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## Reviewing the Diagnostic Classifications used for Low Back Pain in Physiotherapy-related Research.

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## Reviewing the Diagnostic Classifications used for Low Back Pain in Physiotherapy-related Research.

### Abstract

**Background:** The evidence-to-practice gap, where clinical practice does not reflect the findings from research evidence, has been identified as a concern in allied health disciplines such as physiotherapy. Failure to provide care according to current (research) evidence raises the potential that patients are receiving care that is either not needed, is ineffective, less effective than current research indicates, or potentially harmful. For research evidence to be translatable to clinical practice, the research should be seen to be applicable, i.e. the clinician should be able to recognise that the research study sample reflects their patient population. **Method:** This study presents a pragmatic clinical review of patient sampling from high level primary research trials investigating physical therapy for low back pain. Only studies where full text copies were freely accessible to clinicians were reviewed. The review collated the characteristics of the study subjects and explored how they related to standard clinical practice. **Results:** A total of 63 full text randomised controlled trials papers were identified and reviewed. Across the studies reviewed, the clinical presentations of included subjects were variably described, with inconsistencies in the diagnostic labels used, the characteristics of the symptoms reported and the nature of the exclusion criteria applied. Of concern was the lack of reporting of patient's clinical presentation according to standard clinical assessment findings to allow the clinician to gauge the applicability of the study. **Conclusion:** A core principle of clinical physiotherapy practice is the clinical assessment of the patient to identify the patient's specific presentation to individualise rehabilitation and exclude serious pathology. To close the evidence-practice gap, we either need to revisit standard clinical practice or focus on the reporting of the research evidence to ensure its applicability.

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### **ABSTRACT**

**Background:** The evidence-to-practice gap, where clinical practice does not reflect the findings from research evidence, has been identified as a concern in allied health disciplines such as physiotherapy. Failure to provide care according to current (research) evidence raises the potential that patients are receiving care that is either not needed, is ineffective, less effective than current research indicates, or potentially harmful. For research evidence to be translatable to clinical practice, the research should be seen to be applicable, i.e. the clinician should be able to recognise that the research study sample reflects their patient population.

**Method:** This study presents a pragmatic clinical review of patient sampling from high level primary research trials investigating physical therapy for low back pain. Only studies where full text copies were freely accessible to clinicians were reviewed. The review collated the characteristics of the study subjects and explored how they related to standard clinical practice. **Results:** A total of 62 full text randomised controlled trials papers were identified and reviewed. Across the studies reviewed, the clinical presentations of included subjects were variably described, with inconsistencies in the diagnostic labels used, the characteristics of the symptoms reported and the nature of the exclusion criteria applied. Of concern was the lack of reporting of patient's clinical presentation according to standard clinical assessment findings to allow the clinician to gauge the applicability of the study.

**Conclusion:** A core principle of clinical physiotherapy practice is the clinical assessment of the patient to identify the patient's specific presentation to individualise rehabilitation and exclude serious pathology. To close the evidence-practice gap, we either need to revisit standard clinical practice or focus on the reporting of the research evidence to ensure its applicability.

**Keywords:** low back pain, diagnosis, evidence-based practice gap

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## INTRODUCTION

Evidence based practice (EBP) has become the dominant paradigm for a range of allied health professions, including physiotherapy. Benefits purported to follow the implementation of EBP into clinical practice relate to the grounding of clinical practice in scientific and empirical proof and achieving safer, more consistent, and more cost effective health care.<sup>1</sup> This perceived quest for “objectivity” is underpinned by the process of EBP. By thoroughly searching the scientific literature and critically appraising the published scientific literature, we aim to rigorously, conscientiously and explicitly utilize the research evidence to inform our clinical practice.

Whilst the traditional model of EBP is based on the pillars of research evidence, patient preference, clinical experience, and practice context, there is a growing awareness of the importance of EBP implementation, which focuses on the translation of research evidence into clinical practice. The process of evidence implementation aims to close evidence – practice gaps, where the clinical practice does not reflect the findings from the research evidence. Most studies into the evidence-practice gap have focused on medicine and nursing, and identified that in countries such as the United States and Netherlands, at least 30%–40% of patients do not receive care according to current scientific (research) evidence. Of particular concern is the finding that 20% or more of the care provided is either not needed or potentially harmful to patients.<sup>2</sup>

Though evidence-practice gaps in physiotherapy are unlikely to result in significant harm to patients, they may lead to treatments with reduced efficacy. Barton et al reported an evidence-practice gap in the management of patello-femoral pain, with more therapists supporting use of a non-research evidence based intervention (kinesio-tape) compared to a research evidenced based treatment (prefabricated foot orthoses).<sup>3</sup>

Kitson et al presented a conceptual model for evidence implementation which consisted of a number of elements, including the nature of the evidence, the context in which the changes were to happen, and how the change was to be facilitated.<sup>4</sup> The authors suggested that by giving equal recognition to each of the model's elements, practitioners should be able to implement research findings successfully into their clinical practice. When considering practices to facilitate research evidence implementation into clinical practice, it may be prudent to revisit the nature of the research evidence presented. A number of issues have been identified about the research evidence, including study methodologies that do not reflect clinical practice; inappropriate patient sampling and outcomes to gauge treatment success, and insufficient “physiotherapeutic” knowledge among researchers so that rigid protocols which ignore individual therapeutic “dose-response” relationships are used.

According to the traditional EBP model in the area of intervention-based research, randomised controlled trials (RCTs) are considered the highest level of primary research design as a result of the inherent strength of this research design. Whilst there have been some discussion about the relevance of this research design to complex allied health interventions such as physiotherapy within the area of EBP, RCTs remain the highest primary level of research evidence.<sup>5</sup>

One aspect of the RCT methodology which strengthens this specific design relates to the appropriate sampling of subjects for inclusion into the study. The sampling of subjects within an RCT requires a balance between the need for scientific rigor, by controlling for potential confounders through strict inclusion and exclusion criteria, and the need to reflect the characteristics of the population for which the study purports to be applicable to. For a clinician, the ability to implement RCT research evidence into clinical practice will depend on the clinician identifying that the research studies' subjects reflect the clinician's patients. The less that the subjects recruited into the study can be linked to the patients that the clinician sees, the less likely the clinician will uptake the research findings.

In clinical practice, physiotherapy clinicians undertake clinical assessments to identify the key attributes of their patients. The World Confederation of Physical Therapists (WCPT) recommends that physiotherapists should undertake a comprehensive assessment of the patient, evaluate these findings to make clinical judgments, and undertake an appropriate intervention. They recommend that through a process of clinical reasoning that identifies existing or potential impairments, activity limitations, participation restrictions, environmental influences or abilities/disabilities, a diagnosis is made. The purpose of this diagnosis “.....is to guide physical therapists in determining the prognosis and most appropriate intervention/treatment strategies for patients/clients and in sharing information with them.”<sup>6</sup>

In the management of low back pain, a standard part of physiotherapy practice is that an assessment, including both a subjective and objective examination, is carried out to identify the patient's specific presentation. It is a fundamental approach to physiotherapy, as the profession has moved away from the role of a technician, that the treatment approach should be individualized to the patient's presentation and not be recipe-based.<sup>7</sup> Whilst some authors have queried the evidence associated with this approach the authors also acknowledge that the studies were often flawed, with small subject numbers and significant

biases.<sup>8</sup> In essence, we still do not know, apart from therapist's clinical experience and patient preference, whether individualized treatment works.

Whilst the diagnostic capacity of clinical examination tests used by physiotherapists is often poor, the information gained can be used to individualize the patients treatment independent of the diagnostic label applied. For example, the treatment for patients with low back pain aggravated by flexion activities is different than that for patients with low back pain during extension type activities, independent on what diagnostic label we might apply to the patients.

Importantly, the clinical assessment seeks not only to differentiate patients according to their clinical presentation, but also to identify those with serious spinal pathology, as they may present with flags that may be identified in the clinical assessment.

### **Study Aims**

This study critically reviewed recent RCT research evidence in terms of the subjects sampled and how it reflected the patients that may be seen in clinical practice. The study had two main aims:

- a) To identify how study samples were characterized in RCTs on the use of physical therapy for low back pain in adults
- b) To identify how the samples were characterized against standard physiotherapy assessment processes.

The aim of this study was not to critically appraise the internal validity or quality of the studies or to review the study findings, but to explore how likely a clinician could take the studies' findings into clinical practice; that is, the applicability/external validity of the research evidence.

### **METHODS**

A pragmatic search of the published evidence related to the physiotherapeutic management of low back pain in adults was undertaken in October 2017. The aim of this search was not to undertake an academic systematic review but to perform a search that a clinician may undertake in clinical practice to identify the most recent highest levels of primary research evidence to treat their patient with low back pain. The access to journals was limited to those that a clinician would be able to access in full text in a publically available database, without subscribing to a database/journal/library.

#### **Selection of Studies**

##### *Participants*

Studies were included if they involved adult patients who had low back pain.

##### *Intervention*

Studies were included if the intervention was based on any physiotherapy/physical therapy treatment of any form.

##### *Outcomes*

Outcomes were not the focus of this review and therefore all outcomes were included.

Eligible studies were identified using a search strategy of key terms: "low back pain," "physiotherapy," "physical therapy." and "randomised controlled trial" in a publically available database (Pubmed©) from January 2015 to September 2017. A two-year window of publication was chosen to ensure only the most recent evidence was reviewed. Inclusion criteria were established with all studies involving adults with low back pain and investigating the use of any physiotherapy/ physical therapy modality. All titles and abstracts were independently screened for inclusion by the two authors, and any disagreements were resolved by consensus. Where there was uncertainty, the full text of the article was retrieved and screened.

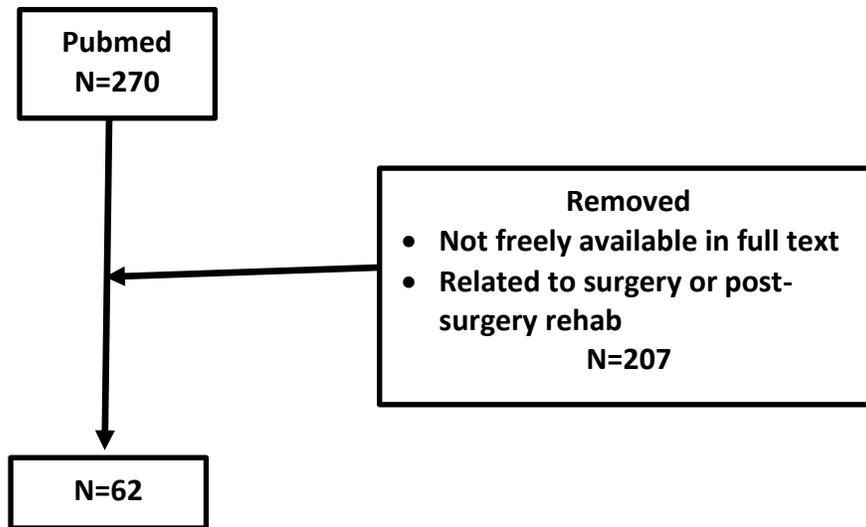
#### **Data Extraction**

##### *Study characteristics*

For all included studies, both authors independently extracted data on the inclusion criteria reported by the authors for inclusion of subjects into the study. A specifically designed data extraction tool was used to collate the data used for this review. Specific data extracted from the studies included author, year, inclusion criteria, exclusion criteria, diagnostic label (if relevant), assessment findings (if relevant), pain description (area, severity, duration), intervention

## RESULTS

A total of 62 RCT studies, available freely in full text, and published between January 2015 and December 2017 were located (see Figure 1).<sup>9-70</sup> There were no disagreements between the two authors from screening title and abstract



**Figure 1: Consort diagram of review process**

Very few studies identified the patho-anatomical lesion that was potentially involved, with only one study labelling the patients' patho-anatomical cause for their low back pain.<sup>25</sup> The most common diagnostic labels used were "chronic low back pain" (n=19 (30.1%)) and "non-specific chronic low back pain" (n= 14 (22.2%)). The range of diagnostic labels are presented in Table 1.

When labelling the patients clinical presentation, the pain was most commonly characterized by area of symptoms (i.e., low back), temporal aspects (acute, subacute, and chronic), causes (non-specific low back pain, lumbar disc herniation with associated radiculopathy) or behavior (mechanical, persistent, and recurrent). The definitions for these are presented in Table 2.

**Table 1.** Diagnostic labels reported in the study

	Diagnostic label	Number of studies
1	Chronic LBP	21
2	Non-specific chronic LBP	18
3	Low Back pain	13
4	Non-specific LBP	8
5	Sub-acute LBP	5
6	Acute/recent onset LBP	3
7	Mechanical BLBP	2
8	Nonspecific persistent LBP	2
9	Persistent non-specific LBP	2
10	LBP with radiculopathy	2
11	Chronic mechanical LBP	1
12	Chronic or recurrent LBP with reduced hip rotation	1
13	Mechanical Chronic LBP	1
14	LBP and movement control impairment	1
15	Nonspecific chronic mechanical LBP	1
16	Non-specific chronic, recurrent LBP	1
17	Lumbar disc herniation with associated radiculopathy	1
18	Persistent Low Back Pain	1

\*Total number of studies >62 as some studies report more than one diagnostic label

**Table 2: Definitions for characterizing subject's pain**

Characterization	Definition
Acute	<ul style="list-style-type: none"> <li>• &lt; 4 weeks <sup>25</sup></li> </ul>
Subacute	<ul style="list-style-type: none"> <li>• 4 to 12 weeks <sup>25</sup></li> <li>• &gt; 4 weeks <sup>69</sup></li> <li>• 3 to 12 weeks <sup>28</sup></li> </ul>
Chronic	<ul style="list-style-type: none"> <li>• &gt; 6 weeks <sup>54</sup></li> <li>• &gt;12 weeks/3 months <sup>19, 25, 28, 29, 31, 42, 65, 70,</sup></li> <li>• &gt; 6 months <sup>39, 63</sup></li> <li>• &gt;12 months <sup>64</sup></li> </ul>
Persistent/Recurrence	<ul style="list-style-type: none"> <li>• from "very often" to "always" <sup>15</sup></li> <li>• &gt; 3 episodes a year <sup>42</sup></li> <li>• Symptoms on less than half the days in a 12 month period in multiple episodes <sup>68</sup></li> <li>• ≥1 episode(s) of LBP over the previous three years, <sup>16</sup></li> </ul>
Mechanical Low Back pain	<ul style="list-style-type: none"> <li>• LBP of a nociceptive mechanical character from assessment <sup>37</sup></li> </ul>

A number of studies also used measures of severity and disability to further classify their study subject's clinical presentation. Table 3 presents the definitions used for severity and disability characteristics.

**Table 3: Definitions for classifying subject's low back pain in terms of severity and disability**

Classification	Definition
Severity	<ul style="list-style-type: none"> <li>• ≥4 in numerical rating scale <sup>13, 19, 23, 30, 55, 59</sup></li> <li>• Minimum pain score of 25 on a 0 to 100 scale <sup>65</sup></li> <li>• Pain greater than any other body region and 4 or more on an 11 point numerical scale <sup>70</sup></li> <li>• Score of 3.0 to 8.0cm on a 0–10cm visual analog scale for pain <sup>31, 50</sup></li> <li>• Pain &gt; 3 on a 1- 10 VAS <sup>20, 22, 24, 28, 56</sup></li> <li>• Pain between 4 and 7 on VAS (0-10) <sup>44</sup></li> <li>• Mild to moderate pain VAS 2 to 7 <sup>49</sup></li> <li>• Pain bothersomeness greater than 4 or pain interference with activities greater than 3 on 0- to 10-point scales <sup>17</sup></li> </ul>
Disability	<ul style="list-style-type: none"> <li>• Oswestry Disability Index (ODI) between 20% and 70% <sup>50</sup></li> <li>• ODI &gt; 20% <sup>21, 56</sup></li> <li>• ODI &gt; 12% <sup>14</sup></li> <li>• ODI &gt; 19 <sup>27, 36</sup></li> <li>• Roland Morris Disability Questionnaire (RMDQ) : 5 points or more <sup>54, 66</sup></li> <li>• Score &lt; 8 on at least one activity from the Patient Specific Functional Scale <sup>36</sup></li> </ul>

When describing the process for including patients with low back pain into the study fifteen studies (23.8%) of reported the clinical assessments that were undertaken (see Table 4).

**Table 4: Clinical assessments performed as part of the sampling process**

Clinical Assessment	Study
Lumbar range of movement	Ammar et al <sup>12</sup> , Gyulai et al <sup>24</sup> , Hidalgo et al <sup>26</sup> , Murtezani et al <sup>43</sup> , Natour et al <sup>44</sup> , Shah & Kage <sup>57</sup> , Vavrek et al <sup>65</sup> , Waqqar et al <sup>67</sup>
Neurological testing	Ammar et al <sup>12</sup> , Fritz et al <sup>21</sup> , Garcia et al <sup>22</sup> , Hahne et al <sup>25</sup> , Vavrek et al <sup>65</sup> ,
Posture Assessment	Ammar et al <sup>12</sup> , Patti et al <sup>48</sup>
Strength	Ammar et al <sup>12</sup> , Steele et al <sup>60</sup>
Balance	Patti et al <sup>48</sup>
Gait analysis	Steele et al <sup>60</sup>
Motor control	Lehtola et al <sup>33</sup> , Saner et al <sup>54</sup>

## DISCUSSION

There has been discussion in the literature about the evidence-practice gap and the need for clinicians to keep up to date with the evidence associated with their patient's clinical management. Issues have been raised about the difficulties associated with the uptake of evidence, particularly related to the amount of literature that is published each year and the ability of a clinician to access and utilize this rising tide of evidence.

This review took a clinically pragmatic view of the evidence translation by only sourcing evidence that would be available to a practicing clinician without having to pay for journal subscriptions or have access to academic library databases. This is also the case in many universities in developing countries who are unable to subscribe to expensive or extensive journal sets. We felt that this was important, as published systematic reviews often fail to identify the key sampling criteria in the included RCTs, making it difficult for the clinician to gauge the study sample applicability. In these case, the clinician would need to go back to the primary source, the published RCT.

Despite these limitations, we found 62 full text papers from 270 papers reporting on RCTs for the physiotherapeutic management of a patient with low back pain over the period from January 2015 to October 2017. This is a significant body of literature and would represent a major time commitment for the clinician to access, read, and appraise. We acknowledge that this number of studies is the worst case scenario as the clinician would usually limit their search by intervention type, but reflects one of the current challenges to EBP implementation – the wealth of published evidence.

This number of studies also explains the growing popularity of secondary evidence sources such as systematic reviews and clinical guidelines; however, we chose not to include these secondary evidence sources. The RCT studies represent the primary source for the study and allowed us to explore the characteristics of the study subjects that would be used by a clinician to determine if they could apply this information when considering how to implement the research evidence into their clinical practice. As described, systematic reviews often do not report the specific criteria of the subjects sampled for a RCT.

When reading a study, the first information that the clinician can use to help determine the applicability of the study to their patient cohort is the diagnostic label used. This study found a wide range of diagnostic labels applied to patients with low back pain. These labels differentiated the LBP based on temporality (acute, vs, subacute, vs chronic), causes (non-specific, lumbar disc herniation with associated radiculopathy) or behavior (mechanical), with varying consistency on the definitions used for these across the studies. Acute was defined as less than 3 to 4 weeks and sub-acute as between 3 to 4 weeks and 12 weeks. Chronic LBP was defined as greater than 6 weeks, >12 weeks, > 6 months, and >12 months.<sup>19,23,28,29,31,39,42,54,63-65,70</sup>

When subjects were recruited based on measures of disability and severity, inconsistencies were also reported in the definitions used. Severity was most commonly based on the VAS 1- 10 scale; however, the cut-off point for inclusion in the study ranged from 2 to 4 out of 10. Measures of disability used included the Oswestry Disability Index (ODI), the Roland Morris Disability Questionnaire (RMDQ) and the Patient Specific Functional Scale. There was also a lack of consistency in the cut-off with ODI scores ranging from 12% to 20%.

Chronic low back pain and non-specific low back pain were the most predominant diagnostic labels, being part of the diagnostic labels used by 71% of studies. The diagnostic label "non-specific low back pain" implies that there is no known patho-anatomical cause for the low back pain. Patho-anatomical causes of low back pain include epidural abscess, compression fracture,

spondyloarthropathy, malignancy, cauda equina syndrome, radiculopathy, or spinal canal stenosis, with all other causes of low back pain being considered non-specific low back pain. In this review, other patho-anatomical causes for low back pain that were reviewed included pregnancy, infection, inflammatory joint diseases, disc herniation, spondylolisthesis, and ankylosing spondylitis. Only one study in this review diagnosed the patients low back pain presentation with a patho-anatomical cause<sup>25</sup>

Some authors have suggested that as non-specific low back pain does not have a known patho-anatomical cause, there are, therefore, no specific treatments that can be provided.<sup>8</sup> This of course presupposes that we understand all potential patho-anatomical structures and have the ability to diagnose them. Most studies in this review reported the absence of patho-anatomical causes for the low back pain; however, very few studies reported how they identified if there was a patho-anatomical cause for the subjects low back pain prior to inclusion into the trial. A number of the studies reported that the patients were cleared of these causes by their medical practitioner or through self-report, but without any evidence of the assessment/examination used, along with the corresponding sensitivity/specificity of the tests used, the diagnosis of non-specific low back pain appears optimistic.

The label “non-specific low back pain” suggests that the low back pain is non-specific. Without reports of clinical assessment findings, it is difficult to identify if the patient’s presentation was specific or different from the others within the sample. It is therefore difficult to translate the findings from this research into clinical practice.

When auditing the research evidence against standard clinical practice, there was a consistent lack of use of standard clinical assessment and presentation of assessment findings to classify patients amongst the research studies. Whilst a number of studies reported using clinical assessment tests such as range of spinal movement and posture assessment, very few studies reported the findings and sub-classified subject responses to the intervention based on their clinical presentation. This process is often difficult in low back pain research where recruitment is problematic, leaving researchers with small subject samples. Any attempts to sub-classify patients according to their clinical presentations leaves the researcher with underpowered statistical analyses. Whilst this is an issue for the strength of findings associated with a single study, if studies utilized diagnostic classifications, based on standard clinical assessment and standardized outcomes, there is an opportunity for combining results of a number of studies using meta-analytical procedures. This may help overcome one of the major issues in clinical research in developed countries – sourcing sufficient patient numbers to allow sub-classifications of patient presentations.

A major issue in contemporary health care is how best to close the perceived gaps between evidence and practice that continue to persist in the management of low back pain. The general approach has been to look at what the clinician is doing and try to understand why the clinician is not using the research evidence.

This review highlights that the research evidence that is currently available is not reflective of current clinical practice. For the evidence-practice gap to close, we either need to change clinical practice or change the way research evidence is collected and presented.

To change clinical practice to fit with the research evidence, the balance of the evidence suggests that for the management of low back pain, we should eliminate clinical assessment, apart from either a questionnaire to identify red flags and the patients understanding of significant pathology they may have, or a letter from their medical practitioner to clear them, and treat all low back pain patients the same, as most have non-specific low back pain. This approach would appear to be in conflict with the concept of clinical reasoning.

## CONCLUSION

To change the way the research evidence is presented, we should see more sub-classification of patients based on their clinical assessment findings as standard secondary outcomes. Even just basing this classification on patient’s relative movement restrictions will more reflect common clinical practice. Whilst this may lead to under-powered analyses of these secondary outcomes, the data presented can be combined across studies. The identification of low back pain presentation types will facilitate the development of management strategies that directly target the low back pain presentation and its consequent disability, and not a theoretical model of what could be wrong with a patient.

Until research evidence is able to be transferred into clinical practice and until researchers start to talk to clinicians, we will remain with an evidence- practice gap in the management of patients with low back pain.

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