers, and people with lived experience across four jurisdictions (MB, ON, NL, NB) who are committed to directing our research program and achieving our goals (Appendix A and Applicant Table). Our team is deliberately large and diverse in order to optimize the expertise of the many disciplines required to do this work (health services research, chronic disease management, performance measurement, community engagement, qualitative and qualitative methods, the ethics of healthcare delivery, program implementation and evaluation in complex PHC settings, and knowledge translation). As shown in Appendix 1, cross-pollination across disciplines has already begun in a way that could not occur if each project was funded through operating grants alone; it is this overarching structure, reflecting the complexity of the shift from specialist to primary care approach in HIV care, that will maximize our productivity, relevance, and output. Our investigators represent both national and international leaders in their fields and have the experience and capacity to leverage team synergy to help manage complex team function, mentor junior investigators and trainees, and build from our platform towards future operating grants. This platform will also be used effectively to support broad implementation of successful interventions and dissemination of our results across Canada and internationally. In support of team collaboration, we have budgeted for yearly face-to-face meetings of the entire team, as well as yearly face-to-face and quarterly teleconference meetings of our subcommittees.

Team leadership: This team will be led by **Dr. Clare Liddy**, a family physician, Ontario Ministry of Health and Long-Term Care career scientist and clinical investigator with expertise in health services research and a particular focus on chronic disease management. She has extensive experience in managing large-scale trials involving diverse stakeholders, most recently working with Dr. W. Hogg to lead a $3.1-million primary care quality improvement initiative aimed at improving chronic disease care in family practices. Dr. Liddy has strong links to policymakers across Canada as she sits on a panel of experts in the area of chronic disease prevention and management for the Public Health Agency of Canada and is an active consultant for the Health Council of Canada. Her co-PAs span the geographical and methodological areas to ensure that each project moves forward in an integrated manner. **Dr. Shabnam Asghari** is a primary healthcare researcher involved in epidemiological studies highlighting the geographical disparities in health services. **Dr. Marissa Becker** is a physician investigator and a Manitoba Health Research Council/Manitoba Medical Services Foundation Clinical Research Professorship in Population Medicine Award recipient who brings expertise in improving HIV treatment outcomes in vulnerable populations. **Dr. Patricia Caetano** is Lead Epidemiologist and Program Director of the Epidemiology and Surveillance unit at Manitoba Health and brings expertise in the application of health privacy legislation for administrative health information for research purposes. **Dr. Christopher Kaposy** brings expertise in public health ethics and health ethics methodology studies. **Dr. Sean B. Rourke**, a neuropsychologist and Scientific and Executive Director of the OHTN, is nationally recognized for his leadership in HIV/AIDS health research and knowledge translation and has extensive expertise in managing large and complex research teams. He will co-lead the LHIV Cohort for Ontario with **Dr. Claire Kendall**, a family physician and CIHR Fellow in HIV/AIDS Health Services Research.

Governance: Our team's activities will be coordinated through three governance committees that will regularly meet to ensure that all team members and stakeholders are actively engaged throughout the duration of the 5-year research program (Appendix 1). The team will be governed by a **Steering Committee** comprised of the nPA, PAs, and project leads, incorporating representation across jurisdictions, sectors, and projects. Philip Lundrigan and Ron Rosenes, team members who have lived with HIV for over 30 years and are nationally recognized HIV/AIDS advocates and educators, will provide feedback on proposed care delivery models, relevant targets for evaluation, community partnerships, and patient, family and community involvement. The Steering Committee will be accountable for monitoring the team grant progress, finances, and reporting to CIHR. This Committee will also play a crucial role to create linkages between the individual projects and set priorities for the development of future initiatives.

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The Steering Committee will be supported by two committees. The **Knowledge Translation and Exchange Committee** will consist of KTE experts, a provider and a person with lived experience. Dr. Wilson, an expert in supporting the use of research evidence in health systems with a specific interest in community-based organizations, will lead this committee. The KTE Committee will work across projects to extract policy-relevant outcomes and to develop and maintain avenues for leveraging our research results in policymaking processes across all jurisdictions involved in the program of research. The **Clinical Practice Implications Committee**, led by Drs. Kovacs and Rachlis, was created to interface with the project leads and the KTE Committee to advise and facilitate the translation of research findings for use by clinicians and to inform the development and/or adaptation of clinical care models. Our Knowledge Users who hold clinical care positions will be invited to join this committee, with a chair rotating amongst members to ensure leadership from all jurisdictions over the course of the team's work.

Team environments: Team members currently work in community-based organizations and existing clinical practices using a range of models of HIV care delivery (Appendix 23). This variety will allow for rich comparison of existing models of care as well as the implementation of emerging innovations for the management of complex chronic conditions. Our researchers work in several academic host organizations (Appendix 24) that are actively and enthusiastically supporting our participation on the team and in our projects. They are providing the protected time and mentorship required as well as access to their organizational strengths and capacities in, for example, interprofessional collaboration, service delivery models, data analysis, education, measurement and evaluation that will continue to provide in-kind infrastructure support, mentorship and opportunity for training and capacity building to ensure our investigators can bring the objectives of this team to fruition.

The host institution for this project will be **The C.T. Lamont Primary Health Care Research Centre (CTLC) at the Bruyère Research Institute (BRI)**. CTLC is a highly productive, stimulating primary healthcare research centre composed of world-class researchers and trainees in multiple disciplines. The CTLC Investigators and trainees include healthcare providers, epidemiologists, health economists, and doctoral specialists in public health, family medicine, and population health. Respected for its rigorous research and methods, CTLC informs policymakers, primary care practices and academics on how best to deliver effective, efficient and equitable primary healthcare. Furthermore, CTLC is currently the central hub for the Canadian Primary Health Care Research and Innovation Network (CPHCRIN), a multidisciplinary pan-Canadian partnership between various medical associations and research institutes related to primary healthcare, including the Canadian Medical Association, the Patient's Association of Canada, and the Canadian Association for Community Health Centres, which will foster avenues for dissemination of project findings across Canada. The CTLC has the requisite support system in place to ensure successful implementation of this proposal, including human resource support, interactive and interprofessional collaboration and existing trainee development, and expertise in program implementation and evaluation. CTLC Scientists have the full support of the University of Ottawa Department of Family Medicine, providing them with ongoing protected research time, operating funds, and administrative support (see letter of support). In the last 5 years CTLC Scientists have been on grants for over $19 M resulting in 154 publications. CTLC has existing research relationships with the Institute for Clinical Evaluative Sciences (ICES); 4 of our CTLC investigators hold affiliated positions with ICES.

5.0 CAPACITY DEVELOPMENT, TRAINING AND MENTORSHIP

Our team is committed to and already emerging as a collaborative community of learning for CBPHC research. By working across disciplines and methodologies, we will enhance the capacity of the team and create environments where policymakers and community members can directly inform research questions, learn from the findings, and drive change. We will build capacity within research disciplines and help train the next generation of students, graduate students, postdoctoral fellows, community fellows and junior investigators in the fields profiled within this application through the team grant funding and by leveraging existing partnerships with advanced capacity building mandates, such as the CIHR-funded Strategic

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Training Grant in HIV/AIDS Health Research program, Universities Without Walls, based at OHTN. Our team already includes 3 graduate students (Kendall, Marshall, Kitson) as well as a postdoctoral fellow (Pinto) and several junior investigators who will be mentored by the team's more senior investigators. Within our host institutes, we will also recruit and train at least 10 graduate students, postdoctoral fellows, and healthcare professional trainees (trained by our interdisciplinary healthcare team of physicians, nurses, pharmacists, psychologists and social workers). Trainees will be provided learning opportunities in a wide range of qualitative and quantitative disciplines. All trainees will be actively involved in our research projects, encouraged to pursue their own interdisciplinary projects within the program, and participate in yearly team meetings to gain skills in collaboration and community-based research, thus building capacity not only in HIV research but integrated care and chronic diseases.

6.0 KNOWLEDGE TRANSLATION AND EXCHANGE (KTE)
Our approach to knowledge translation is informed by two systematic reviews of the factors that influence the use of research evidence in decision-making, which showed that use increases when the evidence is **timely** and involve **interactions** between policymakers/stakeholders and researchers(82,83). Our knowledge translation plan emphasizes our commitment to stakeholder engagement and to mobilizing the findings in ways that ensure knowledge users can efficiently find and use relevant and high-quality research evidence when they need it.

6.1 Integrated knowledge translation and stakeholder engagement
To inform policy and practice about how to advance the primary healthcare of persons living with HIV, our team has adopted a highly integrated approach to knowledge development and mobilization. To ensure our research questions, methods, findings and approach to sharing the findings are not only methodologically robust but also relevant and tailored to what our knowledge users need to support change, we consulted with research and knowledge user members of our team through two face-to-face meetings to prioritize research objectives and potential interventions. We will sustain this interaction through our **KTE Committee**, consisting of KTE experts, a provider and a person with lived experience. This Committee will draw on established KTE frameworks for supporting the use of research evidence(84–88) and will focus on targeted knowledge-sharing, ongoing and timely interactions, and the establishment of trusting relationships between researchers and stakeholders(89). Within this framework, our KTE Committee will collate our actionable messages and advise on our program's **tangible KTE products and tools** to ensure they can be used by policymakers, providers and other stakeholders. (Products/tools include: 1) quality indicators for primary HIV care; 2) key organizational features of high-quality HIV care; 3) evaluation of e-consultation service for provider decision support; 4) an easy-to-use guide on navigating ethical issues in primary care practice; 5) new self-management tools for people with HIV.) We have budgeted for our KTE Committee to meet in person twice per year, once each with the entire team and the Steering and Clinical Practice Implications Committees, as well as by teleconference four times per year, such that relevant stakeholders are present at key stages in the research process.

We have assembled a highly collaborative team comprised of members from each of our relevant target audiences, who will themselves champion our findings in their work and practices, acting as role models and early adopters, influencing their colleagues, and helping to scale up models of care in their own and other jurisdictions. We are working with existing provider networks including the provider network of OHTN; the Ontario HIV Clinic Network, which currently meets at least four times a year and holds two education days each year for physicians and other clinic staff; two integrated Manitoba clinics; and the Eastern Health HIV Clinic. We are also connected with representatives of community-based HIV/AIDS agencies and organizations integrally involved in primary/community care services in their regions. Most importantly, we have engaged people living with HIV who can provide valuable guidance to the team as well as provide a link to the broader HIV community. For populations that are more marginalized and perhaps less likely to advocate on their own behalf, we will work with the organizations that serve them to develop relevant and culturally appropriate education programs and tools that will enhance their capacity.

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We will capitalize on established HIV knowledge networks, including the Canadian AIDS Treatment Information Exchange (CATIE), which provides information for community-based organizations and people with HIV, and the Ontario AIDS Network's skills development program for community-based organizations, which provides an effective venue to influence the services provided by these agencies.

We will use a variety of techniques to ensure our findings are disseminated over the course of the grant. We will actively disseminate our research ("pushing" our research to those who can use it) and expect to generate several peer-reviewed publications for open access journals under creative commons licenses such that our work is widely available for adoption, adaptation and dissemination. We plan on presenting at national and international meetings including the North American Primary Care Research Conference, Family Medicine Forum, the annual OHTN conference and the Canadian Association for Health Services and Policy Research Conference. We will also make our tools and messages available in user-friendly formats (facilitating users' ability to "pull" research into their activities) using the OHTN website as a central hub for the development of a dedicated space to organize our outputs and facilitate their use. We will monitor the use and scale-up of these products and tools through download tracking and follow-up interactions with the targeted decision-makers, and report back on their impact on quality of HIV care.

6.2 Coming full circle: End-of-grant knowledge translation

Supporting evidence-informed approaches to advancing primary healthcare for people living with HIV depends on the creative interplay of, on the one hand, the best available data and research evidence and, on the other hand, the tacit knowledge and views and experiences of those who will be involved in or affected by the issue. In partnership with the McMaster Health Forum we will produce an **issue brief** that draws on the best available data and research evidence (including the findings produced through this grant) to: 1) define the problem(s) faced in Canada in shifting to an E-CCM approach to HIV service delivery; 2) identify and describe what's known about possible policy and program options in adopting an E-CCM approach; and 3) identify key implementation considerations for these options. We will convene a **stakeholder dialogue** that provides 18-22 policymakers, professional and community leaders, patients/citizens and researchers with the opportunity to bring their tacit knowledge, views and experiences to bear on the problem, options and implementation considerations. In keeping with the McMaster Health Forum's "tried and tested" approach to effective dialogues to address pressing health system issues, we will inform this process through several activities, which include: 20 **key informant consultations** (within and beyond Canada), brief **video interviews** with willing dialogue participants about the major insights and plans for action that they derived from their participation in the dialogue, a print **summary of the dialogue**, **personalized interactive stakeholder briefings**, and **evaluation** of the process to continue to improve this approach for other similar types of projects in the future(90).

7.0 ETHICS

The multi-stakeholder, participatory approach we have embraced to develop and carry out this research provides safeguards for ensuring that our research activities are relevant, ethical, and are best situated to create positive impact for people living with HIV in Canada. Our team's approach to this work has been rooted in the greater and meaningful involvement of people living with HIV/AIDS (the GIPA/MIPA principal) to create mutually beneficial partnerships and involve stakeholders and people with HIV at every stage of the research development process – a commitment we will uphold as we conduct the research and disseminate the results. Our team also includes a number of bioethicists who will be engaged as ethical consultants through the course of the team's work, in addition to their role in developing and implementing Project 4). Many of the organizations and individuals involved on this team have signed on to The Ontario Accord (ref: http://www.ontarioaidsnetwork.on.ca/living_serving.php), a statement of solidarity with GIPA/MIPA created in July 2011 by HIV-positive people and their allies. For projects that involve collaborations with Aboriginal communities and organizations, the team will work to ensure that Ownership, Control, Access, and Possession (OCAP) principles are followed and that our partnerships advance meaningful and ethical engagement of Aboriginal peoples in research. All projects within this

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program of research will be reviewed for ethics approval by all required provincial bodies prior to data collection, linkage and analysis. For the studies utilizing health administrative data, the standard processes to access, link, and analyze these datasets intrinsically contain a number of privacy protections. Individual-level data are never accessible without encryption of their provincial personal health number, a process that facilitates linkage to multiple datasets while ensuring that all data are anonymized for confidentiality and protection of privacy. Cells with 5 subjects or less will not be released or reported.

8.0 ANTICIPATED OUTCOMES AND IMPACT OF OUR LHIV INNOVATION TEAM
Our work has the potential to fundamentally change the way HIV care is provided in Canada. We expect that the innovations developed and tested through this program will be transferable to care for multiple chronic conditions in general. We anticipate that our team will have the following direct outcomes:
Reducing critical knowledge gaps in the continuum of HIV care: We will be the first to explore HIV care from a primary care lens in a universal payer system, making our work world-leading and relevant to other settings. We will identify for the first time what happens to the heathcare utilization of people diagnosed with HIV but not in ongoing care, and will map out the healthcare utilization of people receiving care and how different models relate to outcomes. Our work will develop and disseminate the first indicators for monitoring HIV PHC in Canada.
Improving the experience of care for people with HIV and their communities: This work has the potential to ultimately increase the number of people accessing and retained in care, thus reducing HIV transmission and improving health outcomes. People with HIV will benefit directly from the implementation of self-management strategies that are low cost and user friendly, and through interventions to improve the care they receive from their primary care providers. We will empower and build capacity for this group through their participation in identifying indicators important to them and by having research results reported back to them and their community advocates.
Supporting community-based providers: Providers and community-based agencies caring for people with HIV will benefit from new knowledge on the key organizational ingredients to improve care. This may encourage team development and optimal composition that will in turn reduce pressures on primary care practices. We will empower practitioners by providing them with easy-to-adopt expert consultation services to assist them in caring for people with HIV, and we will develop and disseminate tools to help providers manage emerging ethical issues in care. We will test and refine our program's interventions through real-world experience (team members' clinics and other primary care settings). We will identify innovative ways (e.g. telehealth, webinars, social media) to build and sustain communities of practice.
Improving access to care and increasing appropriate use of the healthcare system: Our work has the potential to significantly improve appropriate service use and reduce costs of HIV care. Effective primary care models have been shown to reduce hospitalizations and emergency room visits and should delay and reduce the impact of other co-morbid conditions common in people with HIV which are themselves costly to treat. Our projects and deliverables will increase access to primary care for people with HIV by overcoming current barriers to care including stigma, geography, capacity of existing service delivery models, and lack of knowledge of chronic disease management. Working across three jurisdictions, we will scale up sustainable methods to identify, manage, and monitor complex chronic conditions.
Impact on policy and policymakers: We will collaborate with policymakers throughout our program to ensure our work provides actionable evidence for more effective health policy. We will ask them what indicators they want measured and can act on and, from this process, we will outline options for policy change based on actual healthcare utilization patterns and their associated costs. We will identify effective ways to share policy-relevant evidence and support its use, such as through the Evidence-based Practice Unit funded by the Ontario Ministry of Health and Long-Term Care. Policymakers will benefit from the depth, breadth and cross-fertilization of our program, as our partner provinces represent the great diversity of the population of persons living with HIV and reflect potentially different policy challenges including the delivery of care in remote and rural regions, stigmatization, and care of specific marginalized populations, such as Aboriginal groups.