Overutilisation of imaging in the management of low back pain

Hazel Jenkins

BMedSc, MChir, MappSc(MI)



Department of Health Professions

Faculty of Medicine and Health Sciences

Macquarie University

Sydney, Australia

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Supervisors' statement

As supervisors of Hazel Jenkins's doctoral work, we certify that we consider her thesis "Overutilisation of imaging in the management of low back pain" to be suitable for examination.

Prof Mark Hancock			
Department of Health Professions			
Faculty of Medicine and Health Sciences	Date: 13/03/2019		
Macquarie University			
Dr Niamh Moloney			
Department of Health Professions			
Faculty of Medicine and Health Sciences	Date: 13/03/2019		
Macquarie University			
Prof John Magnussen			
Department of Clinical Medicine			
Faculty of Medicine and Health Sciences	Date: 13/03/2019		
Macquarie University			

Candidate's statement

I, Hazel Jenkins, hereby declare that the work contained within this thesis, "Overutilisation of

imaging in the management of low back pain", is my own and has not been submitted to any

other university or institution, in part or in whole, as a requirement of a degree.

I, Hazel Jenkins, hereby declare that I was the principal researcher of all work included in this

thesis, including the work published with multiple authors.

I, Hazel Jenkins, hereby declare that this thesis is an original piece of work and it is written by

me. Any assistance that I have received in the preparation of this thesis has been

appropriately acknowledged. In addition, I also certify that all information sources and

literature are indicated in this thesis.

Signed

15 March 2019

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Publications, presentations and awards

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Presentations

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CAA NSW conference, Sydney, Australia, September 2015. Jenkins HJ, Hancock MJ, Maher CG, French SD, Magnussen JS. Understanding patient beliefs regarding the use of imaging in the management of low back pain. *Poster*

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XIV International Forum for Back and Neck Pain Research in Primary Care, Buxton, England, June 2016. Jenkins HJ, Hancock MJ, Maher CG, French SD, Magnussen JS. Understanding patient beliefs regarding the use of imaging in the management of low back pain. *Poster*

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Abstract

Low back pain is one of the leading causes of disability globally and is associated with significant costs to the health care system. Improving the management of low back pain is necessary to optimise patient outcomes while minimising associated costs. For the majority of people with low back pain their pain cannot be attributed to a specific cause and the use of medical imaging does not improve management of these patients. Imaging is only indicated infrequently, in cases where serious pathology (e.g. malignancy or infection) is suspected. Overuse of imaging has been associated with increased healthcare costs and risks such as overdiagnosis, with the potential for further inappropriate investigations and treatments, increased rates of surgery, and radiation exposure. Effective interventions to reduce the use of non-indicated imaging would help improve patient management and reduce associated healthcare costs.

The work presented in this thesis details the development of an intervention to reduce the use of non-indicated imaging for low back pain. Systematic reviews were performed to assess the extent of overuse of imaging for low back pain (Chapter 2) and the effectiveness of previously tested interventions to reduce imaging (Chapter 3), followed by a survey to establish whether patients believe imaging to be important in the management of low back pain (Chapter 4). The results of these studies indicated the need for a novel intervention to reduce imaging for low back pain, addressing both practitioner and patient related barriers. Chapters 5 and 6 describe the development and preliminary testing of this intervention.

The development of the intervention was systematically performed using the Behaviour Change Wheel and the Theoretical Domains Framework. Development of the intervention was informed by experts in the field of low back pain and key stakeholders, including general practitioners and healthcare consumers (Chapter 5). Finally, a qualitative study was performed to assess general practitioners' experiences using the intervention in clinical practice. Barriers and facilitators to using the intervention in clinical practice were identified and used to inform implementation strategies of the final intervention (Chapter 6). The developed intervention incorporates a low back pain education and management booklet, designed to be used by general practitioners with patients during a clinical consult, and a training session to instruct practitioners in the use of the booklet. The booklet can be used by general practitioners to screen patients for the need for imaging, reassure and educate

patients about their low back pain (and where appropriate why imaging isn't required), and provide customised management advice to the patient. The intervention was found to be useful by general practitioners, likely to reduce non-indicated imaging as designed, and suitable for future effectiveness testing.

Chapter 1

Introduction

1.1 The nature and impact of low back pain

1.1.1 Definition of low back pain

Low back pain is defined as pain between the lower ribs and the lower gluteal folds (1), and may be associated with pain and/or neurological symptoms into the lower limb(s) (2). Symptomatic presentation is often classified as acute (pain less than 6 weeks), subacute (pain between 6 to 12 weeks), and chronic (pain greater than 12 weeks); however, this does not reflect the individual variability in pain presentation and prognosis (as presented in section 1.1.2 below) and the value of this classification is challenged by the recurrent nature of low back pain (3, 4).

1.1.2 Prognosis of low back pain

A 2003 systematic review of low back pain prognosis presented the average course of recovery, with most cases of low back pain thought to undergo rapid improvement in the first four weeks, followed by slower improvement up to twelve weeks, before plateauing (5). More recently, data driven statistical methods (e.g. latent class analysis, hierarchical cluster analysis) have been used to further assess low back pain prognosis (6). Multiple trajectories of recovery from acute low back pain have subsequently been identified, complicating the prognosis of low back pain (6). These include: rapid recovery, gradual recovery, fluctuating pain, persistent mild pain, and persistent severe pain (6). Currently the exact trajectory of low back pain recovery cannot be reliably predicted for individual patients. Factors associated with an increased risk of persistent pain have been identified, including: back pain of high intensity, presence of leg pain, smoking, depression, pain catastrophizing and fear avoidance behaviours, higher physical work demands, lower education level, compensable work injury, and lower work satisfaction (2, 7). However, none of these individual factors strongly predict the course of low back pain (8). Nonetheless, screening tools such as the STarT Back Tool (9, 10) and the Orebro Musculoskeletal Pain Questionnaire (11, 12) have been developed and validated to identify people at greater risk of persistent pain.

1.1.3 Recurrence of low back pain

Further complicating the clinical picture of low back pain is the recurrent nature of the condition (4). Reported one year recurrence rates vary from 24% (13) to 82% (3), depending on study design, follow-up period, method of data collection, and definition of recovery and recurrence. A systematic review of low back pain recurrence rates (14) found that available studies were too heterogenous to perform meta-analysis. An important limitation of most included studies was the lack of an inception cohort design. Two studies using inception cohorts have found recurrence rates of 33% (13) and 54% (15) by 12 months. Predictors of recurrence have been investigated and only a clinical history of two or more previous episodes of low back pain was consistently associated with increased risk of recurrence (15, 16).

1.1.4 Prevalence of low back pain

Low back pain is a common condition, but estimates of prevalence vary substantially based on differences in methodology, included population, and definitions of low back pain between prevalence studies (17, 18). These differences result in reported prevalence rates ranging from 12% to 33% for point prevalence and 11% to 84% for lifetime prevalence (17). A number of factors may impact the prevalence rate of low back pain and higher rates have been reported within high-income countries and among females (18). Although low back pain occurs across the lifespan (4, 18, 19), prevalence rates are higher in adults in their 5th to 7th decades (18). Prevalence rates for low back pain do not appear to be increasing over time (18). Although the number of people with back pain globally increased by 17% between 2005 and 2015 (20), this is likely due to increasing population numbers and an aging population, rather than an increase in prevalence rates (2, 18).

1.1.5 Low back pain disability

The disability associated with low back pain is a global problem, which is increasing with time. Due to the prevalence and the often chronic and recurrent nature of low back pain, it is the leading cause of years lived with disability globally (1, 20, 21) and the fourth highest contributor to disease burden as measured in disability adjusted life years (22). In 50% of all countries worldwide, low back pain is the leading cause of disability, and it is in the top four causes in the remaining countries (21). The amount of disability associated with low back pain is increasing over time, with an 18% increase in years lived with disability between

2006 to 2016 (21), likely reflecting an increasing and ageing population (2, 18). Low back pain is a significant contributor to chronic pain burden (23), restriction in activities of daily living (24-27), and work absenteeism (27-29).

1.1.6 Cost of low back pain

Costs related to low back pain are high, and involve both direct and indirect costs (30). Direct costs are those that involve a monetary exchange such as medical consultations, imaging studies, and medication use (30). Indirect costs are those where there is no monetary exchange, such as reduced work place productivity from absenteeism, or lost household productivity (30). In 1996 low back pain was ranked as the sixth most costly health condition in the United States, with national direct costs of USD12 billion (27). In 2013, the third highest expenditure for personal health costs in the United States was combined low back and neck pain, accounting for direct costs of USD87.6 billion (31). Other studies have reported direct annual costs in the United States of USD13 billion in 2000 to USD25billion in 2007 (32). Indirect costs are likely to be substantially higher, but are difficult to calculate (30). A systematic review of cost of low back pain studies (30) found the median ratio of indirect to direct costs to be nearly six to one. In Australia, indirect costs for low back pain were calculated at AUD8.1 billion in 2001 (33), AUD15.6 billion in 2015 (34), and have been projected to increase to AUD21.8 billion in 2030 (34).

1.2 Diagnosis and management of low back pain

1.2.1 Diagnosis of low back pain

Diagnosis of the exact underlying cause of low back pain is often difficult. Low back pain may be attributable to serious pathology (e.g. cancer, infection, referral from organ pathology), acute trauma (e.g. fracture), or other anatomical structures within the low back (e.g. intervertebral discs, vertebral endplates, spinal nerves, muscles, or joints) (2, 7, 35-39).

Medical investigations, such as imaging, lack diagnostic accuracy for identifying nociceptive sources of low back pain for the majority of patients (7, 38), but aid in the diagnosis when there is strong clinical suspicion of serious underlying pathology (e.g. malignancy, infection, or fracture) (7). This lack of diagnostic certainty can make decisions regarding appropriate management difficult for clinicians.

1.2.2 Clinical practice guidelines

Clinical practice guidelines have been developed to aid clinicians in the appropriate assessment and management of low back pain. A comparison of international guidelines for low back pain found the main messages regarding assessment to be generally consistent (40). These include: 1) perform a diagnostic triage to direct appropriate management; 2) only use imaging if serious pathology is suspected, or imaging results are likely to change patient management; and 3) perform an assessment of psychosocial prognostic factors to identify patients with increased risk of chronicity (40).

1.2.3 Diagnostic triage

Diagnostic triage uses specific history and clinical examination findings to classify patients presenting with low back pain into one of three categories: serious spinal pathology, radicular pain/radiculopathy, or non-specific low back pain (35, 37, 40, 41).

1.2.4 Serious spinal pathology

Less than 5% of all low back pain presentations are caused by serious spinal pathology for which a specific diagnosis is required to direct appropriate management (e.g. vertebral fracture, malignancy, infection, cauda equina syndrome, and axial spondyloarthritis) (37, 42-44). Studies assessing the imaging findings of consecutive patients presenting with low back pain in primary care consistently report prevalence rates of malignancy, infection, and cauda equina syndrome at less than 1% (42, 44-46). Prevalence rates for new vertebral fractures that are likely to be associated with low back pain have also been reported at less than 1% (42, 46-48). Higher prevalence rates for vertebral fracture of 5% (44) and 9% (45) have been reported; however, these studies are not specific to new vertebral fractures and include vertebral compression from old fractures that might not be the cause of current pain presentations. De Schepper et al. (46) assessed MRI images for old and new vertebral fractures and found prevalence rates of 3% and 0.8% respectively. The prevalence of axial spondyloarthritis is estimated at up to 1.4% of the population (49), and up to 5% of low back pain presentations (50); however, other studies have found prevalence rates of less than 1% (42, 44, 48). The higher prevalence rates were found in patients with more chronic low back pain presentations and it is likely that the lower prevalence rates are more accurate for acute pain presentations.

To aid diagnostic triage, clinical practice guidelines for low back pain endorse a number of clinical findings, known as 'red flags' that indicate the increased likelihood of serious spinal pathology, and the potential need for further investigation (7, 40).

1.2.4.1 Red flags for serious spinal pathology

The use of red flags to direct diagnostic triage in the management of low back pain has been included in many clinical practice guidelines (7, 40, 51) since the release of the Agency for Health Care Policy and Research guidelines for the management of acute low back pain in 1994 (52). Comparison of clinical practice guidelines show some red flags to be consistently reported as being useful to assess for serious pathology (40); however, strong diagnostic accuracy has not been consistently demonstrated (53). The red flags most consistently reported in guidelines are for: malignancy (history of malignancy and unexpected weight loss); fracture (significant trauma and prolonged use of corticosteroids); and infection (fever and history of HIV) (40). Many other red flags are also reported in the literature, but show high variability (51, 53-55), lack evidence of diagnostic accuracy (53-55), and lack clarity of why they have been selected within guidelines (55). Additionally, many guidelines do not provide sufficient detail on how to apply red flags in clinical practice, leading to practitioner variation and limiting diagnostic certainty (54). This has led to recent concerns regarding the overall diagnostic and clinical value of using red flags to triage patients (53-55).

Most individual red flags show low diagnostic accuracy for increased risk of serious spinal pathology, whereas, improved diagnostic accuracy has been demonstrated with combinations of red flags (53, 56). A high quality inception cohort study of over 1000 patients presenting to primary care in Australia found over 80% of patients had at least one red flag; however, the incidence of serious pathology was less than 1% (42). In another cohort study of over 600 patients, the percentage of patients with at least one red flag was similar at 81%, but the incidence of serious pathology was higher at 4% (46). This increase can be explained as the study did not recruit an inception cohort, instead it included only patients who had been previously referred for imaging. Therefore, a higher incidence of pathology would be expected (46).

The use of individual red flags to indicate the likelihood of serious spinal pathology has been called into question (44, 53, 56-59) and has been shown to inappropriately increase the use of further investigations such as imaging (47, 60). Of further concern, the absence of red

flags may not indicate an absence of serious spinal pathology, thus delaying appropriate diagnosis. Two studies demonstrated a lack of any red flags in 64% of patients with diagnosed spinal malignancy (56) and 24% of patients with a vertebral fracture (46). However, these findings have not been consistently demonstrated across studies, with another study finding that all cases of malignancy demonstrated at least one red flag (46). This discrepancy may be due to the low prevalence of malignancy or variability in the type and application of red flags used between studies.

More recent clinical practice guidelines incorporate the red flags that have shown higher diagnostic accuracy and stress the importance of multiple red flags or strong clinical suspicion of serious pathology (61). In patients with relatively few red flags, and a lower risk of serious pathology, some guidelines are recommending the strategy of watchful waiting, where a trial of conservative management is performed and symptoms monitored for progression prior to any further diagnostic workup (58, 61).

1.2.4.2 Imaging for serious spinal pathology

Clinical practice guidelines are consistent in their recommendation that the use of imaging (X-ray, CT, MRI) may be important to aid diagnosis and management of serious spinal pathology (40, 62). MRI is the most sensitive modality to aid diagnosis of malignancy, infection, and cauda equina syndrome (63-66), all of which require prompt diagnosis and management. Vertebral fracture is well demonstrated on X-ray or CT (66, 67), although recency of fracture and possible underlying pathological causes (e.g. malignancy or infection) may be better demonstrated on MRI (67). MRI and X-ray are useful in the diagnosis of axial spondyloarthritis, with identification of radiographic sacroiliitis being one of the key diagnostic criteria (49).

1.2.5 Radicular Pain/radiculopathy

Patients classified with radicular pain/radiculopathy present with pain or neurological symptoms into the leg associated with spinal nerve irritation or compression (37). Radicular pain refers to leg pain due to nerve irritation, whereas radiculopathy results in neurological changes (e.g. weakness, sensory disturbances) due to nerve root dysfunction (37). While many people with back pain experience some associated leg pain (68, 69), somatic referred pain accounts for a large proportion of these presentations and the prevalence of true radicular pain/radiculopathy from spinal nerve involvement is likely to be less than 10% (7,

37). Radicular pain/radiculopathy are commonly associated with disc herniation, spinal degeneration, spondylolisthesis, and spinal stenosis (37). The prevalence of spinal stenosis on X-ray has been estimated at 3% to 20% (44-46, 70) and the prevalence of disc herniation with likely nerve root impingement ranges from 5% to 69% (44-46, 48). The wide range is likely due to the lack of definitive radiographic criteria and differences in study populations. Poor correlation between radiographic findings and clinical presentation (71-74) brings into question the usefulness of radiographic assessment for radicular pain/radiculopathy.

1.2.5.1 Imaging for radicular pain/radiculopathy

Clinical practice guidelines do not recommend the use of imaging for most cases of radicular pain/radiculopathy (40, 62, 75). Although imaging can be used to assess for the potential causes of spinal nerve compression or irritation, such as disc herniation or spinal stenosis, imaging findings are often inconsistent with clinical symptoms (71-74) and a clinical diagnosis is usually sufficient to direct appropriate management. A randomised controlled trial found that although radiographic evidence of stenosis and nerve root compression was more common in patients with radiculopathy compared to those with low back pain alone, the use of MRI did not improve clinical outcomes (74).

Imaging is recommended when there is progressive or widespread radiculopathy that is not responding to conservative care (76). Imaging may be informative in these cases to rule out underlying serious pathology that may be contributing to spinal nerve compromise or to assess for the need for possible surgical referral (7, 62). Where imaging is to be performed, MRI is the preferred modality, with CT used if MRI is unavailable or contraindicated (7, 66).

1.2.5.2 Management of radicular pain/radiculopathy

The natural history of radicular pain/radiculopathy is usually favourable, with most cases responding well to conservative management (77) and similar patient outcomes observed between surgical and non-surgical management at one to two year follow-up (78, 79). Clinical practice guidelines recommend conservative management of radiculopathy unless there is widespread or progressive radiculopathy or there is a lack of response to conservative care, in which case surgical advice should be sought (7, 75). For conservative management it is recommended to advise patients to maintain normal activity and supervised exercise or spinal manipulative therapy can be suggested (75, 80). There is insufficient or unfavourable evidence to recommend epidural or extraforaminal

glucocorticoid injections, neuropathic pain medications, systemic corticosteroids, minor tranquilisers, non-steroidal anti-inflammatory drugs, opioids, antidepressants, traction, or acupuncture (37, 75, 81, 82).

1.2.6 Non-specific low back pain

The majority of low back pain presentations (90-95%) do not present with signs and symptoms consistent with serious spinal pathology or radicular pain/radiculopathy and are instead classified as non-specific low back pain. In this category the precise nociceptive source of the low back pain cannot be reliably determined (37) due to the low diagnostic accuracy of clinical examinations or investigations (7, 38, 41, 83).

A number of other factors in addition to nociceptive inputs have been identified that may contribute to low back pain or related disability (2). These include biological factors (e.g. muscle strength or morphology), psychological factors (e.g. depression, fear avoidance beliefs), comorbidities (e.g. obesity, sleep disturbance), social factors (e.g. education level), lifestyle factors (e.g. smoking, physical inactivity), and genetic factors (2).

1.2.6.1 Imaging for non-specific low back pain

Clinical practice guidelines recommend against the use of imaging in patients with non-specific low back pain. Often imaging of the low back will identify specific findings such as degenerative changes, spondylolisthesis, disc and vertebral endplate changes, and developmental vertebral anomalies (46, 84-89). Although these imaging findings may reflect a possible nociceptive input, correlation with clinical symptoms is low (62, 73, 84, 87, 90, 91). Many of these imaging findings are commonly found in asymptomatic patients (86, 87, 92-94) and there is no strong evidence they are predictive of, or associated with, new episodes of low back pain (95-97) or associated with past episodes of low back pain (94). Although some studies have found MRI findings, such as disc and vertebral endplate changes, to be more common in patients with low back pain (38, 98-102), no definitive causative link has been demonstrated (38). Therefore, it is uncertain whether imaging findings for an individual patient contribute to a current episode of low back pain or, if they contribute, it is uncertain to what degree.

Importantly, patient management and outcomes for acute non-specific low back pain are unlikely to significantly change as a result of imaging (62, 103, 104). Randomised controlled

trials of X-ray compared to no imaging (105-108), MRI or CT compared to no-imaging (109-111), or MRI compared to X-ray (45) do not show significant and clinically meaningful improvement in clinical outcomes between imaging and control groups and in one study the imaging group showed poorer patient outcomes (106). Observational studies assessing the use of early imaging (imaging in the first six weeks) in the management of low back pain (107, 112-114) also failed to find significant association between patients who received early imaging and improvement in clinical outcomes and in two studies early imaging was associated with poorer patient outcomes (112, 114). Early imaging was associated with improved outcomes in an observational study (115); however, this was performed in a cohort of patients with chronic pain and unsuccessful treatment in primary care and was not representative of the majority of patients presenting with non-specific low back pain.

1.2.6.2 Assessment of psychosocial prognostic factors for non-specific low back pain

Psychosocial prognostic factors have been shown to impact on the course of low back pain, and the presence of these factors has been associated with increased risk of low back pain chronicity or disability (2, 7, 116). Most clinical practice guidelines recommend that an assessment of psychosocial prognostic factors is performed to inform management by identifying those patients at increased risk of chronicity, who may need more aggressive early intervention (40, 117). These psychosocial prognostic factors have been termed 'yellow flags', and similar to red flags, a wide variety are reported in the literature (2, 7, 116). Comparison of clinical practice guidelines for low back pain found that only three are consistently endorsed: beliefs that pain and activity are harmful, treatment preferences that do not fit in with best practice, and a lack of social support (40). To standardise the assessment of psychosocial prognostic factors, screening tools such as the STarT Back Tool (9, 10) and the Orebro Musculoskeletal Pain Questionnaire (11, 12) have been developed and validated and are recommended by several guidelines (40).

1.2.6.3 Management of non-specific low back pain

Conservative, or non-surgical, management is generally recommended for non-specific low back pain, with some guidelines recommending referral to a specialist if the patient is failing to improve after four weeks of care (40). Since many cases of low back pain improve significantly in the first few weeks after onset, a systematic review of clinical practice guidelines found that most recommended initial management of: advice to stay active,

reassurance that the pain is not due to a serious cause, and the use of non-steroidal antiinflammatory medications or weak opioids (40). In more chronic cases exercise,
psychosocial therapy, NSAIDs, and antidepressants are recommended (40). In a recent
guideline from the American College of Physicians pharmacologic management has been
discouraged for both acute and chronic low back pain due to low quality evidence of
effectiveness (82). In particular, opioids should only be considered with due consideration
of associated risks and benefits and after a sufficient trial of alternative management
options (82). Stratified management of low back pain from early identification of
psychosocial prognostic factors has shown mixed results on patient outcomes (10, 116) and
while the STarT Back Tool (9, 10) and the Orebro Musculoskeletal Pain Questionnaire (11,
12) may help identify patients at risk of chronicity, it is currently unclear whether this
consistently impacts patient management and outcomes (10, 116-118).

1.3 The use of imaging in the management of low back pain

Imaging is commonly used in the management of low back pain (119, 120); however, as described in section 1.2 above, it is only indicated for the assessment of potential serious spinal pathology and some cases of radiculopathy (62). Imaging overuse has been a concern for many years due to the increased risks and costs associated with non-indicated imaging (7, 52, 61, 62, 103). To assess the extent of overuse of imaging in the management of low back pain, consideration needs to be made of the proportion of patients who receive imaging and whether the imaging is indicated or non-indicated when compared to clinical practice guidelines.

1.3.1 Risks and increased costs associated with imaging

Risks, such as radiation exposure and overdiagnosis leading to further medical interventions, and increased costs have been related to the use of imaging for low back pain (62). The risks and costs of imaging need to be considered against the likely benefits before a determination to refer a patient for imaging is made.

1.3.1.1 Radiation exposure

X-rays and CT scans are associated with radiation exposure that may have associated long-term risks for the patient (62). The average exposure from a lumbar X-ray series is 1.5mSv, and from a lumbar CT scan is 6mSv (121). These doses of radiation exposure are

approximately equivalent to one and four times the normal level of background radiation exposure per year in Australia (122). Risks associated with high level radiation exposure are well recognised, with short and long-term outcomes from acute exposures such as the atomic bombings of Hiroshima and Nagasaki being extensively studied (123). Exact risks associated with low doses of radiation exposure are difficult to determine due to confounding factors such as background levels of radiation and the length of time from radiation exposure to cancer diagnosis (124). Risks of low level exposure have been extrapolated using the linear no-threshold model (123, 124) and although this method has been criticised it is recognised that no safe level of radiation exposure can be determined (125). Estimates of increased risk of death from malignancy due to a single exposure are low, with lumbar X-ray classified as having minimal increased risk and lumbar CT scan classified as very low increased risk (126). The additional risk of cumulative radiation exposure and the age of the patient at exposure also needs to be considered. Although exact harms have not been specifically demonstrated from a single exposure to low dose radiation, epidemiological studies have associated protracted low-level occupational radiation exposure with increased malignancy risk (127). Children are at higher risk of harm due to the increased radiosensitivity of growing tissues (128) and CT scans in children have also been associated with increased malignancy risk (129, 130). For patients with clear indicators for imaging for low back pain, as defined in clinical practice guidelines, potential radiation exposure should not be considered a barrier to imaging. For those where indicators are unclear, referral for X-ray or CT will expose the patient to increased risk from radiation exposure, without clear benefit.

1.3.1.2 Overdiagnosis

Overdiagnosis occurs when people are diagnosed with a condition that would not have resulted in symptoms or harm if it remained undiagnosed (131, 132). This can then lead to unnecessary patient worry and the risk of further unnecessary tests or interventions that may have other risks and increased cost associated with them (131-133). Overdiagnosis from the use of imaging for low back pain has been identified as an issue that can lead to poorer patient outcomes and increased surgical intervention (45, 62, 74, 133-135). Many findings may be detected on imaging of the low back, with up to 94% of imaging studies having at least one reported finding (46); however, as outlined in section 1.2.6.1, the clinical relevance of many imaging findings is uncertain and unlikely to be the direct cause of the

low back pain. The diagnosis of imaging findings, while being of little benefit in informing patient management may cause subsequent patient anxiety, medicalisation of low back pain, and increased disability from a belief that a pathological cause to the low back pain exists (47, 74, 109, 114, 136). Additionally, diagnoses such as spinal degeneration, disc protrusion, and nerve root compromise may lead to further investigations and interventions such as spinal injections and surgery (113, 135, 137, 138). These management options show little evidence of benefit in most cases of low back pain but do increase the risk of harm to the patient and are generally not recommended in guidelines for the treatment of non-specific low back pain (40, 75).

1.3.1.3 Increased costs

Imaging for low back pain increases costs, both those directly related to the imaging procedure itself, and downstream costs from an increase in subsequent investigations and interventions. Costs to the health care system related to imaging are high: in 2010/2011 CAD68 million was spent in Canada (139), and in 2017/2018 AUD180 million in Australia (140). Overall 7% of all costs related to low back pain are estimated to be attributed directly to imaging (30) and the use of early imaging has been associated with up to a 30% increase in overall costs (113). A retrospective cohort study of workers with acute occupational low back pain found early MRI, in patients where it was not clearly indicated, was associated with a mean increase in subsequent health care costs of over USD12,000 per person over a two year period (114). Subsequent follow on costs, such as increased imaging use and further interventions, and indirect costs associated with disability and workplace absenteeism can be difficult to attribute directly to imaging. Costs directly paid by the patient are also often missed in the available studies that use health care records to estimate costs and as such only capture government and insurance payments. Therefore, costs associated with imaging use are likely to be even higher than those currently provided.

1.3.2 Proportion of low back pain imaging in clinical practice

A number of observational studies have assessed the proportion of imaging amongst patients presenting with low back pain in primary care. This varies from 2% (141) to 80% (142), depending on the study population, inclusion criteria, and type of imaging assessed. A recent systematic review found moderate quality evidence that 24.8% of patients presenting with a new episode of low back pain in primary care receive some form of

imaging (120). The proportion of X-ray use has not changed significantly over the last 20 years, whereas CT and MRI use shows an increasing trend (120). Therefore, overall imaging use has not decreased over time despite the introduction of clinical practice guidelines encouraging judicious use of imaging (52, 61) and various interventions to try and reduce imaging use (143).

1.3.3 Proportion of indicated imaging for low back pain

Approximately one quarter of patients presenting to primary care with a new episode of low back pain receive imaging (120). Although this proportion is considered high, some of this imaging would be indicated to assess for possible serious spinal pathology. Theoretically, less than 5% of low back pain presentations are thought to be due to potential serious spinal pathology (37), and imaging proportions should therefore reflect this. The sensitivity and specificity of clinical findings used to indicate possible serious spinal pathology (red flags) are not sufficiently high to expect to be able to image only those cases with pathology and not have any false negative or false positive results (53). Therefore, a higher proportion of imaging than indicated by the prevalence of serious spinal pathology is necessary to ensure that no cases of serious spinal pathology are missed. In particular, the perceived risk of missing a rare but serious spinal pathology may contribute to the increased use of imaging by clinicians (144). However, imaging prevalence should not be so high that many people without serious spinal pathology are being imaged unnecessarily and exposed to risk without associated benefit. Determining a suitable proportion of indicated imaging is challenging due to variability in the red flags reported in clinical practice guidelines and the way these are applied in clinical practice.

A number of studies have assessed suitability for imaging by assessing consistency with clinical practice guidelines (60, 145-148), with proportions of indicated imaging ranging from 3.4% (146) to 76.0% (145). More studies need to be conducted with consistent application of red flags with higher diagnostic accuracy to help determine what proportion of imaging is indicated in primary care.

1.3.4 Proportion of non-indicated imaging for low back pain

Proportions of non-indicated imaging are unclear with some reports ranging widely from 3.3% (148) to 88.5% (149). The proportions reported may be related to the variability in specific red flags used to assess non-indication of imaging. Variability may also be due to

differences in study populations (e.g. general practice, workers compensation, veterans), imaging type assessed (e.g. X-ray, CT, MRI), and the method of calculation of non-indicated imaging proportions (e.g. the proportion of referred images that are non-indicated; or the proportion of non-indicated patients that are referred for imaging). It is currently unknown whether proportions of non-indicated imaging differ when subgrouping for relevant variables is applied. No systematic review of this topic has been conducted.

Chapter 2 will address the lack of evidence on the proportion of nonindicated imaging decisions occurring in clinical practice

1.4 Reducing non-indicated imaging for low back pain

Imaging overuse has long been identified as a concern in the management of low back pain and interventions to reduce non-indicated imaging have subsequently been developed and implemented in clinical practice (143). Despite this imaging proportions have not decreased over time (120) and high proportions of non-indicated imaging continue to be reported in recent years (114, 150, 151). A number of barriers to successful implementation of interventions to reduce non-indicated imaging have been identified, such as limited time in patient consultation and patient pressure for imaging (152), which need to be considered in developing future interventions. The development and implementation of an effective intervention to reduce non-indicated imaging for low back pain would improve low back pain management, decrease patient risk, and reduce associated healthcare costs.

1.4.1 Interventions to reduce non-indicated imaging for low back pain

Practitioner-directed interventions to reduce non-indicated imaging most commonly include the provision of practitioner education materials, including appropriate guidelines (143, 153). However, the effectiveness of changing clinical practice by providing practitioner education material is not supported by current evidence across multiple healthcare related fields (143, 154-156). Other trialled interventions for practitioners include practitioner audit and feedback (157), reminders of correct care (157), and interactive practitioner educational workshops (158). System or policy level interventions have also been implemented in an effort to reduce imaging for low back pain, including restricting imaging referral rights in hospitals (159) and limiting access to medical benefit payments for imaging (160, 161). It is

currently unclear which, if any, of these interventions demonstrate evidence of effectiveness.

A previous systematic review (143), assessing the effectiveness of interventions to improve the appropriate use of imaging for musculoskeletal conditions has been performed; however, this review only included studies published before 2007, was not specific to low back pain, and could not reach clear conclusions due to the limited studies available.

Chapter 3 will address this gap by investigating the effectiveness of interventions designed to reduce imaging rates for the management of low back pain

1.4.2 Identified barriers to reducing non-indicated imaging for low back pain

Identification of barriers to behaviour change is important to determine what interventions need to address. A number of barriers to reducing non-indicated imaging use in primary care have been identified, including both practitioner and patient specific barriers (152, 162). Commonly reported practitioner barriers are presented in Box 1 (152, 163-169).

Box 1: Commonly reported practitioner barriers to reducing non-indicated imaging for low back pain (152, 163-169)

- Lack of knowledge of when to refer for imaging
- Uncertainty in their diagnostic skills and fear of missing serious pathology
- Time constraints within the consult
- Perceived usefulness of imaging and a lack of knowledge of risks of non-indicated imaging
- Uncertainty in their ability to reassure the patient
- Perceived pressure from the patient to refer for imaging
- Ownership of imaging equipment
- Perceived expectations from healthcare systems or third party payers

In particular, practitioners with higher referral rates for imaging are more likely to think that imaging will reassure the patient and that refusing imaging will adversely affect the practitioner-patient relationship (164).

Patients report that they feel imaging is useful to provide a diagnosis and direct management, that they are unaware of the associated risks, and that they are often advised to obtain imaging from friends or family (162, 166, 170, 171). Patients report that they expect imaging when they present for a low back pain consult (162, 170) and quantitative studies have also shown that between 45% to 74% of people expect to receive X-rays or think they are useful in the management of low back pain (171-173). It is uncertain if these beliefs also apply to CT and MRI. Beliefs of the importance of imaging were not significantly different in patients who had current low back pain compared to those that did not have low back pain (172, 173), but they were more likely in those who consulted a practitioner for their low back pain (173) or in those referred for non-indicated imaging (171). There is little information whether other patient characteristics (e.g. age, educational background, cultural background) are also associated with beliefs of the importance of imaging. This information would help inform whether patient expectations of imaging may be a potential barrier to appropriate imaging use, whether patient expectations are more common in specific patient groups, and aid in the development of more targeted interventions to reduce imaging overuse in these groups.

Chapter 4 will address this gap by investigating patient beliefs regarding the importance of imaging in the management of low back pain and the patient characteristics (demographic, social, and cultural) associated with these beliefs

1.4.3 Development of behaviour change interventions

Developing interventions that will successfully change behaviour in clinical practice is challenging. Systematic reviews have identified different methods for designing interventions and a wide variety of developed interventions; however, it is currently unclear which are most effective (154, 174, 175). More complex interventions, designed to address multiple aspects of behaviour change, and implemented over a longer period of time appear

to be more effective than single interventions implemented in a short period of time or at a single time point (154, 174). To develop complex behaviour change interventions it is strongly recommended that a theoretical framework is used to guide the process and provide strong rationale for the resultant intervention (153, 156, 176), rather than using intuitive processes or selection by convenience (177). Despite this, most previously trialled interventions to reduce imaging for low back pain have been single, rather than complex interventions, that were performed over a short period of time (143, 153, 156, 174), with no reported theoretical framework for development of the intervention (153). Various frameworks have been suggested to aid intervention development (175) including the Theoretical Domains Framework (166, 178) and the Behaviour Change Wheel (179, 180). Common to these frameworks are key steps to be considered in the development and assessment of an intervention (Box 2) (175).

Box 2: Steps in the development and assessment of a behaviour change intervention (175)

- 1. Identification of the problem to be addressed or behaviour to be changed
- 2. Identification of barriers or facilitators to addressing the problem/behaviour
- 3. Use of theory to identify appropriate intervention components (behaviour change techniques and implementation strategies)
- 4. Evaluation of the proposed intervention, including user engagement

1.4.3.1 The Theoretical Domains Framework

Psychological theories can be used to help explain behaviour change and potentially inform selection of appropriate intervention components to facilitate behaviour change (177). However, the multitude of psychological theories available are not easily translated into behaviour change research and the Theoretical Domains Framework was developed to simplify this process (177). A consensus process, evaluating current psychological theories related to behaviour change, led to the identification of 12 key behaviour change domains (177). Further validation and assessment of the framework led to the identification of 14 final domains (Box 3) (181).

Box 3: Domains within the Theoretical Domains Framework (181)

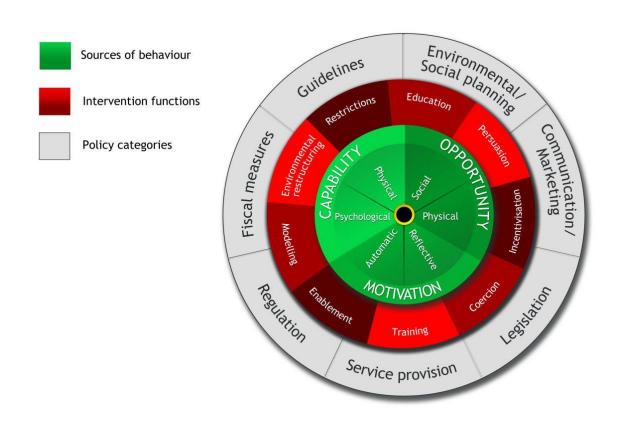
- 1. Knowledge
- 2. Skills
- 3. Social/Professional role and identity
- 4. Beliefs about capabilities
- 5. Optimism
- 6. Beliefs about consequences
- 7. Reinforcement
- 8. Intentions
- 9. Goals
- 10. Memory, attention and decision processes
- 11. Environmental context and resources
- 12. Social influences
- 13. Emotions
- 14. Behavioural regulation

Each of the 14 domains within the Theoretical Domains Framework have been subsequently mapped to specific behaviour change techniques that would be most likely to create behaviour change within that domain (182). The Theoretical Domains Framework can therefore be used to inform which behaviour change techniques would be most appropriate to be incorporated into a behavioural change intervention, by mapping barriers to behaviour change to relevant domains within the Theoretical Domains Framework and then selecting from the behaviour change techniques associated with each identified domain (178). The Theoretical Domains Framework can also be used to guide interviews and questionnaires to allow complete assessment of influences on behaviour change related to the 14 domains (178, 183). The Theoretical Domains Framework has been used to develop interventions across multiple fields of healthcare (184), including low back pain (149, 158, 166, 185, 186).

1.4.3.2 The Behaviour Change Wheel

The Behaviour Change Wheel was developed through the synthesis of 19 behaviour change frameworks to create a process to inform the development and assessment of behaviour change interventions (179, 180). The Behaviour Change Wheel (Figure 1) models and integrates behaviour change theory with specific processes to facilitate intervention development (179, 180).

Figure 1: The Behaviour Change Wheel. Reproduced with consent from: The behaviour change wheel: A new method for characterising and designing behaviour change interventions (179)



When using the Behaviour Change Wheel, the behaviour to be changed is analysed and sources of that behaviour, related to capability, opportunity, and motivation, are identified. The sources of behaviour are then mapped to intervention functions, whereby behaviour change techniques to address each intervention function can be selected. Finally, the source of behaviour and intervention functions are mapped to policy categories which guides selection of appropriate implementation strategies (180). The Theoretical Domains Framework can be integrated within the Behaviour Change Wheel to facilitate more indepth analysis of the sources of behaviour (180). Several healthcare-related interventions have utilised the Behaviour Change Wheel in their development (187-190); however, to date, none have addressed reducing imaging for low back pain. The benefit of using the Behaviour Change Wheel (with or without the Theoretical Domains Framework) over the Theoretical Domains Framework alone is that it provides a more complete and structured

procedure for intervention development and includes assessment and selection of suitable implementation strategies (179, 180).

Chapter 5 will outline the development of a theory-informed intervention to reduce imaging in the management of low back pain, using the Behaviour Change Wheel with inclusion of the Theoretical Domains Framework

1.4.4 Evaluation of behaviour change interventions

The effectiveness of a developed intervention in clinical practice may be limited by low efficacy of the intervention (whether the intervention produces the desired effect when implemented as designed (191)) and failure of successful implementation within clinical practice (153, 176, 191). For example, Schectman et al. (192) trialled a patient education intervention to reduce imaging for low back pain which did not show evidence of effectiveness. However, implementation failure meant that many patients did not receive the required educational materials, adversely affecting the results of this trial. Therefore, before large scale effectiveness studies of a developed intervention are conducted, it is important to first assess the efficacy and the feasibility of implementing the developed intervention in clinical practice (176). Feasibility testing is needed to identify potential barriers to successful implementation of the intervention in clinical practice, which can then be addressed prior to effectiveness testing.

Chapter 6 will outline preliminary feasibility testing of the developed intervention aiming to reduce imaging in the management of low back pain

1.5 Thesis aims

1.5.1 Overarching aim

The overarching aim of this thesis is to develop and perform feasibility testing on an intervention to reduce non-indicated imaging in the management of low back pain (Specific aims 4 and 5 below).

An initial needs assessment will be used to investigate the need for such an intervention and will be used to inform the subsequent development process (Specific aims 1-3 below).

1.5.2 Specific aims

Aim 1: To estimate how common inappropriate imaging decisions for low back pain are, including both inappropriate referral (overuse) and inappropriate non-referral (underuse), and to investigate the criteria used to judge imaging appropriateness (Chapter 2).

Aim 2: To investigate the effectiveness of interventions designed to reduce imaging rates for the management of low back pain (Chapter 3).

Aim 3: To quantitatively investigate beliefs regarding the need for imaging in managing low back pain in patients presenting to general practitioners and to investigate whether personal characteristics, pain characteristics or back pain beliefs may be associated with imaging beliefs (Chapter 4).

Aim 4: To develop an intervention aiming to reduce non-indicated imaging for low back pain, by targeting both general practitioner and patient barriers concurrently (Chapter 5).

Aim 5: To explore general practitioner experiences using the low back pain education and management booklet in clinical practice to determine: 1) how practitioners used the booklet; 2) barriers and facilitators to use of the booklet; 3) how helpful practitioners found the booklet; and 4) suggestions for improvement to the booklet or associated practitioner training in using the booklet (Chapter 6).

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Chapter 2

Imaging for low back pain: is clinical use consistent with guidelines? A systematic review and meta-analysis

2.1 Preface

In Chapter 1 it was shown that imaging for low back pain is commonly used. However, the proportion of this imaging that is non-indicated when compared to clinical practice guidelines is currently unknown. To assess the need for an intervention to reduce non-indicated imaging for low back pain, it is first important to determine the amount of non-indicated imaging currently being performed. Chapter 2 presents a systematic literature review and meta-analysis to determine the proportion of non-indicated imaging decisions in the management of low back pain.

The study presented in Chapter 2 has been published as:

Jenkins HJ, Downie AS, Maher CG, Moloney NA, Magnussen JS, Hancock MJ. Imaging for low back pain: is clinical use consistent with guidelines? A systematic review and meta-analysis. The Spine Journal. 2018; 18(12):2266-77

2.2 Co-authors' statement

As co-authors' of the paper, *Imaging for low back pain: is clinical use consistent with guidelines? A systematic review and meta-analysis*, we confirm that Hazel Jenkins has made the following contributions to this paper:

- Conception and design of the study
- Collection and assembly of the data
- Analysis and interpretation of the data
- Drafting and critical revision of the paper

Aron Downie Date: 01/02/2019

Chris Maher Date: 01/02/2019

Niamh Moloney Date: 01/02/2019

John Magnussen Date: 01/02/2019

Mark Hancock Date: 01/02/2019

Pages 42-53 of this thesis have been removed as they contain published material. Please refer to the following citation for details of the article contained in these pages.

Jenkins H. J., Downie A. S., Maher C. G., Moloney N. A., Magnussen J. S., Hancock M. J. (2018) Imaging for low back pain: is clinical use consistent with guidelines? A systematic review and meta-analysis. *The Spine Journal*. 18(12) p.2266-2277.

DOI: 10.1016/j.spinee.2018.05.004

2.10 Published supplementary material

Supplementary File 1: Detailed search strategy for MEDLINE, EMBASE and CINAHL

MEDLINE search strategy

- 1 exp General Practitioners/cl, sn, sd, td, ut [Classification, Statistics & Numerical Data, Supply & Distribution, Trends, Utilization]
- 2 General pract*.mp.
- 3 exp General Practice/cl, sn, td [Classification, Statistics & Numerical Data, Trends]
- 4 exp Primary Health Care/cl, sn, sd, td, ut [Classification, Statistics & Numerical Data, Supply & Distribution, Trends, Utilization]
- 5 primary care.mp.
- 6 PCP*.mp.
- 7 exp Family Practice/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- 8 family pract*.mp.
- 9 *practice patterns, Physicians'/
- 10 Physiotherap*.mp.
- 11 Chiropract*.mp.
- 12 Osteopath*.mp.
- 13 exp Ambulatory Care/st, sn, td, ut [Standards, Statistics & Numerical Data, Trends, Utilization]
- 14 ambulatory medical care.mp.
- 15 exp "Delivery of Health Care"/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- exp Emergency Service, Hospital/st, sn, td, ut [Standards, Statistics & Numerical Data, Trends, Utilization]
- exp Emergency Medical Services /st, sn, td, ut [Standards, Statistics & Numerical Data, Trends, Utilization]
- 18 emergency department/
- 19 emergency department.mp.
- 20 *Insurance claim reporting/
- exp Workers' Compensation/og, st, sn, td, ut [Organization & Administration, Standards, Statistics & Numerical Data, Trends, Utilization]
- exp "Insurance Claim Review"/ec, sn, td, ut [Economics, Statistics & Numerical Data, Trends, Utilization]
- exp Fee-for-Service Plans/st, sn, td, ut [Standards, Statistics & Numerical Data, Trends, Utilization]
- exp Health Maintenance Organizations/st, sn, td, ut [Standards, Statistics & Numerical Data, Trends, Utilization]
- 25 exp Health Care Surveys/mt, sn, td, ut [Methods, Statistics & Numerical Data, Trends, Utilization]
- 26 health services utilization.mp.
- 27 practice variation.mp.
- 28 exp Fees, Medical/st, sn, td [Standards, Statistics & Numerical Data, Trends]

- exp Insurance, Health/sn, sd, td, ut [Statistics & Numerical Data, Supply & Distribution, Trends, Utilization]
- 30 exp Health Benefit Plans, Employee/sn, sd, td, ut [Statistics & Numerical Data, Supply & Distribution, Trends, Utilization]
- 31 1 or 2 or 3 or 4 or 5 or 6 or 8 or 9 or 10 or 11 or 12 or 13 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 28 or 29 or 30
- medical management.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]
- exp Lumbar Vertebrae/ra, us [Radiography, Ultrasonography]
- exp Magnetic Resonance Imaging/sn, sd, td, ut [Statistics & Numerical Data, Supply & Distribution, Trends, Utilization]
- 35 magnetic resonance imaging.mp.
- 36 MRI.mp.
- 37 exp Tomography/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- 38 exp Tomography, X-Ray/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- 39 exp Tomography, X-Ray Computed/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- 40 CT.mp.
- 41 exp Diagnostic Imaging/sn, td, ut [Statistics & Numerical Data, Trends, Utilization]
- 42 imaging.mp.
- 43 exp Radiography/di, sn, td, ut [Diagnosis, Statistics & Numerical Data, Trends, Utilization]
- 44 exp Radiology/di, sn, td, ut [Diagnosis, Statistics & Numerical Data, Trends, Utilization]
- 45 exp X-Rays/
- 46 X-ray*.mp.

51

- 47 Ultrasound.mp.
- 48 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 45 or 46 or 47
- 49 exp Back Pain/cn, di, in, pa, ra, sn, us [Congenital, Diagnosis, Injuries, Pathology, Radiography,
- Statistics & Numerical Data, Ultrasonography]

(lumbar adj3 pain).mp.

- 50 (back adj3 pain).mp.
- exp Low Back Pain/cl, cn, di, ep, eh, et, pa, ra, us [Classification, Congenital, Diagnosis, Epidemiology,
- Ethnology, Etiology, Pathology, Radiography, Ultrasonography]
- exp Back Injuries/di, ep, eh, et, ra, us [Diagnosis, Epidemiology, Ethnology, Etiology, Radiography, Ultrasonography]
- exp Sciatica/cn, di, ep, eh, et, pa, ra, sn, us [Congenital, Diagnosis, Epidemiology, Ethnology, Etiology, Pathology, Radiography, Statistics & Numerical Data, Ultrasonography]
- 55 Sciatica.mp.
- radicular syndrome.mp.
- exp Radiculopathy/di, ep, et, pa, ra, us [Diagnosis, Epidemiology, Etiology, Pathology, Radiography, Ultrasonography]

- 58 Radiculopathy.mp.
- 59 backache.mp.
- 60 nerve compression syndrome/
- 61 piriformis muscle syndrome/
- exp Spondylosis/di, ep, eh, et, pa, ra, us [Diagnosis, Epidemiology, Ethnology, Etiology, Pathology, Radiography, Ultrasonography]
- 63 spondylosis.mp.
- exp Spondylolisthesis/di, ep, eh, et, ra, sn, us [Diagnosis, Epidemiology, Ethnology, Etiology, Radiography, Statistics & Numerical Data, Ultrasonography]
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- 66 31 and 48 and 65
- 67 limit 66 to yr="1995 -Current"
- limit 67 to (clinical study or clinical trial, all or comparative study or controlled clinical trial or dataset or duplicate publication or evaluation studies or government publications or journal article or multicenter study or observational study or pragmatic clinical trial or published erratum or randomized controlled trial or technical report)

EMBASE search strategy

- 1 exp general practice/
- 2 exp primary medical care/
- 3 exp general practitioner/
- 4 general pract*.mp.
- 5 exp primary medical care/
- 6 primary care.mp.
- 7 exp primary health care/
- 8 primary health care.mp.
- 9 PCP*.mp.
- 10 family practice.mp.
- 11 exp physiotherapy/
- 12 physiotherap*.mp.
- 13 exp chiropractic/
- 14 exp chiropractic practice/
- 15 chiropract*.mp.
- 16 exp osteopathic medicine/
- 17 osteopath*.mp.
- 18 exp ambulatory care/
- 19 ambulatory care.mp.
- ambulatory medical care.mp.
- 21 exp emergency health service/
- 22 exp emergency ward/

- 23 emergency department.mp.
- *insurance claim reporting/
- 25 exp workman compensation/
- workers compensation.mp.
- insurance claim review.mp.
- 28 exp national health insurance/
- 29 exp health maintenance organization/
- 30 health maintenance organization*.mp.
- 31 exp health care utilization/
- 32 health services utilization.mp.
- 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20

or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32

- 34 exp nuclear magnetic resonance imaging/
- 35 magnetic resonance imaging.mp.
- 36 MRI.mp.
- 37 exp tomography/
- 38 exp computed tomography scanner/
- 39 CT.mp.
- 40 exp diagnostic imaging/
- 41 imaging.mp.
- 42 exp radiology/
- 43 exp radiology department/
- 44 exp X ray/
- 45 x-ray*.mp.
- 46 exp ultrasound/
- 47 ultrasound.mp.
- 48 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47
- 49 (back adj3 pain).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
- 50 (lumbar adj3 pain).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
- 51 exp low back pain/
- 52 low back pain.mp.
- 53 back injur*.mp.
- 54 exp sciatica/
- sciatica.mp.
- 56 exp "nerve root compression"/
- 57 radicular syndrome.mp.
- 58 exp radiculopathy/
- 59 exp backache/

60 exp piriformis syndrome/ 61 (piriformis adj3 syndrome).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword] 62 exp spondylolisthesis/ 63 spondylolithesis.mp. 64 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61 or 62 or 63 65 33 and 48 and 64 66 limit 65 to yr="1995 -Current" 67 limit 66 to journal 68 limit 67 to "reviews (maximizes specificity)" 69 67 not 68 **CINAHL** search strategy S71 S36 AND S55 AND S69 Limiters - Published Date: 19950101-20161231 S56 OR S57 OR S58 OR S59 OR S60 OR S61 OR S62 OR S63 OR S64 OR S65 OR S66 OR S67 OR S68 S69 S68 (MH "Spondylosis+") S67 "backache" S66 "radiculopathy" S65 (MH "Radiculopathy") "sciatica" S64 S63 (MH "Piriformis Syndrome") S62 (MH "Sciatica") S61 "back injuries" (MH "Back Injuries+") S60 S59 "lumbar pain" S58 "back pain" (MH "Low Back Pain") S57 S56 (MH "Back Pain+") **S55** S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 S54 "ultrasound" S53 (MH "Ultrasonography+") S52 "x-ray" S51 (MH "X-Rays") S50 (MH "X-Ray Film") S49 (MH "Radiology Service") (MH "Radiography+") S48 S47 "diagnostic imaging" (MH "Digital Imaging") S46 S45 (MH "Diagnostic Imaging+")

S44	СТ
S43	"tomography"
S42	(MH "Tomography, X-Ray+")
S41	(MH "Tomography, X-Ray Computed+")
S40	(MH "Tomography+")
S39	"MRI"
S38	"magnetic resonance imaging"
S37	(MH "Magnetic Resonance Imaging+")
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OR S16	5 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR
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S35	(MH "Health Benefit Plans, Employee")
S34	(MH "Insurance, Health+") OR (MH "Medicare")
S33	"practice variation"
S32	(MH "Health Resource Utilization")
S31	(MH "Health Maintenance Organizations")
S30	(MH "Fee for Service Plans")
S29	"insurance claim review"
S28	"worker's compensation"
S27	"workers compensation"
S26	(MH "Worker's Compensation")
S25	(MH "Insurance Carriers")
S24	(MH "Insurance, Liability")
S23	(MH "Insurance, Health, Reimbursement+")
S22	(MH "Billing and Claims")
S21	"emergency department"
S20	(MH "Emergency Medicine/UT/TD/SN/ST")
S19	(MH "Health Care Delivery+/UT/TD/SN/ST") OR (MH "Health Care Delivery, Integrated/UT/TD/SN/ST")
S18	(MH "Emergency Medical Services+/ST/SN/TD/UT")
S17	(MH "Emergency Service+/UT/TD/SN/EV")
S16	"ambulatory medical care"
S15	(MH "Ambulatory Care/UT/TD/SN/EV")
S14	"osteopathic"
S13	(MH "Osteopaths/UT/TD/SN/EV") OR (MH "Osteopathic Medicine/UT/TD/SN/EV") OR (MH
"Osteo	pathy+/UT/TD/SN/EV")
S12	"chiropractic"
S11	(MH "Chiropractic+/UT/TD/SN/EV")
S10	"physiotherapy"
S9	(MH "Physical Therapy+/UT/TD/SN/EV")
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S8

(MH "Practice Patterns/UT/TD/SN/EV")

- S7 (MH "Prescribing Patterns/UT/TD/SN")
- S6 "PCP"
- S5 "primary care"
- S4 (MH "Primary Health Care/UT/TD/SN")
- S3 (MH "Family Practice/UT/TD/SN/CL")
- S2 "General Practitioners"
- S1 (MH "Physicians, Family/CL/SN/UT/TD")

Supplementary Table 1: Risk of bias assessment of included studies

Vverall risk of bias summary score	Moderate	Moderate	High	Moderate	Moderate	Moderate	High
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Likelihood of non-response bias	>	>	>	>	>	>	>
Random selection or census used	>-	>-	>	>	>	>	z
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Citation	Allen (2014)[36]	Ammendolia (2007)[42]	Bishop (2003)[35]	Charlesworth (2016)[34]	Cook (1998)[33]	Eccles (2001)[45]	Emery (2013)[46]

High	Low	High	Moderate	Moderate	Low	Moderate	High	Moderate	Low	High	Moderate
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Low	Moderate	Moderate	High	High	High	Moderate	Low	Moderate	Moderate
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Tahvonen														
(2016)[23]	>	>	>	>	>	z	>	z	>	>	>	>	>-	Moderate
Tan (2016)[6]	Z	z	>-	>	>-	>	>	>-	>-	>-	>-	>-	>-	Moderate
Thackeray (2017)[41]	z	>-	>-	>-	>-	>-	>	>-	>	>-	>	>	>-	Moderate
Webster (2013)[38]	z	>-		> >	>	>	>-	>	>-	>	>	>-	>-	Moderate

presenting to primary care, but did not need to show national representativeness to be assessed as low ROB. Two separate parameters of interest for ROB assessment were identified: count of imaging referral/non-referral, and presence of clinical indicators for imaging appropriateness. These were each assessed independently for validity and reliability (item 7), consistency of mode of data collection (item 8), and appropriateness of the length of prevalence period (item 9). Prevalence period (item 9) was only *Modifications were made to four of the ten original domains [14]. The definition of the representative population (item 1) was specified as being a LBP population relevant to studies requiring patient recall, and periods under one year were considered appropriate.

Supplementary Table 2: Inappropriate imaging proportions in people referred for imaging

Inappropriate imaging proportion in people referred for imaging	oortion in people refer	red for imaging			
Indicators of inappropriate imaging (category)	Imaging type	Study	Patients referred for imaging (N)	Non-indicated imaging referrals (N)	Proportion of patients inappropriate for imaging of those referred for imaging % (95%CI)
Cohort assessed: LBP patients presenting for care	ting for care				
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI/Myelogram	Cook (1998)[31]*	25889	12925	49.9 (49.3, 50.5)
Absence of red flag clinical features	Xray/CT/MRI	Schectman (2003)[35]	157	69	43.9 (36.4, 51.8)
Absence of red flag clinical features	Xray/CT/MRI	Kost (2015)[28]	123	15	12.2 (7.5, 19.2)
Absence of red flag clinical features	Xray/CT/MRI	Rao (2015)[42]	52	2	3.8 (1.1, 13.0)
Absence of red flag clinical features	Xray	Suarez-Almazor (1997)[22]	127	47	37 (29.1, 45.7)
Absence of red flag clinical features	Xray	Muntion-Alfaro (2006)[25]	126	29	53.2 (44.5, 61.7)
Absence of red flag clinical features (no age criteria)	Xray	Ammendolia (2007)[40]	55	26	47.3 (34.7, 60.2)
Absence of red flag clinical features	Хгау	Liu (1995)[26]	34	4	11.8 (4.7, 26.6)
Absence of red flag clinical features	Xray	Gonzalez-Urzelai (2003)[30]	19	80	42.1 (23.1, 63.7)

Absence of red flag clinical features (including age >50)	Xray	Ammendolia (2007)[40]*	55	12	21.8 (13.0, 34.4)
Absence of yellow flag clinical features (including psychological symptoms)	Xray	Ammendolia (2007)[40]*	55	7	12.7 (6.3, 24.0)
Absence of red flag clinical features	Xray	Richards (2002)[41]*	2	0	0 (0.0, 65.8)
No clinical suspicion of pathology	Xray/CT/MRI	Schlemmer (2015)[6]	3320	961	28.9 (27.4, 30.5)
No clinical suspicion of pathology	Xray/CT/MRI	Lin (2016)[27]	26	23	88.5 (71.0, 96.0)
No clinical suspicion of pathology	MRI	lp (2014)[29]	100	22	22 (15.0, 37.1)
No clinical suspicion of pathology	MRI	Liu (1995)[26]	14	72	35.7 (16.3, 61.2)
No clinical suspicion of pathology or no recorded history of a prior episode with similar symptoms	Xray/CT/MRI	Bishop (2003)[33]*	31	~	22.6 (11.4, 39.8)
Cohort assessed: Patients referred for lumbosacral imaging	. lumbosacral imaging				
Absence of red flag clinical features	Xray	Eccles (2001)[43]	275	155	56.4 (50.5, 62.1)
Absence of red flag clinical features (no age criteria)	Xray	Espeland (1999)[20]	100	31	31.0 (22.8, 40.6)
Absence of red flag clinical features	Xray	Tahvonen (2016)[21]	50	34	68.0 (54.2, 79.2)

Absence of red flag clinical features	MRI	Kennedy (2014)[45]	284	136	47.9 (42.1, 53.7)
Absence of red flag clinical features	MRI	Mohammadi (2016)[47]	279	89	24.4 (19.7, 29.7)
Absence of red flag clinical features (no age criteria)	MRI	Rao (2002)[23]	66	32	32.3 (23.9, 42.1)
Absence of red flag clinical features	MRI	Kovacs (2013)[46]	25	25	20.0 (8.9, 39.1)
Absence of red flag clinical features (including age >50)	Xray	Espeland (1999)[20]*	323	147	45.5 (40.2, 51.0)
Absence of red flag clinical features (no age criteria)	Xray	Espeland (1999)[20]*	323	109	33.7 (28.8, 39.1)
Absence of red flag clinical features (including age >50)	Xray	Espeland (1999)[20]*	100	30	30.0 (21.9, 39.6)
Absence of red flag clinical features (including age >50)	MRI	Rao (2002)[23]*	66	30	30.3 (22.1, 40.0)
No clinical suspicion of pathology	MRI	Gidwani (2015)[19]	110661	33998	30.7 (30.5, 31.0)
No clinical suspicion of pathology	MRI	Emery (2013)[44]	611	218	35.7 (32.0, 39.6)

*Individual results not included in meta-analysis

Supplementary Table 3: Inappropriate imaging proportions in people presenting for care

Inappropriate imaging proportion in people presenting for care	oortion in people prese	enting for care			
Indicators of inappropriate imaging category	Imaging type	Study	Patients assessed as inappropriate for imaging (N)	Non-indicated imaging referrals (N)	Proportion of patients referred for imaging of those inappropriate for imaging % (95%CI)
Cohort assessed: LBP patients presenting for care	ting for care				
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Allen (2014)[34]	10406	5119	49.2 (48.2, 50.2)
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Charlesworth (2016)[32]	101530	17278	17.0 (16.8, 17.3)
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Hong (2017)[37] (GP)	478640	71096	14.9 (14.8, 15.0)
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Hong (2017)[37] (Chiropractor)	306507	62310	20.3 (20.2, 20.5)

Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Pham (2009)[24]	35039	9637	27.5 (27.0, 28.0)
Imaging performed under six weeks in patients with non-specific LBP	Xray/CT/MRI	Tan (2016)[5]	145320	55658	38.3 (38.1, 38.6)
Imaging performed under six weeks in patients with non-specific LBP	Xray/Advanced imaging	Thackeray (2017)[39]	454	96	21.1 (17.6, 25.1)
Imaging performed under six weeks in patients with non-specific LBP	Xray	Fritz (2013)[38]	2184	502	23.0 (21.3, 24.8)
Imaging performed under six weeks in patients with non-specific LBP	Xray	Tacci (1999)[48]	86	55	56.1 (46.3, 65.5)
Imaging performed under six weeks in patients with non-specific LBP	MRI	Graves (2014)[18]	1770	336	18.98 (17.2, 20.9)
Imaging performed under six weeks in patients with non-specific LBP	MRI	Webster (2013)[36]	332	123	37.0 (32.0, 42.4)
MRI performed under 12 weeks in patients with non-specific LBP	CT/MRI	Allen (2014)[34]*	10406	1800	17.3 (16.6, 18.0)

Absence of red flag clinical features	Xray/CT/MRI	Rao (2015)[42]	54	2	3.7 (1.0, 12.5)
Absence of red flag clinical features	Xray	Suarez-Almazor (1997)[22]	537	47	8.8 (6.7, 11.4)
Absence of red flag clinical features (no age criteria)	Xray	Ammendolia (2007)[40]	245	26	10.6 (7.4, 15.1)
Absence of red flag clinical features	Xray	Gonzalez-Urzelai (2003)[30]	83	œ	9.6 (5.0, 17.9)
Absence of red flag clinical features	Xray	Liu (1995)[26]	64	4	6.3 (2.5, 15.0)
Absence of red flag clinical features (including age >50)	Xray	Ammendolia (2007)[40]*	179	12	6.7 (3.9, 11.4)
Absence of yellow flag clinical features (including psychological symptoms)	Xray	Ammendolia (2007)[40]*	132	7	5.3 (2.6, 10.5)
Absence of red flag clinical features	Xray	Richards (2002)[41]*	ĸ	0	0.0 (0.0, 56.2)
No clinical suspicion of pathology	Xray/CT/MRI	Schlemmer (2015)[6]	7696	961	12.5 (11.8, 13.2)
No clinical suspicion of pathology	MRI	Liu (1995)[26]	152	2	3.3 (1.4, 7.5)

Cohort assessed: LBP patients referred for imaging or orthopaedic consult

Absence of red flag symptoms	MRI	Rao (2002)[23]*	29	30	44.8 (33.5, 56.6)
(including age >50)					
Absence of red flag clinical	MRI	Rao (2002)[23]*	87	32	36.8 (27.4, 47.3)
features (no age criteria)					

*Individual results not included in meta-analysis

Supplementary Table 4: Inappropriate non-referral for imaging proportions in people presenting for care

Indicators of appropriate imaging	Imaging type	Study	Patients assessed as	Patients not referred	Proportion of patients not referred for
(category)			appropriate for imaging (N)	for imaging (N)	imaging of those appropriate for imaging % (95%Cl)
Cohort assessed: LBP patients presenting for care	ng for care				
Presence of red flag clinical features	Xray/CT/MRI/Myelogram	Cook (1998)[31]	1096	746	68.1 (65.3, 70.8)
Presence of red flag clinical features	Xray/CT/MRI	Rao (2015)[42]	52	2	3.8 (1.1, 13.0)
Presence of red flag clinical features	Xray	Suarez-Almazor (1997)[22]	426	346	81.2 (77.2, 84.6)
Presence of red flag clinical features (no age criteria)	Xray	Ammendolia (2007)[40]	203	174	85.7 (80.2, 89.9)
Presence of red flag clinical features	Xray	Liu (1995)[26]	105	75	71.4 (62.2, 79.2)
Presence of red flag clinical features	Xray	Gonzalez-Urzelai (2003)[30]	22	11	50.0 (30.7, 69.3)
Presence of red flag clinical features (including age >50)	Xray	Ammendolia (2007)[40] *	269	226	84.0 (79.2, 87.9)
Presence of yellow flag clinical features (including psychological symptoms)	Xray	Ammendolia (2007)[40]*	316	268	84.8 (80.4, 88.4)

Presence of red flag clinical features Xray	Xray	Richards (2002)[41]*	2	0	0.0 (0.0, 65.8)
Clinical suspicion of pathology	Xray/CT/MRI	Schlemmer (2015)[6]	7148	4789	67.0 (65.9, 68.1)
Clinical suspicion of pathology	MRI	Liu (1995)[26]	17	∞	47.1 (26.2, 69.0)
Cohort assessed: LBP patients referred for imaging or orthopaedic consult	ed for imaging or orthopaedic co	onsult.			
Presence of red flag clinical features (including age >50)	MRI	Rao (2002)[23]*	212	143	67.5 (60.9, 73.4)
Presence of red flag clinical features (no age criteria)	MRI	Rao (2002)[23]*	192	125	65.1 (58.1, 71.5)

*Individual results not included in meta-analysis

Supplementary Table 5: Comparison of effect sizes in original meta-analysis and sensitivity analysis

Inappropriate ima	ging proportion in po	eople presenting for	care; Imaging perf	ormed under six wee	Inappropriate imaging proportion in people presenting for care; Imaging performed under six weeks in patients with non-specific LBP
Sub-group:	All studies	Studies	Studies	Studies assessing	Studies
		performed in	performed in	combined	performed 2010
		general practice	workers	Xray/CT/MRI	and later only
		only	compensation	only	
			only		
Included studies:	11 studies[5, 18,	7 studies[5, 24,	3 studies[18, 36,	6 studies[5, 24,	9 studies[5, 18,
	24, 32, 34, 36-39,	32, 34, 37-39]	48]	32, 34, 37]	32, 34, 36-39]
	48]				
Effect size (95%CI) <u>:</u>	27.7 (21.3, 35.1)	26.0 (16.9, 37.7)	35.6 (18.2, 57.9)	26.3 (18.3, 36.2)	25.4 (18.7, 33.4)
<u>1</u> 2.	100.0	100.0	98.0	100.0	100.0

Inappropriate ima	ging proportion in p	Inappropriate imaging proportion in people presenting for care; Absence of red flag clinical features	care; Absence of re	ed flag clinical featur	res		
Sub-group:	All studies	Studies	Studies				
		performed in	performed prior				
		general practice	to 2010 only				
		only					
Included studies:	5 studies[22, 26,	3 studies[22, 26,	4 studies[22, 26,				
	30, 40, 42]	30]	30, 40]				
Effect size (95%CI):	9.0 (7.4, 11.0)	8.7 (6.8, 11.0)	9.2 (7.5, 11.3)				
<u>5.</u>	0.0	0.0	0.0				
Inappropriate ima	Inappropriate imaging proportion in people referred for		naging; Absence of I	imaging; Absence of red flag clinical features	ıres		
Sub-group:	All studies	Studies	Studies assessing	Studies assessing	Studies assessing	Studies	Studies
		performed in	combined	Xray only	MRI only	performed 2010	performed prior
		general practice	Xray/CT/MRI			and later only	to 2010 only
		only	only				
Included studies:	14 studies[20-23,	11 studies[20,	3 studies[28, 35,	8 studies[20-22,	4 studies[23, 45-	6 studies[21, 28,	9 studies[20, 22,
	25, 26, 28, 30,	22, 25, 26, 28,	42]	25, 26, 30, 40,	47]	42, 45-47]	23, 25, 26, 30,
	40, 42, 43, 45-47]	30, 35, 43, 45-47]		43]			35, 40, 43]

Effect size (95%CI):	34.8 (27.1, 43.3)	34.0 (25.6, 43.6)	15.5 (3.7, 46.7)	44.0 (34.1, 54.3)	31.5 (19.6, 46.5)	26.0 (13.5, 44.1)	40.4 (32.6, 48.7)
건	91.0	91.9	95.2	85.2	91.7	94.7	82.8
Inappropriate ima	ging proportion in p	Inappropriate imaging proportion in people referred for imaging; No clinical suspicion of pathology or trauma	maging; No clinical su	uspicion of patholog	gy or trauma		
Sub-group:	All studies	Studies	Studies assessing	Studies			
		performed in	MRI only	performed 2010			
		general practice		and later only			
		only					
Included studies:	6 studies[6, 19,	3 studies[26, 29,	4 studies[19, 26,	5 studies[6, 19,			
	26, 27, 29, 44]	44]	29, 44]	27, 29, 44]			
Effect size (95%CI):	31.6 (28.3, 35.1)	30.3 (20.6, 42.3)	31.3 (27.0, 35.9)	31.5 (28.2, 35.1)			
<u>성</u>	86.5	71.5	71.9	89.2			

Sub-group:	All studies	Studies	Studies assessing	Studies
		performed in	Xray only	performed prior
		general practice		to 2010 only
		only		
Included studies:	6 studies[22, 26,	3 studies[22, 26,	4 studies[22, 26,	5 studies[22, 26,
	30, 31, 40, 42]	30]	30, 40]	30, 31, 40]
Effect size	65.6 (51.8, 77.2)	71.0 (55.4, 82.9)	75.9 (65.0, 84.3)	74.2 (64.1, 82.2)
•1	93.9	85.7	84.8	91.8

Supplementary Figure 1: Forest plot of proportion of patients presenting for care deemed appropriate for imaging due to presence of red flag clinical features

_			•					 50.0% 100.0%
Proportion %								 0.0% 50
Proportion % (95%CI)	44.2 (41.1, 47.4)	21.0 (14.2, 29.8)	62.1 (54.6, 69.1)	45.3 (40.8, 49.9)	10.1 (6.3, 15.6)	76.0 (70.6, 80.6)	3.4 (3.2, 3.6)	
Clinical setting	General practice	General practice	General practice	Chiropractic	General practice	Veterans	Workers compensation	
Imaging type	Xray	Xray	Xray	Xray	MRI	MRI	Xray/CT/MRI	
Author, year	Suarez-Almazor, 1997	Gonzalez-Urzelai, 2003	Liu, 1995	Ammendolia, 2007	Liu, 1995	Rao, 2002	Cook, 1998	

Chapter 3

Effectiveness of interventions designed to reduce the use of imaging for low-back pain: a systematic review

3.1 Preface

In Chapter 2 it was shown that approximately one third of imaging referrals for low back pain are non-indicated when compared to clinical practice guideline recommendations. An effective intervention to reduce non-indicated imaging for low back pain is therefore indicated. Prior to developing a new intervention it is necessary to assess what interventions have previously been used, and the effectiveness of these interventions. Chapter 3 presents a systematic literature review of the effectiveness of interventions aiming to reduce imaging for low back pain.

The study presented in Chapter 3 has been published as:

Jenkins HJ, Hancock MJ, French SD, Maher CG, Engel RM, Magnussen JS. Effectiveness of interventions designed to reduce the use of imaging for low-back pain: a systematic review. Canadian Medical Association Journal. 2015;187(6):401-8.

3.2 Co-authors' statement

As co-authors' of the paper, Effectiveness of interventions designed to reduce the use of imaging for low-back pain: a systematic review, we confirm that Hazel Jenkins has made the following contributions to this paper:

- Conception and design of the study
- Collection and assembly of the data
- Analysis and interpretation of the data
- Drafting and critical revision of the paper

Mark Hancock	 Date: 01/02/2019
Simon French	 Date: 01/02/2019
Chris Maher	 Date: 01/02/2019
Roger Engel	 Date: 01/02/2019
John Magnussen	 Date: 01/02/2019

Pages 81-88 of this thesis have been removed as they contain published material. Please refer to the following citation for details of the article contained in these pages.

Jenkins H. J., Hancock M. J., French S. D., Maher C. G., Engel R. M., Magnussen J. S. (2015) Effectiveness of interventions designed to reduce the use of imaging for low-back pain: a systematic review. *Canadian Medical Association Journal*. 187(6) p.401-408.

DOI: 10.1503/cmaj.141183

3.10 Published supplementary material

Appendix 1: Search strategy

For each database search terms were used for each of four key domains: low back pain; imaging; intervention; study design.

Terms within each domain were combined with 'or'.

The four key domains were combined with 'and'

Medline Database

Search terms for low back pain	Search	terms	for	low	back	pain
--------------------------------	--------	-------	-----	-----	------	------

exp Back Pain/

backache.ti,ab.

exp Low Back Pain/

(lumbar adj pain).ti,ab.

lumbago.ti,ab.

back disorder*.ti,ab.

exp Spine/

low back pain.mp.

lumbar.mp.

back pain.mp.

lumbosacral.mp.

spine.mp.

Spinal.mp.

Search terms for imaging:

diagnostic imaging/ or image interpretation, computer-assisted/ or magnetic resonance imaging/ or radiography/

CT.mp.

x-ray.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]

MRI.mp.

radiograph*.mp.

imaging.mp.

radiology.mp.

imaging utili?ation.mp.

diagnostic imaging.mp.

diagnostic x-ray.mp.

Magnetic resonance imaging.mp.

Computed tomography.mp.

Search terms for intervention:

exp *education,continuing/

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(education* adj2 (program* or intervention* or meeting* or session* or strateg* or workshop* or visit*)).mp.
(behavio?r adj2 intervention*).mp.
pamphlets/
(leaflet* or booklet* or poster* or pamphlet*).mp.
((written or printed or oral) adj information).mp.
(information* adj2 campaign).mp.
(education* adj1 (method* or material*)).mp.
advance directives/
outreach.mp.
((opinion or education* or influential) adj2 leader*).mp
facilitator*.mp.
academic detailing.mp.
consensus conference*.mp.
guideline adherence/
practice guideline*.mp.
(guideline? adj2 (introduce* or issu* or impact or effect* or disseminat* or distribut*)).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 training program*).mp.
reminder systems/
reminder*.mp.
(recall adj2 system*).mp.
prompt*.mp.
algorithm*.mp.
feedback/ or feedback.mp.
chart review*.mp.
((effect* or impact or records or chart*) adj2 audit).mp.
compliance.mp.
marketing.mp.
((standard or usual or routine or regular or traditional or conventional or pattern) adj2 care).mp.
(program* adj2 (reduc* or increase* or decreas* or chang* or improve* or modify* or monitor* or care)).mp.
(program* adj1 (health or care or intervention*)).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 treatment program*).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 care program*).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 screening program*).mp.
((effect* or impact or evaluat* or introduce* or compara*) adj2 prevent* program*).mp.
(computer* adj2 (dosage or dosing or diagnosis or therapy or decision*)).mp.
((introduce* or impact or effect* or implement* or computer*) adj2 protocol*).mp.
((effect* or impact or introduce*) adj2 (legislation or regulations or policy)).mp.
appropriate*.mp.
computer decision support.mp.
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general practitioner belief*.mp.
primary prevention.mp.
population-based.mp.
media campaign.mp.
continuing education.mp.
guideline*.mp.
computer-based guideline*.mp.
clinical practice guideline*.mp.
practice pattern feedback.mp.
theory-informed.mp.
guideline adherence.mp.
utili?ation review.mp.
patient education.mp.
Implementation.mp.
intervention*.mp.
Search terms for study design:
clinical trial.pt.
comparative study.pt.
controlled clinical trial.pt.
randomized controlled trial.pt. and Clinical trial, all.pt
time series stud*.mp. or time series.mp
interrupted time series.mp.
before and after time series.mp.
matched controlled.mp.
cluster randomi?ed trial*.mp.
quasi-randomi?ed trial*.mp.
clinical trial/
controlled clinical trial/
randomized controlled trial/
Comparative Study/
Randomi?ed.ab.
quasi-experimental.mp.
Embase Database
Search terms for low back pain:
exp Back Pain/
backache.ti,ab.
exp Low Back Pain/
(lumbar adj pain).ti,ab.
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lumbago.ti,ab.

```
back disorder*.ti,ab.
exp Spine/
low back pain.mp.
lumbar.mp.
back pain.mp.
lumbosacral.mp.
spine.mp.
Spinal.mp.
Search terms for imaging:
diagnostic imaging/ or image interpretation, computer-assisted/ or magnetic resonance imaging/ or
radiography/
CT.mp.
x-ray.mp.
MRI.mp.
radiograph*.mp.
imaging.mp.
radiology.mp.
imaging utili?ation.mp.
diagnostic imaging.mp.
diagnostic x-ray.mp.
Magnetic resonance imaging.mp.
Computed tomography.mp.
Search terms for intervention:
exp *education,continuing/
(education* adj2 (program* or intervention* or meeting* or session* or strateg* or workshop* or visit*)).mp.
(behavio?r adj2 intervention*).mp.
pamphlets/
(leaflet* or booklet* or poster* or pamphlet*).mp.
((written or printed or oral) adj information).mp.
(information* adj2 campaign).mp.
(education* adj1 (method* or material*)).mp.
advance directives/
outreach.mp.
((opinion or education* or influential) adj2 leader*).mp.
facilitator*.mp.
academic detailing.mp.
consensus conference*.mp.
guideline adherence/
practice guideline*.mp.
```

```
(guideline? adj2 (introduce* or issu* or impact or effect* or disseminat* or distribut*)).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 training program*).mp.
reminder systems/
reminder*.mp.
(recall adj2 system*).mp.
prompt*.mp.
algorithm*.mp.
feedback/ or feedback.mp.
chart review*.mp.
((effect* or impact or records or chart*) adj2 audit).mp.
compliance.mp.
marketing.mp.
((standard or usual or routine or regular or traditional or conventional or pattern) adj2 care).mp.
(program* adj2 (reduc* or increase* or decreas* or chang* or improve* or modify* or monitor* or care)).mp.
(program* adj1 (health or care or intervention*)).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 treatment program*).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 care program*).mp.
((effect* or impact or evaluat* or introduce* or compare*) adj2 screening program*).mp.
((effect* or impact or evaluat* or introduce* or compara*) adj2 prevent* program*).mp.
(computer* adj2 (dosage or dosing or diagnosis or therapy or decision*)).mp.
((introduce* or impact or effect* or implement* or computer*) adj2 protocol*).mp.
((effect* or impact or introduce*) adj2 (legislation or regulations or policy)).mp.
appropriate*.mp.
computer decision support.mp.
general practitioner belief*.mp.
primary prevention.mp.
population-based.mp.
media campaign.mp.
continuing education.mp.
guideline*.mp.
computer-based guideline*.mp.
clinical practice guideline*.mp.
practice pattern feedback.mp.
theory-informed.mp.
guideline adherence.mp.
utili?ation review.mp.
patient education.mp.
Implementation.mp.
intervention*.mp.
```

Search terms for study design: clinical trial.pt. comparative study.pt. controlled clinical trial.pt. (randomized controlled trial and Clinical trial, all).pt. (time series stud* or time series).mp. interrupted time series.mp. (before and after time series).mp. matched controlled.mp. cluster randomi?ed trial*.mp. quasi-randomi?ed trial*.mp. clinical trial/ controlled clinical trial/ randomized controlled trial/ Comparative Study/ Randomi?ed.ab. quasi-experimental.mp. **Cinahl Database** Search terms for low back pain: lumbar N2 vertebra (MH "Lumbar Vertebrae") "Spinal" "Spine" "Lumbosacral" "back pain" "Lumbar" "low back pain" (MH "Spine+") "back disorder*" "lumbago" lumbar W1 pain lumbar N5 pain (MH "Low Back Pain") "backache" (MH "Back Pain+") Search terms for imaging: "Computed tomography" "Magnetic resonance imaging"

"diagnostic x-ray"

```
"diagnostic imag*"
"imaging utili?ation"
"Radiology"
"Imaging"
"radiograph*"
"MRI"
"x-ray"
"CT"
(MH "radiography")
(MH "diagnostic imaging")
(MH "magnetic resonance imaging")
Search terms for intervention:
"intervention*"
"Implementation"
"patient education"
"utili?ation review"
"guideline adherence"
"theory-informed"
"practice pattern feedback"
"practice pattern feedback"
"clinical practice guideline*"
"computer-based guideline*"
"guideline*"
"continuing education"
"media campaign"
"population-based"
"primary prevention"
"general practitioner belief*"
"computer decision support"
"appropriate*"
(("effect*" or "impact" or "introduce*") N2 ("legislation" or "regulations" or "policy"))
(("introduce*" or "impact" or "effect*" or "implement*" or "computer*") N2 "protocol*")
("computer*" N2 ("dosage" or "dosing" or "diagnosis" or "therapy" or "decision*"))
(("effect*" or "impact" or "evaluat*" or "introduce*" or "compara*") N2 "prevent* program*")
(("effect*" or "impact" or "evaluat*" or "introduce*" or "compare*") N2 "screening program*")
(("effect*" or "impact" or "evaluat*" or "introduce*" or "compare*") N2 "care program*")
(("effect*" or "impact" or "evaluat*" or "introduce*" or "compare*") N2 "treatment program*")
("program*"N1 ("health" or "care" or "intervention*"))
```

```
("program*" N2 ("reduc*" or "increase*" or "decreas*" or "chang*" or "improve*" or "modify*" or
"monitor*" or "care"))
(("standard" or "usual" or "routine" or "regular" or "traditional" or "conventional" or "pattern") N2 "care")
"Marketing"
"compliance"
(("effect*" or "impact" or "records" or "chart*") N2 "audit")
"feedback*"
"chart review*"
"algorithm*"
"prompt*"
("recall" N2 "system*")
"reminder*"
(MH *reminder systems*)
(("effect*" or "impact" or "evaluat*" or "introduce*" or "compare*") N2 "training program*")
("guideline?"N2 ("introduce*" or "issu*" or "impact" or "effect*" or "disseminat*" or "distribut*"))
"practice guideline*"
(MH "guideline adherence")
"consensus conference*"
"academic detailing"
"facilitator*"
(("opinion" or "education*" or "influential") N2 "leader*")
"Outreach"
(MH "advance directives")
("education*" N1 ("method*" or "material*"))
("information*" N2 "campaign")
(("written" or "printed" or "oral") N1 "information")
("leaflet*" or "booklet*" or "poster*" or "pamphlet*")
(MH "pamphlets")
("behavio?r*" N2 "intervention*")
("education*" N2 ("program*" or "intervention*" or "meeting*" or "session*" or "strateg*" or "workshop*" or
"visit*"))
(MH "education,continuing")
(MH "education,continuing")
Search terms for study design:
follow-up stud*
(MH "Evaluation Research+")
(MH "Prospective Studies+")
random*
(MH "Comparative Studies")
```

"randomi*ed controlled trial" "randomi*ed controlled trial" "controlled clinical trial" (MH "Clinical Trials+") "quasi-randomi?ed trial*" "cluster randomi?ed trial*" "matched controlled" "before and after time series" "interrupted time series" "time series stud*" or "time series" "randomi?ed controlled trial*" and "Clinical trial" "controlled clinical trial" "comparative study" clinical W3 trial **Cochrane Central Database** Search terms for low back pain: MeSH descriptor: [Back Pain] explode all trees backache MeSH descriptor: [Low Back Pain] explode all trees lumbar next pain Lumbago back disorder* MeSH descriptor: [Spine] explode all trees low back pain lumbar back near pain lumbosacral spine Spinal lumbar near vertebra* Search terms for imaging: MeSH descriptor: [Diagnostic Imaging] explode all trees MeSH descriptor: [Magnetic Resonance Imaging] explode all trees MeSH descriptor: [Radiography] explode all trees CTx-ray MRI radiograph*

imaging

```
radiology
imaging utili?ation
diagnostic imaging
diagnostic x-ray
Magnetic resonance imaging
Computed tomography
Search terms for intervention:
MeSH descriptor: [Education, Continuing] explode all trees
(education* near (program* or intervention* or meeting* or session* or strateg* or workshop* or visit*))
(behavio?r near intervention*)
MeSH descriptor: [Pamphlets] explode all trees
(leaflet* or booklet* or poster* or pamphlet*)
((written or printed or oral) next information)
(information* near campaign)
(education* next (method* or material*))
MeSH descriptor: [Advance Directives] explode all trees
outreach
((opinion or education* or influential) near leader*)
facilitator*
academic detailing
consensus conference*
MeSH descriptor: [Guideline Adherence] explode all trees
practice guideline*
(guideline? near (introduce* or issu* or impact or effect* or disseminat* or distribut*))
((effect* or impact or evaluat* or introduce* or compare*) near training program*)
MeSH descriptor: [Reminder Systems] explode all trees
reminder*
(recall near system*)
prompt*
algorithm*
MeSH descriptor: [Feedback] explode all trees
feedback
chart review*
((effect* or impact or records or chart*) near audit)
compliance
marketing
((standard or usual or routine or regular or traditional or conventional or pattern) near care)
(program* near (reduc* or increase* or decreas* or chang* or improve* or modify* or monitor* or care))
(program* next (health or care or intervention*))
```

```
((effect* or impact or evaluat* or introduce* or compare*) near treatment program*)
((effect* or impact or evaluat* or introduce* or compare*) next care program*)
((effect* or impact or evaluat* or introduce* or compare*) near screening program*)
((effect* or impact or evaluat* or introduce* or compara*) near prevent* program*)
(computer* near (dosage or dosing or diagnosis or therapy or decision*))
((introduce* or impact or effect* or implement* or computer*) near protocol*)
((effect* or impact or introduce*) near (legislation or regulations or policy))
appropriate*
computer decision support
general practitioner belief*
primary prevention
population-based
media campaign
continuing education
guideline*
computer-based guideline*
clinical practice guideline*
practice pattern feedback
theory-informed
guideline adherence
utili?ation review
patient education
Implementation
intervention*
```

Search terms for study design:

Search terms for study design not used for Central due to the nature of the database

Appendix 2: Health outcomes, results from studies

Study	Secondary outcome	Number of	Number of	Intervention	Control	Intervention	Control	Risk ratio	Effect with adjustment for
	measure	patients	patients	group event	group	group	group	%56)	clustering as reported in
		intervention	control		event	outcome	outcome	confidence	original study
						measure (%)	measure	interval)*†	
							(%)		
Dey et al.	Sickness certificates	1049	1138	186	219	17.7	19.2	0.9 (0.8-1.1)	Risk difference (95%CI)
(2004)									-1.5% (-10.3 to 7.3)
Dey et al.	Prescribed opioids or	1049	1138	196	213	18.7	18.7	1.0 (0.8-1.2)	Risk difference (95%CI)
(2004)	muscle relaxants								-0.03% (-5.5 to 5.4)
Dey et al.	Referred to secondary	1049	1138	36	26	3.4	2.3	1.5 (0.9-2.5)	Risk difference (95%CI)
(2004)	care								1.1% (-0.3 to 2.6)
Dey et al.	Referred to	1049	1138	273	157	26.0	13.8	1.9 (1.6-2.3)	Risk difference (95%CI)
(2004)	physiotherapy or								12.2% (2.8 to21.6)
	educational program								
Schectman et	Referral to physical	588	544	58.8	70.7	10.0	13.0	0.8 (0.6-1.1)	Not reported
al. (2003)	therapy								
Schectman et	Referral to specialist	588	544	50.6	38.6	9.8	7.1	1.2 (0.8-1.8)	Not reported
al. (2003)									

* Not adjusted for clustering

† Values less than 1 represent a decrease in the intervention group compared to control

Chapter 4

Understanding patient beliefs regarding the use of imaging in the management of low back pain

4.1 Preface

In Chapters 2 and 3 it was shown that non-indicated imaging for low back pain is common and that effective interventions to decrease imaging use have not been clearly demonstrated. Interventions to date have only targeted practitioners rather than patients, despite qualitative evidence presented in Chapter 1 that patient requests for imaging are an important barrier to reducing imaging use. The extent that patients believe imaging to be important in the management of low back pain will inform whether there is a need to address patient beliefs as part of an intervention to reduce imaging use. Chapter 4 presents the results of a survey of 300 patients presenting for general medical care to determine their beliefs regarding the use of imaging for low back pain.

The study presented in Chapter 4 has been published as:

Jenkins HJ, Hancock MJ, Maher CG, French SD, Magnussen JS. Understanding patient beliefs regarding the use of imaging in the management of low back pain. European Journal of Pain. 2016;20(4):573-80. doi: 10.1002/ejp.764.

Ethics approval for the study presented in Chapter 4 was obtained through the Macquarie University Human Research Ethics Committee on 29th May, 2014; Reference number: 5201400333 (Chapter 8, Appendix 1)

4.2 Co-authors' statement

As co-authors' of the paper, *Understanding patient beliefs regarding the use of imaging in the management of low back pain*, we confirm that Hazel Jenkins has made the following contributions to this paper:

- Conception and design of the study
- Collection and assembly of the data
- Analysis and interpretation of the data
- Drafting and critical revision of the paper

Mark Hancock	 Date: 01/02/2019
Chris Maher	 Date: 01/02/2019
Simon French	 Date: 01/02/2019
John Magnussen	Date: 01/02/2019

Pages 103-110 of this thesis have been removed as they contain published material. Please refer to the following citation for details of the article contained in these pages.

Jenkins H. J., Hancock M. J., Maher C. G., French S. D., Magnussen J. S. (2016) Understanding patient beliefs regarding the use of imaging in the management of low back pain. *European Journal of Pain*. 20(4) p.573-580.

DOI: <u>10.1002/ejp.764</u>

4.11 Published supplementary material

Appendix 1: Survey questions

Section A: Demographic Data 1. Date of Birth (dd/mm/yy): _____ 2. Gender: ■ Male **□** Female 3. What is the highest level of education that you have completed? ☐ Primary school ☐ Some secondary school ☐ Completed secondary school ☐ Some additional training (apprenticeship, TAFE courses etc.) ☐ Undergraduate university ☐ Postgraduate university 4. What is your health insurance status? ■ None ☐ Private hospital only ☐ Private ancillary (Extras) only ☐ Private hospital and ancillary (Extras) ☐ Department of Veteran Affairs 5. What is your cultural background? ☐ Australian/European/British/North American

☐ Aboriginal/Torres Strait Islander/Pacific Islander

☐ Asian

	Middle Eastern
	African
	Hispanic
П	Other

Section B: Low Back Pain Characteristics

6.	Have you	experier	iced low	back pai	n (pain a	nywhere	in the a	rea betw	een the	lowest
	rib and th	e buttoc	k crease	, as pictu	red)					
	- tick <u>all</u> t	hat apply	,							
		Now					Su			
		In the la	ast 6 mo	nths			44	'\ (1	Mh
		In the la	ast 12 m	onths						
	0	Previou	s to the	last 12 m	onths					
		I have n	ever exp	perienced	d low bac	ck pain (<u>r</u>	olease go	straight	to section	<u>on C</u>)
7.	Are you p	resentin	g to you	r GP for lo	ow back	pain toda	ay?			
		Yes								
		No								
For th	e following	g questio	ns, 8-11	, with a s	scale of 1	-10 plea	se circle	one num	nber onl	у
8.	How wou	ld you ra	te your l	low back	pain on a	a 0-10 sc	ale at th	e present	t time, tl	nat is
	right now	, where () is "no p	oain" and	l 10 is "pa	ain as ba	d as it co	ould be"?		
0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as it could
9.	In the pas	st, how in	tense w	as your v	vorst low	/ back pa	in rated	on a 0-10) scale w	here 0
	is "no pai	n" and 10) is "pair	n as bad a	as it coul	d be"?				
0	1	2	3	4	5	6	7	8	9	10
No Pain	I .	1	1	1	1	I	1	1	ı	Pain as bad

as it could

10.	Currently	(right no	w), how	much is	low back	c pain int	erfering	with you	ır daily	
	activities r	rated wh	ere 0 is '	'no inter	ference"	and 10 i	s "unabl	e to carr	y on acti	vities"?
0	1	2	3	4	5	6	7	8	9	10
No Interferen	ce									Unable to carry on
11.	In the pas				•		-	-		
0	1	2	3	4	5	6	7	8	9	10
No Interferen	ce					<u> </u>		<u> </u>	l	Unable to carry on
Section 12.	n C: Imagin Have you pain?				tic imagi	ng (x-ray	, CT, MR	l etc.) fo	r low bad	ck
	•	No								
		Yes								
	If yes, wha	at type of	f imaging	g and wh	en?					
	e interested general view				_	_		oain. Ple	ase indic	cate
Please	number <i>Al</i>	LL statem	nents and	d indicat	e whethe	er you <i>ag</i>	ree or d	isagree v	vith each	1
	nent by circ	•								
1=CO	MPLETELY C	OISAGREE	5= C	OMPLET	ELY AGRI	EE				
1 COMPLET DISAGRE			3		4	COMPLETEL AGRE	Y			

COMPLETELY COMPLETELY DISAGREE AGREE

13. X-rays or scans are necessary to					
get the best medical care for low back					
pain					
	1	2	3	4	5
14. Everyone with low back pain					
should have spine imaging (e.g X-ray,	4	2	2	4	F
CT or MRI)	1	2	3	4	5

Section D: Back Pain Beliefs Questionnaire

Bowey-Morris J, Davis S, Purcell-Jones G, Watson PJ. Beliefs about back pain: results of a population survey of working age adults. Clinical Journal of Pain.27(3):214-24.

We are interested in what people think about low back pain. Please indicate your general views towards back trouble, even if you have never had any.

Please number *ALL* statements and indicate whether you *agree* or *disagree* with each statement by circling the appropriate number on the scale.

1=COMPLETELY DISAGREE 5= COMPLETELY AGREE

1 2 3 4 5
COMPLETELY
DISAGREE

AGREE

	COMPLETELY DISAGREE				COMPLETELY AGREE
15. There is no real treatment for					
back trouble	1	2	3	4	5
16. Back trouble will eventually stop					
you from working	1	2	3	4	5
17. Back trouble means periods of					
pain for the rest of one's life	1	2	3	4	5
18. Doctors cannot do anything for					
back trouble	1	2	3	4	5
19. A bad back should be exercised					
	1	2	3	4	5
20. Back trouble makes everything in					
life worse	1	2	3	4	5
21. Surgery is the most effective way					
to treat back trouble					

	1	2	3	4	5
22. Back trouble may mean you will					
end up in a wheelchair	1	2	3	4	5
23. Alternative treatments are the					
answer to back trouble	1	2	3	4	5
24. Back trouble means long periods					
of time off work	1	2	3	4	5
25. Medication is the only way of					
relieving back trouble	1	2	3	4	5
26. Once you have had back trouble					
there is always a weakness	1	2	3	4	5
27. Back trouble must be rested					
	1	2	3	4	5
28. Later in life back trouble gets					
progressively worse	1	2	3	4	5

Thank you for completing this questionnaire. We value your time and appreciate that you have contributed to our research.

Chapter 5

Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain

5.1 Preface

The needs assessment performed in Chapters 2 to 4 indicated that an effective intervention to reduce non-indicated imaging for low back pain is required. Strategies to decrease patients' belief that imaging is important in the management of low back pain (Chapter 4) should be considered as part of the intervention. Chapter 5 presents a study using the Behaviour Change Wheel and qualitative feedback from preliminary testing to develop an intervention to reduce non-indicated imaging for low back pain.

The study presented in Chapter 5 has been published as:

Jenkins HJ, Moloney NA, French SD, Maher CG, Dear BF, Magnussen JS, et al. Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain. BMC Health Services Research. 2018;18(1):734. doi: 10.1186/s12913-018-3526-7.

Ethics approval for the study presented in Chapter 5 was obtained through the Macquarie University Human Research Ethics Committee on 10th May, 2016; Reference number: 5201600298 (Chapter 8, Appendix 2)

5.2 Co-authors' statement

As co-authors' of the paper, Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain, we confirm that Hazel Jenkins has made the following contributions to this paper:

- Conception and design of the study
- Initial development and revision of the intervention
- Participant recruitment, and interviews
- Collection and assembly of the data
- Analysis and interpretation of the data
- Drafting and critical revision of the paper

Niamh Moloney	 Date: 01/02/2019
Simon French	 Date: 01/02/2019
Chris Maher	 Date: 01/02/2019
Blake Dear	 Date: 01/02/2019
John Magnussen	 Date: 01/02/2019
Mark Hancock	 Date: 01/02/2019

RESEARCH ARTICLE

Open Access



Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain

Hazel J. Jenkins^{1,2*}, Niamh A. Moloney¹, Simon D. French², Chris G. Maher³, Blake F. Dear⁴, John S. Magnussen⁵ and Mark J. Hancock¹

Abstract

Background: Imaging is overused in the management of low back pain (LBP). Interventions designed to decrease non-indicated imaging have predominantly targeted practitioner education alone; however, these are typically ineffective. Barriers to reducing imaging have been identified for both patients and practitioners. Interventions aimed at addressing barriers in both these groups concurrently may be more effective. The Behaviour Change Wheel provides a structured framework for developing implementation interventions to facilitate behavioural change. The aim of this study was to develop an implementation intervention aiming to reduce non-indicated imaging for LBP, by targeting both general medical practitioner (GP) and patient barriers concurrently.

Methods: The Behaviour Change Wheel was used to identify the behaviours requiring change, and guide initial development of an implementation intervention. Preliminary testing of the intervention was performed with: 1) content review by experts in the field; and 2) qualitative analysis of semi-structured interviews with 10 GPs and 10 healthcare consumers, to determine barriers and facilitators to successful implementation of the intervention in clinical practice. Results informed further development of the implementation intervention.

Results: Patient pressure on the GP to order imaging, and the inability of the GP to manage a clinical consult for LBP without imaging, were determined to be the primary behaviours leading to referral for non-indicated imaging. The developed implementation intervention consisted of a purpose-developed clinical resource for GPs to use with patients during a LBP consult, and a GP training session. The implementation intervention was designed to provide GP and patient education, remind GPs of preferred behaviour, provide clinical decision support, and facilitate GP-patient communication. Preliminary testing found experts, GPs, and healthcare consumers were supportive of most aspects of the developed resource, and thought use would likely decrease non-indicated imaging for LBP. Suggestions for improvement of the implementation intervention were incorporated into a final version.

(Continued on next page)

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



^{*} Correspondence: hazel.jenkins@mq.edu.au

¹Department of Health Professions, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia

²Department of Chiropractic, Faculty of Science and Engineering, Macquarie University, Sydney, Australia

(Continued from previous page)

Conclusions: The developed implementation intervention, aiming to reduce non-indicated imaging for LBP, was informed by behaviour change theory and preliminary testing. Further testing is required to assess feasibility of use in clinical practice, and the effectiveness of the implementation intervention in reducing imaging for LBP, before large-scale implementation can be considered.

Keywords: Low back pain, implementation intervention, Diagnostic imaging, Intervention development, Behaviour change wheel

Background

Low back pain (LBP) is a common problem, with a mean one-year prevalence of 38.1% [1]. It is one of the leading causes of global disability [2] and care seeking [3], and is associated with high direct (medical) and indirect (non-medical) costs [4], resulting in large economic and social burden.

Diagnostic imaging, such as x-ray, CT, or MRI, is commonly used to investigate LBP but has limited utility. Imaging is only indicated in cases of suspected serious pathology (e.g. cancer or infection), or cases of specific pathology (e.g. spinal stenosis) where surgery is being considered [4]. These are estimated to account for less than 10% of all LBP presentations [3, 4]. For other LBP presentations, imaging has not been shown to improve clinical outcomes and is associated with unnecessary radiation exposure, increased costs to the patient and healthcare system, and potentially inappropriate treatment [5]. Although clinical practice guidelines recommend imaging only in certain cases of LBP, poor adherence to these guidelines is seen in clinical practice [4, 6, 7].

Overuse of imaging for LBP has been identified as a problem in general medical practice [5, 8, 9], with between one-third to one-half of requested imaging considered inappropriate [10–14]. Many potential barriers to reducing imaging for LBP have been reported, including both practitioner and patient-related factors [15]. Interventions aiming to address practitioner-related barriers have been assessed, including guideline dissemination, practitioner education, audit and feedback of imaging practices, and clinical decision support [16]. Only clinical decision support demonstrated evidence of effectiveness [16], however, this can be difficult to implement in general medical practice.

A large proportion of patients believe that imaging is important for the correct diagnosis and management of LBP [17–19]. This belief has been associated with increased imaging referrals [20, 21], and therefore may be an important barrier to address. Several studies have investigated population-based education interventions aiming to change beliefs about back pain, with varying results on the use of imaging [22–25]. Individualised patient education has been shown to improve general back pain beliefs [26, 27], however, whether individualised patient education is an effective intervention to

reduce imaging for LBP has not been studied [16]. The development of an effective intervention, addressing both practitioner and patient related barriers to reducing non-indicated imaging, which can be successfully implemented in clinical practice, would be of great public health value.

The process of designing effective interventions to change behaviour in clinical practice is challenging. Process models, including the Behaviour Change Wheel [28, 29] and the Theoretical Domains Framework [30], have been developed to guide the development of implementation interventions to facilitate behaviour change [31]. These typically incorporate elements of: 1) analysis of the underlying behaviour; 2) selection of appropriate intervention techniques; 3) design of an implementation strategy; and 4) evaluation of the developed intervention [32–34]. Previously developed interventions to improve LBP care and reduce inappropriate imaging have generally not used an underlying theoretical framework [31, 35].

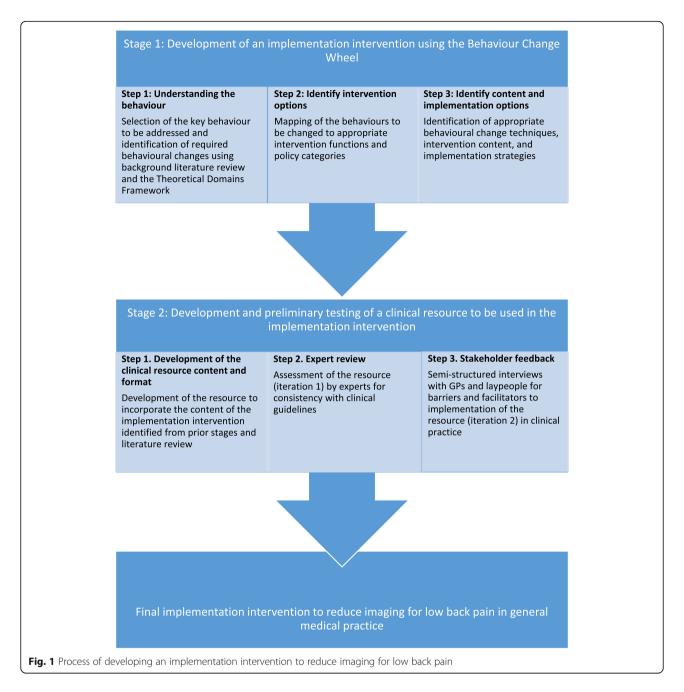
Preliminary testing of developed interventions is important to improve implementation of the intervention within clinical practice [33]. Identification of barriers and facilitators to the implementation of developed interventions is rarely conducted [31], potentially reducing the effectiveness and impact of the intervention in a clinical setting.

The aim of this study was to develop an implementation intervention aiming to reduce non-indicated imaging for LBP, by targeting both general medical practitioner (GP) and patient barriers concurrently.

Methods

Overview of development and preliminary testing of the implementation intervention

Figure 1 outlines the process used to develop, and perform preliminary testing of, an implementation intervention to reduce GP referral for non-indicated imaging in the management of LBP using the Behaviour Change Wheel [28, 29], with integration of the Theoretical Domains Framework [28, 30]. Ethics approval was granted by Macquarie University Human Research Ethics Committee (MUHREC), reference number: 5201600298.



Stage 1: Development of an implementation intervention using the behaviour change wheel

The three steps of the Behaviour Change Wheel [28], as depicted in Fig. 1, were initially completed by one author. To perform an in-depth analysis of the behaviours to be changed, barriers and facilitators to reducing imaging for LBP were identified through literature review. The APEASE criteria as defined in the Behaviour Change Wheel (Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects and safety, Equity) were considered to direct the selection of appropriate intervention options, content, and implementation options [28].

Discussion among all authors was used to arrive at a consensus of a draft implementation intervention that was considered to be appropriate, practical and economical within a primary care setting.

Stage 2: Development and preliminary testing of a clinical resource to be used in the implementation intervention

In stage 1, it was determined that development of a purpose-designed clinical resource would be required to incorporate identified intervention content and implementation strategies. This clinical resource would be a LBP management and education booklet, to be used by GPs during a clinical consult, to improve the GPs ability to manage LBP without referring for non-indicated imaging, while simultaneously reducing pressure from the patient to refer for imaging. Development and preliminary testing of the resource was performed as described in Fig. 1. A review of the literature was used to identify: 1) key educational messages to be incorporated into the resource; 2) patient perspectives on the management of LBP and what information they wish to receive; and 3) evidenced-based management strategies for LBP. The draft resource was sent for design and marketing feedback to optimise visual impact and readability.

Expert review of the clinical resource (iteration 1)

The first iteration of the developed clinical resource was sent for assessment to five international LBP experts, including radiologists, rheumatologists, and general medical practitioners. They were asked to complete a written questionnaire asking: 1) if the information in the resource was consistent with current guidelines; 2) if they thought use of the resource would be likely to change behaviour; and 3) if the information was provided in a suitable format. Questionnaire responses were summarised and the resource was modified based on these responses, after discussion and consensus from all authors, to develop a second iteration of the clinical resource.

Stakeholder feedback on the clinical resource (iteration 2) and its proposed implementation into clinical practice Stakeholder feedback was sought through semi-structured interviews from GPs and health consumers (laypeople with a history of LBP) to identify barriers and facilitators to implementation of the clinical resource in clinical practice. GPs and health consumers were recruited from Sydney (and surrounding areas), New South Wales, Australia.

Convenience sampling of GPs was performed until thematic saturation was reached. To be included, GPs needed to be in current practice and seeing patients with LBP. GPs were sampled to include a range of gender, years of experience, and practice location in different socioeconomic areas.

Health consumers were recruited through advertisements in print format and on social media until thematic saturation was achieved. To be included, laypeople needed to be over the age of 18, have a history of LBP, and be able to read and understand English. Sampling was conducted to ensure a range of gender, ages, and cultural and educational backgrounds.

All participants were provided with a copy of the second iteration of the clinical resource and asked to read it before participating in an audio-recorded interview with one of the authors. Participants received an AUD\$30 gift voucher for their time. Interview questions included:

background demographic questions; current beliefs about imaging for LBP; barriers and facilitators to implementation of the resource in clinical practice; appropriateness of the included information; and whether use of the resource would be likely to change behaviour.

Interviews were transcribed and coded by one author. Thematic analysis using the Theoretical Domains Framework [30] was initially performed by one author, with iterative review and discussion from other authors, until final themes and potential changes to the resource and its implementation were determined.

Final implementation intervention to reduce imaging for LBP in general medical practice

The draft implementation intervention was revised based on results from preliminary testing. Potential changes to the implementation intervention were discussed with all authors before final changes to the implementation intervention components (including the clinical resource) were made.

Results

Stage 1: Development of a draft implementation intervention using the behaviour change wheel Step 1: Understanding the behaviour

The behavioural problem to be addressed was defined by the authors as: GPs referring for non-indicated imaging in patients presenting with LBP. LBP was not restricted to type (i.e. acute or chronic) or whether the patient had received prior management. Instead the focus was on any presentation of non-specific LBP where imaging was not indicated. Barriers and facilitators to reducing GP referral for non-indicated imaging were identified through literature review, and are outlined in Table 1. Figure 2 depicts a concept map of how the identified barriers are likely to drive an increase in GP referral for non-indicated imaging. Patient-related barriers are likely to increase the likelihood of a patient requesting imaging from the GP. GP-related barriers are likely to increase the likelihood of the GP using imaging to help manage the LBP consult. The interaction between the patient and GP behaviours during a clinical consult is likely to increase GP referral for non-indicated imaging. Therefore, both patient and GP behaviours during a clinical consult need to be addressed concurrently in the implementation intervention.

Table 1 lists the specific changes required in GPs and patients to decrease GP referral for non-indicated imaging based on the identified barriers and facilitators. These changes were mapped to capability, opportunity, and motivation components (COM-B model) from the Behaviour Change Wheel and to domains from the Theoretical Domains Framework that need to be considered to bring about a change in behaviour (Table 1).

Table 1 Changes required at the general practitioner (GP) and patient level to reduce GP use of non-indicated imaging for low back pain, mapped to the associated barriers and facilitators, the domains of the Theoretical Domains Framework, and the Behaviour Change Wheel

Change Wheel			
Changes required to reduce referral for non-indicated imaging for low back pain	Barriers and facilitators (identified through literature review) that will be influenced by the identified change	Theoretical Domains Framework component	COM-B component (Behaviour Change Wheel)
General practitioner (GP) changes require	d:		
- GPs need to have the skills to: 1. Screen for clinical suspicion of underlying pathology to determine if imaging is necessary 2. Communicate with patients to explain their diagnosis and advise them that they don't need imaging	Barriers: - Diagnostic uncertainty [30, 46, 54, 55] GPs uncertain in their skills in adequately diagnosing low back pain without imaging; Fear of missing a diagnosis of underlying pathology - Unsure how to advise patients that imaging is not needed [52] GPs uncertain how to convincingly explain to patients that imaging is not needed Facilitators: - Communication with patients [46] GPs confident in communicating with patients, to educate and reassure them	Skills	Physical capability
 GPs need to have knowledge of: 1. Guidelines and appropriate indications for imaging 2. Limitations of imaging in the diagnosis and management of low back pain 3. Risks of imaging 4. Key concepts required in patient explanations explain why imaging isn't necessary 	Barriers: - Lack of guideline awareness [30, 46, 52, 55] GPs lack knowledge and awareness of current guidelines recommending appropriate use of imaging for low back pain - Unsure how to advise patients that imaging is not needed [52] GPs uncertain how to convincingly explain to patients that imaging is not needed Facilitators: - Guideline awareness [51, 52] GPs display knowledge of current guidelines recommending appropriate use of imaging for low back pain - Awareness of limitations of imaging [51] GPs aware of limitations of imaging in providing diagnoses, directing management, or reassuring patients Awareness of danger of radiation exposure [51] GP aware that x-rays and CT scans add to radiation exposure and may be harmful	Knowledge	Psychological capability
- GPs need to use a decision- making process which incorporates the appropriate use of imaging	Barriers: - Diagnostic uncertainty [30, 46, 54, 55] GPs uncertain in their skills in adequately diagnosing low back pain without imaging; Fear of missing a diagnosis of underlying pathology Facilitators: - Availability of guidelines [51] Guidelines act as a memory-aid and are more likely to be followed if they are accessible, concise and user-friendly.	Memory, attention, and decision process	Psychological capability

Table 1 Changes required at the general practitioner (GP) and patient level to reduce GP use of non-indicated imaging for low back pain, mapped to the associated barriers and facilitators, the domains of the Theoretical Domains Framework, and the Behaviour Change Wheel (*Continued*)

Changes required to reduce referral for non-indicated imaging for low back pain	Barriers and facilitators (identified through literature review) that will be influenced by the identified change	Theoretical Domains Framework component	COM-B component (Behaviour Change Wheel)
- GPs need to have: 1. Increased time for patient education 2. Cues to remind them of imaging appropriateness 3. Resources to give to patient to improve ability to educate and reassure the patient in a limited time	Barriers: - Time constraints [30, 48–50, 54, 55] GPs don't have enough time with patients to provide explanations and reassurance; Imaging seen as a quick way to reassure the patient and increase patient compliance - Diagnostic uncertainty [30, 46, 54, 55] GPs uncertain in their skills in adequately diagnosing low back pain without imaging; Fear of missing a diagnosis of underlying pathology - Perceived need to give the patient something to take home [30] GPs feel that patients expect to receive something from the consult and an imaging referral is often used to achieve this	Environmental context and resources	Physical opportunity
- GPs need to use their role as a trusted source of information provision to educate patients	Facilitators: - Communication with patients [46] GPs confident in communicating with patients, to educate and reassure them - Senior GP who adheres to guidelines [52] Having a senior GP to model correct behaviour and act as a potential opinion leader to the other GPs	Social influences	Social opportunity
 GPs need to be confident in their ability to: 1. Screen for clinical suspicion of underlying pathology to determine feel that imaging Ps feel that imaging is necessary 2. Reassure patients without imaging 	Barriers: - Perceived patient expectations [30, 46, 48, 50–52, 54, 55] GPs feel that patients often want or expect imaging, and that they don't understand the limited usefulness of imaging to manage low back pain; Fear that patients will be upset if they don't receive imaging or may devalue the GP	Beliefs about capabilities	Reflective motivation
- GPs need to be aware of the risks and benefits of referring for imaging, and the likely consequences of referring for imaging when it isn't indicated	Barriers: - Perceived usefulness of imaging and negative consequences to following guidelines [30, 46, 47, 49–52, 55] GPs feel that imaging will be useful – provide diagnosis, help to reassure the patient, help to facilitate patient management, build patient relationships; They feel there are more negative consequences associated with following guideline advice not to refer for imaging - Pressure from patients [20, 49–51, 54, 55] GPs report that they receive direct pressure from patients to refer for imaging; They feel that if they don't comply with the request patients will devalue them and go elsewhere to obtain imaging - Perceived patient anxiety [30, 46, 47, 49, 51, 55] GPs perceive that imaging will help to reassure anxious patients that their condition is not serious and will increase compliance with advice - Possible litigation [48, 51, 55]	Beliefs about consequences	Reflective motivation

Table 1 Changes required at the general practitioner (GP) and patient level to reduce GP use of non-indicated imaging for low back pain, mapped to the associated barriers and facilitators, the domains of the Theoretical Domains Framework, and the Behaviour Change Wheel (*Continued*)

Changes required to reduce referral for non-indicated imaging for low back pain	Barriers and facilitators (identified through literature review) that will be influenced by the identified change	Theoretical Domains Framework component	COM-B component (Behaviour Change Wheel)
	GPs feel that they may open themselves to possible litigation if they don't refer for imaging - Specific patient characteristics [46, 50] Specific patient characteristics more likely to lead to increased imaging (i.e. elderly, workers compensation claims, etc.) Facilitators: - Perceived positive consequences to following guidelines [30, 55] GPs are in agreement with the guidelines and feel that more positive consequences are associated with following guideline advice not to refer for imaging		
Patient changes required:			
 Patients need to have knowledge of: 1. Limitations of imaging in the management of low back pain 2. Risks of imaging 3. Signs to be aware of that may indicate the need for imaging 	Barriers: - Perceived reassurance and explanation of symptoms from imaging [19, 21, 45, 56] Patients feel that imaging will provide reassurance to them by excluding pathological causes of low back pain and providing a diagnosis, particularly when pain levels are high or not resolving - Lack of awareness of risks of imaging [19] Patients report being unaware of potential risks of imaging, and even where some risks are recognised report that potential benefits outweigh these risks.	Knowledge	Psychological capability
- Patients need to be aware of the decision process that was used to determine that they don't need imaging	Barriers: - Perceived reassurance and explanation of symptoms from imaging [19, 21, 45, 56] Patients feel that imaging will provide reassurance to them by excluding pathological causes of low back pain and providing a diagnosis, particularly when pain levels are high or not resolving Facilitators - Communication with patients [46] Patients whose GPs communicate with them adequately are more likely to be reassured without the use of imaging	Memory, attention, and decision process	Psychological capability
 Patients need to receive educational resources focusing on patient reassurance, appropriate management and why imaging isn't required 	Barriers: - Perceived reassurance and explanation of symptoms from imaging [19, 21, 45, 56] Patients feel that imaging will provide reassurance to them by	Environmental context and resources	Physical opportunity

Table 1 Changes required at the general practitioner (GP) and patient level to reduce GP use of non-indicated imaging for low back pain, mapped to the associated barriers and facilitators, the domains of the Theoretical Domains Framework, and the Behaviour Change Wheel (Continued)

Changes required to reduce referral for non-indicated imaging for low back pain	Barriers and facilitators (identified through literature review) that will be influenced by the identified change	Theoretical Domains Framework component	COM-B component (Behaviour Change Wheel)
	excluding pathological causes of low back pain and providing a diagnosis, particularly when pain levels are high or not resolving - Lack of awareness of risks of imaging [19] Patients report being unaware of potential risks of imaging, and even where some risks are recognised report that potential benefits outweigh these risks		
- Patients need to have less access to contradictory information sources, or more access to evidence-based information sources	Barriers: - Influences from friends, family, or other healthcare practitioners, and previous experience that imaging is important [19] Advice from friends, family, or other healthcare practitioners, and previous experience of referral for imaging for low back pain likely to increase perceived need for imaging	Social influences	Social opportunity
 Patients need to be aware of possible outcomes of the suggested management plan, and possible consequences of being referred for imaging when not indicated 	Barriers: - Perceived reassurance and explanation of symptoms from imaging [19, 21, 45, 56] Patients feel that imaging will provide reassurance to them by excluding pathological causes of low back pain and providing a diagnosis, particularly when pain levels are high or not resolving	Beliefs about consequences	Reflective motivation
- Patients need to feel that they are receiving emotional support from the GP without imaging	Barriers: - Emotional support and validation of pain from GP referring for imaging [21] Patients feel that GPs who comply with their wishes to refer for imaging are providing necessary emotional support and validating their pain	Emotion	Automatic motivation

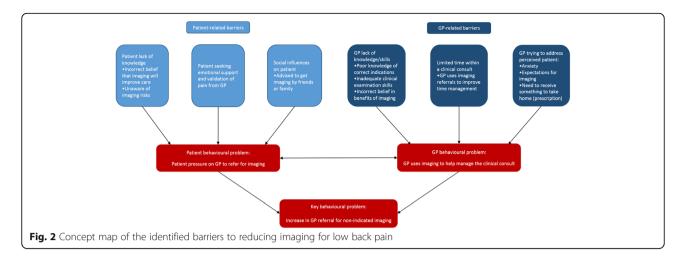
Step 2: Identify intervention options

Using the Behaviour Change Wheel [28], suitable intervention options were identified from nine intervention functions (means by which an intervention will change behaviour) and seven policy categories (means by which an intervention will be delivered) as presented in Additional file 1.

The intervention functions that met the APEASE criteria were: Training; Education; Environmental restructuring; Enablement; Modelling; and Persuasion. Although education alone (such as guideline dissemination, or provision of information) has not shown evidence of effectiveness [16], it was decided that it was important to include this

intervention function to address the domain of 'Knowledge' from the Theoretical Domains Framework. The combination of education with the other identified intervention functions was hypothesised to be more effective than education alone. Clinical decision support and regular reminders of correct indications for imaging have shown evidence of effectiveness at reducing imaging for LBP [16] and are, therefore, important to include in the implementation intervention through environmental restructuring.

The policy categories that met the APEASE criteria were: Service provision; Communication/marketing; and Environmental/social planning. Regulations and guidelines around the appropriate use of imaging currently



exist, and rather than develop new guidelines, the aim of the developed implementation intervention is to increase current guideline adherence. Changes to fiscal measures and legislation are outside the ability of the research team, and may lead to issues with acceptability and safety if clinical decision-making is made too restrictive.

Step 3: Identify content and implementation options

Results from the prior stages of the Behaviour Change Wheel were used to guide selection of appropriate behavioural change techniques, and the resultant content and mode of delivery of the implementation intervention, as presented in Table 2.

It was determined that a clinical resource for GPs to use within the clinical consult would be required to facilitate delivery of the content of the implementation intervention to both GPs and patients. The clinical resource would be designed to facilitate GP-patient communication. The resource would: 1) provide clinical decision support; 2) act as a reminder to the GP of correct indicators for imaging; 3) facilitate GP communication with the patient by providing key messages to be delivered to the patient during a consult (e.g. explaining clinical reasoning for not using imaging); 4) provide customisable management strategies to be delivered to the patient; and 5) be sent home with the patient to act as a management 'prescription' and an ongoing educational resource for LBP.

A GP training session was included in the implementation intervention to: 1) provide GP education on indicators for imaging for LBP; and 2) explain and demonstrate the integration of the clinical resource into a LBP consult. Figure 3 depicts how the intervention components have been designed to address the identified barriers, and improve GP and patient behaviours.

Stage 2: Development and testing of the clinical resource Development of the clinical resource content and format

Currently available LBP clinical resources were assessed for inclusion in the draft implementation intervention. It was determined that a purpose-designed resource would be necessary to incorporate the content of the implementation intervention, and facilitate mode of delivery (Table 2). In particular, the resource needed to: 1) be a tool that the GP could work though with the patient in a time-efficient manner; 2) include clinical decision support and key educational messages; 3) include customisable management advice; and 4) be appealing, quick and easy for the patient to read after the consult. The developed clinical resource was a LBP management and education booklet that could be individualised to the patient.

The clinical resource content was developed using LBP guidelines [36–38], review articles [4, 39], and other educational resources [40–43]. Key messages to deliver to patients were identified through literature review of qualitative studies providing patient feedback on LBP management [44, 45], while always considering if these were likely to help reduce patients' desire to receive imaging. The first iteration of the clinical resource included:

- A decision tree, based on diagnostic triage, for the GP to complete to provide clinical decision support for the GP, and facilitate GP-patient communication to demonstrate why imaging is not required
- Information on: LBP and common causes; why imaging usually isn't necessary; and what the patient can do to help their LBP
- 3. A customisable LBP management plan for the GP to complete, including advice to stay active, simple pain management strategies, information on what to do if the pain does not resolve, and symptoms that may indicate need to return to the GP
- 4. Links to further evidence-based resources about LBP

Table 2 Mapping of the intervention function (means by which an intervention will change behaviour), to behaviour change technique, and to content and mode of delivery of the draft implementation intervention

Intervention function (targeted to GP/Patient)	Behavioural change technique	Implementation intervention: content	Policy category	Implementation intervention: mode of delivery
Education (GP)	Information about health consequences	Guidelines for appropriate diagnosis and management of low back pain	Communication/ marketing Service provision	Providing GP with educational material Copies of current guidelines provided to GP [4, 38] Training session with GP Verbal discussion of guidelines
		Information regarding the appropriate diagnosis and management of low back pain	Communication/ marketing	Providing GP with educational material Copies of developed clinical resource provided to GPs to read
	Prompts/cues	Decision tree for appropriate imaging for low back pain (clinical decision support)	Environmental/social planning	Providing GP with clinical resources Copies of developed clinical resource provided to GPs to use during a consult, includes decision tree for clinical decision support
		Management plan	Environmental/social planning	Providing GP with clinical resources Copies of developed clinical resource provided to GPs to use during a consult, includes customisable management plan
Training (GP)	Feedback on the behaviour	Explanation of the goals of using the clinical resource to reduce imaging for low back pain	Communication/ marketing Service provision	Providing GP with training material Information sheet about the developed clinical resource provided to GPs to read Training session with GP Verbal discussion of goals
	Instruction on how to perform a behaviour	Instruction on how the developed clinical resource can be used: - as clinical decision support - as a checklist or reminder of correct management - to provide key educational messages to patients - to provide individualised management advice - in a time-efficient manner	Communication/ marketing Service provision	Providing GP with training material Information sheet about the developed patient education booklet provided to GPs to read Training session with GP Verbal discussion of how to use the developed clinical resource
Modelling (GP)	Demonstration of a behaviour	Modelling of appropriate information to be given to the patient during a consult	Environmental/social planning Service provision	Providing GP with clinical resources Copies of developed clinical resource provided to GPs to use during a consult, includes key messages to be delivered to patient Training session with GP Demonstration by training facilitator of how to use the developed clinical resource
Environmental restructuring and Enablement (GP)	Adding objects to the environment	Developed clinical resource for use during a consult - Facilitate GP-patient communication - Provide a tool to help educate and reassure patients during a consult, in a time-efficient manner	Environmental/social planning	Providing GP with clinical resources Copies of developed clinical resource provided to GPs to use during a consult

Table 2 Mapping of the intervention function (means by which an intervention will change behaviour), to behaviour change technique, and to content and mode of delivery of the draft implementation intervention (*Continued*)

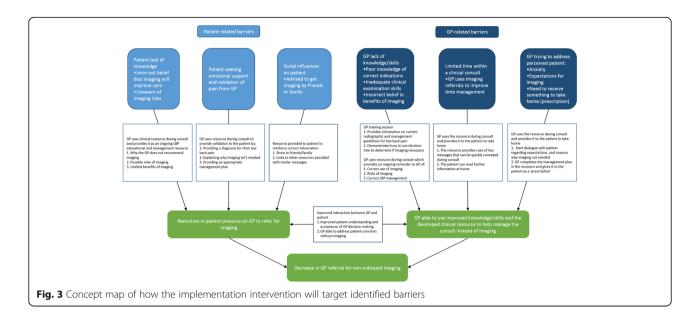
Intervention function (targeted to GP/Patient)	Behavioural change technique	Implementation intervention: content	Policy category	Implementation intervention: mode of delivery
		- Provide clinical decision support, and a reminder of appropriate imaging use and management advice to give to patient		
Education (Patient)	Information about health outcomes	Information to: - Address common misconceptions around low back pain, with a particular focus on imaging - Reassure the patient that their low back pain is not serious - Explain why imaging is not necessary - Provide suitable management advice - Provide information regarding symptoms associated with more serious pathology	1. Communication/ marketing	Providing patient with educational material GP delivers the developed clinical resource to the patient during a consult, providing key messages and individualising the management plan Patient can use the resource as an ongoing resource of information and individualised management advice
Persuasion (Patient)	Credible source	Clinical resource delivered by GP and developed by a reputable university research team	Environmental/social planning	Providing patient with clinical resources GP delivers the developed clinical resource to the patient during a consult, providing key messages and personalising the management plan
	Information about health consequences	Decision tree for appropriate imaging for low back pain (clinical decision support)	1. Service provision	GP-Patient consult GP uses the decision tree in the clinical resource during the consult to explain to the patient why they don't need imaging, facilitates shared decision making
Environmental restructuring and Enablement (Patient)	Adding objects to the environment	Customisable clinical resource given to patient in consult - Facilitate GP-patient communication - Short, appealing and easy to read with limited text and clear information - Reinforce or remind of information provided within the consult - Provide appropriate, individualised management advice - Provide links to other resources with guideline consistent messages	Environmental/social planning	Providing patient with clinical resources GP delivers the developed clinical resource to the patient during a consult, providing key messages and personalising the management plan Patient can use the booklet as an ongoing resource of information and individualised management advice

Expert review of the first iteration of the clinical resource

All five experts initially approached consented to be involved in the study. All experts reported that the key messages and specific content within the clinical resource were consistent with current knowledge and published guidelines. Potential barriers to the use of the resource, or its ability to change behaviour were suggested, including: confusion regarding the intended audience: whether it was designed to educate GPs or patients; complexity of some

of the language used, potentially limiting patient understanding; and the time the GP would need to explain the resource to the patient.

Resultant changes to the first iteration of the clinical resource Changes to specific wording were adopted to: 1) increase clarity to show that the intended audience was the patient; 2) simplify the language; and 3) highlight messages of patient reassurance and the limitations of imaging.



Stakeholder feedback on the second iteration of the clinical resource

Thematic saturation was reached with the recruitment of ten GPs and ten health consumers. Of the GPs, six were female, two had a special interest in LBP, and they had a mean of 12.4 years in clinical practice (range: 1–30 years). Of the health consumers, five were female, seven had a university level education, seven came from a Caucasian cultural background, and the average age was 41.4 years (range: 30–65 years). Nine of the health consumers had previously received imaging for LBP.

Content and format of the clinical resource Both GPs and health consumers agreed that the general content and layout of the developed resource were appropriate, that it included important and useful information, and was appealing to read. Some wording was identified as potentially confusing. For example, 'specific cause of low back pain' was interpreted by some to refer to the mechanism of action causing the LBP (e.g. lifting), rather than as an underlying pathology (e.g. infection) as intended. It was identified that the management plan in its current format would only be useful to the patient if completed by the GP, which may not always be possible. Some GPs raised concerns that the use of ice as a treatment strategy was not in line with their clinical practice. Finally, the links to additional resources were reported to be too small to read, and the website addresses were too long to easily use.

Barriers and facilitators to implementation of the developed clinical resource in clinical practice Specific barriers and facilitators to implementation of the clinical resource by GPs and health consumers were identified and are presented in Additional file 2.

Hardcopy format of the clinical resource:

Barriers to the use of the clinical resource as a hard-copy booklet were identified by GPs, including: potential purchasing costs; recency of included information; and difficulty following electronic links. Electronic formats, in particular A4 formatted handouts, which could be printed out for the patient, were preferred by most GPs. Some GPs were also happy to use email or website options, however, others reported that they would be unlikely to use these.

Conversely, most health consumers found the clinical resource as a hardcopy booklet a facilitator of use, reporting that they would be more likely to keep and continue referring to a booklet whereas printed handouts were often thrown away. Email or website options were not preferred as they would forget to look at them, although it was recognised that the links to other online resources would be easier to follow from these.

Usefulness of the clinical resource:

Most GPs and health consumers reported that they would find the resource useful to either use in clinical practice or to receive. GPs felt that LBP can be difficult to manage and resources are needed. They also reported that patients seem more satisfied if they receive something to take home with them. The few GPs who said they were unlikely to find the resource useful reported that they didn't feel much pressure to refer for imaging and didn't require added resources.

Health consumers thought that the information in the resource was relevant and important to them, and that it would help to reinforce the GPs opinion and advice. Some GPs felt that the resource wouldn't be useful with

all patients, and that they would be more likely to use the resource with patients needing further reassurance or explanations. Health consumers also felt that receiving the resource wouldn't always be appropriate, such as when imaging was indicated, or if they were experiencing high pain levels.

Use of the clinical resource in a LBP consult:

A commonly reported barrier to the use of the resource from GPs was the ability to conveniently store a hardcopy booklet and remember to use it. Most GPs preferred an electronic option that could be stored on the computer. There was some concern that using the resource might be time-consuming for a standard consult, but others felt that it would aid time management. Health consumers felt that the resource was time-efficient to read and easy to refer to.

GPs provided different suggestions on how the resource could be used in clinical practice. These included: 1) as a reminder for themselves of correct management; 2) as an explanatory aid during the consult to explain the LBP diagnosis and management to the patient, and explain why imaging is not necessary; 3) filling in the resource to provide the patient with an individualised management plan; and 4) as an educational resource for the patient to take home.

Health consumers said they were more likely to use the resource if it had been individualised to them, and that it would be most useful if the information was reinforced by the GP taking them through it. Health consumers reported they would be likely to continue using the resource to remind them of appropriate LBP management.

Perceived likelihood of the clinical resource to decrease imaging for LBP Themes related to whether the clinical resource (iteration 2) would be likely to help reduce imaging for LBP are presented in Table 3.

GPs reported that they thought that using the resource would be likely to facilitate appropriate imaging decisions by decreasing pressure from patients to refer for imaging. They also felt it would provide a useful reminder of correct imaging decisions for themselves. Some GPs did feel that there may be negative consequences of not imaging if a patient really wanted it.

Health consumers reported that the information in the resource was likely to make them more accepting of the GP decision not to image by: 1) reassuring them about the generally benign nature of LBP and why imaging is unnecessary; 2) being able to see why the GP made their decision; and 3) providing management and follow-up advice they could keep referring to. Some health consumers reported that reading the resource alone had provided an adequate explanation of why imaging wasn't always necessary, and they would be less likely to think imaging was necessary in the future. Conversely, some

health consumers reported that they still believed imaging to be necessary to ensure no serious pathology was present, or in situations where they were experiencing high pain levels, despite reading the resource.

Resultant changes to the second iteration of the clinical resource

Changes to the clinical resource from the aforementioned stages included: 1) changes to wording; 2) modification of the management plan; and 3) changes to the presentation of website links. A PDF copy of the final clinical resource is available in Additional file 3.

Resultant changes to the implementation intervention

Changes were made to the draft implementation intervention to address the identified barriers to using the clinical resource. Although not specifically tested in this study, the GP training session was modified to incorporate feedback from GPs and health consumers. Changes to GP training included: 1) emphasising the importance of individualising the resource to the patients; 2) emphasising that patients are likely to continue to refer to the resource after the consult; 3) providing suggested methods of using the resource in practice; 4) informing GPs of certain patient characteristics that may result in patients being more or less likely to use the resource; and 5) providing suggestions for storage of the resource in a conspicuous location to aid recall and use.

Consideration was given to whether an electronic version of the resource should be developed, but it was decided that it was not practical at this stage. Given consumers strongly favoured a hardcopy booklet it was decided to continue with the booklet version and test feasibility of use in clinical practice. While not addressed at this stage, cost of printing of the resource, and keeping the material updated also need to be considered, prior to broad implementation in clinical practice.

Final implementation intervention to reduce GP referral for non-indicated imaging for LBP

The final implementation intervention, after development and modifications from preliminary testing, comprises of:

- 1. A developed clinical resource in the form of a LBP management and education booklet (PDF available in Additional file 3) designed to:
 - Provide clinical decision support to the GPs
 - Provide a reminder to GPs of appropriate clinical indicators for imaging of the low back
 - Facilitate communication between GPs and patients to provide reassurance and explain why imaging isn't required in their case

Table 3 Themes from qualitative interviews on possible change in behaviour with use of the clinical resource (iteration 2)

General practitioner

Booklet would help to decrease imaging pressure from patients "Yeah [help decrease pressure felt to refer patients for imaging] because I mean it's got the resources, the references at the back and the websites that they can look up for more information to see why it's not necessary, rather than just coming from my word of mouth" (GP10)

Booklet provides a reminder of correct imaging decisions for the GP "...[algorithm] also helpful for the doctor as a reminder maybe for someone who doesn't, just as a reminder you know, think of those sort of red flags that need to be screened for" (GP8)

Potential negative consequences of not referring for imaging when a patient really wants it

"if people are hell-bent on getting imaging you're pretty dumb not to give it to them, because it'll be the one that you don't that'll be the one that has some bizarre weird tumour or something" (GP5) "I think if someone was adamant that they wanted an x-ray I think that they would be unhappy leaving the room without an x-ray request form, whether you give them this paperwork or not" (GP10)

Health consumers

Information in the booklet is reassuring

"I found it quite reassuring you know that quite a lot of people who have imaging might show up you know some kind of change which isn't actually going to be problematic in terms of effect to their life" (MoP2)

"I guess it's reassuring to know that everyone will get back pain, or most people will get back pain, but the what you can do to decrease it is super helpful" (MoP6)

Useful to receive the booklet from the GP to give appropriate information and management

"I think it would be helpful [to receive the booklet from the GP] because I think different people approach GPs with a different pace of knowledge and different set of expectations" (MoP1) "it [having the GP go through the booklet] highlights that you are going through and thinking about it and that you've got a booklet telling you the same thing and a GP telling you the same thing which sort of reinforces the message" (MoP1)

"I should think so [feel reassured]. I know I mean again a lot of people are different but I think the fact that you're getting it through the GP I think for a lot of people that gives it extra credibility" (MoP3)

Booklet demonstrates why the GP made their decision not to refer for imaging

"that little the thing on page 2 [flowchart] makes it very clear on which way, which pathway you need to go basically" (MoP8) Booklet provides a reminder of management advice

"I think it's good that GPs told me things but I might get distracted by other things happening in life as well, so if I had a booklet I could always refer back and so it's like a dictionary – if I need to look up something I can always refer to this booklet" (MoP5) Booklet can be used to by patients to monitor their progress and when they need to go back to the GP

"If you haven't been to the doctor for a while and you think hang on what should I do again, like what should I do, should I go back - that whole when should I return for further medical advice [in the booklet] that I think that's really good" (MoP4)

"Yes [would feel reassured back pain being managed correctly]; that sort of makes you feel that you know what to do if it gets worse. So you know it's been managed at the level it's at and then if it gets any worse you can look here and go, oh yeah, that happens, probably should go get that checked" (MoP7)

Reading booklet changed beliefs on the importance of imaging "I think a lot of people believe, and I certainly believed, that this [imaging] would give you that answer" (MoP1)

"[the booklet states] that you should always look to solve pain with the least amount of surgery, doctors, x-rays, things as possible first" (MoP4)

"I do think it [the booklet] would have changed the way I thought

Table 3 Themes from qualitative interviews on possible change in behaviour with use of the clinical resource (iteration 2) (*Continued*)

about imaging at first" (MoP2)

"Yeah, yeah for sure [booklet change beliefs]. Now I know that imaging won't necessarily show anything or it will only show something that most people will also have but not necessarily have pain for. I didn't know that at all" (MoP7)

Booklet unlikely to change beliefs on the importance of imaging "Not to me [booklet help change beliefs], I think, I would still, I would still get an x-ray or something at the start just to make sure" (MoP9)

"I believe in a pain threshold if it's really painful then generally it's a sign something serious is wrong so that then you should probably consider getting imaging more strongly" (MoP1)

- Provide the GP with a useful clinical resource that they can give the patient to take home instead of a non-indicated imaging referral
- Provide the patient with a resource, individualised for them by the GP, to include information on: why the GP determined they didn't need imaging, what management strategies they should undertake, and what to do if their LBP does not resolve
- Provide the patient with educational resources they can continue to refer to, and share with friends or family
- Be quick, easy, and appealing to read
- 2. GP training session with a trained facilitator (outline available in Additional file 4) designed to:
 - Educate GPs on the appropriate use of imaging through discussion and the provision of published resources [4, 38]
 - Explain why the clinical resource was developed and how it is intended to be used through discussion, provision of an information sheet (available in Additional file 5), and demonstration of how to use the clinical resource in clinical practice

Discussion

This study used the Behaviour Change Wheel, informed by current evidence and stakeholder feedback, to develop an implementation intervention targeting both GP and patient behaviours concurrently, with the aim of reducing non-indicated imaging in patients with LBP. The resultant implementation intervention includes: 1) GP use of a developed clinical resource during a consult for LBP to facilitate patient management without referring for non-indicated imaging, and 2) a GP training session to provide GP education on appropriate indicators of imaging, and demonstrate the intended use of the clinical resource. Facilitators and barriers to the use of the resource in clinical practice were identified, and where possible, the implementation intervention was modified accordingly. This included

alteration to wording within the resource identified as potentially confusing, and the delivery of additional information during GP training. GPs and health consumers thought the clinical resource would be beneficial to clinical practice. Health consumers reported that use of the resource was likely to make them more accepting of the GP decision not to image.

Systematic use of the Behaviour Change Wheel, with integration of the Theoretical Domains Framework, allowed for a structured approach to development of an implementation intervention informed by prior research. Previously, most interventions aiming to reduce imaging for LBP have attempted to improve GP knowledge of appropriate imaging referral, however, little evidence of change in imaging referral rates has been observed [16]. Using the Behaviour Change Wheel it was determined that both GP and patient related barriers need to be addressed to facilitate GP ability to manage the clinical consult without referring for non-indicated imaging, and decrease pressure from patients to refer for imaging. Use of the Behaviour Change Wheel led to the determination of key domains requiring behaviour change in both GPs and patients, including: Knowledge; Memory, attention, and decision process; and Environmental context and resources. Resultant mapping of behavioural change techniques led to the development of an evidence-informed and targeted implementation intervention. Further strengthening this study, preliminary testing was performed, with feedback from LBP experts, GPs and health consumers resulting in key changes to the final implementation intervention.

Limitations of this study include the inability to address all identified barriers to reducing imaging for LBP. Potential strategies to reduce barriers within the health care system, such as inadequate referral systems and pressure from external or third party payers (i.e. insurance payments) [46–51] did not meet the APEASE criteria as defined in the Behaviour Change Wheel process, as they would require government or systems level changes.

Not all identified barriers from the various stake-holders could be addressed due to a lack of practicability and acceptability. GPs reported that the ability to store and remember to use the clinical resource as a hardcopy booklet was a barrier to use, and an electronic printable version was suggested as a better option. However, the resource would not easily translate into a printable document, and would require removal of key components seen as integral to the intervention by both GPs and health consumers, such as the clinical decision support and the individualised management plan. Furthermore, health consumers reported that they would be much more likely to accept and use the resource as a hardcopy booklet compared to a printed handout, producing a discrepancy that could not be immediately resolved

amongst the stakeholders. Feasibility testing with the resource as a hardcopy booklet is planned prior to future effectiveness testing, to assess whether GPs will use it as trained.

Printing costs and ongoing currency of the clinical resource were also raised as potential barriers to use. While not the focus of this study, consideration is needed about how the clinical resource will be maintained and distributed, and who will meet the associated ongoing costs when moving into future feasibility and effectiveness testing prior to large-scale implementation.

Finally, some health consumers reported that reading the clinical resource did not decrease their desire for imaging. In this study, to assess the appropriateness of the clinical resource content and its format, the health consumers were only provided with the clinical resource to read without any interaction with a GP. It is likely that the combination of GP explanation with reading the clinical resource will be more effective in educating patients than patients simply reading the resource alone. Some GPs also reported that they did not feel the clinical resource would be appropriate for all patients. The clinical resource has not been designed for use with all LBP patients. Some patients may require imaging to optimise management of their LBP, and some patients may respond well to GP advice and not require additional resources. Although the clinical resource may not be used with all LBP patients, using it with those patients who need more education or reassurance is likely to reduce rates of non-indicated imaging for LBP. Future feasibility and effectiveness testing will be used to assess how the implementation intervention is used in practice, and whether it is effective in reducing non-indicated imaging for LBP.

Two other studies have used behaviour change theory, incorporating the Theoretical Domains Framework, to develop an intervention to improve management of LBP [30, 52] with varied evidence of effectiveness [52, 53]. Both of these studies addressed overuse of imaging as one component of LBP management rather than as the primary focus. Similar barriers and facilitators to the current study were identified, however, patient related barriers were not specifically addressed and the focus of the interventions was on GP education. French et al. (2013) included a patient education handout within the intervention [30]. However, this was not an interactive, purpose-designed resource to aid GP ability to manage LBP without the use of non-indicated imaging, as in the current study.

Conclusion

Behaviour change theory and preliminary testing were used to develop an implementation intervention to reduce non-indicated imaging for LBP in general medical practice. The implementation intervention includes: 1) GP use of a developed clinical resource during a consult for LBP to facilitate patient management without the use of non-indicated imaging, and 2) a GP training session to provide GP education on appropriate indicators of imaging, and demonstrate the intended use of the resource. Feasibility and pilot testing now needs to be conducted on the intervention prior to future effectiveness testing.

Additional files

Additional file 1: Selection of appropriate intervention options.

Mapping of the Com-B components and the Theoretical Domains

Framework to intervention functions and policy categories that meet the APEASE criteria. (DOCX 15 kb)

Additional file 2: Barriers and facilitators to using the booklet. Barriers and facilitators to the use of the second iteration of the developed clinical resource in clinical practice. (DOCX 17 kb)

Additional file 3: Patient education booklet. PDF copy of the final clinical resource: LBP education and management booklet. (PDF 797 kb)

Additional file 4: Outline of GP training. Outline of GP training session. (DOCX 17 kb)

Additional file 5: GP information sheet. (PDF 260 kb)

Abbreviations

APEASE: Affordability, practicability, effectiveness and cost-effectiveness, acceptability, side-effects and safety, equity; COM-B: Capability, opportunity, motivation, behaviour; GP: General medical practitioner; LBP: Low back pain; MUHREC: Macquarie University human research ethics committee

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors' contributions

HJ, NM, SF, CM, BD, JM and MH conceived and designed the study. HJ performed the initial steps of the Behaviour Change Wheel. HJ, NM, SF, CM, BD, JM and MH were involved in discussion of the results and development of the draft implementation intervention. HJ, MH, and NM developed the initial clinical resource, which was finalised with consensus from SF, CM, BD and JM. HJ, NM, SF and MH designed the semi-structured interview questions. HJ performed and transcribed the interviews. HJ, MH, NM, and SF performed thematic analysis of the interview data. The themes and resultant changes to the implementation intervention were finalised with consensus from HJ, NM, SF, CM, BD, JM and MH. HJ drafted the initial manuscript. HJ, NM, SF, CM, BD, JM and MH revised and approved the final manuscript.

Ethics approval and consent to participate

Ethics approval was granted by Macquarie University Human Research Ethics Committee (MUHREC), reference number: 5201600298. All participants gave their consent and permission to participate in this study.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Author details

¹Department of Health Professions, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia. ²Department of Chiropractic, Faculty of Science and Engineering, Macquarie University, Sydney, Australia. ³Musculoskeletal Health Sydney, Sydney Medical School, University of Sydney, Sydney, Australia. ⁴Department of Psychology, Faculty of Human Sciences, Macquarie University, Sydney, Australia. ⁵Department of Clinical Medicine, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia.

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5.10 Published supplementary material

Additional file 1: Mapping of the Com-B components and the Theoretical Domains

Framework to intervention functions and policy categories that meet the APEASE criteria

COM-B* component	Theoretical Domains Framework	Intervention function [†] (meets APEASE [#] criteria Y/N)	Policy Category [‡] (meets APEASE [#] criteria Y/N)
Physical	Physical skills	Training (Y)	Service provision (Y)
capability			Guidelines (N)
			Fiscal measures (N)
			Regulation (N)
			Legislation (N)
Psychological capability	Knowledge	Education (Y)	Communication/marketing (Y)
			Service provision (Y)
			Guidelines (N)
			Regulation (N)
			Legislation (N)
Psychological	Memory, attention,	Training (Y)	Service provision (Y)
capability	and decision process	Environmental restructuring (Y)	Environmental/social planning (Y)
		Enablement (Y)	Guidelines (N)
			Fiscal measures (N)
			Regulation (N)
			Legislation (N)
Physical	Environmental	Training (Y)	Service provision (Y)
opportunity	context and resources	Environmental restructuring (Y)	Environmental/social planning (Y)
		Enablement (Y)	Guidelines (N)
		Restriction (N)	Fiscal measures (N)
			Regulation (N)
			Legislation (N)
Social opportunity	Social influences	Environmental restructuring (Y)	Service provision (Y)

Reflective motivation	Beliefs about capabilities	Modelling (Y) Enablement (Y) Restriction (N) Education (Y) Persuasion (Y) Modelling (Y) Enablement (Y)	Environmental/social planning (Y) Guidelines (N) Fiscal measures (N) Regulation (N) Legislation (N) Communications/marketing (Y) Service provision (Y) Environmental/social planning (Y) Guidelines (N) Fiscal measures (N) Regulation (N) Legislation (N)
Reflective motivation	Beliefs about consequences	Education (Y) Persuasion (Y) Modelling (Y)	Communication/marketing (Y) Service provision (Y) Guidelines (N) Regulation (N) Legislation (N)
Automatic motivation	Emotion	Persuasion (Y) Modelling (Y) Enablement (Y) Incentivisation (N) Coercion (N)	Communications/marketing (Y) Service provision (Y) Environmental/social planning (Y) Guidelines (N) Fiscal measures (N) Regulation (N) Legislation (N)

Key:

^{*}COM-B: Capability, Opportunity, Motivation, and Behaviour; as defined in the Behaviour Change Wheel 'Intervention function: means by which an intervention will change behaviour; as defined in the Behaviour Change Wheel

*APEASE: Affordability, Practicability, Effectiveness and cost-effectiveness, Acceptability, Side-effects and safety, Equity; as defined in the Behaviour Change Wheel

[†]Policy category: means by which an intervention will be delivered; as defined in the Behaviour Change Wheel

Reasons APEASE criteria not met

Intervention functions:

Restriction: Enforced restriction to GP ability to refer for non-indicated imaging is limited due to lack of: 1)

Practicability (lack of suitable diagnostic criteria); 2) Acceptability (GP acceptance of limitation to referral rights); and 3) Safety (lack of suitable diagnostic criteria may miss cases requiring imaging)

Incentivisation: The use of incentives to limit GP referral for non-indicated imaging is limited due to lack of: 1)

Affordability (ability of the research team to provide monetary incentives); 2) Practicability (ability of the research team to produce health-care or government level changes to provide incentives); and 3) Safety (incentives may lead to non-imaging when required)

Coercion: Creating an expectation of punishment for GP's if they refer for non-indicated imaging is limited due to lack of: 1) Practicability (lack of suitable diagnostic criteria); 2) Acceptability (GP acceptance of this possibility); and 3) Safety (lack of suitably specific diagnostic criteria may lead to failure to image when required)

Policy categories:

Guidelines: The creation of guidelines is not required as guidelines currently exist, and new guidelines are not currently indicated. Distribution and education of current guidelines will be used within the developed implementation intervention.

Fiscal measures: Using the tax system to impact the financial cost is not indicated due to a lack of: 1)

Practicability (ability of the research team to change fiscal measures); and 2) Acceptability (government, GPs and health consumers may not accept change).

Regulation: Rules or principles of practice behaviour are currently evident, however, not routinely adhered to.

The aim of this research is to increase adherence to current regulation.

Legislation: Enforced restriction to GP ability to refer for non-indicated imaging through legislation is limited due to lack of: 1) Practicability (ability of the research team to change legislation); 2) Acceptability (GP acceptance of limitation to referral rights); and 3) Safety (enforcement of diagnostic criteria with limited specificity may miss cases requiring imaging)

Additional file 2: Barriers and facilitators to the use of the second iteration of the developed clinical resource in clinical practice

Theme	General	General practitioner	Laypeople (with a history of low back pain)	tory of low back pain)
	Barriers	Facilitators	Barriers	<u>Facilitators</u>
Format of the	Hardcopy format of booklet - cost	Hardcopy format of booklet – easier	Hardcopy format of booklet –	Hardcopy format of booklet –
booklet	"if I had to pay for this booklet to	to use	unlikely to use further resources	more useful
	have in my practice I'd probably	"I think it's probably easier to give	"I probably wouldn't use them	"I think it works best as a booklet,
	have a few of them just to have in	out a hard copy [booklet] and we	[links to low back pain sources]	if it's one piece of paper are you
	case or one for each doctor and	don't have email at our surgery so I	because I have to type something	going to be able to fit all this
	then I'd just do a copy and	wouldn't be emailing patients a link	in. I'm more likely to google at	information in because this is 4
	printout like the one you sent me"	or anything" (GP1)	that point" (MoP7)	bits of paper and I think you need
	(GP8)			everything in there" (MoP4)
	Hardcopy format of booklet –			
	maintaining currency			
	"it [hard copy] might go out of			
	date in 10 years time" (GP4)			

Electronic format of booklet – email not useful	Electronic format of booklet – easier to use A4 printout	Electronic format of booklet – unlikely to use A4 printout	Electronic format of booklet – likely to use
"I wouldn't [email a PDF], I know	"If I could print it out yes [more likely	"I prefer this way. We get lots of	"Yes [an email copy would be
others would but I tend not to	to hand out A4 information sheet	those A4 print outs whenever we	useful too]; I guess I prefer most
give my direct email address to a	than booklet], so I'm always looking	go to the doctor and I do review	things to be by email now
patient because then I get	for good summaries that are nice and	them and then I take away the	certainly email would help for the
bombarded with ridiculous emails	simple for patients" (GP10)	pieces of information that I need,	additional resources" (MoP2)
in the future" (GP10)		but there's something about this	
		and the management plan, like to	
		know that you've got something	
	"yes that would be great too [online	to go through in the future"	
	version, email to patient]" (GP3)	(MoP7)	
		Electronic format of booklet –	
		unlikely read email	

Usefulness of	Uncertainty of usefulness of	Belief in the usefulness of the	Uncertainty of usefulness of	Belief in the usefulness of the
the booklet	booklet in all patients	booklet	booklet in all patients	booklet
	"You know so many people have a	"if you actually give them a booklet	"maybe a bit one-sided, maybe	"the booklet would encourage
	fixed idea about what they expect	that says that they don't need it in	there is, even though, people	me for one that I need to listen to
	and walk in expecting things [from	the absence of the red flags then I	know there is times when you	the doctor at the end of the day
	a GP appointment]; Other people	think they'll be more convinced"	should get an xray" (MoP9)	and him telling me that well you
	would be more receptive [to	(GB)	si 2011 pag 0204+ si pos c.s. 4:"	don't really need the xray mate o
	receiving the booklet]" (GP4)	"there's a need for this information	agony I'm not really sure if I want	you do, and only that person can
	"It's difficult to say how, you know	to be made available to patients	a booklet given to me and go	tell me that and in the booklet
	people are very polite. You know	generally so I think they would	home and read it" (MoP10)	and the GP are both on the same
	you think they might but whether	receive it well" (GP6)		page nere of course i a use the
	or not they're going to read it I			DOOKIEL (MOPIU)
	don't know" (GP1)			"Yes [likely to read]; Because I
				have back pain: It's yen,

ಧ or In professional so I liked the look of, e have back pain; It's very

you like doctor google something

and get um conflicting

information" (MoP7)

information, as opposed to when

like when I read it I feel like I'm

not getting, like, inaccurate

"I did like the links you had at the back page I think that was really helpful I had a look at some of them and thought that they were useful resources" (MoP2)

Don't need the booklet	Low back pain is a difficult area to
"I didn't think that I'd probably	manage, with a need for resources
use it in my practice, possibly	"yes [remember to use booklet]
because I don't usually get a lot of	absolutely partly because you know
I guess pressure to do imaging	low back pain freaks me out; if I had it
with back pain so it doesn't	to hand I can think thank goodness
normally come up" (GP5)	I've just got that book so I can just
	bring it out and we can just go
	through it" (GP4)

"there's a need for this information

to be made available to patients

generally so I think they would

receive it well" (GP5)

Useful with patients needing further reassurance and explanations

"I think it would be the ones who are more needing something else too – to tell them that they don't need imaging, so on an as needed basis, not with everyone" (GP7)

Useful as an ongoing reference or reminder

"The main times that I want to work through a piece of paper with someone is if I want to refresh my memory. So for example the red flags type of thing so if I want to fall back onto a check list because I want to reassure myself that I'm not missing anything." (GP10)

Useful to meet patient expectations

"Yes I'd like to fill in these things as I think the patients feel it's sort of individualised for them and it gives

you a focus for discussing what :reatments they can do themselves"

"yeah I think that patients who leave without a piece of paper in their hand are usually less satisfied than those who leave with a piece of paper in their hand" (GP10)

 Use of the booklet in clinical expended during a consultation
 Too time consuming to use hid manner] I with the practice
 Aids time-efficient delivery of information informati

going through it in that way rather think it's actually good to have than kind of just going with the something like this because whatever flow of the consultation" (GP2)

I say there or even if I forget to say they will still have this thing to look

into" (GP8)

Time-efficient to read

"the booklet's not a big booklet so

it's not like you have to sit there and you need an hour to read it it's only a good little 10 to 15 minute read"

Unlikely to individualise the	Would individualise the booklet
booklet	"l'd probably use it [the booklet] to
"probably not filling it out but I'd	write things in or tick in, but probably
probably go through it with them	not every patient" (GP3)
but I probably wouldn't –	
depends, depends on how much	
time I have" (GP3)	

Forgetting to use the bookletBooklets available and accessibleduring a consult"I would [remember to use booklet]"I think the main thingprovided that I've got enough copies[disadvantage] was the amount of resources in terms of maybe itand it's in an accessible area. If I had resources in terms of maybe itwould just get lost amongst all the other pamphlets and bookletsthe booklet and I'm in a rush I might of me that we do have" (GP7)on my desk then yes I would." (GP9)

Individualised advice

"it [individualised options] just gives you that sort of idea that it's more, well it's personal to you rather than being just some information that the GPs dolling out" (MoP6)

"I don't know, it's definitely that thing about what they can write in it and then handing you something and taking you through it, it makes it more tangible and more tactile" (MoP4)

"I have a special box where I keep these kind of brochures and various things and I tend to pull them out. I also keep another one where there are folders where I keep print outs of these patient education material that I collected" (GP8)

Electronic version

"Yes I think on the computer its easier [to remember to use]" (GP3)

Use the booklet to explain diagnosis and management

"I'd just listen to their history and then do my examination so I knew what we're dealing with and have a better idea and then I'd bring it [the booklet] out as I'm explaining what we're going to do next" (GP4) Give the booklet to the patient to read only

Booklet more useful if reinforced by the GP

"I think the booklet would help, but I think you actually need someone to sort of reinforce that information" (MoP1)

Happy to read the booklet at home

"I might just give it [the booklet] to them completely to read" (GP6)

"I'd be happy to take it home and read it but I suppose there would be some people who would like to have it explained to them but yeah no it's all pretty easy for me to understand so I'd be happy to take it home and read it" (MoP8)

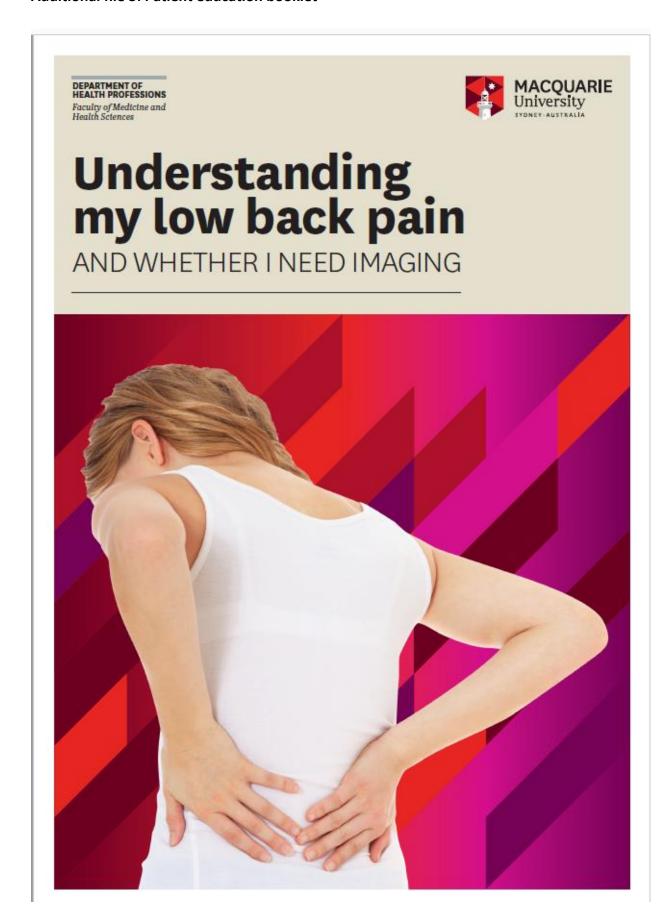
"I would think so yes [be likely to read it] it's a short enough leaflet that you can read it very quickly without getting confused by excessive facts or being too long" (MoP3)

Use booklet as an ongoing reference

"having it written down about what you should do in the future so you don't have to remember all the doctor said, that's really good as I always forget everything"

(MoP4)

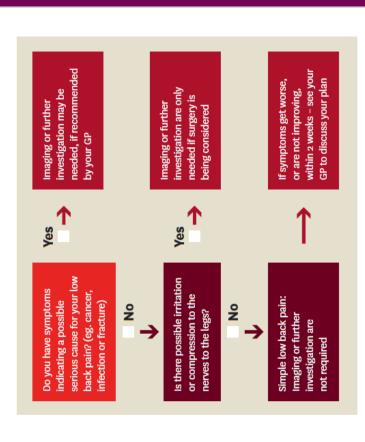
"I think it might be something I personally will probably look at next time my back pain comes back and before I go to the doctor" (MoP5)



Do I need imaging or further investigations?

Imaging or further investigations don't usually help low back pain. Your GP can show you whether you need further investigations based on the flowchart below:

Name:



All about low back pain

WHAT IS CAUSING MY LOW BACK PAIN?

Common causes of low back pain include minor soft tissue injuries such as muscle spasm or joint sprain. Less than 1 in 100 people with low back pain have a serious cause for their pain (eg. fracture, cancer, infection or inflammatory arthritis).

These conditions are usually obvious and your GP will take a clinical history and perform an assessment to 'check' for them.

I HAVE STRONG PAIN - DOESN'T THIS MEAN A BAD INJURY HAS OCCURRED? No – lots of research shows that strong pain does not equal a bad injury. Many people experience a lot of pain. This does not mean there is any damage in their back.

Some factors that can change the pain you feel include your mood and stress levels, your sleep quality and your lifestyle and general fitness levels.

HOW COMMON IS SIMPLE LOW BACK PAIN?

It is common and often reoccurs.

Four out of five people will get low back pain at some time in their life. Half of these will go on to get further episodes of back pain throughout their life. Recurrence is common and does not mean that there is greater reason for concern.

K PAIN? WHAT IS SIMPLE LOW BACK PAIN?

Low back paln, where no indication of a serious cause can be found. Pain may be mild or very strong, but it

typically improves a lot over the first couple of weeks.
There may also be pain into the legs.
As the back gets better, the leg pain usually improves too.

imaging needed? Why isn't

Imaging (eg, x-rays, CTs or MRI scans) doesn't usually help find the cause of pain.

most cases of back pain is the same whether The treatment and speed of recovery for imaging is used or not.

WON'T IMAGING SHOW WHAT IS CAUSING MY LOW BACK PAIN?

No - the underlying cause of back pain cannot usually be seen on imaging.

Imaging can help diagnose serious causes of low back pain - but, these are very rare and your GP will check for signs of them.

'CHANGES' ON IMAGING OF THEIR BACK -WHAT IF I HAVE THESE 'CHANGES' TOO? I KNOW OTHER PEOPLE WHO FOUND

Many 'changes' can be seen on imaging, but it Is unknown if they are causing your pain.

have imaging 'changes'. For example, 6 out of 10 Most of the 'changes' seen on imaging are normal and more common the older you get. Even people without back pain commonly middle aged people without back pain have changes on imaging such as disc bulges or degeneration.

WHY SHOULDN'T I GET IMAGING JUST IN CASE??

Unnecessary imaging has some risks:

- can increase the risk of cancer. Less Radiation exposure (for x-ray and CT) radiation is better
- It can cost you money and is time consuming
- seen and may cause stress, anxiety and worry, even though they are Changes on imaging are often usually unimportant
- Imaging has been associated with worse patient outcomes and an increase in unnecessary surgery

IS THERE ANYTHING ELSE I CAN DO?

The best thing you can do is to stay as active

decrease my low back pain?

What can I do to help

- Try to stay positive and take steps towards a healthier lifestyle.
- your pain might feel worse. Managing these When you feel stressed, angry or worrled feelings might help your low back pain.
- changes to dlet, alcohol intake and smoking. with low back pain. You might find it helpful to address poor sleep patterns and consider Lifestyle factors may also be associated

temporary mild pain, is good for your back.

and strong. Movement, even if it causes

Activity keeps the back mobile, flexible

HOW WILL ACTIVITY HELP MY LOW

Research shows that bed rest or prolonged

inactivity can delay recovery.

WHAT EXERCISES CAN I DO WHEN I HAVE

Any exercise you enjoy can help decrease

LOW BACK PAIN?

your pain and get you moving.

MY BACK HURTS - HOW CAN I STAY ACTIVE?

Aerobic exercises like walking or swimming

Gentle stretches or exercises

(such as Tal Chi or Yoga) Some suggestions include:

exercises and stretches if you are unsure.

You can also ask your GP for some safe

You may need to take things a bit easier for a few days, but y<mark>ou also need to get back into your normal activities as soon as possible.</mark>

Normal activities include your regular work, household and recreational activities. Staying active is safe with simple low back pain – even if there is some pain. Pain with movement does not mean you are doing any damage to your back.

What is my low back pain management plan?

THE FOLLOWING SUGGESTIONS MAY HELP REDUCE YOUR PAIN AND INCREASE YOUR RECOVERY:

- · Take it easy for the first day or two after the pain starts if needed, then start
 - getting back into your normal daily activities as soon as possible.
 - Try to avoid staying in one position for a prolonged time.
- · Try some gentle exercise such as walking, swimming or stretching.

POSSIBLE PAIN-RELIEF STRATEGIES RECOMMENDED BY YOUR GP:

☐ Pain-relief medications:	□ Heat	☐ Referral to a physiotherapist / chiropractor / osteopath / other	OTHER SUGGESTIONS FROM YOUR GP (EG. SPECIFIC EXERCISES, STRESS RELIEF,

SLEEP STRATEGIES ETC.)

What should I do next?

Feeling generally unwell with your low back pain (for example: fever or CONTACT YOUR HEALTH CARE PRACTITIONER IF YOU HAVE ANY OF THE As long as your pain is improving you do not need to return for a review Occasionally low back pain does not improve or symptoms may change. Numbness around your back passage or genitals or in both legs for a review Pain which gets worse rather than better over several weeks WHEN SHOULD I RETURN FOR FURTHER MEDICAL ADVICE? Please come back If your pain is not improving after Difficulty passing or controlling urine or stool Unsteadiness on your feet unexplained weight loss) FOLLOWING SYMPTOMS: Please come back in - u w 4 10



Where can I find more information about low back pain?

There are a number of resources on the internet you can access to get quality information about the diagnosis and treatment of low back pain. Some suggested online resources include:

Low back pain information; South Australia Health; Government of South Australia www.sahealth.sa.gov.au/lowbackpain

What is acute low back pain; NPS MedicineWise

https://tinyurl.com/nps-acute-low-back-pain

Low back pain video; Evans Health Lab

http://www.evanshealthlab.com/low-back-pain-video/

Low back pain – why imaging is commonly not recommended; NPS MedicineWise

https://tinyurl.com/nps-imaging-low-back-pain

ACKNOWLEDGEMENTS

The following information sources were used in the development of this booklet:

- Burton K, Klaber Moffett J, Main C, Roland M, Waddell G, The Back Book 2nd Edition (2002), The Stationary Office, England
- · National Health and Medical Research Council: Acute Low Back Pain
- · Orthopaedic Spinal Services, SA Health: Advice for Managing Low Back Pain
- · Orthopaedic Spinal Services, SA Health: Scans and Low Back Pain
- · NPS MedicineWise: Back Pain Choices

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Additional file 4: GP training session

The GP training is a 20 minute face to face session with a trained facilitator (either a low back pain researcher involved in the study or a facilitator trained by the research team)

The following items will be discussed during the training session:

1. Introduction

- The patient education booklet is a novel educational tool, designed to provide
 patient education and reassurance, and ultimately decrease the inappropriate use of
 imaging in the management of low back pain
- The booklet is flexible in its use and how you decide to use it will depend on your clinical judgement
- During this session I will show you how the booklet has been designed to be used and why this will be helpful in clinical practice
- 2. Appropriate use of imaging in the management of low back pain
 - Explain why imaging, when not clinically indicated, is a problem, and why we are trying to reduce this
 - Discuss indications for imaging, and the appropriate diagnosis and management of low back pain
 - Provide relevant low back pain publications. Highlight imaging guidelines in Maher et al. (1), and summary of best evidence in LBP management in Qaseem et al. (2)
- 3. Reason for booklet development and the benefits of use
 - Provide GP information sheet for ongoing reference
 - Outline the intended goals of using the booklet
 - Explain why the booklet is different/novel and give reasons for inclusion of each of the elements
 - Decision tree (clinical decision support)
 - Information about low back pain (key educational messages)

- Information about limitations of imaging (key educational messages)
- Self-management advice (key educational messages)
- Management plan
- When to return/what to do next
- Further resources
- Outline potential benefits of use
 - Time-efficient way to ensure you provide all necessary information to the patient
 - o Aids to help explain to the patient why imaging is not necessary
 - Management plan giving the patient the booklet as a 'prescription' instead
 of an imaging referral
 - Giving the patient more information about what to do next if symptoms don't resolve, and other reputable resources
 - Patient can use the booklet as an ongoing resource
- 4. Demonstration of use of the booklet by the training facilitator
 - Demonstrate the suggested use of the booklet
 - Emphasise how the booklet can be used time efficiently
 - Emphasise the importance of individualising the booklet for the patients
- 5. Explain which patients might be most appropriate, and which may not respond as well
- 6. Suggest storage options for the booklet; Explain why a booklet was used rather than an electronic option
- 7. Ask for any questions

References:

1. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. The Lancet. 2017;389(10070):736-47.

2. Qaseem A, Wilt TJ, McLean RM, Forciea MA. Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of PhysiciansNoninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain. Annals of Internal Medicine. 2017;166(7):514-30.

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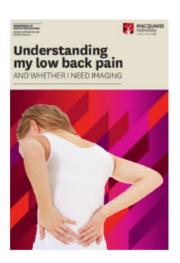
Faculty of Medicine and Health Sciences



GP information sheet

UNDERSTANDING MY LOW BACK PAIN AND WHETHER I NEED IMAGING BOOKLET

The booklet 'Understanding my Low Back Pain and whether I need imaging' has been designed as a patient education resource for GPs to deliver during a standard clinical consult.



Who should the booklet be given to?

The booklet has been designed for patients with:

- Either a new episode or a recurrence (including a flare up of mild ongoing pain) of acute low back pain of less than 6 weeks duration
- No signs or symptoms of serious causes of low back pain (eg. fracture, infection, tumour or inflammatory arthritis) and no indications for low back surgery
- No current indications for imaging or further investigations

What are the aims of the booklet?

The aims of the booklet are to:

- Assist GPs to reassure patients that they are receiving the best management for low back pain without the use of imaging referrals
- Facilitate all elements of clinical consultation for low back pain including: screening, delivery of key messages and personalised management advice
- Provide the patient with further information to read from a list of trusted resources

How has the booklet been designed to be used?

Although this booklet could be used in many ways, it has been designed to be integrated into a standard consult:

- The patient is diagnosed with simple low back pain based on their GPs assessment
- The patient is shown the diagnosis algorithm on the first page. The GP checks the boxes and uses this to reassure the patient that they have simple low back pain and to explain imaging is not needed
- The GP can use the information in the booklet to help emphasise key messages about low back pain for each individual patient. The patient can read the rest of the booklet at home to increase time efficiency.
- The 'What is my low back pain management plan?' and 'What should I do next' sections are filled out as appropriate for the patient
- The patient is made aware of the extra resources available online before they are given the booklet
- The patient is able to use the booklet as an ongoing resource, for current and future episodes of low back pain

FIND OUT MORE Hazel Jenkins Macquarie University NSW 2109 Australia T: +61 (2) 9850 9383 hazel jenkins@mq.edu.au

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Chapter 6

General practitioner experiences using a low back pain management booklet aiming to decrease imaging for low back pain

6.1 Preface

In Chapter 5 the Behaviour Change Wheel was used to develop an intervention to reduce non-indicated imaging for low back pain, consisting of a clinical resource: a low back pain education and management booklet; and practitioner training to use the booklet with patients during a clinical consult. Preliminary testing of the booklet in Chapter 5 showed that practitioners thought the booklet to be potentially useful; however, usefulness could be limited by poor uptake and use of the booklet in clinical practice. Chapter 6 presents an analysis of practitioner experiences using the low back pain education and management booklet in clinical practice, and identifies barriers and facilitators to using the booklet.

The study presented in Chapter 6 has been submitted for publication to Family Practice as:

Jenkins HJ, Moloney NA, French SD, Maher CG, Dear BF, Magnussen JS, Hancock MJ. General practitioner experiences using a low back pain management booklet aiming to decrease imaging for low back pain.

The study is presented in the format of the submitted manuscript.

Ethics approval for the study presented in Chapter 6 was obtained through the Macquarie University Human Research Ethics Committee on 10th May, 2016; Reference number: 5201600298 (Chapter 8, Appendix 2)

6.2 Co-authors' statement

As co-authors' of the paper, General practitioner experiences using a low back pain management booklet aiming to decrease imaging for low back pain, we confirm that Hazel Jenkins has made the following contributions to this paper:

- Conception and design of the study
- GP recruitment, training, and interviews
- Collection and assembly of the data
- Analysis and interpretation of the data
- Drafting and critical revision of the paper

Niamh Moloney	 Date: 01/02/2019
Simon French	 Date: 01/02/2019
Chris Maher	 Date: 01/02/2019
Blake Dear	 Date: 01/02/2019
John Magnussen	 Date: 01/02/2019
Mark Hancock	 Date: 01/02/2019

6.3 Title Page

Title: General practitioner experiences using a low back pain management booklet aiming to decrease imaging for low back pain

Running head: General practitioner use of a low back pain management booklet

Article category: Qualitative research

Authors:

Hazel J Jenkins^{a,b}; Niamh A Moloney^a; Simon D French^{b,c}; Chris G Maher^d; Blake F Dear^e; John S Magnussen^f; Mark J Hancock^a;

^aDepartment of Health Professions, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia

^bDepartment of Chiropractic, Faculty of Science and Engineering, Macquarie University, Sydney, Australia

^cSchool of Rehabilitation Therapy, Queen's University, Kingston, Canada

^dSydney School of Public Health, Faculty of Medicine and Health, University of Sydney, Sydney, Australia and Institute for Musculoskeletal Health, Sydney, Australia

^eDepartment of Psychology, Faculty of Human Sciences, Macquarie University, Sydney, Australia

^fDepartment of Clinical Medicine, Faculty of Medicine and Health Sciences, Macquarie University, Sydney, Australia

Corresponding author: Mrs H. J. Jenkins <u>Address: Rm347, 17 Wally's Walk, Macquarie</u>

<u>University, 2109, Australia; Email: hazel.jenkins@mq.edu.au</u>

Key messages

- Imaging is currently overused in the management of low back pain.
- A booklet was developed to help GPs manage low back pain without imaging.
- GPs used the booklet during consults with patients and provided it as a handout.
- GPs found the booklet useful to reassure patients and provide management advice.
- GPs found the booklet difficult to store and digital options were requested.
- GPs can consider using this booklet to help manage patients with low back pain.

6.4 Abstract

Background

This study aimed to investigate general practitioner (GP) experiences using a low back pain

(LBP) management booklet, aiming to reduce non-indicated imaging for LBP.

Methods

Fourteen GPs were recruited and trained to use the booklet with LBP patients over a

minimum five month period. Quantitative data on use of the booklet were collected and

analysed descriptively. Qualitative data were collected in GP interviews and thematically

analysed.

Results

GPs used the booklet with 73 patients. GPs thought the booklet helped improve patient

management and helped reduce pressure to refer for imaging. Facilitators of use included

patient's requesting imaging and lower practitioner confidence in managing LBP. Barriers

included accessible storage and remembering to use the booklet.

Discussion

The booklet was considered useful and practical to implement in clinical practice by

participating GPs. A digital version would likely address key identified barriers to larger scale

use.

Keywords

Low back pain; Diagnostic imaging; General practitioners; Patient education;

Implementation science; Feasibility studies

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6.5 Introduction

Imaging is overused in the management of low back pain (LBP), with approximately one third of imaging referrals inconsistent with clinical guidelines (1). Imaging is indicated when there is suspicion of serious underlying pathology such as infection or cancer, but does not generally improve outcomes for patients with for non-specific LBP (2, 3). Overuse of imaging may lead to inappropriate diagnoses, further unnecessary investigation or treatment, and unnecessary radiation exposure (2-5). In the 2017/18 financial year, Medicare, the Australian public healthcare system, spent AUD\$180 million on low back imaging (6). Decreasing non-indicated imaging for LBP in general practice is challenging, and few effective interventions have been demonstrated to date (7).

An intervention was recently developed (8) to help general practitioners (GPs) reduce non-indicated imaging for LBP. The intervention was developed to address identified GP and patient behaviours within a clinical consult which lead to an overuse of imaging for LBP. The intervention includes GP training and provision of a LBP management booklet designed to be used during clinical interactions with patients. The training session (Appendix 1) is used to demonstrate the use of the booklet to GPs and provide education on appropriate imaging for LBP. The booklet (Appendix 2) can be used to screen the patient for indicators for imaging, educate and communicate with the patient about low back pain and the need for imaging, and provide a customised patient management plan.

Effectiveness testing of developed interventions is necessary before recommendations are made for general use. However, effectiveness testing may be negatively impacted by poor uptake or use of the intervention and prior feasibility-testing is recommended to assess for barriers and facilitators to using the intervention (9). It is unknown whether GPs will be able to successfully use the developed booklet during clinical interactions with patients.

The aim of this feasibility study was to explore GP experiences using the developed LBP management booklet in clinical practice to determine: 1) how GPs used the booklet; 2) barriers and facilitators to use of the booklet; 3) how helpful GPs found the booklet; and 4) suggestions for improvement to the booklet or associated GP training in using the booklet.

6.6 Methods

GPs from metropolitan Sydney, Australia were asked to trial the use of the booklet within clinical practice. This paper is reported in accordance with the standards for reporting qualitative research (10) and the consolidated criteria for reporting qualitative research (COREQ) (11). Ethics approval was granted by Macquarie University Human Research Ethics Committee, reference number: 5201600298.

General practitioner recruitment

Purposive sampling of GPs currently seeing patients with LBP was performed, between May to October 2017, to achieve adequate diversity in practice location, years in clinical practice and sex. We estimated a minimum of ten GPs would be required for this study, based on the sample size needed for thematic saturation during a previous qualitative study on the development of the LBP management booklet (8).

Study procedure

GPs attended a twenty minute face-to-face training session with one of the research team (HJ) to instruct them in the study aims and requirements, appropriate management of LBP (3, 12), and how to use the booklet. Demographic information and beliefs about the usefulness of imaging for LBP were obtained from GPs (Appendix 3).

The study period ran for a minimum of 5 months from GP training until study completion in April, 2018. GPs were asked to use the booklet with patients presenting with LBP as they

deemed appropriate, and complete a de-identified record sheet of patients with whom they used the booklet. Recorded data included LBP characteristics, how the booklet was used, suspicion of underlying pathology, and imaging referral (Appendix 4).

At the conclusion of the study period GPs participated in a fifteen minute audio-recorded semi-structured interview with one of the researchers (HJ). Open-ended interview questions were developed, related to the four aims of this study (Appendix 3). Further 'probe' questions were developed to be used as required to explore GP responses. Probe questions related to GP behaviour were developed using the Theoretical Domains Framework (13, 14). GPs were given an AUD\$60 gift voucher for their time in attending the training session and participating in the end of study interview.

Quantitative data analysis

Data from the de-identified patient record sheets were used to assess how GPs used the booklet, including: 1) how many patients the LBP management booklet was used with; 2) characteristics of patients the booklet was used with; 3) concerns of possible serious pathology; 4) proportion of imaging referral when the booklet was used; 5) proportion of imaging referral in patients with no underlying suspicion of serious pathology; and 6) how the booklet was used with each patient (e.g. customised or not customised, discussed throughout the consult or provided at the end of the consult only). In the case of missing data, the partial data provided was included in the analysis with adjusted denominators.

Qualitative data analysis

Interviews were initially transcribed by one researcher (HJ) and imported into NVivo qualitative data analysis software; QSR International Pty Ltd. Version 12, 2018 for analysis. Coding was performed for each study aim prior to performing thematic analysis (15). Aims

two and three, relating to GP behaviour, were initially coded using the domains outlined in the Theoretical Domains Framework (13). Thematic analysis of all coded data was then performed to determine final themes for each study aim.

Two researchers (HJ and NM), both with prior experience in coding and using the Theoretical Domains Framework independently coded three interviews. Coding was compared and discussed, and sufficient consistency was observed between the two researchers after two rounds of discussion to allow one researcher (HJ) to code the remaining interviews. Themes were initially developed by HJ, before discussion with MH, NM, and SF to reach consensus. The resultant themes were then sent to all authors for overall discussion and final consensus.

6.7 Results

General practitioner participants

Twenty-one GPs were approached to participate. Of these, four (19%) declined as they either did not consistently see patients with LBP, or did not want to participate. Of the 17 GPs that participated in the study, 14 (82%) completed the interview at the end of the study. The other three GPs did not use the booklet during the study period and declined to participate in the final interview. Of the 14 GPs, 57% were female, with a mean (SD) of 16.6 (10.0) years in clinical practice. Sixty-four percent reported performing continuing education in LBP in the last two years. Only two GPs (14%) reported a special interest in LBP. All GPs either completely disagreed or disagreed with the statements 'Imaging of the lumbar spine is useful in the workup of patients with acute low back pain' (8/14 completely disagreed, 6/14 disagreed) and 'I am likely to order imaging for acute low back pain' (13/14 completely disagreed, 1/14 disagreed). Practice locations were in a spread of low (14%), medium (36%),

and high (50%) socioeconomic areas, as determined by postcode and socioeconomic index (16).

How general practitioners used the booklet

GPs participated in the study for between five to 11 months (mean, SD: 8.4, 2.2), and used the booklet between zero to 15 times (mean, SD: 5.2, 4.1) each, for a total use with 73 LBP patients. The patient record form was fully completed for 71% of patients (52/73), with partial data available for the rest.

Characteristics of patients with whom the low back pain management booklet was used: The booklet was most commonly used with LBP presentations of less than 2 weeks duration (30/52, 57.7%, 95%CI: 44.2, 70.1). Previous episodes of LBP had been experienced by 39 of 57 patients (68.4%, 95%CI: 55.5, 79.0). Prior imaging for LBP was performed in 16 of 57 patients (28.1%, 95%CI: 18.1, 40.8). GPs reported concern of underlying serious pathology in four of 57 patients (7.0%, 95%CI: 2.8, 16.7).

Frequency of imaging referral when the low back pain management booklet was used: Imaging referral was provided to six of 57 patients (10.5%, 95%CI: 4.9, 21.1) with whom the booklet was used, however, suspicion of underlying serious pathology was reported in three of these patients. Of the 53 patients with no suspicion of underlying serious pathology, three received imaging referrals that were likely to be non-indicated (5.7%, 95%CI: 1.9, 15.4).

Method of use of the low back pain management booklet: GPs commonly customised the booklet to the patient and either discussed the booklet throughout the consult (27/60, 45.0%, 95%CI: 33.1, 57.5), or gave the customised booklet to the patient to read at the end of the consult (25/60, 41.7%, 95%CI: 30.1, 54.3). For the remaining patients, GPs did not

customise the booklet and either handed it to the patient to take home (4/60, 6.7%, 95%CI: 2.6, 15.9), or discussed the booklet with patients who subsequently declined to take it home (4/60, 6.7%, 95%CI: 2.6, 15.9). This quantitative data was consistent with themes arising from the interviews (Table 1). GPs who did not use the booklet during the consult but provided it to the patient to read at home thought there was value in providing the patient with further information, but thought they had either already discussed what they needed with the patient using their own strategies, or were running short of time for further discussion.

General practitioner intention to continue using the low back pain management booklet:

Most GPs reported that they found the booklet useful, and would be likely to continue using it in the future, particularly with specific patients: those that requested imaging or required more reassurance or information about their low back pain.

"I genuinely think it's [the booklet] really useful and I'll continue to use it" (GP10)

"I'd certainly consider using it [the booklet], but not necessarily with every single patient that I see with back pain" (GP8)

Two GPs reported that they would be unlikely to continue to use the booklet, as they either don't keep paper booklets in their office, or they would forget to use it. These GPs reported that they already felt confident that patients would follow their advice without additional resources and were low users of the booklet in the current study.

"I suspect that there'd be more of me forgetting to use it [the booklet] again [moving forward]" (GP11)

Barriers and facilitators impacting use of the booklet

Themes relating to barriers and facilitators impacting on GPs use of the LBP management booklet are presented in Table 2. Key barriers to use included the ability to conveniently store and remember to use the booklet, and a lack of time during the consult. Facilitators included the ease of use of the booklet, and the perceived usefulness of the booklet to help educate and reassure the patient in a time efficient manner, particularly for GPs who felt less confident in their ability to manage patients with LBP. In particular, the request for imaging by the patient acted as a reminder to use the booklet.

How helpful general practitioners found the booklet

The effects on LBP management of using the booklet, as identified by GPs (Table 3), were consistent with how the booklet had been designed to work (8) (Figure 1). Most GPs reported that using the booklet improved their ability to manage patients with LBP without using non-indicated imaging, particularly with patients who were requesting imaging or needed more reassurance. Some GPs already felt confident managing LBP without non-indicated imaging, and didn't feel using the booklet greatly impacted them. Three GPs reported some uncertainty as to whether using the booklet would reduce patient pressure for imaging, particularly if the patient had a strong desire for imaging.

Suggested improvements to the low back pain management booklet: Very few suggestions were made about improving the content or layout of the booklet. One GP suggested a checklist of specific symptoms indicating the need for imaging instead of the decision-tree. Other suggestions for improvement (e.g. links to other LBP information sources) were already present in the booklet but were overlooked by GPs. Further emphasis of these features in the booklet during GP training is indicated to increase GP awareness of them.

Suggested improvements to the implementation of the low back pain management booklet:

The most commonly reported barrier to using the booklet was the ability to store and remember to use a hardcopy version. GPs suggested a digital version of the booklet would facilitate use.

"I generally find that paper resources are harder to use than computer-based resources because you've got to stop and find them in drawers of other paper resources. So perhaps just a PDF version of the same thing would be more useful" (GP11)

"I think looking forward, a booklet like that must have something online because you're going to lose a lot of doctors that just don't use things that are paper based, they don't look for it, it's not what they do, not how they've been taught" (GP12)

Suggestions for format of a digital version varied including: 1) an A4 information handout to be printed off the computer and handed to patients; 2) a digital version of the booklet that could be worked through with the patient in a similar fashion to the hardcopy booklet, and printed out as needed; or 3) a digital copy of the booklet which could be emailed to patients. Digital versions were suggested to be integrated within practice management software with built-in electronic reminders, to further trigger memory to use the booklet. GPs reported that they were quite accustomed to using digital documents and printing information sheets for patients, and would be likely to use the booklet in the same way.

"The practice software does have information sheets that are built into the software as well, so I mean if the booklet could be incorporated in that way it would be helpful.

Because we do print off information sheets" (GP6)

"You know something that's easy to access and easy to print off would be doable. So I've got some things saved, some PDF's saved in a share drive that I can access pretty easily, so yes potentially having it [the booklet] that way would be good" (GP9)

Additional benefits to a digital version of the booklet were suggested, such as decreased cost, increased accessibility, and keeping content up-to-date.

Some GPs saw benefit in a hardcopy version of the booklet being available to patients in the waiting room in addition to the digital version.

"I think so, absolutely [patient pick up the booklet in the waiting room and bring to the GP]. I mean I don't want to waste your money printing lots of them but I think it could be worthwhile, and the other thing is that someone could actually pick them up if they're coming to see you about that particular problem. They could see that [the booklet] there, and pick it up and bring it in with them, and then they're ready to discuss it with you" (GP3)

Suggested improvements to the training session: Most GPs felt the face-to-face training provided was adequate, and they were able to use the LBP management booklet effectively. The need for face-to-face training was seen as a potential barrier, and an online option, such as a pre-recorded video or webinar, was suggested. Only two GPs reported concerns that online training may not be suitable, as it may get lost in the volume of online information they receive, or GPs may not be motivated to engage in it. Two GPs suggested that increased information on appropriate examination routines within the training session would be useful. One GP requested more information on possible management strategies such as exercises.

6.8 Discussion

This study found most GPs considered the LBP management booklet to be useful in clinical practice, and likely to work as designed to help improve LBP management and reduce non-indicated imaging. The booklet was feasible to use in clinical practice; however, important barriers to use were identified, including available storage and remembering to use the booklet. A digital version of the booklet was strongly favoured by all GPs. GPs were more likely to use and continue to use the booklet in particular circumstances, including when patients requested imaging or needed more reassurance, or when GPs felt less confident in managing LBP.

Strengths of this study included the use of both quantitative and qualitative methods to assess the feasibility of use of the booklet in clinical practice. Quantitative data showed variable use of the booklet by GPs and qualitative analysis identified and explored barriers and facilitators potentially influencing the use of the booklet in clinical practice. The hard-copy format of the booklet was identified by GPs as one of the main reasons they did not use it. This is consistent with concerns raised during development (8), and previous research utilising hard-copy patient education material in an intervention to improve GP management of LBP (17). Hard-copy patient education booklets have been successfully used in interventions to reduce antibiotic prescriptions for upper respiratory tract infections (18, 19). This discrepancy in results may be related to the more frequent presentation of upper respiratory tract infections to GPs compared to LBP, facilitating GP memory of the educational resources (20).

A limitation of this research was the lack of feedback from patients regarding their experience in receiving the booklet. Future research would benefit from exploring patient feedback to assess how useful they found the booklet. Feedback from health consumers

during booklet development (8) did indicate their intention to both engage with the hard-copy booklet, and continue to refer to the booklet after the consult. However, as the previous study was not performed in a clinical context, it is unknown how patients would engage with the booklet when received from their GP. It is also unknown whether patients would engage with a digital version of the booklet rather than the hard-copy version they were provided in the previous study. Another possible limitation is the potential low usage of the booklet by the participating GPs. On average GPs used the booklet less than once per month (mean usage: 5 booklets in 8 months); however, it is possible that this usage may reflect the low volume of LBP patients seen by the GPs rather than a lack of usage of the booklet. Qualitative reporting from the GPs on the approximate percentage of LBP patients that they used the booklet showed varied use, from using the booklet with no patients (1 GP) to using it with all presenting patients (3 GPs). The majority of GPs (8 GPs) reported using the booklet with between 10-40% of low back pain presentations.

In this study it was identified that GPs were more likely to use the booklet with patients who requested imaging or required more reassurance that imaging wasn't required. During development of the intervention (8) it was identified that a key barrier to the appropriate use of imaging by GPs was patients requesting imaging or believing in the importance of imaging. Therefore, it seems likely that using the booklet with these patients may help to reduce this barrier. Poorer imaging beliefs in patients have also been shown to be associated with particular demographic characteristics such as patients with older age, lower educational levels, and those coming from cultural backgrounds other than Britain, North America, Europe, or Australia (21). Therefore, it is important that GPs are informed during training that the booklet may be more useful or necessary in these specific

populations and that the booklet is available in a suitable format to be useful to these patients.

The results of this study will be used to further inform development of the intervention to reduce non-indicated imaging for LBP in general practice. Implementation options for a digital version of the LBP management booklet will be explored to aid GP storage and recall, and facilitate use. To allow GPs to continue to educate and reassure patients during a consultation, a digital version of the booklet that can be worked through on the computer in a similar manner to the hard-copy version will likely be necessary. A printable version will be developed to allow GPs to provide the patient with a customised management plan and written reinforcement of their advice, which was seen as important by both GPs and patients (8).

6.9 Conclusion

This feasibility study forms one of a series of studies to develop and test an intervention to reduce non-indicated imaging for LBP. GPs reported that the LBP management booklet was useful for clinical practice, particularly with patients requesting imaging. GPs thought using the booklet helped improve patient management and helped reduce pressure to refer for non-indicated imaging. A digital version of the booklet was preferable to GPs. A successful intervention to reduce non-indicated imaging for LBP would decrease healthcare costs and patient risk.

Declarations

- 1. Ethics approval: Ethics approval was granted by Macquarie University Human Research Ethics Committee, reference number: 5201600298.
- 2. Funding: No funding was used to support this study
- 3. Competing interests: The authors have no competing interests to declare

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6.11 Tables

Table 1: Themes related to 'How general practitioners used the booklet'

Theme	Quotes
Used as designed throughout the	"I go through it [the booklet] together with them
consult to: 1) show patients why they	[patients], so I actually use it as an educational
don't require imaging, 2) demonstrate	tool" (GP2)
key educational messages, and 3) provide a customised patient management plan	"I like the diagrams that are in there [decision tree at beginning] that I can sort of go through and say, well you don't have all these symptoms, so you don't need any imaging" (GP2)
	"Yes, that's not bad [to have somewhere to write patient management] because you're not giving them necessarily a prescription for prescription drugs, so it doesn't hurt to write something down, some instructions, and when to come back in for review" (GP8)
Used at the end of the consult only, by customising the management plan and providing it to the patient	"Mostly at the end of the consultation, I'd talk to them about it all and then at the end I'd remember to use it [the booklet], and go through it then and fill in some information" (GP9)
No customisation, given to the patient as a hand-out to read at home at the end of the consult only	"If I thought that someone didn't need imaging, I simply, towards the end of the consult, gave it [the booklet] to them. I gave it to them to take and read, and in our practice there was a follow-up appointment made at the time, and at that time we discussed the content of the book" (GP5)
Used throughout consult to discuss the key messages, but not customised or given to the patient	"Whilst I did go through it [the booklet] with a few patients who were half-interested in looking at it, they didn't want to take it away, they just thought that they didn't want the material but were happy just to talk about it" (GP6)

Table 2: Themes related to 'Barriers and facilitators impacting use of the booklet'

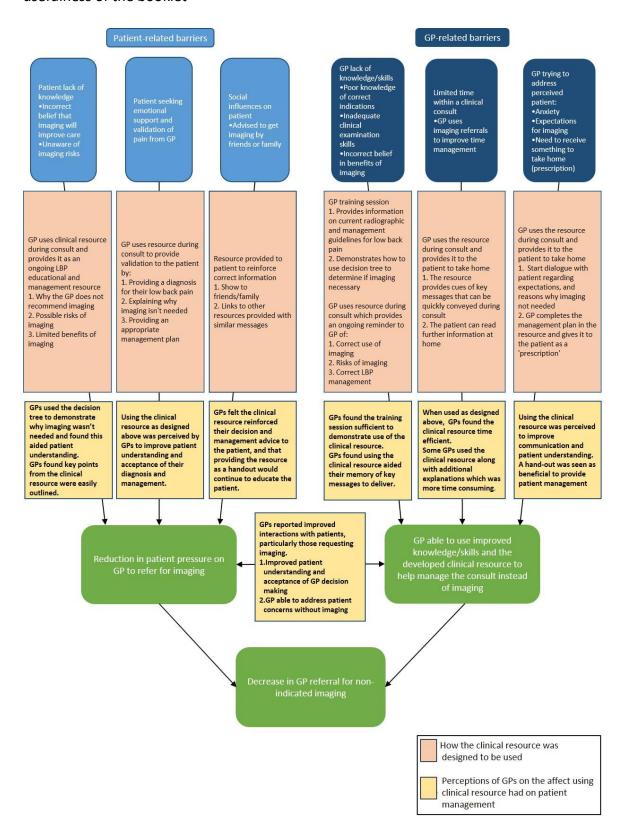
Theme	Facilitator or Barrier	Quotes
Storage location and	Facilitator: Storing the booklet in a	"Yes I did find the booklet OK to use, and because it was
remembering to use the	visible location with convenient	somewhere where I can reach it, it was good" (GP2)
booklet	access	
	Barrier: Nowhere to store the booklet	"In offices you just lose pieces of paper and little booklets and all of
	with good visibility or convenient access	the rest. You don't have room to store everything" (GP4)
	Barrier: Forgetting to use the booklet	"I only used the one and I think that's probably not the booklet, but because it's difficult to remember" (GP1)
GP having the necessary	Facilitator: Training or GP prior	"I think it [the training] was absolutely fine, the booklet's quite self-
knowledge/ skills to use the booklet	knowledge was sufficient to use the booklet	explanatory, it's quite clearly laid out so that was fine" (GP1)
	Barrier: Some points were missed in the training session, and the booklet wasn't used completely	"Yes, I think I missed a few points [in training] so that's what I failed to explain fully to my patients" (GP14)
Perceived usefulness of the booklet within a consult	Facilitator: The information in the booklet is appropriate and useful for patient education	"My general experience [with the booklet] was that it was very helpful, that it helps explain this to the patients really well. It was very didactical, it followed a logical order and I found it very useful" (GP7)
	Facilitator: The booklet was used because the GP felt the patient required more education or reassurance	"I think for instance I felt [in the patients that did use the booklet with] there was an expectation that was either voiced or implied of imaging, and so to sort of counter that view the booklet was handy" (GP5)
	Barrier: Booklet was not needed as current GP method of managing clinical consults sufficient	"So I think that the main reason that I didn't use the booklet more is that I do feel quite confident in being able to sort out when to use imaging" (GP1)
	Barrier: GP felt the patient didn't require more education or reassurance	"Not everybody comes and asks for an X-ray, some of them understand it's muscular not underlying bone pathology there you know" (GP13)
	Barrier: Low back pain an uncommon presentation for the GP	"I might see a back pain patient you know, maybe only once a fortnight because I don't have that big throughput" (GP3)
Time efficiency of using the booklet in a consult	Facilitator: Use of the booklet improved time efficiency in the consult	"I think also at least in a couple of cases [when used the booklet] that I recall, I was very much pushed for time. It's handy to say, here it is, have a read" (GP5)
	Barrier: Not enough time in a consult to use additional resources	"The time factor [why didn't use the booklet with other patients], because if lots of patients are waiting, if you don't have a lot of time, then I didn't go into this much detail" (GP13)
	Barrier: Using the booklet took additional time in the consult	"I mean it [using the booklet] did add time for me. I could imagine that there could be ways to do it that it wouldn't, but that's just not how I, I suppose, talk to people" (GP9)
Perceived receptiveness of	Facilitator: GP felt the patient would	"Yes they [the patients] liked it [the booklet], I think patients always
the patient to receiving the booklet	be receptive to receiving the booklet	like to go away with something, so yes I think they liked it" (GP9)
	Barrier: GP felt the patient would not be receptive to receiving the booklet	"Whilst I did go through it [the booklet] with a few patients who were half-interested in looking at it, they didn't want to take it away" (GP6)

Table 3: Themes related to 'How helpful general practitioners found the booklet'

Theme	Quotes
Improved GP knowledge of how to manage patients with LBP	"I feel like having read the information [in the booklet], it's something that I've incorporated into the talk I give to patients with back pain" (GP6) "It [the booklet] also helped me, remind me of a few things which I forget sometimes because I can't necessarily always remember all these things or sometimes I just focus more on one thing or the other" (GP7)
Improved GP-patient communication and management	"It was useful to have that approach [in the booklet] to show them [the patients] when we might need it [imaging] and when we don't need it" (GP5) "I actually found the booklet really comprehensive. I found it really helpful [to reduce unnecessary imaging], so I don't think you need, I mean I wouldn't use other things" (GP2) "Yes, yes, it allows you to initiate it [conversation with patient that imaging isn't necessary]" (GP12)
Perceived to improve patient understanding and acceptance	"I think the booklet was, for me, a quick way of explaining the rationale behind not imaging, and the patient seemed to appreciate this to a greater depth when given the booklet" (GP5) "I think if you did have someone who was quite adamant to want imaging it [the booklet] would be then more useful for those certain patients" (GP6) "I find that when I did that [use the booklet], it had a fairly good response with the patients because they realise the importance of it. First of all it was reassuring for them that they don't have something that serious so that they need an X-ray. On the other hand it also gives them a framework of what we can be doing, or can be done for them, to alleviate their back discomfort or pain and that this is something quite manageable without the need for a lot of investigations" (GP7)
Reinforced GP management advice, both during and after the consult	"I think giving people written data, you know like a written pamphlet, gives a bit more credibility to what you say, so you can educate people about not needing imaging" (GP11) "It [the booklet] probably backs me up, makes me feel more confident, and I think I've got some research backing me up and then I can counter it [patient request for imaging], and I can say well look there's this and they've done this, and they've looked at this, and if you're worried then this can be our plan" (GP3) "I think they [the patients on receiving the booklet] appreciated that it wasn't just my opinion that they didn't need medication, or an X-ray, and it was acknowledged by, if you like, another valid source, that such investigations were unnecessary" (GP5)
Confident in current ability to manage patient with LBP without non-indicated imaging, additional resources not required	"I think it [the booklet] would be reassuring for lots of GPs but for me personally I think I can communicate my confidence to the patient and I might be wrong but I feel they're OK with me just explaining why they don't need anything" (GP1) "I'm pretty confident that I don't need to do the imaging in the first place, so I don't know whether it [using the booklet] makes a tremendous difference for me really" (GP7)
Uncertain whether using the booklet will impact patient pressure for imaging	"I guess it [the booklet] helps reinforce the message for people who are accepting the message, but I think the people that really have come in with an agenda and you can't sway them, the booklet's not going to sway" (GP4)

6.12 Figures

Figure 1: Concept map of the barriers to reducing imaging for LBP, how the LBP management booklet was designed to address these barriers, and GP perceptions of the usefulness of the booklet



This figure has been adapted with consent from Figure 3 in 'Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain' (8), a concept map of how the intervention was designed to target identified barriers to appropriate use of imaging for LBP. GP perceptions of the usefulness of the booklet have been added in the yellow boxes.

6.13 Submitted supplementary material

Appendix 1: Outline of GP training session

The GP training is a 20 minute face to face session with a trained facilitator (either a low back pain researcher involved in the study or a facilitator trained by the research team)

The following items will be discussed during the training session:

1. Introduction

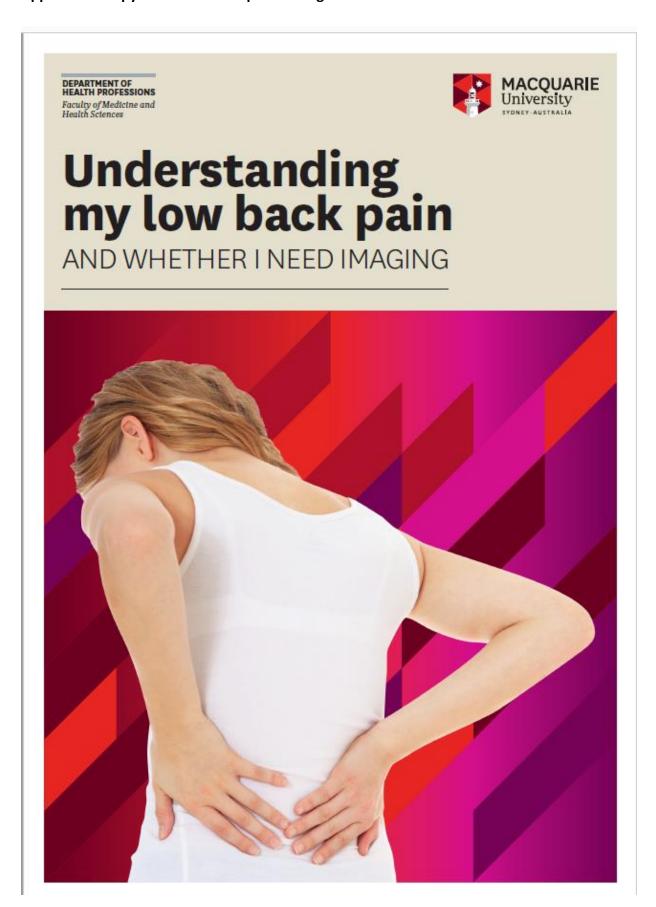
- The patient education booklet is a novel educational tool, designed to provide
 patient education and reassurance, and ultimately decrease the inappropriate use of
 imaging in the management of low back pain
- The booklet is flexible in its use and how you decide to use it will depend on your clinical judgement
- During this session I will show you how the booklet has been designed to be used and why this will be helpful in clinical practice
- 2. Appropriate use of imaging in the management of low back pain
 - Explain why imaging, when not clinically indicated, is a problem, and why we are trying to reduce this
 - Discuss indications for imaging, and the appropriate diagnosis and management of low back pain
 - Provide relevant low back pain publications. Highlight imaging guidelines in Maher et al. (Maher et al., 2017), and summary of best evidence in LBP management in Qaseem et al. (Qaseem et al., 2017)
- 3. Reason for booklet development and the benefits of use
 - Provide GP information sheet for ongoing reference
 - Outline the intended goals of using the booklet
 - Explain why the booklet is different/novel and give reasons for inclusion of each of the elements

- Decision tree (clinical decision support)
- Information about low back pain (key educational messages)
- Information about limitations of imaging (key educational messages)
- Self-management advice (key educational messages)
- Management plan
- When to return/what to do next
- Further resources
- Outline potential benefits of use
 - Time-efficient way to ensure you provide all necessary information to the patient
 - Aids to help explain to the patient why imaging is not necessary
 - Management plan giving the patient the booklet as a 'prescription' instead
 of an imaging referral
 - Giving the patient more information about what to do next if symptoms don't resolve, and other reputable resources
 - Patient can use the booklet as an ongoing resource
- 4. Demonstration of use of the booklet by the training facilitator
 - Demonstrate the suggested use of the booklet
 - Emphasise how the booklet can be used time efficiently
 - Emphasise the importance of individualising the booklet for the patients
- 5. Explain which patients might be most appropriate, and which may not respond as well
- 6. Suggest storage options for the booklet; Explain why a booklet was used rather than an electronic option
- 7. Ask for any questions

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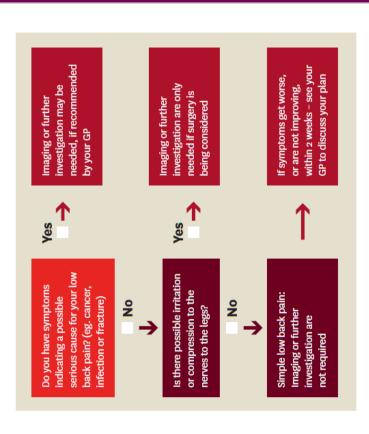
Appendix 2: Copy of the low back pain management booklet



Do I need imaging or further investigations?

Imaging or further investigations don't usually help low back pain. Your GP can show you whether you need further investigations based on the flowchart below:

Name:



All about low back pain

WHAT IS CAUSING MY LOW BACK PAIN?

Common causes of low back pain include minor soft tissue injuries such as muscle spasm or joint sprain. Less than 1 in 100 people with low back pain have a serious cause for their pain (eg. fracture, cancer, infection or inflammatory arthritis).

These conditions are usually obvious and your GP will take a clinical history and perform an assessment to 'check' for them.

I HAVE STRONG PAIN - DOESN'T THIS MEAN A BAD INJURY HAS OCCURRED? No – lots of research shows that strong pain does not equal a bad injury.

Many people experience a lot of pain. This does not mean there is any damage in their back.
Some factors that can change the pain you feel include your mood and stress levels, your

HOW COMMON IS SIMPLE LOW BACK PAIN?

sleep quality and your lifestyle and general

fitness levels.

It is common and often reoccurs.

Four out of five people will get low back pain at some time in their life. Half of these will go on to get further episodes of back pain throughout their life. Recurrence is common and does not mean that there is greater reason for concern.

WHAT IS SIMPLE LOW BACK PAIN?

Low back paln, where no indication of a serious cause can be found.
Pain may be mild or very strong, but it

typically improves a lot over the first

couple of weeks.

There may also be pain into the legs.

As the back gets better, the leg pain usually improves too.

imaging needed? Why isn't

Imaging (eg, x-rays, CTs or MRI scans) doesn't usually help find the cause of pain.

most cases of back pain is the same whether The treatment and speed of recovery for imaging is used or not.

WON'T IMAGING SHOW WHAT IS CAUSING MY LOW BACK PAIN?

No - the underlying cause of back pain cannot usually be seen on imaging.

Imaging can help diagnose serious causes of low back pain - but, these are very rare and your GP will check for signs of them.

'CHANGES' ON IMAGING OF THEIR BACK -WHAT IF I HAVE THESE 'CHANGES' TOO? I KNOW OTHER PEOPLE WHO FOUND

Many 'changes' can be seen on imaging, but it

Most of the 'changes' seen on imaging are normal and more common the older you get. Is unknown if they are causing your pain.

have imaging 'changes'. For example, 6 out of 10 Even people without back pain commonly middle aged people without back pain have changes on imaging such as disc bulges or degeneration.

WHY SHOULDN'T I GET IMAGING JUST IN CASE?

Unnecessary imaging has some risks:

- can increase the risk of cancer. Less Radiation exposure (for x-ray and CT) radiation is better
- It can cost you money and is time consuming
- seen and may cause stress, anxiety and worry, even though they are Changes on imaging are often usually unimportant
- Imaging has been associated with worse patient outcomes and an increase in unnecessary surgery

IS THERE ANYTHING ELSE I CAN DO?

The best thing you can do is to stay as active

decrease my low back pain?

What can I do to help

- Try to stay positive and take steps towards a healthier lifestyle.
- your pain might feel worse. Managing these When you feel stressed, angry or worrled feelings might help your low back pain.
- changes to dlet, alcohol intake and smoking. with low back pain. You might find it helpful to address poor sleep patterns and consider Lifestyle factors may also be associated

temporary mild pain, is good for your back.

and strong. Movement, even if it causes

Activity keeps the back mobile, flexible

HOW WILL ACTIVITY HELP MY LOW

Research shows that bed rest or prolonged

inactivity can delay recovery.

WHAT EXERCISES CAN I DO WHEN I HAVE

Any exercise you enjoy can help decrease

LOW BACK PAIN?

your pain and get you moving.

MY BACK HURTS - HOW CAN I STAY ACTIVE?

Aerobic exercises like walking or swimming

Gentle stretches or exercises

(such as Tal Chi or Yoga) Some suggestions include:

exercises and stretches if you are unsure.

You can also ask your GP for some safe

You may need to take things a bit easier for a few days, but y<mark>ou also need to get back into your normal activities as soon as possible.</mark>

Normal activities include your regular work, household and recreational activities. Staying active is safe with simple low back pain – even if there is some pain. Pain with movement does not mean you are doing any damage to your back.

What is my low back pain management plan?

THE FOLLOWING SUGGESTIONS MAY HELP REDUCE YOUR PAIN AND INCREASE YOUR RECOVERY:

- · Take It easy for the first day or two after the pain starts If needed, then start
 - getting back into your normal daily activities as soon as possible.
- Try to avoid staying in one position for a prolonged time.
 Try some gentle exercise such as walking, swimming or stretching.

POSSIBLE PAIN-RELIEF STRATEGIES RECOMMENDED BY YOUR GP:

☐ Pain-relief medications:	 ☐ Heat ☐ Referral to a physiotherapist / chiropractor / osteopath / other 	OTHER SUGGESTIONS FROM YOUR GP (EG. SPECIFIC EXERCISES, STRESS RELIEF, SLEEP STRATEGIES ETC.)	
		OTE	_

What should I do next?

Please come back In

Please come back if your pain is not improving after

As long as your pain is improving you do not need to return for a review

WHEN SHOULD I RETURN FOR FURTHER MEDICAL ADVICE?

Occasionally low back pain does not improve or symptoms may change.

CONTACT YOUR HEALTH CARE PRACTITIONER IF YOU HAVE ANY OF THE FOLLOWING SYMPTOMS:

1 Difficulty passing or controlling urine or stool

2 Numbness around your back passage or genitals or in both legs

3 Unsteadiness on your feet

4 Pain which gets worse rather than better over several weeks

5 Feeling generally unwell with your low back pain (for example: fever or unexplained weight loss)



Where can I find more information about low back pain?

There are a number of resources on the internet you can access to get quality information about the diagnosis and treatment of low back pain. Some suggested online resources include:

Low back pain information; South Australia Health; Government of South Australia www.sahealth.sa.gov.au/lowbackpain

What is acute low back pain; NPS MedicineWise

https://tinyurl.com/nps-acute-low-back-pain

Low back pain video; Evans Health Lab

http://www.evanshealthlab.com/low-back-pain-video/

Low back pain – why imaging is commonly not recommended; NPS MedicineWise

https://tinyurl.com/nps-imaging-low-back-pain

ACKNOWLEDGEMENTS

The following information sources were used in the development of this booklet:

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- · National Health and Medical Research Council: Acute Low Back Pain
- · Orthopaedic Spinal Services, SA Health: Advice for Managing Low Back Pain
- · Orthopaedic Spinal Services, SA Health: Scans and Low Back Pain
- NPS MedicineWise: Back Pain Choices

CRICOS Provider 00002J

Appendix 3: GP baseline questionnaire and outline of semi-structured interview questions

Baseline Questionnaire

Code: _								
1.	Sex:	☐ Mal	e					
☐ Female								
2.	Year o	of gradu	ation from medical	degree:				
3.	3. Number of years practicing as a general practitioner:							
4. Do you have a special interest in back pain as a general practitioner?								
			☐ Yes					
			□ No					
5.	Have	you dor	ne any continuing ec	ducation in b	oack pain in	the last 2	years?	
			☐ Yes					
			□ No					
6.	We ar	e intere	ested in what you th	ink about in	naging for lo	ow back pa	in as a ger	neral
practit scale.	ioner.	Please	indicate your views	below by ci	rcling the ap	propriate	number o	n the
	PLETELY DIS	SAGREE	5= COMPLETELY AGREE					
				COMPLETELY				COMPLETELY AGREE
Imaging of the lumbar spine is useful in								
the workup of patients with acute low				_	_	_	_	
back p	oain			1	2	3	4	5
I am likely to order imaging for acute low								
back pain			1	2	3	4	5	
				I.	1	l .	l .	

<u>Semi-structured Interview Guide</u>

Questions 1-10 below were asked to all participants. The subsequent probes were used only as required to explore the participants' responses further.

Introduction to participant:

I'd like to ask you some questions about the patient education booklet that you have recently used in clinical practice. There are no right or wrong answers and we are very much interested in your feedback and suggestions for improvement.

Do I have your permission to use de-identified quotes from this interview in publication?

1. What was your experience in using the booklet in clinical practice? (Aim 1: How GPs used the booklet)

Possible additional probes:

"How did you use the booklet with patients?"

"Did you use the booklet routinely with patients presenting with simple low back pain or did you pick particular patients? If so, why?" (TDF: memory, attention and decision processes)

"What are your feelings about using this booklet in clinical practice?" (TDF: emotion)

"How many (or what proportion of) low back pain patients did you use the booklet with?" (TDF: behavioural regulation)

2. "What is your plan in using this booklet with patients with LBP, moving forward?" (Aim

1: How GPs used the booklet)

Possible additional probes:

"How would you continue to use the booklet?" (TDF: goals)

"For the next 10 patients with simple LBP, how many do you intend to use this booklet with?" (TDF: intention)

3. How practical did you find incorporating the booklet into your consults? (Aim 2: Barriers and facilitators impacting use of the booklet)

Possible additional probes:

"Were you able to integrate the booklet into your consults? How did you do this/Why weren't you able to?" (TDF: skills)

"Did you remember to use this booklet? Why/why not?" (TDF: memory, attention and decision processes)

"Were you able to use the booklet in a time efficient manner? Why/why not?" (TDF: environmental context and resources)

"Where did you place the booklet in your office?" (TDF: environmental context and resources)

"How did you find using this resource as a booklet? Would an online or electronic option be preferable?" (TDF: environmental context and resources)

"Did you feel you had the necessary knowledge and skills to be able to use the booklet in clinical practice?" (TDF: knowledge, skills)

4. How did you find the training session you received in using the booklet? (Aim 2: Barriers and facilitators impacting use of the booklet)

Possible additional probes:

"Was the training you received in using the booklet at an appropriate level? Why/why not?" (TDF: skills, knowledge)

"Did the training help you feel confident in using the booklet?" (TDF: beliefs about capabilities, skills)

5. "What were your experiences in using the booklet with your patients?" (Aim 3: How helpful GPs found the booklet)

Possible additional probes:

"Did you find patient expectations influenced your use of the booklet?" (TDF: social influences)

"How receptive do you think patients were to receiving this booklet?" (TDF: beliefs about consequences)

"How do you think using the booklet would affect the amount of pressure given from patients to refer for imaging?" (TDF: beliefs about consequences)

6. Do you think that using the booklet helped you to manage patients with LBP without imaging? Why/why not? (Aim 3: How helpful GPs found the booklet)

Possible additional probes:

"How did using the booklet affect your decision making process when determining whether to refer a patient with LBP for imaging?" (TDF: memory, attention and decision processes)

"Did using the booklet change your confidence in your ability to manage patients without imaging? Why/why not?" (TDF: beliefs about capabilities)

"Did using the booklet improve your patient communication/reassurance, or your ability to resist patient pressure for imaging?" (TDF: skills)

"Did using the booklet help reduce patient pressure for imaging?" (TDF: beliefs about consequences)

"When you used the booklet, were there circumstances that you still ended up referring for imaging? If so, why?" (TDF: behavioural regulation)

7. Do you think the booklet is a useful tool for clinical practice? Why/why not? (Aim 3: How helpful GPs found the booklet)

Possible additional probes:

"Do you think this booklet, its content and format, is appropriate to use in clinical practice?" (TDF: environmental context and resources)

8. What suggestions would you make to help improve the booklet or its integration into clinical practice? (Aim 4: Suggestions for improvement to the booklet or associated GP training)

Possible additional probes:

"Is there anything you can think of that would make the booklet more appropriate or acceptable to you?" (TDF: environmental context and resources)

"Is there anything you can think of that would help you to use this booklet?" (TDF: reinforcement)

"How would you suggest that the booklet should be rolled out for use in clinical practice?"

"Do you have any suggestions to improve the training session?"

"Could the training be given in a different format (information sheet, online module etc.)?"

Appendix 4: Copy of the patient record sheet

DEPARTMENT OF HEALTH PROFESSIONS

Faculty of Medicine and Health Sciences

Use of a patient education booklet for low back pain

MACQUARIE University

Individual patient record: please complete for patients presenting with low back pain of any cause or duration, on their first visit to you for that episode

Reason for imaging referral A: For suspected pathology B: Other (brief description) MA: Not applicable								
Referred patient for imaging of the imaging of the back? Y: Yes (what type?) N: No								
How was the patient education booklet used? A: Throughout the consult and filled in the details B: Throughout the consult but didn't fill in the details C: At the end of the consult and filled in the details D: At the end of the consult but didn't fill in the details E: Other (brief description) NA: Not applicable								
Concerns that this episode of low back pain associated with possible serious pathology? Y: Yes N: No								
Patient had previous imaging of the low back? Y: Yes N: No U: Unsure								
Patient had previous episodes of low back pain? Y: Yes N: No								
Patient previously attended a healthcare practitioner for current episode of low back pain? Y: Yes N: No								
Duration of current episode of low back pain in weeks								
Patient given education booklet? Y: Yes N: No								
Date								
Patient Number	1	2	3	4	5	9	7	8

Chapter 7

Discussion and conclusions

7.1 Preface

The primary outcome of this thesis was the development of an intervention to reduce non-indicated imaging for low back pain. A needs assessment was performed (and presented in chapters 2 to 4) to determine the necessity of developing an intervention to reduce non-indicated imaging for low back pain. The need for a new intervention was demonstrated and the development and preliminary testing of the intervention are presented in chapters 5 and 6.

7.2 Needs assessment

7.2.1 Main findings

7.2.1.1 Non-indicated imaging decisions are common in primary care

To determine the need for an intervention to reduce non-indicated imaging for low back pain, a systematic review of 33 studies assessing proportions of non-indicated imaging decisions for low back pain was performed in Chapter 2. This study provided evidence that non-indicated imaging decisions are common in primary care, and that these included both referring for imaging when it wasn't indicated, and not referring for imaging when it was indicated.

The included studies used variable criteria to determine whether imaging was indicated or not, that were generally consistent with clinical practice guidelines for the appropriate use of imaging available at the time the study was performed (1-5). Criteria included the identification of individual red flags or an overall clinical suspicion of serious pathology as reported by the practitioner. Patients not meeting these criteria but referred for imaging were considered to have received non-indicated imaging. Some studies included patients with non-specific low back pain only, and defined non-indicated imaging as any imaging performed in the first six weeks after initial presentation. Meta-analyses demonstrated moderate quality evidence that 27.7% (95%CI: 21.3, 35.1) of patients were referred for non-indicated imaging when any imaging in the first six weeks in patients diagnosed with non-specific low back pain was used as the criterion for non-indication. In comparison, lower

proportions of non-indicated imaging were found when the criteria of an absence of clinical suspicion of pathology (7.0%; 95%CI: 1.8, 23.3) or an absence of red flags (9.0%; 95%CI: 7.4, 11.0) were used.

Some studies only assessed patients previously referred for imaging to determine whether the imaging referral was indicated or not. In this population, approximately one third of imaging referrals were non-indicated, with low quality evidence that 34.8% (95%CI: 27.1, 43.3) of referrals are non-indicated when absence of red flags is used as the criterion and moderate quality evidence that 31.6% (95%CI: 28.3, 35.1) of referrals are non-indicated when absence of clinical suspicion of pathology was used as the criterion.

The proportion of patients not referred for imaging when indicated was surprisingly high, with approximately two thirds of patients determined to be indicated for imaging not receiving imaging referrals. Low quality evidence found 65.6% (95%CI: 51.8, 77.2) of patients indicated for imaging did not receive imaging when the presence of red flags was used as the criterion and moderate quality evidence found that 60.8% (95%CI: 42.0, 76.8) of patients indicated for imaging did not receive imaging when clinical suspicion of pathology was used as the criterion.

7.2.1.2 Limited effectiveness of interventions to decrease imaging for low back pain

The need to reduce the proportion of non-indicated imaging was demonstrated in Chapter 2. In Chapter 3 a systematic review was performed to determine what interventions have been used to reduce imaging for low back pain and the effectiveness of those interventions. Study designs were selected to reduce the associated risk of bias, including randomised controlled trials and interrupted time series studies, as recommended by the Cochrane Effective Practice and Organisation of Care group (EPOC) (6). Seven studies were included in the review; however, meta-analysis could not be performed due to the heterogeneity of those studies. Outcome measures used in the included studies varied, including imaging counts, the proportion of imaging used per 1000 patients (with any presentation), and the proportion of imaging in low back pain presentations. All studies investigated total imaging of the low back as the primary outcome of interest, rather than the proportion of non-indicated imaging when compared to clinical practice guidelines.

Results from this systematic review indicated that reductions of imaging use of 22.5% (95%CI: 8.4, 36.8) and 36.8% (95%CI: 33.2, 40.5) were found for interventions incorporating

reminders or clinical decision support for practitioners respectively; however, these were only single studies and results should be interpreted cautiously. Other interventions trialled included practitioner audit and feedback, practitioner education, and guideline dissemination; however, no consistent evidence of effectiveness was demonstrated for these particular interventions. An important finding was that no studies investigated interventions targeting patients. Since publication of Chapter 3 in 2015 (7), similar findings have been found in a review of interventions to reduce low back pain imaging in emergency departments (8). Furthermore, the use of watchful waiting (9) and restrictions to clinician referral rights (10, 11) have also been shown to be effective in reducing low-value imaging of the low back.

7.2.1.3 Patients expect imaging to be used in the management of low back pain

The need for the development of a successful intervention to reduce non-indicated imaging for low back pain was demonstrated in Chapters 2 and 3. It is recommended that the development of complex interventions is informed by the identification of barriers limiting appropriate behaviour (12-14). A systematic review of barriers to guideline adherent management of low back pain found that a key barrier to reducing non-indicated imaging as reported by practitioners was patients requesting or demanding imaging (15); hence, an intervention targeting this barrier may be required. Previous studies have shown that patients who think imaging to be important for low back pain are more likely to receive non-indicated imaging (16, 17). To assess whether patients believe imaging to be important in the management of low back pain and whether these beliefs are likely to be a potential barrier to reducing non-indicated imaging for low back pain, a survey of patients presenting for general medical care was performed (Chapter 4).

Consecutive patients presenting for general medical care (for any reason) were approached to participate in the survey, with a 79.6% response rate and 300 surveys completed. Patients commonly believed that imaging was important in the management of low back pain, with 54.3% (95%CI: 48.7, 58.9) agreeing or strongly agreeing with the statement 'X-rays or scans are necessary to get the best medical care for low back pain'. Further, 48.0% (95%CI: 42.4, 53.6) agreed or strongly agreed with the statement 'Everyone with low back pain should have spine imaging (e.g X-ray, CT or MRI)'. Multivariate logistic regression analysis demonstrated that patients who were older, who had a lower educational background, who did not come from Australian, European, British, or North American

cultural backgrounds, who had poorer general beliefs about low back pain, or who had previously received imaging for low back pain were more likely to believe that imaging was important or necessary.

7.2.1.4 Results of the needs assessment

The main findings from the needs assessment studies were that:

- 1. Non-indicated imaging decisions are common in the management of low back pain
- 2. Currently no interventions to reduce imaging for low back pain have shown strong evidence of effectiveness
- 3. Patients believe that imaging is important in the management of low back pain, which may contribute to higher proportions of non-indicated imaging referrals.

It was therefore determined that there was need for an intervention to reduce nonindicated imaging for low back pain and that patient related barriers should be considered and addressed when developing the intervention.

7.2.2 Clinical and research implications

The main finding from the needs assessment was that an intervention to decrease non-indicated imaging for low back pain should be developed. Other implications for clinical practice and research arising from the studies in Chapters 2 to 4 related to: the criteria for assessing indication for imaging, outcome measures used to determine the extent of imaging for low back pain, and identifying and addressing patients who have stronger beliefs that imaging is important in the management of low back pain.

7.2.2.1 Implications associated with current criteria used to indicate the need for imaging for low back pain

As seen in Chapter 2, different criteria for assessing the proportion of non-indicated imaging have been used, resulting in variable findings. The appropriateness of the criteria used to determine indications for imaging for low back pain have been questioned (18), with low diagnostic accuracy of individual red flags to indicate the presence of serious pathology being demonstrated (19-22) and a high prevalence of individual red flags reported in patients presenting with low back pain to primary care (21). Using the presence of individual red flags as the criterion to indicate need for imaging in clinical practice may lead

to an overuse of imaging in clinical practice, and in research may lead to overestimation of imaging underuse and underestimation of imaging overuse. More recent clinical practice guidelines recommend that imaging is only indicated when a strong clinical suspicion of pathology is suggested by the presence of combinations of red flags (1, 2). Sensitivity analysis performed in Chapter 2 found lower proportions of non-indicated imaging decisions in studies published after 2010, which may reflect the change in clinical practice guidelines after this time to emphasise combinations of red flags, rather than individual red flags, as indicators for imaging (1, 2). Further research into specific criteria, with good levels of sensitivity and specificity, which can be consistently applied to determine the appropriateness of imaging is required both for clinical and research purposes.

7.2.2.2 Implications associated with the outcome measures used to determine the extent of imaging for low back pain

The most appropriate outcome measure to determine the extent of imaging use in the management of low back pain would be the proportion of patients presenting with low back pain who are referred for imaging. In Chapter 3 only two of the included studies (23, 24) used this outcome measure. The remaining studies used the proportion of imaging referrals per 1000 patients presenting for care for any condition (25, 26) or counts of imaging use with no denominator information (27-29). These less robust outcome measures are associated with significant potential bias, in particular that changes in imaging counts or proportions may reflect changes to the number of patients presenting with low back pain rather than a change in the proportion of low back pain patients referred for imaging. Aggregated system-level or administrative data may be useful to facilitate the collection of data for large-scale randomised controlled trials without requiring patient recruitment. However, the ability to capture precise data regarding low back pain presentations and associated imaging may be limited depending on the system used, impacting the ability to conduct an effectiveness study with a sufficiently robust primary outcome measure.

7.2.2.3 Implications associated with identifying and addressing patients who have stronger beliefs that imaging is important in the management of low back pain

Not all patients presenting for care believe that imaging is important in the management of low back pain. It is important to be able to determine the patients who are more likely to believe imaging to be important so that interventions to reduce imaging can be targeted to

these patients and practitioners can address these inappropriate beliefs as part of their care. Patient characteristics associated with increased beliefs in the need for imaging identified in Chapter 4 included older age, lower educational background, non-Australian/European/British/North American cultural background, poorer general beliefs about low back pain, and previous referral for imaging for low back pain. Interestingly, current low back pain was not associated with an increased belief in the need for imaging, whereas current low back pain has been associated with poorer general beliefs about low back pain in previous studies (30, 31).

It is important that interventions to reduce imaging for low back pain are designed to be accessible and appropriate for patients with the demographic characteristics listed above, and include strategies to improve general beliefs about low back pain, as well as beliefs related to imaging for low back pain.

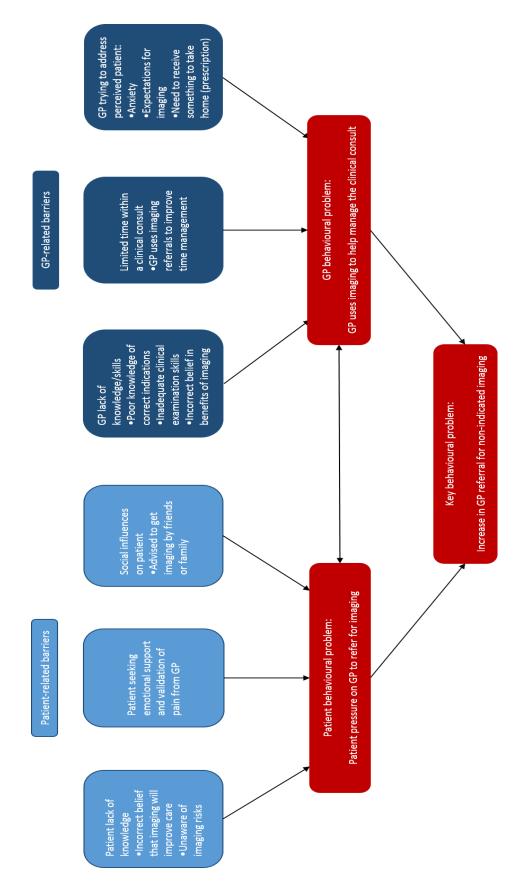
7.3 Intervention development and preliminary testing

7.3.1 Main findings

To address the findings from the needs assessment, the Behaviour Change Wheel, with incorporation of the Theoretical Domains Framework, was used to develop an intervention to reduce non-indicated imaging for low back pain (Chapter 5). Barriers and facilitators to reducing non-indicated imaging related to both practitioners and patients were identified through literature review. A concept map was developed to demonstrate how the identified barriers impact on practitioner and patient behaviours within a clinical consult and thus result in increased non-indicated imaging referrals (Figure 1).

Figure 1: Concept map of the identified barriers to reducing imaging for low back pain.

Reproduced with consent from 'Using behaviour change theory and preliminary testing to develop an implementation intervention to reduce imaging for low back pain' (32)



The Behaviour Change Wheel was used to identify the required behavioural change techniques and implementation strategies to be included in the intervention. The final intervention included training of general practitioners to use a low back pain education and management booklet with patients during a clinical consult. The booklet was developed to include the identified behavioural change techniques required for the intervention to: facilitate practitioner-patient communication, provide clinical decision support for the practitioner, provide educational material and customised management advice for the patient, and help reduce pressure from patients to refer for imaging. Patients would also receive a customised copy of the booklet to take home to reinforce the delivered messages. The developed booklet was designed to be time-efficient to use, easily stored and accessed, and aid practitioners in communicating with patients about low back pain and the need for imaging.

Experts in the field of low back pain provided feedback on the appropriateness of the booklet content. Subsequently, thematic analyses of semi-structured interviews with practitioners and health consumers with a history of low back pain were used to determine the acceptability of the booklet. Minor modifications to the booklet and training session content were made to address potential barriers to use. Practitioners and health consumers thought the booklet would be useful in a clinical consult and health consumers thought that use of the booklet would help them understand why imaging wasn't required. Practitioners thought a hardcopy booklet may be difficult to implement in clinical practice, whereas health consumers liked the hardcopy booklet format and thought they would be more likely to continue to use and refer to the booklet rather than other options such as printed handouts or digital copies.

Prior to assessing the effectiveness of a developed intervention it is important to determine whether the intervention is feasible to use in clinical practice, to limit implementation issues from adversely affecting the effectiveness of the intervention (12, 33, 34). It was determined important to assess whether practitioners would use the booklet as designed, whether they considered the booklet to be useful when used clinically, and whether there were any barriers to use that would adversely affect implementation. This was undertaken by means of a qualitative study to explore general practitioner experiences using the developed booklet in clinical practice (Chapter 6). Fourteen practitioners completed the study and generally reported that the booklet was a useful tool for clinical practice and that

using it was likely to reduce the use of non-indicated imaging. Practitioners identified how and why they thought the booklet was useful in managing low back pain and these findings were consistent with the ways in which the intervention was designed to target identified barriers. Practitioners reported that they were more likely to use the booklet if patients requested imaging, when the practitioner felt lower confidence in managing low back pain, or when they had limited time in the consult to educate the patient. The main barrier limiting use of the booklet was a lack of ability to conveniently store and remember to use the hardcopy booklet. Practitioners felt strongly that a digital version of the booklet would increase use in clinical practice.

7.3.2 Clinical and research implications

The work in this thesis led to the development of an intervention to reduce non-indicated imaging for low back pain. Preliminary testing showed that the intervention is acceptable for clinical practice, appears to address the identified barriers in the way it was designed, and, therefore, may help to reduce non-indicated imaging for low back pain. It is also likely that the developed intervention could be successfully implemented in different geographic locations and with different healthcare providers who refer for low back pain imaging, as barriers to reducing non-indicated imaging tend to be similar in these different settings (15). Consideration would need to be made of appropriate translation or modification of the booklet for different geographical regions to account for cultural and language variations (35). Important barriers to implementation of the intervention in clinical practice were identified in Chapter 6 and changes should be made to address these prior to clinical trials or large-scale implementation of the intervention. This intervention, if demonstrated to be effective, has substantial scope as a low cost method to decrease non-indicated imaging for low back pain, thus improving patient care, decreasing risks associated with imaging, and reducing healthcare costs.

7.3.2.1 Addressing barriers to implementation of the intervention

The most commonly reported barrier to implementing the low back pain education and management booklet in clinical practice was the ability to store, and remember to use, the booklet in a hardcopy format (Chapter 6). Low usage rates of patient handouts by practitioners in other studies aiming to improve low back pain management have been reported (23). In contrast, studies using hardcopy booklets to reduce non-indicated

prescription of antibiotics for upper respiratory tract infections have shown hardcopy booklets to be effective and feasible to use in clinical practice (36, 37); however, patient presentations for upper respiratory tract infections are approximately twice as common as patient presentations for low back pain (38), potentially acting as a reminder to practitioners to use hardcopy booklets in those cases.

In Chapter 6, all practitioners reported that they would be likely to find a digital option easier to store and remember to use in clinical practice. It was also identified that they thought the booklet content in a digital version would be easier to keep up-to-date, and the booklet could be printed or emailed to patients as required.

Digital options for patient education are becoming more common (39-42); however, internet availability and patient e-health literacy are limitations that need to be considered (39). The ability of the practitioner to customise the booklet to the patient and hand-deliver it in the same manner as a prescription has also been found to be important (43). This was an intended component of the hardcopy booklet and should be considered in the development of a digital version. In Chapter 5, it was found that health consumers thought they would be more likely to use, and continue to reference, a hardcopy booklet rather than a digital version. This discrepancy between practitioner and health consumer preferences is difficult to resolve and the availability of both digital and hardcopy versions of the booklet is likely to be necessary to facilitate uptake and use in different clinical scenarios.

A single face-to-face training session of less than 15 minutes was generally reported to be sufficient to enable practitioners to use the low back pain education and management booklet as designed (Chapter 6). The suitability and practicality of a face-to-face training session with future large-scale implementation of the intervention was raised and online training was suggested as a suitable alternative. Face-to-face training sessions have shown limited uptake in other studies aiming to improve low back pain management (26). Online training of practitioners in the use of patient education materials or other interventions has been shown to be effective in other fields (36, 44) and should be explored as an option for the developed intervention.

It is important that use of the booklet is targeted to the patients who require more education or reassurance about the use of imaging for low back pain. In Chapter 6 it was identified that practitioners would be unlikely to use the booklet with every low back pain

patient, but would instead use it with patients requesting imaging or needing more reassurance about their low back pain. In Chapter 4 it was identified that patients were more likely to believe imaging to be useful in the management of low back pain if they were older, had lower educational backgrounds, or were from cultural backgrounds other than Australia, England, North America or Europe. Moving forward, it is important that practitioners are informed during their training session that patients with these demographics may require further education regarding the usefulness of imaging and that the booklet may be more useful in these situations. Translation of the booklet to languages other than English and consideration of cultural traits may be required to ensure patients from these higher risk demographics benefit from use of the booklet.

Consideration should also be given to whether there are broad barriers that will limit the effectiveness of any intervention to reduce imaging for low back pain. Practitioner ownership of imaging facilities has been associated with increased imaging rates (45-47). It is possible that the implementation of any intervention designed to reduce imaging rates will be met with resistance in such practices, as financial remuneration will be impacted by the intervention. In these cases, when practitioner resistance is a major limiting factor, health care policy interventions such as restriction of practitioner referral rights may be necessary and some evidence of effectiveness has recently been shown with these types of interventions (10, 11).

7.3.2.2 Considerations for future effectiveness testing of the intervention

Effectiveness testing is considered an essential component of the development of interventions prior to large-scale implementation (12, 34). When performing effectiveness testing the selection of appropriate study design and outcome measures is necessary and it is also important to consider the cost effectiveness of the intervention (12, 33, 34).

Randomised controlled trials are considered the most robust design for testing the effectiveness of an intervention. Alternative study designs may be necessary depending on the intervention to be tested and the likelihood of different biases in study design occurring (12). In Chapter 3, two of the included studies in the review used an interrupted time-series study design (27, 29). Although this quasi-experimental design does not use randomisation, bias can be reduced by data being collected over a period of several years and at a minimum of three time points both before and after implementation of the intervention (48). The

absolute change in effect on the delivery of the intervention can be calculated similar to a before and after study; however, trend lines over time can also be compared, to determine differences between pre-intervention and post-intervention trends (48, 49).

Should a randomised controlled trial study design be used for future testing of the developed intervention to reduce non-indicated imaging for low back pain, it would be important to consider whether randomisation would occur at the patient, practitioner, or practice level. In the case of an intervention to reduce imaging for low back pain, the study would be assessing the ability of the intervention to change practitioner behaviour.

Randomisation would need to be performed at the practice level as a cluster randomised controlled trial, to avoid any contamination between control and intervention groups (12, 50). Cluster randomised controlled trials were the most common study design used in studies included in the review in Chapter 3. An important consideration when designing a cluster randomised controlled trial is that sample sizes will need to be appropriately increased to account for similarities in practitioner decision-making within each cluster (50).

The developed intervention aims to decrease non-indicated imaging for low back pain. The most appropriate outcome measure to determine the effectiveness of the intervention would be the proportion of non-indicated imaging within a low back pain population. Previously conducted effectiveness studies detailed in Chapter 3 have generally used the proportion of total imaging for low back pain rather than the proportion of non-indicated imaging as an outcome measure, possibly due to the challenges of assessing non-indicated imaging as discussed in section 7.2.2.1 above. Although the amount of total imaging use is potentially less informative, the low percentage of patients presenting with serious pathology in primary care (21) means it is likely that reductions in imaging use will largely represent reductions in non-indicated imaging. However, some studies that have assessed both total imaging and non-indicated imaging proportions have found opposite results in the effectiveness of the intervention depending on the outcome measure used (23, 25), highlighting the need to choose the outcome measure that will best answer the research question. Furthermore, the results of Chapter 2 show that inappropriate non-referral for imaging is also a potential concern and may need to be addressed when testing the effectiveness of the developed intervention. Ideally, the intervention would improve appropriate decision-making to both reduce non-indicated imaging and to increase indicated imaging. Assessment of low back pain patients not referred for imaging would be required to ensure reducing imaging use was not negatively impacting on the proportion of indicated imaging. Limitations in the ability to collect the required outcome data may impact the successful conduct of an effectiveness study and feasibility studies to determine the ability to collect the planned outcome data may be necessary prior to effectiveness studies being conducted (12, 34, 51).

7.3.2.3 Cost of the developed intervention

An intervention may demonstrate effectiveness; however, implementation costs compared to potential cost savings may be too high to make it feasible to use in clinical practice or for wide-scale implementation. A successful intervention to reduce non-indicated imaging for low back pain has the potential to save substantial cost to patients and healthcare systems. In Chapter 2 approximately one-third of imaging referrals were non-indicated. A reduction in imaging costs of one third would have equated to AUD60 million in the 2017-2018 financial year to the Australian healthcare system alone (52), with further savings related to out-of-pocket patient expenses. The costs associated with the intervention to reduce nonindicated imaging for low back pain were considered in Chapter 5 as part of the development process. The development of the intervention, including the patient education and management booklet, has been completed and funded as part of this thesis. Future costs are low and relate to the initial development of digital versions of the booklet and online practitioner training and ongoing costs related to printing of the booklet and upkeep of the content within the booklet. Therefore, if the intervention is shown to be effective in reducing non-indicated imaging, savings to the health-care system are likely to be much higher than the low costs of ongoing booklet upkeep and printing. Practitioners did raise concerns about who would meet the costs associated with the booklet in clinical practice and this needs to be considered prior to large-scale implementation.

7.4 Conclusions

This thesis details the development of an intervention to reduce non-indicated imaging for low back pain. Need for such an intervention was demonstrated with systematic reviews demonstrating high proportions of non-indicated imaging decisions in primary care and limited effectiveness of previously tested interventions to reduce imaging for low back pain. The developed intervention is theory-informed and addresses both practitioner and patient related barriers to the appropriate use of imaging for low back pain. The importance of

patient expectations for imaging use in the management of low back pain was demonstrated in this thesis and these had not been previously addressed in interventions to reduce imaging use. Preliminary testing of the developed intervention demonstrated that it is likely to be useful in clinical practice, particularly when patients request imaging or practitioners feel less confident in managing low back pain. Barriers to implementing the intervention in clinical practice were explored and will be addressed prior to planned effectiveness testing. A successful intervention to reduce non-indicated imaging for low back pain would result in substantial reductions in healthcare costs, improve patient care, and decrease risks associated with imaging.

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Appendix 1 and 2 of this thesis have been removed as they may contain sensitive/confidential content