

FINAL REPORT: EVALUATION OF THE INTEGRATED CLIENT CARE (WOUND CARE) PROJECT

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BACKGROUND

The Problem

Although not always recognized as a pressing health care problem, wounds are a common, complex and costly condition [1]. Approximately 1.5 million Ontarians will sustain a pressure ulcer, 111,000 will develop a diabetic foot ulcer, and between 80,000 and 130,000 will develop a venous leg ulcer [1]. Up to 65% of patients afflicted by chronic wounds report experiencing decreased quality of life, restricted mobility, anxiety, depression, and/or severe or continuous pain [2]. The estimated cost to care for a pressure ulcer in the community in 2006 was \$27,000 CDN and has only risen in the last decade [3]

The burden of treating wounds is growing rapidly due to increasing health care costs, an aging population and, a sharp rise in the incidence of diabetes and obesity worldwide [4]. Community-based care for people with wounds is often fragmented and inconsistent, leading to prolonged healing times and ineffective use of resources. Proficient care requires an interprofessional team of physicians, nurses and other health-care providers working together to provide a definitive diagnosis, optimal treatment and client education [5]. Conversations with Ontario CCACs during the development of the protocol for the Intermediate Wound Care Field Evaluation for the Medical Advisory Secretariat of the Ontario Ministry of Health and Long Term Care (MOHLTC) identified three problems with current wound care practices (in order of priority): 1) inconsistent application of best practice guidelines; 2) lack of standardized documentation and tracking of wound outcome measures; and 3) poor co-ordination of care [6].

Setting

Ontario, Canada is the most populous Canadian province with approximately 13 million residents [8 - (2010 estimate)]. Residents are covered by a single-payer, universal health insurance program that includes almost all physician services and inpatient care, as well as most home care, and some long-term care. Fourteen geographically organized, publicly funded Community Care Access Centres (CCACs), have the responsibility for the coordination of the majority of home care services (including rehabilitation, post-acute care and medically required domestic help), for all Ontarians requiring these services (over 700,000 referrals in 2013/2014) [9]. CCACs do so through complex bulk service contracts with a range of large and small, for-profit and not-for-profit, multidisciplinary and unidisciplinary private Service Provider Organizations (SPOs). Patients are referred to CCAC case managers by their primary care physician, at discharge from hospital care or through other community based health providers. A CCAC case manager assesses each patient's home care needs, including for wound care, and if they are in need of care, enters them into a referral database, which allocates the patient to one of the partner SPOs according to a market-based randomization algorithm.

The specific care to be provided is determined by the SPO employee (nurse, PT, OT, etc) and is approved by a case manager from the CCAC. The specific services and the intensity of services provided vary depending on client need but may consist of homemaking, personal support (i.e. assistance with bathing), and health professional visits (i.e. nursing, physiotherapy). Since the system is publicly funded, service maximums have been put in place; for example, homemaking services cannot exceed 60 hours in a 30-day period. Currently, this is reimbursed on a fee for service basis, with the fee determined in negotiations between SPOs and CCACs every few years, with variance according to region and by type of service. The system is currently non-competitive, with market share for each SPO fixed by contract.

The Integrated Client Care Project

As the steward of publicly funded healthcare in Ontario, the MOHLTC began seeking an organizational and structural solution to these problems that would both improve quality of care and bend the curve of rising system costs for wound care. Harrison et al's 2005 study showed that remedying these issues could improve the effectiveness and efficiency of delivery and of outcomes of wound care [7] and the MOHLTC objective was to implement a tailored intervention across the province in a sustainable fashion.

The Integrated Client Care (ICC) Project was a multi-year initiative to develop and test a new, integrated model of homecare in Ontario which would address these goals [10]. The aim of this new model was to improve health outcomes for patients without substantially increasing system cost. This was to be achieved by more accurate matching of care provided to each specific patient's needs. At system level, this was expected to redirect care resources towards more complex patients, the 20% of the patients which require 80% of the resources. The ICCP project was designed to be an innovation development and demonstration collaboration between the payer (MOHLTC) and the sector (CCACs and SPOs) and was sponsored and funded by the MOHLTC. Because of the key coordinating role of the CCACs, the MOHLTC commissioned their representative body, the Ontario Association of CCACs (OACCAC) to develop and implement the new model of care. The model of care was to be implemented using 6 elements (See figure 1) and the first clinical grouping chosen on which to test ICCP was community-based wound care.

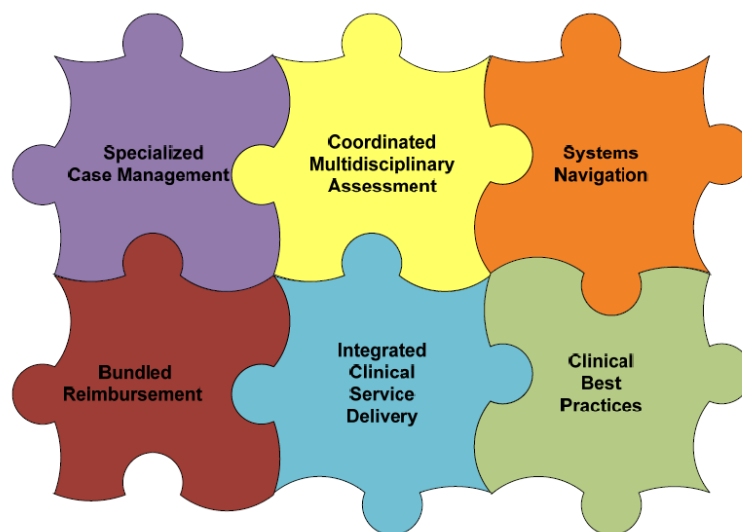


Figure 1 – Original depiction of the six elements in the ICCP model of care.

These “puzzle pieces” were to be used as an integrated framework of interventions that would rewire how the CCACs managed their work with contracted Service Provider Organizations (SPOs). The ICCP also required the OACCAC to develop ways to measure outcomes accordingly, and then to re-orient the SPO payment structures away from a fee for service reimbursement model towards one that rewarded successful patient outcomes.

The Evaluation

In May 2009, our team was selected through a peer-review process to conduct an independent, prospective, formative and summative, participant observation evaluation of both the implementation and the impact of the then-named “ICCP Wound Care project”, using mixed methods and a broadly realist approach. Our conduct was independent, such that our evaluation and subsequent report was not subject to MOHLTC, or any other control. Although, review and comment prior to submission and publication was welcomed, in accordance with a longstanding contractual arrangement between the MOHLTC and the Institute for Clinical Evaluative Sciences (ICES). The evaluation was to be prospective and participant, in that we were commissioned soon after the project launched, and took part in formative work all the way through to close observation of the implementation at scale of the final intervention.

The qualitative evaluation was formative in the sense that we proposed to observe processes and raise questions of clarification, and return reports on our understanding and interpretation of what we saw to the commissioning funder of the evaluation, the MOHLTC, and through them to other stakeholders. These were intended to inform mid-course corrections in the development and implementation process. The qualitative evaluation also had a summative component. We worked closely with the Ministry of Health and Long Term Care, the CCACs and service providers to understand the implementation issues and processes as they unfolded in real time, and how and to what extent these remained connected to the original underlying theory of change. The perspective was organizational; that is, we attempted to understand the actions of organizations in the sector as the MOHLTC engaged with them on the project, rather than following qualitatively the experience of patients who were receiving home care. In terms of patient outcomes, we assessed this exclusively through our quantitative evaluation.

The quantitative evaluation was exclusively a summative evaluation of the prospective randomized trial that compared patient outcomes after implementation of the ICCP intervention between patients whose care was coordinated by CCACs that took part in ICCP, compared to those that did not, with the intended allocation decided by randomization.

The overall approach was realist in that we specified evaluation approaches only broadly in advance, and adapted these as the intervention was developed and implemented, in order to understand the forces driving change in the intervention and its implementation, as well as its impact. To do this, we followed the evolution of the initiative for an additional three years beyond the funded period, as it transitioned from the ICCP “project” to become the “new” scale up initiative known as Outcome Based Pathways/Outcome Based Reimbursement (OBP/OBR).

This report presents the final summative results of both our qualitative and quantitative evaluation, with data on effectiveness from the randomized trial, and insight into the evolution of the ICCP intervention and the barriers and facilitators to its implementation from the qualitative research.

EVALUATION METHODS

QUALITATIVE METHODOLOGY

Design

The qualitative findings reported here are based on data collected through ethnographic research methods including key informant interviews and observation. Ethnography is the study of social interactions, behaviours, and perceptions that occur within groups, teams, organizations, and communities. It aims to identify, explore, and link social phenomena which, on the surface, may have little connection with each other [11] but may in fact explain an entire outcome. It also allows phenomena to be viewed in the context in which it occurs, thereby aiding an in-depth and contextually sensitive understanding of underlying behaviour and its effects [12]. Participants (MOHLTC, the Executive steering committee, the OACCAC and Project Staff, CCACs, SPOs, etc.) and observational situations were sampled on an opportunistic or purposive basis based on the natural progression of the ICCP. Interview data was collected both through informal conversations during observation periods and scheduled semi-structured interviews with key stakeholders.

Sampling & Data Collection

Trained field evaluators spent time observing in several meetings, implementation workshops and QI sessions over the entire course of the project. The observations included both participant and non-participant field notes, gathering text based data such as policy documents, guidelines and communications and conversations with key informants from OACCAC, the CCACs and the SPOs.

We also conducted semi-structured interviews with administrators, providers and team members, at various points in the project. Qualitative sampling requires that enough data has to be generated to sufficiently explore the issues under investigation. The data reaches a point of saturation when no new information or themes are being generated. Additionally, qualitative samples do not have to observe the representativeness of the population because the purpose is to explore, not measure. We were able to interview participants from 13 of the 14 CCACs and several SPOs as well as the OACCAC staff and leadership.

Analysis

Concurrent to data collection, we undertook analysis in a similar fashion to Muller, who describes five overlapping stages of narrative analysis: entering the text (reading and preliminary coding of transcripts and field notes to gain familiarity), interpreting (finding connections in the data through successive readings and reflection), verifying (searching the text and other sources for alternative explanations and confirmatory and disconfirming data), representing (writing up an account of what has been learned), and illustrating (selecting representative quotes). We shared this process among the two principal observers (KD,MZ) and met frequently during the study period to review and discuss the meaning of our initial drafts, followed by exchange of new drafts, comments in text and redrafts until agreement was reached.

QUANTITATIVE METHODOLOGY

Design

In parallel with the ongoing qualitative evaluation, the quantitative evaluation was designed as a cluster randomized trial, with allocation of intervention randomized at the cluster level (CCAC) and analysis of outcomes based on individual level data (patients). Comparisons were made with clusters allocated to usual care.

Randomized trials are the most reliable method for determining whether an innovation or intervention causes the desired outcomes. In this work we were evaluating an intervention on behalf of policy makers, with the role of assessing the effectiveness of the intervention and prospects for province wide scale up. This goal was particularly suitable for a pragmatic approach to a randomized trial (pRCT), which is a specific way of designing a randomized trial to give information on real world effectiveness, evaluating outcomes under conditions of actual use. Because of this characteristic, pRCTs can yield results that are both valid and generalizable, and thus relevant for making “real world” decisions about large scale changes, for example in practice guidelines, health care delivery, drug formularies or payment structures [13, 14]

Intervention and comparison groups

The new model of care was planned to be implemented through six integrated changes to home care organization, delivery and reimbursement to promote improved outcomes and integrated care. Figure 1 illustrates the entire suite of interventions intended to be included in the ICCP.

Under the leadership of the OACCAC, the sector developed ten best practice outcome based wound care pathways and two pathways for rehabilitation after hip or knee replacement (Table 1). For each wound condition, CCACs randomized to intervention had access to these milestone based outcome¹ pathways via an enhanced portal within the CHRIS database, while those randomized to ‘no intervention’ continued to use CHRIS as per usual business. In the interventional group, progress of each patient along these pathways was entered directly into the CHRIS electronic record by front line clinicians, or on paper and then entered later by office staff. The non-interventional (control) CCACs were not intended to undergo any changes in delivery, organization or reimbursement and were expected to continue with usual care and usual reporting of wound healing.

Among the interventional group, the appropriate pathway for each patient were determined initially through a CCAC case manager assessment (without direct contact with the patient, based on referral information) and confirmed by the first visiting front line clinician, usually a nurse, employed by a service provider organization. Patient progress through the milestones specific to their particular wound and general health needs was recorded by front line clinicians, and also monitored by CCAC case managers with the intention that they would intervene if progress was insufficient, or if required care was not provided. These outcomes pathways were developed by OACCAC and CCAC staff from the underlying clinical pathways² for each wound care type, (see attached outcomes based pathways for pilonidal sinus and diabetes lower limb ulcers – Appendix A).

Table 1: List of wounds targeted by outcome-based pathways

Arterial Leg Ulcer	Pilonidal Sinus
Diabetic Foot Ulcer	Pressure Ulcer
Maintenance Wound	Surgical Wound
Malignant Wound	Traumatic Wound
Non-Healing Wound	Venous Leg Ulcer

¹ Outcome pathways are the quality management tool used by the CCACs to measure whether patients were meeting expected timelines for initiation of each stage of evidence based care and milestones towards and including wound healing.

² Clinical pathways are multidisciplinary care tools based on evidence-based clinical practices (as against outcomes) for a specific group of patients with a predictable clinical course.

Outcome measures: selection of tracer conditions

Collectively the pathways classify all admitted patients' wounds into one or more of 10 categories (see figure 2). We selected two of these wound types, diabetic foot ulcers and pilonidal sinus, as tracer conditions to assess the impact of the intervention on two different patient populations. Diabetic foot ulcers afflict older, sicker, individuals, and if not managed successfully may result in foot amputations and significant morbidity. This combination of diabetes and lower limb ulceration is very disabling, and costly to the healthcare system [15]. Pilonidal sinus, on the other hand, is a condition that occurs mostly in younger, healthy adults, but can be difficult to heal due to the peri-anal location of the wound. It may result in significant personal economic impact due to lost work days [16].

Study Participants - Clusters

Ontario is divided into 14 health regions, known as Local Health Integration Networks (LHINs) each with a Community Care Access Centre (CCAC) that coordinates delivery of provincially-funded community-based services. Home care is provided on either a short- or long-stay basis, where the latter refers to patients who receive care for a minimum of 60 days in a single episode [17]. These fourteen (14) clusters in the province were randomized either to the arm which was supposed to receive ICCP wound care intervention early (7 CCACs) or to the one allocated to usual care (7 CCACs). Randomization was stratified for size (larger and smaller) and geographic area (urban versus rural) (Figure 3 – randomization schedule)

Study Participants – Individual Patients

The patient grouping used for analysis included all home care referrals admitted from January 1st to December 31st 2013 with a documented diagnosis for diabetic foot ulcer or pilonidal sinus (see definitions below) in the province of Ontario. The year 2013 was selected as the majority of CCACs that applied the intervention commenced the use of outcome-based pathways early that year.

Data sources

We used multiple linked population-based databases, including the Registered Persons Database (RPDB), which includes demographic information on all Ontario residents; the Canadian Institute for Health Information Discharge Abstract Database (DAD), which consists of standardized chart abstractions for all inpatient hospital episodes; the National Ambulatory Care Reporting System (NACRS), which consists of standardized reporting on all emergency department visits; the Ontario Health Insurance Plan (OHIP), which includes all billing claims for physicians paid on a fee-for-service basis and the Home Care Database (HCD), which includes information about each patient, their primary diagnosis and services received for each referral.

Defining eligible referrals and follow up periods

For analysis we developed two wound cohorts, one to represent more complex wounds in an older population (diabetic ulcers), and one to represent simpler wounds in a younger population (pilonidal sinus). We had two considerations in selecting the wound-types for analysis. First, we required that the wounds have good specificity and minimal misclassification in administrative coding (i.e. a physician or coder would be confident when documenting the condition).

Second, analysis required that the wound could be accurately identified using physician billings. The latter constraint was due the availability of hospital data; at the time of the analysis hospital discharge records were only available covering the period up to March, 2013. As the majority of the referrals applying the pathways were admitted in 2013, using the available hospital data would have limited the

timeframe for this analysis. However, physician billings were available throughout the period. For this first analysis, we thus selected pilonidal sinus and diabetic foot ulcer for further assessment as both conditions can be treated or clinically managed on an outpatient basis and are associated with specific billing or diagnostic coding.

For both cohorts we applied the same initial inclusion and exclusion criteria, as follows. We first included all home care referrals that admitted between January and December 2013. We then excluded referrals where clients had invalid or incomplete data (missing age or sex, died prior to admission date), were less than 18 year of age and where no nursing services were provided (i.e. only home making services were provided). For all analyses we commenced client follow-up from the referral admission date; clients were followed to a maximum follow-up date of April 30, 2014, allowing for a minimum of 4 months of follow-up for all clients.

We defined a referral as including a diagnosis for pilonidal sinus if a physician had billed for the treatment of the condition in the 30 days prior to the home care admission date. Similarly, for diabetic foot ulcers we required a diagnosis for diabetes, determined using a validated algorithm [18], and a physician documented diagnosis for diabetic foot ulcer in the 30 days prior to home care admission. Billing and diagnoses codes used for case identifications are presented in Table 2. Given the severity of both conditions, we assumed that any subsequent home care requiring nursing services would have received some management for these diseases.

Table 2a: Billing codes and descriptions used to identify cases of diabetic foot ulcer

*Diagnosis Code	Description
707	Debcubitus ulcer, bed sore

*Physician diagnosis codes are restricted to the first three characters of the *International Classification of Diseases 9th Revision*

Table 2b: Billing codes and descriptions used to identify cases of pilonidal sinus

Billing Code	Description
R035	Pilonidal cyst - simple excision or marsupialization
R054	Pilonidal cyst - simple excision or marsupialization if patient's BMI greater than 40
R036	Pilonidal cyst - excision and skin shift
Z106	Abscess or haematoma - Local anaesthetic - ischiorectal or pilonida
Z107	Abscess or haematoma - General anaesthetic - ischiorectal or pilonida

Analysis

For each wound cohort we performed two analyses. Our primary analysis was an intention-to-treat (ITT) analysis, where arms were compared by intended allocation status (7 CCACs allocated to the intervention vs. 7 CCACs allocated to control). Our secondary analysis compared centres that applied pathways for the conditions of interest (pilonidal sinus or diabetic foot ulcer) to the remaining centres which did not (5 intervention centres vs. 9 control centres); we refer to this as the ‘per-protocol analysis’ (PP).

Outcomes Measures

The primary outcome was defined as successful discharge from home care, indicated as “service plan complete” in the HCD. We defined a discharge date as the date of last clinical service. We preferentially selected this date as clients could have continued to receive non-clinical services prior to discharge from home care.

Additional variables

For each client, we collected baseline demographic and socioeconomic indicator information (age, sex, rural status, neighbourhood income quintile) and also derived a Charlson Comorbidity Score for each patient by assessing diagnostic codes recorded in hospital records in the five years prior to the referral admission date [19,20,21].

Statistical Methods

We quantified the agreement between the administrative database case definition for pilonidal sinus and diabetic foot ulcer and those collected by the centres using the Kappa statistic. For all baseline characteristics we expressed continuous variables as means (standard deviations [SD]) or medians (interquartile range [IQR]) and categorical variables as proportions. We used standardized differences, which reflect the mean between-group differences as a proportion of the pooled SD, to assess for differences between groups; a standardized difference greater than 10% is generally considered meaningful [22]. Unlike t-tests and other statistical tests of hypothesis, standardized differences are not influenced by overall sample size, between-group differences in sample size, or clustering [23]. We graphically assessed the differences in groups on successful discharge from home care using Kaplan-Meier plots.

As the purpose of the outcomes-based pathway is to promote coordinated care resulting in earlier wound healing, we used as our principle analysis a Cox-proportional hazards model to conduct a time-to-event analysis and derived hazard ratios (HR) and 95% confidence intervals (CI) for the study outcome, with the non-intervention group serving as the reference for all analyses. Clients were censored if they died, were admitted to hospital, were lost to follow-up (went on vacation for >30 days), were admitted to a long-term care facility or were not discharged by the maximum follow-up date of April 30, 2014. All models accounted for the potential clustering by centre and were adjusted for potential confounders: age, sex, rural residence, neighbourhood income quintile, and Charlson comorbidity score. We also present an unadjusted proportion of patients discharged in the follow up period. We performed all hypothesis tests using a two-sided test and interpreted a p-value of less than 0.05 as statistically significant. All statistical analyses were conducted with SAS for UNIX version 9.2 (SAS Institute, Cary, NC).

RESULTS

QUALITATIVE FINDINGS

The qualitative findings reported here are based on data collected through ethnographic methods including over 36 months of field observation and approximately 60 key informant interviews over that same period. Our analysis of this extremely rich data set has produced three key themes which provide insight into the implementation and uptake of the ICCP project. In no specific order these are 1) Leadership and Relationships; 2) Commitment and Engagement and 3) Fidelity of the Intervention

Leadership & Relationships

In an attempt to embody line with it's "stewardship" approach to system transformation, the Ministry of Health and Long Term Care delegated the responsibility for the implementation of the ICCP Wound Care initiative to the Ontario Association of Community Care Access Centres which in turn delegated the task to a specially hired consultant team that was located within the OACCAC. The locus of authority over this team lay with the OACCAC, and although expectations of the project had been laid out in a contract between the MOHLTC and the OACCAC, the actual relationship between these two bodies in regard to steering the project was not precisely defined. The OACCAC appears to have been given a wide contractual mandate to develop the intervention from the theory, design the implementation plan and manage the project and engagement of key stakeholders. However a lack of strong accountability structures from several levels of oversight (the Steering Committee, the MOHLTC, the OACCAC) allowed the project to develop and roll out in ways that differed significantly from the original intended goals and timelines.

The relationship between the OACCAC and the CCACs themselves also contributed to the divergence from the original goals. As a representative, member driven association, aimed largely at providing shared services for its members, the OACCAC could only monitor and offer assistance in terms of implementation, rather than actively require member participation in new initiatives. OACCAC are not in a position of "authority" or even leadership with the CCACs and so their ability to mandate or strongly encourage CCACs to support, let alone implement, elements of the ICCP project was hampered. CCACs participated "voluntarily" as and when they saw fit, rather than consistently, and collectively, as members of a system moving towards the same goal. The failure to implement ICCP/OBP/OBR in some of the CCAC sites randomized to receive the intervention is a marker of the autonomy of CCACs in relation to the OACCAC. The lack of site specific external funding to CCACs for implementation reinforced the voluntary nature of the project engagement (CCACs largely carried their own costs related to ICCP). The OACCAC/CCAC relationship is largely driven by the CCACs, and not the OACCAC, and therefore a sector-wide effort towards common ICCP goals requires explicit prior buy in from each CCAC (and possibly individual CCAC contracts for implementation with LHINs or MOHLTC).

Commitment & Engagement

The OACCAC was initially very cautious regarding the ambitious scope of ICCP and dealt with this in two ways. Firstly, it engaged in a lengthy development process, in order to create operationalizable forms for the 6 elements of ICCP. This started with an exploratory process in four volunteer CCAC+SPO partnerships using a Quality Improvement approach (process modeling) led by CHQI/HQO. Although intended to produce operational prototypes for all six of the elements of ICCP, it resulted in none.

Each CCAC and their SPO partners had done quality improvement work in one form or another in order to improve outcomes and cost savings around wound care for their individual organizations and they did

not want to lose traction on those gains by taking on an exploratory and as yet imprecisely defined “externally” driven project. Their lack of clarity around both the end goal of the OBP/OBR initiative and the specific means by which these would be reached made ICCP seem risky, which the leadership of several CCACs was not enthusiastic about taking on. In addition, the CCACs have multiple accountabilities, the most important of which is their actual accountability agreement with the LHINs through which they receive their funding. This relationship requires several other “priority” QI projects, which make demands on their limited innovation resources. Given the autonomy of the CCACs in relation to the OACCAC, leadership of sector wide projects such as this one should not be in the hands of the OACCAC. Instead, explicit contracts for activities need to be established with each participating CCAC, possibly with the LHINs, and leadership of the project itself may best be held by the appropriate MOHLTC directorate, or in an explicitly formed leadership table, with clear accountability to the MOHLTC.

Service Providers, although they are the front line care providers in the case of Wound Care were involved only indirectly throughout the process, and even then only through a few CCACs which chose to draw them into discussions about how they, the SPOs, would implement the pathways in the field, rather than through direct SPO partnership in the project. Since the implementation of pathways with actual patients in their homes was obviously going to be an SPO function, this distancing of the project from SPOs was hard to explain. Interviewees from SPOs expressed a strong desire for a higher level of engagement in project management and improved leadership of the project by the OACCAC. Participants felt the implementation needed much clearer overall direction, consistent messaging and two-way communication. Primary care Physicians were also not actively included in the change process; their lack of inclusion undermined the goal of interdisciplinary assessment and efficient use of community services to improve outcomes and reduce costs. In some cases, they were even detrimental to the intended goals due to discrepancies in definition of “best practices” between physicians in primary care and CCACs. Future projects aimed at integrating care in the community should identify mechanisms for including important providers of such care, whether these are Family Physicians Practices, Service Provider Organizations and Volunteer sector agencies from the beginning of such initiatives.

OACCAC separated the ICCP effort from its own priority business activities by setting it up as a “side project” staffed by contract employees. In mid-2012, the external contracted Project Management Team within OACCAC was disbanded and responsibility was transferred to the internal Client Services group. At this point “ICCP” was viewed as having ended and OACCAC transitioned to a program now referred to as “OBP/OBR”. OBP/OBR was composed of the implementation of outcomes based pathways and the Client Care Model. External consultant work was also financed to develop pricing for OBR and pilot tests were done in two CCACs, but no attempt was made to integrate the results of these studies into the ICCP effort. In future, if an exploratory project is deemed important, the development efforts should be mainstreamed within participating organizations, and led by senior staff, rather than marginalized to contractors (permitting the organizations to distance themselves from the work). Ontario needs a better way of identifying and testing potential innovations in a purposeful and energetic way, prior to making a transparent and objective decision regarding the merits and deficits of the innovation.

The OACCAC moved very quickly to proposing province-wide spread of OBP/OBR to be tested in a large proof of concept (POC) phase, covering half of the CCACs in Ontario, and agreed that this evaluation would be randomized. By this point it was clear that this large scale POC could not test OBR which had neither been agreed upon by CCACs nor developed in an operationalizable format. The POC could

therefore only evaluate the effect of OBP. Agreement was reached between the MOHLTC, the evaluation team and the OACCAC on a cluster randomized trial design to evaluate OBP in 14 CCACs, 7 of which would be offered the OBP intervention early and 7 which would go live 6 months later. To date, OBP has been implemented in some of the first 7 CCACs planned to receive it. The second wave has been postponed several times, causing dissatisfaction among those CCACs which were planning for it. Ontario is well placed, with its province wide consistent insurance scheme, and its focus on innovation, to be a leading jurisdiction in development, testing and implementation of useful innovations, especially for complex healthcare delivery solutions, such as ICCP. Achieving this leading position in health system innovation engine requires that the province develops a consistent and transparent approach which integrates effective implementation with rigorous evaluation.

Fidelity of the Intervention

ICCP was originally intended to tailor care to match each patient’s needs regarding intensity and interdisciplinary clinical skills in order to efficiently use resources. While this first conceptual iteration had six integrated elements (see Fig 1), the MOHLTC’s most desired outcome in general has long been to move the whole health system away from fee for service reimbursement towards a system which rewards quality and efficiency [24]. In the case of Home Care reform this was to be based in Porter’s theory of value for outcomes, where value is the quality of a patient’s experiences relative to the dollars spent for care or services, over the full cycle of care and where quality includes both clinical outcomes and the patient’s experiences.

Once the first set of early implementation sites were selected, the OACCAC commissioned the Centre for Healthcare Quality Improvement (now known as Health Quality Ontario, HQO) to guide teams through a standardized implementation approach using QI principles and tools. HQO is a provincial umbrella agency responsible for promoting evidence-based standards of care, recommending best practices, and monitoring, publicly reporting on and supporting quality of care [25]. Two QI specialists were assigned to work with the four spotlight CCACs to implement the six “puzzle pieces” (Figure 1) and over the course of one year met bi-weekly with the teams. This QI work provided an in-depth understanding of the home care process for wound care clients as it mapped the ‘current state’ of wound care delivery from the perspective of CCACs and SPOs and looked for areas of inefficiency in the processes. However, many felt that it was not well aligned with the intended cultural and organizational shifts expected for implementation of the ICCP initiative and so in the end was unable to provide CCACs and SPOs with specific guidance on how to implement the integration components (specialized case management, integrated care delivery, coordinated assessment, etc). After a year of QI work, the end goal of the ICCP remained unclear to the participants; a clearer shift from QI to implementation planning and execution would have increased understanding by the CCACs and SPOs of the actions expected of them, and the goals, increasing their engagement.

At POC implementation the intervention was reduced to just two process changes - outcome based pathways (OBPs), presented by OACCAC as a means of implementing Clinical Best Practices, and the Client Care Model (CCM) of case management, and offered by OACCAC as a response to the need for Specialized Case Management. The outcome based pathways were developed by a provincial working group within the OACCAC and the Client Care Model was a program developed by the OACCAC and being implemented provincially, neither of these originating from the ICCP initiative, and it remains unclear how these came to be the components which were launched at scale in the large “Proof of Concept” phase. While it is perfectly acceptable to evaluate a multicomponent intervention and decide that only some of the components were effective and should be retained in the innovation as it moves to wards scale up, we concluded that future attempts should be more explicit and transparent in this

process- individual components should be identified explicitly, designed, tested in pilot scale implementations, and as a result, adapted, scaled up, or abandoned.

Outcome Based Reimbursement (OBR) was discussed at length throughout the ICCP development process but stalled on the issue of determining an accurate “price” for bundled services in each wound group. Two of the fourteen CCACs did do some pilot work on price estimation for a small number of patients and wound categories. This attempt at a bundled price focused on nursing and other SPO delivered care; the bundle was not at any time investigated as a total care bundle including physician services and other expenditure for this high need group of patients. Because of the immense difficulty of establishing the actual cost for each bundle due to the proprietary nature of data in this sector, the Impact Assessment Team suggested implementation of a shadow billing system to allow groups to trial “OBR” at no financial risk; ie, payment would temporarily remain based on previous per patient costs adjusted by current volume; over time actual cost data would be accumulated, allowing time to prepare a proposal for a bundled price system to prevent losses but still take reasonable risk. This was supported by MOHLTC staff, but not implemented by the ICCP project team or the OACCAC. Outcomes Based Reimbursement has not yet been tested adequately; future efforts to deploy OBR in the home care setting are warranted, as the theory is plausible, and evidence to reject it does not yet exist.

The Impact Assessment Team also proposed an audit & feedback intervention alongside the pathways as a way to bolster the intervention following the lack of progress on an Outcomes Based Reimbursement process. The OACCAC revised the CHRIS software algorithms to produce a fully automated, system wide and province wide audit and feedback system but was unable to disseminate the regular monthly reports to end users due to privacy and confidentiality precautions. The ease with which the OACCAC was able to deploy a sophisticated Audit and Feedbacks system is encouraging, given that evidence is accumulating of its effectiveness in the general implementation literature. The availability of this as yet undeployed system is an opportunity that could be utilized at low cost, for future improvement efforts.

QUANTITATIVE FINDINGS

Actual Implementation and Intervention Application

In late 2012 and early 2013, seven CCACs (of a total of 14) were randomly selected to apply outcomes-based pathways for the management of wounds among their referral clients. Due to time and resource constraints as well as concerns about the validity of the intervention, two CCACs randomized to the intervention group elected not to apply the intervention, while one CCAC not randomized to the intervention opted to apply the intervention early. This was possible because the CHRIS software which enabled the use of OBPs was available to all 14 CCACs, but at the request of the OACCAC was to be switched on and used only in the intervention CCACs immediately, and was supposed not to be switched on in the control CCACs until the trial was complete. This was adhered to by five of the seven CCACs in the intervention group and six of the seven in the control group. Additionally, among the six centres that applied the intervention, three elected to use the available outcome-based pathways on only a subset of their wound care, and not all wound care. Table 3 summarizes this information.

Scientific limitations and assumptions made during data analysis are provided in Appendix B.

Table 3: Summary of implementation

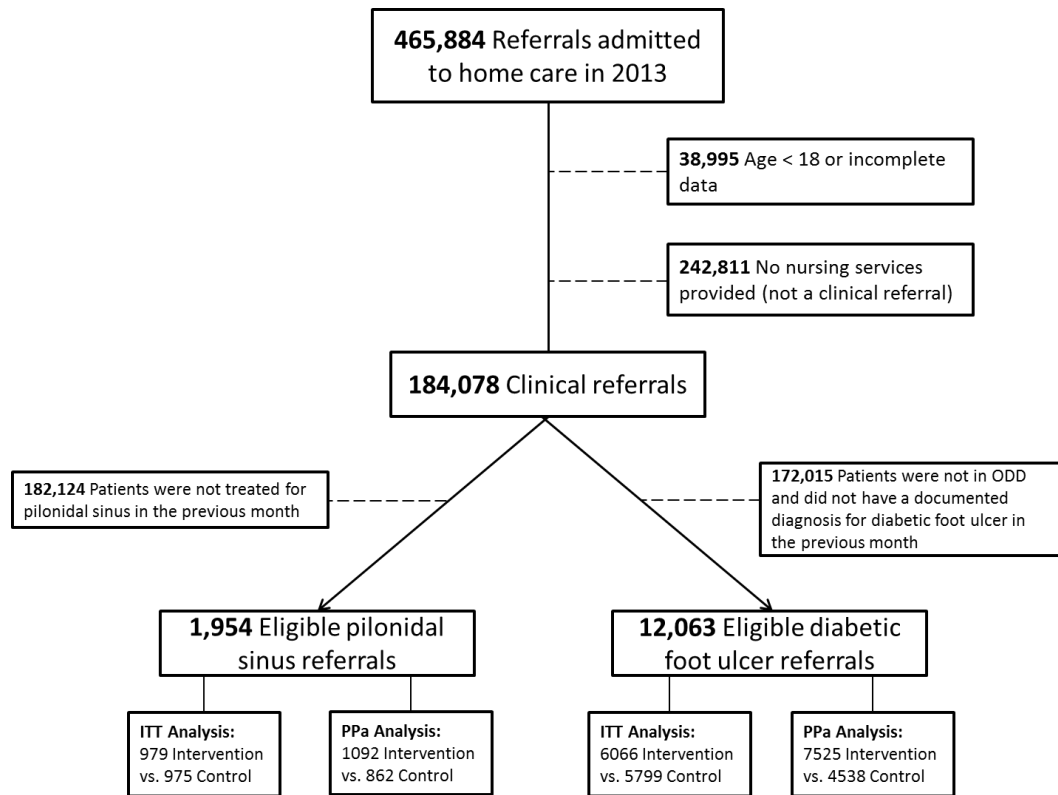
Health Region (names added for anonymity)	Randomized to intervention (Y/N)	Applied intervention (Y/N)	Date first intervention applied	*Wounds managed with outcome-based pathways
Silver	N	Y	June 10, 2013	Diabetic Foot Ulcer Pilonidal Sinus Pressure Ulcer Surgical Wound Traumatic Wound Venous Leg Ulcer
Green	N	N		
Gold	N	N		
Yellow	N	N		
Black	N	N		
Pink	Y	Y	January 31, 2013	All
Orange	N	N		
Purple	Y	Y	November 26, 2012	All
White	Y	N		
Gray	Y	Y*	July 15, 2013	Surgical Wound Traumatic Wound
Teal	Y	Y	February 7, 2013	Arterial Leg Ulcer Diabetic Foot Ulcer Pilonidal Sinus Pressure Ulcer Surgical Wound Traumatic Wound Venous Leg Ulcer
Brown	Y	Y	November 26, 2012	All
Red	N	N		
Blue	Y	N		

*"Gray" health region applied a subset of the outcomes-based pathways; they did not apply either of the candidate pathways involved in the current analysis and thus were not included in the per-protocol secondary analysis

*Wounds were listed if at least one referral admitted in 2013 applied the corresponding outcomes-based pathway (source of data: OACCAC)

Patients

We identified 465,884 referrals to any of the 14 Ontario home care centres in 2013. Of these, 38,995 had invalid or incomplete data or were for clients under 18 years of age. We further excluded 242,811 referrals that received no nursing services as they represented a non-clinical referral, for a total of 184,078 clinical home care referrals. Among these, we identified 12,063 meeting the definition of diabetic foot ulcer and 1,954 meeting the definition of pilonidal sinus, as defined in the methods section (Figure X). The Kappa agreement for the case definitions were 0.20 (95% CI, 0.198 to 0.206) and 0.36 (95% confidence interval [CI], 0.353 to 0.362), respectively.



*A small number of referrals (n=117) appear in both referral groups (pilonidal sinus and diabetic foot ulcer).

Figure X: Patient flow

Diabetic Foot Ulcer Cohort

Baseline data

Patients were a median of 66 year of age (IQR: 56-76) and were mostly male (60.7%). Apart from the diagnosis of diabetes, a large proportion (45.6%) had significant additional co-morbidities as indicated by a Charlson score of 2 or more (Table 4). No appreciable differences were observed between patients in the control and intervention arms for either of the primary (ITT) or secondary analyses.

Primary analysis

In the intention to treat analysis, 72.7% (4411/6066) patients in the control arm and 73.6% (4412/5997) patients in the intervention arm were discharged in the follow-up period with a median time to successful discharge of 26 days (IQR: 9-65) and 23 days (IQR: 8-62), respectively.

Results from the adjusted analysis provide no evidence to suggest a difference in the successful discharge between the two arms (HR, 1.05 ; 95% CI, 0.94 to 1.16; P = 0.39) (Table 5 and Fig. X).

Additional analyses

The results of additional analyses were consistent with the primary analyses (Table 7).

Table 4: Baseline characteristics of home care referrals with a diabetic foot ulcer diagnosis in 2013

Characteristic	Control (N=6,066)	Intervention (N=5,997)	Combined (N=12,063)	Standardized Difference
Age - yr				
<i>Mean ± SD</i>	64.82 ± 14.13	65.60 ± 14.21	65.21 ± 14.18	5%
<i>Median (IQR)</i>	65 (55-75)	66 (56-76)	66 (56-76)	
Female Sex				
	2,319 (38.23%)	2,425 (40.44%)	4,744 (39.33%)	4%
Urban Status				
	5,314 (87.60%)	5,055 (84.29%)	10,369 (85.96%)	9%
Neighbourhood Income Quintile				
<i>low</i>	1,665 (27.45%)	1,339 (22.33%)	3,004 (24.90%)	12%
	1,411 (23.26%)	1,211 (20.19%)	2,622 (21.74%)	7%
	1,167 (19.24%)	1,236 (20.61%)	2,403 (19.92%)	3%
	940 (15.50%)	1,199 (19.99%)	2,139 (17.73%)	12%
<i>high</i>	837 (13.80%)	986 (16.44%)	1,823 (15.11%)	7%
Charlson Co-morbidity Score				
<i>0 - 1</i>	3,211 (52.93%)	3,340 (55.69%)	6,551 (54.31%)	6%
<i>2 - 3</i>	1,734 (28.59%)	1,587 (26.46%)	3,321 (27.53%)	5%
<i>≥ 4</i>	1,121 (18.48%)	1,070 (17.84%)	2,191 (18.16%)	2%

Table 5: Outcomes analysis for home care referrals with diagnosis of diabetic foot ulcer

Analysis	Home care Discharge <i>no. successful discharge / total no. patients (%)</i>	*Adjusted Hazard Ratio (95% CI)	P Value
Primary Analysis – ITT			
<i>Control</i>	4411/6066 (72.7)	<i>Reference</i>	
<i>Intervention</i>	4412/5997 (73.6)	1.05 (0.94 – 1.17)	0.39
Secondary Analysis – PP			
<i>Control</i>	5495/7525 (73.0)	<i>Reference</i>	
<i>Intervention</i>	3328/4538 (73.3)	1.05 (0.94 – 1.16)	0.39

*Results from a Cox-proportional hazards model adjusted for age, sex, rural residence, neighbourhood income quintile, and Charlson co-morbidity score

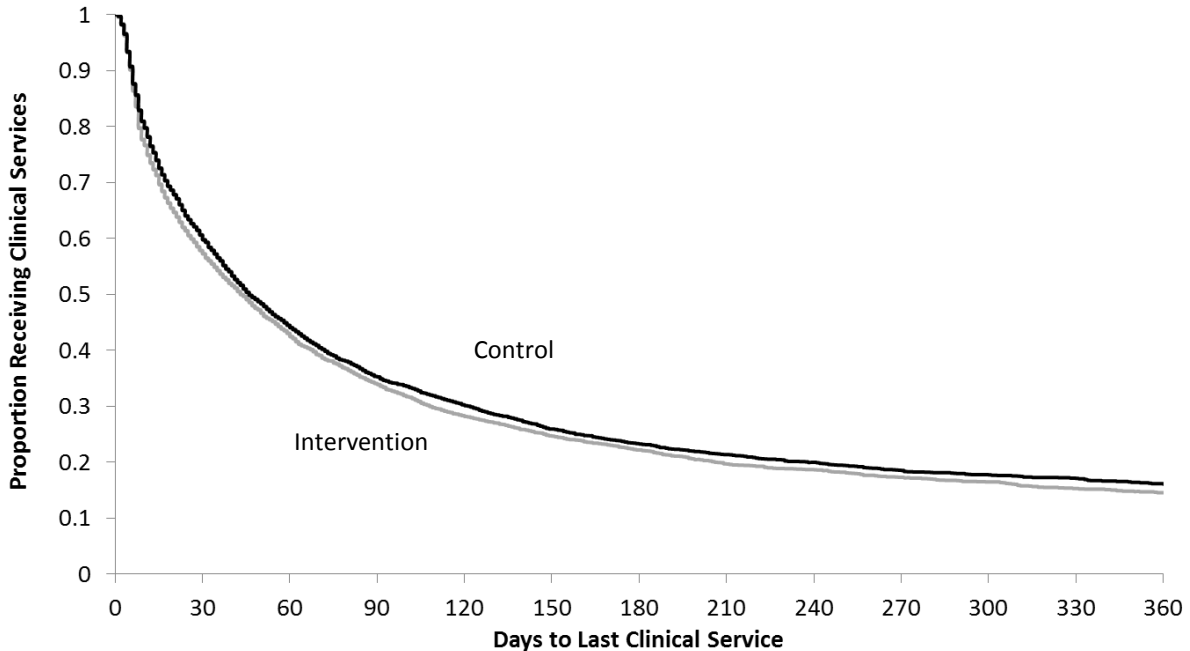


Figure X: Kaplan Meier curve of the proportion of clients who were successfully discharged from home care over the study period among the home care referrals with a diagnosis of diabetic foot ulcer.

Pilonidal Sinus Cohort

Baseline data

Patients were a median of 34 year of age (IQR: 24-48) and were mostly male (67.5%). Apart from the diagnosis for pilonidal sinus, these patients were predominantly healthy as indicated by a Charlson co-morbidity score of 0 or 1 (95%) (Table 6). No appreciable differences were observed between patients in the control and intervention arms for either of the primary (ITT) or secondary analyses.

Primary analysis

In the intention to treat analysis, 91.0% (891/979) patients in the control arm and 89.0% (868/975) patients in the intervention arm were discharged in the follow-up period with a median time to successful discharge of 28 days (IQR: 16 to 53) and 30 days (IQR: 16 to 52), respectively.

Results from the adjusted analysis provide no evidence to suggest a difference in the successful discharge between the two arms (hazard ratio [HR], 0.96 ; 95% CI, 0.82 to 1.12; P = 0.58). (Table 7 and Fig. X).

Additional analyses

The results of additional analyses were consistent with the primary analyses (Table 5).

Table 6: Baseline characteristics of home care referrals with a pilonidal sinus diagnosis in 2013

Characteristic	Control (N=979)	Intervention (N=975)	Combined (N=1,954)	Standardized Difference
Age - yr				
<i>Mean ± SD</i>	37.09 ± 15.66	37.64 ± 15.84	37.36 ± 15.75	3%
<i>Median (IQR)</i>	33 (24-48)	34 (24-49)	34 (24-48)	
Female Sex				
	312 (31.87%)	323 (33.13%)	635 (32.50%)	3%
Urban Status				
	879 (89.79%)	881 (90.36%)	1,760 (90.07%)	2%
Neighbourhood Income Quintile				
<i>low</i>	213 (21.76%)	169 (17.33%)	382 (19.55%)	11%
	191 (19.51%)	168 (17.23%)	359 (18.37%)	6%
	206 (21.04%)	194 (19.90%)	400 (20.47%)	3%
	193 (19.71%)	253 (25.95%)	446 (22.82%)	15%
<i>high</i>	175 (17.88%)	186 (19.08%)	361 (18.47%)	3%
Charlson Co-morbidity Score				
<i>0 - 1</i>	934 (95.40%)	929 (95.28%)	1,863 (95.34%)	0%
<i>2 - 3</i>	38 (3.88%)	30 (3.08%)	68 (3.48%)	4%
<i>≥ 4</i>	7 (0.72%)	16 (1.64%)	23 (1.18%)	9%

Table 7: Outcomes analysis for home care referrals with diagnosis of pilonidal sinus

Analysis	Homecare Discharge <i>no. successful discharge / total no. patients (%)</i>	*Adjusted Hazard Ratio (95% CI)	P Value
Primary Analysis – ITT			
<i>Control</i>	891/979 (91.0)	<i>Reference</i>	
<i>Intervention</i>	868/975 (89.0)	0.96 (0.82 – 1.12)	0.58
Secondary Analysis – PP			
<i>Control</i>	981/1092 (89.9)	<i>Reference</i>	
<i>Intervention</i>	778/862 (90.3)	0.95 (0.80 – 1.11)	0.50

*Results from a Cox-proportional hazards model adjusted for age, sex, rural residence, neighbourhood income quintile, and Charlson co-morbidity score

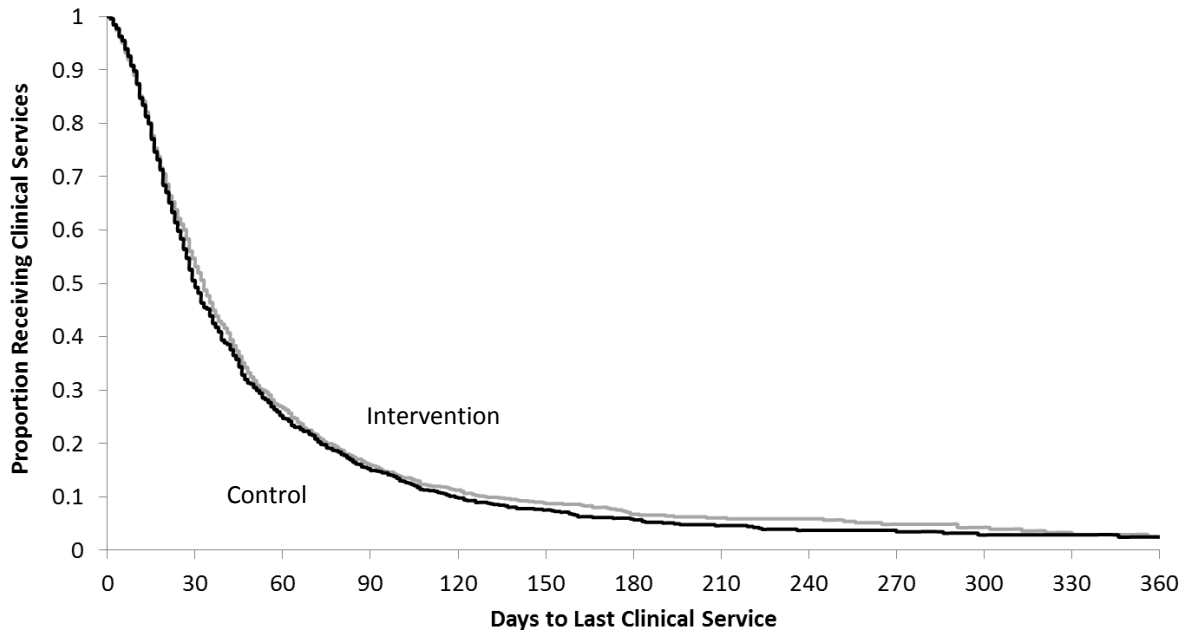


Figure X: Kaplan Meier curve of the proportion of clients who were successfully discharged from home care over the study period among the home care referrals with a diagnosis of pilonidal sinus.

DISCUSSION

Our aim was to conduct a realist, mixed methods evaluation of the ICCP to 1) understand the implementation journey from participant organizational perspectives and to 2) estimate the impact of the ICCP intervention on wound healing rates and patient-centered outcomes. We feel we were able to accomplish both of these evaluation aims, despite several challenges in design, collaboration and data availability.

The ICCP initiative was a complex intervention introduced into a complex system - transformation to a new way of tracking outcomes and receiving payment in multiple independent organizations with multiple accountabilities and relationships. Complex interventions have greater scope for variation in their delivery, and so are vulnerable to one or more components not being implemented as originally intended for a variety of reasons [26]. We became aware early on in our evaluation that the intervention as intended, and the intervention as implemented were divergent, and we could not simply 'measure' the outcome of the project with numbers - by unpacking the underlying interests and relations of the actors involved we are able to provide a more realistic understanding of the implementation as it actually occurred and therefore a more useful perspective on the measured outcomes and paths forward.

Our evaluation was pragmatic and explicitly sought to include the real-world setting of this experiment in its design. Had we bounded our evaluation of this program to simply measuring the uptake of the original planned intervention, we would have had to abandon our evaluation due to lack of data and divergence of the intervention from the intended plan. In contrast, our realist and formative evaluation of the 'intervention' from its conception to its implementation, using participant observer approach, and

a complex systems lens has allowed us to understand stakeholder perspectives. This in turn assists us in describing and understanding the changes made to the intervention as it developed, was piloted and implemented, and also to incorporate inter-organizational relationships into our understanding of the determinants of the effectiveness of the ICCP program *as implemented*.

What do the numbers tell us?

The main objective of the quantitative pragmatic randomized trial was to compare wound healing rates of clients treated by service providing organizations (SPOs) working with CCACs that were randomized to the intervention arm (using the ICCP intervention), to those of clients treated by providers working with CCACs which were in the control group (standard practice, no ICCP interventions). **Because only the Outcomes Based Pathways were implemented and because the CCM model was applied to both arms, this reduces the primary answerable question to whether or not the OBPs were applied and whether they changed patient outcomes.**

Our primary, intention to treat analysis shows no evidence of a difference (either increase or decrease) in successful discharge outcomes, compared to those in the standard of care group. Given that the trial was pragmatic (intended to answer whether or not this intervention was effective in the context of the Ontario health system) and as large as possible (including all eligible patients receiving home care for either diabetes related ulceration or pilonidal sinus in an entire province over a period of a year) this leads to the conclusion that, *as implemented*, the ICCP intervention failed to improve wound healing times in comparison with usual care approaches.

Our per protocol analysis, which corrects for contamination due to two CCACs electing not to implement the intervention, and one control CCAC which chose to implement early, also showed no impact, confirming that the intervention was not effective in achieving the intended goals even after allowing for the fact of local variability in implementation. The scientific strengths and limitations of the randomized control trial and analyses conducted are outlined in Appendix A.

Faced with the results above, one conclusion that can be drawn is that the intervention is not yet sufficiently acceptable to Ontario CCACs for widespread implementation, and that significant work remains to be done to correct the implementation process to improve uptake. These efforts could focus on the concepts outlined in the REAIM model, a framework designed to enhance the quality, speed, and public health impact of efforts to translate research into practice [27]. These concepts are :

- Reach to the intended target population
- Efficacy or effectiveness
- Adoption by target staff, settings, or institutions
- Implementation consistency, costs and adaptations made during delivery
- Maintenance of intervention effects in individuals and settings over time

What does the qualitative data tell us?

The focus of our qualitative evaluation was to observe and understand the process of development and implementation of the intervention from the stakeholder perspective. As described above, the intervention as implemented bore little relationship to the intervention which the MOHLTC commissioned the OACCAC to produce and implement and so analysis of how and why that evolution occurred provides significant insight into the outcome of ICCP type projects in Ontario Home Care.

Due to simultaneously *powerful* and *powerless* relationships, effectively the OACCAC was able to co-opt the intervention development process and steer it to best match with their own planned program innovations, controlling or preventing undesired change while at the same time appearing to meet their accountabilities to the Ministry. The implementation of the Outcome Based Pathways served as a plausible intervention to address the best practices component of ICCP and the Client Care Model represented a shift to specialized case management, although neither were exactly what was originally intended. The challenges of these relationships mixed with the challenges of major sector changes in management, reimbursement and performance measurement made for a rather mix. The market share environment and contractual obligations of the existing system made the aims of ICCP appear as a direct threat to the system status quo. The implementation of changes in business process could not be standardized because of the wide variation in role definitions and payment structures that exists between the CCACs, the CCACs and their SPOs and between SPOs; this made everyone fairly nervous as some organizations would have quite a bit to lose. ICCP was initially rolled out to “spotlight” CCACs who had volunteered in partnership with one SPO organization. Before any lessons could be learned the implementation was scaled up to involve all CCACs and all SPOs providing wound care services which created further confusion since the messaging was not consistent and was driven by the OACCAC – an association of the CCACs, not the SPOs. The lack of results illustrates the challenge of implementing major change into a system without accounting for organizational interests and relationships

The actual implementation of the Outcomes Based Reimbursement, arguably the main objective of the ICCP initiative, has been its biggest struggle. Our observations suggest that this is multifactorial; the interplay between the enormity of the change being requested, the lack of power within the OACCAC to insistently implement such a change, lack of close collaboration between the OACCAC, CCACs and SPOs, and risk aversion within the CCACs and SPOs themselves. With the proposed shadow billing system mentioned above, a tentative price could have been determined and implemented, with no financial risk to any party, and then refined through negotiation over time as evidence accumulated the change in income and quality of care; however mixed messaging about the goal and details of OBR created very high anxiety around the financial risk to stakeholders both in the CCACs and the SPOs which prevented movement on this issue. The implementation team was distracted from the overarching OBR goal by trying to set an acceptable price for each specific bundled diagnosis whereas it could think of this in a more aggregated form, as intended in the original ICCP plan, where total costs for all patients in the entire *program* of wound care are the focus (and where higher costs for complex cases balance out with lower costs for less complex cases). Future efforts to avoid this stalemate could start by affirming a shadow billing approach for the experimental period and reaching prior agreement on this as a way to minimize financial risk.

The choice of QI as a means to develop the intervention also diverted energy and attention away from actual change. Quality improvement is a locally focused, bottom up, open-ended approach to organizational improvement and is ill-suited to achieving targeted and pre-specified system level change of the kind needed to achieve the goals of the ICCP strategy. QI methods could have been more appropriately applied later in the implementation to assist with standardizing local business processes.

The ICCP/OBP & OBR initiative was launched with a vision of increased value for outcomes and a move to alternative reimbursement models within the Ontario Ministry of Health and Long Term Care – a vision from the top for what must happen for the healthcare sector to remain sustainable. The actual ICCP project intervention was implemented mainly by a team of “outside” actors with little leverage (within the OACCAC) and operating in isolation.. The CCAC and SPO business arrangements are difficult

to change, and gradually prevailed over the innovative intent and led to its transformation along “safe” lines, towards what the main actors wanted; a more robust data management system and to maintain current reimbursement approaches. Future attempts at radical change in fundamental organizing concepts for home care will require a more explicit and detailed initial description of the changes planned, with explicit and transparent efforts to ensure financial stability in the period during evaluation, and to safeguard the transparency and rigour of implementation, and of evaluation.

Conclusions

A bold and promising theory based innovation, previously applied only in a hospital setting was attempted in the home care setting. This type of approach to value for health outcomes can be a world leading initiative and the system must continue its efforts in the direction of value for outcomes. Perhaps the transformation of the intervention that we have outlined is not a failure but rather a “necessary evolutionary process” [28]; a trajectory entirely mediated by the interactions of actors, agendas and accountabilities within, and by external forces to, the existing system. These relationships are typically unpredictable and non-linear and have unpredictable results. Stronger definition of project goals, leadership oversight and stakeholder involvement are required to bring such a complex initiative to fruition.

While the quantitative results reported here largely show no effect of the intervention, this arises largely because the original intervention was substantially diluted in implementation and severely impacted by weak project management and incomplete engagement by key stakeholders. A key element, outcome based reimbursement was compromised by excessive focus on pricing data analysis efforts rather than identifying creative strategies for low risk implementation, which could have achieved sector wide consensus; instead little progress was made and “price” remains a sticking point. Only with mandatory OBR will the financial levers to achieve improved value in wound care be fully realized.

It is important to note that this lack of implementation does not constitute a failure of the theory of outcomes based reimbursement. In fact, the theory remains largely untested and now that the business processes – especially the information technology systems have been strengthened to allow for outcome measurement and payment, it is vital that work continues to test the full intervention. In our opinion, this theory remains a relevant to home care in Ontario, and would benefit from another attempt at implementation and evaluation, drawing on the valuable lessons learned from this first effort.

RECOMMENDATIONS FOR THE FUTURE

ICCP resulted in identification of some key areas for improvement in providing care to wound and orthopaedic patients receiving home care. In the end, two complex process changes were implemented to address these areas (outcome based pathways and revised case management model). This is a major achievement. Unfortunately, due to a diffusion of focus, less headway was made on other important elements.

All was not lost; major challenges were identified and overcome by the sector - business processes have been revised to allow for outcome measurement, using wound care pathways, which are outcome oriented (rather than clinically focused). There is now an opportunity to rethink how best to implement a low risk initial approach to OBR using shadow payment, and to increase efforts to implement aspects of the system explicitly aimed at system navigation and integration of care with other providers- e.g. family physicians, other professionals in the community.

Going forward, we offer the following insights & cautions as well as recommended next steps:

Insights & Cautions

1. The opportunity to be the first in the world to test this innovative, system-level change remains open and important. This evaluation should be seen as a point-in-time, formative view of the implementation ICCP & OBP/OBR initiatives which can be used to inform next steps, spread & sustainability and course correction where necessary.
2. Multi-method evaluation (qualitative & quantitative) should continue to be employed as a way to carefully observe a learning system such as this to understand the foundational pieces that inform success (and challenges) and to track commitment and clarity of understanding of the shared goals by all stakeholders.
3. System level change initiatives based on novel theories must go beyond specifying broad goals to clearly defining expectations and required deliverables. Notwithstanding this need for clarity, the open-ended process of problem conception and solution development should leave room for creativity. In other words, clarity of goals and specificity of means need not preclude, but rather encourage, creative and decentralized development of solutions.
4. Leadership of major change initiatives must be carefully considered and placed within organizations/teams, which receive a clear mandate and the necessary power to reach intended goals.
5. Implementation should engage with all stakeholders more deeply from the beginning. The strategy for working first with the CCACs, and then only later through them to SPO's did not achieve synergistic collaboration between these two key groups early on in the process, thus missing an opportunity to root changes in the front line experience.
6. Quality Improvement approaches alone cannot be used as system level change strategy and must only be leveraged where appropriate. QI works well when there are clearly defined objectives and common processes. Neither was the case here.
7. Because of the complexity of the implementation and extended timeframes required for uptake and business process revision, the impact of the change initiatives on client outcomes may not be evident for some time.

Potential Next Steps

1. System wide audit and feedback mechanisms, which came close to successful implementation because they were skillfully built into the OACCAC IT system (CHRIS), should be revisited, as they

are a proven, low cost, effective intervention to promote practice change under conditions very like those in wound care- complex patients, where multiple disciplines and individuals are involved in care over a prolonged time. These need to be highly accessible, report on a small and accurate number of outcomes and be delivered in a “push” style system which does not rely on providers to go and find the information.

2. The Client Care Model implementation should be revisited to include a focus on the system navigation role for care coordinators, as this would be a valuable addition to the Home Care system for complex patients. Other community based stakeholders and potential team members in wound care should be considered for inclusion in initiatives to promote wound care improvement.
3. A shadow billing system should be put in place with all CCACs and SPOs to accurately capture outcome-based cost and resource use for aggregate groups of wound care patients. This is the only way to mitigate the risk of determining a price in the absence of evidence and move the sector into an outcome based reimbursement model.
4. A longitudinal analysis of client outcome data should be done in one year’s time to assess the true impact of the change initiatives on outcome measures such as healing time, length of stay, re-hospitalization, amputations etc.

Appendix A – Diabetic Foot Ulcer and Pilonidal Sinus Outcome Based Pathways

TO BE ATTACHED IN PDF FORM

Appendix B – Scientific Strengths and limitations of the RCT design & analyses as conducted

The major strengths of this quantitative evaluation are that it is a randomized trial, eliminating confounding and cancelling out imprecision in measurement; and that it is as large as it is possible to be, given that essentially all patients with the condition of interest during the period of interest, in the entire province of Ontario were included in the study, thanks to the comprehensive coverage of ICES data.

We chose a cluster randomized evaluation design in order to minimize contamination by allocating entire natural units (CCACs and their Service Provider partners). One view of this trial might argue that the crossover of 3 out of the 14 CCACs to the other arm of the trial (two from intervention to control, one from control to intervention) as well as the relatively weak implementation of the intervention in each CCAC (with poor coverage of eligible patients, and a very slow ramp up towards a less than complete coverage) suggests that the trial itself was flawed. Using the concept of pragmatism as meaning a real world trial, we would suggest that this result is the actual real world performance of the intervention, and thus far from being a failed trial, we would argue that it is an accurate evaluation of the impact of this novel intervention under real world conditions as they currently exist in Ontario Home Care.

The data itself has inherent limitations in that it is administrative data. The ICES definition of Diabetes has been validated [18] and although it may be less sensitive for early diabetes in which no hospital admissions and discharges would have occurred, and few primary care visits with that diagnosis may as yet have taken place, it is likely to be extremely accurate for any long standing condition, in which multiple primary care and hospital visits for reasons of diabetes are likely to have taken place- the patients who have both diabetes and an ulcer are extremely likely to have fallen in that latter group as ulceration due to diabetes is a late stage complication [29]. Similarly for pilonidal sinus, the differential diagnosis is straightforward and involves a surgical procedure which is accurately captured on ICES data and [30] while this may not be always correct, the imprecision is washed out in both arms due to the randomization preventing bias.

One other advantage of administrative data is that it allows for large but affordable trial. The outcomes were measured within an existing administrative data system which reduced primary data collection burden for the RCT to zero.

We only included patients with confirmation that nursing services were provided. Given the spectrum of severity of both conditions, we would assume that home care requiring nursing services within 30 days of the diagnosis of the condition would receive some management for these diseases. It is possible that some patients were receiving nursing care for other conditions entirely, and their diabetes or pilonidal sinus wounds were not being dressed by the visiting nurse, but this seems unlikely, given the relative severity of these two wounds (albeit chronically for diabetes and acute for pilonidal sinus). Even if this was a problem, because this is a randomized trial, this would only have widened the confidence interval rather than biased the point estimate of effect.

The Kappa for agreement between the ices definition of diabetic foot ulcer, and the CCAC definition was 0.2 This would be considered low to medium degree of correlation; while that for pilonidal sinus was 0.36 which would be considered medium.

These modest Kappas suggest that either the ICES definition or the CCAC definition is neither sensitive nor specific. Since the ices definitions are validated (while there is no such validation for the CCAC cases,

we would tend to think of ICES as the gold standard here). This points to one potential explanation for the apparent lack of effect- it is that the wound care pathways are not applied to patients who all have the wounds of interest, and many with those wounds do not get allocated to CCAC, or once there to wound care pathways. Furthermore, the analyses were complicated by the differences in data collection between the arms. CCACs that applied the CHRIS system could be monitored on their application of the wound care pathways; however, CCACs that did not use the CHRIS system could not be monitored as their reporting was not standardized (followed usual care). It is possible that groups in the control arm applied the pathways irrelevant of their access to CHRIS; this would nullify any effect of the pathways, if they truly existed.

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