2020

Financial Impact Associated with Implementation of the Low Back Pain Clinical Practice Guideline in Outpatient Physical Therapist Practice

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Financial Impact Associated with Implementation of the Low Back Pain Clinical Practice Guideline in Outpatient Physical Therapist Practice

by

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A dissertation submitted in partial fulfillment of the requirements
for the degree of Doctor of Philosophy

Nova Southeastern University
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Physical Therapy
2020

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Abstract

Dysfunction and disability arising from low back pain (LBP) affects more people than any other condition globally, and results in changes to the quality of life for many individuals. The financial burden of managing low back pain is among the highest both in the United States and globally. Clinical practice guidelines (CPGs) provide recommendations on patient management strategies and have the potential to simultaneously improve patient outcomes and lower health care costs. Limited evidence exists on the impact of CPG implementation on downstream medical costs that are incurred after physical therapist care. A retrospective observational study was conducted that examined the financial impact of implementing a LBP CPG in outpatient physical therapist practice, along with patient outcomes. Retrospective billing and clinical data from 270 patients with LBP who were treated at multiple sites within one health system were analyzed from September 2017 to March 2018, six months before implementation activities began and from June 2018 to December 2018, six months into the implementation of the LBP CPG. Costs for direct physical therapy and downstream medical charges, physical therapy utilization, and patient reported outcomes for the pre-implementation group were compared with the post-implementation group. The results of the study shed light on the positive impact that the implementation of the LBP CPG in outpatient physical therapist practice had on lowering downstream costs.

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Chapter 1: Introduction

Introduction to the Chapter

Impairments and disability arising from low back pain (LBP) affects more people than any other condition globally, and results in changes to the quality of life of many individuals.[1] LBP has been the leading cause of years lived with disability (YLD) for more than 30 years according to the Institute of Health Metrics and Evaluation's Global Burden of Disease Study (GBD).[2,3] The high prevalence of low back pain may be attributed to population growth and technological advances that lead to increased global life expectancy. Low back pain is the leading cause of YLDs for both men and women who live in high-income, high-middle-income, and middle-income countries according to the GBD study; and ranked within the top five causes of YLD in low-income countries for non-communicable disorders.[2] Low back pain also carries a significant financial burden to health systems, society, and to the individuals experiencing it.[4] Management of non-specific LBP in primary care is one of the most expensive conditions internationally.[5,6]

Background to the Problem

The United States is not exempt from the high prevalence of LBP and its associated costs. The financial burden of treating LBP is among the highest in the United States (U.S.).[7] According to the 2012 National Health Interview Survey conducted by the Centers for Disease Control and Prevention (CDC), LBP was found to affect 28.4% of respondents in the 3 months prior to the survey.[8] Additional studies have found similar rates of low back pain, stating that more than seven million American adults cite LBP as the cause of their disability and activity limitations.[9] The economic impact of LBP on both the direct, or health care related costs, and indirect, or costs associated with lost or reduced wages, work and home productivity, is also

extensive. A 2006 report cited the total economic impact of LBP to be $100 to $200 billion dollars (equivalent to $119 to $238 billion in 2013), of which two thirds were indirect costs.[10] The enormous burden of LBP to the individuals effected, the societal costs from reduced work productivity, and the rising prevalence makes management of LBP a priority in health care research.[11] Effective management strategies must assess both the patient impact and value of an available treatment option in order to efficiently address the public epidemic of LBP.[12] This is especially true in the United States where an opioid crisis has been declared by the CDC.[13] Frequent and over prescription of opioids for LBP has contributed to the crisis and non-pharmaceutical management for LBP, such as physical therapy, is associated with reduced long term opioid use.[14,15]

The current need to address health conditions such as LBP through policy and improved practice standards is in part due to previous management strategies that were not based on evidence, resulting in unwarranted variations in the care provided. Management strategies for LBP that at not based on evidence can lead to poor outcomes for patients.[16] For example when patients are treated with interventions that are known to be ineffective, such as ultrasound.[17] Current management trends lean towards more advanced imaging, more surgery, opioid prescriptions, and worse patient outcomes, which creates additional unnecessary costs to providing care.[18] One strategy to overcoming unwarranted variation is the development and implementation of Clinical Practice Guidelines (CPGs), which are statements based on systematic review, that delineate a course of care or treatment pathway for a specific condition.[19]

CPGs have been developed for a multitude of health conditions both within and outside of the field of physical therapy, as evidenced by the numerous categories of CPGs found in repositories and listed on the American Physical Therapy Association (APTA) website.[20,21]

When initiated in a timely fashion, evidence-based physical therapist management (including the use of CPGs) can result in the diminishment of a patients' symptoms related to LBP.[22,23] When physical therapy alone does not fully resolve a patient's LBP, additional health care services may be provided. The charges for additional services such as pharmaceutical management, radiological services, emergency department visits, physician, orthopedic or neurologic specialist visits that are incurred after an episode of physical therapy are considered downstream costs.

To help reduce downstream costs and costs related to excessive provider services, and improve patient outcomes, research is needed into how best to achieve this. Examination of CPGs is one method currently available to assist in this effort. Dissemination and implementation of CPGs are used to inform physical therapists of best practice standards and impact the way they manage patient care. In order to address the rising costs of health care, physical therapists are encouraged, and in some cases required, to utilize best practice methods to manage their patients.[24,25]

The purpose of this dissertation study is to understand the financial impact associated with the implementation of the LBP CPG in outpatient physical therapist practice on the total cost of physical therapy care and downstream medical costs, as well as patient outcomes.

Statement of the Problem

Many of the CPGs developed before the introduction of the Affordable Care Act of 2010 excluded value and cost into their recommendations and instead focused only on clinical outcomes.[26,27] However, the addition of the term value, which is defined as health outcomes achieved for dollar spent, is now often recommendation in research on evidence based practice.[28] Past research on the health outcomes of CPG implementation for LBP in outpatient physical therapist practice is conflicting, ranging from support to little or no effect, therefore more

evidence is needed to determine the impact of CPGs on patient outcomes.[19,29,30] More recent research has examined the cost effectiveness of early versus delayed physical therapy services, increasing the body of evidence on both patient outcomes and cost of physical therapist services.[31,32] Yet despite the increasing body of knowledge, the impact of CPG implementation in outpatient physical therapist practice on downstream medical costs for LBP has been not be explicitly examined, creating a gap in literature that is needed to be filled to fully ascertain the impact of CPGs. Knowledge of downstream costs can inform health care organizations on the impact that interventions and providers have on patients across the continuum of care and aid in resource management and identification of improvement opportunities.

Relevance and Significance

CPGs are developed through systematic review of evidence-based diagnostic and management strategies for a specific health condition. The methodology associated with development of CPGs has varied considerably, highlighting the need for standardization. The APTA created a manual for the development of transparent and trustworthy CPGs.[33] Once developed, CPGs may be placed in national repositories such as Guidelines Trust, created by the ECRI Institute.[20] A CPG cannot be listed on the Guidelines Trust website unless it has met specific inclusion criteria, which promotes consistency and standards for all CPGs despite differing methodologies.[34,35]

Professional health organizations often lead the development of CPGs through working groups and task forces made up of content experts that are familiar with the health condition and the commonly utilized management strategies. CPGs need to be updated and checked for clinician use and efficacy regularly. A definitive number of years in which a CPG must be updated has not been established, although many researchers suggest that 3-5 years is the most

appropriate timeframe to maintain the currency of the recommendations.[36] New research is estimated to take 3-5 years to be developed, tested, and implemented before it is deemed appropriate to be included in a CPG.[36] This all depends however, on the speed in which change occurs in the pathology or health condition, economic influences, diagnostic capabilities, and the value placed on the condition by patients and the healthcare industry.[36]

The APTA displays CPGs related to the field of physical therapy on the website apta.org. The APTA website offers users quick access to clinical summaries, research articles, CPGs, and psychometric properties on commonly used patient outcome measures. Easy access to research helps encourage its utilization and assists physical therapists in making clinical decisions based on current evidence. All CPGs listed on apta.org were developed from systematic reviews from professional organizations and are under 5 years old. CPGs contain evidence-based practice principles that include the integration of the best research evidence, clinical expertise and patient needs that will result in the best patient outcomes. Although CPGs delineate clinical management for a specific condition, they provide flexibility for therapist and patient input by providing broad recommendations. For example, therapeutic exercise is recommended as a treatment approach in many CPGs, however, specific exercises and their exact dosage are often left out. This places responsibility on the physical therapist to determine the appropriate intervention strategy to be implemented for each patient. The ever-changing reimbursement models also impact patient management decisions by physical therapists, as the cost of health care services are factored into the definition of value.

A shift has occurred in the American health care system from a fee-for-service to a value-based system for healthcare reimbursement. The shift has been led by the Centers for Medicare and Medicaid Services (CMS). The value-based payment model reimburses health care providers

for the delivery of effective outcomes and efficient patient care instead of reimbursement for the type and number of services provided.[37] Value-based models include bundled payments, accountable care organizations, and patient-centered medical homes. The change in reimbursement model requires health care providers to investigate and utilize treatment options that result in enhanced health outcomes while simultaneously reducing the cost of health care. APTA promotes value-based practice by encouraging the uptake of CPGs through their position on the use of data to improve the quality of physical therapist services.[38] Uniform and consistent treatment pathways delineated through CPGs have the potential to create more efficient and effective care, which can reduce healthcare costs and increase overall value.[39] The bundled payment model seeks to reduce healthcare costs, while simultaneously encouraging the collaboration of healthcare providers in the care of a single patient for a given condition.[40] Research on the downstream costs that are incurred with CPG uptake is needed to support a bundled payment model by providing a clear definition of anticipated costs based on anticipated treatments, delivered by various practitioners.[41]

The CPG on LBP that will be used in this study is titled "Low Back Pain Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health" authored by Delitto et al.[42] The recommendations set forth in this CPG detail an evidenced-based pathway to the differential diagnosis, examination, and interventions for LBP. The CPG emphasizes that physical therapists should prioritize recurrent and chronic low back pain over acute and sub-acute, as chronic pain is the most predominant presentation of LBP.

Research Questions and Hypotheses

The primary aim of this research study was to examine the impact of CPG implementation by outpatient physical therapists for patients with LBP on direct and downstream costs. And the secondary aim was to determine the impact on patient outcomes.

Specific questions and hypotheses that were addressed include:

Question 1: What impact does the implementation of the LBP CPG in outpatient physical therapist practice have on direct physical therapy costs and downstream medical costs?

Hypothesis 1: The direct and downstream costs associated with the management of patients with LBP by outpatient physical therapists will be lower after the implementation of the LBP CPG compared to management provided prior to implementation.

Question 2: What impact does the implementation of the LBP CPG in outpatient physical therapist practice have on patient reported outcomes?

Hypothesis 2: Patients diagnosed with LBP will experience a greater change in scores on the Oswestry Disability Index (ODI) and numeric pain rating scale (NPRS) and that meet the minimal clinically important difference (MCID) after the implementation of the LBP CPG than prior to implementation.

Assumptions

The development and implementation of a CPG in healthcare is a complex process that often relies on assumptions regarding concepts or ideas that cannot be easily captured for logistic reasons. A potential obstacle in this study is the ability (or inability) to fully capture the downstream costs associated with an episode of low back pain. An assumption was made that downstream costs occurred and were documented within the participating health system, and the utilized electronic medical health record. If a patient went to a health care facility outside of the

selected health system or received care for the same condition under a different diagnosis, the downstream cost may not have been fully captured. Further, costs that were incurred after an episode of physical therapist care may indicate that the cause of low back pain was not appropriate for physical therapist services because a red flag was present, thus demonstrating appropriate and safe clinical decision-making skills. Additionally, an assumption was made that the level of CPG adherent care already in practice within the health system at baseline had the capacity to be increased. If the physical therapists were already providing treatments that aligned with the CPG for LBP, a small or no difference in outcomes was expected. To address this potential obstacle, data on patient management was collected on the same group of physical therapists for six months prior to the CPG implementation and again six months into CPG implementation.

Definition of Terms

- Clinical Practice Guideline (CPG): Systematic statements based on evidence that delineate a course of care for a specific health condition.
- Implementation: Also known as knowledge translation, incorporating the recommendations in the CPG (or other evidence-based resource) into everyday clinical practice.
- Downstream costs: The charges for additional services such as pharmaceutical management, imaging services, emergency department services, surgery, other rehabilitation services, other services that are incurred after an episode physical therapy.
- Post-implementation CPG care: Physical therapist services provided after the health system implementation of the CPG for LBP by Delitto et al.
- Value: Health outcomes achieved for dollar spent.

- Evidence based practice: Clinical decision-making that influences the selection of assessment tools and physical therapy interventions that are based on evidence obtained through rigorous research methodologies, peer-reviewed articles, physical therapist experience, and patient preference.

Summary

The greater emphasis placed on value in health care has led to a shift in the focus of clinical research. At present, clinicians and researchers should be considering not only the efficacy of their evaluations and treatment options, but also the direct and downstream costs associated with them. The emphasis placed on improving outcomes at lower costs to health conditions that affect a large proportion of the U.S. population places chronic low back pain front and center of health care research. Research on downstream costs associated with CPG implementation is needed to better understand the true value of physical therapist care for patients with LBP in the U.S. health system. Additionally, CPGs may be used to inform researchers, payors, and policy makers on the necessity of future CPG development and help inform cost saving efforts using evidence-based practice.

Chapter 2: Literature Review

Introduction

Patients, clinicians, administrators, and policy makers are all interested in achieving and supporting the highest level of health. Strong health systems support improving patient outcomes through evidenced-based health policies, information sharing, and a motivated workforce.[43] Despite spending more money than any other country in the world, the United States health system was only ranked number 37 according to the World Health Organization (WHO) assessment of the world's health systems in 2000.[44] More recent findings show that the United States continues to outspend other high income countries on prescription medications, diagnostic imagining, and hospital and physician visits while remaining at the bottom when it comes to life expectancy at birth, infant mortality, persons living with two or more chronic conditions, and obesity rates.[45]

To address concerns pertaining to the quality and rising cost of health care in the US, specific policy aims have been established. The Institute of Healthcare Improvement, an independent not for profit organization, has challenged the United States to deliver high value care at a lower cost. The framework of the Triple Aim calls on health systems in the United States to simultaneously pursue three areas of health care delivery (1) "improving the patient experience of care (including quality and satisfaction); (2) improving the health of populations; and (3) reducing the per capita cost of health care."[46]

The examination of health care interventions can bolster the goals of the Triple Aim and assist in the determination of which treatment options, provided by which practitioners, at the opportune time have the potential to benefit the greatest number of people. Research into cost-effective management strategies for expensive conditions such as LBP are a priority in the

United States as the cost of health care continues to rise while the outcomes of population health remain low.

Physical therapy management is commonly recommended for patients with LBP, creating the need for effective diagnostic and treatment pathways utilized by PTs to address the growing needs of adults with advanced age, the opioid crisis, and known and unknown causes of LBP.[47] Clinical practice guidelines (CPGs) aim to connect research to clinical practice to produce effective and efficient patient outcomes without additional and unnecessary costs. CPGs are evidence based declarations or statements that delineate a course of care, diagnostic, and intervention pathway for a specific health condition.[19] They can be created for any health condition. The history of evidence-based practice, the intended beneficiaries of CPG recommendations, and the method of CPG development and validation processes are all important factors to consider when analyzing a CPG for clinical use.

History: Why CPGs are developed

Historically, a disconnect between research and clinical practice has existed where clinicians based patient management decisions on experience or theory.[48] Differences in personal health care provider experiences and training lead to unwarranted variations in clinical practice, as well as variations in health outcomes for patients with identical diagnoses.[48,49] According to the Institute of Medicine, once big data began to emerge in the 1970's that demonstrated variations and inappropriate management patters for patients with the same health condition, an expansion of randomized clinical trials and evidence-based medicine occurred.[49] CPGs were part of this evolution. To help bridge the gap between research and practice, CPGs are developed, implemented, and updated regularly.[48] However, for CPGs to be effectively implemented by

clinicians, an effective mode of dissemination needs to be utilized and a process for continual revision of CPGs is critical.[33,49]

Who benefits from CPGs

When implemented appropriately, CPGs have the potential to benefit both patients and health care providers.[50] Patients benefit from improved quality of care that is based on evidence; and health care providers benefit from improved options to inform their clinical decisions. This is especially true when guidelines contain information on which interventions to avoid in addition to which ones have been shown to promote positive patient outcomes. Researchers benefit from the creation of guidelines and the methods used to evaluate them through the promotion of scientific inquiry. Additionally, the identification of a gap in knowledge obtained through systemic review of data is used to generate future research questions. Administrators and health policy maker's benefit from information on an intervention's cost effectiveness that is gained through research on CPGs, which is particularly useful in a time when reimbursement systems are moving towards value-based models.

Despite the abundant potential benefit to patients, providers, researchers, and policy makers, potential harms also exist from use of CPGs. Previous lack of agreed-upon CPG development standards created the potential for a CPG to contain incorrect information as well as the possibility of containing outdated information. Incorrect advice on patient management can lead to poor patient outcomes as well as health care policies that can negatively impact the provision of health care.[50] For this reason, development standards and measurement tools have been created that assess the quality of the development process for a CPG.

How CPGs are developed

Governments, professional associations, and heath care organizations often undertake the task of CPG development and dissemination. The job of connecting research to a recommendation has proven to be a difficult task.[48] Several national organizations have created CPG development protocols and validation processes. International variations in CPG development requirements exist between countries. In the United States ECRI Guidelines Trust, which assumed responsibility of the CPG repository from the National Guideline Clearinghouse (NGC), which was formerly part of the Agency for Healthcare Research and Quality, provides inclusion criteria for entities that are developing guidelines.[51] These criteria include:

1. Be available in English, online for free or for a fee, and published within the last 5 years.
2. Include recommendation statements providing guidance on patient care.
3. Be produced by a medical specialty association, professional medical society, or other relevant clinical practice guidelines development organization.
4. Be based on a verifiable systematic review of evidence that includes:
    - Search Strategy: a) A listing of database(s) searched; b) A summary of search terms used; and c) Specific time-period covered by the literature search including the beginning date and end date (month/year)/
    - Study Selection: a) Total number of studies identified by the literature searches; b) Total number of studies retained after applying the inclusion/exclusion criteria; and c) A summary of inclusion and exclusion criteria.
    - Evidence analysis: Evidence tables OR GRADE tables OR a narrative synthesis of the evidence reviewed.

CPG Review Process

Due to previous variability in the development process of guidelines, a system of review and validation was created by an international group of researchers in 2003 called Appraisal of Guidelines, Research and Evaluation (AGREE) Collaboration.[52] The group of researchers created an instrument that assesses reliability (internal consistency, intra-class correlation) and validity (face, construct, criterion) through 23 questions and 6 domains (scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, editorial independence) called AGREE. It should be noted that the AGREE tool does not measure the quality or strength of the recommendations in a given CPG, but rather evaluates the method in which the CPG was developed.

The AGREE tool was updated in 2010 and is known as AGREE II. The updated version AGREE II contains the same 23 items and 6 domains as the original however minor changes of nomenclature and the inclusion of limitations and strengths were added.[53,54] A recent 2020 Marcel et al[55] study examined the quality of 544 rehabilitation CPGs using the AGREE II tool and concluded that most of the CPGs appraised had poor applicability. Marcel et al stated that more work needs to be done to aid in the knowledge translation of CPG recommendations and that a gap still exists between research and actual implementation by clinicians.

Prior studies have endeavored to accomplish the task of ascertaining the impact of CPG implementation on patient outcomes, and very few have examined the impact of a CPG on direct or downstream costs. While no definitive conclusion regarding the impact and cost-effectiveness of an LBP CPG and physical therapist practice has been made, several studies have added to the growing body of research, as well as justified the need for additional investigation.

Evidence of CPG Effectiveness

Rutten et al performed an observational prospective cohort study from 2005 to 2006[22] that examined the connection between adherence to the Dutch LBP CPG by physical therapists and patient outcomes. The Rutten study differed from other studies of similar nature by not utilizing the common method to measure CPG adherence via billing codes. Instead, the authors created their own electronic Web based collection method that measured adherence through 25 quality clinical indicators documented by the physical therapist. The quality clinical indicators were separated into two phases: diagnostic and treatment. The results of the Rutten et al study found greater effectiveness and lower utilization of care for patients who received guideline adherent care, however found no change in measured levels of pain on the visual analog scale (VAS). While the method of CPG adherence measurement was more detailed than measurement via billing records, creating an electronic database is outside of the financial scope of the proposed study. The positive attributes of implementing a CPG for LBP found in the Rutten et al study align with results from previous studies with differing methodologies.[7,56]

Fritz et al first proposed the method of determining guideline adherence through examination of billing codes in their 2007 study "Does Adherence to the Guideline Recommendation for Active Treatments Improve the Quality of Care for Patients With Acute Low Back Pain Delivered by Physical Therapists."[7] In their retrospective study, CPG adherence was determined through examination of billing records. If 75% of the billing codes reflected active treatment (manual therapy; therapeutic exercise; neuromuscular re-education; patient education; therapeutic activities; self-care management training; and traction), the care was considered CPG adherent. While this manner of ascertaining CPG adherence has the potential to overlook factors that might lead to non-adherence such as depression, comorbidities or

extraneous factors, it is considered a pragmatic method to examine adherence in large samples. Another potential disadvantage to this method of CPG adherence measurement lies within the assumption that the billing record accurately reflects the clinical encounter. Due to broad definitions of physical therapy interventions that are described in current procedural terminology codes (CPT) as well as broad guideline recommendations, the potential exists for interventions that are actually performed to go undocumented or documented incorrectly, thus leading to miscalculations in CPG adherence. Overcoming these possible disadvantages would require the examination of daily physical therapy documentation in addition to the billing records to match codes to physical therapy notes. This was not be feasible for this study, as it would prohibitively extend the length of time for data collection.

Fritz et al concluded that patients who received physical therapist treatment aligning with the CPG recommendation of active care had fewer overall clinical visits, lower charges, decreased patient disability, and pain than patients who did not receive CPG adherent care. Pain and disability using the VAS and Oswestry Disability Index (ODI); collection of the number of visits, and the charges for physical therapy services was collected in the dissertation study via electronic billing records in a similar fashion to the 2007 Fritz et al study. However, financial assessment of physical therapy charges was expanded to include downstream costs into the analysis, an analysis that reflects current emphasis on value in health care research and practice. It is recommended that each health care provider treating patients with low back pain understand how their application of an intervention impacts not only the cost and frequency of services from his or her own specialty, but also how it impacts the cost to the overall health system.

Karlen and McCathie found improved patient outcomes and lower utilization as well as examined the construct of value in evidence based-care for patients with non-specific LBP in a

2015 case report.[28] The ODI and utilization of physical therapy services were recorded; and similar to other related studies, CPT codes were used to record physical therapist adherence or application of evidence-based care. A multifaceted implementation or knowledge translation strategy was applied to one large health system that relied upon a multidisciplinary team approach and commitment to the Triple Aim by the IHI. Value was defined as the quality of physical therapist care divided by cost of the care (quality/cost). Change scores in the ODI measured the quality or efficacy of patient care, and cost was measured via the amount of charges for physical therapy services before contractual adjustments were made per episode of LBP. Karlen and McCathie pointed out that the definition of value not only indicates the importance of improving patient outcomes from the patient perspective, it also takes into account the cost of providing physical therapist management without creating a hierarchy between the two. It is of little benefit for physical therapists to focus their efforts on trying discharge patients as soon as possible to reduce the cost denominator in the value equation, or similarly allowing treatment to extend beyond time norms in the hopes of spontaneous improved patient outcomes. Karlen and McCathie concluded that the value of physical therapist services increased via improved clinical outcomes and decreased physical therapist service utilization due to a multitactic CPG implementation strategy and highlighted the importance of examining value to a population experiencing LBP. While the study shed light onto the methodology of implementing a similar program in other health systems, it did not examine the downstream costs of patients receiving physical therapist services for LBP.

CPG Implementation

While evidence exists that supports the connection between CPG implementation and improved patient outcomes, cost, and utilization of physical therapy care, several studies have

concluded the opposite. Most noteworthy was the study by Bekkering et al[29] that focused on the method of CPG knowledge translation used by the practicing physical therapists. The results of the study found that both groups, one that received the CPG by mail, and the other group that received an active or multifaceted implementation strategy experienced the same level of improved patient outcomes the first 12 weeks. The authors concluded that no difference existed between a standard and multifaceted CPG implementation strategy. A drawback to the methodology of the Bekkering et al study was the lack of ensuring whether or not the CPG provided to the physical therapists was actually adhered to. Additionally, no analysis was done to examine the financial impact of CPG implementation. The conclusion of 'no benefit' to CPG implementation made by the authors was based off poor internal validity as nothing was done to ensure adherence or actual treatment selection by the physical therapists. The authors placed the fault of not knowing what treatment choices were actually made by the physical therapists in their study on the CPG itself. As stated earlier, CPGs provide broad recommendations, and it is up to the physical therapist to select appropriate treatment categories that align with a CPG, as well as select interventions appropriate for the specific patient's needs. As the previously mentioned studies have demonstrated, it is possible to ascertain this information fully or partially through billing records and physical therapist documentation.[7,22,28]

Hoeijenbos et al also performed a study in 2005 that assessed the effectiveness of different types of CPG implementation.[30] Their study examined the difference between an active implementation strategy directed at PTs that included education, discussion, feedback, interactive sessions and reminders; and a standard dissemination strategy of mailing the CPG, self-assessment forms, Quebec Pain Back Pain Disability Scale, a summary of the guideline, and a research article about the development of the guideline to the PT study participants. The results

of the study did not find a significant difference in quality of life measures for patients at the one-year follow up questionnaire. The authors acknowledged that one possible reason for the results was that baseline knowledge of CPG recommendations or commonly used treatments by both groups of PTs were not obtained before the intervention. It is possible that both groups were following the recommendations found in the Dutch CPG before the study began, making the results or lack of change in quality of life throughout the study appear to be due to the ineffectiveness of the CPG implementation strategy or the recommendations themselves. It can also be argued that both groups did in fact receive multifaceted implementation strategies and that the only difference was in the method of delivery, in person or via mail.

A similar finding that active or multifaceted CPG implementation strategies have little to no impact on patient outcomes or cost of care was made by authors Van der Wees et al in their 2008 systematic review.[19] Similar to the Bekkering 2005 study, the Van der Wees study focused on knowledge translation more than CPG adherence to assess the impact on patient outcomes and cost of care. While the authors found CPG implementation to have a positive effect on professional practice, they concluded that it did not affect patient outcomes or cost of care. One possible reason for the findings in the Van de Wees et al study was that the authors did not utilize the common method of CPG measurement via CPT codes from the billing record and did not focus on value (health outcomes achieved per dollar spent.)

CPG Cost Analysis

Examination of the cost-effectiveness of LBP CPGs by general practitioners has been investigated. In 2012 authors Becker et al published a study that examined the German College of General Practitioners and Family Physicians (DEGAM) guideline.[57] One difference of note in this study was that the CPG was provided to both patients and treating health care professionals.

The DEGAM CPG contains information relevant to both patients and providers, which differs from CPGs directed only at providers that may contain recommendations on how and what advice to provide patients. Becker et al compared two CPG implementation strategies: physician education combined with motivational interviewing by nurses (intervention group), postal dissemination of printed CPG (control) and their impact on direct and indirect costs and patient outcomes.

The economic and patient outcome analyses of the Becker et al study demonstrated improved results for the intervention groups over the controls. However, the findings were not significant for all but one cost-effectiveness ratio: the comparison of days in pain. The Becker et al study supports the methodology of a cluster randomized controlled trial alongside a cost-effectiveness analysis to produce detailed information on the value of a specific intervention. The methodology of a controlled trial *alongside* a cost-effectiveness analysis adds to the strength of the study and aids in the justification of a cost-effectiveness or value-based study on the effect of a CPG for LBP in the United States.

The previously mentioned 2005 Hoeijenbos et al study that examined the effect of an active versus standard CPG implementation strategy also conducted a cost analysis.[30] While not using the exact term 'downstream costs,' the authors also examined and analyzed direct and indirect costs associated with an episode of non-specific low back pain. Financial information regarding physical therapist service utilization, other health care services, medications costs, and the financial impact from work absence and productivity loss were obtained by a patient questionnaire. Subjects in the study did not report actual dollar amounts, but instead provided the hours lost, the names and frequency of additional services obtained, and the names of

medications, which the authors converted to numerical amounts using inflation rates for their data analysis.

The Hoeijenbos et al study did not find a statistically significant difference between the intervention and control groups regarding direct costs, productivity costs, and quality of life at the one-year follow up. The only significant difference found between the two groups was the medical (direct) cost at 6 weeks, with the intervention group demonstrating significantly lower costs than the control group. This difference was absent at the 12, 26, and 52-week follow-ups. While the Hoeijenbos et al study examined similar costs and patient outcomes as the dissertation study, one difference of note is that Hoeijenbos et al included CPG development and implementation costs into their analysis citing that cost contributions may influence decision-makers. The dissertation study did not include these costs as an existing CPG was used.

A 2012 Fritz et al[31] study that examined downstream costs related to the utilization of physical therapy services revealed lower overall costs when patients received early referral to PT as well as guideline adherent physical therapy care. Authors Fritz et al performed a retrospective study that examined the downstream costs associated with early physical therapy timing, defined as referral to PT within 14 days of initial physician visit for a diagnosis of LBP, and delayed PT timing defined as PT referral within 15-90 days of initial physician visit. The authors also compared guideline adherent care to non-adherent care in their cost analysis. Strong evidence was found between early PT intervention and lower subsequent health care utilization and costs. The results of the study also linked guideline adherent care to lower subsequent health care utilization and costs; however, the association was not found to be as strong as the link for early PT.

The main finding of this study was that early timing of physical therapist care resulted in lower utilization and lower downstream health care costs for LBP.[31] The authors acknowledged that the feeling of self-efficacy may be stronger in the beginning phase of an episode of LPB and may affect patient outcomes and lower overall health care utilization. Self-efficacy may also be related to the CPG recommendation to stay active, as well as the recommendation for patient education that emphasizes that LBP can have a natural cessation of symptoms. The authors suggest that a more detailed examination of the PT management strategies may reveal a stronger association between CPG adherent care and lower utilization and downstream costs.

Childs et al followed up on the 2012 Fritz et al study in their examination of early and guideline adherent physical therapy for LPB and its effects on utilization and costs.[32] This 2015 study was performed within one military health care system on a large number of participants. The Childs et al study was nearly identical to the 2012 Fritz et al study in which all data was collected via electronic database and spanned a large geographical area. Similar to the 2012 study, no patient outcomes were recorded. One difference between the two studies was found in the analysis of the Childs et al study in which the authors examined the effects of timing (early or delayed) with content of care (adherent or non-adherent), creating four combined categories (early + adherent, early + non-adherent, delayed + adherent, delayed + non-adherent). The authors found that early and guideline adherent care was associated with the lowest health care utilization, and costs among the four categories, which supported the results from the 2012 Fritz et al study. The authors concluded that more research is needed in the form of randomized controlled studies to definitively conclude causality between early, adherent, early + adherent care and utilization and cost. The dissertation study differed from the Childs et al and Fritz et al studies most notably in the aim, which was to examine the relationship between physical

therapist care for LBP post CPG implementation and downstream costs *alongside* patient outcomes, and not on timing of physical therapist services. Another difference can be noted in the type of health system from which the data will be gathered. The dissertation study took place within one health system, the Ohio State University Medical Center(OSUWMC) however, OSUMC is not a military or governmental institution and therefore has the potential to be generalized to multiple health systems throughout the United States.

Following up on their identified need for a randomized clinical trial to examine the impact of early physical therapy on patient outcomes, health care utilization, and costs, authors Fritz et al performed a randomized clinical trial and published their findings in two separate articles. The first study published in 2015 focused on patient outcomes (ODI, pain intensity, pain catastrophizing, quality of life, fear avoidance behavior) and health care utilization.[23] The second study published in 2017 using the same data set, focused on the cost effectiveness of early physical therapy for acute low back pain.[6] The studies concluded that early physical therapy for acute non-specific LBP resulted in modest improvements for most of the patient outcomes examined (although did not reach a minimal clinically important difference) and that compared to usual care, early physical therapy is more cost effective one year following the initial visit with primary care providers.

The Fritz et al randomized controlled study results demonstrated the positive impact that early physical therapy has on patient outcomes and costs for patients with acute non-specific LBP however, the objectives of these studies did not specifically examine how CPGs contributed to the overall findings. While the authors stated that the interventions provided to the patients who received early physical therapy were evidence-based, they could not explicitly conclude whether the implementation and use of a CPG directly related to their findings. The dissertation

study aimed to examine the impact of the implementation of a CPG on patient outcomes and direct and downstream costs, which will expand upon recent research regarding the timing of physical therapist services. As evidence regarding the downstream costs associated with the use of CPGs is emerging, determining effective and efficient methods that a health system can undertake to improve the value of health care services will improve future endeavors and strategic planning when considering system wide changes.

Clinical Practice Guideline for Low Back Pain

The CPG on LBP used in this study is titled "Low Back Pain Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability and Health" funded by the Orthopaedic Section of the American Physical Therapy Association by Delitto et al.[42]

The recommendations set forth in this CPG detail an evidenced-based pathway to the differential diagnosis, examination, and interventions for patients with LBP. The CPG emphasizes that physical therapists should prioritize recurrent and chronic low back pain over acute and sub-acute, as chronic pain is the most prevalent presentation of LBP. Following a differential diagnostic examination that ensures that the patient condition is appropriate for physical therapist delivered treatment, interventions may include: manual therapy (thrust manipulation and non-thrust mobilizations), trunk coordination and strengthening exercises, nerve mobilization, traction, patient education and counseling, and progressive endurance and fitness activities.[42]

AGREE II Review

The Delitto et al CPG was reviewed by the AGREE committee in 2015 and given the following score on the six domains (Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity of Presentation, Applicability, Editorial Independence):[58]

Table 1. AGREE II Domains

Domain 1 Scope and Purpose	**Domain 2** Stakeholder Involvement	**Domain 3** Rigor of Development	**Domain 4** Clarity of Presentation	**Domain 5** Applicability	**Domain 6** Editorial Independence	**Overall Assessment**
78%	50%	57%	85%	21%	8%	61%

Percentages were calculated using the following formula:

$$\frac{\text{(Obtained Score- Minimum Score)}}{\text{(Maximum Possible Score-Minimum Possible Score)}}$$

The overall AGREE II score for the LBP CPG is 61% and the appraisal rating is 4.7 on a 7point scale.

Two of the appraisers on the AGREE committee provided comments regarding the specific scores given to the CPG. They noted that while the CPG lacked editorial independence and clarity on the rigor of its development, the clinical information it provided was useful. The appraisers also noted that the information in the CPG was presented in a clear manner however, large bodies of evidence and descriptions of how to assess quality of movement were omitted. The recommendations to improve the CPG included the identification of facilitators and barriers to implementation, as well as information regarding cost or 'resource implication.' Despite this gap, the appraisers recommended that the CPG be used in clinical practice and positively acknowledged the inclusion of subgrouping patients with low back pain. This study examined

the financial implications of physical therapist management after the implementation of the LBP CPG in both direct physical therapy costs as well as downstream costs.

Guideline Categories

Impairment/Function-Based Diagnosis

The CPG utilizes a treatment-based classification system that corresponds to the International Classification of Functioning, Disability, and Health (ICF) developed by the WHO. Treatment-based classification expands the definitions of acute, subacute, and chronic LBP beyond the traditional definition of time since onset of symptoms to include:[42]

- Acute low back pain with mobility deficits
- Acute low back pain with movement coordination impairments
- Acute low back pain with radiating pain
- Sub acute low back pain with mobility deficits
- Sub acute low back pain with mobility coordination impairments
- Sub acute low back pain with radiating pain
- Chronic low back pain with movement coordination impairments
- Chronic low back pain with radiating pain

Treatment-based classification (TBC) is similar to subgrouping of patients with nonspecific low back pain. Due to the wide variability in presentation and lack of definitive biological diagnostic features of nonspecific low back pain, the identification of patient subgroups has been a longstanding and continuous trend in LBP research. Identifying baseline patient characteristics helps to distinguish which patients are more likely to respond positively to different treatment approaches. The classification of patients with LBP has progressed in physical therapist research since 1995 when patients were grouped according to the acuity of their symptoms and the level of physical demands they would return to, then later as clinical prediction rules, and finally as treatment-based classification systems.[59-61] Throughout all of the

classification attempts in the past 20 years, the desire to streamline clinical decision-making through evidence has remained the same.

An example subgrouping can be found in the Keele Subgroups for Targeted Treatment Back Screening Tool (StarT Back) that matches patient's scores to specific treatment approaches. However, the utility of subgrouping patients with nonspecific low back pain has recently come under questioning.[59] Criticisms of the tool state that the subgroups are based off poor research methodologies, and the lack of hypothesis testing for subgroups immersed within large samples of subjects with nonspecific LBP. Despite the recent opposition to subgrouping, the benefits of creating treatments based on patient characteristics for a heterogeneous group of patients is still considered useful and aligns with the ICF treatment-based classification system used in CPGs and supported by the WHO.

Recent research has focused on TBC systems and their integration into advice presented in CPGs.[62,63] Alrwaily et al expanded and updated the original TBC system from 1995 and addressed its previous limitations. One of the main differences between the 1995 and the 2016/2017 version is the focus on a triage system that places patients with LBP into one of 3 categories: medical management, rehabilitation management, and self-care management. The triage system can be utilized by any first contact health provider. Additionally, patients who are triaged into 'Rehabilitation Management' are further classified based on their clinical presentation into one of three treatment categories: symptom modulation, movement control, and functional optimization.

Patient Examinations

The LBP CPG recommends the use of validated self-reported outcome measures, physical impairment measures, and self-reported mental impairment measures to assess baseline

and change scores that mark patient status and progression. The Oswestry Disability Index, the Roland-Morris Disability Questionnaire, and the Quebec Back Pain Disability Scale are all recommended for self-measurements of pain and disability. Measurements of pain on the visual analog and numeric pain scales are also recommended.

Physical impairment measures recommended by the CPG include the assessment of:[42]

- Active range of motion using an inclinometer
- Segmental mobility testing
- Pain provocation with segmental mobility testing
- Movement testing
- Prone instability test
- Judgments of centralization during movement testing
- Judgments of the presence of aberrant movement
- Straight leg raise
- Slump test
- Trunk muscle power and endurance
- Passive hip internal rotation, external rotation, flexion and extension

Mental impairment measures are recommended to assess the influence of psychological factors on low back pain. The instruments recommended are screening tools that the physical therapist can use to determine prognostic factors and serve as a basis of referral to appropriate health care providers. The psychological factors include symptoms of depression, fear-avoidance behavior, pain catastrophizing, and psychological distress. The outcome measures include:[42]

- Fear-Avoidance Beliefs Questionnaire
- Pain Catastrophizing Scale
- Örebro Musculoskeletal Pain Screening Questionnaire
- Subgroups for Targeted Treatment Back Screening Tool

Interventions

The treatment pathways delineated by the CPG are general categories of available physical therapist interventions, and all contain some level of evidence from randomized controlled trials and/or systematic reviews. The interventions recommended in the CPG fall into

one of three categories: treatments matched to subgrouping of patients; treatments aimed at preventing recurrence; treatments aimed at influencing the progression from acute to chronic low back pain. Summaries of the interventions included in the CPG are as follows:[42]

- Manual therapy: thrust manipulation for patients with mobility deficits and acute LBP with corresponding buttock or thigh pain. Manipulation or mobilization techniques for patients with subacute and chronic LBP with corresponding related lower extremity pain.
- Trunk coordination, strengthening, and endurance exercises: trunk coordination, strengthening, and endurance exercises for patients with subacute and chronic LBP with movement coordination impairments and patients post-laminectomy.
- Centralization and directional preference exercises: repeated movements in the direction of preference determined on evaluation for patients with acute LBP with referred lower extremity pain; and patients with acute, subacute, and chronic LBP with mobility deficits.
- Flexion exercises: to be used in combination with progressive walking exercises, manual therapy, nerve mobilization, and strengthening exercises for older patients with chronic, radicular LBP.
- Lower quarter nerve mobilizations**:** lower quarter nerve mobilization procedures for patients with subacute and chronic radiating LBP.
- Traction: intermittent prone traction for subgroup of patients with signs of nerve root compression (positive crossed straight leg raise). Traction is NOT recommended for patients with acute, sub-acute non-radicular LBP or chronic LBP.
- Patient education and counseling: recommendation to NOT counsel patients in a way that increases the perceived threat associated with LBP. Specifically, the recommendations state that physical therapists should NOT recommend bed rest nor educate patients on

pathoanatomical causes for LBP. Education counseling should include strategies that highlight (1) the inherent structural and anatomical strength of the spine, (2) neuroscientific explanations of the experience of pain, (3) favorable prognosis of LBP, (4) active coping strategies, (5) early return to normal and/or vocational activities even in the presence of pain, (6) emphasis on improvement in function, not just in pain level.

The treatment recommendations provided in the CPG are general and do not denote specific techniques nor do they provide dosage or duration of interventions, thus leaving space for therapist interpretation and individual provision.

How to Determine CPG Adherence via CPT Codes

Current procedural terminology (CPT) codes are used to describe a medical procedure or service provided by physical therapists and other health care professionals.[64] They communicate between providers and payers what health care procedure was performed. They are developed and maintained by the American Medical Association (AMA).[65] The cost associated with a procedure is reflected in the CPT code, however the main objective of the code is to reveal what was done in the clinic or hospital in an easy to read and useful manner.

Difficulties exist in the precise measurement of physical therapist adherence to CPGs in clinical practice. The measurement norm created in 2007 determined CPG adherence by the percentage of active versus passive CPT codes recorded in the patient billing record.[7] While this method may fail to gather important information through the use of broad billing codes as well as the inability to measure psychological factors that may impact patient outcomes such as the therapeutic alliance between physical therapist and the patient/client, it is a pragmatic method and has been used with success in previous research.[56] Since the creation of the standard for CPG adherence measurement via CPT codes, treatment recommendations for LBP have changed

slightly. Previous international CPGs recommended spinal manipulation/manual therapy only for acute LBP.[7,60] The CPG used in this study provides evidence for the utility of hip and spinal manipulation and/or mobilization for patients with subacute and chronic LBP with mobility deficits and back-related lower extremity pain in addition to patients with acute LBP.

It is important to note that implementation of CPGs does not guarantee successful patient outcomes nor serve as the absolute standard of care. The complete individual patient presentation is the best determinant for treatment selection and prognosis; however, departures from the CPG should be noted and documented in the patient chart. Adherence to the LBP CPG was not measured via CPT codes in the dissertation study as that was not feasible. An assumption of increased CPG adherence was made for the post implementation group based on an increased awareness of the contents of the LBP CPG.

Outcome Measures: Reliability and Validity

Patient outcomes were measured by use of the Oswestry Disability Index (ODI) and the numeric pain rating scale (NPRS). The LBP CPG that was used in this study recommends the use of the Oswestry Disability Index.

Oswestry Disability Index

The Oswestry Disability Index (ODI) is the most commonly used patient outcome measure for patients with LBP. The ODI is a disease-specific questionnaire that measures disability related to back pain and is commonly used to monitor changes that result from specific interventions. Originally developed in 1980, there are 10 items on the ODI and 5 response options for each question ranging from no disability (0) to maximum disability (5). Adding all of the responses with their corresponding numbers together and then multiplying it by two

creates the final score ranging from 0-100. Higher scores indicate more disability than lower scores.

Psychometric properties of the ODI have been examined and reliability has been found to range from 0.66-0.85.[66,67] One criticism of the ODI can be found in its inability to distinguish among very high or among very low functioning levels of disability, known as the floor or ceiling effect.[67] Additionally, the uni-dimensionality of some of the test items have been questioned with regards to their ability to only capture disability from low back pain, without influence from contributing factors, such as depression.

The minimal detectable change (MDC) is the smallest amount of change that can be detected that exceeds the standard measurement of error. MDC for the ODI has been measured between 12.8-15.5 points in adult patients with diagnoses of spinal stenosis, lumbar disc pathology, spondylolisthesis, sacroiliac joint dysfunction.[68,69] Minimal clinically important difference (MCID) measures the amount of change that the patient perceives as important. The MCID may be below or above the standard measurement of error and the MCD. The MCID for the ODI has been measured between 7.5-19.5 points for adult patients with diagnoses of lumbar spine surgery, sacroiliac surgery, chronic LBP.[68,69]

Numeric Pain Rating Scale

The numeric pain rating scale (NPRS) is a commonly used tool for self-reported pain on an 11-point scale ranging from 0 (no pain) to 10 (worst pain imaginable). Individuals select a number along the scale to represent their current level of pain. The responsiveness of the NPRS has been evaluated on individuals with low back pain and found to have a minimal detectable change of 2 points and clinically meaningful change value of 2 points.[70]

Summary

The effectiveness for patients, and costs associated with CPG utilization for LBP has not been definitively determined, thus creating the need for additional studies to examine value in health care and specifically the epidemic of LBP. The gap found in previous studies that lacked examination of downstream costs associated with CPG implementation alongside patient outcomes in physical therapy care for patients with LBP created the justification of this study. Conflicting evidence, as is the case with CPG implementation, creates the need for more research to weigh in on one side or the other of the issue.

This study focused on the financial impact of CPG implementation for patients with LBP in physical therapist practice while simultaneously adding to the body of research that has previously examined the impact of CPG implementation on patient outcomes. As the health sector transitions into a value-based model for reimbursement, the examination of all health care costs become a factor in policy and individual health care provider's decisions. The examination of downstream costs associated with CPG implementation in this study will add to the burgeoning body of research focused on value in health care in the United States.

Chapter 3: Methodology

Study Design

The methodology details the characteristics of the subjects, step-by-step procedures of data collection, and data analysis. The conceptual design of this investigation is retrospective observational.

The principle aim of this investigation was the examination of downstream medical costs, direct physical therapy service costs, and physical therapist utilization associated with the physical therapist management of individuals with LBP pre and post LBP CPG implementation. The primary investigator (PI) addressed this aim by comparing the direct and downstream costs associated with physical therapist outpatient care of patients with LBP during two distinct time periods. The first period, labeled pre-implementation, occurred between September of 2017 and March of 2018 and represented six months prior to the implementation of the LBP CPG at the Ohio State University Wexner Medical Center (OSUWMC). The second period, labeled post-implementation, occurred between June of 2018 and December of 2018 and represented six months *into* CPG implementation (three months were provided for the implementation process). Downstream costs were evaluated via billing record charges before contractual adjustments for additional medical services such as pharmaceutical management, imaging services, emergency department services, surgery, other rehabilitation and "other" services that were incurred after physical therapy services for diagnoses related to LBP. Direct physical therapist charges were evaluated via the billing record for total charges before contractual adjustments corresponding to an episode of care for physical therapist services provided to individuals with diagnoses related to LBP. Physical therapist service utilization was evaluated via the billing record for the number

of physical therapy sessions associated with an outpatient episode of care for individuals with diagnoses related to LBP.

The secondary aim of this investigation was to examine the impact of CPG implementation on individuals diagnosed with LBP via patient-reported outcome measures of the Oswestry Disability Index (ODI) and the numeric pain rating scale (NPRS). The PI addressed this aim by analyzing patient-reported outcome measure change scores (last scored ODI- first scored ODI; last scored NPRS- first scored NPRS) on individuals diagnosed with LBP for an episode of physical therapy care during the period of 6 months prior to CPG implementation and compared it to change scores associated with an episode of physical therapy care for a period of 6 months into the CPG implementation.

The effectiveness of the implementation strategy used by OSUMC was also examined through assessing the change scores in patient reported outcomes and associated costs of care before and 6 months into the system wide implementation of the CPG for LBP. This can assist in future administrative decisions within the health system regarding the use of guidelines and the manner in which they are disseminated.

Implementation

All data was collected from physical therapists who provided physical therapy services to patients at 38 clinic locations within OSUWMC. The pre-implementation group consisted of 21 physical therapists and the post-implementation group consisted of 16 physical therapists (all 16 were part of pre-implementation group). The discrepancy in the number of physical therapists in the pre and post-implementation groups is due to 5 physical therapists no longer working within the OSUWMC health system or no longer working in the outpatient setting with patients diagnosed with LBP.

A multifaceted implementation strategy was undertaken by OSUWMC (the PI was not involved in the planning or execution) and included the following activities:

- Formation of Low Back Outcome Team
- Education provided to team on treatment-based classification system and LBP CPG via web-based platform:
    - Case reviews
    - Baseline knowledge assessed via audience polling questions
    - Low Back Outcome team provided feedback to implementation administrators
    - Training session was recorded and made available for asynchronous viewing
- Flowsheets for tracking clinical decision-making related to treatment-based classification created
- Clinicians provided feedback on intervention flowsheets to implementation administrators
    - Pain science information integrated into flowsheets based on feedback
- Low Back Outcome Team updated via email and provided a PowerPoint presentation on episode naming, proper coding and new intervention sheets that included pain science

It should be noted that implementation is an ongoing process that does not have a specific end point and that the activities listed above represent only the activities that were undertaken between the two pre-selected time periods labeled in this study as pre-implementation and post-implementation.

Procedures

Subjects

Individuals with LBP who received physical therapy services from one of the participating physical therapists at one of the thirty-eight OSUWMC outpatient physical therapy clinics were included in the data analysis. All patient related data was collected via the electronic health and billing records.

Inclusion Criteria

1) Physical therapy or medical diagnosis of low back pain classified via the International Statistical Classification of Disease and Related Health Problems (ICD-10) Codes of M54.10, M54.17, M54.5, M54.16, M54.12, M54.40, M54.41, M54.42, M99.03, M99.04, M99.05, M51.26, M51.24, M40.30

2) Men and women 18-80 years of age.

3) Medical records with data for patient reported outcome measures of ODI and NPRS.

Exclusion Criteria

1) Back surgery in previous 12 months.

Sampling

The intention of this study was to analyze the data from OSUWMC outpatient physical therapy settings for individuals who met the inclusion and exclusion criteria and who were treated by the selected group of physical therapists. All samples were randomly selected from each group (pre and post-implementation) by the OSUWMC IT department and Information Warehouse. All demographic, clinical, and cost related data was collected from patient electronic billing and medical records. Sample size estimation was calculated at 135 data points for each

group (pre and post CPG implementation) using the statistical sample size estimator G*Power for Mac version 3.1.[71] A medium effect size, alpha level of 0.05, and a power level of 0.80 was used to calculate the estimated sample size.

Data Collection

The independent variable in this study was the group, based on the time interval, and consisted of two levels: pre-implementation group and post-implementation group. The dependent variables consisted of patient reported outcomes, physical therapy care utilization, and direct and downstream cost, all of which were obtained from patient medical and billing records. Patient reported outcomes include the NPRS at rest and when active and ODI. Physical therapy services utilization includes the number of physical therapy sessions received by a patient for a diagnosis of LBP listed in the inclusion criteria. Direct costs include the charges for physical therapy services per date of service before contractual adjustments. Downstream costs include charges for additional services before contractual adjustments for:

- Pharmaceutical management
- Imaging services including radiological, electromyogram, ultrasound, magnetic resonance technology, computerized tomography of head, body or general,
- Emergency department services
- Surgery including anesthesia, nursing and blood storage
- Other rehabilitation services for occupational therapy, speech language therapy, respiratory therapy, cardiology
- "Other" services: clinic fees, medical surgical supplies and devices, other non-defined services

Patient demographics include age, sex, race/ethnicity, and insurance provider. Detailed information on each variable of interest is provided in the Appendix.

The PI extracted all data from patient medical and billing records with the assistant of the OSUWMC IT department and Information Warehouse. Patient confidentiality was protected and ensured through a coding system that de-identified private patient information by offsetting the medical record numbers and dates of services. The PI maintained and was responsible for all coded patient data.

Data was collected during two time intervals. The first data collection interval was from September 2017 to March 2018, six months prior to LBP CPG implementation to the time when the CPG implementation occurred (pre-implementation). The pre-implementation data collection included patient demographics, patient reported outcomes, physical therapy utilization, and direct physical therapy costs for all patient records that contained complete information (initial and final ODI and NPRS scores) indicating that an episode of physical therapy care had been completed. Information regarding downstream costs was collected during the pre-implementation time interval for costs accumulated prior, concurrent and downstream to the episode of physical therapy care.

The second data collection interval was from June 2018 to December 2018, the time following the CPG implementation to six months *into* the implementation, as implementation is an ongoing process (post-implementation). Data on patient demographics, patient reported outcomes, physical therapy utilization, and direct and downstream physical therapy costs for all patient records that contained discharge information was collected during post-implementation time period in the same manner as in the pre-implementation time period.

Statistical Procedures and Data Analysis

Data Management

Data management and storage was performed using the statistical software SPSS.[72] The PI was responsible for handling all data and maintaining patient confidentiality accordance to Health Insurance Portability and Accountability Act (HIPAA).[73] All categorical data was coded numerically, and all data was organized in a code book and checked for errors by the process of data cleaning before being analyzed. All data was stored in the PI's computer and was password protected.

Data Sharing Plan

Data sharing occurred between OSUWMC and Nova Southeastern University. The PI received de-identified data from Biomedical Informatics, which was stored on the PI's computer and was password protected. Biomedical Informatics collaborated with the OSU Finance department to link medical record and billing data for the same person.

Statistical Analyses

To answer the research question of whether the implementation of the LBP CPG was associated with lower direct and downstream costs, improved patient outcomes, and lower utilization of physical therapist services, statistical analyses were performed that compared pre-CPG implementation values to post CPG implementation values. Statistical analyses included pre-implementation and post-implementation means comparisons using either the *t* test or the Mann-Whitney U tests, depending on whether statistical assumptions were met.[74] Parametric data on the interval or ratio measurement scale was analyzed using the *t* test if the data were found to be normally distributed. This applied to pre and post CPG implementation comparisons of direct physical therapy costs and downstream medical costs, and physical therapy utilization

rates. Non-parametric data on the ordinal measurement scale and/or data that did not meet assumptions of normal distribution on the interval or ratio scales was analyzed using the Mann Whitney U test. This applied to pre and post CPG implementation comparisons of perceived disability on the ODI and pain levels on the NPRS.

All statistical tests were performed with an alpha level set to .05 and a 95% confidence interval.

Resources

The IT department and Information Warehouse at OSUWMC provided assistance in extracting data from patient's electronic medical and billing records during both pre and post-implementation time intervals. The PI independently performed statistical analyses and manuscript preparation per requirements of Nova Southeastern University's Doctor of Philosophy Program.

Chapter 4: Results

Introduction

Statistical tests were selected to best answer the research questions pertaining to the impact of the implementation of the LBP CPG on direct and downstream costs and patient reported outcomes in both pre and post-implementation groups. All de-identified data from OSUMC was categorized and coded depending on its measurement scale. Once coded, all data was analyzed using IBM SPSS software.

Data Analysis Results

Demographics

Demographics in both groups were found to be near equivalent. The profile of a patient with LBP in both groups is a white, non-Latino female between 55-58 years of age (see Table 2). Payor class had near equivalent distribution between managed care, Medicare, and Medicaid; and the presence of multiple diagnoses of LBP was split almost evenly between those who had multiple diagnoses and those who had just one diagnosis of LBP (see Table 3).

Table 2. Patient Demographics

Characteristic	Pre-Implementation: mean (%) N=135	Post-implementation: mean (%) N=135
Gender		
Male	56 (41.5)	45 (33.3)
Female	79 (58.5)	90 (66.7)
Age (years)*		
Average (std. deviation)	54.54 (13.26)	57.55 (11.13)
Range	25-80	22-79
Race		

White	83 (61.5)	72 (53.3)
African American/Black	46 (34.1)	56 (41.5)
Asian	1 (0.7)	1 (0.7)
Other/more than one race	5 (3.7)	6 (4.4)
Ethnicity		
Not Hispanic or Latino	131 (97)	132 (97.8)
Latino/Hispanic Other	3 (2.2)	3 (2.2)
Refused to answer	1 (0.7)	

*Analyzed with t-test

Table 3. Payor Class, ICD-10 Codes

	Pre-Implementation (%)	**Post-Implementation (%)**
Payor Class	**N=135**	**N=134**
Managed care	45 (33.3)	41 (30.4)
Medicare	41 (30.4)	45 (33.3)
Medicaid	47 (34.8)	45 (33.3)
Other government	2 (1.5)	3 (2.2)
Multiple Diagnosis	**N=135**	**N=135**
No	61 (45.2)	63 (46.7)
Yes	74 (54.8)	72 (53.3)
Primary Diagnosis code	**N=135**	**N=135**
Radiculopathies	50 (37)	37 (27.4)
Low back pain	47 (34.8)	56 (41.5)
Lumbago	26 (19.3)	28 (20.7)
Other diagnoses related to lumbar spine conditions	12 (8.9)	14 (10.4)

Downstream and direct PT costs

Mean costs for services that occurred prior, concurrent, and downstream to physical therapist management of patients with LBP were calculated using t-tests (see Table 4). All downstream costs were lowered post-implementation. Statistically significant reductions in cost post-implementation were found for downstream imaging (p= 0.043); downstream “other” (p= 0.02); downstream pharmacy (p=0.028); downstream surgical costs (p= 0.031) (see Table 4).

Based on these results, the null hypothesis is rejected and the alternative hypothesis stating a reduction in downstream costs post CPG implementation is accepted.

As noted in Table 4, all prior costs increased from pre to post-implementation. Further statistical analyses were performed to ascertain whether the statistically significant lower downstream post-implementation costs were offset by increases in prior costs from pre to post-implementation. Total costs for prior, concurrent, downstream and total direct physical therapy were analyzed using t-tests (see Table 5). The difference in mean prior costs were not statistically significant (this was also true for concurrent costs) between the pre and post-implementation groups. Post-implementation downstream costs (mean= $4,636.00 USD) were lower than pre-implementation downstream costs (mean= $15,502.00 USD) and the difference was statistically significant (p=0.021). Direct physical therapy costs were also lower post-implementation (mean= $2,862.59 USD) than pre-implementation (mean= $3,459.13 USD) and the difference was statistically significant (p=0.046). Total costs (prior + concurrent + downstream + direct physical therapy) decreased in the post-implementation group (pre-implementation average = $43,743.90; post-implementation average $ 33,476.48), however, the finding was not statistically significant (p= 0.26).

Table 4. Mean Costs ($ USD) Pre and Post Implementation

Cost Category	**Pre-Implementation Mean (Std. Dev)**	**Post-Implementation Mean (Std. Dev)**	**t**	**Sig. (2-tailed)**	**95% Confidence Interval**	
N=135					**Lower**	**Upper**
Prior Imaging	2306.78 (3428.10)	3043.26 (8819.36)	-0.9	0.367	-2339.87	866.91
Concurrent Imaging	2443.38 (4801.39)	2221.21 (4901.98)	0.38	0.707	-940.56	1384.90
Downstream Imaging	1937.81 (5259.59)	969.36 (1689.66)	2.037	**0.043**	32.34	1904.60

Prior "other"	3964.33 (16565.26)	6077.37 (25250.28)	0.813	0.417	-7230.33	3004.30
Concurrent "other"	4480.39 (11531.65)	3097.50 (6435.00)	1.217	0.225	-854.82	3620.60
Downstream "other"	5773.26 (21194.88)	1499.85 (3230.46)	2.307	**0.022**	627.08	7919.70
Prior Pharmacy	805.99 (4762.77)	1154.05 (6663.43)	0.493	0.623	-1739.43	1043.30
Concurrent Pharmacy	850.87 (3113.31)	1029.87 (6124.005)	0.303	0.762	-1343.13	985.13
Downstream Pharmacy	854.50 (3268.44)	210.60 (877.398)	2.211	**0.028**	70.45	1217.40
Prior Emergency	419.70 (1040.13)	739.16 (3268.41)	1.082	0.28	-900.673	261.74
Concurrent Emergency	666.46 (4217.37)	818.04 (5292.76)	-0.26	0.795	-1298.36	995.19
Downstream Emergency	287.67 (952.73)	203.32 (752.22)	0.807	0.42	-121.341	290.05
Prior Surgery	3641.76 (17278.63)	5248.41 (29652.97)	0.544	0.587	-7422.21	4208.90
Concurrent Surgery	3776.91 (14573.96)	1900.54 (8502.01)	1.292	0.197	-982.73	4735.50
Downstream Surgery	6246.12 (24834.43)	1447.24 (6569.749)	2.171	**0.031**	445.87	9151.90
Prior Other Rehabilitation	351.19 (2576.27)	521.89 (4078.34)	0.411	0.681	-988.124	646.72
Concurrent Other Rehabilitation	1080.44 (7615.46)	126.96 (432.14)	1.452	0.148	-339.051	2246.00
Downstream Other Rehabilitation	403.17 (2372.50)	316.36 (3094.49)	0.259	0.796	-573.938	747.55

Bold values indicate statistical significance

Table 5. Mean Combined Costs ($ USD)

Cost Category	**Pre-Implementation mean (Std. Dev.)**	**Post-Implementation mean (Std. Dev.)**	**t**	**Sig. (2-tailed)**	**95% Confidence Interval**	
					Lower	**Upper**
Total Prior Costs	N= 121 11483.77 (38753.07)	N= 119 16784.14 (66999.29)	-0.796	0.427	-18415.9	7815.16

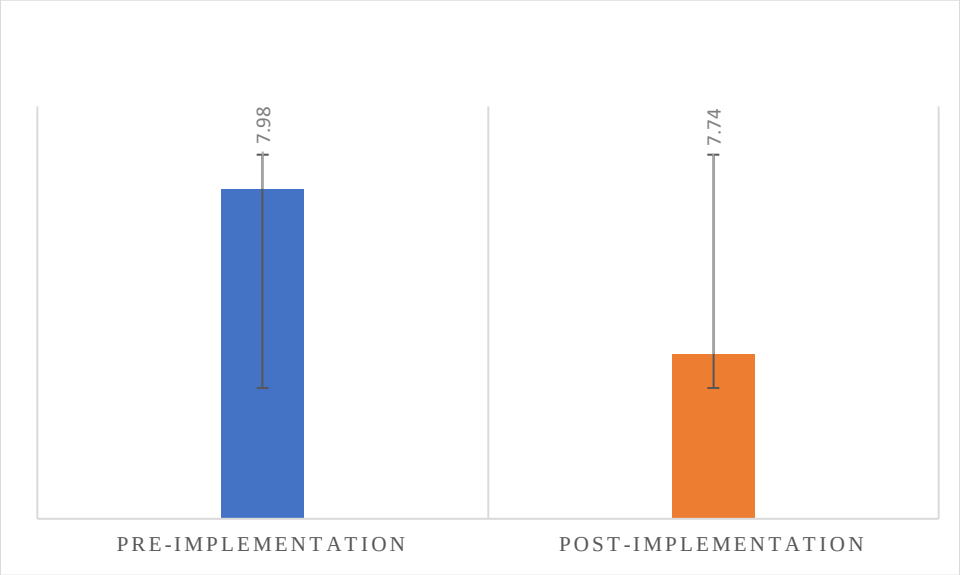
Total Concurrent Costs	N= 109 13298.46 (34194.55)	N=97 9194.13 (22945.97)	1.158	0.248	-2873.688	11082.355
Total Downstream Costs	N=71 15502.53 (53250.66)	N=93 4635.62 (11951.90)	2.314	**0.021**	1618.986	20114.836
Total Direct Physical Therapy	N=135 3459.13 (2837.86)	N=135 2862.59 (1967.95)	2.007	**0.046**	11.35	1181.73
Total Cost All	43743.90 (75216.26)	33476.48 (72621.14)	1.141	0.255	-7449.297	27984.127

Bold values indicate statistical significance

Physical therapy utilization

The mean number of physical therapy visits was 7.98 (Std. dev= 5.85) in the pre-implementation group and 7.74 (Std. dev= 5.22) for the post-implementation group (see Figure 1.) The mean difference in physical therapy visits between the groups was a fraction of a visit (0.23) and was not statistically significant (p= 0.73).

Figure 1. Physical therapy utilization, mean visits



Patient reported outcomes

Average scores for initial patient outcomes and change scores for patient outcomes were analyzed using non-parametric Mann Whitney U Tests and are provided in Table 6. The patient reported outcome data met the assumptions for the non-parametric test of dependent variables ODI and pain measured on the ordinal scale and normal distribution of data. Statistically significant differences were not found on initial patient outcomes scores between the pre and post-implementation groups, which is a desired result as it establishes equivalency in the groups at baseline.

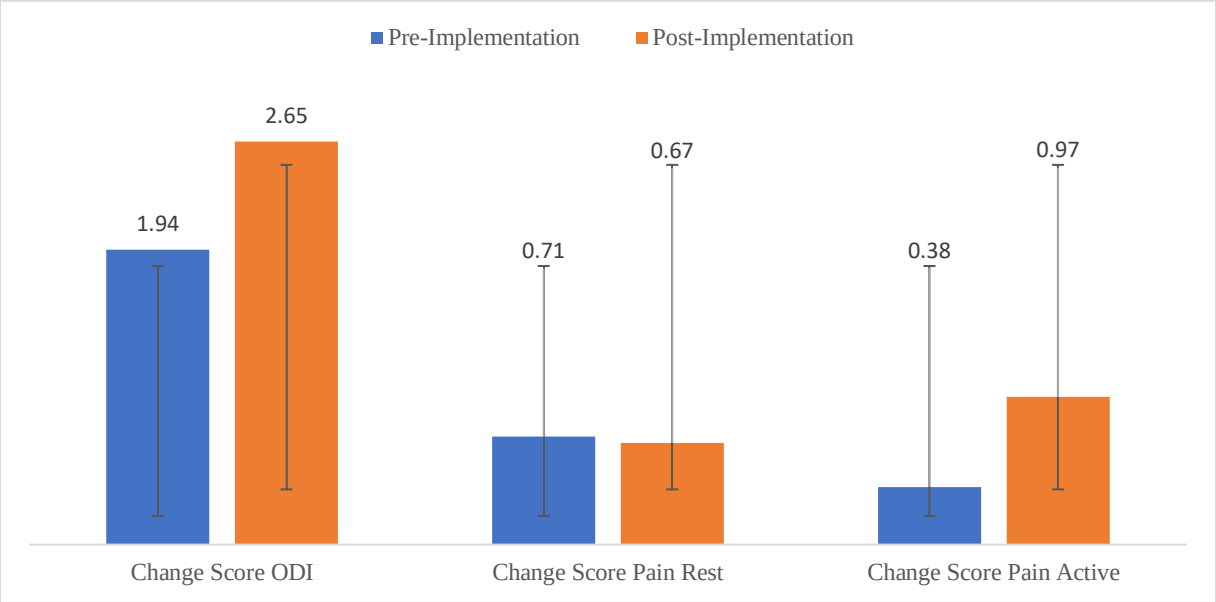
All outcome scores for ODI and pain decreased from initial to final measurement in both groups and are represented as positive values in change scores on Figure 2. ODI and active pain had larger change scores in the post-implementation group than pre-implementation group, however, change scores for pain at rest were less in the post implementation group. None of the changes scores on the ODI or pain achieved statistical significance (see Table 6). The small reduction in ODI scores, even though not statistically significant, do represent an improvement in disability however, both pre and post-implementation groups stayed in the same category of 'severe disability' with scores in the range of 41-60 (see Appendix I). Additionally, none of the changes scores met MCID values (2 points for pain; 7.5-19.5 points for ODI).

Table 6. Patient Reported Outcomes

	Pre-Implementation mean (Std. Dev.)	**Post-Implementation mean (Std. Dev.)**	**Z**	**Mann-Whitney U**	**Sig. (2-tailed)**
Initial ODI	48.70 (18.47)	46.94 (17.70)	-0.697	8665.5	0.486
Initial Pain Rest	5.34 (3.08)	5.31 (2.94)	-0.245	8956	0.806
Initial Pain Active	6.84 (2.60)	6.64 (2.54)	-0.887	8549.5	0.375

Change Score ODI	1.94 (10.47)	2.65 (8.99)	-0.159	9025	0.873
Change Score Pain Rest	0.71 (2.92)	0.67 (3.03)	-0.369	8878.5	0.712
Change Score Pain Active	0.38 (2.34)	0.97 (3.22)	-1.298	8315	0.194

Figure 2. Outcome Measure Change Score



Summary

Both research questions were answered using statistical analysis, which provides partial insight into the efficacy of the LBP CPG when implemented into outpatient physical therapist practice, as well as the selected methodology and study design. The patient perspective is often a difficult to capture or missing piece that can offer insight into management of health conditions.

It is important to consider that while statistically significant results are imperative, they do not necessarily represent whether or not a patient actually improved and was able to have full participation in their life. The next chapter will discuss how the results of the statistical analysis can be placed into context physical therapist practice and research.

Chapter 5: Discussion

Introduction

In order to "advance the profession of physical therapy to improve the health of society," as stated in the APTA mission statement[75] and work towards a more cost effective health system in the United States, prioritization must be given to research that decreases unwarranted variation in practice and includes the direct and downstream costs alongside patient outcomes.

Downstream and direct costs and patient reported outcomes are core elements of value in healthcare. Clinical practice guidelines are keystone to adding value and bridging the gap between evidence and clinical practice because they provide action statements that can be easily implemented in the clinic. CPGs have the potential to strengthen the impact of evidence-based practice and reduce the cost of care. This can only be accomplished when the contents of CPGs are recognized and understood by providers and health systems that deliver services to the population of interest. In this study, the implementation of the LBP CPG was examined through the lens of downstream and direct physical therapy costs and patient outcomes. The two research questions were answered through statistical analyses and placed within the context of current research in physical therapy.

Discussion and Interpretation of Results

The results of the statistical analysis lead to the acceptance of hypothesis 1 (rejection of null hypothesis) and rejection for hypothesis 2 (acceptance of null hypothesis).

Hypothesis 1: The direct and downstream costs associated with the management of patients with LBP by outpatient physical therapists will be lower after the implementation of the LBP CPG compared to management provided prior to implementation. ACCEPTED

Hypothesis 2: Patients diagnosed with LBP will experience a greater change in scores on the Oswestry Disability Index (ODI) and numeric pain rating scale (NPRS) and that meet the minimal clinically important difference (MCID) after the implementation of the LBP CPG than prior to implementation. REJECTED

The statistically significant lower costs for direct physical therapy and downstream medical costs (imaging, "other," pharmacy, surgery) found in the dissertation study are positive results for the potential impact of CPGs on cost-effective care in a US health system. However, a statement about improved value (patient outcomes per dollar spent) cannot be made as none of the patient outcomes achieved statistical significance despite demonstrating values in the direction of improvement in disability and pain.

While the results of all patient reported outcome measures (except active pain change scores) demonstrated improved change score values from pre to post-implementation, they did not meet the threshold for statistical significance, minimal detectable change (MDC), which is the score value that exceeds the standard measurement of error or the minimal clinically important difference (MCID), which is the perceived change or improvement by the patient. The MCID for the ODI is between 7.5 and 19.5 points for patients with LBP diagnoses, and the difference found in the study averaged 1.94 and 2.65 points for pre and post-implementation, respectively. The MCID value for pain in patients with LBP is 2 points and the average change scores in the study for the pre-implementation group were 0.71 (rest), 0.38 (active); post-implementation changes scores were 0.67 (rest), 0.97 (active). One potential reason for the small change between initial and last scores on the outcome measures (differences in the same individual), noted in both pre and post-implementation groups, is that many of the measurements were taken on the same day. Recording patient outcomes on the same day may be the result of

the patient only having one physical therapy visit, however average visits were between 7.74 and 7.98 for both groups. Further investigation into the recording of patient outcomes is warranted.

Another potential reason that the differences in patient outcomes were so small between the pre and post-implementation groups (between group differences) may be because the implementation activities did not actually impact practice. This may be because care that aligned with the LBP CPG recommendations was already being provided before the implementation activities were undertaken. The implementation activities may not have impacted the practice of physical therapy to the same degree as they did downstream costs. The physical therapists may have already been providing effective care pre-implementation but improved on the efficiency of their care post-implementation, possibly from improved triaging of patients based on the treatment-based classification system, thus lowering the costs. However, it is interesting to note that the total cost of physical therapist services was lowered in the post-implementation group and achieved statistical significance but PT utilization, or the number of visits, was near identical in both groups. A deeper look into the interventions provided via CPT codes will help understand this better.

The results of the study highlight the importance of considering meaningful change for patients. The core elements of evidence-based practice include best-available evidence, a clinician's knowledge and skills, and patient's wants and needs. Caution is needed if success of a program is claimed when it achieves statistically significance lower costs but does not produce meaningful change to patients. Doing so may run the risk of contributing to excessive health care costs when patients continue to seek healthcare services for what they perceive as unresolved conditions.

Caution is taken when interpreting the results of the statistical analyses as the rejection of hypothesis 1 may result in a type 1 error from wrongly rejecting the null hypothesis. This can occur when findings are interpreted to have occurred as the result of the study intervention. This type of error is especially true for retrospective studies such as this study.

Literature Review

The results of this study add to the growing body of evidence that highlights the significant cost burden of managing LBP and the potential for CPG implementation activities to decrease costs as well as improve patient outcomes. Authors Lily et al[76] concluded in their 2019 retrospective study that guideline adherent care for the management of LBP results in lower health care costs. Lily et al defined guideline adherence to include non-surgical management of patients newly diagnosed with LBP who did not obtain imaging within 30 days of diagnosis, and who did not obtain imaging without or before a trial of physical therapy. The authors concluded that non-adherent care was common in their study sample and the addition of imaging within 30 days of LBP diagnosis and/or obtained before the initiation of physical therapy resulted in statistically higher costs. Their results found that costs associated with surgical management of newly diagnosed LBP accounted for 29.3% of all healthcare costs examined yet represented only 1.2% of patients. Despite examining costs associated with the management of low back pain, the Lily et al study did not perform a full examination of value (health outcomes/cost of care) because it did not consider patient wants and needs or patient reported outcomes, which are integral to evidence-based practice.

While the CPG examined in the study is directed at the physical therapist management of LBP and does not dictate a pathway for imaging, the role of the physical therapist in ordering plain imaging for the management of musculoskeletal conditions is an emerging area of practice

due to expansions in direct access and its impact on lowering utilization and costs[77-79] and should be included in future studies on CPGs for LBP.

The results of this study went a step further than the previously mentioned studies in the literature review that examined utilization of physical therapist services and its association to guideline adherence and timing of services.[30-32] This study examined utilization of physical therapist services as well as downstream costs. While the utilization rate of physical therapist services was not changed by the implementation of the LBP CPG, downstream costs were significantly lowered.

The decreased levels of pain and disability found in the study aligns with previous studies.[7,22] Implementation of CPGs has the potential to positively impact patient reported outcomes. As stated previously, the amount of change from initial to final measurement did not meet the MCD or MCID for disability or for pain and should be interpreted with caution.

Implications

Implications for Practice

The results of the study have the potential to impact the management of LBP in outpatient physical therapist practice. The reduction of scores on patient outcomes found in the dissertation study, albeit small in size and not statistically significant, may encourage physical therapists to act on the statements found in the LBP CPG.

Administrators may also be encouraged to implement evidence-based resources into their hospitals and clinics based on the results of the study regarding direct physical therapy and downstream costs. OSUWMC serves as an example of a system approach to implementing evidence into practice via a multifaceted implementation strategy. Evidence that supports cost

savings for the management of LBP, a highly prevalent health condition, will serve as further encouragement for administrators to implement the LBP CPG into their hospitals and clinics.

Health insurance providers and policy makers are interested in improving the health of their customers and constituents and reducing costs wherever possible. As the study findings conclude, use of CPGs in physical therapist practice has the potential to lower costs. Insurers may start using cost effectiveness analyses into their reimbursement decisions and having data on the impact of CPGs will aid in this process.

Implications for Further Research

Research always builds on previous findings and the results of the study add to the growing body of research on the effectiveness of CPGs in physical therapist practice. This is especially true for research that examines downstream costs. The excessive cost of health care in the United States is everyone's problem to solve and the results of the study should stimulate further investigation into how to reduce the cost of managing LBP, namely through the use of CPGs and other evidence-based practice approaches.

Limitations and Delimitations

Delimitations

All analyses were performed on care that was provided during a six-month time frame, either prior to the implementation of the LBP CPG or six months into the implementation. This time frame was selected to represent a snapshot in time but does not fully capture all costs for each patient in the study sample. Costs for care that was initiated during the last weeks or days of the time frame may not have been captured if they extended beyond the pre-set time frame of six months.

The population of interest in the study was limited to individuals who have low back pain and are specifically diagnosed with one of the following ICD-10 codes: M54.10, M54.5, M54.16, M54.41, M54.42, M99.03, M51.26, M54.40, M54.17, M99.04, M54.14, M54.18, M54.15. The ICD-10 codes do not capture all patients with low back pain. However, the CPG has identified which diagnoses are likely to respond to the recommendations provided in the guideline.

Limitations

The primary aim of this study was to examine downstream costs associated with the implementation of the LBP CPG in outpatient physical therapist practice. The economic impact of LBP can be examined from multiple perspectives. In this retrospective cohort study, both direct physical therapy and downstream medical costs were examined from the health system perspective, even though costs for the management of LBP are also carried by patients, payors, and society. Non-direct medical costs such as transportation to the physical therapy clinic or child care expenses that may have accrued from time spent obtaining medical care, indirect costs such as time lost from work, and intangible costs from pain and suffering were not analyzed.[80] To capture all costs associated with LBP as well as how a specific evidence-based resource such as a CPG impacts all costs was outside the scope of this study. The PI hypothesizes that non-direct and indirect costs from time off work, childcare and transportation would have also decrease in line with downstream costs when guideline adherent care was provided due to reduced visits to other health care providers and services.

One limitation of the study that arose during data collection was the inability to capture adherence to the LBP CPG through analysis of CPT codes, as was originally planned. While it is a common method used to measure CPG adherence, analyzing CPT codes does not fully capture

elements of the physical therapy visit or provide justification as to why certain procedures were selected over other ones. It also does not capture additional factors that contribute to improved patient outcomes such as the therapeutic alliance, which has previously been demonstrated to positively impact patient outcomes for individuals with chronic LBP.[81] The data pulled from the OSUWMC records did not provide sufficient detail to utilize this method. The assumption was made that CPG adherence was higher after implementation activities were undertaken at OSUWMC and the physical therapists had greater awareness of the contents in the CPG. However, this assumption has the potential to overestimate adherence post-implementation and underestimate knowledge of evidence-based management strategies pre-implementation.

A limitation of the retrospective study design utilized in the study was the inability to determine causation between CPG implementation and lowered downstream costs and changes in patient outcomes. Due to pragmatic reasons, the design of the study limited the ability of the PI to establish a true cause and effect relationship between CPG implementation and downstream and direct costs. The nature of retrospective observational designs allows for examination of events and phenomenon, but not actual control or manipulation of variables. Additionally, the absence of a control group limited the ability to control for many of the common threats to internal validity such as history, maturation, repeated testing, and regression towards the mean. An experimental controlled trial study is the best way to determine cause and effect, however, was not feasible for this dissertation study.

A limitation of the statistical analyses was the decision to not use a Bonferroni correction (alpha level divided by the number of t tests) when performing multiple t tests, which would have lowered the alpha level to 0.0028 (0.05/18) for the comparisons of means for prior, concurrent, and downstream costs and would have resulted in no statistically significant findings.

Not using a Bonferroni correction was also a limitation for the combined costs and outcome measure analyses. This increases the odds of committing a type 1 error or incorrectly rejecting the null hypothesis, as was done for hypothesis 1 of this study. The decision to not use a Bonferroni correction was based on the small sample size of 135 subjects per group and the decision to accept the hypothesis that downstream costs were lowered if even one of the costs was lowered (every cost did not need to be lowered to accept hypothesis 1.)

Recommendations

Several recommendations are made from the results of the study and from a review of the methodology used. With regard to the primary aim of the study to examine the impact of implementing the LBP CPG on downstream medical costs after an episode of physical therapist care, a more robust economic analysis can be made in future studies. For example, models that calculate the quality-adjusted-life-year (QALY) can be used to inform cost utility and measure the impact of an intervention on quality of life. Including indirect costs in the cost effectiveness analysis is also recommended for future studies that examine CPGs in physical therapist practice. Using indirect costs will also inform researchers on the patient perspective and may provide an opportunity to measure other important information directly from patients, such as perceived improvement or change. Another method to gather patient perspectives would be to use a mixed methodology that includes qualitative investigation into the patient experience.

It is recommended that adherence to CPGs is explicitly measured alongside cost analysis. An assumption was made in the study that evidence-based care improved after the implementation of the LBP CPG. Measuring adherence via CPT codes or by direct observation would provide more detail and inform future efforts for implementation.

It is also recommended that methods of dissemination and implementation include a multifaceted approach, which was performed at OSUWMC however, the implementation strategy that was used could be examined for areas of improvement. A second or follow-up survey to the initial baseline knowledge survey that was performed during the initial implementation activities could be performed and would serve as good information on knowledge translation. Other ideas for implementation activities could include tools such as video or in person tutorials on how to perform the patient examination and each intervention, methods to self-assess for performance and knowledge of CPG contents, and materials directed at patients and consumers so they can make shared decisions on how to manage their LBP with their provider.

Knowledge translation efforts and activities are not the sole responsibility of the end user or clinician or health system. Ideally, a knowledge translation task force or committee would have been established by the LBP CPG developers or the supporting section, making uptake of the recommendations easier to perform in the clinic.

Summary

Evidence-based practice is a vital part of physical therapy care delivery. Gaps continue to exist between research and practice. CPGs have the potential to bridge that gap and play an important role into controlling health care spending. This is accomplished by providing evidence on the most effective and efficient ways to manage health conditions. As new payment models are developed in health care, clinicians, administrators, and policy makers will have to find new ways to add value while at the same decrease costs. The results of this study shed light on the positive impact that the implementation of the LBP CPG into outpatient physical therapist practice had on lowering downstream costs

Appendix I

Variables of interest and their level of measurement:

- Age
  - *Ratio* (years)

- Sex
  - *Categorical* (2 levels: female, male)

- Race
  - *Categorical* (4 levels: White, African American/Black, Asian, Other/More than one race)
- Ethnicity
  - *Categorical* (3 levels: Not Hispanic or Latino, Latino/Hispanic, Refused to answer)

- Insurance provider
  - *Categorical* (4 levels: Medicare, Medicaid, Managed Care, Other/Government)

- Numeric Pain Reporting Scale (NPRS)
  - *Ordinal* on a scale from 0-10

- Oswestry Disability Index (ODI)
  - *Ordinal* on a scale of 0-100
  - Raw scores can be converted into a *categorical* scale with 5 levels:
    - 0-20 Minimal disability
    - 21-40 Moderate disability
    - 41-60 Severe disability
    - 61-80 Crippling back pain
    - 81-100 Bedridden

- Physical therapy utilization
  - *Ratio* (number of physical therapy visits per episode of care)

- Direct physical therapy costs before contractual adjustments: for entire episode of care.
  - *Ratio* measured in USD

- Downstream costs before contractual adjustments for: pharmaceutical management, imaging services, emergency department services, surgery, other rehabilitation services, other services.
  - *Ratio* measured in USD

References

1. Buchbinder R, Blyth FM, March LM, Brooks P, Woolf AD, Hoy DG. Placing the global burden of low back pain in context. *Best Practice & Research Clinical Rheumatology.* 2013;27(5):575-589.
2. Vos T, Abajobir AA, Abate KH, et al. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 2016: a systematic analysis for the Global Burden of Disease Study 2016. *The Lancet.*390(10100):1211-1259.
3. (IHME) IfHMaE. *Findings from the Global Burden of Disease Study 2017.* Seattle, WA: IHME; 2018.
4. Fatoye F, Wright J, Gebrye T. Cost-effectiveness of physiotherapeutic interventions for low back pain: a systematic review. *Physiotherapy.* 2020.
5. Edwards J, Hayden J, Asbridge M, Gregoire B, Magee K. Prevalence of low back pain in emergency settings: a systematic review and meta-analysis. *BMC Musculoskeletal Disorders.* 2017;18(1):143.
6. Fritz JM, Kim M, Magel JS, Asche CV. Cost-Effectiveness of Primary Care Management With or Without Early Physical Therapy for Acute Low Back Pain: Economic Evaluation of a Randomized Clinical Trial. *Spine.* 2017;42(5):285-290.
7. Fritz JM, Cleland JA, Brennan GP. Does adherence to the guideline recommendation for active treatments improve the quality of care for patients with acute low back pain delivered by physical therapists? *Medical care.* 2007;45(10):973-980.
8. Blackwell DL, Lucas JW, Clarke TC. Summary health statistics for U.S. adults: national health interview survey, 2012. *Vital Health Stat 10.* 2014(260):1-161.
9. Ma VY, Chan L, Carruthers KJ. Incidence, prevalence, costs, and impact on disability of common conditions requiring rehabilitation in the United States: stroke, spinal cord injury, traumatic brain injury, multiple sclerosis, osteoarthritis, rheumatoid arthritis, limb loss, and back pain. *Archives of physical medicine and rehabilitation.* 2014;95(5):986-995. e981.
10. Katz JN. Lumbar disc disorders and low-back pain: socioeconomic factors and consequences. *JBJS.* 2006;88(suppl_2):21-24.
11. Freburger JK, Holmes GM, Agans RP, et al. The rising prevalence of chronic low back pain. *Archives of internal medicine.* 2009;169(3):251-258.
12. Gatchel RJ. The Continuing and Growing Epidemic of Chronic Low Back Pain. Paper presented at: Healthcare2015.
13. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2016. *Jama.* 2016;315(15):1624-1645.
14. Kazis LE, Ameli O, Rothendler J, et al. Observational retrospective study of the association of initial healthcare provider for new-onset low back pain with early and long-term opioid use. *BMJ Open.* 2019;9(9):e028633.
15. Shmagel A, Ngo L, Ensrud K, Foley R. Prescription medication use among community-based US adults with chronic low back pain: a cross-sectional population based study. *The Journal of Pain.* 2018;19(10):1104-1112.

16. Mafi JN, McCarthy EP, Davis RB, Landon BE. Worsening trends in the management and treatment of back pain. *JAMA internal medicine.* 2013;173(17):1573-1581.
17. Ebadi S, Henschke N, Forogh B, et al. Therapeutic ultrasound for chronic low back pain. *Cochrane Database of Systematic Reviews.* 2020(7).
18. Flynn TW, Smith B, Chou R. Appropriate use of diagnostic imaging in low back pain: a reminder that unnecessary imaging may do as much harm as good. *journal of orthopaedic & sports physical therapy.* 2011;41(11):838-846.
19. Van der Wees PJ, Jamtvedt G, Rebbeck T, de Bie RA, Dekker J, Hendriks EJ. Multifaceted strategies may increase implementation of physiotherapy clinical guidelines: a systematic review. *Australian Journal of Physiotherapy.* 2008;54(4):233-241.
20. Institute E. Guidelines Trust. https://guidelines.ecri.org/. Published 2020. Accessed January 3, 2020.
21. Association APT. Clinical Practice Guidelines. https://www.apta.org/patient-care/evidence-based-practice-resources/cpgs. Published 2020. Accessed August 12, 2020.
22. Rutten GM, Degen S, Hendriks EJ, Braspenning JC, Harting J, Oostendorp RA. Adherence to Clinical Practice Guidelines for Low Back Pain in Physical Therapy: Do Patients Benefit? *Physical therapy.* 2010;90(8):1111-1122.
23. Fritz JM, Magel JS, McFadden M, et al. Early physical therapy vs usual care in patients with recent-onset low back pain: a randomized clinical trial. *Jama.* 2015;314(14):1459-1467.
24. Compenstaion SoCDoIRDoW. Workers' Compenstation Medical Treatment Utilization Schedule. In: Regulations CCo, ed. *8*2006.
25. Bernhardsson S, Johansson K, Nilsen P, Öberg B, Larsson ME. Determinants of guideline use in primary care physical therapy: a cross-sectional survey of attitudes, knowledge, and behavior. *Physical therapy.* 2014;94(3):343-354.
26. Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures. *Circulation.* 2014;129(22):2329-2345.
27. Schwartz JA, Pearson SD. Cost consideration in the clinical guidance documents of physician specialty societies in the United States. *JAMA internal medicine.* 2013;173(12):1091-1097.
28. Karlen E, McCathie B. Implementation of a quality improvement process aimed to deliver higher-value physical therapy for patients with low back pain: case report. *Physical therapy.* 2015;95(12):1712-1721.
29. Bekkering GE, Van Tulder MW, Hendriks EJ, et al. Implementation of clinical guidelines on physical therapy for patients with low back pain: randomized trial comparing patient outcomes after a standard and active implementation strategy. *Physical Therapy.* 2005;85(6):544-555.
30. Hoeijenbos M, Bekkering T, Lamers L, Hendriks E, van Tulder M, Koopmanschap M. Cost-effectiveness of an active implementation strategy for the Dutch physiotherapy guideline for low back pain. *Health policy.* 2005;75(1):85-98.
31. Fritz JM, Childs JD, Wainner RS, Flynn TW. Primary care referral of patients with low back pain to physical therapy: impact on future health care utilization and costs. *Spine.* 2012;37(25):2114-2121.

32. Childs JD, Fritz JM, Wu SS, et al. Implications of early and guideline adherent physical therapy for low back pain on utilization and costs. *BMC health services research.* 2015;15(1):150.
33. Association APT. APTA Clinical Practice Guideline Process Manual. In: Alexandria, VA2018.
34. Institute E. Inclusion Criteria. https://guidelines.ecri.org/inclusion-criteria. Published 2020. Accessed January 3, 2020.
35. Quality AfHRa. Guideline Summaries. https://www.guideline.gov/. Accessed June 18, 2017, 2017.
36. Vernooij R, Sanabria AJ, Solà I, Alonso-Coello P, Martínez García L. Guidance for updating clinical practice guidelines: a systematic review of methodological handbooks. *Implement Sci.* 2014;9(3).
37. Services CfMM. Value-Based Programs. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs. Published 2020. Updated 1/6/2020. Accessed August 13, 2020.
38. Association APT. *Delivery of Value-Based Physical Therapist Services.* APTA2015.
39. Owens DK, Qaseem A, Chou R, Shekelle P. High-value, cost-conscious health care: concepts for clinicians to evaluate the benefits, harms, and costs of medical interventions. *Annals of Internal Medicine.* 2011;154(3):174-180.
40. Association APT. Bundled Payment Models. http://www.apta.org/BundledModels/. Published 2016. Updated 1/14/2016. Accessed March 14, 2016.
41. Association APT. No Turning Back: 4 Ways Budled Payments Will Change Rehab Care. *PT in Motion.* 2016.
42. Delitto A. GS, Van Dillen L., Whitman J.L., Sowa G., Shekelle P., Denninger T.R., Godges J.J. . Low Back Pain Clincial Practice Guidelines Liked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association. *Journal of Orthopaedic & Sports Physical Therapy.* 2012;42(4):A1-A57.
43. Organization TWH. Heath Systems. http://www.who.int/topics/health_systems/en/. Published 2018. Accessed May 29, 2018.
44. Organization WH. World Health Organization Assesses the World's Health Systems. World Health Report Web site. http://www.who.int/whr/2000/media_centre/press_release/en/. Published 2000. Accessed March 14, 2016.
45. Squires D, Anderson C. US health care from a global perspective: spending, use of services, prices, and health in 13 countries. *The Commonwealth Fund.* 2015;15:1-16.
46. Improvement IfH. The IHI Triple Aim. Initiatives Web site. http://www.ihi.org/engage/initiatives/tripleaim/Pages/default.aspx. Published 2016. Accessed March 14, 2016.
47. O'Connell NE, Cook CE, Wand BM, Ward SP. Clinical guidelines for low back pain: a critical review of consensus and inconsistencies across three major guidelines. *Best practice & research Clinical rheumatology.* 2016;30(6):968-980.
48. Turner T, Misso M, Harris C, Green S. Development of evidence-based clinical practice guidelines (CPGs): comparing approaches. *Implementation science.* 2008;3(1):45.
49. Steinberg E, Greenfield S, Wolman DM, Mancher M, Graham R. *Clinical practice guidelines we can trust.* National Academies Press; 2011.

50. Eccles M, Grimshaw J. The potential benefits, limitations and harms of clinical guidelines. *Clinical Guidelines from Conception to Use.* 2000:19.
51. Trust EG. Inclusion Criteria. https://guidelines.ecri.org/inclusion-criteria/. Published 2020. Accessed June 12, 2020, 2020.
52. Terrace L. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care.* 2003;12:18-23.
53. Enterprise A. AGREE History. http://www.agreetrust.org/about-the-agree-enterprise/agree-history/. Published 2013. Accessed August 28, 2017.
54. Brouwers M KM, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna S, Littlejohns P, Makarski J, Zitzelsberger L for the AGREE Next Steps Consortium. . AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J.* 2010;Available online July 5, 2010.
55. Dijkers MP, Ward I, Annaswamy T, et al. Quality of Rehabilitation Clinical Practice Guidelines: An Overview Study of AGREE II Appraisals. *Arch Phys Med Rehabil.* 2020.
56. Bekkering G, Hendriks H, Van Tulder M, et al. Effect on the process of care of an active strategy to implement clinical guidelines on physiotherapy for low back pain: a cluster randomised controlled trial. *Quality and Safety in Health Care.* 2005;14(2):107-112.
57. Becker A, Held H, Redaelli M, et al. Implementation of a guideline for low back pain management in primary care: a cost-effectiveness analysis. *Spine.* 2012;37(8):701-710.
58. Evaluation AoGRa. *A critical group appraisal of: Low Back Pain. Clinical Practice Guideline Linked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association using the AGREE II Instrument.* www.agreetrust.org April 28, 2015 2015.
59. Saragiotto BT, Maher CG, Hancock MJ, Koes BW. Subgrouping Patients With Nonspecific Low Back Pain: Hope or Hype? *Journal of Orthopaedic & Sports Physical Therapy.* 2017;47(2):44-48.
60. Koes BW, van Tulder M, Lin C-WC, Macedo LG, McAuley J, Maher C. An updated overview of clinical guidelines for the management of non-specific low back pain in primary care. *European Spine Journal.* 2010;19(12):2075-2094.
61. Delitto A, Erhard RE, Bowling RW. A treatment-based classification approach to low back syndrome: identifying and staging patients for conservative treatment. *Physical therapy.* 1995;75(6):470-485.
62. Alrwaily M, Timko M, Schneider M, et al. Treatment-based classification system for low back pain: revision and update. *Physical therapy.* 2016;96(7):1057-1066.
63. Alrwaily M, Timko M, Schneider M, et al. Treatment-based Classification System for Patients with Low Back Pain: The Movement Control Approach. *Physical Therapy.* 2017;97(12):1147-1157.
64. Association AM. CPT Purpose and Mission. https://www.ama-assn.org/practice-management/cpt-purpose-mission. Published 2017. Accessed October 2, 2017.
65. Association APT. About the CPT Process: How a Code Becomes a Code. http://www.apta.org/Payment/Coding/AboutCPTProcess/. Published 2017. Updated 2/22/2017. Accessed October 1, 2017.
66. Lee C-P, Fu, T.-S., Liu, C.-Y., & Hung, C.-I. Psychometric evaluation of the Oswestry Disability Index in patients with chronic low back pain: factor and Mokken analyses. *Health and Quality of Life Outcomes.* 2017;15:192.

67. Brodke DS, Goz V, Lawrence BD, Spiker WR, Neese A, Hung M. Oswestry Disability Index: a psychometric analysis with 1,610 patients. *The Spine Journal.* 2017;17(3):321-327.
68. Copay AG, Glassman SD, Subach BR, Berven S, Schuler TC, Carreon LY. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and pain scales. *The Spine Journal.* 2008;8(6):968-974.
69. Copay AG, Cher DJ. Is the Oswestry Disability Index a valid measure of response to sacroiliac joint treatment? *Quality of Life Research.* 2016;25(2):283-292.
70. Childs JD, Piva SR, Fritz JM. Responsiveness of the numeric pain rating scale in patients with low back pain. *Spine.* 2005;30(11):1331-1334.
71. Buchner A, Erdfelder E, Faul F. Teststärkeanalysen. *Handbuch quantitative Methoden.* 1996:123-136.
72. Norušis MJ. *SPSS/PC+ for the IBM PC/XT/AT.* Vol 1: Spss; 1986.
73. Portney LG, Watkins MP. *Foundations of clinical research: applications to practice.* Vol 2: Prentice Hall Upper Saddle River, NJ; 2000.
74. Plichta S, Kelvin, E. *Munro's Statistical Methods for Health Care Research.* 6th Edition ed. New York, NY: Wolters Kluwer Health/ Lippincott Williams and Wilkins; 2013.
75. Association APT. Vision, Mission, and Strategic Plan. https://www.apta.org/apta-and-you/leadership-and-governance/vision-mission-and-strategic-plan. Published 2020. Accessed July 7, 2020, 2020.
76. Kim LH, Vail D, Azad TD, et al. Expenditures and Health Care Utilization Among Adults With Newly Diagnosed Low Back and Lower Extremity Pain. *JAMA Network Open.* 2019;2(5):e193676-e193676.
77. Keil AP, Baranyi B, Mehta S, Maurer A. Ordering of Diagnostic Imaging by Physical Therapists: A 5-Year Retrospective Practice Analysis. *Physical Therapy.* 2019;99(8):1020-1026.
78. Boyles RE, Gorman I, Pinto D, Ross MD. Physical therapist practice and the role of diagnostic imaging. *journal of orthopaedic & sports physical therapy.* 2011;41(11):829-837.
79. Garrity BM, McDonough CM, Ameli O, et al. Unrestricted Direct Access to Physical Therapist Services Is Associated With Lower Health Care Utilization and Costs in Patients With New-Onset Low Back Pain. *Phys Ther.* 2020;100(1):107-115.
80. Dunet D. CDC coffee break: introduction to economic evaluation. *Atlanta Centers for Disease Control.* 2012.
81. Ferreira PH, Ferreira ML, Maher CG, Refshauge KM, Latimer J, Adams RD. The therapeutic alliance between clinicians and patients predicts outcome in chronic low back pain. *Physical therapy.* 2013;93(4):470-478.