date

No. of research proposal

THE ISRAEL NATIONAL INSTITUTE FOR HEALTH POLICY RESEARCH

Section 2: English Abstract

Full title of research project

The Economic Implications of (Non) Adherence to the Low Back Pain Treatment Guidelines by Primary Care Practitioners

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Key Words

Low back pain, primary care practitioners, cost

Abstract

An abstract of up to **300 words** should include these headings: (1) Scientific Background (2) Objectives (3) Methodology (4) Findings (5) Conclusions (6) Policy Implications / recommendations

1. Scientific Background
Low back pain (LBP) is a major public health problem worldwide and has been estimated to cost 2% of the gross domestic product in developed countries. Studies have shown that there is overuse, exposure to excess radiation, and inappropriate care being provided by primary care physicians (PCPs). In 2007, Israeli LBP guidelines were disseminated with the aim of reducing inappropriate care and costs.
2. Objectives
To evaluate whether the introduction of the LBP guidelines in 2007 caused a change in the patterns and cost of LBP treatment in Israel
3. Methodology
We compared the use of services and the cost of LBP care in the two leading Israeli health plans, before the dissemination (2006) and after (2009 and 2012). Analysis of variance and regression models were used to estimate the effect of the change on use and cost.
4. Findings
Clalit: The mean utilization of x-rays rose from 0.079 in 2006 to 0.261 in 2009 and to 0.229 in 2012 ($p<0.05$). The mean number of anti-depressants purchased rose from 0.618 in 2006 to 0.695 in 2009, and to 0.741 in 2012 ($p<0.05$). The total mean LBP utilization cost per LBP patient rose when comparing both 2006 to 2009 and 2006 to 2012.
Maccabi: The mean utilization of x-rays decreased from 0.21 in 2006 to 0.18 in 2012 ($p<0.05$). The mean CT utilization rose from 0.009 in 2006 to 0.11 in 2012

Section 3: Hebrew Abstract

כותרת מלאה של המחקר

ההשלכות הכלכליות של (אי) ציות להנחיות הקליניות בטיפול בכאבי גב תחתון על ידי רופאי משפחה

חוקרים: שם מלא ושיוך מוסדי

עמיר שמואלי, האוניברסיטה העברית
דניאל דויטשר, מכבי שרותי בריאות
מאיה לוונטר-רוברטס, מכון מחקר כללית

מילות מפתח

כאבי גב תחתון, רופאים ראשוניים, עלות

תקציר

תקציר שאורכו עד **200 מילים**, אשר יכלול כותרים אלה: (1) רקע (2) מטרות (3) שיטה (4) ממצאים עיקריים (5) מסקנות (6) המלצות / השלכות לקובעי המדיניות

תקציר דו"ח סופי

רקע מדעי

כאבי גב תחתון (להלן כג"ת) מהווים בעיה משמעותית עולמית בתחום בריאות הציבור שעלות הכלכלית החברתית שלו מוערכת בכ2% מהתוצר הלאומי במדינות המפותחות. מחקרים הראו שיש מתן דימות לא במקומה, חשיפה לקרינה מיותרת, וטיפול לא מתאים ע"י רופאים ראשוניים. ב2007, קווים מנחים הופצו במטרה לצמצם עלויות ולשפר את יעילות ואיכות הטיפול.

מטרות המחקר

לבחון האם חל שינוי בדפוסי הטיפול ועלותו עם הפצת הקווים המנחים בישראל

שיטות המחקר

השוונו את השימוש בשרותים ועלותם של כג"ת בקופות החולים כללית ומכבי, לפני ההפצה (2006) ואחרי (2009 ו-2012)
ניתוח דו ורב-משתני הופעלו כדי לאמוד את האפקט של ההפצה על הטיפול הניתן ועלותו

ממצאים עיקריים

<u>כללית:</u>
שימוש ממוצע בצילומי רנטגן עלה מ-0.079 ב-2006 ל-0.261 ב-2009 ול- 0.229 ב-2012 ($p<0.05$). רכישה ממוצעת של תרופות נגד דכאון עלתה מ- 0.618 ב- 2006 ל-0.695 ב- 2009, ול- 0.741 ב- 2012 ($p<0.05$). סה"כ עלות שימוש ממוצעת למטופל עם כג"ת עלתה בהשוואה בין 2006 & 2009 ובין 2006 & 2012.

<u>מכבי:</u>

Section 4: Executive Summary- Hebrew

Executive Summary

רקע מדעי

כאבי גב תחתון (להלן כג"ת) מהווים בעיה משמעותית עולמית בתחום בריאות הציבור שעלות הכלכלית החברתית שלה מוערכת ב-כ2% מהתוצר הלאומי במדינות המפותחות. כג"ת גורמים להיעדרות גבוהה ולפריון נמוך בעבודה, ולכן הם מטילים נטל רב על כלכלת המדינות המפותחות. כג"ת הם הבעיה הפיזית השכיחה ביותר שעבורה אנשים מבקרים אצל רופאים, וגורמים יותר נטל תחלואה מכל מחלה אחרת, ומשפיעה על שמונים אחוז ממבוגרים מתישהו בחייהם. מחקרים הראו שהטיפול המקובל בכג"ת כולל מתן דימות לא במקומה, חשיפה לקרינה מיותרת, וטיפול לא מתאים ע"י רופאים ראשוניים. במטרה לצמצם עלויות ולשפר את יעילות ואיכות הטיפול, חוברו בעולם ובישראל קווים מנחים עבור הרופאים המטפלים בכג"ת, והם הופצו בישראל ב2007. המחקר העולמי מראה קשר בין יישום הקווים המנחים הללו ותוצאות תפקוד טובות יותר, ירידה בשימוש בשרותי בריאות, וירידה בהוצאות החברתיות על כג"ת.

מטרות המחקר

מטרת המחקר היתה לבחון האם חל שינוי בדפוסי הטיפול הניתן על ידי רופאים ראשוניים ועלותו עם הפצת הקווים המנחים בישראל בשנת 2007 בקופות החולים כללית ומכבי.

שיטות המחקר

במחקר רטרוספקטיבי זה נשלפו (באופן אנונימי) ממאגרי כללית ומכבי נתוני מטופלים שביקרו אצל רופא ראשוני ואובחנו באחת האבחנות של כג"ת ב-2006 ("לפני"), ב-2009 , וב- 2012 ("אחרי"). נתונים לגבי: אבחנות רקע, מאפיינים דמוגרפיים, שימוש בבדיקות הדמיה, רכישת תרופות, ביקורים אצל פיזיותרפיסטים ואצל מומחים, נאספו מהרשומות הרפואיות. עלויות הטיפול חושבו תוך שימוש במחירון משרד הבריאות מ 2009.

ממוצעי השימושים ועלותם בשנת 2006 הושוו לאלה בשנת 2009 ובשנת 2012. השוואת סך עלויות הטיפול "לפני" ו"אחרי" תוך פיקוח על המאפיינים הדמוגרפיים והקליניים של המטופלים בוצעה באמצעות ניתוח רגרסיה.

ממצאים עיקריים

<u>כללית:</u>

שימוש ממוצע בקוהורט בבדיקות דימות עלה: א) בצילומי רנטגן עלה מ-0.079 ב-2006 ל-0.261 ב-2009 ול- 0.229 ב-2012 ($p<0.05$) ב) בצילומי CT עלה מ-0.035 ב-2006 ל-0.039 ב-2009, ול-0.047 ב-2012 ($p<0.05$). רכישה ממוצעת של תרופות נגד דכאון עלתה מ- 0.618 ב- 2006 ל- 0.695 ב- 2009, ול- 0.741 ב- 2012 ($p<0.05$). התגלתה ירידה בממוצע ביקורים אצל מומחים. לדוגמא, ממוצע ביקורים אצל אורטופדים ירדה מ-1.041 ב-2006 ל-1.001 ב-2009, ול- 0.917 ב-2012 ($p<0.05$). שימוש ממוצע בניתוחי גב עלה מ-0.009 ב-2006 ל-0.012 ב-2012 ($p<0.05$). סה"כ עלות שימוש ממוצעת למטופל עם כג"ת עלתה מ- 2020.54 ש"ח ב-2006 ל- 2080.67 ש"ח ב- 2009 ($p<0.05$) ול- 2056.53 ש"ח ב- 2012 ($p=0.095$). בניתוח הרב משתני, ההבדל בסה"כ עלות שימוש ממוצעת בין 2006 ל-2009 לא היה מובהק אך נראתה ירידה מובהקת של 61 ₪, בין 2006 ו-2012 ($p<0.05$).

<u>מכבי:</u>

שימוש ממוצע למטופל עם כג"ת בצילומי רנטגן ירד מ-0.21 ב-2006 ל-0.18 ב-2012 ($p<0.05$). שימוש ממוצע בצילומי CT עלה מ-0.009 ב- 2006 ל-0.11 ב- 2012 ($p<0.05$). רכישה ממוצעת של תרופות נגד דכאון עלתה מ- 0.90 ב- 2006 ל-1.06 ב- 2009, ול-1.24 ב- 2012 ($p<0.05$). נראתה ירידה בממוצע ביקורים אצל רופאים אורטופדים בין 2006 ו-2012, מ-1.89 ל- 1.83 ($p<0.05$) ועליה בממוצע ביקורים אצל נוירולוגים, מ-0.30 ל-0.31, ואצל ראומטולוגים, מ-0.05 ל-0.06, ($p<0.05$) בהשוואת אותן השנים. סה"כ עלות שימוש ממוצעת למטופל עם כג"ת עלתה בהשוואה בין 2006 & 2009 ובין 2006 & 2012, מ- 1136.42 ש"ח ב-2006, ל- 1176.00 ש"ח ב-2009, ול- 1172.75 ש"ח ב-2012.

בניתוח הרב משתני, התגלתה עליה מובהקת ($p<0.05$) בסה"כ עלות השימוש ממוצעת בין 2006 ל-2009 (26.7 ₪) ובין 2006 ל-2012 (29.6 ₪).

מסקנות

למרות הבדלים בין הקופות, רוב התוצאות מראות שהרופאים הראשוניים ממשיכים לתת טיפולים בעיקר בתחומי בדיקות דימות ותרופות עבור כג"ת שהם לא מתאימים להנחיות; ולכן, לא הולמים. בשתי הקופות ניכרת ירידה בהפניות להתייעצות עם רופאים אורטופדיים, אך בסך הכל, עלות הטיפול הממוצעת לא פחתה בטווח הקצר.

המלצות/השלכות לקובעי מדיניות

למרות מגבלות המחקר בפיקוח על שינויים כלליים שהתרחשו לאורך זמן בפרקטיקה הרפואית, הממצאים מעידים כי פרסום ההנחיות בדבר הטיפול המומלץ בכג"ת בשנת 2007 לא הביא לירידה המצופה בעלות הטיפול הרפואי ולהגברת המועילות שלו. מסתמן צורך ביישום תכנית התערבות יעילה להעלאת המודעות של הרופאים הראשוניים להנחיות ובתמריצים לעידוד הציות של רופאים להנחיות הקליניות.

מקורות

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4. Andronis L, Kinghorn P, Qiao S, Whitehurst DG, Durrell S, McLeod H. Cost-Effectiveness of non-invasive and non-pharmacological interventions for low back pain: a Systematic Literature Review. Appl Health Econ Health Policy. 2017 Apr;15(2):173-201.

Section 5: Comprehensive scientific report - English

הנחיות:
הדוח המדעי המלא ייכתב **באנגלית** בצורה המקובלת של מאמר בעיתון מקצועי ולפי הסעיפים הבאים ככותרות משנה:

1. **Scientific background** (what is already known)
2. **Research objectives** (what does the work intents to solve)
3. **Methodology**
4. **Findings**
5. **Discussion and Conclusions**
6. **Policy Implications and Recommendations**
7. **References**

לתשומת לב
- הפירוט בסעיפים 1 – 6: לא יעלה על **עשרים** עמודים (כולל תרשימים)
- פונט: Arial מספר 12
- מרווח בין שורות – 1.5

הדוח המדעי המלא ישמר בארכיון המכון ויימסר לצד ג' רק לאחר קבלת הסכמה מפורשת של החוקר האחראי.

Scientific Background

Low back pain (LBP) is a major public health problem worldwide which affects roughly 80% of adults at some point during their lives. The most common physical condition for which patients consult their doctors is back pain.[1] Of those who seek care for LBP, about 85-95% are evaluated as suffering from non-specific low back pain (NSLBP), low back pain not attributable to a recognizable nor a specific pathology (e.g. infection, tumor, fracture, inflammatory disorder, etc.).[2]

Low back pain results in high morbidity prevalence and as a result is a leading cause of work absenteeism and low productivity, placing a huge financial burden on the economies of developed countries.[3-4] The Global Burden of Disease 2015 study found that LBP causes more global disability than any other condition.[5]

LBP is also a main healthcare cost driver. Low back pain has been estimated to cost 2% of the gross domestic product in developed countries.[6] In the United States, the healthcare costs of LBP sufferers increased by 65% between 1997 and 2005, a more rapid rise than in healthcare costs among non-LBP sufferers or that experienced in overall healthcare expenditure for the identical period.[7]

Approximately 20% of the United Kingdom's healthcare spending is attributed to spinal pain, exceeding that spent on most other medical conditions.[8]
The concern about the high and rising LBP cost of care lies in the apparent ineffectiveness of LBP treatment and management. Studies have shown that there is overuse (particularly regarding imaging and opioids), exposure to excess radiation, and inappropriate care being provided instead of 'high value, cost-conscious care,' best-suited to the individual patient.[1,9-13] Researchers in the United States, in Australia, and in Italy revealed deviations of primary care physician LBP treatment and management from current guidelines, and noted that doctors were referring significant numbers of patients for imaging (while discouraged by guidelines) and prescribing medications not recommended by guidelines to a substantial proportion of patients.[14-19]
An Australian simulated patient study showed the selection of pain medicines for LBP to be concordant with LBP guidelines while the recommendations relating to referrals (to physical therapy and for imaging) were found to be discordant to guidelines.[20] Similarly, a simulated patient study carried out in France discovered some of the physicians' recommendations, such as, the non-prescription of physical therapy and imaging, to be compliant with clinical practice guidelines (CPGs) and others, such as, drug and sick leave prescriptions, to be inconsistent with CPGs.[21]
Self-reporting in a US study found that a majority of PCPs would not send for imaging in the case of NSLBP (a survey rather than a data based study).[22]
Various US studies have demonstrated that imaging leads to a cascade of unnecessary diagnostic and therapeutic interventions, as a result of identification of a lesion which proves only to be incidental.[23-26] Graves et al. found an association between non-adherence by physicians to guidelines for early magnetic resonance imaging (MRI) and an increased likelihood of health care utilization (e.g. injections and surgery) and higher costs for outpatient, inpatient and nonmedical services.[23]
Kim et al. found that deviation from guideline-consistent management was common and accrued higher costs compared to patients managed according to guidelines.[27] For example, they reported higher expenditure among patients who received early imaging (within 30 days of diagnosis) and that imaging alone accounted for twenty

percent of the nonsurgical health care costs (more than half a billion dollars annually).[27]

The substantial rise witnessed in LBP expense was not accompanied by evidence of improvements in self-assessed health status, functional disability, work limitations, nor in social functioning.[1,18,28] Several randomized trials involving patients in primary care with NSLBP compared patients who received imaging to those who did not. In these studies, imaging was not associated with improvements in pain or in quality of life.[29-33]

In an effort to reduce the costs and to improve the effectiveness and quality of care for LBP sufferers, evidence-based guidelines for LBP have been formulated, updated and disseminated to primary care physicians (PCPs) worldwide and in Israel. Studies have found evidence supporting the cost-effectiveness of guideline-endorsed treatments and the cost-effectiveness of guideline implementation.[32,34-38] Better functional outcomes, decreased health care utilization, and reduced healthcare costs have been shown to be associated with guideline implementation by patients and practitioners.[1,37,39-40] A review by Jenkins et al. found that the implementation of interventions designed to reduce imaging had a significant effect on primary care doctors' use of imaging and suggests that implementation of similar low-cost interventions have the potential to substantially reduce LBP expenditure.[41] Two Cochrane reviews concluded that implementation tools developed to improve healthcare professionals'(HCPs) adherence to LBP guidelines probably lead to improvements in their guideline-consistent behavior and therefore to improvements in their LBP management.[42-43]

As the management of LBP has been linked to inefficiency and waste worldwide, overuse and inappropriate care must also be addressed in Israel, with the aim of improving the provision of care and lowering LBP costs. In 2007-8, LBP diagnosis and treatment guidelines (for PCPs) were formulated in Israel by a multidisciplinary, expert group. The essential recommendations in cases of NSLBP are:

1) to offer pain relief medications - paracetamol as first-line treatment and non-steroidal anti-inflammatories (NSAIDs) as a second-line option
2) not to refer for imaging, epidural steroid injections, nor for the use of transcutaneous electrical nerve stimulation (TENS)

3) to encourage the patient to remain active and to continue working and doing their regular activities and
4) to emphasize psychosocial factors in LBP prevention and treatment.[44]

Self-reports from previous research showed that fifty percent of PCPs were implementing LBP guidelines.[45] Actual figures for the number of imaging tests undergone and for the types of medications being prescribed by PCPs and purchased by patients (in cases of NSLBP) were evaluated in this study to determine whether the real practice patterns of Israeli PCPs are guideline-concordant, and the implications on effectiveness and medical care cost.

Research Objectives

To evaluate whether a change occurred in the patterns and cost of LBP treatment administered by PCPs working for the Maccabi and Clalit sickness funds between the year 2006 ('pre' 2007, the year prior to the second dissemination of guidelines), 2009 ('post' 2007, the year of the second dissemination of Israeli LBP guidelines) and 2012 (a few years later).

Aims

1) To determine the *types, the number, and the timing* of imaging tests undergone by LBP patients in the years 2006, 2009, and 2012
2) To determine the *types* and *quantity* of medications *prescribed* and of medications *purchased* in the years 2006, 2009, and 2012
3) To quantify the *number* of PT and specialist referrals *made* by PCPs and *utilized* by LBP patients during 2006, 2009, and 2012
4) To calculate the utilization cost for: imaging tests [X-ray, magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), computed tomography (CT), ultrasonography (US), bone scan, electromyography (EMG)], medication, PT visits, specialist visits, lumbar injections and lumbar surgery)
5) To calculate the *total* LBP utilization cost (sum of: imaging tests, medication, PT visits, specialist visit, lumbar injection and lumbar surgery costs) per patient for one year from the date of LBP diagnosis (in the years 2006, 2009, and 2012)
6) To compare the total LBP utilization costs per patient of the years 2006, 2009, and 2012 and to evaluate whether a significant difference exists between these

years (in terms of the variables regarding: imaging, medication, PT, specialists, utilization of other services)

Further Aims

1) To assess whether an association exists between the total LBP utilization cost and the *PCPs' ages*

2) To assess whether an association exists between the total LBP utilization cost and the following *patient* characteristics: age, gender, co-morbidities, and clinic locations

Methodology

Study Design and Population

This is a retrospective study based on unidentified patient data extracted from the Clalit and Maccabi sickness funds' electronic data sources. The study population included patients who presented to PCPs from June 1st 2006 through May 31st 2007 (referred to as 2006 in what follows), from January 1st 2009 through December 31st 2009, and from January 1st 2012 through December 31st 2012 who were recorded under the following diagnoses: spondylosis lumbar without neurology, lumbosacral spondylosis without neurology, spondylosis lumbar, disc herniation-lumbar no neurology, intervertebral disc degeneration-lumbar, degeneration intervertebral disc lumbar/sacral, low back pain, sprain lumbar back, disc herniation-lumbo-sacral no neurology, flat back, prolapse lumbar disc without myelopathy, muscle spasm/cramp/pain lumbar, myofascial pain syndrome lumbar, lumbosacral root lesions, sciatica, thoracic or lumbosacral radiculitis uns, lumbosacral/thoracic pain with radicular syndrome of lower limbs, lumbar spondylosis with neurology, disc herniation-lumbar with neurology, disc herniation-lumbo-sacral with neurology, spinal stenosis lumbar, pain sacroiliac, sacral pain, sacroiliac pain, sprain sacroiliac, sprain back sacral area. In Clalit, free text searches were also used to identify LBP patients.

Patients younger than 25, and patients who presented with 'red flags' such as: significant trauma, history of cancer, osteoporosis, prolonged steroid use, unexplained weight loss, thoracic pain, diffuse neurological deficit, fever, and suspected structural deformity or systemic disease were excluded from the study. ('Red flag' cases may be indicative of something other than routine,

musculoskeletal LBP and therefore, the guidelines are not relevant as early imaging testing may be indicated.) Patients listed in the Clalit and Maccabi cancer registries and patients listed as purchasing medication for acquired immune deficiency syndrome (AIDS) were excluded. Pregnant women (documented as pregnant during the year prior to the index date up to one year after the index date), patients who were listed under post-surgical LBP (from 3 months before index to 3 months after), and patients who did not have continuous membership in their respective sick fund for a minimum of two years were excluded from this study.

The final study sample included: 420,064 Clalit patient files (according to cohorts: *2006*- 132,783; *2009*- 145,241; and *2012*- 142,040) and 204,552 Maccabi patient files (according to cohorts: *2006*- 61,892; *2009*- 66,545; and *2012- 76,115*).

Variables

Demographic Characteristics of Patient Population

Age and gender of the LBP patients' PCPs was extracted only by Clalit. Due to a significant amount of missing data, the variable of PCP gender was excluded from the final analysis. For analysis purposes, the following groups were defined: 1) < 29 year, 2) 30-39 years, 3) 40-49 years, 4) 50-59 years, and 5) > 60 years.

Patients' age and gender were extracted by both Clalit and Maccabi. For analysis purposes, the following groups were defined: 1) 25-34 years, 2) 35-44 years, 3) 45-54 years, 4) 55-64 years, and 5) > 65 years.

Medical Characteristics of Patient Population

Specific conditions and the taking of certain medications can be contraindications for several of the guideline-consistent treatments for LBP. Therefore, data was collected regarding these conditions and regarding the taking of these medicines within the study population.

Information about the presence of the following co-morbidities: hypertension, cirrhosis, kidney disease, gastric ulcer, intestinal ulcer, platelet disorder, asthma, coronary artery disease (CAD), aspirin allergy was extracted by both sick funds. For analysis, absence of the specified co-morbidity (per patient) was coded as, absent =0, and presence of each co-morbidity coded as, present =1.

Data regarding the intake of diuretics and of antithrombotic agents (by the LBP patients) was extracted by both sick funds. To indicate whether the patient was

taking or not taking either of the above specified medications, the coding used was: not taking medication = 0, and taking specified medicine = 1.

Other patient-related factors which may be associated with the treatment provided by the PCPs were evaluated including: 1) LBP occurrence = whether the diagnosis of LBP had been recorded previously in his/her PCP file within five years prior to the study diagnosis date; 2) lower extremity (LEX) symptoms = whether a symptom of pain, tingling, and/or weakness in the buttock, thigh, and/or leg was recorded in the patient file; 3) patients' clinic locations = whether the clinic where the patient was seen is located in an urban or rural area; 4) number of PCP visits = the number of visits made by the patient to his/her PCP in the year prior to his/her diagnosis date. For analysis purposes, the coding was as follows: no LBP occurrence (recorded in previous 5 years) = 0, record of LBP occurrence = 1, no LEX symptoms = 0, record of LEX symptom = 1. The location of the clinic visited by the patient was recorded as 'urban' and 'rural'.

The independent variables used in this study are listed in Table 1.

Table 1. Independent Variables

Variable	Type	Categories	Coding
Date of LBP diagnosis	Continuous	01/06/06 – 31/05/07, 01/01/09- 31/12/09, 01/01/12 – 31/12/12	
PCP's age	continuous	1) < 29 year, 2) 30-39 years, 3) 40-49 years, 4) 50-59 years, and 5) > 60 years	
Patient's age	continuous	1) 25-34 years, 2) 35-44 years, 3) 45-54 years, 4) 55-64 years, and 5) > 65 years	
Patient's gender	nominal	m/f	F=female M=male
Co-morbidities	nominal	Hypertension, cirrhosis, kidney disease, gastric ulcer, intestinal ulcer, platelet disorder, asthma, coronary artery disease, aspirin allergy, taking diuretics, taking antithrombotic agents	0 = absent or not taking 1 = present or taking
Pain occurrence	nominal	No record of LBP 5 years prior to diagnosis date/ record of LBP 5 years prior to diagnosis date	0= no record 1=record
Lower extremity symptoms*	dichotomous	y/n	0 = no 1 = yes

Patient's clinic location	nominal	Urban/rural	0 = Rural 1 = Urban
Number of PCP visits	continuous		

***** symptoms - includes pain, tingling, weakness

Study Outcomes (dependent variables)

Study outcomes (dependent variables) consisted of utilization, prescription, referral, and cost data in the following services categories: 1) imaging 2) medication 3) physiotherapy and specialists and 4) lumbar injections and lumbar surgery. The outcomes' study period spanned from the date of LBP diagnosis through the 'follow-up', the year following the index date. The Clalit 'imaging' category (excluding EMG) was subdivided into 'early' and 'late' to determine how long after the diagnosis date each test was done. Tests done within 12 weeks of the diagnosis date were included in 'early' and tests done more than 12 weeks after the diagnosis date were included in the 'late' sub category. (Data regarding 'timing' was not available from Maccabi.) Each type of imaging test for which utilization and cost were evaluated is depicted in Table 2.

Table 2. Imaging Tests

Imaging type	**Subcategory**
X-ray	lumbar, sacral, pelvis, hip
MRI & MRA	lumbar, pelvis, hip
CT	lumbar, sacral, pelvis, hip, LEX, urinary tract
Bone scan	
US	kidney, pelvis, miscellaneous(misc)
EMG	

Data in the category of 'medication' was extracted and analyzed according to medications 'prescribed' and medications 'purchased' by the LBP patient. The sub categories within 'medication' included: analgesics, NSAIDs, anti-convulsants, anti-depressants, anti-anxiety, and muscle relaxants.

In the 'physiotherapy and specialists' outcome group, the data was extracted and analyzed according to: a) 'referrals' to PT and to specialists and b) visits 'utilized' by

the LBP patient. Analysis was carried out on the information collected regarding orthopedists, neurologists, and rheumatologists (and neurosurgeons for Maccabi). In both health plans, the cost for each type of imaging test was calculated using the Ministry of Health's (MOH) April 2018 pricelist.

Outcome variables are listed in Table 3.

Table 3. Outcome variables

Variable	Type	Categories	Information source
Number of each type of Imaging **utilized**	Continuous	X-ray, MRI, MRA, CT, bone scan, US, EMG	Clalit or Maccabi database
Number of each type of Medication **prescribed**	continuous	analgesics, NSAIDs, anti-convulsants, anti-depressants, anti-anxiety, and muscle relaxants	Clalit database
Number of each type of Medication **purchased**	continuous	analgesics, NSAIDs, anti-convulsants, anti-depressants, anti-anxiety, and muscle relaxants	Clalit or Maccabi database
Number of physiotherapy **referrals** given	continuous		Clalit database
Number of physiotherapy sessions **utilized**	continuous		Clalit or Maccabi database
Number of each type of specialist visit **utilized**	continuous	Orthopedist, neurologist, rheumatologist	Clalit or Maccabi database
Number of lumbar injections and lumbar surgery **utilized**	continuous	Lumbar injection, lumbar surgery	Clalit database
Total LBP utilization cost	continuous	imaging tests, medication, physiotherapy sessions, specialist visits, lumbar injections, lumbar surgery	Based on Ministry of Health's price list of April 2018*

*See: http://www.health.gov.il/Subjects/Finance/Taarifon/Pages/PriceList.aspx

Statistical Analysis

Study data was extracted from multiple electronic medical records from the Clalit and the Maccabi data warehouses and was analyzed using R. A p-value of <0.05 was considered statistically significant for all tests. Due to a significant amount of

missing data (15%), the variable of PCP gender was excluded from the final Clalit analysis.

In Clalit, independent t-tests and ANOVA tests were employed to assess changes in the outcome variables and multivariate regression with repeated measures was used to estimate the time effect on total LBP costs, controlling for changes in the independent variables. In Maccabi, one-way ANOVA and Chi-square tests were utilized according to the scale of the variable, followed by Bonferroni test, in order to adjust for multiple comparisons and to control for Type I error.

Ethical Considerations

The study received Helsinki approval from both the Clalit and Maccabi ethics review boards.

Results

Study Participants

Clalit

The main characteristics of the Clalit study population are presented in Table 4. The study population was 50.0% male across the study years with a mean patient age of 51.2 years (median = 50.5 years). The most prevalent of the specified co-morbidities were hypertension (29.4%) and the use of antithrombotic agents (30.4%). Approximately one third (34.2%) of the 2009 cohort had been recorded as complaining of LBP previously and slightly more than half (57.9%) of the 2012 cohort had records of previous LBP complaints. Across the cohorts, only an average of 2.83% of patients were recorded as complaining of LEX symptoms (in addition to LBP). Almost all (92.3%) of the study patients visited urban health clinics.

Table 4. Characteristics of Study Population

Clalit								
	2006		**2009**		**2012**		***P* value**	
N	132783		145241		142040		**2006-2009**	**2006-2012**
Patient's age (mean ± SD)	51.68 ± 15.16		51.16 ± 15.04		50.71 ± 14.98		<0.0001	<0.0001
	n	%	n	%	n	%		
PCPs' Age								
<29	18,778	14.14	22,004	15.15	22,049	15.52	<0.0001	<0.0001
30-39	24,941	18.78	27,847	19.17	29,538	20.80	<0.0001	<0.0001

40-49	33,929	25.55	35,652	24.55	32,393	22.81	<0.0001	<0.0001
50-59	26,818	20.20	31,251	21.52	30,717	21.63	<0.0001	<0.0001
>60	28,317	21.33	28,487	19.61	27,343	19.25	<0.0001	<0.0001
Patients' Gender								
Female	67,862	51.11	72,826	50.14	69,333	48.81	<0.0001	<0.0001
Male	64,921	48.89	72,415	49.86	72,707	51.19	<0.0001	<0.0001
Co-morbidities								
Hypertension	37,357	28.13	43,831	30.18	42,144	29.67	<0.0001	<0.0001
Cirrhosis	3190	2.40	5339	3.68	7174	5.05	<0.0001	<0.0001
Kidney disease	7659	5.77	6642	4.57	5565	3.92	<0.0001	<0.0001
Gastric ulcer	125	0.09	173	0.12	168	0.12	0.0449	0.0532
Intestinal ulcer	8590	6.47	13055	8.99	18902	13.31	<0.0001	<0.0001
Platelet disorder	14770	11.12	21595	14.87	34847	24.53	<0.0001	<0.0001
Asthma	2442	1.84	11397	7.85	12184	8.58	<0.0001	<0.0001
Coronary Artery Disease	6267	4.72	7470	5.14	7403	5.21	<0.0001	<0.0001
Aspirin allergy	491	0.37	824	0.57	1189	0.84	<0.0001	<0.0001
Taking diuretics	24602	18.53	27272	18.78	24207	17.04	0.0922	<0.0001
Taking antithrombotic agents	36989	27.86	45012	30.99	45563	32.08	<0.0001	<0.0001
Pain occurrence	8473*	6.38	49645	34.18	82215	57.88	<0.0001	<0.0001
Lower extremity symptoms	1271	0.96	2027	1.40	1834	1.29	<0.0001	<0.0001
Patient's clinic location								
rural	8021	6.00	11887	8.18	12295	8.66	<0.0001	<0.0001
urban	124664	93.89	133271	91.76	129647	91.27	<0.0001	<0.0001
Number of PCP visits (mean ± SD)	7.547 ± 6.383		8.308 ± 6.799		8.033 ± 6.504		<0.0001	<0.0001

* data requires further inspection

Maccabi

The main characteristics of the Maccabi study population are presented in Table 5. The study population ranged between 47.8-48.3% male across the study years with a mean patient age ranging between 48.1-49.3 years. The most prevalent of the specified co-morbidities were hypertension (27.0%) and the use of antithrombotic agents (28.4%).

Table 5. Characteristics of Study Population

Maccabi								
	2006		**2009**		**2012**		***P* value**	
N	61,892		66,545		76,115		**2006-2009**	**2006-2012**
Patient's age (mean ± SD)	48.1 ± 13.7		48.7 ± 13.7		49.3 ± 13.7		<0.0001	<0.0001
	n	%	n	%	n	%		
Patients' Gender								

Female	32,289	52.17	34,481	51.82	39,342	51.69	0.190	0.190
Male	29,603	47.83	32,064	48.18	36,773	48.31	0.190	0.190
Co-morbidities								
Hypertension	17,943	28.90	18,119	27.73	18,482	24.28	<0.0001	<0.0001
Cirrhosis	2,103	3.40	2,595	3.90	3,082	4.05	<0.0001	<0.0001
Kidney disease	1,023	1.65	1,089	1.64	1,154	1.52	0.080	0.080
Gastric ulcer	188	0.30	183	0.28	191	0.25	0.176	0.176
Intestinal ulcer	4,175	6.75	4,473	6.72	4,689	6.16	<0.0001	<0.0001
Platelet disorder	7,385	11.93	7,909	11.89	8,898	11.69	0.327	0.327
Asthma	2,943	4.76	2,987	4.49	2,875	3.78	<0.0001	<0.0001
Coronary Artery Disease	3,004	4.85	2,763	4.15	2,779	3.65	<0.0001	<0.0001
Aspirin allergy	96	0.16	88	0.13	93	0.12	0.245	0.245
Taking diuretics	10,782	17.42	11,446	17.20	11,965	15.72	0.0922	<0.0001
Taking antithrombotic agents	16,676	26.94	19,175	28.82	22,295	29.29	<0.0001	<0.0001
Patient's clinic location	Not available							
rural								
urban								

Study Outcomes

Clalit

A. Utilization, Prescriptions, Referrals

The results of the independent t-tests and anova tests revealed significant differences ($p<0.05$) in the mean number of 'early' and 'late' x-rays, MRIs, CTs, and bone scans utilized (per patient) when comparing the year 2006 to 2009 and the year 2006 to 2012. The mean imaging utilization of x-rays, CTs, and MRIs ('early' and 'late') all rose significantly when comparing both 2006 to 2009 and 2006 to 2012. The differences are displayed in Table 6. (The variable, 'imaging' [excluding EMG] was subdivided into 'early' and 'late' as explained in the methodology section page 8.)

The mean x-ray **imaging** utilized (both 'early' and 'late') per LBP patient, increased significantly ($p<0.05$) when comparing the years 2006 to 2009 (mean difference 'early': 0.182; 'late': 0.037) and the years 2006 to 2012 (mean difference 'early': 0.150; 'late': 0.030). The mean CT imaging utilized (both 'early' and 'late') per LBP patient, increased significantly ($p<0.05$) when comparing the years 2006 to 2009 (mean difference 'early': 0.004; 'late': 0.018) and the years 2006 to 2012 (mean difference 'early': 0.012; 'late': 0.032). See Table 6.

Table 6. Imaging Utilized per LBP Patient

CLALIT – IMAGING UTILIZATION					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
EARLY IMAGING (*Mean ± SD*)					
X-ray	0.079 ± 0.363#	0.261 ± 0.665	0.229 ± 0.663	<0.0001	<0.0001
MRI & MRA	0.004 ± 0.060	0.005 ± 0.074	0.010 ± 0.103	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	0.035 ± 0.183	0.039 ± 0.195	0.047 ± 0.213	<0.0001	<0.0001
CT Urinary Tract	0.001 ± 0.024	0.000 ± 0.016	0.001 ± 0.028	0.0024	0.0133
Bone Scan	0.010 ± 0.010	0.009 ± 0.094	0.008 ± 0.088	0.0008	<0.0001
Ultrasonography					
Kidney	0 ± 0.021	0 ± 0.019	0 ± 0.018	0.2607	0.1350
Pelvis/Hip	0.001 ± 0.039	0.001 ± 0.037	0.002 ± 0.045	0.5480	0.0005
Misc	0.010 ± 0.101	0.012 ± 0.112	0.016 ± 0.128	<0.0001	<0.0001
LATE IMAGING (*Mean ± SD*)					
X-ray	0.024 ± 0.224	0.061 ± 0.355	0.054 ± 0.345	<0.0001	<0.0001
MRI, MRA	0.003 ± 0.056	0.005 ± 0.069	0.007 ± 0.085	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	0.081 ± 0.273	0.099 ± 0.299	0.113 ± 0.317	<0.0001	<0.0001
CT Urinary Tract	0.000 ± 0.022	0.000 ± 0.018	0.001 ± 0.024	0.0280	0.2488
Bone Scan	0.026 ± 0.161	0.022 ± 0.148	0.017 ± 0.130	<0.0001	<0.0001
Ultrasonography					
Kidney	0.001 ± 0.025	0.000 ± 0.019	0.000 ± 0.014	0.0109	<0.0001
Pelvis/Hip	0.001 ± 0.032	0.001± 0.033	0.002 ±0.043	0.7565	<0.0001
Misc	0.009 ± 0.099	0.011 ± 0.111	0.015 ± 0.126	<0.0001	<0.0001
EMG	0.063 ± 0.257	0.063 ± 0.258	0.062 ± 0.257	0.6922	0.3243

data needs further inspection

When comparing the years 2006 to 2009 and 2006 to 2012 as regards **medication** prescribed and purchased, a significant difference ($p<0.05$) was found between the mean number of medications both *prescribed* and *purchased* in the following drug categories: analgesics, NSAIDs, anti-convulsants, anti-depressants, anti-anxiety, and muscle relaxants (with the exclusion of the mean number of analgesics and anti-anxiety medication *prescribed* only when comparing 2006 and 2012). These results can be seen in Table 7.

The mean number of NSAIDS *prescribed* per LBP patient increased significantly ($p<0.05$) when comparing the years 2006 to 2009 (mean difference: 0.427) and the years 2006 to 2012 (mean difference: 0.342). The mean number of prescriptions given by PCPs for anti-depressant (mean difference 2006/2009: 0.333 & 2006/2012: 0.573), anti-convulsant (mean difference 2006/2009: 0.014 & 2006/2012: 0.020), and for anti-anxiety (mean difference 2006/2009: 0.035) medication also increased significantly.

As regards the mean medications purchased, there was a significant increase in anti-convulsant (mean difference 2006/2009: 0.004; mean difference 2006/2012: 0.005) and anti-depressant (mean difference 2006/2009: 0.077; mean difference 2006/2012: 0.123) purchases. It is interesting to note that the mean number of analgesics (mean difference 2006/2009: -0.047; mean difference 2006/2012: -0.555), NSAIDs (mean difference 2006/2009: -0.125; mean difference 2006/2012: -0.172), anti-anxiety (mean difference 2006/2009: -0.107; mean difference 2006/2012: - 0.167), and muscle relaxants (mean difference 2006/2009: - 0.020; mean difference 2006/2012: -0.064) *purchased,* all decreased significantly during the two periods being compared.

Table 7. Medication Prescribed & Purchased per LBP Patient

CLALIT – MEDICATION PRESCRIBED & PURCHASED					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Medication *prescribed* (Mean ± SD)					
Analgesics	1.056 ± 2.689	1.383 ± 3.265	1.058 ± 3.860	<0.0001	0.8590
NSAIDs	1.630 ± 2.597	2.057 ± 2.835	1.972 ± 2.757	<0.0001	<0.0001
Anti-convulsants	0.012 ± 0.323	0.026 ± 0.537	0.032 ± 0.629	<0.0001	<0.0001
Anti-depressants	0.804 ±3.240	1.137 ±4.113	1.377 ±4.894	<0.0001	<0.0001
Anti-anxiety	0.609 ±2.634	0.644 ±2.852	0.619 ±2.909	0.0009	0.3530
Muscle relaxants	0.184 ±0.722	0.221 ±0.799	0.165± 0.768	<0.0001	<0.0001
Medication *purchased* (Mean ± SD)					
Analgesics	2.070± 4.343	2.023± 4.274	1.515 ±3.668	0.0022	<0.0001
NSAIDs	2.260± 3.216	2.135± 3.047	2.088± 2.950	<0.0001	<0.0001
Anti-convulsants	0.009 ±0.250	0.013 ±0.292	0.014 ±0.315	<0.0001	<0.0001
Anti-depressants	0.618 ±2.463	0.695 ±2.690	0.741 ±2.846	<0.0001	<0.0001

Anti-anxiety	0.523 ±2.119	0.416 ±1.892	0.356 ±1.741	<0.0001	<0.0001
Muscle relaxants	0.187 ±0.702	0.167 ±0.666	0.123 ±0.594	<0.0001	<0.0001

A significant increase in the number of **referrals to PT** (for both periods compared) is seen in Table 8 as well as in the number of PT visits utilized (only when comparing 2006 and 2009).

Table 8. Physiotherapy Prescribed & Utilized per LBP Patient

CLALIT – PHYSIOTHERAPY					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Physiotherapy referrals *(Mean ± SD)*	0.074 ± 0.303	0.084 ± 0.324	0.079 ± 0.310	<0.0001	<0.0001
Physiotherapy visits (*Mean ± SD*)	0.503±2.416	0.526 ± 2.398	0.489 ± 2.300	0.0127	0.1220

When analyzing the mean number of **specialist visits** utilized per patient, a significant decrease is apparent for both periods with regard to orthopedists and neurologists and relevant for rheumatologists when comparing 2006 to 2012. Results are displayed in Table 9. A significant decrease was noted in the mean number of lumbar injections utilized for both time periods (Table 9). In contrast, a significant increase was demonstrated in the mean lumbar surgery utilized, when comparing 2006 to 2012.

Table 9. Specialist Visits per LBP Patients

CLALIT – SPECIALIST VISITS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Specialist visits *(Mean ± SD)*					
Orthopedist	1.041 ±1.819	1.001 ±1.739	0.917 ±1.624	<0.0001	<0.0001
Neurologist	0.159 ±0.644	0.150 ±0.612	0.136 ±0.576	0.0003	<0.0001
Rheumatologist	0.023 ±0.234	0.024 ±0.237	0.019 ±0.201	0.2069	<0.0001

A significant decrease was noted in the mean number of lumbar injections utilized for both time periods (Table 10). In contrast, a significant increase was demonstrated in the mean lumbar surgery utilized, when comparing 2006 to 2012.

Table 10. Lumbar Injections and Surgery Utilized

CLALIT – INJECTIONS & SURGERY					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Lumbar injections *(Mean ± SD)*	0.034 ±0.278	0.029 ±0.234	0.021 ±0.190	<0.0001	<0.0001
Lumbar surgery (*Mean ± SD)*	0.009 ±0.102	0.010 ±0.109	0.012 ±0.119	0.0215	<0.0001

B. Costs

The ANOVA tests demonstrated that the mean **imaging** costs of x-rays, CTs, and MRIs ('early' and 'late') all rose significantly when comparing both 2006 to 2009 and 2006 to 2012. Results are in Table 11.

Table 11. Imaging Costs (IS, 2018)

CLALIT – IMAGING COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
EARLY IMAGING (Mean± SD)					
X-ray	10.558 ± 48.724#	34.950 ± 89.220	30.747 ± 89.017	<0.0001	<0.0001
MRI & MRA	7.938 ± 132.344#	11.945 ± 162.133	23.021 ± 227.274	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	46.102 ± 243.859	52.753 ± 260.185	63.357 ± 283.958	<0.0001	<0.0001
CT Urinary Tract	0.365 ± 16.204	0.183 ± 11.174	0.514 ± 19.058	0.0024	0.0133
Bone Scan	12.177 ± 120.191	10.737 ± 112.764	9.330 ± 105.370	0.0008	<0.0001
Ultrasonography					
Kidney	0.551 28.822	0.439 25.408	0.401 24.926	0.2607	0.1350
Pelvis/Hip	0.694 ± 18.195	0.651 ± 17.441	0.949 ± 21.271	0.5480	0.0005

Misc	4.628 ± 47.434	5.442 ± 52.437	7.282 ± 60.090	<0.0001	<0.0001
LATE IMAGING (Mean ± SD)					
X-ray	3.282 ± 30.076#	8.181 ± 47.598	7.264 ± 46.266	<0.0001	<0.0001
MRI, MRA	6.830 ± 123.169#	10.297 ± 152.215	15.847 ± 187.691	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	108.101 ± 364.333	132.293 ± 399.053	150.935 ± 422.929	<0.0001	<0.0001
CT Urinary Tract	0.334 ± 15.086	0.211 ± 12.003	0.399 ± 16.679	0.0280	0.2488
Bone Scan	31.643 ± 192.145	26.732 ± 176.832	20.663 ± 155.837	<0.0001	<0.0001
Ultrasonography					
Kidney	0.715 ± 34.103	0.457 ± 25.406	0.258 ± 18.694	0.0109	<0.0001
Pelvis/Hip	0.479 ± 14.970	0.499 ± 15.477	0.834 ± 20.197	0.7565	<0.0001
Misc	4.374 ± 46.261	5.352 ± 51.984	6.787 ± 59.035	<0.0001	<0.0001
EMG	36.119 ± 148.184	36.342 ± 148.789	35.561 ± 148.365	0.6922	0.3243

Data needs further inspection

With regard to medication, a significant rise was seen in the mean cost per patient for anti-convulsants and for anti-depressants when comparing both 2006 to 2009 and to 2012. A significant decline in mean cost per patient was revealed for: analgesics, NSAIDs, anti-anxiety, and muscle relaxants in both time periods being compared. Figures are displayed in Table 12.

Table 12. Medication Costs (IS, 2018)

CLALIT – MEDICATION COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Medications purchased *(mean ± SD)*					
Analgesics	394.85 ± 829.04	385.76 ± 815.81	288.81 ± 700.12	0.0022	<0.0001
NSAIDs	131.08 ± 186.67	123.87 ± 176.82	121.15 ± 171.17	<0.0001	<0.0001
Anti-convulsants	0.98 ± 28.17	1.48 ± 32.89	1.54 ± 35.58	<0.0001	<0.0001
Anti-depressants	35.63 ± 142.23	40.10 ± 155.35	42.74 ± 164.31	<0.0001	<0.0001

Anti-anxiety	12.716 ± 51.65	10.111 ± 46.11	8.65 ± 42.43	<0.0001	<0.0001
Muscle relaxants	56.84 ± 213.18	50.72 2 ± 2 202.18	37.34 ± 180.20	<0.0001	<0.0001

A significant rise in **PT** cost was seen just when comparing 2006 to 2009 (Table 13).

Table 13. Costs of Physiotherapy Visits (IS, 2018)

CLALIT – PHYSIOTHERAPY COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Physiotherapy (*Mean ± SD*)	15.10 ± 72.48	15.77 ± 71.93	14.68 ± 69.00	0.0127	0.1220

A significant decrease was revealed when comparing costs of specialists' visits during both study periods (with the exception of rheumatologists in 2006 compared to 2009). See Table 14.

Table 14. Costs of Specialist Visits (IS, 2018)

CLALIT – SPECIALISTS COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Specialist *(Mean ± SD)*					
Orthopedist	152.00 ± 265.53	146.20 ± 253.90	133.84 ± 237.10	<0.0001	<0.0001
Neurologist	23.15 ± 94.01	21.92 ± 89.35	19.92 ± 84.08	0.0003	<0.0001
Rheumatologist	3.32 ± 34.23	3.48 ± 34.57	2.77 ± 29.40	0.2069	<0.0001

Regarding lumbar injection, there was a significant decrease in the costs during both study periods compared. On the other hand, the cost for lumbar surgery rose significantly when comparing both time periods (Table 15).

Table 15. Injections & Surgery Costs (IS,2018)

CLALIT – INJECTIONS & SURGERY COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Lumbar injections *(Mean ± SD)*	18.52 ± 149.82	15.37 ± 126.13	11.19 ± 102.44	<0.0001	<0.0001

Lumbar surgery (*Mean ± SD)*	433.17 ± 4771.31	478.31 ± 5099.54	583.81 ± 5585.96	0.0215	<0.0001

The total mean LBP utilization cost per LBP patient rose when comparing both 2006 to 2009 (mean difference: 60.13, significant) and 2006 to 2012 (mean difference: 35.99, significant).

Table 16. Total Mean LBP Utilization Costs Per Patient (IS,2018)

Clalit- Total Mean LBP Utilization Costs Per Patient					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Total mean LBP utilization costs per patient	2020.54	2080.67	2056.53	0 .0051	0.0954

The multivariate regression, taking into account the possibility of repeated observations in repeated cohorts, indicated no significant difference between mean LBP costs in 2006 and in 2009 (8.59 NIS). The difference became negatively significant between 2006 and 2012 (61.57 NIS). Results are displayed in Table 16.

Table 17. Multivariate Regression with Repeated Measures Analysis

Effect	**Estimate**	**Std Error**	**t value**	**p-value**
(Intercept)	684.328	77.690	8.808	0.000000
Patient age	24.767	0.832	29.779	0.000000
Patient Gender	-187.556	19.846	-9.450	0.000000
Hypertension	201.583	28.261	7.133	0.000000
Cirrhosis	355.801	50.244	7.081	0.000000
Kidney disease	-71.951	49.407	-1.456	0.145312
Gastric ulcer	1047.036	288.878	3.624	0.000290
Intestinal ulcer	452.380	32.446	13.942	0.000000
Platelet disorder	156.612	26.213	5.975	0.000000
Asthma	262.165	39.269	6.676	0.000000
Coronary artery disease	206.056	47.837	4.307	0.000017
Aspirin allergy	1026.630	122.698	8.367	0.000000
Taking diuretics	252.822	31.798	7.951	0.000000
Taking antithrombotic agents	562.664	25.856	21.761	0.000000
Rural/Urban	-101.470	35.534	-2.856	0.004295
Cohort 2009 (vs. 2006)	**8.590**	**23.861**	**0.360**	**0.718857**
Cohort 2012 (vs. 2006)	**-61.573**	**24.511**	**-2.512**	**0.012003**
PCP age	-1.637	1.192	-1.374	0.169403

Maccabi

A. Utilization, Prescriptions, Referrals

The results of the one-way anova and the chi-square tests revealed significant differences ($p<0.05$) in the mean number of **x-rays, MRIs, CTs, and EMGs** utilized (per patient) when comparing the year 2006 to 2009 and the year 2006 to 2012. The mean imaging utilization of x-rays decreased significantly when comparing 2006 to 2012, while the mean utilization of CTs and MRIs both rose significantly when comparing both 2006 to 2009 and 2006 to 2012. The differences are displayed in Table 18.

Table 18. Imaging Utilized per LBP Patient

MACCABI – IMAGING UTILIZATION					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
IMAGING (*Mean ± SD*)					
X-ray	0.21 ± 0.49	0.21 ± 0.49	0.18 ±0.46	NS	<0.0001
MRI	0.009±0.10	0.015±0.13	0.018±0.14	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	0.009±0.33	0.10 ± 0.35	0.11 ± 0.37	<0.0001	<0.0001
EMG	0.047±0.23	0.051±0.24	0.051±0.24	0.006	0.006

When comparing the years 2006 to 2009 and 2006 to 2012 as regards **medication** purchased, a significant difference ($p<0.05$) was found between the mean number of medications purchased in the following drug categories: anti-convulsants and anti-depressants. These results can be seen in Table 19.

The mean number of anti-convulsants and anti-depressants purchased increased significantly when comparing both study periods.

Table 19. Medication Purchased per LBP Patient

MACCABI– MEDICATION PURCHASED					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Medication *purchased (Mean ± SD)*					
Analgesics	1.58 ± 3.50	1.57 ± 3.46	1.42 ± 3.30	NS	NS
NSAIDs	1.91 ± 2.67	1.89 ± 2.72	1.92 ± 2.74	NS	NS

Anti-convulsants	0.32 ± 2.38	0.37 ± 2.54	0.43 ± 2.71	0.001	0.001
Anti-depressants	0.90 ± 3.59	1.06 ± 4.06	1.24 ± 4.49	<0.001	<0.001
Anti-anxiety	1.29 ± 4.51	1.24 ±4.43	1.22 ± 4.53	0.074	0.074
Muscle relaxants	0.027±0.041	0.023±0.036	0.014±0.033	0.103	0.103

A significant increase in the number of **visits to PT** was seen when comparing 2006 to 2012. Results are displayed in Table 20.

Table 20. Physiotherapy Utilized per LBP Patient

MACCABI – PHYSIOTHERAPY					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Physiotherapy visits (*Mean ± SD*)	2.31±5.81	2.27 ± 5.58	2.33 ± 5.70	NS	<0.001

When analyzing the mean number of **specialist visits** utilized per patient, a significant decrease is apparent when comparing 2006 and 2012 with regard to orthopedists. Regarding visits to neurologists, rheumatologists, and neurosurgeons, a significant rise was revealed when comparing both study periods. Results are displayed in Table 21.

Table 21. Specialist Visits per LBP Patients

MACCABI – SPECIALIST VISITS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Specialist visits *(Mean ± SD)*					
Orthopedist	1.89 ±2.80	1.89 ±2.79	1.83 ±2.67	NS	<0.001
Neurologist	0.30±1.10	0.31±1.09	0.31±1.07	<0.001	<0.001
Rheumatologist	0.05 ±0.41	0.06 ±0.40	0.06 ±0.45	0.024	0.024
Neurosurgeon	0.003±0.11	0.004±0.09	0.004±0.10	0.032	0.032

B. Costs

The ANOVA tests demonstrated that the mean **imaging** cost of x-rays decreased significantly when comparing 2006 to 2012. The mean cost of CTs, MRIs, and

EMGs rose significantly when comparing both 2006 to 2009 and 2006 to 2012. Results are in Table 22.

Table 22. Imaging Costs (IS, 2018)

MACCABI– IMAGING COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
IMAGING (*Mean ± SD*)					
X-ray	28.6 ± 66.0	27.5± 66.0	25 ± 61.5	NS	<0.0001
MRI	20.5 ± 229.3	32.1 ± 287.9	39.8 ± 315.8	<0.0001	<0.0001
CT (lumbar, sacral, pelvis, hip, LEX)	121.3±444.9	137.8±473.4	150.4±489.8	<0.0001	<0.0001
EMG	27.3±132.7	29.3±138.1	29.5±137.6	0.006	0.006

With regard to medication, a significant rise was seen in the mean cost per patient for anti-convulsants and for anti-depressants when comparing both 2006 to 2009 and to 2012. A significant decline in mean cost per patient was revealed for analgesics when comparing 2006 to 2012. Figures are displayed in Table 23.

Table 23. Medication Costs (IS, 2018)

MACCABI – MEDICATION COSTS					
	2006	**2009**	**2012**	***P* value**	
				2006-2009	**2006-2012**
Medications purchased *(mean ± SD)*					
Analgesics	302.5±667.4	300.4±661.4	270.2±629.9	NS	NS
NSAIDs	110.9±155.3	110.0±157.9	111.8±159.2	NS	NS
Anti-convulsants	35.7±268.4	41.2±286.8	48.2±305.3	0.001	0.001
Anti-depressants	52.2±207.7	62.7±234.9	71.7±259.3	<0.001	<0.001
Anti-anxiety	31.4±110.1	30.3±108.2	29.9±110.6	0.074	0.074
Muscle relaxants	8.1±126.0	7.0±107.9	4.3±101.2	0.103	0.103

A significant rise in **PT** cost was seen just when comparing 2006 to 2012 (Table 24).

Table 24. Costs of Physiotherapy Visits (IS, 2018)

MACCABI – PHYSIOTHERAPY COSTS					
	2006	2009	2012	*P* value	
				2006-2009	2006-2012
Physiotherapy (*Mean ± SD*)	69.2±174.19	68.16±167.52	69.98±171.13	NS	<0.001

A significant decrease was revealed when comparing costs of specialists' visits during both study periods (with the exception of orthopedists in 2006 compared to 2009). See Table 25.

Table 25. Costs of Specialist Visits (IS, 2018)

MACCABI – SPECIALISTS COSTS					
	2006	2009	2012	*P* value	
				2006-2009	2006-2012
Specialist *(Mean ± SD)*					
Orthopedist	276.87±408.48	276.13±407.31	267.27±389.69	NS	<0.001
Neurologist	44.0±160.1	45.91±158.89	45.37±155.5	<0.001	<0.001
Rheumatologist	7.23±59.15	7.4±58.84	9.05±65.36	0.024	0.024
Neurosurgeon	0.5±16.2	0.54±13.68	0.6 ±13.9	0.032	0.032

The total mean LBP utilization cost per LBP patient rose when comparing both 2006 to 2009 (mean difference: 39.58, significant) and 2006 to 2012 (mean difference: 36.33, significant).

Table 26. Total Mean LBP Utilization Costs Per Patient (IS,2018)

Maccabi- Total Mean LBP Utilization Costs Per Patient					
	2006	2009	2012	*P* value	
				2006-2009	2006-2012
Total mean LBP utilization costs per patient	1136.42±1512.68	1176±1560.78	1172.75±1559.48	<0.001	<0.001

The multivariate regression, taking into account the possibility of repeated observations in repeated cohorts, indicated a significant rise between mean LBP costs in 2006 and in 2009 (26.7 NIS) and between 2006 and 2012 (29.6 NIS). Results are displayed in Table 27.

Table 27. Multivariate Regression with Repeated Measures Mixed-effect Model

Variable	B (SE)	Z	P
(Constant)	186.0 (46.8)	3.97	<0.001
Sex	209.9 (6.9)	30.33	<0.001
Age	17.1 (0.3)	54.42	<0.001
Anti Thrombotic	276.6 (9.2)	30.22	<0.001
Diuretic	256.3 (11.0)	23.25	<0.001
Allergy to Aspirin	441.2 (94.4)	4.68	<0.001
Cirrhosis	258.5 (18.3)	14.14	<0.001
Asthma	238.1 (16.9)	14.05	<0.001
CAD	153.7 (18.4)	8.34	<0.001
Gastric ulcer	490.4 (67.8)	7.23	<0.001
Hypertension	162.9 (9.6)	16.89	<0.001
Intestinal ulcer	237.8 (14.2)	16.76	<0.001
Kidney	155.7 (28.3)	5.49	<0.001
Platelet	238.0 (46.8)	3.97	<0.001
Year = 2009 (Reference: 2006)	**26.7 (7.6)**	**3.50**	**<0.001**
Year = 2012 (Reference: 2006)	**29.6 (7.5)**	**3.94**	**<0.001**
District (Reference=0)			
1	-550.8 (44.4)	-12.41	<0.001
2	-423.9 (44.5)	-9.54	<0.001
3	-408.0 (44.4)	-9.18	<0.001
4	-409.3 (44.2)	-9.25	<0.001
5	-444.8 (44.4)	-10.02	<0.001

Discussion and Conclusions

The present study assessed the patterns and costs of LBP treatments in the Clalit and Maccabi health services in the years 2006 (before the introduction of the LBP guidelines), 2009, and 2012 (after).

Clalit

We found the treatment patterns with regard to imaging, certain medications, referrals to PT, and lumbar surgery to be inconsistent with the IMA LBP guidelines and thus inappropriate. This was demonstrated by the significant rise in: 1) imaging utilization 2) the prescription of anti-depressants 3) the purchasing of anti-depressants and of anti-convulsants 4) referrals to PT and 5) lumbar surgery utilization. The study revealed a significant increase in the total LBP expenditure, resulting from the increase utilization of the abovementioned LBP services. However, when controlling for patients' characteristics and the ages of the PCPs, the total LBP cost increase between 2006 and 2009 was not significant. A significant total LBP cost decrease was revealed when comparing 2006 to 2012. These results might indicate that PCPs adopted the LBP guidelines with some lag.

Maccabi

We found the treatment patterns with regard to imaging, certain medications, visits to PT and to specialists to be inconsistent with the IMA LBP guidelines and thus inappropriate. This was demonstrated by the significant rise in: 1) imaging utilization 2) the purchasing of anti-depressants and of anti-convulsants 3) visits to PT and 4) visits to specialists.

When comparing 2006 to 2012, a significant decrease in x-ray imaging and in visits to orthopedists was revealed, possibly a more hopeful finding. Although, when controlling for patients' characteristics, the total LBP cost increase seen between 2006 and 2009, and between 2006 and 2012 remained stable and significant, a less encouraging finding.

As mentioned in the scientific background section, the finding of guideline-discordant LBP treatment among PCPs has also been demonstrated in other studies.

The decrease in costs observed for specialist visits and for lumbar injections (in Clalit) is a hopeful finding, implying guideline-consistent, appropriate behavior.

The significant rise in lumbar surgery costs is not encouraging. Although they are small, the percentages of patients undergoing lumbar surgery rose from 0.09 percent in 2006 to 1.15 percent in 2012. The large 2019 US study by Kim et al. also showed that only a small proportion of patients had surgery (1.2%) and emphasized

that those who underwent surgical intervention accounted for almost thirty percent of the total 12-month expenditures tracked in their study.[27]

This was the first Israeli study, to our knowledge, to assess real practice patterns reflecting the appropriateness of the LBP care being provided by PCPs in Clalit and in Maccabi. The review of medical records allowed for measuring compliance in a real-world setting and for a large study sample.

Due to data availability limitations, we used utilization data and not referral/prescription data which may have better reflected PCP guideline-adherence. As prescription data became comprehensive in Clalit in 2008, this may have affected the accuracy of the 2006 prescription results. The medication group entitled 'analgesics' included both simple analgesics plus opioids. This limited our ability to draw conclusions regarding each type of these medications separately.

To conclude, this study has shown that PCPs continue to provide LBP treatments which are inconsistent with guidelines and thus inappropriate and not cost-effective. This was demonstrated by the significant rise in: 1) imaging utilization 2) the prescription of anti-depressants 3) the purchasing of anti-depressants and anti-convulsants 4) referrals to PT 5) visits to PT 6) visits to specialists and 7) lumbar surgery utilization. The study revealed a significant increase in the total LBP expenditure in both Clalit and Maccabi, resulting from the increased utilization of the abovementioned LBP services.

In Clalit, the results relating to certain medications, referrals to specialists, and the decrease in total mean costs between 2006 and 2012 (revealed in the regression analysis) may indicate some guideline-consistent behavior. In Maccabi, some decline in x-ray utilization and in visits to orthopedists may indicate guideline consistent behavior.

Policy Implications and Recommendations

Our study results emphasize the need for improving LBP guideline implementation by Israeli PCPs to provide appropriate patient care and to reduce LBP related national expenditure. Exploration of effective implementation programs is required. Incentives to PCPs may prove an effective method.

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