

OSTEOPOROSIS KNOWLEDGE TRANSLATION IN LONG-TERM CARE

To Carl, Isabella and Lucie

EVALUATING THE FEASIBILITY AND EFFECTIVENESS OF EVIDENCE-BASED
KNOWLEDGE TRANSLATION INTERVENTIONS TARGETING OSTEOPOROSIS
AND FRACTURE PREVENTION IN ONTARIO LONG-TERM CARE HOMES

By

COURTNEY CLARE KENNEDY, BSC, MSC

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of the Requirements for the Degree Doctor of Philosophy

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Department of Clinical Epidemiology and Biostatistics, Health Research Methodology

McMaster University

Hamilton, Ontario, Canada

TITLE: Evaluating the Feasibility and Effectiveness of Evidence-based Knowledge Translation Interventions Targeting Osteoporosis and Fracture Prevention in Ontario Long-term Care Homes

AUTHOR: Courtney Clare Kennedy, BSc (University of Alberta), MSc (Queen's University)

SUPERVISOR: Professor Lehana Thabane, PhD

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ABSTRACT

Background: Despite strong evidence, strategies for improving bone health are underutilized. Knowledge translation (KT) interventions aim to improve uptake of evidence-based practices, however the feasibility and effectiveness of such strategies require further evaluation within Long-term Care (LTC). In this thesis, we examined the impacts of a province-wide osteoporosis strategy and a more intensive multifaceted KT strategy including expert-led educational meetings, audit/feed-back, and action planning for quality improvement. Both studies targeted interdisciplinary LTC teams (physicians, nurses, pharmacists, dietician, and other staff).

Methods: In the first thesis study, we examined the impact of the *Ontario Osteoporosis Strategy for LTC* by investigating changes in facility-level prescribing rates (vitamin D, calcium, osteoporosis medications) before and after its implementation (2007 versus 2012). The second study was a pilot cluster randomized trial evaluating the feasibility and effectiveness of a 12-month, multifaceted, interdisciplinary KT intervention [Vitamin D and Osteoporosis Study (ViDOS)]. Prescribing outcomes included: vitamin D ≥ 800 IU (primary), calcium ≥ 500 mg/day, and osteoporosis medications (high-risk residents only). Feasibility outcomes included recruitment, retention, data collection, intervention fidelity, and process changes. We analyzed resident level data using the generalized estimating equations (GEE) technique, adjusting for clustering.

Results:

In both studies, significant improvements were observed for vitamin D and calcium prescribing. In the first study, prescribing increased by 38% and 4%, respectively, between 2007 and 2012. In the ViDOS trial, the 12-month intervention resulted in an absolute improvement of 15% and 7%, respectively (intention to treat cohort). There was no significant effect for prescribing of osteoporosis medications in either study. In the ViDOS study, recruitment and retention rates were 22% and 63%, respectively; good intervention fidelity was achieved and intervention homes reported several process changes.

Conclusion:

This thesis study demonstrated that KT interventions targeting evidence-based osteoporosis and fracture prevention strategies were feasibly and effectively applied with interdisciplinary LTC teams.

PREFACE

This is a sandwich thesis consisting of four individual manuscripts that are either published, conditionally accepted, or submitted to peer-reviewed journals. The copyright material is reproduced with permission from the publisher of the journal. All of the papers included in this document were part of the student's thesis research program on evaluating the effectiveness of knowledge translation interventions in Ontario Long-term Care (LTC) homes.

The contribution of the student to the impact evaluation of the *Ontario Osteoporosis Strategy in LTC (paper 1)* included: conceiving the evaluation study; working with the pharmacy provider to obtain data downloads; overseeing the data validation process; data preparation and cleaning; data analysis and interpretation; and drafting the manuscripts.

The second thesis study, the Vitamin D and Osteoporosis Study (ViDOS) trial, received an operating grant from the Canadian Institutes of Health Research (Funding Reference Number: MOP-114982). Dr. Papaioannou was the Principal Investigator on this grant, and the student was the PhD trainee. The contribution of the student to the ViDOS trial (*papers 2-4*) included: contributing to the conception and study design; co-writing the grant proposal; consulting with co-investigators regarding methodological development; liaising with the pharmacy provider regarding data collection; lead writer of the study protocol; developing slide presentations for steering group and data safety committee meetings; overseeing the coordination and implementation of the study; developing the data management system; providing methodological support to the study coordinators;

leading the data management committee; data preparation and cleaning; data analysis and interpretation; presenting the work at international meetings; and drafting the manuscripts.

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LIST OF ABBREVIATIONS

95% CI	95% Confidence Interval
BMD	Bone Mineral Density
CAROC	Canadian Association of Radiologists and Osteoporosis Canada
CIHI	Canadian Institute for Health Information
CIHR	Canadian Institutes of Health Research
CQI	Continuous Quality Improvement
CRT	Cluster Randomized Trial
DOC / ADOC	Director of Care / Assistant Director of Care
DXA	Dual-energy X-ray absorptiometry
FRAX	Fracture Risk Assessment tool
GEE	Generalized Estimating Equations
GOAL	Gaining Optimal Osteoporosis Assessments in Long-Term Care
HRT	Hormone Replacement Therapy
ICC	Intraclass Correlation Coefficient
KT	Knowledge Translation
KTA	Knowledge to Action
LTC	Long-term Care
MAR	Medication Administration Record
ODB	Ontario Drug Benefit
OR	Odds Ratio

PAC	Professional Advisory Committee
PDSA	Plan Do Study Act
Q1 / Q3	Quartile 1 / Quartile 3
RAI-MDS	Resident Assessment Instrument–Minimum Data Set
RCT	Randomized Controlled Trial
SD	Standard Deviation
SERM	Selective Estrogen Receptor Modulator
ViDOS	Vitamin D and Osteoporosis Study
WHO	World Health Organization

CHAPTER 1: INTRODUCTION TO THESIS

INTRODUCTION TO THE THESIS

1. BACKGROUND

1.1 Long-Term Care in Ontario

There has been a rapid increase in the number of seniors over age 85 (the 'oldest old'). In Canada, as the baby boomers enter this age group beginning in 2021, this cohort is projected to nearly triple in size to approximately 2.5 million (1). Along with this increase in the 'oldest old', there has also been a consequent increase in the number of people admitted to long-term care [LTC (2)]. This important sector provides residential care for older adults who need access to 24-hour nursing, supervision, or higher levels of personal care (3). LTC homes (also termed nursing homes) are funded by the Ontario Ministry of Health and Long-Term Care and governed by the Long-Term Care Homes Act, 2007 (4). Under this legislation, LTC homes are monitored and annually inspected by the Long-Term Care Home Quality Inspection Program.

Resident Characteristics

The average LTC resident in Ontario is 82 years old, 48% are 85 years or older, and 69% are women (5). Approximately 75% have moderate to severe limitations in activities of daily living (personal hygiene, toilet use, locomotion and eating) and approximately 60% have moderate to severe limitations in cognitive function (short-term memory, skills for daily decision-making, expressive communication). Based on data from the Canadian Institute for Health Information (CIHI) utilizing the Resident Assessment Instrument-Minimum Data Set (RAI-MDS 2.0)], approximately 13% of residents will experience a

fall over 30 days (5). CIHI data from 2009/2009 indicates that 7.9% and 25% of residents had a documented hip fracture or osteoporosis diagnosis, respectively (6).

Home Characteristics

As of 2010, there were approximately 625 LTC homes in Ontario and a total of 76,904 beds [99% occupancy rate (6)]. Approximately 59% are for-profit, 25% are non-profit/charitable, and 17% are municipal government-run facilities. It is estimated that approximately 75% of direct nursing care is provided by personal support workers, 13% by registered practical nurses, and 11% by registered nurses (6).

1.2 Osteoporosis and Fractures

The World Health Organization (WHO) defines osteoporosis as a systemic skeletal disease "characterized by low bone mass, microarchitectural deterioration of bone tissue leading to enhanced bone fragility, and a consequent increase in fracture risk (7)." Age-related bone loss is a complex process occurring due to a combination of genetic, hormonal, biochemical, and environmental factors (8). As individuals age, the increasing fragility of bones occurs due to an imbalance that occurs between bone resorption and formation (i.e., less new bone is formed than resorbed) resulting in bone loss and structural damage (9).

In a population-based study (10), the absolute lifetime risk of any osteoporotic fracture after age 60 was 44% for women and 25% in men (mortality adjusted and assuming a lifespan of 85 years). The corresponding estimates for hip and clinical vertebral fractures,

respectively, were 9% and 18% in women and 4% and 11% in men. The risk of osteoporotic fractures increased with each subsequent age decade, even in the oldest categories. In those aged 80 and older, the 5-year risk of fracture was 17% in women and 11% in men.

Consequences of Fractures

The consequence of fractures, particularly hip and vertebral, can be devastating and may be most severe in the very elderly (11). Fractures are associated with substantial pain, reduced quality of life, mobility limitations, greater dependence in self-care, institutionalization, and mortality (11-14). Fractures contribute to significant excess costs and healthcare spending, with each incident hip fracture in Canada costing approximately \$45,000 (15). Acute care costs related to osteoporotic fractures are estimated at \$1.2 billion and \$3.9 billion when outpatient care, prescription drugs, indirect costs, and long-term care are included (16).

1.3 Osteoporosis and Fractures in LTC

The elderly residing in LTC are particularly vulnerable to fractures due to a high prevalence of osteoporosis [approximately 50-80% (17, 18)] combined with an increased risk of falling (19). Hip fractures are one of the leading causes of hospitalization for LTC residents and occur at a higher rate than in the community (20). In an Ontario study (7), the hip fracture rate for LTC residents was approximately 2-4 times that of similarly aged community-dwelling individuals. The estimated incidence of hip fractures in LTC is 3-

6%, with a prevalence of hip fracture up to 25% (21); an estimated 36% of female and 54% of male residents die within one-year of hip fracture (22).

Vertebral fractures are also common in LTC. Using a DXA vertebral fracture assessment technique, Rondondi et al. (18) estimated that one in three LTC residents had a prevalent vertebral fracture. This has important implications given that vertebral fractures are associated with chronic pain and substantial reductions in physical functioning [including bending- and walking-related activities (23)], self-care, mobility and ambulation (12). Furthermore, vertebral fractures are an important clinical marker of future fractures, particularly in the oldest old. In women age 85 years and older, the 5-year risk of hip fracture following a vertebral fracture was 24% (24).

1.4 Osteoporosis Clinical Practice Guidelines

In 2010, updated Osteoporosis Canada Clinical Practice guidelines (25) were published to address the paradigm shift that has occurred in the past decade; rather than focusing on the treatment of low bone mineral density (BMD), the current emphasis is on using risk-based assessments that consider absolute risk of fracture (26, 27). To guide treatment decisions, the 2010 Osteoporosis Canada guidelines utilize an integrated risk-based approach based on identifying a patient's 10-year absolute fracture risk. Two tools are recommended to assess 10-year fracture risk: the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool (28) and the Fracture Risk Assessment tool (FRAX) of the WHO (26). The CAROC tool assesses fracture risk based on sex, age, BMD, prior fragility fracture, and glucocorticoid use. The FRAX tool uses clinical risk

factors for fracture with and without the use of femoral neck BMD. Clinical risk factors included body mass index, prior fracture, parental history of hip fracture, glucocorticoid uses, rheumatoid arthritis/secondary causes of osteoporosis, current smoking, and alcohol intake.

Treatment Considerations

Pharmacologic therapy is indicated for patients at 1) high absolute fracture risk (> 20% probability over 10 years) based on the risk tools and 2) individuals over age 50 with a hip or vertebral fracture or more than one fragility fracture. Individuals designated as moderate risk, should undergo careful clinical evaluation and also be considered for pharmacological treatment, particularly in the presence of additional risk factors such as falls and height loss. Supplementation with 800-1000 IU/day vitamin D is recommended for adults with moderate risk of vitamin D deficiency; higher intakes could be indicated for some individuals (e.g., 2000 IU/day). The optimal daily intake for elemental calcium is 1200 mg through diet and supplements.

1.5 Challenges with Implementing Osteoporosis Guidelines in LTC

Our team has previously examined barriers to evidence-based osteoporosis practices in LTC including surveys of family physicians (29, 30) and front-line staff. We also conducted a qualitative study, adjunct to the work described in this thesis, with interdisciplinary LTC teams including physicians, nurses, pharmacists, dieticians (31, 32). Similar work has been conducted in the United States by Colon Emeric and colleagues (33, 34).

As summarized in Table 1, a number of barriers emerged related to knowledge gaps and patient-related factors including confusion by practitioners in applying general practice guidelines to elderly residents. Although LTC physicians recognize the value of osteoporosis medications for high-risk residents (29, 30), there is still a great deal of uncertainty regarding: (1) the assessment of fracture risk e.g., BMD testing is difficult in LTC residents (2) the practicality of utilizing risk assessment tools (46, 47) if required information is often missing (3) treatment benefits for LTC residents who have shortened life span and polypharmacy; and (4) knowing whom to treat, particularly residents at moderate fracture risk (30). Residents with multiple concurrent health problems (multiple comorbidity) provide additional challenges for practitioners trying to apply guidelines developed for patients without additional comorbidities (35).

The utility of the FRAX and CAROC tools in the LTC cohort is questionable. The CAROC tool is based on BMD, which is not frequently utilized in the LTC setting. FRAX was designed for patients age 40-90, which excludes many LTC patients (36). Furthermore, Greenspan et al. (36) demonstrated that treatment would be recommended in 81-98% of residents if the FRAX tool were used, suggesting that alternative screening strategies may be required in this group.

Other barriers are related to gaps in care processes. For example, osteoporosis and fracture prevention is not routinely made part of care-plans, and there is a lack of standardized osteoporosis and fracture information collected at admission and quarterly reviews (31, 33, 37). Some barriers are related to technology/structure, including

inaccessibility of required risk variables (e.g., resident or parental fracture history), not having enough time to obtain required information and lack of a fracture risk tool designed for the LTC setting (31, 33, 34, 37).

Adapting Practice Guidelines for LTC

Given the difficulty in applying general practice guidelines within LTC, a Canadian Institutes of Health Research (CIHR) -funded consensus meeting (PI: Dr. Papaioannou) was held in 2013 with LTC stakeholders, osteoporosis and geriatrics leaders to adapt the 2010 Osteoporosis Canada guidelines (25) for frail elderly or LTC residents. The guidelines will be published shortly and a dissemination plan will be implemented to educate LTC practitioners across Canada.

1.6 General Barriers to Evidence-based Practice in LTC

Despite a growing emphasis on quality improvement in LTC homes, in general the use of clinical practice guidelines within LTC homes is low (38, 39). Challenges associated with the uptake of evidence-based practices in the LTC setting include structural characteristics [e.g., high staff turnover, paperwork/regulatory demands, resource constraints, high proportion of non-professional staff, physicians often not located at the LTC home (38-40)] and practice-level challenges [i.e., polypharmacy and shortened life-expectancy (33, 41)]. Workplace factors have also been postulated as barriers to knowledge use in LTC, including entrenched ways of learning and communicating (40), and the absence of a learning and research culture (40, 42, 43).

There is a lack of research on medical interventions conducted in the LTC setting (41), and the majority of practice guidelines do not adequately discuss issues related to elderly patients and often include procedures or recommendations that are not feasible (44, 45). Traditional medical practice and research focus on single disease models, which fails to account for the complexities of multiple comorbidity common in this cohort (35). Despite these numerous challenges, LTC homes may have good "learning capacity" and be able to implement practice changes, as they are small, less hierarchical than acute-care settings, and rely on collaborative decision making (40).

2. OSTEOPOROSIS & FRACTURE CARE-GAP

In non-LTC cohorts, the osteoporosis care-gap has been well documented (46-49). In LTC, a few studies have examined osteoporosis-related prescribing and reported that only 9-25% of all residents (including those at highest risk) received osteoporosis therapy (50-53). Fewer than 20% were prescribed calcium and vitamin D (54). In addition, poor documentation of fractures and osteoporosis in medical and pharmacy records has been noted as a wide-spread problem (37), which makes it difficult to identify those individuals who are at high-risk for future fractures (25).

3. BRIDGING THE EVIDENCE-PRACTICE GAP

3.1 Knowledge Translation & Implementation Science

The CIHR formally define knowledge translation (KT) as "a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application

of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system (55)". Strauss and colleagues less formally define KT as "the methods for closing the gaps from knowledge to practice (56)".

For years it has been documented that even good quality evidence is not being used consistently in practice and that knowledge translation may prove to be an effective way to bridge this gap (57). In 1997, Grol challenged that "evidence-based medicine should be complemented by evidence-based implementation (58, 59)". Indeed, in the past 15 years, this has blossomed into an interdisciplinary research field termed implementation science: "research relevant to the scientific study of methods to promote the uptake of research findings into routine healthcare in clinical, organisational or policy contexts (60)."

Implementation Research in Long-term Care

Despite a growing body of KT evidence in acute care or community settings, implementation research in LTC is still in its early stages (40, 61, 62). In a 2012 scoping review (62), only 3.6% (n= 61) of all KT articles identified were related to older adults, and of these, half were done in the LTC setting. The majority of studies included only a single KT strategy (e.g., audit and feedback alone). Only 40% targeted mixed professional groups (i.e., medical, nursing, rehabilitation, pharmacy) despite the emphasis on collaboration among the disciplines practicing in LTC. A recent systematic review of interventions to improve interdisciplinary care in LTC (e.g., staff education, case conferences, care planning) confirmed a benefit for some patient outcomes with an

interdisciplinary approach. Given the paucity of implementation research in the LTC setting, it is imperative to examine the feasibility and effectiveness of KT interventions that utilize a combination of behaviour change strategies (multifaceted KT interventions) and that are targeted at interdisciplinary teams.

3.2 Knowledge Translation to Improve Osteoporosis & Fracture Care

3.2.1 Ontario Osteoporosis Strategy

The Ontario Ministry of Health and Long-Term Care launched the *Ontario Osteoporosis Strategy* in February 2005 (63). The main goals of this initiative are to reduce hip and other osteoporotic fractures, and to reduce morbidity, mortality and costs from osteoporotic fractures. One of the secondary fracture prevention initiatives is the Fracture Clinic Screening Program, developed and operated by Osteoporosis Canada in partnership with the Ontario Orthopaedic Association and the Ontario College of Family Physicians (63, 64). Utilizing Osteoporosis Screening Coordinators located in 38 high volume fracture clinics across the province, this program facilitates diagnosis and appropriate care by identifying and assessing men and women who have had a fragility fracture. As of March 2013, over 40,000 patients with a fragility fracture (aged 50 and older) had met with an Osteoporosis Screening Coordinator to discuss bone health and fracture risk.

Another core component of the *Ontario Osteoporosis Strategy* is public health KT including professional education and outreach (63, 65). These programs and activities

include: BoneFit- a comprehensive workshop on evidence-informed exercise training, Women's College Hospital Multidisciplinary Osteoporosis Telemedicine Program (consultations, treatment and education to remote communities), Continuing Medical Education events sponsored by Osteoporosis Canada, *and the Ontario Osteoporosis Strategy for LTC* (described below).

A detailed logic model has been implemented to provide a framework for research and evaluation activities (63). The Osteoporosis Research, Monitoring and Evaluation Work Group is also in place to provide ongoing monitoring of a core set of performance indicators developed for the *Ontario Osteoporosis Strategy* using consensus methods (63).

3.2.2 Ontario Osteoporosis Strategy for LTC

Launched in 2007, the *Ontario Osteoporosis Strategy for LTC* is a provincial KT initiative dedicated to increasing the uptake of evidence-based osteoporosis/fracture prevention strategies in LTC homes (63, 66). The goals are to prevent unnecessary fractures from falls and handling during care, provide information about simple low cost care interventions, and reduce the pain and suffering from osteoporosis and fractures. One of the key activities has been the development and wide-scale dissemination of Fracture Prevention Tool-Kits which include practical, evidence-based materials tailored specifically to the LTC setting (e.g., posters, best practices check-lists, pocket cards, point of care tools). In addition, a 10-minute DVD was developed to be used as a resource for

staff training and education. Optional training webinars were developed to introduce LTC homes to the concepts and materials contained in the Tool-kits.

In 2011, the *Ontario Osteoporosis Strategy for LTC* website [www.osteoporosislongtermcare.ca (66)] was launched and promoted in all LTC homes across Ontario. The website contains user-friendly information, tools and resources including PowerPoint modules and an online community of practice that enables individuals to collaborate, network, and share ideas and success stories.

4. OUTLINE OF THE THESIS: OVERALL AIMS & RATIONALE

The overall aim of this thesis was to consider the success of knowledge translation initiatives for improving the uptake of evidence-based osteoporosis and fracture prevention practices in LTC.

Evaluation is an important part of determining whether a program is meeting its goals. In the context of public health, an impact evaluation assesses the extent to which program objectives are being met including whether changes in knowledge, attitudes, or behavior have occurred (67). Observational studies may represent a feasible or appropriate study alternative to evaluating public health interventions given the difficulty with implementing randomized controlled trials (RCTs) in this context (68). Thus, the first paper examined the impact of the *Ontario Osteoporosis Strategy for LTC*, by investigating osteoporosis-related prescribing trends before and after implementing this strategy (2007 versus 2012). Given that it has been demonstrated that LTC home

characteristics (e.g., size, ownership, chain affiliation) may influence quality of care outcomes, we also examined whether they played a role in prescribing outcomes observed in Ontario.

In addition to provincial-wide KT initiatives, there was a perceived need for more intensive KT activities to improve the uptake of osteoporosis and fracture prevention best practices in LTC homes. Greater understanding about whether a more targeted KT model is feasible and effective could guide future widespread implementation across the province. Thus, we developed a multifaceted KT intervention that utilized professional behaviour change strategies that have been demonstrated as effective in other settings (i.e., audit and feed-back, educational meetings, continuous quality improvement). In order to rigorously evaluate this intervention, a pilot, cluster randomized trial was implemented in 40 Ontario LTC homes. The second paper describes the study protocol for this trial, the Vitamin D and Osteoporosis Study (ViDOS). The third paper presents the main clinical results of the ViDOS trial and the fourth paper presents the feasibility of implementing this type of intervention using a cluster randomized trial methodology.

Given the paucity of KT research in LTC, we aimed to contribute to the field of implementation science by examining whether professional behaviour strategies, with proven benefits in community or acute care settings, are transferable to the LTC sector.

5. METHODOLOGICAL CONSIDERATIONS

There were many methodological considerations to take into account in designing the thesis studies. Below we provide an overview of some of these issues, in addition to providing a more complete description of why we chose our primary trial outcome (Vitamin D), a description of the primary data source for both studies (Medical Pharmacies Group Limited), and the target professional audience for whom the KT interventions were directed (Professional Advisory Committees in LTC homes).

5.1 Primary Outcome: Vitamin D

We chose vitamin D as the primary outcome as it is inexpensive, safe, well-tolerated and has high-quality evidence for falls and fracture reduction in LTC residents. Meta-analyses demonstrate that vitamin D reduces falls (69), and calcium and vitamin D reduce fractures in LTC residents (70). In a CIHR Knowledge Translation Research Synthesis grant on strategies for hip fracture prevention in older LTC residents, vitamin D supplementation was the intervention with the strongest evidence (71). Despite the indication for widespread use in LTC residents, previous studies in Ontario indicate sub-optimal prescribing (50). Appropriate vitamin D was considered a dosage ≥ 800 IU/day, which reflects current practice guidelines and the strong evidence that suggests this is the minimum dose consistently associated with prevention of fractures (25, 72).

5.2 Primary Data Source: Medical Pharmacies Group Limited

For both thesis projects, our primary data were downloaded from a central pharmacy database at Medical Pharmacies Group Limited (73). This large pharmacy provider

delivers medication and consulting services to over 40,000 LTC residents residing in approximately one-third of all Ontario LTC homes. De-identified clinical data including demographic, prescribing, and co-morbidities were download by the Director of Systems Services at Medical Pharmacies. Prescribing data represented all medications dispensed to all residents residing in LTC homes we included in the thesis studies. Algorithms were created to calculate the total dosage of vitamin D and calcium supplements based on all daily/weekly/monthly preparations, including multivitamin and medications (e.g., alendronate with vitamin D). Algorithms were also created to detect an osteoporosis medication prescription.

Co-morbidity data were derived from a database that contained diagnoses appearing on the Medication Administration Record (MAR; i.e., legal record of the drugs administered to the resident). Initially, the list of a resident's diagnoses are derived from an admission sheet containing medical history provided to the pharmacy by nursing staff. Further updates to the list may have occurred following admission when diagnoses were included on physician orders or quarterly medication reviews.

5.3 Target Audience: Professional Advisory Committee

The KT interventions were targeted at the team of professionals providing care to LTC residents. In the ViDOS study, in order to enhance participation we conducted the educational meetings in conjunction with Professional Advisory Committee (PAC) meetings that occur quarterly to address resident care and quality improvement objectives. The PAC team typically consists of the Administrator (responsible for the

overall operation of a Long Term Care home), Medical Director (physician who oversees medical care and services), Director of Care (registered nurse who supervises the care of all residents), Consultant Pharmacist (specialist pharmacist who advises on medication regimens), Director of Food Services/Dietician, and other nursing, medical or rehabilitation staff. In addition to PAC team members, all physicians responsible for the care of residents within the LTC home were invited to participate and were eligible for continuing medical education credits with the Ontario College of Family Physicians.

5.4 Importance of Pilot Studies

Pilot trials are designed to assess a number of feasibility objectives prior to conducting a larger trial (74). Particularly in situations where there is little previous data to inform the process, they are considered essential pre-requisites that will enhance success of a future, wide-scale trial. In the design of a pilot study, it is important to specify explicit criteria for determining the success of feasibility objectives. Since there were many unknowns in conducting this type of KT intervention in the Canadian LTC setting, it was important to include a number of explicit feasibility outcomes including recruitment, retention, and fidelity with intervention. However, given the considerable resources required to implement such a trial, in addition to examining feasibility outcomes, we appropriately powered the study to assess the statistical significance of prescribing our clinical primary outcome (appropriate prescribing of vitamin D).

5.5 Clustering Effect of Data

In the thesis studies, the KT interventions were targeted at teams of health professionals practicing within LTC homes. Thus, patient data were clustered within LTC homes, which means that residents within the same LTC home may be more similar to each other than residents in other LTC homes. The statistical measure of this similarity within clusters is the intraclass correlation coefficient (ICC), which is expressed as the ratio of the between-cluster variance to the total variance (total variance=between-cluster plus within-cluster) (75). The ICC takes a value between 0 and 1; a high ICC indicates a lot of similarity in response within clusters and conversely a low ICC means that individuals within clusters are effectively responding independently of one another. The consequence of increased similarity within clusters, is a loss in statistical power (i.e., larger number of patients will be required than in an individual patient RCT).

It is imperative to take the clustering effect into account in the statistical analysis, as failing to do so may result in overestimated statistical significance and overly narrow confidence intervals (75). In patient-level analyses, we adjusted for the clustering effect using the Generalized Estimating Equations (GEE) technique (76). In cluster-level analyses, 95% confidence intervals were adjusted using the method by Donner and Klar (77).

5.6 Influence of LTC Home Characteristics

In a recent survey of Directors of Care (n=392), Berta et al. (78) examined the impact of organizational factors on utilization and implementation of care protocols including:

rural/urban location, LTC home size, chain membership, and type of ownership (for-profit, non-profit, government-operated). Results indicated there was no significant difference in care protocol usage, however the approach to implementing care protocols differed in relation to ownership and size. For example, in for-profit and government-operated homes, the belief in continuous improvement for resident care was higher, larger (compared with medium or smaller) LTC had more autocratic decision-making, and for-profit homes used more external sources of training and education.

The relationship between type of ownership (i.e., for-profit versus non-profit) has received considerable study in relation to quality of care outcomes. In general, non-profit LTC homes have been associated with higher quality of care (79), although multi-facility chains may have greater resources to facilitate implementation of clinical practice guidelines (80). It has been suggested that smaller LTC homes may be less innovative or able to adopt operational changes, although Berta et al. (81) found that Directors of Care perceived smaller LTC homes as being easier to manage administratively and more conducive to caregiving relationships that included emotional care and support. Larger facilities may benefit from efficiencies of scale, however they were perceived as being more difficult to manage and focused on operational efficiency. In the United States, smaller facilities have also been shown to have higher scores on quality indicators of resident care (82).

The first paper examined the influence of organizational characteristic on osteoporosis-related prescribing in LTC homes across Ontario including facility size (small: < 100;

medium: 100-199; large: ≥ 200 beds), profit status (for-profit, municipal/government, non-profit), chain affiliation (chain/non-chain), and community population size (where the LTC home was located). We also included the potential impact of organizational characteristics in the design of the ViDOS trial by stratifying homes based on home size (< 250 versus ≥ 250 beds) and ownership (for-profit/non-profit). Furthermore, LTC homes from across Ontario, in communities of various population sizes and geographical locations (including rural and northern) were included.

5.7 Capturing Falls, Fractures and Osteoporosis Diagnoses in LTC

In the ViDOS trial, one of our secondary objectives was to collect incident falls and fracture data as part of our feasibility and safety data; however, the study was not powered to compare to outcomes between study groups. Our rationale to include falls and fractures as a feasibility measure (i.e., rather than an outcome measure) was due to the anticipated number of problems with collecting falls and fractures data in LTC homes. Given resource constraints, it was not possible to have a trained research assistant collect the information; instead we asked each LTC home to record falls and fracture information.

Others have noted the difficulty in collecting falls and fractures in LTC. In a 2005 Health Canada report (83), the investigators of a Canadian falls prevention collaborative outlined several problems with the reporting system for collecting falls and resultant injuries in LTC homes. None of the primary data sources, including medical records, critical incident reports, and RAI-MDS 2.0 (84), function well to collect falls prevalence or

incidence data. Even though RAI-MDS 2.0 is a standardized system, data provided is only the number of fallers within a given time period (reports are generated for the past 30 or past 31-180 days). Although it is possible to determine whether a hip or "other" fracture occurred within the given reporting period, more detailed information, including the date of fracture, is not available. There may also be gaps between reporting periods.

Despite these limitations, utilizing RAI-MDS 2.0 reports as a standardized method to collect some data would have been an option for our study, however it was not possible for us to incorporate this in our design as many Ontario LTC homes had not yet implemented RAI-MDS when we began the study in 2009. During the study, we confirmed that the LTC homes used different approaches to fill in the datasheets we provided (e.g., internal falls monitoring systems, electronic medical record reports, and critical incident forms), and that obtaining the information often required auditing medical charts. Although explicit instructions were given regarding completing the standardized excel sheet, a noted limitation is that the accuracy of the data was dependent on the LTC staff members and the sources they checked.

High-Risk Residents: Prevalent Fracture or Osteoporosis Diagnosis

To ascertain high-risk residents (i.e., documented diagnosis of osteoporosis or prevalent fracture), we examined diagnosis data from the Medical Pharmacies database. This data source is limited in that there is potential for errors of omission. Diagnoses added to this database are based on admission health assessments and new diagnostic information is not frequently updated. However, when we compared our baseline estimates for hip

fractures and osteoporosis diagnosis, they were reasonably similar to rates reported in a provincial report that utilized 2008/09 RAI-MDS 2.0 data (6). They reported rates of 25% and 7.9% for osteoporosis and hip fractures, respectively, and we reported rates of approximately 28% and 6% in the ViDOS trial. In general, prior fractures or osteoporosis diagnosis (prior to entering the facility) may be undiagnosed as they are not always documented among residents' charts. This would be a limitation of RAI-MDS data as well.

6. OVERVIEW OF FOUR THESIS PAPERS

This thesis consists of four distinct manuscripts involving the evaluation of knowledge translation initiatives for improving the uptake of osteoporosis and fracture-prevention best practices in Ontario LTC homes.

The first paper, "Osteoporosis Prescribing in Ontario Long-term Care Homes: Have Practices Changed Five Years After Implementing a Provincial Knowledge Translation Strategy?", is an observational study that examined prescribing trends before and after implementing the *Ontario Osteoporosis Strategy for LTC*. In this study, we also examined the influence of LTC home characteristics (i.e., home size, profit status, chain affiliation, number of prescribing physicians per home, population size of the community) on prescribing rates. In December 2013, it was conditionally accepted (pending minor suggested revisions) in the *Canadian Journal on Aging*.

The second paper, "An Interdisciplinary Knowledge Translation Intervention in Long-term Care: Study Protocol for the Vitamin D and Osteoporosis Study (ViDOS) Pilot Cluster Randomized Controlled Trial", provides a comprehensive overview of the intervention, methods, and analytic strategy for the ViDOS trial. It was published in 2012 as a study protocol in the journal Implementation Science.

The third paper, "A Successful Knowledge Translation Intervention in Long-term Care: Final Results from the Vitamin D and Osteoporosis Study (ViDOS) Pilot Cluster Randomized Controlled Trial", presents the final clinical results for this trial. There is some overlap in the introduction and methods with the second paper that was necessary in order to stand alone as a publication. It has been submitted for publication as Original Research to the Journal of the American Geriatrics Society (JAGS).

The fourth paper, "Implementing a Knowledge Translation Intervention in Long-term Care: Feasibility Results from the Vitamin D and Osteoporosis Study (ViDOS)", presents the trial feasibility results and additional information on process change that occurred after the study. It has been submitted for publication as a Brief Report to the Journal of the American Medical Directors Association.

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Table 1. Summary of Barriers to Evidence-Based Osteoporosis and Fracture Care

Structure	Practice Guidelines – not feasible/applicable for LTC residents
	Information for risk assessment tools not easily accessed
	Staff turn-over
	Competing demands/time constraints
	Physicians infrequently on-site
	Staff mix: less skilled than other sectors
Process	Osteoporosis & fracture history/risk: not assessed at admission/quarterly
	Diagnoses/risk variables not being capture electronically
	Osteoporosis/fracture prevention not being incorporated into formal care-plans
Patient-level	BMD is impractical
	Co-morbidities/complex patients
	Poly-pharmacy common
	Decreased life-span
	Side-effects of medications/calcium
	Confusion regarding whom to treat (particularly moderate risk)

Practitioner- Uncertainty about risk-based assessment/decision
level Question whether treatment is worth it in elderly individual

 Poor compliance with proper administration of bisphosphonates

 Staff have limited knowledge regarding Osteoporosis & fracture
 assessment/treatment

CHAPTER 2:

Thesis Paper 1: Osteoporosis Prescribing in Ontario Long-term Care

Homes: Have Practices Changed Five Years after Implementing a Provincial
Knowledge Translation Strategy?

PREFACE TO CHAPTER 2

This chapter describes an observational study examining prescribing trends before and after the implementation of a provincial strategy aimed at improving osteoporosis and fracture prevention in Ontario Long-term Care (LTC) homes. This work was conducted in 2012-2013.

This work was conditionally accepted (pending minor suggested revisions) in December 2013 to the *Canadian Journal on Aging*. Upon final acceptance, a request will be made to the publisher of the journal to obtain permission to include copyright material.

The student contribution to this work (*paper 1*) included: conceiving the evaluation study; working with the pharmacy provider to obtain data downloads; overseeing the data validation process; data preparation and cleaning; data analysis and interpretation; and drafting the manuscripts. The co-authors were involved as follows: Dr. Ioannidis participated in the data validation process, provided assistance with data analysis, and provided critical review of the manuscript. Dr. Thabane advised on statistical analysis and interpretation and provided critical review of the manuscript. Dr. Adachi, Dr.

Giangregorio and Ms. Pickard participated in data interpretation and provided critical review of the manuscripts. Mr. O'Donnell performed the data downloads from the pharmacy database, performed validation checks, and provided critical review of the manuscript. Dr. Papaioannou was involved in the conception of the study, provided funding support, participated in data interpretation, and provided critical review of the manuscripts.

Osteoporosis Prescribing in Ontario Long-term Care Homes: Have Practices Changed Five Years After Implementing a Provincial Knowledge Translation Strategy?

Courtney C. Kennedy, MSc

Epidemiologist, Department of Medicine, Division of Geriatrics, McMaster University
St. Peter's Hospital, GERAS Centre, 88 Maplewood Avenue, Hamilton, Ontario L8M 1W9

Email: kennedyc@hhsc.ca; **Phone:** 905-521-2100 ext. 77715; **Fax:** 905-318-2654

George Ioannidis, PhD

Biostatistician, Department of Medicine, McMaster University, Charlton Medical Centre
25 Charlton Ave East, Hamilton, Ontario, L8N 1Y2

Email: g.ioannidis@sympatico.ca; **Phone:** 905-529-1317; **Fax:** 905-521-1297

Lehana Thabane, PhD

Professor/Associate Chair, Clinical Epidemiology and Biostatistics, McMaster University
St Joseph's Healthcare-Hamilton, 50 Charlton Avenue East, 3rd Floor Martha Wing, Room H325,
Hamilton, Ontario L8N 4A6

Email: thabanl@mcmaster.ca; **Phone:** 905-522-1155 ext 33720/34905; **Fax:** 905-528-7386

Jonathan D. Adachi, MD

Professor, Department of Medicine, McMaster University
Alliance for Better Bone Health Chair in Rheumatology
Charlton Medical Centre, 25 Charlton Ave East, Hamilton, Ontario, L8N 1Y2

Email: jd.adachi@sympatico.ca; **Phone:** 905-529-1317; **Fax:** 905-521-1297

Denis O'Donnell, BScPhm, PharmD

Director Clinical Research, Medical Pharmacies Group Limited
590 Granite Court, Pickering, ON L1W 3X6

Email: dodonnell@medicalpharmacies.com; **Phone:** 905-420-7335; **Fax:** 905-642-1295

Lora M. Giangregorio, PhD

Associate Professor, Department of Kinesiology, University of Waterloo

200 University Ave West, Waterloo, Ontario, N2L 3G1

Email: lora.giangregorio@uwaterloo.ca; **Phone:** 519 888 4567 x 36357

Laura E. Pickard, MA

Research Coordinator, Department of Medicine, McMaster University

St. Peter's Hospital, GERAS Centre, 88 Maplewood Avenue, Hamilton, Ontario L8M 1W9

Email: pickardl@hhsc.ca; **Phone:** 905-521-2100; **Fax:** 905-318-2654

Alexandra Papaioannou MD, MSc

Professor, Department of Medicine, Division of Geriatrics, McMaster University

Eli Lilly Canada Chair in Osteoporosis

St. Peter's Hospital, GERAS Centre, 88 Maplewood Avenue, Hamilton, Ontario L8M 1W9

Email: papaioannou@hhsc.ca; **Phone:** 905-521-2100 ext. 77715; **Fax:** 905-318-2654

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KEY WORDS

Osteoporosis, prescribing, long-term care, nursing home, vitamin D, calcium

ABSTRACT

Purpose: The purpose of this study was to describe prescribing trends before and after implementing a provincial strategy aimed at improving osteoporosis and fracture prevention in Ontario long-term care (LTC) homes (www.osteoporosislongtermcare.ca).

Methods: Data were obtained from a pharmacy provider for 10 LTC homes in 2007 and 166 homes in 2012. We used weighted, multiple linear regression analyses to examine facility-level changes in vitamin D, calcium and osteoporosis medication prescribing between 2007 and 2012.

Results: After five years, the estimated increase in vitamin D, calcium and osteoporosis medication prescribing rates, respectively, was 38.2% (95% confidence interval [CI]: 29.0, 47.3; $p < 0.001$), 4.0% (95% CI: -3.9, 12.0; $p = 0.318$), and 0.2% (95% CI: -3.3, 3.7; $p = 0.91$).

Conclusions: Although causality cannot be assessed in this study, our findings suggest that wide-scale knowledge translation activities were successful in improving vitamin D prescribing within Ontario LTC, although ongoing efforts are needed to target homes with low uptake.

INTRODUCTION

An estimated 60-80% of Long-term Care (LTC) residents have osteoporosis (1, 2) and in Canada it is estimated that the fracture rate for LTC residents is approximately 2-4 times that of similarly aged community-dwelling residents (3). Combined with age-related losses in bone quantity and quality (4), the high prevalence of sarcopenia (5), frailty (6), and falls (7) in LTC residents may synergistically increase susceptibility for fractures (8-11). Furthermore, many LTC residents have sub-optimal vitamin D levels (12, 13), which is associated with lower bone mineral density (14-16), decreased lower extremity function (17, 18), falls (13, 18) and fractures (19-22). In a Canadian LTC study (12), 54% of all residents and 69% of residents taking ≤ 400 IU/day had sub-optimal levels [25-hydroxyvitamin D (25(OH)D) < 75 nmol/L] for bone health (14).

In 2005, the Ontario Ministry of Health and LTC launched the *Ontario Osteoporosis Strategy* (23, 24). This ongoing, population-based, strategic action plan is targeted at improving osteoporosis prevention and care across all residents in Ontario, with the overall goal of reducing morbidity, mortality, and costs from osteoporosis-related fractures. Its five main objectives are: health promotion; access and appropriate utilization for bone mineral density testing; targeted post-fracture care including improved assessment and treatment for osteoporosis; professional education; and research and evaluation (23, 24). To accomplish and implement these objectives, several initiatives are targeted at distinct populations. In 2007, a LTC-focused component of this provincial

strategy was added (the remainder of the paper is focused on that component, the *Ontario Osteoporosis Strategy for LTC*).

The *Ontario Osteoporosis Strategy for LTC* has undertaken a province-wide program of outreach activities to increase awareness about fracture prevention specifically in LTC, with a focus on the importance of appropriate vitamin D and calcium intake, and falls prevention. To date, knowledge translation activities have included: environmental scans, systematic reviews, barrier analysis, creating & disseminating a 10-minute educational video and Fracture Prevention Toolkits, launching a web-site (www.osteoporosislongtermcare.ca), and educational outreach (12, 25-31).

Osteoporosis and fracture prevention in LTC is multi-faceted and includes falls prevention activities, risk assessments, ensuring adequate intake of calcium and vitamin D, and balance and strengthening exercises (32, 33). For residents at highest risk of fractures, hip protectors and osteoporosis medications are options that should be considered (25, 32). Pharmacologic therapy is indicated for patients at 1) high absolute fracture risk (> 20% probability over 10 years) based on risk tools (34, 35) and 2) individuals over age 50 with a hip or vertebral fracture or more than one fragility fracture (32). Several studies in Ontario (12, 36) and other regions (37-42) have demonstrated that the management of osteoporosis and fractures is sub-optimal in LTC residents.

In 2007, at the outset of the *Ontario Osteoporosis Strategy for LTC*, we conducted an environmental scan to examine the prescribing of vitamin D, calcium and osteoporosis

medications in a convenience sample of ten Ontario LTC homes. In 2012, we had access to prescribing records and facility characteristics for a large, unselected cohort of Ontario LTC homes (n=166). Thus, the primary purpose of this analysis was to describe and compare vitamin D, calcium, and osteoporosis medication prescribing rates before and after implementing the *Ontario Osteoporosis Strategy for LTC*. A secondary objective was to examine the association between resident/facility characteristics and prescribing rates. Although we cannot infer any causal associations in this descriptive study, our analysis of prescribing trends and correlates will highlight the impact of wide-scale outreach activities and provide guidance regarding the direction of future knowledge translation efforts.

METHODS

Setting

In Ontario, all LTC homes are licensed or approved by the provincial health ministry. Termed "nursing homes" or "aged care homes" in other jurisdictions, these facilities provide assistance with activities of daily living and access to 24-hour nursing care (43).

Study Cohorts

Data for both cohort years (2007 and 2012) were obtained from Medical Pharmacies, a large pharmacy provider who provides medications, clinical support, and consulting services to approximately one-third of all LTC homes in Ontario (> 40,000 residents). As outlined in Figure 1, in August 2007, de-identified medication and demographic data were downloaded from a sample of 10 LTC homes from across Ontario. The homes were quasi-randomly selected by the pharmacy database manager (i.e., no formal randomization technique was employed, but the manager selected a convenience sample of homes to ensure geographical coverage across the province). In August 2012, data were downloaded for all Ontario LTC homes serviced by Medical Pharmacies (n=206), excluding 40 homes who participated in the Vitamin D and Osteoporosis Study (ViDOS). Briefly, ViDOS was a pilot, cluster randomized trial examining the feasibility and effectiveness of a more intensive, multifaceted, knowledge translation intervention targeting fracture prevention in LTC (30). Professional Advisory Committees (physicians, nurses, pharmacists, and other staff) at intervention homes participated in three small-

group, interactive educational meetings over 12-months. Content at the sessions, which were facilitated by an expert opinion leader, included a standardized presentation, question and answer session, action planning for quality improvement, and audit and feedback review. Control homes received the same knowledge translation as all other LTC homes in Ontario (described below).

Knowledge Translation Activities

Targeting LTC healthcare professionals (including medical, nursing, pharmacy, rehabilitation, dietary), the *Ontario Osteoporosis Strategy for LTC* has implemented several key knowledge translation activities including educational meetings, educational outreach, and development and dissemination of educational materials.

Physicians and nurse consultants with expertise in osteoporosis and geriatrics provide ongoing continuous medical education including presentations at annual conferences [Ontario Long Term Care Physicians, Registered Nurses Association of Ontario (RNAO)] and LTC forums; materials and practice tools are distributed at exhibitor booths.

Partnerships with these professional organizations and other stakeholder groups (e.g., Ontario College of Family Physicians, Residents and Family Councils, Ontario Long Term Care Association, Ontario Association of Non-Profit Homes & Services for Seniors, corporate multi-facility chains, provincial falls prevention strategy) have resulted in opportunities to engage LTC professionals, corporate leaders, and policy makers. For example, representatives from these organizations serve on the *Ontario Osteoporosis*

Strategy for LTC's advisory council and have facilitated surveys regarding awareness and information needs among their members.

The development and dissemination of educational materials has been another key component of the *Ontario Osteoporosis Strategy for LTC*. Fracture Prevention Toolkits were developed and delivered to all LTC homes in the province. The Toolkits provide practical, evidence-based materials tailored specifically to the LTC setting including: posters, best practices check-lists, pocket cards, and point of care tools. In addition, a 10-minute DVD (Meeting the Challenge of Osteoporosis and Fracture Prevention) was developed as a resource for staff training and education. Optional training webinars were developed to introduce LTC homes to the concepts and materials contained in the Toolkits. In 2011, the *Ontario Osteoporosis Strategy for LTC* website (www.osteoporosislongtermcare.ca) was launched and promoted in all LTC homes across Ontario. In addition to providing information and resources (e.g., PowerPoint modules), registered users receive e-newsletters and have access to an online community of practice that encourages the sharing of ideas and best practices.

Targeted educational outreach is also delivered by 13 Osteoporosis Canada area managers who are responsible for implementing and integrating all *Ontario Osteoporosis Strategy* (including non-LTC) projects, building relationships, and disseminating information in the community and institutions (23). Within LTC, these area managers deliver in-services to front-line staff and families and encourage the implementation of Toolkits and best practices for fracture prevention.

Data Sources and Outcomes

Data were downloaded from a central pharmacy database that contained all residents' medication/supplement orders. In 2007, we included the bisphosphonates etidronate, alendronate, and risedronate as osteoporosis medications. In 2012, we added more recently approved medications [i.e., zoledronic acid (November 2007), teriparatide (February 2010), denosumab (August 2010)]. We calculated the total quantity of vitamin D (IU) and calcium (mg) consumed daily, which included multi-vitamins/minerals, and medications containing calcium and vitamin D. Daily values were derived from weekly and monthly formulations. In 2012, validation checks were performed, comparing our program with a method that included manual identification of medications by pharmacists; discrepancies were reviewed until matching results were obtained.

A binary outcome was created for prescription of any osteoporosis medication. Based on daily intakes, we created binary outcomes for vitamin D ≥ 800 IU/day and calcium ≥ 500 mg/day. These were chosen to be consistent with 2010 Osteoporosis Canada clinical practice guidelines (32) which recommend vitamin D supplementation ≥ 800 IU/day for adults over age 50, and 1200 mg/day of elemental calcium from both diet and supplementation. Typically, supplementation with 500 mg/day of calcium would be required to meet daily targets, as dietary intake of calcium among Canadian LTC residents has been estimated to be far below the recommended amount. In one small Canadian study (44), mean dietary intake was 600 mg/day (SD=261) for women and 780 mg/day (SD=268) for men in LTC.

Facility characteristics such as number of beds, profit status, geographical location, and chain affiliation were collected from publically available information on the Health Ministry web-site.

Analyses

Descriptive statistics [means, standard deviations (SD), counts (%), ranges (min, max) and quartiles (Q1, Q3; i.e., middle 50%)] were tabulated as appropriate. Only facility-level demographic characteristics (mean age, percentage female, and number of resident beds) were available for the 2007 cohort; additional characteristics including profit status, chain affiliation, and mean number of doctors per facility are reported for 2012.

Differences in demographic characteristics between cohort years were examined using the general linear model (GLM) procedure.

Facility-level prescribing rates were calculated as point prevalence estimates: the numerator was all residents with the relevant medication/supplement order on the day of the data download, and the denominator was all current residents on that day. Box-plots were constructed to describe the distribution of prescribing rates across LTC homes. The average change in facility-level prescribing rates between cohort years (2012 compared to 2007) was determined using weighted multiple linear regression analyses, adjusted for age, sex, and home size. This technique accounts for differences in precision, which is a function of the sample size and the estimate itself. Each facility-level prescribing rate was assigned a weight equal to the reciprocal of its variance.

Correlates of prescribing were examined only for the 2012 cohort, as additional resident and facility-level data were available. The generalized estimating equations technique (45), assuming an exchangeable correlation structure, was used to examine the relationship between resident/facility characteristics and prescribing rates. Facility-level variables included: home size (small: < 100; medium: 100-199; large $\geq$ 200 beds), profit status (for-profit, municipal/government, non-profit), chain affiliation (chain/non-chain), number of prescribing physicians per home, and the population size of the community in which the home was located in. Resident variables included age and sex. The LTC home was the clustered variable in all analyses. The results are reported as odds ratios [OR's] and 95% CI's.

All analyses were conducted separately for vitamin D, calcium, and osteoporosis medications using SAS version 9.1 and SPSS v. 20. The criterion for statistical significance was $\alpha=0.05$. Ethics approval was received from the Hamilton Health Sciences/McMaster University Faculty of Health Sciences Research Ethics Board.

RESULTS

The 2007 cohort was n=2098 residents living in 10 LTC homes, and the 2012 cohort was n=21,699 residents living in 166 LTC homes (Figure 1). Facility characteristics are displayed in Table 1. The mean facility size (i.e., number of beds) was greater for the 2007 versus 2012 cohort ($p<0.05$). The percentage of all residents taking vitamin D (≥ 800 IU/day), calcium (≥ 500 mg/day), and osteoporosis medication, respectively, was 31.3% (34.9% of women; 25.8% of men), 26.2% (31.1% of women; 16.8% of men), and 17.2% (21.6% of women; 8.8% of men) in 2007, and 59.4% (63.2% of women; 50.4% of men), 33.0% (37.5% of women; 22.3% of men), and 18.1% (22.2% of women; 8.3% of men) in 2012.

Change in Facility Prescribing Rates: 2007 to 2012

Table 2 presents the weighted, mean facility-level prescribing rates for 2007 and 2012, and the estimated change between cohort years. Between 2007 and 2012, prescribing rates increased by 38.2% (95% CI: 29.0, 47.3; $p<0.001$) for vitamin D and by 4.0% (95% CI: -3.9, 12.0; $p=0.318$) for calcium, but the latter was not significant. There was no significant difference in osteoporosis medication prescribing rates between cohort years (0.2%, 95% CI: -3.3, 3.7; $p=0.91$).

Distribution of Prescribing across LTC homes

Figure 2a illustrates the spread in vitamin D (≥ 800 IU/day) prescribing rates across LTC homes, ranging from 7 - 55% in 2007 and 23 - 95% in 2012. The prescribing rates of

vitamin D for the middle 50% of homes (i.e., Q1, Q3) were 24 - 47% in 2007 and 48 to 73% in 2012.

Figure 2b shows the spread in calcium (≥ 500 mg/day) prescribing rates across LTC homes, ranging from 14 - 43% in 2007 and 2 - 78% in 2012. The calcium prescribing rates for the middle 50% of homes were 22 to 32% in 2007 and 22 to 40% in 2012.

As displayed in Figure 2c, compared with the supplements, there appeared to be less dispersion in prescribing rates for osteoporosis medications across LTC homes and the distributions were similar for both cohort years. Osteoporosis medication prescribing across LTC homes ranged from 7 - 31% in 2007 and 0 - 53% in 2012. Prescribing rates for the middle 50% of homes were 10 to 23% in 2007 and 13 to 23% in 2012.

In 2012, we also examined the various types of osteoporosis medications prescribed. The percentage of all residents who received an osteoporosis medication, by sub-type was 17.2% bisphosphonate and 0.9% denosumab.

Correlates of Prescribing (2012)

We examined several facility-level (home size, profit status, chain affiliation, number of prescribing physicians, community population size) and resident variables (age and sex) in relation to prescribing rates. As displayed in Table 3, increasing age, number of physicians, and community size were positively associated with prescribing. Males were less likely to be prescribed osteoporosis supplements/medications. There were no

significant associations between prescribing and chain status, profit status, or LTC home size.

DISCUSSION

This study examined prescribing patterns before and after the initiation of a provincial knowledge translation strategy focused on improving fracture prevention within Ontario LTC homes (www.osteoporosislongtermcare.ca). Although we cannot assess causality, our results suggest some improvement in evidence-based prescribing practices during the study period.

There was increased uptake of the recommendation to prescribe appropriate amounts of vitamin D (i.e., ≥ 800 IU/day). Between 2007 and 2012, the estimated increase in vitamin D prescribing was nearly 40% and by 2012 the upper quartile of LTC homes was prescribing vitamin D (≥ 800 IU/day) to 73-95% of residents (Figure 2a). Despite the substantial increase in overall vitamin D prescribing, the considerable spread in prescribing between homes suggests ongoing knowledge translation efforts are needed to target homes with low rates and that home-specific barriers should be addressed.

We observed a 4% non-significant increase in calcium prescribing between 2007 and 2012; there appeared to be greater dispersion in facility prescribing rates for 2012 (Figure 2b). We hypothesize that this spread may reflect some of the uncertainty about the risks and benefits of calcium in light of publications reporting an increased risk of cardiovascular events associated with calcium supplementation (46). Furthermore, in the 2010 Osteoporosis Canada clinical practice guidelines (32), there is greater emphasis on obtaining calcium thru dietary rather than supplements. Few studies have reported on

dietary calcium intake in LTC residents, however one small Canadian study suggests that 500 mg supplementation would be required for most LTC residents to meet the daily calcium target (44).

Despite the availability of newly approved medications, prescribing of osteoporosis medications did not appear to increase between 2007 and 2012. In both cohort years, three quarters of LTC homes had prescribing rates <23% and with the exception of outliers, all homes had prescribing rates <34% (Figure 2c). We are not able to comment on the appropriateness of the prescribing rates, since we did not have access to information regarding the risk status of residents (i.e., documented osteoporosis or fractures). We do know from our recent surveys that many LTC physicians recognize the value of osteoporosis medications for high risk residents (27, 47), but there is still a great deal of uncertainty regarding: 1) the assessment of fracture risk e.g., BMD testing is difficult in LTC residents (30, 31, 47) and application of existent tools (35, 48) may be impractical; 2) treatment benefits for LTC residents; and 3) knowing whom to treat, particularly residents at moderate fracture risk (47). To address these practice-level barriers for managing osteoporosis and fractures in LTC, in early 2013 the *Ontario Osteoporosis Strategy for LTC* held a Canadian Institutes of Health Research (CIHR) consensus conference to adapt the 2010 Osteoporosis Canada clinical practice guidelines for frail elderly and LTC residents. Future knowledge translation efforts will be aimed at disseminating these guidelines to LTC practitioners.

Comparison with Other Studies

The 2007 prescribing rates in our study were similar or higher than other studies conducted prior to this time. In these studies only 6-25% of residents, many of whom were selected based on high-risk status, received an osteoporosis medication (38-40, 42, 49). Several studies did not examine vitamin D and calcium use, as they utilized reimbursement databases and supplements are not adequately captured. In a Canadian study based on 2005/2006 Resident Assessment Instrument - Minimum Data Set 2.0 data (RAI-MDS 2.0; n= 17 LTC homes in Ontario and Manitoba), approximately 27% of high-risk residents (i.e., documented osteoporosis or fracture) were prescribed any calcium and vitamin D, with 6.5% and 3.6% prescribed calcium or vitamin D, respectively, and 19% prescribed a multivitamin (36). In American studies, Kamel et al. (41) reported <12% of all residents received any calcium or vitamin D supplementation and Gupta et al. (50) reported that 57% of female residents received calcium and 32% vitamin D, but this included low dose supplementation (e.g., vitamin D 200 IU/day).

There were limited studies with which to compare our 2012 results. Of the few available, our prescribing rates were similar for calcium and substantially higher for vitamin D. In Canadian studies (2009-2010 data), 25% to 45% were taking calcium supplementation and <35% were taking vitamin D ≥ 800 IU/day (12, 51). Similarly, in a recent American study based in an academic-affiliated LTC centre, 35% of residents received vitamin D ≥ 800 IU/day prior to a quality improvement intervention (52).

Prescribing Correlates and Variation between Homes (2012)

In multivariable analyses, both female gender and increasing age were associated with prescription of vitamin D, calcium and osteoporosis medications. The association with gender is similar to other studies (42, 49), but the association with age is in contrast to another study which found a reverse association with age in LTC residents with fractures (49). When we examined facility-level variables, increasing number of physicians/home was associated with greater prescribing of vitamin D and calcium. Although we are not entirely sure why this relationship existed, we know that some LTC homes in Ontario adopt standardized policies such as admission orders for vitamin D and calcium (31). Although we were unable to examine the use of standard policies in this study, it is possible that homes with several physicians may have a greater need to employ standardized care policies such as standard orders for vitamin D and calcium. It is also possible that homes with a higher number of physicians have a greater chance of having at least one advocate for implementing osteoporosis best practices. There was only a small association between increasing community size and calcium and osteoporosis prescribing (e.g., approximate 6% increase in odds for a community of 1,000,000 versus 100,000). Chain status, profit status, and LTC home size were not significantly related to prescribing rates, which was similar to other studies examining osteoporosis management (42, 49).

We observed considerable spread in prescribing rates between homes, particularly for vitamin D and calcium. We were not able to control for differences in resident case-mix

amongst facilities, and it is possible varied case-mix was in part responsible for observed differences in facility-level prescribing. However, given there are few contra-indications for calcium and vitamin D it seems unlikely that this was a major contributing factor. Our results, and those of others (42, 49), indicate that most facility characteristics are not associated with osteoporosis-related prescribing. Similarly, studies examining variation in anti-psychotic prescribing have reported that substantial inter-home variation remained after adjusting for a range of facility and resident characteristics (53, 54). In contrast, studies examining non-prescribing quality measures including restraint use, pressure ulcer prevalence, staffing levels, complaints, and government regulatory measures report that non-profit versus for-profit homes demonstrate higher quality of care (55-57).

If resident and facility characteristics cannot adequately account for differences in prescribing, further attention is needed to consider other potential factors including facility culture, operational policies, staffing levels, and prescriber characteristics. Interestingly, research by Curtis et al. (58) suggests that for osteoporosis medications, prescribing sub-cultures within individual LTC homes were not as influential as individual physician preferences. In a three-level model, the physician clustering effect was not significant and the authors emphasize the importance of targeting knowledge translation efforts at individual physicians. Similarly, a recent study in Ontario LTC homes indicated that prescriber characteristics were more influential than resident characteristics in influencing antibiotic treatment courses (59).

Implications for Knowledge Translation

We are encouraged that adequate vitamin D and calcium prescribing improved after implementing the *Ontario Osteoporosis Strategy for LTC*. It is possible that other factors contributed to the observed uptake, particularly: 1) increased media, societal, and academic attention regarding the benefits of vitamin D; and 2) the publication of the updated Osteoporosis Canada clinical practice guidelines in 2010 (32). While these were likely contributing factors, passive approaches to disseminating research evidence (e.g., publication of clinical guidelines, academic conferences) are not sufficient to produce large practice changes (60). For example, despite the publication and dissemination of Canadian osteoporosis guidelines in 2002 (61), a considerable osteoporosis care gap remained in both community-dwelling and institutionalized cohorts (62-65). Similarly, the benefits of calcium and vitamin D for LTC residents have been well known since Chapuy's widely cited publication in 1992 (66), yet little uptake in their use occurred in the decade after it was published (38, 41, 67).

Considerable knowledge translation efforts are required to make substantial improvements in health care practices. As Grol (68) suggests: "For guidelines to have an impact on actual care, they need to be integrated with other quality improvement initiatives, such as performance measurement and quality improvement programmes. This requires intensive collaboration between the organisations responsible for these tasks, which is lacking in most countries." We believe initiatives such as the *Ontario Osteoporosis Strategy* (23) are taking important and necessary steps in translating

research evidence into practice and policy via an integrated approach that involves multiple sectors including government, health care organizations, community agencies, patient associations, researchers, and front-line professionals.

In addition to practice-level barriers to osteoporosis and fracture care [i.e., impracticality of bone mineral density testing, difficulty in applying fracture risk assessment tools, uncertainty regarding benefits for LTC residents, and confusion regarding whom to treat (26, 27, 30, 31, 47, 69, 70)], several organizational barriers also exist. These include: not including osteoporosis and fracture risk assessment as part of standardized processes (e.g., admission, quarterly reviews); not capturing risk variables electronically, and failure to incorporate preventative osteoporosis and fracture strategies into formal care-plans (30, 31, 70-72). Given the interdisciplinary, team-based approach to care in LTC facilities, it is imperative that knowledge translation efforts need to target both practice-level and organizational changes.

Strengths and Limitations

The strengths of this study include the use of a pharmacy database that has a well-developed system for capturing vitamin D, calcium, and osteoporosis medication variables. Our sample of LTC homes, particularly in the smaller 2007 cohort, were subject to both sampling bias (i.e., non-representative sample of homes) and sampling error (i.e., even with random sampling, difference between the sample and population values). For both cohort years we lacked a complete range of resident variables,

particularly patient case-mix. We were able to examine some facility and resident characteristics in our 2012 cohort, but were unable to consider other factors such as staffing ratios and prescriber characteristics. The benefits of using a single pharmacy database were the completeness and uniformity of its medication information; however, it is possible the LTC homes serviced by the provider are not representative of other LTC homes in the province. Due to our continued partnership that we have had with the provider, including initiatives to improve other types of prescribing (73, 74), it is possible that some homes would represent the best case scenario. If this were the case, it is possible that overall our rates could be over-estimated, however since we used the same pharmacy provider for both cohort years, it would not impact our estimates of five-year change.

Summary

For the past several years, the *Ontario Osteoporosis Strategy for LTC* has implemented wide-scale knowledge translation activities in LTC homes across the province. Although we cannot assess causality in our study, our findings suggest that wide-scale knowledge translation activities were successful in improving vitamin D prescribing within Ontario LTC, although ongoing efforts are needed to target homes with low uptake.

The consensus meeting we held in 2013, to adapt the Osteoporosis Canada clinical practice guidelines for the frail elderly and LTC residents, will provide more explicit guidance regarding the management of osteoporosis and fractures in LTC. Ongoing knowledge translation activities should be aimed at disseminating these adapted

guidelines and decreasing variation in management practices between LTC homes. Wide-scale changes to knowledge management systems are also necessary for improving fracture risk assessment and better integrating practice guidelines. Even though this impact evaluation only examined prescribing outcomes, we are encouraged by the substantial uptake observed for vitamin D prescribing five years after initiating the *Ontario Osteoporosis Strategy for LTC*. Future evaluations should also consider process changes and examine falls and fractures outcomes.

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Table 1: Comparison of LTC Home baseline characteristics for 2007 and 2012 cohorts

	2007	2012
	n=10	n=166
Resident age, mean (SD)	82.9 (1.73)	83.7 (2.66)
Proportion female, mean (SD)	0.66 (0.06)	0.70 (0.07)
Home size (number of beds)		
mean (SD)	209.8 (45.0)	130.7 (77.6) [†]
min, max	118, 286	16, 459
Prescribers per home, mean (SD)	NA	5.83 (3.82)
For-Profit, %	NA	56.6%
Corporate chain affiliation, %	NA	44.6%
Community size (location of home), median	NA	53,203
(Q1, Q3)		(7638, 507 096)

NA=data not available.

[†]p<0.05

Table 2: Change in Facility-level Prescribing Rates from 2007 to 2012, percent (95% CI)

	Mean, Weighted Facility Prescribing Rates*		Prescribing Change*
	2007	2012	2012-2007 (95% CI)
Vitamin D	25.4 (16.7, 34.1)	63.6 (60.8, 66.3)	38.2 (29.0, 47.3)
Calcium	23.5 (0.16, 0.31)	27.6 (25.3, 29.8)	4.0 (-3.9, 12.0)
OP medication	15.4 (12.1, 18.7)	15.6 (14.6, 16.6)	0.2 (-3.3, 3.7)

*Weighted by the reciprocal of the error variance of facility prescribing rates and adjusted for age, sex, and facility size.

Table 3: Associations between Prescribing Rates and Resident/Facility Characteristics in 2012

	Vitamin D	Calcium	Osteoporosis Medications
	<i>OR (95% CI)</i>		
Resident-level			
Age, per 10 years	1.08 (1.05, 1.11)	1.05 (1.02, 1.09)	1.06 (1.02, 1.11)
Male sex	0.61 (0.57, 0.65)	0.48 (0.45, 0.52)	0.33 (0.30, 0.37)
Facility-level			
Community population, per 100 000 persons	1.00 (0.99, 1.00)	1.01 (1.00, 1.01)	1.01 (1.00, 1.01)
Number of prescribing physicians	1.05 (1.02, 1.09)	1.03 (1.01, 1.05)	1.01 (0.99, 1.04)
Corporate chain affiliation ^a	0.96 (0.69, 1.33)	0.95 (0.67, 1.34)	1.03 (0.81, 1.30)
LTC home size			
Medium (100-199 beds) ^b	0.97 (0.74, 1.27)	1.04 (0.84, 1.28)	1.08 (0.91, 1.27)
Large (≥ 200 beds) ^b	0.78 (0.53, 1.13)	0.90 (0.67, 1.19)	0.85 (0.63, 1.14)
Profit status			
Municipal ^c	1.10 (0.76, 1.59)	1.03 (0.71, 1.48)	0.96 (0.73, 1.28)
Non-profit ^c	1.06 (0.71, 1.58)	1.35 (0.91, 2.02)	1.20 (0.92, 1.58)

Bolded estimates indicate significance at alpha <0.05.

^aReference category is no chain affiliation.

^bReference category is small (< 100 beds).

^cReference category is for-profit.

Figure 1: Flow-chart of the study population

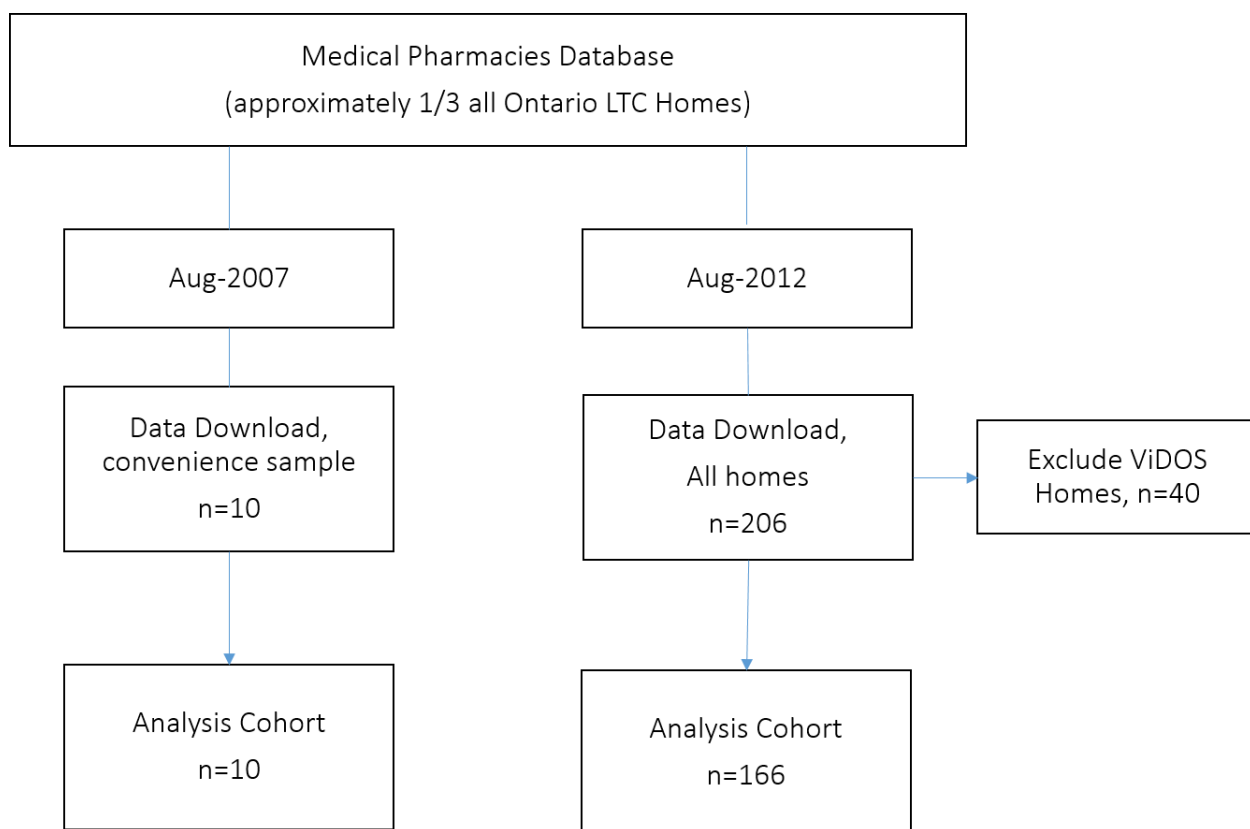
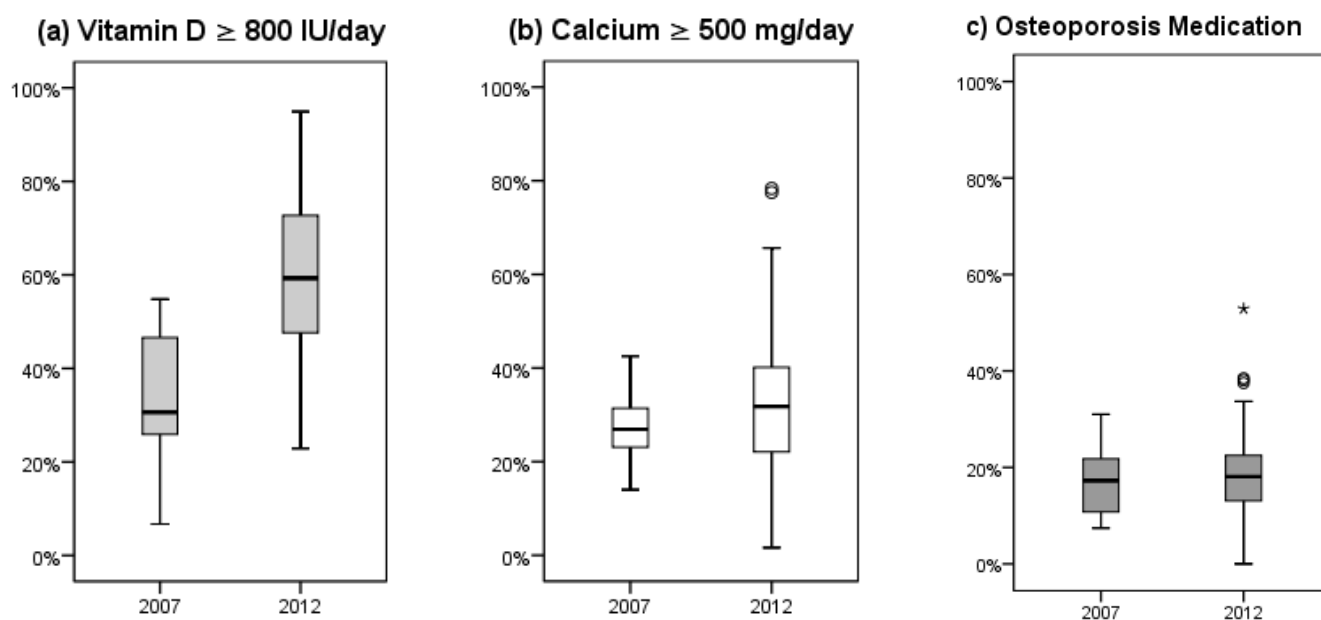


Figure 2: Distribution of facility-level prescribing rates across Ontario LTC homes for (a) vitamin D ≥ 800 IU/day (b) calcium ≥ 500 mg/day and (c) osteoporosis medication.



CHAPTER 3

Thesis Paper 2: An Interdisciplinary Knowledge Translation Intervention in Long-Term Care: Study Protocol for the Vitamin D and Osteoporosis Study (ViDOS) Pilot Cluster Randomized Controlled Trial

PREFACE TO CHAPTER 3

This chapter is the complete study protocol for the Vitamin D and Osteoporosis Study (ViDOS), a cluster randomized controlled trial conducted in 40 Ontario LTC homes to evaluate a multifaceted, interdisciplinary KT intervention for integrating osteoporosis and fracture prevention practices.

The Vitamin D and Osteoporosis Study (ViDOS) trial received an operating grant from the Canadian Institutes of Health Research (Funding Reference Number: MOP-114982). Dr. Papaioannou was the Principal Investigator on this grant, and the student was the PhD trainee. The ViDOS study was conducted from 2009-2012.

This work was published (online first) in May 2012 in the journal *Implementation Science*.

The student and co-author contributions to this work appear at the end of this article.

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**An Interdisciplinary Knowledge Translation Intervention in Long-term Care: Study
Protocol for the Vitamin D and Osteoporosis study (ViDOS) Pilot Cluster
Randomized Controlled Trial**

STUDY PROTOCOL

Open Access

An interdisciplinary knowledge translation intervention in long-term care: Study protocol for the vitamin D and osteoporosis study (ViDOS) pilot cluster randomized controlled trial

Courtney C Kennedy^{1,2,3*}, George Ioannidis^{1,4}, Lora M Giangregorio⁵, Jonathan D Adachi^{1,4}, Lehana Thabane³, Suzanne N Morin⁶, Richard G Crilly⁷, Sharon Marr^{1,2}, Robert G. Josse⁸, Lynne Lohfeld³, Laura E Pickard^{1,2}, Susanne King^{1,2}, Mary-Lou van der Horst^{1,2}, Glenda Campbell⁹, Jackie Stroud⁹, Lisa Dolovich¹⁰, Anna M Sawka¹¹, Ravi Jain¹², Lynn Nash¹⁰ and Alexandra Papaioannou^{1,2*}

Abstract

Background: Knowledge translation (KT) research in long-term care (LTC) is still in its early stages. This protocol describes the evaluation of a multifaceted, interdisciplinary KT intervention aimed at integrating evidence-based osteoporosis and fracture prevention strategies into LTC care processes.

Methods and design: The Vitamin D and Osteoporosis Study (ViDOS) is underway in 40 LTC homes (n = 19 intervention, n = 21 control) across Ontario, Canada. The primary objectives of this study are to assess the feasibility of delivering the KT intervention, and clinically, to increase the percent of LTC residents prescribed ≥ 800 IU of vitamin D daily. Eligibility criteria are LTC homes that are serviced by our partner pharmacy provider and have more than one prescribing physician. The target audience within each LTC home is the Professional Advisory Committee (PAC), an interdisciplinary team who meets quarterly. The key elements of the intervention are three interactive educational sessions led by an expert opinion leader, action planning using a quality improvement cycle, audit and feedback reports, nominated internal champions, and reminders/point-of-care tools. Control homes do not receive any intervention, however both intervention and control homes received educational materials as part of the Ontario Osteoporosis Strategy. Primary outcomes are feasibility measures (recruitment, retention, attendance at educational sessions, action plan items identified and initiated, internal champions identified, performance reports provided and reviewed), and vitamin D (≥ 800 IU/daily) prescribing at 6 and 12 months. Secondary outcomes include the proportion of residents prescribed calcium supplements and osteoporosis medications, and falls and fractures. Qualitative methods will examine the experience of the LTC team with the KT intervention. Homes are centrally randomized to intervention and control groups in blocks of variable size using a computer generated allocation sequence. Randomization is stratified by home size and profit/nonprofit status. Prescribing data retrieval and analysis are performed by blinded personnel.

Discussion: Our study will contribute to an improved understanding of the feasibility and acceptability of a multifaceted intervention aimed at translating knowledge to LTC practitioners. Lessons learned from this study will be valuable in guiding future research and understanding the complexities of translating knowledge in LTC.

* Correspondence: kennedyc@hhsc.ca; papaioannou@hhsc.ca

¹Department of Medicine, McMaster University, 1280 Main Street West, Hamilton, Ontario L8S 4K1, Canada

²Hamilton Health Sciences - St. Peter's Hospital, Juravinski Research Centre, 88 Maplewood Avenue, Hamilton, Ontario L8M 1W9, Canada

Full list of author information is available at the end of the article



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Trial registration: ClinicalTrials.gov NCT01398527.

Keywords: Knowledge translation, Long-term care, Nursing home, Osteoporosis, Fractures, Vitamin D, Multifaceted, Interdisciplinary, Feasibility, Audit and feedback, Reminders, Interactive, Educational meeting, Opinion leader

Background

The field of knowledge translation (KT) attempts to bridge the gap between the generation of research evidence and the application of this evidence into clinical practice. KT is commonly defined as ‘a dynamic and iterative process that includes synthesis, dissemination, exchange and ethically-sound application of knowledge’ [1]. Examining the effectiveness of KT strategies across different contexts, healthcare professions, and target behaviors is essential [2] if we are to effectively bridge the gap between research evidence and clinical practice. To guide decision makers in choosing the best implementation strategies, rigorous evaluations of KT programs, including well-designed cluster randomized trials, are needed [3].

Despite a growing body of KT evidence in acute care or community settings, KT research in long-term care (LTC) is still in its early stages [4-6]. Recent LTC initiatives have examined the role of organizational context and/or developed empirically-based theories related to KT in LTC [7-9]. However, few studies within the LTC setting have focused on evaluating the effectiveness of common behaviour change strategies (*e.g.*, audit and feedback, educational materials, reminders) [10,11], particularly those involving multifaceted interventions. In a recent scoping review by Bostrom *et al.* [5], only 3.6% ($n=61$) of KT studies identified were related to older adults, and approximately one-half of them were done in LTC. Problematic is the fact that the majority of these studies were not targeted at the organizational level, did not report on system level outcomes, and included only a single KT strategy (*e.g.*, audit and feedback alone). The majority of KT interventions, regardless of setting, have not targeted the entire interdisciplinary team (*i.e.*, physicians, nurses, pharmacists, dietitians, rehabilitation therapists, and other professionals) [12]. Of the LTC studies in the Bostrom review [5], 60% did not target mixed professional groups despite the emphasis on collaboration among the disciplines practicing in LTC [13]. Previous multifaceted interventions for interdisciplinary teams have had some success within the LTC setting [14,15].

Implementing evidence into practice requires whole system change [2,16], particularly in the LTC setting [5,17]. Berta *et al.* [6] suggest the majority of factors that may enhance the uptake and use of evidence-based practices in LTC are organizational and include: a working culture that facilitates cooperation and knowledge

exchange; standardization of activities; experienced clinical leaders that engage others in the process; and ultimately the incorporation of guidelines that are reinforced by regulatory bodies. Other factors that enhance implementation of evidence-based practices in LTC include strong leadership [17-19], medical directives, and building best practices recommendations into training materials [20].

Identifying the knowledge-to-action gaps

The topic of our KT intervention is evidence-based osteoporosis management and fracture prevention strategies [21-27]. Previous research by our team indicates that many LTC providers are unaware of osteoporosis and fracture prevention best practices, or have concerns surrounding diagnosis and treatment in elderly patients [28,29]. Furthermore, as a recent survey of LTC Medical Directors and Directors of Nursing documented, barriers to fracture care were modifiable and could be overcome through education and changes to local care delivery systems [30]. Rather than focusing on individual providers, we propose a model that takes a more collective approach and emphasizes integrating evidence-based practices into care processes.

In addition to proper assessment of individuals at high risk for fracture [21], we are emphasizing the wide-scale implementation of adequate levels of vitamin D (≥ 800 IU/day) because it is a tolerable, low-cost intervention with strong evidence that it can prevent fractures and falls in LTC residents [22,24,26,27,31]. In an environmental scan of 15 LTC homes we conducted in 2008 ($n=3,132$ residents), the overall rate of vitamin D use was 38% [32], and there was considerable variation between homes with rates ranging from 11 to 62%. Another study [33] we conducted using data collected via the Resident Assessment Instrument (RAI) 2.0 [34,35] found similar results.

We developed a multifaceted, interdisciplinary KT intervention to improve the use of evidence-based osteoporosis and fracture prevention practices in LTC homes. The current report outlines the research design and protocol for evaluating this KT intervention.

Methods

Study population

The Vitamin D and Osteoporosis (ViDOS) study is currently underway in 40 LTC homes (19 intervention and 21 control) in Ontario, Canada. In Canada, LTC homes

(also known as nursing homes or homes for the aged) are government-regulated facilities designed for individuals who require onsite nursing care, 24-h supervision, or personal support [36]. Our recruitment strategy included LTC homes located in communities of all sizes and geographical regions across the province of Ontario.

In order to make this study as generalizable as possible, we have only two facility-level eligibility criteria, and no patient-level criteria. All LTC homes serviced by our partner pharmacy provider (Medical Pharmacies Group Limited) and who have more than one prescribing physician (at the time of recruitment) were eligible for recruitment into the study. Medical Pharmacies is a large pharmacy provider whose services include medication packaging and distribution, clinical support, and consulting services to approximately one-third of all LTC homes in Ontario. Our rationale for excluding LTC homes with only one treating physician is to maintain anonymity during the presentation of prescribing reports at educational sessions. Furthermore, the requirement of having at least two physicians per home decreases sample size as it contributes to a lower intracluster correlation coefficient [37].

Aims and objectives

The aim of the ViDOS study is to evaluate the feasibility and effectiveness of a multifaceted KT intervention to better integrate evidence-based osteoporosis and fracture prevention care processes in LTC. In addition to measuring feasibility of the intervention, the primary clinical objective is to determine if the intervention can increase the proportion of residents who are prescribed adequate levels of vitamin D (≥ 800 IU/day). Secondary objectives include: to determine if the intervention increases the prescribing of calcium supplements (≥ 500 mg/day elemental calcium); to determine if the intervention increases the prescribing of osteoporosis medications in high-risk individuals (*i.e.*, documented osteoporosis or prior hip fracture); to understand the experience of the LTC team with the intervention and which components were perceived as feasible, acceptable, and effective; and to document falls and fractures occurring during the study period.

Study outcomes

Feasibility

Feasibility outcomes are measured at the facility-level and include (some are only relevant to intervention homes): the proportion of homes that are recruited and retained, attendance of Medical Directors and other professionals at educational sessions, internal champions identified, action plan items identified and initiated, performance reports provided and reviewed, falls and fracture data collection completed. A criterion of $\geq 80\%$

will be used as the criterion for success on each of these feasibility measures, with the exception of recruitment. Other cluster randomized controlled trials (RCTs) in nursing homes aimed at changing the behaviour of health professionals have noted recruitment in the 40 to 50% range [38-40], thus our recruitment criterion for success was 40%.

Clinical

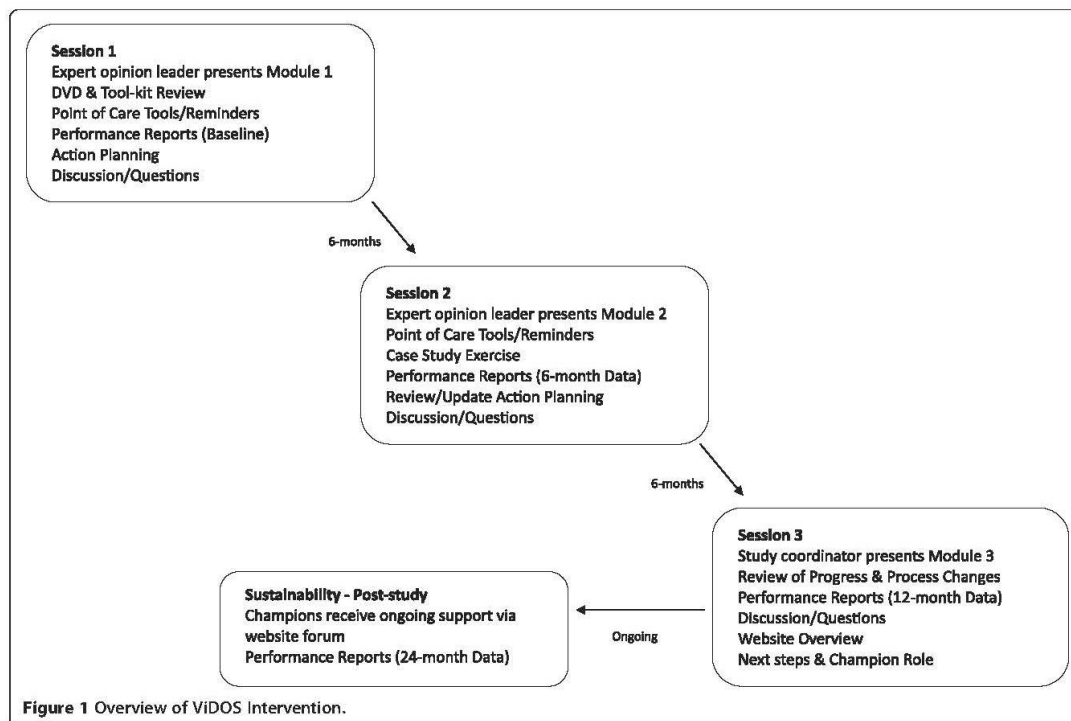
The primary clinical outcomes are the proportion of residents prescribed vitamin D ≥ 800 IU/day at 6 and 12 months. The secondary prescribing outcomes are the proportion of residents prescribed ≥ 500 mg/day of elemental calcium and the proportion of high risk residents (*i.e.*, those with a fracture or documented osteoporosis) prescribed an osteoporosis medication (oral and IV bisphosphonates, teriparatide, denosumab) at 6 and 12 months. Other secondary outcomes include the number of falls, hip fracture and all fracture (hip, wrist, spine, foot, humerus, ribs, clavicle, ankle, other) for the data collection periods (*i.e.*, three months of falls and fracture data collected three times during the study, see Figure 1).

Study design

The ViDOS study is a pilot, cluster RCT [41] comparing a multifaceted KT intervention with a control group. The intervention is delivered over a 12-month time period with data collection extending to 16 months. Allocation by clusters of LTC homes rather than individual practitioners was chosen to minimize contamination because we are targeting interdisciplinary care teams. Because few other studies have examined this type of interdisciplinary multifaceted intervention within LTC, the study was designed as a pilot RCT that emphasizes feasibility outcomes [42].

Randomization and consent

Stratified block randomization was used to randomly allocate LTC homes to the intervention or control arm of the study (recruitment is now closed). LTC homes were stratified based on home size and profit/non-profit. Profit status was taken into consideration because there is some evidence that the quality of care is higher in non-profit homes compared to for-profit homes [43-45]. The allocation sequence was computer generated using nQuery 6.0 software by an off-site research member who is not involved in the recruitment, enrollment of clusters, or data analysis. Once the appropriate representative from the home was consented, the independent member assigned intervention and control groups based on the sequence and notified the coordinating centre. Because the homes are not blinded to treatment arms, the homes were informed of their allocation.



Intervention

A multifaceted strategy was chosen based on the consistent evidence that the most successful KT interventions tend to be interactive and multifaceted [3,10,11,14,15,46-49]. Systematic reviews of single interventions such as audit and feedback [50,51], reminders (*i.e.*, tools to aid decision-making and/or prompt a clinical action) [50], and opinion leaders [52] have also demonstrated some effectiveness in changing professional practice. As described below, we tailored our KT intervention to fit within the existing operational and organizational culture of each LTC home.

Target audience

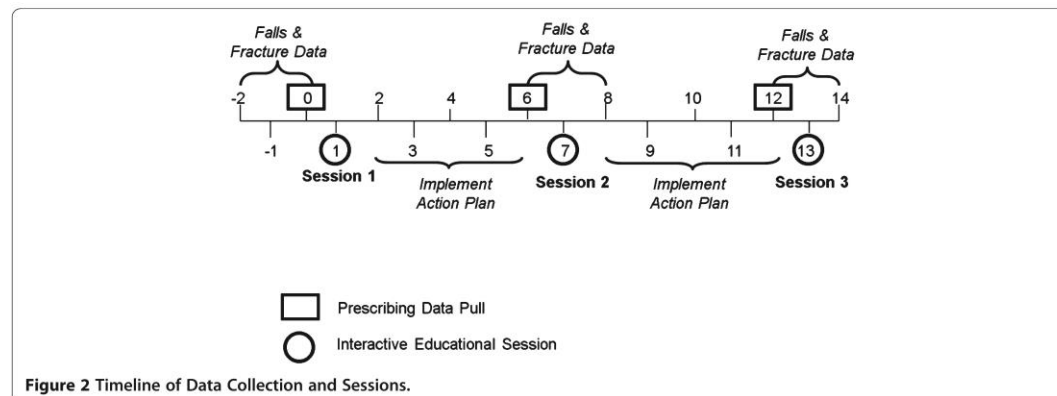
The target audience of the multifaceted intervention is the Professional Advisory Committee (PAC), an interdisciplinary team [53] that meets quarterly to address resident care and quality improvement objectives. Members of the committee typically include: the Administrator, Medical Director, Director of Care, Consultant Pharmacist, Director of Food Services/Dietician, and other nursing, medical or rehabilitation staff. In addition to PAC team members, all physicians responsible for the care of residents within the LTC home are invited to the sessions and are eligible for continuing medical education credits with the Ontario College of Family Physicians.

Development and piloting the intervention

The multifaceted intervention was developed and piloted in consultation with the PAC team at a local LTC home. This home identified several procedural and organizational barriers that we addressed in the final version of our modules and materials. Learning modules and materials were built around a toolkit (including DVD, posters, panel cards, case studies) we developed for the *Ontario Osteoporosis Strategy in LTC* (www.osteoporosislongtermcare.ca [54]) in consultation with stakeholders. Materials were based on a research synthesis on hip fracture prevention strategies in LTC [22] and incorporate the 2010 Osteoporosis Canada Clinical Practice Guidelines [21].

Multifaceted intervention components

As outlined in Figures 1 and 2, intervention homes take part in three interactive educational sessions, approximately six months apart. To maximize participation, these sessions are delivered during a regularly scheduled meeting of the PAC team. An expert opinion leader facilitates the first two interactive educational sessions (approximately 45 to 60 min in length) via webinar technology, with the study coordinator on-site to facilitate and distribute materials. A Geriatric Nursing Consultant leads the third session (approximately 30 min) via



webinar. The key components of the multifaceted intervention (Table 1) are:

1. Expert opinion leader: Utilizing the framework by Locock *et al.* [55], we define an expert opinion leader as 'a credible authority (often an academic or consultant) able to explain the evidence and respond convincingly to challenges and debate.' Such a person is distinct from a peer opinion leader who may be more influential as a role model in daily practice. The expert opinion leader may be particularly valuable in the initial stages of implementing change by 'translating it into a form which is acceptable to practitioners and takes account of their local experience' [55]. In our study, the expert opinion leaders are physicians specializing in osteoporosis and/or geriatrics who are active in national/international research and guidelines development.
2. Learning modules: At each session, a learning module is presented and there is opportunity for discussion and active participation. In brief, the first module introduces the study and materials, reviews best practices for OP management and fracture prevention, and provides an orientation to action planning for quality improvement. The second module emphasizes integration of osteoporosis and fracture prevention into care processes, reviews barriers and facilitators, shares strategies from other intervention homes, and provides a case-study exercise. The third module reviews accomplishments and action plan progress, provides information on hip protectors, identifies internal champions, and discusses post-study sustainability including an orientation to resources on our website (www.osteoporosislongtermcare.ca [54]).
3. DVD: At the first interactive educational session, the 10-minute 'Meeting the Challenge of Osteoporosis and Fracture Prevention' DVD is viewed, and a copy is left at the LTC home so that other staff and residents/families can be educated (available at www.osteoporosislongtermcare.ca [54]).
4. Performance reports (audit and feedback): Aggregate/facility-level data for vitamin D, calcium, and osteoporosis medication prescribing are presented in a graphical format at each interactive educational session. Reports are based on the previous month's prescribing and are benchmarked against other ViDOS intervention homes. Confidential, individual performance reports are also provided to each physician.
5. Reminders/Point-of-care tools are distributed and discussed in the educational sessions. These tools include the process indicator checklist, treatment alert, and x-ray requisition stamp (summarized in Table 1). Tools were developed in consultation with the pharmacy provider, the *Ontario Osteoporosis Strategy in LTC* [54] steering group, and our pilot LTC home.
6. Action planning: This quality improvement component is built around the plan-do-study-act (PDSA) cycle [56,57]. In brief, the PDSA process engages teams in planning and managing change by breaking goals into manageable chunks, testing ideas and assessing the results in order to better monitor the impact of changes. Some LTC homes may be familiar with the PDSA process from the 'Long-Term Care Best Practices Initiative' [12]. After the learning module is presented, PAC teams discuss and complete an action plan worksheet at sessions one and two to address barriers and identify organizational strategies, process changes, and specific action items for team members. Teams work on implementing action plans and progress is reviewed at the next session. Strategies generated from sessions are shared with other LTC homes.

Table 1 Key Components of the Multifaceted VIDOS intervention

Interactive Educational Sessions	Presentation of three learning modules that include a summary of best practices, special considerations for assessing/treating the elderly, key messages, integration of OP/fracture prevention into care processes, and a case study. Opportunity for discussion and active participation via problem-based learning and completion of action plans.
Expert Opinion Leader/ Study Coordinator	Expert opinion leader leads first and second interactive educational sessions via webinar (with study coordinator facilitating on-site). A Geriatric Nursing Consultant leads the third interactive educational session via webinar.
DVD	A 10-min DVD, 'Meeting the Challenge of Osteoporosis and Fracture Prevention,' is viewed at the first interactive educational session (and a copy left for the team to educate other/new staff members, residents, families). This DVD was created by the <i>Osteoporosis Strategy for LTC</i> (www.osteoporosislongtermcare.ca [54]) and is specific to the LTC context.
Performance Reports (Audit and Feedback)	Performance reports for vitamin D, calcium, and osteoporosis medications prescribing (aggregated for all residents in a home) and benchmarked against other VIDOS intervention homes, are presented at each interactive educational session. Confidential, individual performance reports are also provided to each physician.
Reminders/Point of Care Tools	Treatment Alert: A tool used by consultant pharmacists to alert physicians and nurse practitioners to assess and consider osteoporosis treatment for residents at increased risk for fracture (based on the 2010 Osteoporosis Canada Clinical Practice Guidelines [21]). X-ray Requisition Stamp: A stamp labeled 'please rule out vertebral fractures' to add to chest X-ray requisitions. Process Indicator Checklist: This tool assists teams with creating internal processes and policies that support and sustain appropriate prescribing and other osteoporosis and fractures best practices (e.g., admission/quarterly assessment, diagnoses documentation, ongoing staff education and training).
Action Planning for Quality Improvement	Discussion/completion of a work-sheet to set specific action items for team members, address barriers and facilitators, and outline best practices strategies. Homes work on action plans between study sessions.
Internal Champion	A PAC team member, such as consultant pharmacist and/or Director of Care, who will network with champions at other LTC homes (via online forum www.osteoporosislongtermcare.ca [54]) and continue to promote best practices after the research team has left.
Tool-kit*	The tool-kit includes: the 10-min DVD ('Meeting the Challenge of Osteoporosis and Fracture Prevention'), informational pocket cards, case studies, and posters. Distributed to all LTC homes as part of the <i>Ontario Osteoporosis Strategy for LTC</i> .
Osteoporosis Long-Term Care Website*	The website (www.osteoporosislongtermcare.ca [54]) with an interactive forum for Internal Champions, is promoted to all LTC homes via the <i>Ontario Osteoporosis Strategy for LTC</i> .

*also provided to all control homes.

- Internal Champions: The concept of an internal champion is introduced at the first session. By the end of the study it is anticipated that each home will have an internally nominated champion, such as the consultant pharmacist and/or Director of Care. Champions will be linked by a forum on our website (www.osteoporosislongtermcare.ca [54]) to facilitate the ongoing sharing of experiences in implementing evidence-based changes in processes of care after the study is completed. Previous studies have found that the sharing of practical tips among LTC homes is useful in the implementation of protocols to improve processes of care [58].

Control homes

Control homes will receive no intervention. After the intervention homes have completed the study, the control group will have the option of attending a group webinar that presents a summary of key messages from educational modules. They will also be provided with an opportunity to appoint an internal champion who will receive post-study resources and updates. All LTC homes (control and intervention) will also have the opportunity to access continuing education through

professional meetings (e.g., the Ontario Long-Term Care Association and the Ontario Long Term Care Physicians).

LTC osteoporosis toolkit and website

Both control and intervention homes received the LTC Osteoporosis Toolkit in 2009/2010, which includes a 10-minute DVD, 'Meeting the Challenge of Osteoporosis and Fracture Prevention,' pocket cards, case studies, and posters. This toolkit was distributed to all Ontario LTC homes as part of the provincial government-funded *Ontario Osteoporosis Strategy* [59]. The toolkit was developed to increase awareness of best practices for osteoporosis and fracture prevention. An introductory group webinar was available to all LTC homes in Ontario to introduce the toolkit components. In late 2011, the *Ontario Osteoporosis Strategy for LTC* website (www.osteoporosislongtermcare.ca [54]) was launched and was promoted in all LTC homes across Ontario.

Post-study sustainability

The final phase of the knowledge to action (KTA) cycle [60] includes building sustainability mechanisms into the intervention. It is anticipated that implementation of

osteoporosis best practices will continue through the work of each LTC home's internal champion, who will be provided with updated resources and support by a forum on our website (www.osteoporosislongtermcare.ca [54]). This will enable the internal champions to interact with each other and share successes and challenges. We will work with our partner pharmacy provider to distribute prescribing reports to LTC homes one year after completing the study. This feedback is important given the high turnover of residents in LTC resulting in a different cohort of residents and staff since the study began.

Data collection

Facility-level

Feasibility data are collected by the study coordinator. Other facility-level data being collected include the number of resident beds, location/type of population centre (*i.e.*, small, medium, or large population centres as defined by Statistics Canada) [61], profit status (profit, non-profit), chain affiliation, and number of treating physicians at baseline.

Patient-level

Figure 2 provides an overview of the data collection time-line. De-identified clinical data including demographic, prescribing, and co-morbidities (from the Medication Administration Record) are collected from the pharmacy database by the Director of Systems Services at Medical Pharmacies (JBS).

Falls and fractures data for every resident are collected by a LTC staff member at each home for three-month periods at three times during the study (coinciding with prescribing data pulls, Figure 2). The information source used to populate the data collection spreadsheets may vary by LTC home and sources are documented by the study coordinator. With the recent wide-scale implementation of the RAI-2.0 assessments across Ontario LTC homes [34,35], future studies collecting information on falls and fracture data will likely use this as a data source. The RAI-2.0 is a standard assessment using common methodology and measures and is completed by trained assessors (typically within 14 days of admission and then on a quarterly basis).

Qualitative data

After intervention homes have completed the study, individual interviews will be conducted with selected participants to better understand their experience with the intervention. A research assistant (not affiliated with the study) will conduct interviews with two PAC team members (physician and the Director of Care or consultant pharmacist) at approximately seven to ten intervention home sites. Organizational changes to policies and

processes in intervention homes will be measured by surveying the Directors of Care regarding the number of items on the process indicator checklist (Table 1) they initiated during the study and by examining changes captured in the action plans.

Trial management

The coordinating centre for the study is at McMaster University. The study coordinator and research assistants are responsible for submitting research ethics applications, scheduling of homes, travel arrangements, developing presentations, obtaining and storing consent forms, tracking and recording all decisions and transformations of data made throughout the investigation, and budgeting. All databases are password protected and kept on a secure network system.

Data monitoring

No formal comparison between control and intervention homes will occur until the end of the study when final analyses are performed. In accordance with Food and Drug Administration recommendations [62], because the elderly are considered a 'potentially fragile population,' a Data and Safety Monitoring Board (DSMB) with expertise in geriatric medicine and clinical trials research will meet to monitor ongoing trial processes. There are no formal stopping rules because the intervention is targeted at health professionals (*i.e.*, does not intervene directly with residents) and because the study is primarily designed to assess feasibility.

Blinding

Study participants, personnel, expert opinion leaders, and the analyst who provides the audit and feedback reports are not blinded to home allocation status. The outcome assessor (JBS) who downloads the demographic, prescribing, and co-morbidity data and the analyst who performs the final data analysis will be blinded to home allocation status. The staff members within each LTC home who are recording falls and fractures data are not blinded.

Data analysis

Quantitative analysis

Data from the trial will be analyzed and reported in accordance with the CONSORT criteria [41,63,64]. The baseline characteristics will be reported as mean (standard deviation) or median (minimum, maximum) values for continuous variables and as counts (percent) for categorical variables. The primary feasibility outcomes will be analyzed using descriptive statistics expressed as percent and corresponding 95% confidence intervals (CI). Our primary analyses will be performed using the intention-to-treat principle. The generalized estimating

equations (GEE) technique, assuming an exchangeable correlation structure [65], will be used to determine differences between groups for the proportion of residents prescribed vitamin D, calcium and other osteoporosis medication, and number of fractures or falls. The GEE method will take into account the clustered nature of the data, given that residents treated within a LTC home are expected to be similar or correlated (clustered variable will be the LTC home). For the model, the unit of analysis will be the resident and the unit of inference will be the home. There is an increased risk of imbalance at the resident-level because of the home-level randomization. Therefore, resident baseline characteristics that will be included in this analysis are: age, gender, co-morbidities, and the number of prescribed medications. Unadjusted and adjusted odds ratios (OR) and corresponding 95% CIs will be reported. All statistical analyses will be performed using the SAS/STAT 9.2 software package (SAS Institute Inc., Cary, NC, USA) with the criterion for statistical significance set at $\alpha \leq 0.05$.

Qualitative analysis

All interview data will be audiotaped and then transcribed verbatim by a professional transcriber. Data analysis will take place concurrently with data collection so that any emerging themes can be incorporated into the interview guide and the codebook. To ensure that we reach informational saturation (all emerging themes are well understood and supported by ample data), any topics that are still unclear after completing the interviews will be revisited in brief telephone conversations with interviewees from LTC homes that provided the least amount of information on those particular topics. A qualitative data management and retrieval software program (QSR-Nvivo) [66] will be used to assist with data organization and retrieval during thematic framework analyses. Both the development of the interview guides and the thematic analyses applied to the transcripts will be guided by two theories that address the change process at the individual and organizational levels: the Theory of Planned Behaviour [67,68], and the Diffusion of Innovations [69-71].

Sample size

Our sample size was calculated to detect a difference in the percentage of residents prescribed ≥ 800 IU/daily vitamin D at follow-up in the intervention versus control groups. We assumed an average of 120 residents per LTC home and that 30% of residents were prescribed ≥ 800 IU/daily vitamin D at baseline [33]. We postulate a 20% increase in vitamin D prescribing in the intervention group and a 5% increase in the control group (to account for the potential impact of other province-wide initiatives such as the *Ontario Osteoporosis Strategy for*

LTC). Based on these assumptions, to detect a 15% difference in prescribing between the groups with an intraclass correlation of 0.10 (two-sided test with significance = 0.05), a sample size of 2,160 residents from 18 LTC homes in each of the intervention and control groups is required to achieve 82% power. Factoring in a potential 10% dropout rate, the recruitment target was 40 LTC homes (20 = intervention, 20 = control).

Ethical considerations

The study was approved by the Hamilton Health Sciences/McMaster University Faculty of Health Sciences Research Ethics Board. A representative from the home provided initial consent prior to randomization, and each PAC team participant provides written informed consent at the first educational session.

Discussion

KT research in LTC is still in its early stages [4-6]. Our project is one of the first RCT studies to examine the effectiveness and feasibility of a multifaceted, interdisciplinary KT intervention in LTC. Given that this is a pilot RCT, feasibility measures such as recruitment and retention, attendance at educational sessions by PAC members, and use of study materials are important outcomes for planning future interventions. Furthermore, results from the upcoming qualitative phase of the pilot study will provide valuable information about the KT-related needs of health professionals working in LTC. It will also assist us in gaining some preliminary data on what may be the most active ingredients of the complex intervention. A better understanding of these factors will enable future researchers and care providers to select and tailor KT strategies that can maximize the uptake and utilization of evidence in LTC.

Increasing the utilization of available evidence by clinicians in daily practice is difficult in any setting, and the LTC environment presents some additional unique challenges. Prescribing for the frail elderly is especially challenging due to the presence of co-morbid illness, frequently large number of medications, functional impairment, cognitive deficits, and age-associated decline in renal function [72-74]. The majority of practice guidelines do not adequately address the challenges of applying recommendations to elderly patients, particularly those with co-morbidities [75]. In addition, the composition and skills of the nursing staff in LTC are different than in other sectors because nurse's aides provide most of the direct care and their care rituals are often focused on task completion [19].

Implementing evidence-based practices in LTC is made more complex by the fact that the physicians are not typically located at the LTC home. Instead they rely on the on-site healthcare team to inform and update

them about their patients' conditions. Clinical leaders are often registered nurses (as opposed to physicians in acute or primary care settings) [76], and they assume greater responsibility for the coordination, decision-making, and administration of drug-related interventions [77].

Heavy paperwork and institutional requirements, limited resource and staffing levels, limited time to implement protocols, the absence of a learning culture, entrenched ways of learning and communicating, 'change fatigue,' and high staff turnover are other postulated factors that inhibit the uptake of evidence-based practices [6,20,78,79]. In a study of registered nurses working with the elderly [80], the most commonly noted barriers to research use were the lack of a cadre of knowledgeable colleagues with whom they could discuss research issues, facility-level barriers, the lack of time to read research studies and the fact that research findings are not readily available in a single location. These nurses believed that establishing networks among colleagues, staff, researchers, and physicians would enhance the uptake of research evidence.

If the above challenges can be addressed, there are elements in the LTC environment that also make it conducive to implementing best practices. For example, as noted by Berta *et al.* [6] LTC homes are 'small, structurally flat, and highly reliant on collaborative decision making'; thus decision makers and staff in LTC may be more amenable to implementing complex innovations than in other practice settings.

The design and implementation of our intervention was founded on the well-known Canadian Institutes of Health Research Knowledge-to-Action cycle [60]. In this paper, we describe how our intervention is adapting knowledge to the local context (LTC homes in Ontario) and continuously assessing barriers and facilitators to knowledge use. Despite the importance of tailoring the intervention based on identified barriers, recent evidence suggests that many studies do not effectively do this [81]. We have tailored the intervention to better meet the needs of LTC care providers by incorporating our educational sessions within regularly scheduled PAC team meetings, developing the reminders and point-of-care tools in partnership with front-line LTC providers, and engaging staff in identifying their own site-specific strategies needed to address barriers (*e.g.*, action planning). We are monitoring knowledge use throughout the study via the performance reports and action plans completed on site and evaluating outcomes using quantitative, qualitative, and process measures. Through ongoing work with internal champions, our partner pharmacy provider, and our website forum (www.osteoporosislong-termcare.ca [54]), we have built in sustainability mechanisms. A Swedish study [18] that examined

whether nurses who continued continuous quality improvement (CQI) activities over several years emphasized that supportive leadership and access to individuals with research expertise were key factors in sustained evidence-based practice.

Our design elements are also congruent with recommendations from the Nursing Home Quality Initiative launched in 2002 by the Centers for Medicare and Medicaid Services in the United States [58]. Lessons learned about implementing CQI in LTC included: forming partnerships with LTC stakeholders, engaging physicians and Medical Directors in the CQI process, teaching CQI principles to all LTC staff, facilitating the exchange of successful strategies and practical tips among LTC homes, and providing one-on-one assistance to LTC staff and administrators. Frequent contact with and involvement of the entire CQI team were identified as essential to overcoming problems stemming from high staff turnover and heavy workload demands on Administrators and Directors of Nursing [58]. ViDOS has taken this advice and worked closely with the entire PAC team, including Medical Directors, to develop and update action plans to improve bone health of LTC residents.

Certainly one of the frequently asked questions regarding multifaceted interventions is: which components of the 'black-box' are most effective? Although we cannot answer this question quantitatively, we will attempt to address this issue in the qualitative phase of the study by asking participants how effective they perceived the various elements of the ViDOS intervention to be, and what individual and organizational factors they believe facilitated or inhibited the change process.

The lessons learned from this pilot RCT will be helpful when planning future KT research on other health issues in LTC settings. This includes insights on the KT process (*e.g.*, recruitment and retention of leaders in innovation), resources (time and budget issues), management (personnel and data management issues), and scientific evidence (effect sizes, intracluster correlation) [42]. It is anticipated the final results of this study will be presented in 2013.

Abbreviations

(ViDOS): Vitamin D and Osteoporosis Study; (LTC): Long-term care; (KT): Knowledge translation; (PAC): Professional advisory committee; (CIHR): Canadian Institutes for Health Research; (CQI): Continuous Quality Improvement; (KTA): Knowledge to action; (PDSA): Plan Study Do Act; (RCT): Randomized Controlled Trial.

Competing interests

Alexandra Papaioannou is or has been a consultant, or on a speaker's bureau, or received unrestricted grants for Amgen, Eli Lilly, Merck Frosst Canada, Novartis, Warner Chilcott; she also has conducted clinical trials for Eli Lilly, Merck Frosst, Novartis and Pfizer. Jonathan D. Adachi is or has been a consultant, or on a speaker's bureau for Amgen, Eli Lilly, GSK, Merck, Novartis, Pfizer, Procter & Gamble, Roche, Sanofi Aventis and Warner Chilcott; he has also conducted clinical trials for Amgen,

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Authors' contributions

AP conceived of the study and contributed to the design and implementation, oversaw its coordination, participated in the delivery of the intervention sessions, and helped to draft the manuscript. CCK contributed to the conception, design and implementation of the study, participated in its coordination, performed data analysis and interpretation, and drafted the manuscript. GI contributed to the conception, design, and implementation of the study, performed data analysis and interpretation, edited the manuscript for important intellectual content, and gave final approval of the version to be published. LMG contributed to the conception, design, and implementation of the study, edited the manuscript for important intellectual content, and gave final approval of the version to be published. JDA, SNM, RGC, SM, RGJ, and MLV contributed to the conception and design of the study, participated in the delivery of the intervention sessions, edited the manuscript for important intellectual content, and gave final approval of the version to be published. LT contributed to the conception and design of the study, provided consultation regarding RCT methodology, edited the manuscript for important intellectual content, and gave final approval of the version to be published. LL contributed to the conception and design of the study, provided consultation regarding qualitative methodology, edited the manuscript for important intellectual content, and gave final approval of the version to be published. SK, LEP, contributed to the conception, design, and implementation of the study, coordinated the study, edited the manuscript for important intellectual content, and gave final approval of the version to be published. GC contributed to the conception, design, and implementation of the study, participated in data acquisition, edited the manuscript for important intellectual content, and gave final approval of the version to be published. JS contributed to the conception and design of the study, coordinated data acquisition, edited the manuscript for important intellectual content, and gave final approval of the version to be published. LD, AMS, RJ, and LN contributed to the conception and design of the study, edited the manuscript for important intellectual content, and gave final approval of the version to be published. All authors read and approved the final manuscript.

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Author details

¹Department of Medicine, McMaster University, 1280 Main Street West, Hamilton, Ontario L8S 4K1, Canada. ²Hamilton Health Sciences - St. Peter's Hospital, Juravinski Research Centre, 88 Maplewood Avenue, Hamilton, Ontario L8M 1W9, Canada. ³Department of Clinical Epidemiology & Biostatistics, McMaster University, 1280 Main St. West, Hamilton, Ontario L8S

4K1, Canada. ⁴Charlton Medical Centre, 25 Charlton Ave East, Hamilton, Ontario L8N 1Y2, Canada. ⁵Department of Kinesiology, Faculty of Applied Health Sciences, University of Waterloo, 200 University Ave West, Waterloo, Ontario N2L 3G1, Canada. ⁶Department of Medicine, Division of General Internal Medicine, MUHC-Montreal General Hospital, 1650 Cedar Avenue, Montreal, QC H3G 1A4, Canada. ⁷Schulich School of Medicine & Dentistry, The University of Western Ontario, Parkwood Hospital, 801 Commissioners Rd. East, London, Ontario N6C 5J1, Canada. ⁸Department of Medicine, Division of Endocrinology and Metabolism, University of Toronto, St. Michael's Hospital, Toronto, Ontario, Canada. ⁹Medical Pharmacies Group Limited, 590 Granite Court, Pickering, Ontario, L1W 3X6, Canada. ¹⁰Department of Family Medicine, McMaster Innovation Park, 175 Longwood Road South, Hamilton, Ontario L8P 0A1, Canada. ¹¹Department of Medicine, Division of Endocrinology and Metabolism, Toronto General Hospital, 200 Elizabeth Street, Toronto, Ontario M5G 2C4, Canada. ¹²Ontario Osteoporosis Strategy, Osteoporosis Canada, 1090 Don Mills Road, Suite 301, Toronto, Ontario M3C 3R6, Canada.

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CHAPTER 4

Thesis Paper 3: A Successful Knowledge Translation Intervention in
Long-term Care: Final Results from the Vitamin D and Osteoporosis Study
(ViDOS) Pilot Cluster Randomized Controlled Trial

PREFACE TO CHAPTER 4

This chapter presents the final clinical results for the Vitamin D and Osteoporosis Study (ViDOS). In this paper, we examine the resident-level prescribing outcomes that were collected at baseline and twelve-months from a centralized pharmacy database. The primary outcome was Vitamin D ≥ 800 IU/day; secondary outcomes were calcium ≥ 500 mg/day and osteoporosis medications (high-risk residents only).

The Vitamin D and Osteoporosis Study (ViDOS) received an operating grant from the Canadian Institutes of Health Research (Funding Reference Number: MOP-114982). Dr. Papaioannou was the Principal Investigator on this grant, and the student was the PhD trainee. The ViDOS study was conducted from 2009-2012.

In February 2014, it was submitted for publication as Original Research to the *Journal of the American Geriatrics Society (JAGS)*.

The student and co-author contributions to this work appear at the end of this article.

**A Successful Knowledge Translation Intervention in Long-term Care: Final Results
from the Vitamin D and Osteoporosis Study (ViDOS) Pilot Cluster Randomized
Controlled Trial**

Courtney C Kennedy, MSc,^a George Ioannidis, PhD,^a Lehana Thabane, PhD,^a
Jonathan D Adachi, MD,^a Sharon Marr, MD, M.Ed.,^a Lora M Giangregorio, PhD,^b
Suzanne N Morin, MD, MSc,^c Richard G Crilly, MD,^d Robert G Josse, MD,^e
Lynne Lohfeld, PhD,^a Laura E Pickard, MA,^a Mary-Lou van der Horst, MScN, MBA,^a
Glenda Campbell, B.Sc.PhM.,^a Jackie Stroud, B.Sc.PhM.,^f Lisa Dolovich, PharmD, MSc,^a
Anna M Sawka, MD, PhD,^e Ravi Jain MHSc, MA,^g Lynn Nash, MD,^a
Alexandra Papaioannou, MD, MSc^a

^aMcMaster University, Hamilton, Ontario, ^bUniversity of Waterloo, Waterloo, Ontario,
^cMcGill University, Montreal, Quebec, ^dWestern University, London, Ontario,
^eUniversity of Toronto, Toronto, Ontario, ^fMedical Pharmacies Group Limited,
^gOsteoporosis Canada, Toronto, Ontario

Corresponding Author:

Dr. Alexandra Papaioannou
Department of Medicine, Division of Geriatrics, McMaster University
Geriatric Education and Research in Aging Sciences (GERAS) Centre
St. Peter's Hospital, Juravinski Research Centre, Rm 151
88 Maplewood Avenue, Hamilton, ON L8M 1W9
Tel: 905-521-2100 x77715; Fax: 905-318-2654; papaioannou@hhsc.ca

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Running Head: Vitamin D and Osteoporosis Study (ViDOS)

STRUCTURED ABSTRACT

Objective: To evaluate the effectiveness of a multifaceted, interdisciplinary knowledge translation (KT) intervention aimed at increasing evidence-based fracture prevention practices in long-term care (LTC).

Design: Pilot, cluster randomized controlled trial.

Setting: 40 LTC homes (21 control; 19 intervention) in Ontario, Canada. Cluster eligibility criteria: More than one physician; received services from our pharmacy provider.

Participants: Interdisciplinary care teams: physicians, nurses, consultant pharmacists, other LTC staff.

Intervention: Three small-group, interactive educational meetings over twelve-months that included a presentation by an expert opinion leader, action planning for quality improvement, audit and feedback review, distribution of educational materials.

Measurements: Resident-level prescribing outcomes were collected at baseline and twelve-months from a centralized pharmacy database. The primary outcome was vitamin D ≥ 800 IU/day; secondary outcomes were calcium ≥ 500 mg/day and osteoporosis medications (high-risk residents only).

Results: At baseline, 5478 residents, mean age 84.4 [Standard Deviation (SD 10.9)], 71% female, resided in 40 LTC homes, mean size= 137 beds (SD 76.7). Using the generalized

estimating equations (GEE) technique to account for clustering within a LTC home, the intervention resulted in a significantly greater increase in prescribing from baseline to twelve-months between intervention versus control arms for vitamin D (odds ratio [OR] 1.82, 95% confidence interval [CI]: 1.12, 2.96) and calcium (OR 1.33, 95% CI: 1.01, 1.74), but not for osteoporosis medications (OR 1.17, 95% CI: 0.91, 1.51). In per protocol analyses (excluding 7 non-participating intervention homes), ORs were 3.06 (95% CI: 2.18, 4.29), 1.57 (95% CI: 1.12, 2.21), 1.20 (95% CI: 0.90, 1.60) for vitamin D, calcium and osteoporosis medications, respectively.

Conclusion: Our KT intervention significantly improved prescribing of vitamin D and calcium and is a model that could potentially be applied to other areas requiring quality improvement.

Trial Registration: ClinicalTrials.gov NCT01398527.

KEY WORDS

fracture, long-term care, vitamin D, prescribing, knowledge translation

INTRODUCTION

Effective knowledge translation (KT) interventions are essential to encourage the uptake of evidence based practices. Ideally, the selection of interventions is guided by evidence of effectiveness and efficiency (1), however good evidence is not always available or may not be generalizable from one setting to another. Compared with community or acute care settings, there has been little KT enquiry in long-term care (LTC) homes (2).

LTC homes provide 24-hour nursing care and supervision to residents who often have multiple co-morbidities, polypharmacy, and shortened life expectancies. Physicians are often located off-site and engage in collaborative decision making with the care team (3). Given these unique characteristics, innovative, interdisciplinary approaches to KT that are tailored to this practice environment are required (4). Furthermore, rigorous evaluation is required to ascertain whether KT strategies proven to be effective in other settings are also effective in LTC.

We developed an interdisciplinary KT intervention for LTC focused on increasing the uptake of vitamin D and other evidence-based fracture prevention strategies. An estimated 60-80% of LTC residents have osteoporosis (5) and in Canada it is estimated that the fracture rate for LTC residents is approximately 2-4 times that of similarly aged community-dwelling residents (6). Meta-analyses demonstrate that vitamin D reduces falls (7), and calcium and vitamin D reduce fractures in LTC residents (8). Despite strong evidence, and acceptance by physicians (9), these strategies are under-utilized in LTC (10, 11). Barriers to implementing appropriate fracture prevention include knowledge

gaps (12, 13), lack of access to bone densitometry, difficulty in applying risk assessment tools within LTC (13), and a lack of standard processes and policies that support bone health (14).

To evaluate our inter-disciplinary KT model, we conducted a pilot, cluster randomized controlled trial (RCT). Our primary clinical objective was to determine if the intervention increased the proportion of residents prescribed vitamin D ≥ 800 IU over twelve-months. Secondary objectives were to examine the influence of the intervention on calcium and osteoporosis medication prescribing.

METHODS

Trial Design, Setting and Participants

The Vitamin D and Osteoporosis Study (ViDOS) was conducted in LTC homes across the province of Ontario, Canada. In Ontario, there are approximately 630 licensed LTC homes that provide residents with onsite nursing care, 24-hour supervision, or personal support (15).

The study was designed as a pilot, cluster RCT comparing a multifaceted, interdisciplinary KT intervention with a control group. Cluster randomization was chosen because the intervention was naturally delivered at the cluster level and to reduce potential contamination in the control arm. The unit of randomization was the LTC home, and the target audience within each home was the core group of interdisciplinary care leaders (i.e., the Professional Advisory Committee), including the Administrator, Medical Director, Director of Care, Consultant Pharmacist, Dietician/Director of Food Services, and other nursing, medical or rehabilitation staff. Further details about the study protocol are published elsewhere (16).

Our sampling frame was LTC homes who received medication and consulting services from Medical Pharmacies Group Limited (approximately one-third of Ontario LTC homes). Homes were eligible if they had more than one prescribing physician and received services from Medical Pharmacies. There were no resident-level exclusion criteria. Our recruitment strategy included homes located in communities of all sizes and

geographical regions across Ontario. Recruitment began in 2009 and was ongoing until the target sample size was reached. The final home completed the intervention in 2012.

A Data and Safety Monitoring Board with expertise in geriatric medicine and clinical trials met twice to review trial processes. Informed consent was obtained from a representative at each LTC home and from individual professionals. The study was approved by the McMaster University/Hamilton Health Sciences Research Ethics Board.

Intervention

The design and implementation of our twelve-month, multi-faceted intervention [Figure 1; (16)] was founded on the Canadian Institutes of Health Research Knowledge-to-Action cycle (17).

Three, small-group, interactive educational meetings, were held at each intervention home during approximately months 1, 6 and 12. Meetings were one-hour in length, typically had 5-10 participants, and were facilitated by one of six expert opinion leaders¹ (18), who were specialist physicians with expertise in osteoporosis or geriatrics. Experts engaged with study participants either in-person (meeting one only) or remotely, with the study coordinator on-site at the first two meetings. At all interactive meetings, the expert delivered a standardized presentation and facilitated a question and answer session. At the

¹ In the framework by Locock et al. (18), an expert opinion leader was considered distinct from peer opinion leaders (i.e., who are role models in daily practice) and was a 'credible authority (often an academic or consultant) able to explain the evidence and respond convincingly to challenges and debate.'

first meeting, a 10-minute video (Meeting the Challenge of Osteoporosis and Fracture Prevention) was shown and left for future use. At the third meeting, post-study sustainability was discussed including an orientation to web-site resources (www.osteoporosislongtermcare.ca).

After the presentation by the experts, interdisciplinary teams engaged in action planning for quality improvement. This process was based on a component of the "plan-do-study-act" (PDSA) cycle (16, 19); teams discussed and completed an action plan work-sheet (Appendix) to address key barriers and facilitators and to outline specific tasks for team members. Educational materials were also distributed including osteoporosis tool-kits (e.g., pocket cards, case studies, and posters), process checklists, and treatment alerts to assist consultant pharmacists with flagging high-risk individuals (16). Informal "champions" (typically Directors of Care) worked with the research team to book educational meetings and encourage participation.

Home-level audit and feedback reports were included in the presentation by the expert. Reports were based on the previous month's prescribing and benchmarked against other intervention homes. Confidential reports containing individual physician results were also provided.

Changes to Intervention

At the first few intervention homes (n=7) the expert attended the meeting in-person; it was not feasible to continue this format and the remainder were conducted remotely. We

planned to use webinar technology to conduct the educational meetings, however many homes did not have an accessible internet connection and experts facilitated meetings via teleconference instead.

Control Arm

Control homes received no intervention except fracture prevention tool-kits that were provided to all LTC homes in the province by the *Ontario Osteoporosis Strategy* (20); www.osteoporosislongtermcare.ca.

Outcomes and Data Collection

Prescribing

Resident-level, de-identified prescribing/clinical data were downloaded from the Medical Pharmacies central database (individually for each home according to intervention dates) by the Director of Systems Services at baseline, six-months, and twelve-months. These point estimates included all residents residing in the LTC home on the day of the data download. To achieve greater balance with the timing of data downloads through-out the study period, control homes were chronologically matched with an intervention home (i.e., the nearest one in the randomization sequence). Only baseline and twelve-month data were used in the primary analyses; six-month data were used to generate interim audit and feedback reports.

The primary outcome was the change in the proportion of all residents prescribed vitamin D ≥ 800 IU/day (including vitamin D2 or D3) from baseline to twelve-months. Secondary prescribing outcomes were the change from baseline to twelve-months in the proportion

of 1) all residents prescribed calcium ≥ 500 mg/day and 2) high-risk residents prescribed an osteoporosis medication (oral bisphosphonate, zoledronic acid, denosumab, teriparatide). Algorithms to calculate dosage included all daily/weekly/monthly preparations and medications and vitamin/mineral supplements that contain vitamin D and calcium. High-risk residents were those with a documented hip fracture, vertebral fracture, or osteoporosis diagnosis on the electronic Medication Administration Record (eMAR). The eMAR captured any medication indications or diagnoses that were present at admission and further updates may have occurred when diagnoses were included on physician orders or quarterly medication reviews.

Falls and Fractures

One of our secondary objectives was to record incident falls and fractures to inform the feasibility of future trials with falls/fracture outcomes and to provide reports to the Data and Safety Monitoring Board. The study was not powered to detect differences in falls and fractures between arms. Each LTC home collected 3-months of incident falls and fracture data at three time-points (corresponding to prescribing downloads), based on electronic/paper-based charts, internal monitoring systems, Resident Assessment Instrument - Minimum Data Set 2.0 (RAI-MDS 2.0), and critical incident reports.

Sample Size

Given effect sizes observed in other KT interventions [e.g., mixed interactive and didactic educational meetings (21)], we were interested in detecting a 15% difference in prescribing of vitamin D ≥ 800 IU/daily between the groups [anticipating a 20% increase

in the intervention group, and a 5% increase in the control group due to ongoing provincial initiatives (20)]. Based on prior work, we anticipated an average of 120 residents per LTC home and a baseline vitamin D (≥ 800 IU/day) prescribing rate of 30% (10). Assuming an intracluster correlation of 0.10, a Type I error of 5%, it was determined a sample size 18 LTC homes ($n=2,160$ residents) per arm was required to achieve 82% power. Factoring in a 10% dropout rate, the recruitment target was 40 LTC homes.

Randomization and Blinding

LTC homes were allocated to control or intervention arms (1:1 allocation ratio) using stratified, block randomization. Stratified allocation was based on home size (<250 versus ≥ 250 beds) and profit/non-profit status. An off-site investigator assigned homes to treatment groups based on a computer-generated allocation sequence. The database manager and analysts were blinded to allocation status; LTC homes, experts, and coordinators were not blinded.

Statistical Methods

The trial was reported in accordance with CONSORT for cluster randomized trials (22). Differences in baseline characteristics between arms were examined using the chi-square procedure and independent samples T-test. Our primary analysis was intention-to-treat (ITT). We analyzed resident level data using the generalized estimating equations (GEE) technique, assuming an exchangeable correlation structure (i.e., specifies that all observations within the same cluster are equally correlated) to account for clustering

within a LTC home (23). We examined the effect of the intervention on the change from baseline to twelve-months in the proportion of residents prescribed vitamin D ≥ 800 IU/day and calcium ≥ 500 mg/day (i.e., treatment group-by-time interaction). The same method was used to examine osteoporosis medication prescribing, including only high-risk residents. Odds ratios (ORs), corresponding 95% confidence intervals [CIs] are reported.

Sensitivity analyses

The above analyses were also conducted in the per protocol cohort, i.e., excluding 7 non-active intervention homes. We also examined the effect of adjusting GEE models for age, sex, and high-risk status.

Cluster-level analyses

For each outcome, we calculated the absolute prescribing change in each LTC home from baseline to twelve-months. We report mean home-level prescribing changes within treatment arms and compare differences between arms, with 95% CIs adjusted for clustering using the method described by Donner and Klar (24).

All statistical analyses were performed using the SAS/STAT 9.2 software package (SAS Institute Inc., Cary, NC, USA) and SPSS v20. The criterion for statistical significance was set at $\alpha = 0.05$.

RESULTS

The baseline cohort consisted of 5478 residents residing in 40 LTC homes (19 intervention, 21 control). Figure 2 illustrates the participant flow.

Facility Characteristics

There were no significant differences in facility characteristics (Table 1) between treatment arms. The mean facility size was larger in control (157 beds, standard deviation [SD] 80.2) versus intervention homes (115 beds, SD 67.9). The majority of LTC homes in the study were for-profit and affiliated with a multi-facility chain (Table 1).

Resident Characteristics

Residents in both arms were similar in baseline demographic characteristics. There was a higher prevalence of hip fractures, osteoporosis diagnoses, and use of vitamin D ≥ 800 IU/day, calcium ≥ 500 mg/day, and osteoporosis medication in the control arm (=2% difference; Table 2).

Prescribing Changes

The median lengths of follow-up (i.e., between baseline and final data download) for all intervention, active intervention, and control homes, respectively, were 12.4 (min 7.4, max 15.0), 12.2 (min 11.4, max 15.0), and 12.1 (min 10.5, max 13.4) months.

The main findings are presented in Table 3. In the ITT cohort, GEE analyses indicated there was significantly greater prescribing change from baseline to 12 months in the intervention versus control groups for both vitamin D and calcium, with ORs 1.82 (95% CI: 1.12, 2.96) and 1.33 (95% CI: 1.01, 1.74), respectively.

The intervention had no significant effect on the change in osteoporosis medication prescribing in high risk residents (OR 1.17, 95% CI: 0.91, 1.51).

The intraclass correlation coefficients for vitamin D, calcium, and osteoporosis medication prescribing were 0.194, 0.112, and 0.052, respectively.

Sensitivity Analyses

In the per protocol cohort, ORs were 3.06 (95% CI: 2.18, 4.29), 1.57 (95% CI: 1.12, 2.21), and 1.20 (95% CI: 0.90, 1.60) for vitamin D, calcium and osteoporosis medications, respectively.

Adjustment for confounding (i.e., age, sex, high-risk status) had little impact on effect estimates (Table 3).

Absolute Prescribing Change

Over the course of the trial, the mean home-level prescribing change for vitamin D ≥ 800 IU/day was 22.2% (95% CI: 17.6, 26.7) in the intervention arm versus 7.5% (95% CI: 5.7, 9.3) in the control arm (between group difference = 14.7%, 95% CI: 13.1, 16.2). Mean home-level prescribing change for calcium ≥ 500 mg/day was 8.8% (95% CI: 6.6, 11.0) in the intervention arm versus 1.8% (95% CI: 0.30, 3.24) in the control arm (between group difference = 7.0%, 95% CI: 6.2, 7.9). In the per protocol cohort, the difference in mean home-level prescribing change between treatment arms was 27.0% (95% CI: 25.5, 28.5) for vitamin D and 13.1% (95% CI: 12.0, 14.2) for calcium.

There was no significant difference in home-level prescribing change between arms for osteoporosis medications (between group difference, ITT = 3.4%, 95% CI: 2.6, 4.2; per protocol = 2.9%, 95% CI: 1.7, 4.1).

Falls and Fractures

Complete falls and fracture data were received from 18 control (baseline residents, n=2727) and 11 intervention (baseline residents, n=1290) homes. During nine-months of data collection (three non-consecutive periods), LTC homes reported 1712 fallers (43.6% single fall, 19.3% two falls, and 37.1% =3 falls) in the control arm and 853 fallers (44.4% single fall, 19.0% two falls, and 36.6% =3 falls) in the intervention arm. In the control and intervention groups, respectively, 79/5128 (1.5%) and 41/2491 (1.6%) of all reported falls resulted in a fracture, including 40/79 (50.6%) and 17/41 (41.5%) hip fractures.

DISCUSSION

In this study, we examined the effectiveness of an interdisciplinary KT intervention aimed at improving the uptake of vitamin D and other evidence-based fracture prevention strategies in LTC. Our results suggest that the ViDOS intervention resulted in significantly greater uptake of appropriate vitamin D and calcium prescribing, with an absolute improvement in prescribing of approximately 15% for vitamin D and 7% for calcium in the ITT cohort.

Given that it is a tolerable, low-cost intervention that is recommended for all older adults (25), vitamin D may be particularly amenable to targeted change. In the community, a multifaceted intervention targeting improved osteoporosis management demonstrated a 13% absolute improvement in vitamin D (26). In LTC, one KT intervention involving consultation and training by specialist osteoporosis nurses demonstrated a relative increase of 64% in calcium and vitamin D prescribing (27), but another study with a similar multifaceted intervention to ours did not demonstrate significant effects (28). In the latter study, participation in the intervention was low, only high-risk residents were included in the analysis and the authors also suggest a possible ceiling effect due to high baseline prescribing rates.

We did not see a significant effect for osteoporosis medication prescribing, however this is not surprising given that this topic received less focus in educational meetings and because it has been well documented that family physicians face a number of barriers for prescribing osteoporosis medications in LTC (9, 13). In a recent survey (13), LTC

physicians indicated that the general osteoporosis guidelines are difficult to apply to LTC residents, particularly with regard to risk assessment. Currently, general osteoporosis clinical practice guidelines (25) are being adapted for the frail elderly residing in LTC.

Our multifaceted KT intervention targeted professional behaviour change, but it also included strategies that encouraged organizational change specific to the LTC setting, i.e., action planning regarding process and policy changes. In addition to the difficulty of applying practice guidelines to the frail elderly, structural and process barriers include a high proportion of unregulated staff, absence of a learning culture, high turnover in management, heavy regulatory and documentation demands, routinized care rituals, and lack of familiarity with clinical practice guidelines, (29-31). Although not all barriers are easily modifiable, the ongoing monitoring of barriers (formally, three times over twelve-months) was an important design feature.

Another important design component was tailoring our intervention to interdisciplinary care teams. Compared with other practice settings, physicians who practice in LTC are typically more removed from daily patient care and more reliant on collaborative decision-making. We engaged the entire interdisciplinary care team by scheduling educational meetings in conjunction with quarterly professional advisory meetings, enabling several off-site professionals to be present simultaneously. Furthermore, we utilized components of the quality improvement PDSA cycle (16, 19), asking LTC teams to brainstorm regarding process and policy changes (reported in a separate publication).

Although not the focus of this paper, we had good fidelity with our intervention including active participation in educational meetings. Other similar KT studies in LTC which included both physicians and LTC staff may have had non-significant (28, 32) or less than optimal results (33) due to poor adherence with educational components. In addition to scheduling educational meetings with regularly scheduled meetings, interviews with ViDOS participants indicated that the direct involvement of an expert was highly valued (34).

The improvements we observed in the ViDOS study demonstrate that interventions for changing provider behaviour can be successfully applied within LTC homes. Previously, these strategies have mainly been evaluated in other practice settings, demonstrating small to moderate effectiveness (35). Cochrane systematic reviews indicate median absolute improvements in care in the range of 4-12% for educational meetings [including interactive and didactic; (21)], educational outreach (36), local opinion leaders (37), audit and feedback (38), and computerized reminders (39). Some organizational interventions (e.g., multidisciplinary collaboration, knowledge management change) also appear to improve some care outcomes (40), and interprofessional education has shown some positive results, but is an area requiring further study (41). We observed similar or larger effect sizes compared with the medians reported in the systematic reviews noted above.

Our study has several strengths. We included the ongoing monitoring of barriers and use of action planning to promote teamwork and communication amongst interdisciplinary professionals. ViDOS homes were geographically diverse and were located in

communities of varied population sizes. In a cluster RCT, individuals within a cluster are more likely to have a similar result to each other than to individuals in other clusters. Thus, our GEE data analysis took into the account clustered nature of the data, which minimizes the possibility of overestimating the treatment effect and spuriously significant findings (42).

Nonetheless, our study is not without limitations. While our study was generalizable in terms of geography and community size, we had an over-representation of chain affiliated and for-profit LTC homes compared with provincial averages (43). Not-for-profit LTC homes have been associated with higher quality of care (44), although multi-facility chains may have greater resources to facilitate implementation of clinical practice guidelines (29). We experienced some challenges with recruitment and retention which has also been noted in other KT trials in LTC (27, 45). This was a pragmatic RCT; some contamination between study arms likely occurred which could have diluted our treatment effect. Six consultant pharmacists and four Medical Directors practiced in both control and intervention homes, and control homes may have been impacted by study activities via diffusion of messages (e.g., homes in the same corporate chain). Future trials should consider adding region as a stratification factor to minimize contamination. Both arms were subject to outside influences including an ongoing province-wide initiative [i.e., *Ontario Osteoporosis Strategy for LTC*, www.osteoporosislongtermcare.ca (20)]. We collected incident falls and fracture data for feasibility and safety data, however obtaining standardized data from LTC homes was a methodological limitation (i.e.,

different falls reporting systems). Our fracture rate was slightly lower than the 2% observed in a Canadian study using a standardized fall risk surveillance tool (46).

Given that our intervention was multi-faceted, it is difficult to determine the most influential components. In general, multifaceted interventions may be more effective than single interventions (47), although Grimshaw et al. (35) have shown that adding more strategies may not improve effect sizes. We did not include measures of organizational context (e.g., work culture, type of leadership), which have been identified as an important factors influencing the uptake of research evidence (48).

Although RCT's evaluating KT interventions are increasing in the LTC setting (27, 28, 32, 49), further implementation research evaluating professional and organizational KT strategies is still greatly needed. The results of this study have informed the next phase of this research program, including a stepped wedge cluster randomized trial underway in 50 LTC homes across Ontario (50). Changes that resulted from our pilot included using pharmacists as champions in the recruitment and intervention delivery, implementing chart audits to collect the required risk information including fracture history, and providing risk-based recommendations to practitioners.

Conclusion

In conclusion, the ViDOS multifaceted, interdisciplinary intervention effectively increased appropriate prescribing of vitamin D and calcium in LTC homes. Although our focus was on improving the uptake of evidence-based practices for osteoporosis and

fracture prevention, the ViDOS model could potentially be applied to a wider range of topics relevant to LTC residents.

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Author Contributions

Conception and design of the study: All authors. Acquisition of data: Stroud, Campbell. Analysis and interpretation of data: Ioannidis, Kennedy, Thabane. Statistical expertise: Thabane, Ioannidis. Trial supervision and implementation: Papaioannou, Kennedy, Pickard, Ioannidis, Thabane, van der Horst, Giangregorio. Facilitation of intervention: Papaioannou, Adachi, Marr, Morin, Crilly, Josse, van der Horst. Drafting of the manuscript: Kennedy. Critical revision of the manuscript for important intellectual content: All authors. Final approval of the article: All authors.

Sponsor's Role

None

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Table 1. Baseline Characteristics of Intervention and Control LTC Homes

Characteristic	Control (n=21)	Active Intervention (n=12)	All Intervention (n=19)
Facility Size (Number of Beds)			
mean (SD)	157 (80.2)	114 (57.0)	115 (68.0)
min, max	49, 375	45, 232	43, 294
Number of Prescribing Physicians			
mean (SD)	4.3 (2.7)	4.7 (2.6)	4.5 (2.7)
min, max	2, 13	1, 10	1, 10
Community Population Size, %			
Small (<30,000)	33	42	47
Medium (30,000 - 100,000)	10	8	11
Large (100,000-1,000,000)	38	33	26
Metropolitan (>1,000,000)	19	17	16
For-Profit, %	81	92	95
Chain Affiliation, %	76	75	84

SD=standard deviation

Table 2. Baseline Characteristics of Residents in Intervention and Control LTC Homes

Characteristic	Control Group	Intervention Group	
		Active*	All
	n= 3293	n= 1367	n= 2185
Age, mean (SD)	84.6 (10.7)	84.4 (10.8)	84.0 (11.1)
	(n=3274)	(n=1361)	(n=2178)
Female, % (n)	71.1	71.5	70.4
	(2329/3277)	(972/1360)	(1532/2175)
Number of medications, mean (SD)	9.2 (4.3)	9.7 (4.9)	9.7 (4.7)
	(n=3293)	(n=1367)	(n=2185)
Vitamin D (≥ 800 IU/day), % (n)	41.8	38.8	36.0
	(1378/3293)	(530/1367)	(787/2185)

Calcium (≥ 500 mg/day), % (n)	34.8 (1145/3293)	32.7 (447/1367)	30.7 (671/2185)
Osteoporosis Medication, % (n)	22.7 (747/3293)	17.7 (242/1367)	17.0 (372/2185)
High risk residents, ** % (n)	34.8 (412/1185)	28.6 (114/399)	26.7 (181/678)
Hip Fracture (prevalent), % (n)	7.0 (230/3290)	5.0 (68/1365)	5.0 (109/2183)
Vertebral Fracture (prevalent), % (n)	1.4 (46/3290)	0.8 (11/1365)	0.9 (20/2183)
Osteoporosis diagnosis, % (n)	31.3 (1030/3290)	26.3 (359/1365)	27.8 (607/2183)

High-risk, % (n)**	36.0	29.2	31.0
	(1185/3293)	(399/1367)	(678/2185)

SD=standard deviation; *Includes residents in 12 intervention homes that participated in the intervention. **Hip fracture, spine fracture, or osteoporosis diagnosis.

Table 3. Effect of ViDOS Intervention on Prescribing Outcomes

Outcome	OR (95% CI)	
	Unadjusted	Adjusted*
ITT cohort		
Primary: Vitamin D (≥ 800 IU/day)	1.82 (1.12, 2.96)	1.85 (1.13, 3.06)
Secondary:		
Calcium (≥ 500 mg/day)	1.33 (1.01, 1.74)	1.33 (1.01, 1.77)
Osteoporosis Medication (high-risk residents)**	1.17 (0.91, 1.51)	1.12 (0.87, 1.44)
Per Protocol cohort		
Primary: Vitamin D (≥ 800 IU/day)	3.06 (2.18, 4.29)	3.14 (2.22, 4.45)
Secondary:		

Calcium (≥ 500 mg/day)	1.57 (1.12, 2.21)	1.58 (1.11, 2.24)
Osteoporosis Medication (high-risk residents)	1.20 (0.90, 1.60)	(1.16 (0.87, 1.53)

*Adjusted for age, sex and high-risk status (hip fracture, spine fracture, or osteoporosis diagnosis).

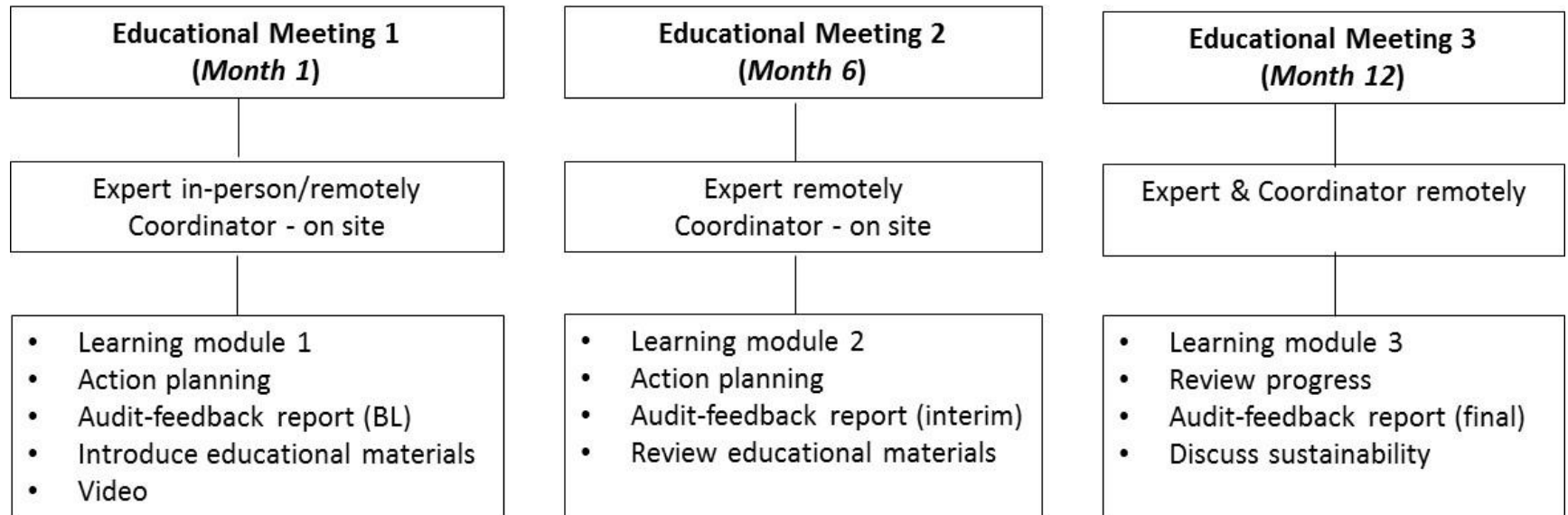


Figure 1. ViDOS Multifaceted Intervention.

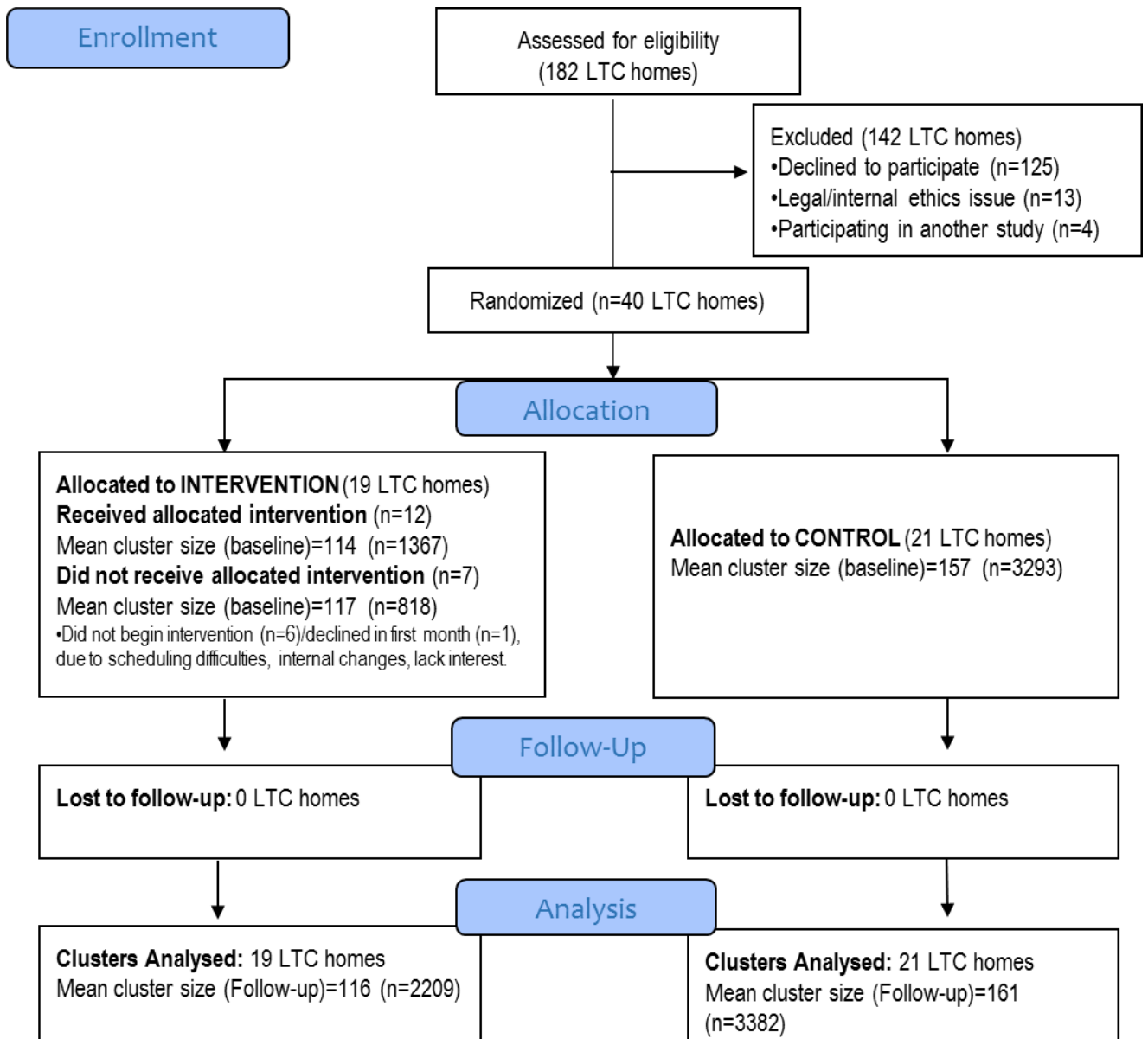


Figure 2. Flow-Chart of Randomization, Allocation, Follow-up and Analysis

Appendix: Action Plan Template

Bone Health Protection Best Practices	What has to happen?	Who should be involved?	What do you need?	What are your next steps?
Daily Vitamin D ₃ 800-2000 IU				
Daily calcium 1200 mg <i>Dietary+ supplement</i>				
Bisphosphonate medications				

Bone Health Protection Strategies	Facilitators	Barriers
<i>People</i>		
<i>Policy</i>		
<i>Procedures</i>		
<i>Processes</i>		
<i>Practice</i>		
<i>Promotion</i>		

CHAPTER 5

Thesis Paper 4: Implementing a Knowledge Translation Intervention in
Long-term Care: Feasibility Results from the Vitamin D and Osteoporosis
Study (ViDOS)

PREFACE TO CHAPTER 5

Chapter 5 presents the feasibility results for the Vitamin D and Osteoporosis Study (ViDOS). This report highlights several important considerations including recruitment, retention, data completion and participation in the intervention

The Vitamin D and Osteoporosis Study (ViDOS) trial received an operating grant from the Canadian Institutes of Health Research (Funding Reference Number: MOP-114982). Dr. Papaioannou was the Principal Investigator on this grant, and the student was the PhD trainee. The ViDOS study was conducted from 2009-2012.

This work was conditionally accepted (pending minor suggested revisions) in February 2014 to the *Journal of the American Medical Directors Association*. Upon final acceptance, a request will be made to the publisher of the journal to obtain permission to include copyright material.

The student supervised the implementation and coordination of the ViDOS trial; conceived of the feasibility study; collected, analyzed, and interpreted the feasibility data; and drafted the manuscript. All authors contributed to the conception and design of the feasibility study and provided critical review of the manuscript.

**Implementing a Knowledge Translation Intervention in Long-term Care: Feasibility
Results from the Vitamin D and Osteoporosis Study (ViDOS)**

Running title: Implementing Knowledge Translation in Long-term Care

C. C. Kennedy, MSc^{1,2}, L. Thabane, PhD², G. Ioannidis, PhD¹, J.D. Adachi, MD
FRCPC¹, A. Papaioannou, MD, MSc, FRCP (C) FACP¹ on behalf of the ViDOS
Investigators

1. Department of Medicine, McMaster University, 1280 Main St West, Hamilton
ON L8S 4K1
2. Department of Epidemiology and Biostatistics, McMaster University, 1280 Main
St West, Hamilton ON L8S 4K1

Corresponding author and reprint requests made to:

Alexandra Papaioannou
Department of Medicine, Division of Geriatrics
McMaster University

Mailing Address:

St. Peter's Hospital, Juravinski Research Centre
88 Maplewood Ave, Hamilton ON L8M 1W9
Phone: (905) 521-2100 ext 77715 Fax: (905) 318-2654
papaioannou@hhsc.ca

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ABSTRACT

Objectives: To evaluate the feasibility of implementing an interdisciplinary, multifaceted knowledge translation (KT) intervention within long-term care (LTC) and to identify any challenges that should be considered in designing future studies.

Design: Cluster randomized controlled trial.

Setting: 40 LTC homes across the province of Ontario, Canada.

Participants: LTC teams comprised of physicians, nurses, pharmacists, and other staff.

Measurements: Cluster-level feasibility measures including recruitment, retention, data completion and participation in the intervention. A process evaluation was completed by Directors of Care indicating which process/policy changes had been implemented.

Results: Recruitment and retention rates were 22% and 63%, respectively. Good fidelity with the intervention was achieved, including attendance at educational meetings. After ViDOS, seven process indicators were being newly implemented by over 50% of active intervention homes.

Conclusion: Despite recruitment and retention challenges, the multifaceted KT intervention produced a number of policy/process changes and had good intervention fidelity.

Trial Registration: ClinicalTrials.gov NCT01398527.

INTRODUCTION

Despite increasing emphasis on implementing evidence-based care in long-term care (LTC) homes, there has been a distinct lack of implementation research [i.e., study of how to implement evidence-based practices (1)]. Given the impact that organizational context has on research implementation (2) and the unique characteristics of the LTC practice setting (3), it is imperative to evaluate knowledge translation (KT) strategies within this practice setting.

We designed a pilot, cluster randomized trial (CRT) to evaluate the feasibility and effectiveness of a multifaceted KT intervention aimed at improving the uptake of appropriate vitamin D prescribing in LTC (the vitamin D and osteoporosis study; ViDOS). A CRT is a rigorous study design that can be applied within LTC homes (i.e., care is naturally provided in clusters), however CRTs have been underutilized in this setting (4). Thus, in this paper our objectives were 1) to evaluate the feasibility of implementing an interdisciplinary, multifaceted KT intervention within LTC using a CRT design, and 2) to identify any challenges that should be considered in the design of future studies.

METHODS

Setting and Participants

Further details of the ViDOS protocol are described elsewhere (5). The target audience was the Professional Advisory Committee (PAC) at each LTC facility including the Medical Director, Director of Care (DOC), pharmacist, dietician, and other physicians, nurses, and staff. LTC homes were located in Ontario, Canada and received medication services from Medical Pharmacies Group Limited, our partner pharmacy provider.

Intervention

The 12-month, multifaceted, KT intervention focused on both professional behaviour change and organizational process changes. Intervention homes participated in three, one-hour, small-group, interactive educational meetings (months 1, 6 and 12) including a standardized presentation, 10-minute DVD, question and answer session, action planning for quality improvement, and audit and feedback review. Meetings were facilitated by one of six expert opinion leaders, who were physicians specializing in osteoporosis or geriatrics. Experts facilitated sessions in person (meeting one) or remotely; a study coordinator was on-site at the first two meetings. Educational materials (osteoporosis tool-kits; process checklists; treatment alerts) were also distributed. Control homes received tool-kits provided to all Ontario LTC homes (www.osteoporosislongtermcare.ca).

Measures

Feasibility outcomes were recruitment, retention, data collection, and intervention fidelity (participation, identification of action items, audit and feedback review). LTC homes recorded falls and fractures for three 3-month periods (baseline, interim, and follow-up), based on based on electronic/paper-based charts, internal monitoring systems, and critical incident reports (5). DOCs completed process evaluations after 12-months indicating which processes/policy changes had been implemented. Target indicators of success were chosen a priori (Table 1). The study was approved by Hamilton Health Sciences/McMaster University Research Ethics Board.

RESULTS

Forty LTC homes were randomized to control (n=21) or intervention (n=19) arms.

Overall, 88% of homes were for-profit and 80% were affiliated with one of seven multi-facility chains. The median facility size was 122 beds (min=43, max=375).

Recruitment: Of 182 LTC homes approached for participation, 40 consented and were randomized into the study (22%). Of the excluded homes, n=125 declined to participate (e.g., lack of interest, competing demands), n=4 were participating in another study, and n=13 were municipal government homes who did not receive approval from internal ethics/regulatory boards.

Retention: Seven intervention homes did not receive the intervention as allocated: 6 withdrew prior to beginning the study and one withdrew after the first educational meeting. The main reasons for withdrawing active participation were due to logistical or scheduling difficulties (n=5; e.g., management changes; Medical Director rounds on weekends). In two homes, consent was initially provided by a representative but the Medical Director declined.

Fidelity: A) Participation: The majority of study meetings were scheduled to coincide with a regularly scheduled PAC meeting. Overall, 164 participants from 12 active intervention homes attended at least one ViDOS educational meeting, including: Medical Directors (n=12), DOC/ADOCs (n=21), Administrators (n=15), pharmacists (n=10), other physicians (n=11), nurse practitioners (n=5), physician assistants (n=3), RNs (n=32), physiotherapists (n=10), Food Services Directors (n=8), dieticians (n=8), and other

(n=29). The Medical Director, DOC/ADOC, and consultant pharmacist attended at least two educational meetings in all homes (except for one home where the Nurse Practitioner attends PAC meetings instead of the Medical Director; Table 1). B) Action Planning: All active intervention homes (n=12) initiated at least 3 action items that either impacted process/policy (e.g., implemented standard admission orders for vitamin D), or were assigned to specific individuals (e.g., dietitian reviewed dietary calcium intakes). All homes also identified several home-specific barriers (e.g., cost of vitamin D; osteoporosis/fractures not recorded in electronic records) and facilitators (e.g., posting audit and feedback reports around home; implementing falls/fractures check-list at admission). C) Audit and Feedback Review: All active intervention homes reviewed audit and feedback reports at the three educational meetings.

Data Completion: Complete falls/fracture data spreadsheets were returned for 18/21 (86%) control homes and 11/12 (92%) of active intervention homes. A standardized data collection method was difficult as LTC homes had various systems in place to collect falls/fractures data.

Policy/Process changes: After 12-months, all active intervention homes completed a Process Indicator Check-list. Seven process indicators were being newly implemented by over 50% of homes after participation in ViDOS (Table 2).

DISCUSSION

Overall, the ViDOS KT intervention was successfully implemented and produced a number of policy/process changes. With the exception of recruitment and retention, we met or exceeded our a priori indicators of success (Table 1). Although not the focus of this paper, the intervention resulted in significant increases in appropriate vitamin D and calcium prescribing (6).

Intervention fidelity is an important feasibility measure, allowing us to consider the "dose" of the KT intervention in which participants received. In our study, we had good compliance with all intervention components including action planning, audit and feedback review, and participation in educational meetings. Despite busy schedules, nearly all homes had a Medical Director, DOC/ADOC, and Consultant Pharmacist present for at least two sessions. Maximizing participation in educational sessions is critical for properly evaluating the effectiveness of an intervention. Similar studies in LTC likely underestimated the impact of an educational intervention due to poor adherence and not necessarily due to an ineffective strategy (7,8).

Despite having our partner pharmacy provider act as a liaison in approaching homes, recruitment was one of our challenges. Gaining the support of corporate leaders within LTC chains was an important factor in encouraging participation amongst individual LTC homes. This was responsible for the high proportion of homes we recruited who were for-profit and part of multi-facility chains. Further, several municipal homes faced additional

legal/ethics board hurdles that prevented their participation. A noted limitation, is whether our results are generalizable to non-profit, non-chain facilities.

Six homes declined to actively participate prior to even beginning the intervention. To ensure cooperation by the entire team and avoid early withdrawal, a short presentation to the PAC team could potentially boost recruitment/retention. Obtaining initial consent from both the Medical Director and DOC may also be beneficial. Furthermore, to overcome logistical challenges, particularly for homes in the far north, providing an opportunity to view modules on a website or participate remotely may improve participation. Our return of data spreadsheets was reasonable (86-92%), however obtaining data took numerous reminders and it was difficult to follow-up on missing data fields. If falls/fractures were a primary outcome, trained research assistants would be necessary. A small incentive (gift certificates) were presented to the LTC staff who collected the data.

In conclusion, although we faced some challenges with recruitment and retention, fidelity with the intervention was good and all components were considered feasible to deliver. LTC homes reported implementing several process/policy changes after participating in the study.

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Table 1. Feasibility Results for the ViDOS RCT

Measure	Target (%)	Observed (%)	Description
Recruitment	40	22	- Acceptance rate was low; took several months - Accomplished target sample size (n=40)
Retention	80	63	7 INT homes withdrew active participation.
Participation	80		<i>Overall:</i> n=164 participants from 12 active INT homes; 56% attended at least 2 meetings* <u>Key roles:</u> ≥ 2 meetings: DOC/ADOC[†]/Pharmacist=100%; Medical Director[†]=92% 3 meetings: DOC/ADOC[†]=83%; Pharmacist=92%; Medical Director[†]=25%
Action Plans	80	100	Completed by all homes
Feed-back Reports	80	100	Reviewed at all INT sessions (months 0, 6, 12)
Data Completion	80	86-92	All spreadsheets: 86% control/92% INT homes

INT=intervention; *Excluding “other” (non-staff/visitors) [†]Due to role changes, may not have been the same person.

Table 2. Percent of Osteoporosis/Fracture Prevention Best Practices Implemented

Process Indicators	<i>Implemented after ViDOS</i>	<i>Implemented before ViDOS</i>	<i>Not done</i>
Admission orders (vitamin D, calcium, bone health medications)	83	8	8
Have 1-2 staff as Osteoporosis Champions	75	0	25
Use “Medication Alerts” for vitamin D, calcium, bone health medications	67	0	33
Osteoporosis and fracture prevention are on agenda of Professional Advisory/Falls Prevention Committees	58	33	8
Use LTC-related knowledge resources – Toolkit, website, clinical guidelines, etc.	58	25	17
Dietary enhancements for residents with osteoporosis – using calcium & vitamin D enriched foods	58	17	25

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Staff receive osteoporosis/fracture prevention education annually	58	17	25
Request on chest X-ray orders to rule out vertebral fractures	42	25	33
Monitor for fracture risk at least quarterly	33	58	8
Falls assessment includes fracture risk	33	58	8
Residents at high risk for hip fracture from falls wearing hip protectors	33	42	25
Osteoporosis & fracture risk is part of physical assessment on admission (e.g., history of fracture)	25	75	0

CHAPTER 6: CONCLUSION OF THE THESIS

CONCLUSION OF THE THESIS

This chapter provides an overview of the main findings presented in this thesis and considers the implications of these results. The strengths and weaknesses of the thesis studies and the directions for future research are also briefly reviewed.

6.1 Calcium and Vitamin D

Provincial Knowledge Translation (KT) Strategy

The first paper considered the impact of the *Ontario Osteoporosis Strategy for Long-term Care (LTC)*, a province-wide KT initiative to increase the uptake of evidence-based osteoporosis and fracture prevention strategies in Ontario LTC homes. Our primary objective was to examine osteoporosis-related prescribing trends before and after implementing this strategy (2007 versus 2012). Although it was not possible to infer any causal associations from this descriptive observational study, our results suggested a substantial uptake in widespread prescribing of vitamin D² with an absolute increase of approximately 38% over five years.

During this period, there was a non-significant increase in calcium prescribing of approximately 4%. However, one of our limitations was we could only examine supplement use and not dietary intake. This is an important consideration given that during the years of this study there was controversy surrounding calcium supplementation (1). Although calcium supplementation has a beneficial risk reduction for all fractures (2),

²The analysis excluded LTC homes that participated in the more intensive ViDOS knowledge translation study.

there has been some indication that it may increase hip fracture risk (3) and is associated with an increased risk of myocardial infarction (4, 5). The 2010 Osteoporosis Canada guidelines reflect these concerns, recommending that 1200 mg/day be achieved through both diet and supplementation (6). The *Ontario Osteoporosis Strategy for LTC* (7) recommended obtaining the 1200mg of calcium daily from diet, with a maximum of 500mg of supplementation if residents are unable to consume enough from diet alone. Although our study could not examine this, it is possible there was a larger change in overall intake (i.e., including dietary intake) during this period, which would not have been reflected by examining supplement use only.

Overall, the first thesis study indicated that widespread KT efforts likely contributed to the improvements in vitamin D and calcium prescribing, a relatively inexpensive and effective strategy for improving bone health in LTC residents. Despite overall improvement in the cohort, some homes still had low rates of supplement prescribing indicating that more intensive KT efforts may be necessary for some LTC homes. A future strategy may consider targeting homes with low rates e.g., homes in the lowest quartile and consider implementing a more intensive KT intervention such as the ViDOS model. However, it is possible that the lower prescribing homes may have greater resistance to change even with more intensive KT efforts.

ViDOS Multifaceted Interdisciplinary Intervention

The second thesis study (Vitamin D and Osteoporosis Study (ViDOS); *papers 2-4*) was a more intensive KT approach that included expert-led interactive educational meetings, continuous quality improvement, and audit and feedback. Results indicated that the

ViDOS KT intervention significantly improved prescribing of vitamin D and calcium. In the intention to treat (ITT) cohort, the 12-month intervention resulted in an absolute improvement of 15% for vitamin D and 7 % for calcium prescribing, and effects were even greater when only active intervention homes were included (27% and 13%, respectively).

In general, compared with acute care or community settings, there has been little enquiry regarding KT interventions in the LTC setting (8). This thesis study demonstrated that interventions for changing provider behaviour can be effectively applied with interdisciplinary LTC teams. The effect sizes we found in the ViDOS study, were similar or larger to those reported in Cochrane systematic reviews of KT interventions based mainly on studies conducted in non-LTC settings. Given that it is a tolerable, low-cost intervention that is recommended for all older adults, vitamin D may be particularly amenable to targeted change.

6.2 Osteoporosis Medications

In the impact evaluation of the *Ontario Osteoporosis Strategy for LTC (paper 1)*, prescribing of osteoporosis medications did not appear to increase between 2007 and 2012 and prescribing rates were reasonably similar between homes. We were not able to comment on the appropriateness of the prescribing rates, since we did not have access to information regarding the risk status of residents (i.e., documented osteoporosis or fractures).

Similarly, in the second project, the more intensive ViDOS intervention did not result in an improvement in osteoporosis medication prescribing in high-risk residents with documented osteoporosis or hip/vertebral fracture. Baseline rates of osteoporosis medication prescribing to high-risk residents were approximately 30%. The rate of overall osteoporosis prescribing (examining all residents and not just the high-risk sub-set) was very similar in both thesis studies at approximately 20%.

Neither of the KT interventions (i.e., *Ontario Osteoporosis Strategy for LTC*; ViDOS) were associated with a significant improvement in osteoporosis medication prescribing, which may be attributable to two main factors: 1) Although some information regarding the management of osteoporosis and fractures with pharmacological therapy was provided, there was a greater emphasis on vitamin D and bone health process changes (e.g., assessment of fractures and osteoporosis); 2) As a recent survey of LTC family physicians documented (9), there are several barriers to fracture risk assessment and osteoporosis management in LTC including inapplicability of the 2010 Osteoporosis Canada guidelines (e.g., lack of access to BMD testing, difficulty acquiring information for risk assessment), and uncertainty regarding treating an elderly cohort with frequent polypharmacy, multiple comorbidity and shortened life-span. Improving upon osteoporosis medication prescribing will likely require a more targeted approach that includes providing support with assessing fracture risk and increased clarity regarding how to manage LTC patients. The latter component will, in part, be addressed by the upcoming publication of modified guidelines for LTC (Osteoporosis Management and Fracture Prevention for the Frail Elderly in LTC).

6.3 Directions for Future Research

The results of the ViDOS study have informed the next phase of this research program, including a stepped wedge cluster randomized trial currently underway in 50 LTC homes across Ontario [Gaining Optimal Osteoporosis Assessments in Long-Term Care (GOAL) (10)]. Changes that resulted from our ViDOS pilot included streamlining our intervention to include expert involvement through video presentations, using pharmacists as champions in the recruitment and intervention delivery, and implementing chart audits to collect the required risk information and providing risk-based recommendations to practitioners.

Future Large-Scale Trial

Both the ViDOS and GOAL studies are focused on prescribing-related primary outcomes (vitamin D and osteoporosis medications, respectively), with falls and fracture data as secondary outcomes. We have already demonstrated that the ViDOS intervention is an effective and feasible model, and we are currently examining the feasibility and effectiveness of the GOAL study intervention. The lessons learned from these studies will pave the way for a future large scale study that is powered to detect fracture outcomes. However, in order to accomplish this objective, partnerships with government, funders, long-term care chains, and pharmacy providers is essential in order to recruit a large enough sample size.

Factors That Drive Uptake in KT Interventions

In the first paper, we examined several organizational factors that may have influenced prescribing, controlling for age and sex. There were no significant associations between

prescribing and chain status, profit status, or LTC home size, however we detected a small positive association between prescribing rates and both the number of prescribing physicians and community size.

Given that facility characteristics did not adequately account for differences in prescribing between LTC homes, there is a need to consider other factors. There has been increased enquiry regarding the influence of contextual factors on knowledge uptake in all healthcare settings including LTC [e.g., Translating Research in Elder Care (11, 12)]. In one common KT framework (11), organizational context refers to characteristics of the healthcare setting including culture (e.g., beliefs, values, receptivity to change), leadership (e.g., style, effectiveness), evaluation (e.g., feed-back mechanisms) and resources (e.g., time, equipment, clinical skills). Successful integration of knowledge into practice is believed to be a function of the type/strength of evidence, contextual characteristics, and the way the process is facilitated (13). Indeed, in a recent acute care randomized trial, many contextual aspects mediated guideline implementation including team communication, organizational buy-in, interprofessional factors, and habituated ways of working (14). Contextual factors also substantially moderate the facilitation process (15).

Future KT studies in LTC should consider using tools to evaluate context pre-and post-intervention [e.g., (16)], as well as incorporating mixed methods and process evaluation in study designs to shed more light on the underlying mechanisms that are driving or inhibiting change.

Multifaceted Interventions Informed by Theory

Both of the KT interventions in this thesis utilized several strategies to influence the transfer of knowledge to interdisciplinary LTC care teams. Although multifaceted approaches (i.e., an intervention that utilizes two or more strategies) have demonstrated some success (17), and are generally recommended, adding more strategies may not improve effect sizes and should be based on explicit rationale or theory for choosing the various components (18). Given potential additional costs and efforts associated with multifaceted interventions, another important area of research is to simultaneously compare various strategies (or combinations of various strategies). Furthermore, future research should consider what level of intensity (e.g., number of sessions) and modalities (e.g., in person, videoconference, expert versus non-expert) are most effective particularly given the resource intensity of scheduling the physician experts. Another area that has not been well studied, is determining what the optimal length (i.e., number of months) an intervention should be to effect change, and whether intervention length impacts upon lasting changes in practice and policy.

Sustainability

In the CIHR Knowledge to Action Cycle (KTA), sustainability is the final phase, referring to "the continued implementation of evidence over time (19)." Despite this intention, few studies have examined outcomes beyond one-year and the majority lack a framework for evaluating sustainability (20, 21). Many studies are focused on short-term outcomes and it has been difficult to confirm whether outcomes are sustained over the longer-term (22). Given that we have a reliable mechanism for collecting accurate

prescribing data (i.e., algorithms with the Medical Pharmacies database), we would be well positioned to conduct a long-term follow-up to examine whether prescribing changes were sustained for ViDOS participants and for the larger cohort of homes across the province.

6.4 Strengths and Limitations

The thesis studies presented here have several strengths. For both studies, our primary data were downloaded from a central pharmacy database at Medical Pharmacies (large pharmacy provider providing services to approximately one-third of all Ontario LTC homes). The accuracy of this data is excellent given that we could capture all medications and supplements prescribed to all residents in the target cohorts. In community settings, even if Ontario Drug Benefit (ODB; prescription data for Canadians over age 65) data is used, it is difficult to capture prescriptions that were not covered by the ODB program or additional supplements that may have been purchased. Algorithms were developed by systems analysts at Medical Pharmacies, in partnership with our research team, which captured all amounts of vitamin D and calcium prescribed, as well as all osteoporosis medications. The benefits of using a single pharmacy database across both thesis studies strengthened comparisons in prescribing rates. Although it is possible that the Medical Pharmacies-serviced homes are different from other homes across the province, it is likely that our results were generalizable since we included homes that were geographically diverse and were located in communities of varied population sizes.

The ViDOS study design had several strengths. We used a cluster, randomized controlled trial design which provides a rigorous evaluation of the cause-effect relation between the

intervention and outcome. Drawing on the CIHR KTA Cycle (19), the formal action planning sessions that occurred at educational meetings allowed the continuous assessment of barriers and facilitators to knowledge use. The interactive sessions also promoted teamwork and communication amongst interdisciplinary professionals, which is important given the interprofessional issues that often impact implementation studies (14). As highlighted in the feasibility paper (*paper 4*), there was good compliance with all intervention components in the ViDOS study including action planning, audit and feedback review, and participation in educational meetings. Good attendance by interdisciplinary professionals who are typically off-site (Medical Directors, physicians, consultant pharmacists) was likely attributable to scheduling educational sessions in conjunction with regular PAC meetings. We ensured the applicability of our intervention to an LTC audience by pre-testing the format and content of sessions with a pilot LTC home.

Several limitations of the thesis projects should be acknowledged. The first study was a descriptive, observational study comparing cohorts that were five-years apart. As such, we need to be cautious about inferring a causal relationship between the intervention and observed prescribing changes. Influences other than the *Ontario Osteoporosis Strategy for LTC* (e.g., increased media attention for vitamin D), may have been responsible, at least in part, for the prescribing change we observed. In that study, the 2007 cohort was limited to only ten LTC homes and for both cohort years we lacked a complete range of resident variables, particularly patient case-mix.

In the ViDOS study, despite having our partner pharmacy provider act as a liaison in approaching homes, recruitment was a challenge. Some municipal homes faced additional legal/ethics board hurdles that prevented their participation and we needed to leverage the support of corporate leadership at multi-facility chains to reach our recruitment target. These factors resulted in the higher proportion of homes that were for-profit (88%) and chain affiliated (80%) compared with provincial averages [approximately 57% and 49%, respectively (16, 17)]. This potentially impacts the generalizability of our results to non-profit, non-chain homes. A strength of the first thesis study was that the 2012 cohort had a nearly identical proportion of for-profit, chain-affiliated homes as the provincial average. Obtaining accurate falls and fracture data is a problem that is faced by LTC researchers in general (23). Use of Resident Assessment Instrument - Minimum Data Set 2.0 (RAI-MDS 2.0) reports (24) as a standardized method to collect incident falls and fracture data was not an option in the ViDOS study as many Ontario LTC homes had not yet implemented this system when the study began in 2009. Our feasibility data indicated that obtaining falls and fracture data from LTC homes directly required a lot of follow-up and was not a standardized approach. LTC homes indicated they used different methods to fill in the datasheets we provided (e.g., internal falls monitoring systems, electronic medical record reports, critical incident forms, auditing medical charts).

There were also limitations in our ability to capture prevalent fracture and osteoporosis diagnosis data. We were able to access diagnosis data from the Medical Pharmacies database, however this data source was likely limited by "errors of omission" for two reasons: 1) Diagnoses added to this database are based on admission health assessments,

which we know often underestimate fracture history and osteoporosis diagnoses (25); 2) New diagnostic information is not frequently updated to the Medical Pharmacies system post-admission. However, when we compared our baseline estimates of hip fractures and osteoporosis diagnosis with a provincial report (using RAI-MDS 2.0 data), rates were reasonably similar (7). The report estimated rates of 25% and 7.9% for osteoporosis diagnosis and hip fractures, respectively, and in the ViDOS trial our rates were approximately 28% and 6%.

To overcome limitations with collecting diagnostic, falls, and fracture data, a future large scale study that adequately identifies high-risk residents and is powered to detect fracture outcomes should utilize a standardized system such as RAI-MDS 2.0 (24) and/or consider acquiring data from government databases.

6.5 Conclusion

Overall, the implications of this project indicate that a broader, public health approach to KT (*Ontario Osteoporosis Strategy for LTC*) and a more intensive approach (ViDOS model) can lead to prescribing changes and improvements in bone health processes.

While the second model is more resource intensive, our feasibility results indicated that a multifaceted, interdisciplinary KT approach is both achievable and effective. However, given that many homes also responded well to the less intensive *Osteoporosis Strategy* KT intervention, future efforts may consider blending these two types of KT to maximize resources and achieve important outcomes.

With the upcoming publication of adapted guidelines for LTC residents (Osteoporosis Management and Fracture Prevention for the Frail Elderly in LTC), we would be well positioned to implement a dissemination and evaluation plan that includes examining the success of various dissemination approaches and to potentially track fracture outcomes.

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Appendix A

February 19, 2014

Dear Courtney:

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