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PHYSIOTHERAPY LOW BACK STRAIN MODEL OF CARE

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Back Strain Task Force

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CONTENTS

1.0	Summary	Page 2
1.1	Executive Summary	
1.2	Purpose of Paper	
1.3	Background	
1.4	Intended Use	
1.5	Definitions	
2.0	Model of Care	Page 5
3.0	Literature Review	Page 7
3.1	Common Methodology	
3.2	Specific Research Topic Areas	
3.2.1	Therapeutic Exercise	
3.2.2	Manual and Manipulative Therapy	
3.2.3	Education	
3.2.4	Electrophysical Agents	
3.2.5	Acupuncture	
3.2.6	Predictive Factors	
3.2.7	Early Access	
3.2.8	Communication	
4.0	Other Considerations	Page 51
4.1	Outcome Measures	
4.2	MoC Evaluation	
4.3	Cost Benefit and Cost Effectiveness Analysis	
5.0	Conclusion	Page 55
Appendices:		
	Appendix 1: Biographies of the Expert Panel Task Force	Page 56
	Appendix 2: General search strategy for low back pain in three databases used for this review, and a sample search	Page 61
	Appendix 3: Type of Low Back Pain – Evaluation Recommendations	Page 62
	References	Page 64

PHYSIOTHERAPY LOW BACK STRAIN MODEL OF CARE

1.0 SUMMARY

1.1 Executive Summary

PABC's 9 member expert panel Task Force reviewed 382 articles which met the inclusion criteria of a thorough literature search conducted by the physiotherapy outreach librarian. Eight specific research topic areas were chosen based on this exhaustive search which resulted in the task force recommended Model of Care for best practice treatment of low back pain. Current best practice evidence indicates that treatment be guided by the following evidence-based principles:

1. Therapeutic exercise: Evidence supports the use of a patient-specific classification-based system to inform the prescription of exercise in the acute and sub-acute phases of recovery to facilitate early functional recovery.

2. Manual Therapy and Manipulation: Evidence recognizes the benefits of spinal manipulation in the first 8 weeks of recovery of nonspecific low back pain, and the effectiveness of intervention based on the Clinical Practice Rule.

3. Education: Literature supports in-person education as a key tool in treating the injured worker, with focus on the content and delivery of a positive message. The message includes the critical advice to stay active even in the presence of pain.

4. Electrophysical Agents: Evidence on electrophysical agents is challenged by inconsistencies in classification and lack of control over parameters and dosages. Usage should be based on the relevant evidence and within the context of other evidence-based interventions available.

5. Acupuncture: There is limited published research regarding the effectiveness of acupuncture or intramuscular stimulation; appropriate use depends upon physiotherapists' clinical judgment.

6. Predictive factors: The evidence supports an assessment of the worker's pain beliefs, cognitions and attitudes to recovery, presence of leg pain, perceived disability, and pain intensity in order to determine the appropriate treatment to optimized timely functional recovery.

7. Early access: The literature indicates potentially significant clinical and financial benefits when workers have early access to a physiotherapist's assessment, clinical management and education.

8. Communication: Physiotherapist-led collaborative communication among worker, employer, case manager and physician regarding the worker's functional abilities and barriers to return to work is expected to shorten time loss from work.

The Model of Care includes the following clinical considerations:

- Minimal intervention in the first three weeks and advice to stay active
- Return to work within 72 hours
- Identify and manage yellow flags
- Determine at 3 weeks if recovery is typical or atypical, and base intervention on assessed progress

1.2 Purpose

This Model of Care is a literature review and consensus paper for the physiotherapy and WSBC management of Acute/Subacute Low Back Sprain/Strain (LBS) of injured workers. It was written to assist physiotherapists in making diagnostic and treatment decisions, as well as disability management decisions. This paper outlines an evidence- and consensus-based review of the literature relating to the goals of:

- 1) Achieving optimal physiotherapeutic and disability management outcomes;
- 2) Improving communication among physiotherapists, WSBC, workers, employers and physicians;
- 3) Increasing the ability to evaluate, recommend and subsequently maximize the efficiency and effectiveness of MoC for injured worker recovery.

Specific research topic areas were identified based on their perceived high prevalence of use and relevance to care of acute/subacute low back pain by physiotherapists in British Columbia. The specific topics addressed include therapeutic exercise, manual and manipulative therapy, education, electrophysical agents (sound energy, light & electrical energy), acupuncture (including intramuscular stimulation (IMS)), predictive factors, early access and communication.

Additionally, outcome measures, implementation, evaluation and cost benefit considerations were added to enhance the practical use of the Model of Care that has resulted from this paper.

1.3 Background

The Physiotherapy Association of British Columbia (PABC) and WSBC (WSBC) are committed to optimizing the effective and efficient recovery of the injured worker, and ensuring their timely return to the workplace. The most prevalent worker injury is low back strain (LBS). Currently, physiotherapists provide services for injured workers with low back strain according to a contracted agreement between PABC and WSBC. In an effort to move from an impairment model to a functional ability model and to thereby improve the combined efforts of physiotherapists and WSBC, WSBC provided funding for a PABC task force to evaluate the current literature on the management of LBS in injured workers, and to propose a treatment approach based on the findings.

This basis for this paper and successful application relies on three assumptions;

- 1) That physiotherapists involved in treating injured workers agree that an early and safe return to the workplace is in the best interest of the worker;
- 2) That WSBC is committed to engage in activities that support evidence-based best practice management of LBS;
- 3) That there is mutual respect with regard to financial accountability.

The authors of this paper are registered physiotherapists in BC, PABC members, and have varying backgrounds and levels of direct experience with the LBS client base. (See Appendix '1' for author biographies).

1.4 Intended Use

This consensus paper is intended to be used as a supplement to clinical judgment in order to enhance the effective management of LBS. Evidence-based practice (EBP) as defined by Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996 is "the integration of best research evidence with clinical expertise and patient values." Clinical decision-making relies on EBP as a critical component

while also considering patient preferences, clinical circumstances, and therapist experience (Cormack, 2002). This paper is also intended to provide recommendations for an MoC based on supportive evidence and/or a rationale in addition to considering the economic interests of all stakeholders. It is expected that this document, requested by WSBC in 2006, will be a critical component in the process of development for future agreements between the PABC and WSBC with respect to the management of LBS.

1.5 Definitions

Acute/Subacute LBS

This paper focuses on LBS in the acute and subacute stage. Acute/subacute LBS is defined as pain in low back and/or buttocks that has been present for 12 weeks or less. Intermittent pain may radiate to the leg(s) or thoracic spine. There is an absence of neurological findings. See Appendix 2 for specific physiotherapy evaluation recommendations including medical 'red flags' (Rosignol, Arsenault, Dionne, Poitras, Tousignault, Truchon, Allard, Cote & Neveu, (2007)).

Physiotherapy

Physiotherapy is a primary care, autonomous, client-focused health profession focused on: improving and maintaining functional independence and physical performance; preventing and managing pain, physical impairments, disabilities and limits to participation; and promoting fitness, health and wellness (Canadian Physiotherapy Association website: www.physiotherapy.ca).

2.0 PROPOSED MODEL OF CARE

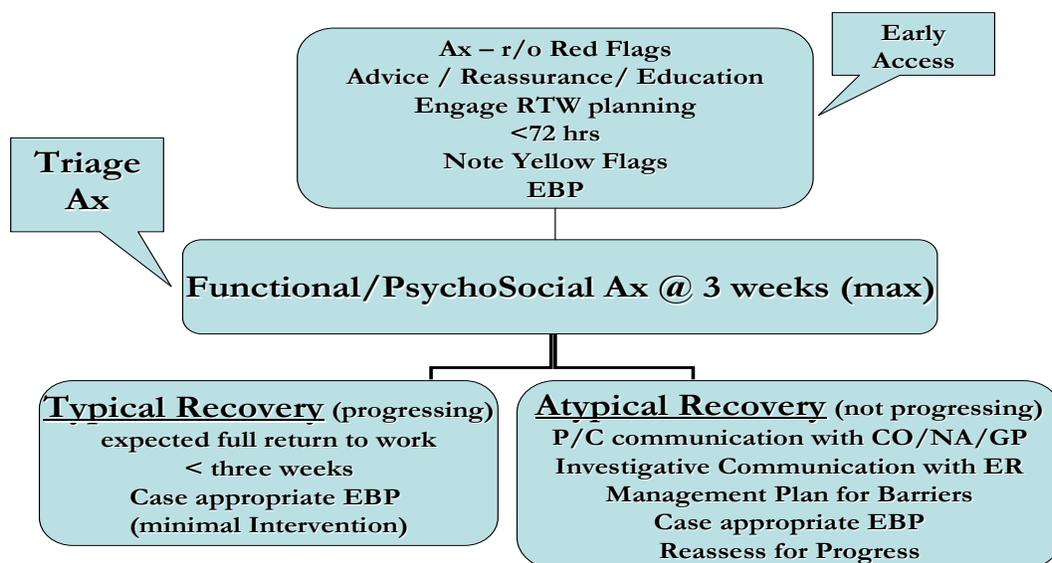
The Model

The MOC establishes a starting point from which to apply the evidence- and consensus-based practices outlined in the above sections. The proposal is derived from the following clinical guideline points:

- Advice to stay active / specific education and reassurance within first week (The New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.) (2004))
- Return to work efforts within 72 hours of absence (negotiated with employer) (American College of Occupational and Environmental Medicine, 2006)
- Manage and review/ note yellow flags 1-4 weeks (The New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.) (2004))
- Assess for typical/atypical course, functional and psychosocial assessment by week 3, Case appropriate evidence-based practice (EBP) treatment, collaboration with stakeholders, reassess regularly (Bekkering GE, Hendriks HJM, Koes BW, Oostendorp RAB, Ostelo RWJ, Thomassen JMC, et al., 2003, Bekkering GE et al., 2003)

The MoC (Figure 1) is based on the task force recommendations, and manages resources such that more complex cases get appropriate services in a timely manner and less complex cases receive appropriately minimal services.

Figure 1: Model of Care



The MoC begins with a referral and early assessment with a physiotherapist within 48 hours.

The expectation is that the physiotherapist completes the assessment, refers to the appropriate non-specific LBP MoC guidelines, provides the recommended advice/education and reassurance, notes yellow flags and engages in communication with the worker and employer regarding return to work planning.

The intervention frequency is limited during the initial stage and is focused on helping the worker to overcome any dysfunctional belief systems regarding the recovery process.

At three weeks, the physiotherapist completes a structured functional and biopsychosocial assessment to triage to the best plan for further intervention:

- If the worker is experiencing a typical recovery where activity levels are returning to work-ready function and psychosocial factors are not barriers to an imminent return to work, the worker is returned to work with minimal therapeutic intervention.
- If the worker is experiencing an atypical recovery whereby limited functional progressions is evident and psychosocial barriers are impeding the return to work process, the physiotherapist engages in a more intensive management strategy. This strategy involves:
 - Close phone and written communication with the general practitioner (GP), claim owner (CO), nurse advisor (NA), employer (ER), and any other stakeholders involved in the planning.
 - Focus on clear identification of return to work barriers, clear expectations for the worker with respect to barriers not to be addressed by WSBC (e.g. childcare, performance issues), and role of each of the stakeholders in the planning of the return to work.
 - The return-to-work plan is followed through with specific re-evaluation points that include both functional and psychosocial metrics (eg. perceived disability measures). These re-evaluation points will serve to determine when progress is not as expected and alternative interventions may be necessary (e.g. ORII).

Physiotherapy interventions during the typical and atypical recoveries are based on evidence described later in this paper.

3.0 LITERATURE REVIEW

3.1 Common Methodology

Types of studies included:

The task force for this project included researchers and the PABC/UBC Physiotherapy Outreach Librarian, as well as clinicians specializing in LBP. The group agreed on seeking the highest level of evidence. Therefore, the search was limited to:

- Randomised controlled clinical trials (RCTs)
- Studies that systematically reviewed and analyzed RCTs such as systematic reviews, meta-analyses
- Clinical practice guidelines.
- Controlled clinical trials and non-randomised controlled clinical trials (CCTs) were included if the evidence from RCTs was not extensive.

Search methods for identification of studies:

Relevant studies meeting the inclusion criteria were identified in the following steps:

- A computer aided search of the following databases (performed during March-April 2007):
 - OVID MEDLINE (1966 to April 2007)
 - OVID EMBASE (1980 to April 2007)
 - EBSCO CINAHL (1982 to April 2007)
 - PEDro- the physiotherapy evidence database (to April 2007)
- Search of the Cochrane Central Register of Controlled Trials in the latest issue of the OVID Cochrane Library

- Screening references given in relevant reviews and identified RCTs.
 - For MEDLINE and EMBASE, the search strategy suggested by the editorial board of the Cochrane Back Review Group (M. van Tulder, Furlan, Bombardier, Bouter, & Editorial Board of the Cochrane Collaboration Back Review Group, 2003) was used.
 - For CINAHL, the Cochrane Back Review Group search strategy was amended by the librarian to work with the EBSCO interface.
 - Search words used for the PEDro database for low back pain were: low back pain, back pain, backache, lumbar, dorsalgia, lumbago.

- General search strategies for LBP were constructed in each database: OVID MEDLINE, OVID EMBASE, and EBSCO CINAHL (Appendix 3) and then combined each of them with each specific PICO question (Population, Intervention, Comparison, Outcome) raised by the team members.

An example of one database (OVID MEDLINE) search strategy for one particular PICO question about the effectiveness of Intramuscular Stimulation for acute / subacute low back pain is also provided in Appendix 3. Such a search was done for each of the above-noted databases on each of the specific topic areas noted in 1.1.

Additionally, a gray literature search was performed, utilizing Google (<http://www.google.ca/>), Google Scholar (<http://scholar.google.com>) (using command language), National Guideline Clearinghouse (<http://www.guideline.gov/>), UK National Library of Guidelines (<http://www.library.nhs.uk/guidelinesFinder/>), and Canadian Medical Association Infobase (<http://mdm.ca/cpgsnew/cpgs/index.asp>), retrieving more practice guidelines for team's review.

In total, 382 papers were retrieved by the Librarian and were reviewed by the task team members. A review of each search, *LBP MoC Literature Levels of Evidence*, is attached.

3.2 SPECIFIC RESEARCH AREAS

3.2.1 Therapeutic Exercise

Background and Purpose

Exercise is a central tenet of physiotherapeutic intervention for lower back pain (LBP). The purpose of this literature review is to identify research that supports or refutes this aspect of the management of acute and subacute low back pain. For purposes of this study, the search parameters included men and women ages 20-65 with non-specific low back pain of 12 weeks or less duration. Most common definitions of acute LBP describe pain lasting from 0-6 weeks and of subacute LBP as pain lasting from 6-12 weeks.

Methods

A systematic search for the role of exercise in acute low back pain using the PICO (Population, Intervention, Comparison, Outcome) model identified 157 studies. Of these, 145 were excluded for the following reasons:

- same study appeared more than once
- included acute and chronic pain patients in the subject sample
- was a study in progress and provided the protocol only
- poor methodological quality
- study was based on specific diagnoses e.g. spondylolisthesis or microdiscectomies
- reviews were not from the last 5 years

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Results

Level 1 evidence – Meta-Analysis

Of the articles identified, one met the criteria for level 1 evidence: meta-analysis. Machado, de Souza, Ferreira, & Ferreira (2006) included 11 studies; eight of which were considered high quality. Five trials reported on acute LBP-less than 6 weeks duration, one reported on subacute LBP -6 weeks to 3 months duration. (One trial reported on chronic LBP -more than 3 months' duration, and four trials reported on a mixed population of patients.)

The authors attempted to summarize the available evidence for the McKenzie method (directional preference for exercise) for the treatment of LBP. They concluded that the McKenzie method is more effective than passive therapies, including ice packs, educational booklets and massage for acute LBP; however, the magnitude of difference was small enough to be potentially clinically insignificant.

Level 2 evidence – Systematic Reviews

A systematic review by Hayden, van Tulder, Malmivaara, & Koes (2005) updated a Cochrane review on exercise for non-specific LBP. The main conclusions were that exercise is as effective as no treatment or other conservative treatments for acute LBP and that there is some evidence of the effectiveness of a graded activity program for subacute LBP in an occupational setting, to improve absenteeism outcomes.

Rackwitz et al. (2006) looked at the effectiveness of segmental stabilizing exercises. The review reported results from only one study that looked at acute LBP, (there were none for subacute LBP, the remaining studies focused on primarily chronic LBP). The study showed that segmental stabilizing exercises are as effective in reducing pain as treatment by a general practitioner (GP) in

reducing short-term disability and pain. The study went on to discuss the rate of recurrence for LBP – approximately 75% report recurrences within 12 months and showed that segmental stabilizing exercises are more effective than treatment by GP in reducing recurrence of pain.

Pengel, Maher, & Refshauge (2002) investigated conservative treatments for subacute LBP. They acknowledged the efficacy of treatment in this sub-group as being very important to prevent the progression to a chronic condition. Thirteen studies were included but overall they found studies to be of generally poor design with low internal validity. Although, when they expanded the methodological criteria to include descriptive and statistical criteria as well as internal validity, they found that “exercise is an effective treatment for subacute low back pain”, and suggested that acute and subacute are different phases of LBP and therefore specific treatments should be identified for each phase in order to be more efficacious.

Level 3 evidence – Clinical Guidelines

Level 3 evidence includes evidence-based clinical guidelines (EBCPGs). The New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.) (2004) describe acute LBP as lasting less than 12 weeks and does not differentiate between acute and subacute LBP. The report advises patients to stay active. It found no evidence of improvement in clinical outcomes with “specific back exercises” and insufficient evidence regarding the effectiveness of “aerobic conditioning” and “conditioning exercises for the trunk”.

The Dutch Physiotherapy guidelines for LBP (Bekkering GE et al., 2003) specifically focussed on research for physiotherapeutic intervention for LBP. They concluded that exercise therapy has no added value in acute (<6 weeks) LBP. They suggest that exercise therapy is useful for those patients with back pain lasting longer than 12 weeks. No mention is made of the subacute phase when other reviews state that exercise may be most beneficial.

Holohan V, Deenadayalan Y, & Grimmer K (2006) stated that there is strong evidence for advice to stay active (in addition to providing printed material) and moderate evidence for physical activity or training, stability exercises and McKenzie exercises.

Level 4 evidence – Randomized Controlled Trials

Fritz, Delitto, & Erhard (2003) undertook an RCT comparing the effectiveness of a patient-specific, classification-based physical therapy with therapy based on general clinical practice guidelines in a group of patients with acute (<3 weeks), work-related low back pain. The classification group received individualized exercises based on their assessment findings (see Table 1, next page) and the general group followed a program of low-stress aerobic exercise and general muscle conditioning regardless of their symptom presentation. The results of this study reported those patients treated using a classification-based approach to physiotherapy (rather than an approach based on the recommendations of clinical practice guidelines) showed greater improvement in disability 4 weeks after initiation of treatment and were more likely to return to unrestricted work within the first 4 weeks after treatment. They were also more satisfied with their treatment after 4 weeks. In addition, treatment using a classification-based approach did not result in increased medical costs, and instead showed a trend toward decreased costs, as compared with an approach based on clinical practice guidelines.

Table 1: Treatment Classifications Used for the Classification Based Group - (Fritz et al., 2003)

Classification	Findings	Treatment
1-Mobilization -Sacroiliac pattern	Unilateral symptoms without signs of nerve root compression, positive findings for sacroiliac region dysfunction (pelvic asymmetry, standing and seated flexion tests)	Joint mobilization or manipulation techniques and spinal active range of motion exercises
-Lumbar pattern	Unilateral symptoms without signs of nerve root compression, asymmetrical restrictions of lumbar side-bending motion, lumbar segmental hypomobility.	Joint mobilization or manipulation techniques and spinal active range of motion exercises
2-Specific exercise -Flexion pattern	Patient preference for sitting versus standing, centralization with lumbar flexion motions.	Lumbar flexion exercises, avoidance of extension activities
-Extension pattern	Patient preference for standing versus sitting, centralization with lumbar extension motions	Lumbar extension exercises, avoidance of flexion activities
3-Immobilization	Frequent previous episodes, positive response to prior manipulation or bracing as treatment, presence of "instability catch" or lumbar segmental hypermobility	Trunk strengthening and stabilization exercises
4-Traction	Radicular signs present, unable to centralize with movements, may have lateral shift deformity	Mechanical or auto-traction

Wand, Bird, McAuley, Dore, MacDowell, & De Souza (2004a) demonstrated that early intervention which included "rehabilitative exercises" delivered on an individual basis (along with advice to stay active, manual therapy-mobilization and manipulation-and education) improved short-term outcomes better than the advise and monitor approach. The long-term follow up showed no significant difference in pain and disability between early and late intervention, although earlier intervention did affect the progression of psychosocial features in a positive manner.

Moffett, Carr, & Howarth (2004) compared the effect of a "Back to Fitness" program to general practitioner (GP) care and then identified a sub-group of patients identified as high fear avoiders. They were then further randomized into 2 groups. The study then compared twice-weekly supervised exercise sessions (with a cognitive behavioural approach underpinning the program) to

“usual general practitioner care”. The results showed that patients with high fear avoidance beliefs in the “Back to Fitness” program were 3 times more likely to be functioning well at 1 year compared to those in GP care. The patients that benefited the most were those who were afraid physical activity would damage their back. Patients with low fear-avoidance beliefs benefited from the Back to Fitness program in terms of function, but not significantly more than patients allocated to usual general practitioner care. Patients who were at risk or distressed/depressed benefited from the Back to Fitness program compared to those randomized to usual general practitioner care, but only in the short term.

Hides, Jull, & Richardson (2001) examined the effect of specific muscle retraining (Lumbar Multifidus) on first episode, acute LBP and compared it to medical management (advice and use of medications). Although it involved a small sample size, the study showed that both groups recovered at similar rates but the specific exercise group experienced fewer recurrences at 1- and 3-year follow up compared to the group who experienced normal activity and medical management.

Discussion and Conclusions

For the purpose of this paper, 12 studies were reviewed including 1 meta-analysis, 4 systematic reviews, 3 clinical guidelines and 4 RCTs. A frequent comment in many of the papers is that there are few high quality studies on which to base current best-practice guidelines. There are commonly accepted practices of early activation and reassurance (after screening for red flags) that are well documented throughout the literature for the acute phase of LBP. A repeated finding through many of the reviews is of exercise therapy being only as effective as staying active and as effective as passive therapies in the acute (<3 weeks) phase.

When the discussion turns to the subacute phase, there are less commonly accepted guidelines. Firstly, there are few references to the subacute phase in much of the literature and if it is referenced there is not a uniform definition. However, there is growing evidence that the subacute phase should be identified separately from the acute phase. From the more recent reviews the evidence appears to be support for a more beneficial role for exercise in the subacute (>3 and <12 weeks) than the acute phase. The case for early exercise intervention seems to be in the role of prevention of recurrence as outlined by 2 of the systematic reviews (Pengel et al., 2002; Rackwitz et al., 2006) and all of the RCTS.

There is also emerging evidence (Fritz et al., 2003) that classifying patients and prescribing specific exercises according to the classification has more beneficial outcomes than general exercises for both acute and subacute phases in the short term, with the trend continuing over the long term. Interestingly, in this study the reported medical costs were less for the classification group (US\$774) than for the practice guidelines group (US\$1003.68).

This idea of classification is also promoted by Stuart McGill PhD and back pain researcher, who states that many of the current RCTs on LBP are of very limited use since non-specific LBP is an inaccurate term. He states that the LBP population is “highly non-homogeneous” and that patients should be “sub-categorized in non-homogeneous groups” in order to conduct more meaningful research.

The following comments from a qualitative analysis¹ derived from a quantitative study (adding exercise or manipulation to GP care and finding small to moderate benefits) are included to provide the perspective of patients. 1334 participants provided 1250 comments that were analyzed using an adapted framework approach. Those patients receiving “usual care” (medication but no explanation for their pain) reported less satisfaction than those receiving exercise therapy or manipulation.

¹ Patient perceptions of physical therapy within a trial for back pain treatments (UK BEAM)
M. R. Underwood¹, G. Harding² and J. Klaber Moffett³ in collaboration with the UK BEAM trial team

Those in the exercise group reported a “sense of self-reliance” in managing their back pain although some were not as motivated to continue their exercise routine outside of the organized classes. The qualitative analysis revealed much clearer differences than the main quantitative analysis, suggesting that “some of the added value from being allocated to additional physical treatment for low back pain is not being captured by existing methods of measurement.” The authors of the study suggest that improvements in assessment methods may be needed to more thoroughly interpret the value that exercises (and manipulation) add to individual patient outcomes.

Relevance of Therapeutic Exercise to the Model of Care

The MoC includes therapeutic exercise in the recommendations as the evidence supports its use within the population of interest. The Physiotherapist is recommended to consider the classification system and subsequent exercise techniques within their clinical decision making. Choosing the appropriate therapeutic exercise(s) is anticipated to facilitate recovery from the episode and result in an earlier realization of functional recovery. Therapeutic exercise is expected to be a component utilized within the acute and subacute phase of the recovery, with the patient assessment within 48 hours to ensure appropriate application and to advise the patient to stay active.

3.2.2 Manual and Manipulative Therapy

Background and Purpose

BC physiotherapists who treat injured workers are trained in manual therapy, and 30 percent have spinal manipulation certification. The purpose of this therapeutic review was to determine whether there is evidence in the literature to support the use of manual therapy/manipulation in the treatment of non-specific acute/subacute low back pain.

Manual therapy, as described by Hengeveld, Elly. Banks, Kevin. Maitland, G.D. (2005) is the passive mobilization of joints through movement of one articular surface relative to another. This book classifies the extent of the mobilization within grades I-IV (1-4):

- I movement of small amplitude at the start of range
- II movement of large amplitude into range but short of pain or resistance
- III movement of large amplitude into the limit of resistance or muscle spasm
- IV movement of small amplitude at the limit of resistance or muscle spasm

Manipulation is a Grade V mobilization, or a high velocity, low amplitude manual thrust beyond the patient's control, usually (but not necessarily) at the limit of passive joint resistance; this is sometimes described as a cavitation or an audible 'pop'.

Methods

Twenty seven (27) articles were reviewed following a literature search according to the methodology previously described. Sixteen (16) articles were retained for this review and deemed to have levels of evidence from level 1 – 4 (Cormack, 2002). The remaining 11 articles were excluded for the following reasons:

- Low back pain poorly defined. Acute versus chronic not specified or specific versus non-specific LBP not clearly identified (4)
- Poor methodology, low patient numbers (1)
- Experiment outline set up but not completed (1)
- Lack of control group (2)
- Focus only on chronic low back pain (3)
- Effect of intervention not specifically studied. E.g. the study was looking at the effect of clinician treatment choice on outcomes (1)
- Study reviewed differences in clinical guidelines between countries but did not specifically investigate manual therapy/manipulation (1)

Results

Of the 16 articles selected for review, two met the Level 1 – Meta-Analysis study design criteria, four met the Level 2 – Systematic Review study design criteria and four met the Level 4 – randomized control trial (RCT) study design criteria. In addition to the ten studies identified, six clinical guidelines Level 3 were included for further review.

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Level 1 evidence – Meta-Analysis

Mein (1996) reported that literature strongly suggests that manipulative therapies are helpful in the treatment of acute and chronic low back pain. But he notes that all trials of manipulative therapy score poorly when assessed for scientific quality for numerous reasons, including problems with blinding of participants and investigators, relatively small sample sizes, ambiguity of sample clinical characteristics, appropriateness of outcome measures, comparable degree of patient – physician contact time and standardization of treatment procedures. Additionally, Mein stressed the

importance of future study to determine which patient populations are most likely to benefit from manipulation and from integrating it as a therapeutic approach in spine rehabilitation programs.

Ferreira, Ferreira, Latimer, Herbert, & Maher (2003) reported spinal manipulative therapy produces slightly better outcomes than placebo, no treatment, massage and short wave diathermy for non-specific low back pain of less than 3 months. The authors noted however that confidence limits indicate that the difference may not be clinically important. Findings of this review were limited by study heterogeneity and failure of many studies to report key data. The review was also limited by the methodological quality of the randomized clinical trials and the common failure to conceal allocation. Failure to adequately blind patients and therapists was also a limiting factor.

Level 2 evidence – Systematic Reviews

Bronfort, Haas, Evans, & Bouter (2004) examined the efficacy of spinal manipulative therapy (SMT) and mobilization (MOB) for the management of low back pain (LBP) and neck pain, with special attention to applying more stringent criteria for study admissibility into evidence and for isolating the effect of SMT and/or MOB. RCTs (from 1966 to end of 2002 from MEDLINE & 1974 to end of 2002 for Embase) that included 10 or more subjects per group receiving SMT or MOB, and using patient-oriented primary outcome measures were included. A total of 69 RCTs met the selection criteria and 43 RCTs were accepted into the study based on admissibility criteria for evidence. Fifteen studies met the selection criteria for acute LBP and only 6 were accepted based on the criteria for evidence.

For acute LBP there is moderate evidence that spinal manipulative therapy provides more short term pain relief than mobilization and detuned diathermy, and limited evidence of faster recovery than a commonly used physical therapy strategy. This study was complicated by including neck pain and comparing acute and chronic conditions. The authors also state that there was generally poor methodological quality with validity scores of less than 50 in 75% within the trials studied.

Cherkin, Sherman, Deyo, & Shekelle (2003) undertook a meta-analysis of RCTs that were published between 1995 and April 2002 that evaluated acupuncture, massage therapy, or spinal manipulation for non-specific back pain. A meta-regression analysis of the results of 26 RCTs evaluating spinal manipulation for acute and chronic back pain reported that spinal manipulation was superior to “sham therapies” and therapies judged to have no evidence of a benefit, but was not superior to effective conventional treatments. The authors used 95 percent confidence intervals and probability values were set below 0.05. The major limiting factor of this paper is the mixing of acute and chronic LBP populations.

Ernst (2006) performed literature searches in four electronic databases for all systematic reviews and meta-analyses of the effectiveness of spinal manipulation in any indication, published between 2000 and May 2005. Reviews were defined as systematic if they included explicit and repeatable inclusion and exclusion criteria for studies. The analysis revealed that there is insufficient evidence to support that spinal manipulation is an effective intervention for any condition. Moreover, given the possibility of adverse effects, this did not recommend spinal manipulation as an advisable treatment. However, the authors failed to define acute or non-specific LBP and many studies reviewed had mixed populations. As identified in other therapy reviews in this paper, simply including all populations with back pain without clearly identifying subgroups limits the quality of the evidence.

A recent paper by Holohan et al. (2006) set out to produce a composite evidence-based treatment algorithm for physiotherapy management of acute LBP using current high quality, English-language clinical guidelines. A systematic literature review of library databases and Internet search engines was performed to identify full text, English-language clinical guidelines on the physiotherapy treatment of acute LBP. Quality assessment of the guidelines was undertaken by two independent reviewers using the AGREE instrument. Guideline recommendations were synthesized into

interventions that were supported by strong, moderate or weak evidence. A composite clinical algorithm for physiotherapy management of acute LBP was developed. Seven guidelines met the inclusion criteria. The authors sought recent guidelines between January 2002 and January 2005 and noted that the majority of these guidelines reflect the medical practitioner's perspective. They noted that treatment options such as exercise therapy, and manipulation and stability training were generally poorly described and insufficient information was provided to allow accurate replication in the clinical setting. However, there was moderate to strong evidence to support the use of manual therapy/manipulation for the treatment of acute non-radiating (non-specific) LBP at 1-2 weeks following onset.

Level 3 evidence – Clinical Guidelines

In the New Zealand Acute Low Back Pain Guide (New Zealand Guidelines Group & Accident Compensation Corporation N.Z.)(2004), acute LBP is defined as existing for less than 3 months. The guide defines red and yellow flags and aims to exclude red flags. The guide includes grade A (meta-analysis, systematic review or RCTs) evidence of improved clinical outcomes for manipulation in the first 4-6 weeks only. The guide notes that patients with red flags must be excluded; this limits the recommendation of the use of manipulation to that of acute non-specific LBP patients.

The European Guidelines for the management of acute non-specific low back pain in primary care (M. van Tulder et al., 2004) reported therapists should consider (referral for) spinal manipulation for patients who are failing to return to normal activities. The authors state they do not know for which subgroup of patient spinal manipulation is most effective and that future studies should focus on identifying these subgroups. The authors note that spinal manipulation should be provided by professionals with competent skills. Manipulation in people with severe or progressive neurological deficit is contraindicated. It is prudent to note that later studies have shown that specific subgroups are likely to benefit from spinal manipulation when screened using a clinical prediction rule (Childs, Flynn and Fritz, 2006).

The UK Clinical Guidelines for management of acute LBP (Waddell, 1996) was largely criticized for including general consensus with scientific evidence. The authors supported the use of spinal manipulation in the management of acute LBP. Given its lack of credibility and datedness, this document is not generally viewed favourably by clinicians. Recent efforts to secure copies from the publisher have been refused citing the report is out of date and no longer in print.

The APA Low Back Pain Position Statement (Rebeck T, Green T., August 2002), Executive Summary, stated that there is evidence to support manipulation as treatment for acute LBP. This was a position paper and the literature was not listed with the protocol for assessing the evidence.

The Dutch Physiotherapy Guidelines for Low Back Pain (Bekkering GE et al., 2003) defined acute low back pain as 0-6 weeks, sub-acute low back pain as 7-12 weeks and chronic low back pain as greater than 12 weeks. The effectiveness of manual therapy/manipulation was not discussed because these techniques demand specific knowledge and training. A future study is proposed on manual therapy guidelines.

The Australian Guidelines - Evidence-based Clinical Guidelines for the Management of Acute Low Back Pain (Bogduk, 1999) state that although manual therapy appears to be more effective than placebo (weak Level I evidence), there are no grounds to prefer manual therapy over other conservative therapy options (Level I evidence). The guidelines reported on high level evidence only and clearly defined the grading from level I-IV. Limitations of this guideline include: 1) it represents primarily a medical model from the physicians' perspective only, and 2) it is very heterogeneous including multiple subcategories of low back pain thus clouding the interpretation of efficacy of interventions.

Level 4 evidence – Randomized Controlled Trials

Wand, Bird, McAuley, Dore, MacDowell, & De Souza (2004b) undertook a single-blind RCT of biopsychosocial education, manual therapy and exercise. A total of 102 subjects were randomly assigned to an 'assess/advise/treat' group and an 'assess/advise/wait' group. The intervention (treat) consisted of biopsychosocial education, manual therapy and exercise. Outcome measures were performed at 6 weeks, 3 months and 6 months. The results revealed that short-term intervention is more effective than advice on staying active, leading to more rapid improvement in function, mood, quality of life, and general health. Furthermore, the timing of intervention was shown to affect the development of psychosocial features. If treatment is provided later, the same psychosocial benefits are not achieved. Therefore, an assess/advise/treat model of care appeared to offer better outcomes than an assess/advise/wait model of care. The authors note that more study is needed and stated that their results are in conflict with Australian and Dutch guidelines. The trial identified acute non-specific LBP and used common outcome measures for determining change in populations. A chi-squared test was performed to rule out baseline differences. However, the study combined manual therapy, exercise and education, so it is difficult to determine which intervention had the greatest effect or whether it was a combination of these treatments.

Rasmussen-Barr, Nilsson-Wikmar, & Arvidsson (2003) compared the effects of stabilizing training with those of manual treatment in patients with sub-acute or chronic LBP. Forty seven (47) patients were randomized to a stabilizing training group or a manual treatment group. The patients underwent a 6-week treatment program on a weekly basis. Pain, health and functional disability level at the start of treatment, after treatment, and at 3 and 12 month follow-ups were assessed. At 12 months, training of the stabilizing muscles of the spine was shown to be effective for alleviating symptoms and reducing recurrence requiring treatment. However the large dropout rate jeopardizes the internal validity of the study. Also 74 percent of the patients in the study had previously seen other physiotherapists and chiropractors before enrolment, and there was no control group (i.e. patients receiving no intervention) for comparisons. It was also noted that manual therapy included traction, soft tissue mobilization and muscle stretching, but no manipulation was performed.

Childs, Flynn, & Fritz (2006) identified that patients who did not receive manipulation for their LBP are at increased risk for worsening disability compared to patients receiving an exercise intervention with manipulation. One hundred and thirty-one patients with LBP were randomly assigned to either receive manipulation with an exercise program ($n = 70$) or an exercise intervention without manipulation ($n = 61$). This was a well-controlled study clearly identifying a subgroup of patients with acute LBP likely to benefit from manipulation based on the clinical prediction rule (CPR). The Oswestry Disability Questionnaire was the primary outcome measure. Chi-squared was done to rule out between-group differences prior to the interventions. All patients were screened for 'red flags' to identify only acute, non-specific LBP. The authors concluded that patients with non-specific LBP who received only exercise without manipulation were eight times more likely to experience a worsening in disability after one week than patients who received manipulation ($P = 0.017$). Patients receiving exercise without manipulation were still four times more likely to experience a worsening in disability four weeks after baseline. Although this result was not statistically significant ($P = 0.052$) a risk of this magnitude is likely of clinical importance. This study supports the use of spinal manipulation as an intervention in non-specific LBP in the first four weeks of treatment.

The RCT by Cleland, Fritz, Childs, & Kulig (2006) investigated the effectiveness of three different manual therapy techniques in a subgroup of patients with low back pain that satisfy the clinical prediction rule (CPR). The CPR was identified as increasing the probability of benefit from spinal manipulation in 97% of patients with acute non-specific LBP that met at least four out of five factors present. The CPR is determined by patients having at least four out of five of the following criteria:

- a. Duration of current episode < 16 days (judged from the patient's self-report)
- b. No symptoms extending distal to the knee (judged from the pain diagram)

- c. Fear-Avoidance Beliefs Questionnaire work subscale (FABQ-W) score <19
- d. At least one hip with >35° internal rotation range of motion (measured in prone)
- e. Stiffness in the lumbar spine (judged from segmental mobility testing)

Clearly, this literature provides strong evidence to support that those patients who satisfy the CPR will benefit from spinal manipulation as a treatment in acute non-specific low back pain.

Discussion and Conclusion

Following a review of the current literature including some recent good quality trials completed since the publication of numerous clinical guidelines to date, it is clear that there are conflicting findings in favour of and against spinal manipulation. The fact that some studies refer to manual therapy and not manipulation per se also confuses the issue. There is general consensus that more study is needed, particularly with clearly identified patient sub-groups, to draw a more definite conclusion on the effectiveness of spinal manipulation in the treatment of non-specific acute low back pain. However, the literature supports the effectiveness of spinal manipulation as an intervention in the first 1-4 weeks after onset of low back pain provided patients are screened for 'red flags' and satisfy the clinical prediction rule (CPR). Red flags are defined in some studies as the presence of neurological symptoms and radiation of pain beyond the knee. Cauda equina syndrome must be ruled out before considering the use of spinal manipulation.

Features of cauda equina syndrome include some or all of: urinary retention, faecal incontinence, widespread neurological symptoms and signs in the lower limb, including gait abnormality, saddle area numbness and a lax anal sphincter. Cauda equina syndrome is a medical emergency and requires urgent hospital referral and immediate hospitalization.

Other potential 'red flags' or suspicious symptoms include:

- Significant trauma
- Weight loss
- History of cancer
- Fever
- Intravenous drug use
- Steroid use
- Patient over 50 years of age
- Severe, unremitting night-time pain
- Pain that gets worse when lying down

Once the clinician is satisfied that no red flags exist (i.e. they are dealing with non-specific acute LBP) and the patient satisfies the CPR, a course of spinal manipulation should be considered based on clinical rationale. The literature does not provide specific directions on the frequency of manipulation in the treatment of acute LBP and thus therapists must use their own clinical reasoning in determining how often to perform this intervention.

The literature reviewed also did not specifically comment on the long-term use of manipulation. However, previous studies, including the New Zealand Clinical Guidelines (Holohan, 2006) have identified that beyond 4-6 weeks this intervention was not more effective than regular physiotherapy treatment. Current guidelines support the referral to multi-disciplinary programs or 'spine clinics' for patients who have not resumed normal activities (e.g. returned to work) at 6-8 weeks post injury. It is the opinion of this author that continuing manipulation beyond this time frame should be based on sound clinical rationale and employed judiciously in patient populations. One could extrapolate that around this time frame (6 -8 weeks) the treatment approach favours more active independent interventions. Spinal manipulation appears to have definite beneficial outcomes in the acute and

early phase of non-specific LBP, but it nevertheless remains a 'passive therapy' and has potential to create false dependence in patient populations if used beyond 6-8 weeks post injury.

Relevance of Manual and Manipulative Therapy to the Model of Care

The evidence recognizes the benefits of spinal manipulation in the first eight weeks of recovery within an episode of non-specific low back pain. The MoC supports the use of spinal manipulation by physiotherapists and recommends the judicious use of the intervention based on the Clinical Practice Rule (CPR). Following the guidelines for the appropriate use of spinal manipulation is expected to facilitate the earlier functional recovery of the injured worker.

3.2.3 Education

Background and Purpose

Patient education (information and advice) is considered one of the key 'modalities' of the physiotherapist's repertoire of treatment interventions. The purpose of this literature review is to identify the effectiveness of patient education, and possibly the most effective method of education, in the management of acute LBP. Note that for the purpose of this review, acute LBP is defined as LBP of less than 12 weeks in duration.

Methods

A systematic search using the question 'The effect of education (information and advice) on the outcome of (acute) low back pain' identified 24 studies. Of these, 10 were excluded from further review for the following reasons:

- Studies targeted a chronic low back pain population only (4)
- Study in progress; paper provided the protocol for a review (1)
- Study targeted the primary-care givers versus acute low back pain population (1)
- Study determined impact of intervention on patient decision-making related to further intervention, i.e., surgery, and had no relevance to the topic of this review (1)
- Study was a preliminary study to another study reviewed (1)
- Paper provided a descriptive summary only (1)
- Study was a comparison of two interventions, which both included education (1)

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Results

Of the fourteen studies identified for further review, no studies met the Level 1 – meta-analysis study design criteria, four met the Level 2 – systematic review study design criteria and 10 met the Level 4 – randomized control trial (RCT) study design criteria. In addition to the 14 studies identified, five clinical guidelines (Level 3) were included for further review.

Level 2 evidence – Systematic Reviews

In their systematic review, Henrotin, Cedraschi, Duplan, Bazin, & Duquesnoy (2006) selected 11 RCTs, including seven of high quality. The results revealed strong evidence for increasing the patient's knowledge and to moderate evidence that physician-related cues increase the confidence in an education booklet and adherence to the exercises. There was more support for a "biopsychosocial" booklet versus a biomedical booklet in order to shift patients' beliefs on LBP. There was strong evidence suggesting that booklets have no effect on absenteeism and that there is conflicting evidence on healthcare use. Thus the authors concluded that, although biopsychosocial booklets can be helpful for shifting patients' beliefs about LBP, information delivery alone is not sufficient to reduce absenteeism and reduce healthcare use.

M. W. van Tulder, Koes, & Malmivaara (2006) reviewed the effectiveness of advice to stay active for acute LBP (compared to bed rest and exercise). Based on the studies they included in their review there is good evidence that advice to stay active is effective for short-term pain relief and for long-term improvement of function in acute LBP.

Waddell, Feder, & Lewis (1997) identified 10 trials on bed rest and eight trials on advice to stay active for acute low back pain that met specific inclusion criteria. Overall, advice to stay active made no or very little difference to the pain or the initial recovery. However, patients were more satisfied with treatment. Also, the review revealed that advice to stay active led to faster return to work, and showed better results in terms of chronic disability, health care use and time off work in the next

year. In addition, there was no evidence that early activity had any harmful effects. The two trials that directly compared advice to stay active with bed rest showed that advice to stay active produced faster recovery.

Cohen et al. (1994) only found two studies that met their criteria for inclusion in a review of group education interventions for LBP. One of the studies indicated a reduction in pain duration and initial sick-leave duration in the short-term, but the intervention also included worksite visits. Thus, it is difficult to draw conclusions regarding the effectiveness of group education.

Level 3 evidence – Clinical Guidelines

Although a few of the clinical guidelines included consensus-based recommendations as well as evidence-based guidelines, the clinical guidelines that were evaluated for the purpose of this review are quite consistent in their recommendations related to advice and/or education for patients with acute LBP. These recommendations can be summarized as follows:

- Provide reassurance and positive messages and avoid negative messages
- The natural course of low back pain is favourable for most patients
- Advise patients to stay active and to resume their normal activities even though it may be painful and that activity will not cause harm.

Level 4 evidence – Randomized Clinical Trials

The results of the high quality RCT by Wand, Bird, McAuley, Dore, MacDowell, & De Souza (2004a) indicated that at six weeks the assess/advice/treat group demonstrated greater improvement than the assess/advice/wait group. The differences in disability and pain were no longer significant at long-term follow-up (at three and six months). However, mood, general health and quality of life were significantly better in the treatment group. The authors concluded that early, pragmatic, multimodal intervention (including biopsychosocial education) is more effective in the short-term than an 'assess, advise and wait approach', but that there is no difference in the long-term for pain and disability.

The high quality RCT by Roberts et al. (2002) found no difference between the intervention group and the control group for function and attitude outcomes. However, there was a significant difference for the knowledge and behaviour outcomes, both at two weeks and at three-months follow-up. The authors concluded that leaflets given to patients with acute LBP in an initial GP consultation may change aspects of behaviour and knowledge.

Another high quality study (Hagen, Eriksen, & Ursin, 2000) found a significant difference between the intervention group (receiving an assessment, information and recommendations to stay active) and the control group following intervention and at follow-up. The authors conclude that early intervention with examination, information, and recommendations to remain active significantly reduces sick leave for persons with LBP. Information should be aimed at reducing fear. However, the authors rightly point out that it cannot be determined which of the components of the intervention are necessary.

Hazard, Reid, Haugh, & McFarlane (2000) in a high quality study looking at the effect of the use of a pamphlet, which was mailed to recently injured workers with back pain and focused on psychosocial recovery issues, found no statistically significant impact on the different outcomes. They concluded that mailed educational material (stressing psychosocial recovery issues) is not effective in reducing pain, health care use or work absence.

Although the high quality study by Burton, Waddell, Tillotson, & Summerton (1999) did not demonstrate a statistical difference between the two booklets in terms of pain and disability scores, it did show a statistical difference in beliefs, which was maintained at one year. The trend related to work loss (i.e., a decrease) was not statistically significant different as most people returned to work. The authors concluded that carefully selected and presented information can have a positive effect on patients' beliefs and clinical outcomes. The authors also stressed the importance of the type of information that is conveyed to the patient and the need for consistent message delivery by the different providers (i.e., the information should not be used in isolation and the different health care professionals need to reinforce the message) to achieve a shift in beliefs, which in turn reduces self-reported disability.

Cherkin, Deyo, Battie, Street, & Barlow (1998) demonstrated a short-term significant difference for the chiropractic group and a trend only for the PT group versus the booklet group in terms of the effects on pain. There was also a trend of better outcomes in terms of functional self-reports, but no statistical difference in the treatment groups versus the booklet group. The authors concluded that chiropractic manipulation and McKenzie intervention are equally effective for persons with acute LBP, but only marginally more effective than a biomedical educational booklet.

The results of Indahl, Haldorsen, Holm, Reikeras, & Ursin (1998) indicate that the minimal intervention group had a statistically significantly better outcome than the control group. The authors concluded that for sub-chronic LBP an approach that includes a clinical examination combined with information about the nature of the problem, provided in a manner designed to reduce fear and promote light activity, can be successful.

The findings from a study by Friedrich, Cermak, & Maderbacher (1996) indicate that patients in a supervised exercise group performed their exercises better at follow-up than the control group. There was also a strong correlation between the quality of exercise performance and the decrease in pain. It should be noted, however, that the inter-tester reliability of the tests employed is questionable, which was also brought up as an issue by the authors. The authors concluded that exercises learned only from a brochure without monitoring from a PT were not performed properly by about half of the patients and appeared to result in fewer improvements in impairment. It should be noted that the authors included clients with neck and back pain. Further, there was no information regarding the duration of pain. Thus, one should be careful in generalizing these findings and the conclusions drawn from them.

Indahl, Velund, & Reikeraas (1995) showed a highly significant reduction in sickness leave in the intervention group (receiving minimal intervention, as defined above) as compared with the control group. At 200 days, 60% were still on sickness leave in the control group vs. 30% in the intervention group. The authors concluded that acute LBP treated as a benign, self limiting condition and a recommendation for light mobilization gives superior results as compared to treatment within a conventional medical system.

An RCT of lesser quality by Stankovic & Johnell (1990) showed that the "mini-back school" intervention had statistically inferior results in all the variables measured, except for sick-leave during recurring episodes and patients' ability to self-help, compared to the McKenzie intervention. The authors conclude that McKenzie is superior to the mini-back school. It should be noted that the McKenzie group received, on average, 110 minutes of treatment versus 45 minutes in the control group. Thus, the difference could, in part, be due to the amount of time the therapist spent with patients regardless of the actual treatment. Also, patients in the back school were told to avoid exercising.

Discussion and Conclusions

For the purpose of this review 14 studies were evaluated, including four systematic reviews. Generally speaking, the selected RCT's (Level 4 evidence) were of high quality. Five clinical guidelines (Level 3 evidence) were also included in the review. Except for the UK and the NZ clinical guidelines, which included consensus-based as well as evidence-based recommendations, the other clinical guidelines were exclusively based on the most recent evidence available at the time. Nevertheless, the content of the different guidelines is quite similar. The selected studies and clinical guidelines provide the following information regarding advice and education for non-specific, acute LBP:

- Advice to stay active and resume normal activities is effective across a number of outcomes measures, especially function and return to work.
- There is no evidence that early activity has any harmful effect.
- Booklets are best used in conjunction with advice and reassurance from the clinician or primary care giver.
- If booklets are used the information included should emphasize biopsychosocial information versus biomedical information.
- The evidence for group-based education is inconclusive.

Relevance of Education to the Model of Care

Evidence suggests the functional recovery of the injured worker can be facilitated by the provision of appropriate education. Within the MoC, the physiotherapist is expected to utilize education as an intervention, with focus on the content and delivery of a positive message that includes the critical advice to stay active even in the presence of pain. The following points highlight the recommended messages and method of delivery.

- Education is an essential 'tool' in the therapist's toolbox. However, excessive use of biomedical terminology should be avoided.
- In the absence of red flags clinicians should encourage patients with acute low back pain to stay active and resume their normal activities, even in the presence of pain.
- Patients should be informed that activity will not cause harm, even it is painful.
- Provide reassurance, but acknowledge the pain.
- The message given to patients should be positive; negative messages should be avoided.
- Address fear-avoidance beliefs.
- While group education and booklets are fine, it is important to spend individual time with the patient to address their specific concerns.

3.2.4 Electrophysical Agents

Background and Purpose

Use of electrotherapy agents (EPAs) by physiotherapists is a Ministry of Health proposed shared reserved act “for the application of hazardous energy”. EPAs provide a key tool in the physiotherapist’s treatment approach. An EPA is a therapeutic medical device or modality used to prevent and alleviate pain, reduce edema or swelling, augment wound healing, or assist in muscle recruitment. EPAs may be categorized by their primary energy form: electrical, sound or light.

Table 2. Summary of EPAs commonly utilized in the management of acute / subacute LBP

	MODALITY	CHARACTERISTICS	CLINICAL INDICATIONS
Electrical	Transcutaneous Electrical Nerve Stimulation (TENS)	Low frequency (1-200 Hz), Low voltage, short pulse duration (~ 60-50 microsec), low intensity	Pain
	Neuromuscular Electrical Nerve Stimulation (NMES)	Low frequency (1-200 Hz), Low voltage, longer pulse width (~ 300 microsec) & higher intensity than TENS	Muscle strengthening, edema/swelling
	Interferential Current (IFC)	Medium Frequency (carrier frequency = 4000 Hz; beat frequency 1-200 Hz), variable pulse width and higher maximum intensity than TENS or NMES	Pain, edema/swelling
	High Voltage Pulsed Current (HVPC)	Low Frequency (1-500 Hz); high voltage, extremely short pulse width (~ 5-65 microsec); long interpulse interval; higher peak intensity but much lower average intensity than TENS or NMES or IFC	Pain, edema/swelling, strengthening of small muscles, tissue healing
Sound	Ultrasound (US)	Frequency 1 or 3 MHz, Intensity ~ 0.5–3 W/cm ² pulsed or continuous	Pain, edema/swelling, tissue healing
Light	Light Amplification by Stimulated Emission of Radiation (LASER)	Wavelength ~ 632.8 nm to 905 nm (HeNe vs IR); Power < 500 mW; Intensity ~ 4-35 Joules	Pain, tissue healing

The selection of the most appropriate modality for a specific desired therapeutic effect (e.g, attenuation of pain, mitigation of edema/swelling) is complicated by a number of factors. First, as

evidenced by the clinical indications listed in Table 2, there is considerable overlap in the therapeutic purposes for devices. Second, there is a lack of clarity in the literature regarding the optimal parameters for each therapeutic purpose (e.g. dosage – intensity, frequency, duration etc.). Third, both the specific pathology/trauma (e.g. ligament sprain versus a fracture) and its phase of healing (acute, sub-acute, or chronic) will necessarily impact the decision of which device to use and what parameters should be selected. Fourth, the contraindications and precautions for each energy form are specific and thus necessarily impact selection. Finally, the therapist must be cognizant that these devices should be used as “... an adjunct to other physical, medical and surgical interventions... [and not as] .. the sole therapeutic intervention in any case” (Bélanger, 2002) (p. xvii).

The quest for evidence to support or refute the inclusion of EPAs in the management of musculoskeletal pathology/trauma has resulted in a recent explosion of literature, particularly over the last fifteen years. This section will review this literature, focused on acute/subacute LBP according to the hierarchy of level of evidence, from greatest to least, of meta-analyses, systematic reviews, evidence-based clinical practice guidelines (EBCPGs) and randomized controlled trials (RCT).

Methods

Literature search

- Key words/MESH terms
- Population/problem: adults, 20-65 years of age; acute or subacute LBP
- Intervention: electrical stimulation, Transcutaneous Electrical Nerve Stimulation, Interferential Current Therapy, High Voltage Pulsed Current; Therapeutic Electrical Stimulation; Aussie Current, Russian Current, Neuromuscular Electrical Stimulation, Electrical Muscle Stimulation, Therapeutic Ultrasound, LASER, Light Therapy, Cold LASER, Therapeutic LASER
- Comparison: no EPA or comparison between differing EPAs
- Outcome: Pain, ROM, strength, QOL, Disability, Function

Fifty eight papers were derived from the literature search; 33 were excluded for the following reasons:

- 1 was a protocol for a future Cochrane Review
- 3 were structured abstracts of articles already included in the review
- 1 was specific to management of acute LBP during emergency transport in an ambulance
- 7 were focused on long-term chronic LBP
- 1 was specific to Chronic/recurrent headache
- 3 focused on atypical EPA therapies ie. Magnetotherapy, Intradiscal electrothermal therapy, and Ultrashort wave
- 4 were with unrelated populations: senile osteoporosis, multiple sclerosis, patients post nerve root block, ligament repair in animals
- 10 were duplicates from other databases
- 2 provided grossly inadequate information indicating very poor quality
- 1 was specific to exercise intervention rather than use of an EPA
- 12 additional papers were included. These papers were derived from an extensive reference list and annotated bibliography (updated every month) that was created and is maintained by the author of this section (AH) for ongoing teaching purposes in university pre-licensure education and post-licensure continuing education courses as well as for targeted research purposes.

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Results

Tabulated summaries of the literature are presented in *LBP MoC Literature Levels of Evidence*, attached, for electrical, sound and light energy respectively. Each appendix presents the level of evidence (according to (Cormack, 2002) hierarchy) from greatest to least, the strength of the evidence *for RCTs only (e.g. factors related to issues that influence the internal validity and reliability of the study), the outcomes, and critical comments regarding the applicability and implications of the findings.

Discussion

Electrical Energy

Electrical energy devices, commonly referred to as Estim devices, technically include any modality that is generated by and delivers electrical energy to the patient. Consequently, this category includes TENS, NMES, HVPC and IFC (see Table 2). Unfortunately, the literature typically presents these modalities as unique 'species' rather than related members of the same species thus resulting in considerable confusion as to their physiological effects.

The literature search performed for this document did not identify any meta-analyses specific to the utilization of Estim for acute/subacute LBP. However, Bjordal, Johnson, & Ljunggreen, 2003, provided evidence to support the efficacy of TENS over placebo for acute postoperative pain. Interestingly, the authors showed that the effect was greater when the trials used TENS of 'sufficient' intensity (35.5% mean weighted reduction in analgesic consumption greater than placebo when there was 'adequate intensity' of dosage in comparison to 4.1% mean weighted analgesic use reduction when there was insufficient intensity) thus highlighting the importance of the use of appropriate prescription parameters - in this case 'intensity' (e.g. milliamperes).

Two systematic reviews were identified: One specific to the subacute LBP population by Pengel et al. (2002) and the other exploring the efficacy of Estim for neck disorders by Kroeling, Gross, Houghton, & Cervical Overview Group (2005). Pengel et al. (2002) reviewed RCTs from 19 databases assessing these papers as per the Cochrane Collaboration Back Review methodology. The authors noted that if the definition of sub-acute LBP was six weeks to three months there was no evidence of high internal validity. However, if the definition was revised to include seven days to six months then there was evidence to support the inclusion of TENS in the treatment plan. Furthermore, if the quality of trials was represented by tight criteria of internal validity, then there was no high quality evidence found for the efficacy of ANY INTERVENTION.

This systematic review clearly highlights the importance of the definition of 'sub-acute' (in terms of duration of weeks) in determining efficacy of treatment. Kroeling et al. (2005) reviewed RCTs and quasi-randomized trials from six databases. Their results provide unclear and conflicting evidence to support Estim for acute and sub-acute cervical spinal dysfunction. For TENS, evidence supported its inclusion in the management of chronic mechanical neck pain but was neither supportive nor unsupportive of its use for acute whiplash associated disorder. This finding reinforces the need to carefully define the study population in terms of condition and acuity.

EBCPGs, unlike meta-analyses and systematic reviews, include the opinion of experts as well as critically reviewing the results of randomized clinical trials. The Dutch Physiotherapy Guidelines for LBP (Bekkering GE et al., 2003) stated that for 'electrotherapy and TENS' (no rationale was provided as to why TENS and electrotherapy were reviewed as separate categories) stated that their effectiveness was unclear for both acute (defined as 0-6 wks) and sub-acute (defined as 7-12 wks) LBP. However, it is important to recognize that none of the five papers included in this review were specific to the LBP population, but instead relied on the extrapolation of findings from other musculoskeletal pathology.

The Philadelphia Panel (Philadelphia Panel, 2001) similarly divided the results for TENS and Estim. This group used the system of grading evidence that was recommended by the Canadian Task Force on Periodic Health Examination wherein both the level of evidence and the strength of that evidence were evaluated for each recommendation. The evidence reviewed for TENS for acute LBP (defined as less than four weeks) resulted in a recommendation of Level C 1, indicating that the trials reviewed were randomized but the clinical importance of the resultant effects was less than 15%. TENS for sub-acute LBP (defined as 4-12 weeks) was listed as 'nd' for 'no data available'. The evidence for Estim for both acute and sub-acute LBP was also listed as 'nd'. The conclusion was that there is a lack of evidence regarding whether to include or exclude the use of TENS/electrical stimulation in the management of sub-acute LBP and some evidence to support its use in acute LBP.

The New Zealand guidelines (New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.), 2004) reported that there was Grade A evidence that TENS resulted in no improvement for acute LBP (defined as less than three months) and thus stated that there was insufficient evidence for physical agents and passive modalities. Unfortunately, there was no clarification of which modalities were included in the classification of 'physical agents and passive modalities'. Finally, the Australian Physiotherapy Association LBP Position Statement (Rebbeck T., Green T., August 2002) did not include a statement on Estim modalities.

There is relatively little high level evidence literature examining the efficacy of the other commonly used electrical modalities (IFC, NMES, and HVPC) with LBP. No meta-analyses or systematic reviews on any Estim devices other than TENS were identified for this review.

Fifteen RCTs incorporating Estim were retrieved: two specific to TENS and LBP (Herman, Williams, Stratford, FargasBabjak, & Trott, 1994; Jarzem, Harvey, Arcaro, & Kaczorowski, 2005); 1 on TENS vs NSAID in acute rib fracture (Oncel, Sencan, Yildiz, & Kurt, 2002); 2 specific to Percutaneous Electrical Nerve stimulation (PENS) (Ghoname et al., 1999; Hamza Ghoname et al., 1999); 2 on NMES in LBP (Glaser, Baltz, Nietert, & Bensen, 2001); 1 on IFT in LBP (Hurley et al., 2001); 1 on IFT in pain free volunteers (Johnson & Tabasam, 2003); 1 examined anti-nociception effects of IFT in an animal model (Jorge, Parada, Ferreira, & Tambeli, 2006); 1 compared TENS to IFT in normals (Cheing & Hui-Chan, 2003); 1 compared IFT to manipulative therapy in acute LBP (Hurley, McDonough, Dempster, Moore, & Baxter, 2004); 1 compared IFT with traction and massage for LBP (Werners, Pynsent, & Bulstrode, 1999); 2 examined manipulation versus TENS, massage and use of a corset for LBP (Hsieh, Phillips, Adams, & Pope, 1992; Pope et al., 1994); and 1 compared TENS to electroacupuncture for LBP (Tsukayama, Yamashita, Amagai, & Tanno, 2002). Given the wide array of devices, parameters and comparative treatments, interpretation of this literature into simple messages is difficult. Consequently, rather than reviewing the methodology and conclusions of each of these papers, (refer to the detail provided in *LBP MoC Literature Levels of Evidence*, attached, for Electrical Stimulation) the key messages that are to be derived from this collection are synthesized into four general categories based upon similar characteristics of the devices (e.g. voltage, carrying frequency) used and their parameters (intensity, pulse width, treatment frequency):

1. Sensory level Estim of low voltage and low frequency (TENS, PENS, for acute/ subacute LBP)
Conflicting results:
 - The effect of TENS is greater than that of sham for objective and functional outcomes in LBP (Jarzem et al., 2005). The strength of this evidence is limited by the absence of the calculation of power and the absence of a measure of statistical accuracy (e.g. Confidence intervals)
 - There is no significant difference in results between TENS (conventional and acupuncture-like combination) versus placebo (Herman et al., 1994). The strength of this evidence is

limited by a significantly disproportionate drop out rate in the TENS group thus jeopardizing the internal validity of the study.

- PENS is more effective than TENS in the management of LBP (Ghoname et al., 1999; Hamza Ghoname et al., 1999). However, it is important to note that the parameters used in these studies for both PENS and TENS are atypical of common clinical practice and, more importantly, would be theoretically incapable of eliciting the physiological responses and functional outcomes that were desired by these authors.
2. Sensory level Estim of low voltage and medium frequency (IFT, HVPC) for acute/sub-acute LBP
 - IFT is more effective than placebo for LBP especially with appropriate electrode position (Hurley et al., 2001). The strength of the evidence for this finding is limited by the absence of a power/sample size calculation but strengthened by the inclusion of data from drop-outs being included in an 'intention to treat' analysis. Moreover, it is an impressive outcome given that the group with the best outcome (the IFT group) had the highest risk of LBP chronicity on entry to the study (e.g. greatest percentage of smoking history, unemployment and analgesic use and lowest percentage of aerobic exercise).
 - IFT is more comfortable and effective than TENS or sham on ischemic induced pain in normal subjects thus suggesting that IFT may be more effective in reducing pain than TENS in a patient population (Johnson & Tabasam, 2003). The strength of this finding is limited by the absence of the calculation of power/sample size.
 3. Motor level Estim of low voltage and low frequency (NMES, FES) for acute/sub-acute LBP
 - Estim at a motor stimulation level had lasting positive effect on function in comparison to placebo in LBP of greater than 6 weeks duration (Glaser et al., 2001). The strength of the evidence is supported by excellent methodology and statistical analysis (e.g. despite a significant drop out rate, the initial calculation of power assumed normalcy of data and the required change to nonparametric statistical analysis to account for the lack of normalcy actually improved the statistical power). Moreover, the data from the drop-outs was included in the analysis. Also of interest is the fact that the 'placebo' in this study was Estim at a sensory level, thus indicating that motor-level stimulation is preferable to sensory-level stimulation for functional improvement.
 4. Multiple interventions, including Estim, for acute/sub-acute LBP
 - Cheing & Hui-Chan (2003) – TENS vs IFT both reduce acute pain more than placebo. This study was undertaken with 'normals' using a heat pain model and there was no calculation of power/sample size.
 - Hurley et al. (2004) - IFT vs manipulation. This study reported no significant difference between groups (including a control group that received both interventions) in terms of recurrence, work absenteeism, medication consumption, exercise participation or healthcare use at 12 months for 240 patients with LBP of 4-12 weeks duration. The finding is supported by strong methodological design and the use of appropriate statistical management of the data (e.g. 'intention to treat' analysis of the data of the drop-outs). However, the confidence intervals were wide indicating that accuracy (not probability) of results is not completely affirmed. The findings must be interpreted through the lens of the sub-acute phase of healing (the authors classified this population as acute but the time period of 4-12 weeks better reflects sub-acute healing). During this phase application of Estim at primarily anti-inflammatory and acute pain inhibition parameters (such as those used in this study) would not be indicated. Indeed, Estim at parameters sufficient to promote muscle action (such as those in Glaser et al., 2001) would be appropriate in conjunction with exercise prescription.
 - Werners et al. (1999) - IFT vs mechanical traction vs massage. Although this study reported no significant difference in outcomes (Oswestry and VAS) these findings are weakened by: the absence of a placebo group and the failure to report how the data of the drop-outs was

analyzed. Furthermore the dosage utilized for the Estim would again be more appropriate for an acute phase wherein reduction of inflammation and acute pain are the objectives. Finally, the treatment duration of 10 minutes of IFT is ~ 1/2 to 1/3 of that recommended.

- Pope et al. (1994) and Hsieh et al. (1992) - spinal manipulation vs TENS vs massage vs corset. Similar to that of the study cited above (Werners et al., 1999) there was no placebo group and the parameters selected for the Estim are questionable. The Estim intervention was comprised of at least 8 hours of muscle stimulation per day! Moreover, despite the objective of muscle stimulation, the electrode placement selected would theoretically be more appropriate for pain modulation than for optimal muscle recruitment. Although the statistical analysis in the study was better than that of Hsieh et al. (1992) the findings from both studies should be interpreted with great caution.
- Tsukayama et al. (2002) – TENS vs electroacupuncture. This paper was the only study retrieved that included patients with LBP duration from as early as 2 weeks. Although the findings indicated that electroacupuncture was preferable to TENS in outcomes of pain score, score from the Japanese Orthopaedic Association LBP Form and the occurrence of adverse events, the strength of these findings is weakened by: lack of a calculation of power/sample size, very wide confidence intervals and the inclusion of a very diverse patient population (n=20) of acute, sub-acute and chronic duration.

In summary, interpretation of the literature on the efficacy of Estim in LBP is limited by poor methodological design that includes: lack of clarity in definition of acuity and thus patient population; lack of clarity in the selection of parameters utilized; absence of calculation of power/sample size and failure to report the statistical use of data from drop-outs. However, there is some clinical evidence of adequate quality to support the claim that sensory-level Estim for pain modulation (when of appropriate dosage) is more effective than placebo in acute, and even greater still in subacute populations. Further, there is some clinical evidence of adequate quality to support the claim that motor-level Estim in the sub-acute phase is more effective than placebo.

Sound Energy

Although generated through an electrical current, ultrasound (US) is delivered to the tissue as an acoustic or sound wave and thus its effects are primarily due to mechanical rather than electrical effect.

With respect to meta-analyses, there were none identified that were specific to its efficacy in the management of acute/sub-acute LBP. However, Van Der Windt et al. (2002) reported a pooled relative risk ratio of 1.04 in favour of US over sham US for acute ankle sprain. This finding may be generalizable, to a limited degree, to other acute soft tissue injury. Almost a decade earlier, Gam & Johannsen (1995) reviewed the literature encompassing various musculoskeletal disorders with no distinction between acute, sub-acute, and chronic, and concluded not surprisingly, there was a lack of firm evidence from well-designed controlled studies to guide effective use of US for treatment of musculoskeletal disorders. Clearly, the heterogeneity of the populations (in terms of pathology, acuity and variability in ultrasound dosage) likely diluted any possible efficacy for more homogenous subpopulations. Consequently, at the highest level of evidence (meta-analysis) there is insufficient evidence to either include or exclude the use of ultrasound in the management of acute/sub-acute LBP.

Only one systematic review was retrieved. Robertson & Baker (2001) reported that there was little evidence that active US is more effective than placebo US. However, this paper is more appropriately classified as a narrative review than a more methodologically rigorous systematic review. Furthermore, the authors, as per the meta-analysis by Gam & Johannsen (1995) cited above, grouped a wide range of musculoskeletal conditions and injuries, treated with a variety of

methodologies and US parameters, together thus potentially diluting findings of potential efficacy for more homogenous subpopulations.

Of the four key EBCPGs for LBP, three addressed the inclusion of US. Both the Dutch (Bekkering GE et al., 2003) and New Zealand (New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.), 2004) guidelines reported that the effectiveness of US is insufficient or unclear. The Australian Physiotherapy Association LBP Position Statement (Rebbeck T, Green T., August 2002) did not specifically address the use of US. However, The Philadelphia Panel (Philadelphia Panel, 2001) stated that for acute LBP, there was Level II Grade C evidence for the use of US. Level II Grade C was chosen to reflect that the studies retrieved were nonrandomized and demonstrated a clinical improvement of less than 15%. The Philadelphia panel made no recommendations on the use of US for the management of sub-acute LBP (defined as duration of 4-12 weeks), due to insufficient data.

Only one RCT was retrieved (Ansari et al., 2006). This randomized, single-blind, placebo-controlled trial examined the effect of US or sham US on 10 patients with non-specific LBP of greater than 3 months duration (range: ~ 3- 24 months). The US group had a significantly better functional rating index and range of motion (ROM) than the placebo group but no significant difference in EMG. However, the results of this trial have to be viewed with caution, as there was no power calculation and a 25% drop out rate, thus raising concerns with respect to its internal validity.

In summary, there is insufficient evidence to either support or refute the use of US in the acute and sub-acute phases of LBP as the evidence is minimal in quantity and limited in quality (particularly in terms of appropriate dosage).

Light Energy

LASER therapy, similar to US, has limited published literature in the domain of musculoskeletal pathology/trauma including that of LBP.

There were no meta-analyses retrieved specific to the use of LASER with LBP. However, there were two that examined the effects of LASER on tissue healing and pain control (Enwemeka et al., 2004), and on an array of musculoskeletal conditions (Gam, Thorsen, & Lonnberg, 1993). Gam et al. (1993) reported that low level LASER therapy (LLLT) resulted in a mean difference in pain scores between LLLT and placebo of 9.5% in favour of LLLT in insufficiently blinded trials but only 0.3% in trials that were adequately blinded. It is important to note however, that none of the included trials focused on acute LBP and one was specific to chronic LBP. Further, the literature was reviewed for the decade of 1980-1990. Almost one decade later, Enwemeka et al. (2004) reported strong evidence in favour of the efficacy of LASER on tissue repair (fail safe number = 370) and somewhat less strong evidence in favour of LASER for pain control (fail safe number = 41).

No systematic reviews were retrieved for the use of LASER in the management of acute/sub-acute LBP.

With respect to EBCPGs, only one of three that were retrieved specifically addressed the incorporation of LASER into the management of LBP. Bekkering GE et al. (2003) stated that the effectiveness of LLLT is unclear for sub-acute LBP (defined as 7-12 weeks duration). Neither the Philadelphia Panel (Philadelphia Panel, 2001) nor The Australian Physiotherapy Association LBP Position Statement (Rebbeck T, Green T., August 2002) specifically addressed the use of LLLT for acute/sub-acute LBP. Finally, although the New Zealand Acute LBP Guide (New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.), 2004) reported that there is insufficient evidence for physical agents and passive modalities, it failed to identify which devices were included

in this categorization. Combining all interventions/modalities, with varying parameters, into one recommendation is not considered ideal academic practice.

Only one RCT specific to LBP was retrieved (Basford, Sheffield, & Harmsen, 1999). Sixty-three subjects, 18-70 years of age with non-radiating LBP of greater than 30 days duration were treated with infrared LASER or sham. The outcomes assessed included a subjective assessment of pain, Oswestry Disability Questionnaire and the Schober Lumbar Mobility test. The methodology of this trial was strong as it included the critical elements of an a priori power calculation, randomization, double-blinding, and reporting of drop outs. The LLLT group demonstrated a moderate reduction in pain and improvement in function that diminished with time. It is important to note that the population included both subacute and chronic LBP patients.

In summary, there is some limited clinical evidence to support the use of LASER in the management of pain in subacute LBP.

Conclusions

The preceding review has made it abundantly clear that there are a number of issues that need to be addressed in order to assist physiotherapy clinicians in their decision-making regarding the use of EPAs in the management of acute and sub-acute LBP. These issues include:

LBP study populations:

- There is inconsistency in the definition of acute, sub-acute and chronic phases of LBP. This inconsistency creates difficulty in ascertaining efficacy of interventions at each phase of recovery i.e. an EPA may be efficacious at one stage of recovery and not efficacious at another.
- There is a dangerous assumption of homogeneity of patients with the diagnosis of non-specific LBP of a given duration. This assumed homogeneity can impact findings of efficacy of interventions. A parallel can be drawn with that of studies investigating efficacy of interventions for chest pain. If patients with differing causes of chest pain are all grouped together in a study examining the efficacy of a vasodilator on chest pain, it is probable that only a portion of those given the drug will experience a reduction in symptoms (i.e. those with chest pain resulting from vasoconstriction). Accordingly, it is important to identify subgroups of the non-specific LBP population who may experience differing responses to specific interventions.
- There is inconsistency in use of outcome measures. The spectrum includes: subjective pain rating scales, analgesic intake, questionnaire outcome measures. etc. This variety of outcome measures could be masking efficacy of interventions. Indeed, Sluka & Walsh, 2003, stated, "It is entirely possible that TENS is effective on some measure of pain or function and ineffective for others" (p. 210).

EPA modalities:

- There is inconsistency in the categorization of Estim modalities. Some meta-analyses, systematic reviews and EBCPGs separate the results of TENS trials from those of other Estim modalities, while others recognize the 'similarities between the species' of Estim. The result of this inconsistency is that broad statements such as 'There is insufficient evidence for the use of electrotherapy and TENS' do little to assist the clinician.
- There is little effort within the literature to educate readers as to the effect of different parameters / dosages. The parameters selected by authors are varied and include frequency, intensity, duration, pulse width, and electrode placement. The implication is that a modality at certain parameters may be efficacious for a given purpose. As an example, motor stimulation sufficient to induce motor twitch when the desired effect is reduction of edema (by assisting with the muscle pump to aid lymphatic drainage) versus NMES at motor

stimulation parameters to induce strengthening of type 11 muscle fibres when there is weakness of muscle secondary to disuse atrophy. Instead, readers are left to grapple with whether the parameters selected by the author are appropriate for the likely signs and symptoms associated with the stage of healing. Indeed, in two narrative reviews on ultrasound (Baker, Robertson, & Duck, 2001; Robertson & Baker, 2001), the authors contended that there is minimal evidence to support the biological rationale for US in pain and soft tissue injury and that there is little evidence that it is more effective than placebo. However, in response, Draper (2002) questioned dosage flaws in the RCTs included in the reviews stating, “After studying the article by Baker and Robertson, I am convinced that the original researchers mistakenly compared placebo ultrasound with placebo ultrasound. What I mean by this is that a study is flawed to begin with if correct parameters are not used” (p. 190).

As a consequence of the issues stated above, it is not possible to make irrefutable conclusions regarding the use of EPAs in the management of acute and sub-acute LBP. Robertson et al. (2006) have recommended that decision-making in use of EPAs where clinical evidence is uncertain, be guided by the following:

Figure 2: Decision-Making in the use of EPA’s (Robertson et al., 2006)

CLINICAL EVIDENCE	BIOPHYSICAL / PHYSIOLOGICAL RATIONALE	RECOMMENDATION
Some	None	Provisional acceptance
None	Sound	Provisional acceptance
Inconclusive	None	Provisional disapproval
Claims only	Contrary to claims	Not acceptable

Accordingly, in combination with the guidance provided by the above table and the results of this literature review examining the level and strength of the existing evidence, the following statements can be made:

1. There is some clinical evidence and sound biophysical/physiological rationale to support that the use of sensory-level Estim for pain modulation (when of sufficient intensity) is more effective than that of placebo in acute, and even greater still in sub-acute, populations, thus suggesting provisional acceptance of this intervention for this purpose.
2. There is some clinical evidence with sound biophysical/physiological rationale to support that the use of motor-level Estim in the sub-acute phase is more effective than that of placebo, suggesting provisional acceptance of this intervention for this purpose.
3. There is insufficient evidence to either support or refute the use of US in the acute or sub-acute phases of LBP, although there is plausible biological/physiological rationale that the evidence of efficacy in this population is conflicting and complicated by insufficient dosage. Consequently there can be no recommendation regarding acceptance or rejection for this purpose.

4. There is some clinical evidence to support the use of LASER in the management of pain in sub-acute LBP, but the biological/physiological rationale is still being debated. Consequently, there can be no recommendation regarding acceptance or rejection for this purpose.

It is important to ensure, however, that the objective for using these modalities is to augment patient function. Although many of these modalities have traditionally been used in a 'passive' mode (e.g. with the patient stationary) it is increasingly clear that their efficacy in the mid to late acute phase (after ~ 4-10 days) and throughout the sub-acute phase (~ 10 days – 3 months) could be enhanced by coupling them with patient motion (this is true primarily for TENS and NMES which are small handheld devices). With appropriate selection of parameters and electrode placement, these devices can be used to assist in the normalization of movement during patient movement/exercise.

Finally, given the quantity and quality of recent EPA literature, it would be prudent for physiotherapists who utilize EPAs to maintain competence in this portion of their practice by attending ongoing continuing education opportunities.

Relevance of Electrophysical Agents to the Model of Care

The research within Electrophysical agents is challenged by inconsistencies in classification and lack of control over parameters/dosages. This limits the ability of the physiotherapist to arrive at irrefutable conclusions surrounding the utilization of these modalities. The MoC recommends the physiotherapist consider the utilization of EPA's based on the available evidence and within the context of other evidence based interventions available.

3.2.5 Acupuncture

Background and Purpose

Acupuncture describes a family of procedures whereby anatomical locations on the skin are stimulated by a variety of techniques, usually penetration by solid metal needles, which are stimulated either mechanically or electrically. In BC, almost 200 physiotherapists are credentialed in the practice of acupuncture as part of their treatment approach.

Acupuncture is one of the oldest forms of therapy with roots in ancient Chinese philosophy. Traditional acupuncture is based on philosophical concepts, one of which postulates that disease in the body manifests as signs of imbalance of the Yin and Yang forces within. These disorders are reflected in the 361 points either on the skin surface or just below it and are located in lines called meridians along the body, which have either Yin or Yang characteristics. Needling appropriate points is said to restore the balance in these forces.

Dry Needling is a technique using needles to treat myofascial pain in any body part. Typically the needles are inserted into identified myofascial trigger points and the needles are removed once the trigger point is activated. The mechanisms underlying the action of both acupuncture and dry needling are unclear. Proposed mechanisms along the principals of the gate control theory and diffuse noxious inhibitory control theory have been cited. There is some evidence that acupuncture or needling may stimulate the production of endorphins, serotonin and acetylcholine within the CNS thus aiding in pain relief.

The purpose of the following is to outline the available evidence regarding the role of acupuncture or needling treatments in the treatment of acute/sub-acute low back pain.

Methods

Thirty four articles were reviewed following a literature search according to the previously described methods. Seven articles were retained for this review. The remaining articles were excluded for the following reasons:

- Study used chronic low back pain patients or the definition of acute low back pain was unclear.
- No control group
- Poor methodology
- No blinding of participants in a controlled study
- Too many variables were compared such that it was impossible to tease out the effect of the acupuncture.
- Acupuncture compared with acupuncture
- No randomization performed

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Results

Level 1 evidence: Meta-Analysis

Manheimer, White, Berman, Forys, & Ernst (2005) performed a meta-analysis of 33 RCTs sub-grouped into acute or chronic pain, style of acupuncture and type of control group used. Only 22 of 33 studies were included in the results. The authors concluded that acupuncture is more effective than sham acupuncture for providing short term relief of chronic low back pain. However, more research is needed to evaluate the effectiveness of acupuncture on acute LBP and the evidence comparing acupuncture to other active therapies is inconclusive. One problem with this study is not

all the studies evaluated used sham acupuncture as a control. TNS and other therapies do not simulate acupuncture so this lessens the credibility of the results. The authors' differences with previous analysis by Van Tulder (1999) were noted.

A meta analysis by Ernst & White (1998) used twelve studies of which nine (377 patients) were found to have data suitable for meta-analysis. Conclusions found acupuncture to be superior to various control interventions. Combined results of four, sham controlled, evaluator-blinded studies did not show acupuncture to be superior to placebo. Limitations include: 1) there were only two studies evaluated acute LBP, thus acute pain was not really studied in clarity, and 2) the trials were heterogeneous in terms of study population, outcomes, and length of follow up.

Level 2 evidence: Systematic Reviews

Furlan et al. (2006) performed a systematic review of 35 studies and 2861 patients, three studies defined acute LBP as 12 weeks or less, thus representing both acute and sub-acute phases. Chinese and Japanese trials were included with methodology being assessed by two reviewers and common outcomes used for evaluation.

Analysis involved acupuncture compared to no treatment, placebo or sham, acupuncture compared to another intervention and acupuncture added to another intervention and compared.

Conclusions noted the best technique for acupuncture for LBP in general seems to be the deeper (1.5cm) stimulation; electro-stimulation does not seem to add any benefit to manual stimulation of the needles. There is insufficient evidence to make any conclusions in acute LBP, as there were only three trials with small sample sizes and poor methodology. There is some evidence for the effect of acupuncture for chronic LBP.

A systematic review by Tulder MW, Cherkin, Berman, Lao, & Koes (2000) evaluated 11 RCTs on the effectiveness of acupuncture for management of non-specific LBP and concluded that no study clearly evaluated acupuncture for acute LBP. They found no evidence that acupuncture is more effective than no treatment and no evidence for the effectiveness of acupuncture for treating LBP. However, poor methodology highlights the need for more high-quality RCTs. Once again, the absence of high-quality trials is a major factor in the conclusion as the outcomes were poorly reported in six of the 11 studies with two studies not reporting the duration of pain. A planned subgroup analysis of acute versus chronic LBP could not be performed properly as no study clearly evaluated acute LBP and nine of the studies used either a mixed population or did not specify.

Level 3 evidence: Clinical Guidelines

The NIH statement on acupuncture (U.S. National Institutes of Health, 1997) uses information from NIH consensus development conferences, which are convened to evaluate scientific information by experts. A 12-member panel including experts on acupuncture, physical medicine, pain and 25 additional experts from similar fields presented data to an audience of 1200. The panel concluded there was strong evidence for the role of acupuncture in the treatment of postoperative dental pain. The panel also concluded acupuncture may be effective for headache, menstrual cramps, fibromyalgia, tennis elbow, carpal tunnel syndrome and low back pain. However, for these pains the data was less convincing. Acupuncture provides relief from acute and chronic pain in some studies, but in other studies there is no evidence of a positive effect. Acupuncture is difficult to study due to inherent difficulties in the use of appropriate controls such as placebos and sham acupuncture.

The New Zealand Low Back Pain Guide, (New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.), 2004), a systematic review of best evidence concluded that no evidence existed to date for the use of acupuncture in the treatment of acute LBP. In this guide, acute LBP is defined

as less than three months. The guide uses Grade A evidence (meta-analysis, systematic review or RCTs).

Other evidence-based guidelines for acute LBP such as the Dutch Physiotherapy Guidelines for Low Back Pain (Bekkering GE et al., 2003), The Australian clinical guidelines (Bogduk, 1999) and the APA Low Back Pain Position statement (Rebbeck T, Green T., August 2002) did not evaluate the use of acupuncture.

Level 4 evidence: Randomized Controlled Trials

A study by Araki, Kawamura, & Mataka (2001) compared manual acupuncture with sham acupuncture using 40 subjects with pain of less than three days duration and found no difference between the effects of acupuncture vs sham acupuncture. This study was limited as it only compared one session of needling on one point with limited follow up.

Eisenberg et al. (2007) performed a RCT investigating the effectiveness and cost of usual patient care plus patient choice of acupuncture, chiropractic or massage therapy compared with usual care alone in patients with acute LBP. Acute LBP was described as less than 21 days. It is notable that this study measured costs of care. Results showed no clinically significant difference in any of the choice procedures vs usual care. The authors did not separate the three choices in their report. The authors did observe however a persistent significant difference in perceived satisfaction with care for LBP in the choice group. It is noteworthy that the choice group selected massage 2:1 over chiropractic or acupuncture. Overall cost of care was \$244 higher in the choice group. The authors conclude that this model needs to be evaluated for chronic pain for which conventional medical care is often costly and of limited benefit. Noteworthy is a problem with the small sample sizes.

A RCT by Kittang, Melvaer, & Baerheim (2001) investigated the effect of acupuncture vs analgesics in 60 patients with acute LBP and found no differences in reduction of pain or stiffness over six months follow up. The authors note, however, patients using acupuncture used less analgesic drugs and reported fewer new episodes of LBP. The authors conclude that acupuncture seems to be safe and effective in the treatment of acute LBP.

Discussion and Conclusion

The evidence available in the literature is limited and does not support the use of acupuncture for the treatment of acute LBP. However, the available research is generally of poor quality and reflects small sample sizes. Acupuncture techniques are also widely variable and it is used differently in physiotherapy than in traditional Chinese medicine. The training and experience of the acupuncturist, and the type and duration of acupuncture treatment delivered may influence the effectiveness of outcomes. Another issue is blinding and placebo. Only recently has a placebo acupuncture needle been developed where previously blinding was not possible. Sham acupuncture points also have their limitations as a control as they may still stimulate and provide a neurophysiological response. Until the recent development of a placebo acupuncture needle (Streitberger & Kleinhenz, 1998), blinding of the participant in a controlled study had not been possible.

A Note about Intramuscular Stimulation (IMS)

Recently physiotherapists have been using needling in the form of IMS. This is a more complex form of dry needling aimed at relieving shortening in paraspinal muscles, which decreases entrapment of the nerve root thus relieving pain. This technique described by Gunn, Ditchburn, King, & Renwick (1976) is based on neurophysiological concepts and is described for use in chronic pain. IMS has not been evaluated in acute LBP and the literature in chronic pain is limited.

Relevance of Acupuncture to the Model of Care

The physiotherapist is challenged to make evidenced based decisions surrounding the utilization of the Acupuncture and Intramuscular Stimulation as limited published research is currently available for review. The MoC recommends the Physiotherapist consider this lack of evidence within their clinical decision making and consider the alternate evidence based interventions available.

3.2.6 Predictive Factors

Background and Purpose

Predictions regarding return to work (RTW) after low back strain (LBS) have important therapeutic and economic consequences. Over the past 20 years, many scientific reports have been published identifying the factors that predict early RTW, and delayed RTW. Who will return to work quickly? Who will require lengthier and more intense treatment? Who is at risk of developing chronic pain? Do predictive factors have the same power for identifying who will return and who will not return to work? These are all important questions.

Research has aimed at identifying individual predictive factors as well as evaluating predictive models. These models are based on both clinical observations and research findings of factors that appear to influence an individual's pain, perceived disability and/or measured abilities. Herein lie some of the key difficulties of summarizing prognostic factors associated with delayed RTW. To find whether something is an important prognostic factor, it must be included in the research. To determine whether interactions of specific factors have an important effect on prognosis requires a certain amount of guesswork, and then research into the selected interactions. The published research in this area also does not build on previous research. As well, there is little research replicating previous work. As a result, it is difficult to determine which factors are predictive, which are not predictive, as well as the relative importance of factors which are most important when interacting with others.

Within predictive research, efforts are being made to discern factors which could help identify which people require which treatment. Some people RTW quickly after LBS, and others have a lengthier recovery. Just as specific interventions could expedite recovery and RTW, it is possible that some interventions provided to the wrong person could delay recovery and RTW. Better methods for identifying people most likely to have delayed RTW should help enable more effective and more cost-effective interventions.

Methods

An extensive literature search was carried out using the following four questions:

- 1) What are the barriers and prognostic factors that affect return to work by injured workers (males, females, 20-65 years of age with acute low back pain), and
- 2) Is there a hierarchy of these?
- 3) What are the barriers and prognostic factors that affect return to work by injured workers (males, females, 20-65 years of age with acute low back pain) and,
- 4) By what methods/surveys/tools are these identified?

From this search, 46 research reports were identified. After review of these reports, 13 of the studies were chosen for inclusion in this report based on their strength of methodology. Many of the remaining 33 reports were studies of chronic LBP, while others did not sufficiently describe their methodology. Still others studied the reliability and validity of specific predictive tools, but did not report on the predictive value of the tool in acute or sub-acute LBS.

The studies included were ranked according to levels of evidence as described by Cormack, 2002. For an overview of these studies, see *LBP MoC Literature Levels of Evidence*, attached.

Results

Thirteen reports were included in this section.

Dionne et al. (2005) completed a prospective cohort study of 1007 people off work due to LBP. All subjects were interviewed within the first three weeks and followed up at 6 and 12 weeks, and at one and two years. The subjects included people who also reported pain in the upper back and the neck, 56% had pain in the legs, 46% reported recurrent pain and not all subjects were receiving disability payments. The primary goal of the study was to identify a unique algorithm that would predict the RTW outcome at two years post-injury report. The authors first analyzed results from over 100 constructs. They then developed the best model, which contained seven predictors: patient's recovery expectations, radiating pain, previous back surgery, intense pain, frequent change in position due to back pain, irritability and bad temper, and difficulty sleeping. Of interest is that the authors did not find job satisfaction, fear avoidance beliefs, gender, duration of pain, understanding of the medical diagnosis or physical demands of the job added to the power of their predictive tool. Overall, their classification error was approximately 40%, with negative predictive values of 74%-91% and positive predictive values of 57%. Since the authors did not report the predictive value of the tool at 6 or 12 weeks, we do not know the relative importance of these factors in prognosis during the acute and sub-acute phases.

Dunn & Croft (2005) studied "bothersomeness" as a predictor of work absence, pain disability and health care use six months following injury. In their prospective inception cohort study they collected information on 935 consecutive subjects with LBP. At six months they had 447 subjects completing their questionnaires. Data is provided to show that the drop-outs were not significantly different at baseline in any of the demographic or research questions. At baseline, the authors assessed bothersomeness ("In the past two weeks, how bothersome has your back pain been?") and then ranked the subjects into two groups: those rating the pain as 'very' or 'extremely' bothersome, and those rating the pain as 'moderately', 'slightly' or 'not at all' bothersome. Those subjects rating the pain as most bothersome at baseline had the greatest pain and disability at baseline. The higher rating at assessment also predicted pain intensity and disability at six months. The authors point out that this simple tool can be useful to classify cases in a standard manner where time and resources are limited. Overall this question identified 80% of the severely disabled subjects at six months.

George, Fritz, Childs, & Brennan (2006) in a secondary analysis of pooled data from three randomized trials investigated sex differences in response to physical therapy interventions for acute LBP. They found similar decreases in pain intensity and disability over a four-week treatment program for both men and women, and that different factors predicted treatment outcomes. For women, baseline pain-related disability, duration of pain and pain intensity predicted change in disability. For men, baseline pain-related disability and fear-avoidance beliefs positively predicted change in disability while receiving stabilization exercises as part of treatment, and leg pain negatively predicted change in disability. Baseline forward flexion range and straight leg raising did not predict change in disability at four weeks. This is one of the few studies looking at predictive factors during the acute – sub-acute phases of recovery. Unfortunately the authors researched only a small sample of potential predictive factors. Similar to others, they found that baseline pain intensity, pain-related disability and leg pain are strong predictors of ongoing pain and disability.

Krause, Dasinger, Deegan, Rudolph, & Brand (2001) in a retrospective cohort study of 433 LBP worker's compensation claimants examined the impact of psychosocial job factors on time to RTW. They found that specific psychosocial job factors were associated with length of work disability independent of injury severity and physical workload. High physical and psychological job demands and low supervisory support were associated with 20% lower RTW rates. Less severe injury diagnosis in the acute phase was associated with five times higher RTW rates. High job control, especially control over work and rest periods was associated with over 30% higher RTW, but only in the sub-acute/chronic phase (30 days after injury). These researchers did not find that job satisfaction and co-worker support were related to time to RTW. They also found that a previous lost-time back injury was associated with a 72% improved RTW rate. One other important finding

from this work was that the predictors differed when attained during the acute (<7 days), sub-acute/chronic phases.

Hagen, Svensen, & Eriksen (2005) in a multivariate analysis of a randomized controlled trial identified prognostic factors that interacted with a brief intervention for RTW in patients with sub-acute low back pain. Patients (n=457) off work 8-12 weeks for LBP were randomized into an intervention and a control group. The intervention group received treatment at a spine clinic including medical examination, reassurance, and encouragement to engage in physical activity. The control group received standard primary health care. The authors state that their findings support a finding that duration of sick leave is more influenced by cognitive factors and by other illnesses. Potential predictors of prolonged sick leave were high psychological work load, perceived large reduction in ability to work, belief that work would aggravate the condition and other illnesses. They also state that treatment may be particularly efficient in changing those cognitions and attitudes that in themselves are predictive of poor prognosis.

Hansson, Hansson, & Jonsson (2006) performed a comparative study of various commonly used health measures ability to predict RTW or not return to work (NRTW) in a cohort of workers sick-listed more than 28 days due to low back problems and neck problems. They differentiated their findings between low back and neck. Of the tests studied, they found the EuroQol (EQ-5D) a generic health-related quality of life measure, to have the highest overall ability to predict RTW or NRTW irrespective of gender, diagnosis or duration of the problem. The EQ-5D could predict 92% of NRTW and 72% of RTW within 90 days. The predictive ability of this test, like each of the others varied over time, over diagnosis and over gender. The authors also reported that the intensity of pain was of great importance for predicting RTW and NRTW.

Lacroix et al. (1990) in a cohort study investigated predictors of RTW outcome in two groups of 50 worker's compensation claimants. The mean time off work was over 40 weeks in each group. As such, the results may not be valid for acute and sub-acute LBS. The finding of interest is that a specific tool - the Schema Assessment Instrument (SAI) - was the only variable to predict RTW significantly in both samples. This tool assesses the accuracy of the patient's understanding of the basis for their medical condition. As such, their findings again point to cognitive factors as key predictors of RTW.

Pransky, Verma, Okurowski, & Webster (2006) in a retrospective cohort study evaluated a rapid prognostic screening method to predict length of disability after acute LBP. They used a multivariate model, finding that length of disability was associated with older age, shorter job tenure, female gender, presence of language barriers, co-morbidity, prior work absence, delayed referral to nurse case manager, attorney involvement not supportive of RTW and low RTW motivation. The authors reported that although only 12% of the overall variance in length of disability was explained by their model, high- and low-risk groups were readily distinguished. The authors do not describe their screening tool, and note that other studies using more extensive screening tools have been able to explain up to 40% of variance in length of disability.

Schultz, Crook, Berkowitz, Milner, & Meloche (2005) in a longitudinal cohort study evaluated the predictive validity of the Psychosocial Risk for Occupational Disability Scale in workers off work for 4-6 weeks with LBP. They reported their tool was able to accurately predict RTW/NRTW in 79% of subjects, with a sensitivity (NRTW) of 61% and specificity (RTW) of 89%. As such this tool is seen as practical and useful for prediction of RTW outcomes in the sub-acute stage after low back injury. Within their findings, they reported that a worker's expectation of recovery correctly classified 72% of RTW/NRTW, making the results of this questionnaire (Expectations of Recovery scale) almost as powerful as the complete test battery that included seven paper and pencil questionnaires.

Storheim, Brox, Holm, & Bo (2005) evaluated prognostic factors for return to work in a prospective study of 93 patients sick-listed for 8-12 weeks for non-specific LBP. They investigated whether personal and work-related factors, physical performance and back-specific questionnaires predicted RTW. A stepwise backward Cox regression model was established to identify the most powerful predictors. These included: fear-avoidance beliefs for work, perceived disability, and cardiovascular fitness. The authors point out that as much as these are predictors of RTW, their findings may support a finding that fear of pain and injury may be more disabling than pain itself. They also reported that their finding of the influence of cardiovascular fitness on RTW has not been supported by other researchers.

Steenstra, Verbeek, Heymans, & Bongers (2005) in a systematic literature search (up to December 2003) of inception cohort studies of workers with LBP on sick leave less than six weeks, found 18 publications which fulfilled their criteria for inclusion. From these studies they found 79 prognostic factors which they then grouped into eight categories. The report that positive predictors of NRTW are specific LBP (diagnosis), high perceived disability, older age, female, social dysfunction, radiating pain, heavier work and recurring higher compensation. They also reported that the following did not influence sick-leave due to LBP: history of LBP, job satisfaction, educational level, marital status, number of dependents, smoking, working longer than 8 hour shifts, occupation type and size of company.

Both Long (1995) and Werneke & Hart (2001) investigated the centralization phenomenon as a prognostic factor for LBP and disability. Long's study assessed patients with a mean duration of symptoms of over seven months, while the former authors assessed patients with acute LBP (average of 13.3 days). The centralization phenomenon, as described by Robin McKenzie, is a movement in pain location towards the midline of the back during specific repeated movements of the low back, and typically a movement of the pain location towards the periphery of the limb with the opposite movements. These patterns are reported in some people with LBP. Both research reports found that when the pain did not centralize, this was predictive of NRTW. Werneke & Hart, 2001, also found that the presence of leg pain was predictive of NRTW. The findings of these two studies may not be generalized to prediction of a worker remaining off work longer than three months. However, the presence/absence of the centralization phenomenon appears to be a significant predictor of delayed RTW.

Discussion

There is no consensus in the scientific literature on which factors are most predictive (in combination or individually) of RTW or NRTW after LBS. There is also no consensus on which prognostic assessment tools are the most effective or cost-effective. There is, on the other hand, some agreement that specific factors such as pain cognitions and perceived disability are important prognostic factors.

A number of factors have been identified by more than one scientific report as important for predicting delayed RTW in the acute and subacute phases of LBS. These include: cognitions/beliefs/attitudes to pain and recovery, radiating (leg) pain, high perceived disability, intense pain, older age, specific diagnosis, heavier work, and female.

Three of the studies reported specific factors not predictive of RTW after LBS. The following factors were found not to be predictive by more than one report: job satisfaction, female, smoking, history of LBP, symptom duration, older age.

There is disagreement in the literature about the prognostic value of a worker's age and gender. As such, more research is necessary before either of these factors can be included or excluded. One possibly surprising finding is that job satisfaction was found to not predict RTW after LBS by three of

the research reports. Krause et al. (2001) found that low supervisory support was predictive of delayed RTW, however answers to specific question of overall job satisfaction did not predict RTW. As well, only Krause et al. (2001) found that physical or psychological job demands were predictive of RTW. These differences could be due to data collection procedures, especially since the Krause et al. (2001) study was retrospective.

The most commonly reported predictor of RTW after LBS was the injured person's beliefs and attitudes towards pain and recovery. Predictive beliefs included fear-avoidance beliefs, beliefs about the severity of the injury and (mis)beliefs regarding the type of injury and whether they would recover. These findings suggest that a standard test of a worker's pain beliefs and attitudes would be of value for predicting RTW. One such tool, although not reported in the included research is the Survey of Pain Beliefs and Attitudes (SOPA).

The presence of leg pain also has predictive value. Two of the reports suggest that it is also whether the leg pain is unchangeable with movement that is the important factor. As such, testing whether leg pain centralizes through the use of Robin McKenzie's system of mechanical diagnosis would be of value. This is especially true since a worker who learns that they can change their pain in a positive manner would likely be modifying their pain beliefs and attitudes to recovery.

Higher perceived disability and intensity of pain also appear as a repeating prognostic factor. Assessment of each should be standard practice for workers with LBS. It is possible that both of these prognostic factors relate to pain beliefs and attitudes, and that when a worker has high perceived disability or high pain reports that this inter-relates with their maladaptive cognitions. As such, although specific assessments of each should be conducted, these factors may improve when a worker's beliefs and attitudes are addressed with appropriate education.

The research does not provide us with the relative importance of individual factors for predicting delayed RTW, or a clinically useful manner in which to identify significant interactions between prognostic factors. However, it is clear that there are some factors, easily obtained from a worker's history and from paper/pen questionnaires, which will assist with identifying those who may have delayed RTW.

Relevance of Predictive Factors to the Model of Care

The MoC recommends the Physiotherapist consider the research available on prognostic factors. The evidence recommends the Physiotherapist assess the worker's pain beliefs/cognitions/attitudes to recovery, presence of leg pain, perceived disability, and pain intensity in order to help predict the most appropriate treatment for a worker. With the identification of these variables, the Physiotherapist is able to modify education and treatment intervention such that the injured worker's functional recovery is optimized.

3.2.7 Early Access

Background and Purpose

Early access refers to the timeliness of the start of physiotherapy services. Early access can be threatened by a number of variables including, an injured worker not knowing that physiotherapy can be effective in promoting recovery (belief system), not having coverage for services (financial limitation), or the non-presence of 'direct' access (policy limitation). Direct access refers to the ability of the physiotherapist to see an injured worker without a physician's referral. The purpose of the following is to review the evidence related to whether earlier access to physiotherapy improves outcomes. Furthermore, current policies related to accessibility to physiotherapy services will be reviewed and implications of changes will be discussed.

Methods

The PICO format used to guide the search was as follows:

Population: Adults (~20-65 years of age e.g. working age); +/- Working; acute LBP

Intervention: Physiotherapy, including manual therapy, exercise, work conditioning/hardening, occupational rehabilitation, education, modalities (electrical stimulation, ultrasound, acupuncture, Laser)

Comparison: Early versus late; early mobilization; delayed intervention

Outcome: Pain, ROM, strength, quality of life, disability, function, return to work

A systematic search using the question 'The effect of early versus late or delayed physiotherapy intervention for low back pain (acute or subacute)' identified twelve (12) studies. Of these, ten (10) were excluded for further review for the following reasons:

- Studies did not compare the same intervention at different times (7)
- Paper was a letter to the editor only (1)
- Study population was not limited to low back pain (1)
- Study was a hypothetical description of an intervention (1)

Results

Of the two studies identified for further review, neither met the Level 1 – Meta-Analysis study design criteria, neither met the level 2 – systematic review study design criteria, and neither met the level 4 – randomized control trial (RCT) study design criteria. Two retrospective cohort study design articles were discovered and included in the review due to the lack of evidence available. In addition to the two studies identified, three evidence-based clinical guidelines (Level 3) that addressed timeliness of intervention were included for further review.

Level 3 evidence – Clinical Guidelines

The New Zealand Low Back Pain Guidelines (New Zealand Guidelines Group & Accident Compensation Corporation (N.Z.), 2004) are based on an extensive literature review and consultation with professional groups. The guide outlines possible Physiotherapeutic interventions such as education (stay active) and reassurance (hurt versus harm), return to work planning/coaching based on function, note potential yellow flags, and control symptoms with manipulation (up to 4-6 weeks). These interventions are recommended to occur in the first week post injury and continue for 4 weeks before re-evaluation of treatment plan.

The Australasian Faculty of Musculoskeletal Medicine: Acute Low Back Pain Guidelines (Bogduk, 1999) are based on evidence without consensus based input. The guideline recommends interventions consisting of education, reassurance, exploration of concerns and disability perceptions, and pain control from time of assessment to one month. These guidelines were designed from a medical perspective and may assume an early initial assessment with an acute low back pain episode.

The Dutch Physiotherapy Guidelines for Low Back Pain (Bekkering GE et al., 2003) are based on scientific evidence of systematic reviews and if no evidence was available, consensus between experts was obtained. The guideline identifies two courses of recovery normal and abnormal. In the normal course the assessment findings discover that the individual is increasing their activities and participation gradually over time to the level prior to the episode. In the abnormal course, disabilities and participation problems do not decrease over time; they may stay the same or even worsen. A consensus group defined the course as abnormal when the activities and participation have not improved within three weeks of the onset. The guideline then recommends interventions specific to the course of recovery in an effort to reduce chronicity and efficiently manage resources (this will be further examined in Issues Related to Cost Effectiveness and Efficiency).

Other evidence

Zigenfus, Yin, Giang, & Fogarty (2000) performed a retrospective cohort on patients participating in physiotherapy within a managed care environment. The authors examined the number of physician visits, time of discharge from care, restricted work days, and days off from work for patients initiating physiotherapy at 1) same or next day, 2) between 2 and 7 days, or 3) 8 to 197 days since onset of episode. The groups were compared based on provider severity ratings and determined to be the same. The authors concluded that initiating therapy early in the course of treatment was associated with fewer physician visits, earlier discharge from care, fewer restricted work days, and fewer days away from work. The authors recognize that, due to the retrospective nature of the study, no causal relationships can be made between early intervention and outcomes. Other factors, like psychosocial elements, not examined in the groups may account for the differences in outcomes.

Alday & Fearon (1997) described the outcomes of a 'spinal protocol' with early intervention between groups of injured workers treated before and during the protocol. The authors recognized that the two groups, by nature of the protocol, were inherently different in time to initiation of therapy therefore confounding the results of the other outcome measures. The protocol group initiated therapy an average of 28.8 days from injury versus 173.3 days. The outcomes for injured workers undergoing the protocol were found to have a significantly lower treatment length, reduced treatment visits, and reduced overall rehab costs. The challenge in interpreting the results is whether these outcomes were solely related to the early intervention, intervention within the protocol, or a combination of both. The authors also limited the comparison between the groups to age and gender, finding them similar, but neglecting comparisons on characteristics in the literature shown to play a role in outcome (e.g. psychosocial factors).

Discussion, Questions/Answers, and Recommendations

Limited evidence is available that looks directly at the question of whether the same intervention provided earlier improves outcomes. The available evidence does suggest a link between early intervention and improvement of outcomes of interest including lower utilization of services and earlier return to work. The potential rationale for why earlier intervention improves outcomes may be related to the earlier restoration of function through education, pain control, and/or physical reactivation. EB CPG's do agree that early detection of yellow flags and treatment directed at overcoming the resultant barriers (e.g. perceived disability) may improve outcomes.

In British Columbia, WSBC manages the disability insurance on behalf of employers and as a result serves to protect workers from financial hardship resulting from a workplace injury. To achieve this end, one of WSBC's guiding principles is to prioritize the rehabilitation and facilitate the return to work of the injured worker. WSBC is also financially accountable to the industries and workers it insures, and it strives to provide these rehabilitative services in a cost effective manner (WSBC). Current WSBC policy and regulation is a barrier to achieving its goal of cost effective rehabilitation.

Q: How is physiotherapy currently accessed within WSBC?

A: The Workers Compensation Act (http://www.qp.gov.bc.ca/statreg/stat/W/96492_00.htm) supports the 'Board' (referring to WSBC) to establish rules and regulations to furnish health care to entitled workers. WSBC policy and regulation currently requires the injured worker's claim to be accepted and implies a need for a physician's referral before an injured worker can access insured physiotherapy services (<http://www.WSBC.com>). WSBC's practice has resulted in an average wait time of 17 days from injury to first access to physiotherapy care.

In 2005, WSBC and the Physiotherapy Association of British Columbia (PABC) agreed in principle that earlier access is beneficial to the recovery of injured workers. WSBC granted physiotherapists direct assess injured workers prior to claim acceptance and agreed to pay for these services under an 'investigative' provision. The injured worker, however, would be responsible for costs of physiotherapy treatment until such time as the claim was accepted. What is the impact on wait times and how is the provision been used? It is unclear if start times have improved as a result of this provision as no comparative statistics are available for review. Physiotherapists can continue to treat during the waiting period and are advised to charge private rates during this time in the event that the claim does not get accepted. Physiotherapy is not an insured service for the majority of residents of BC under the provincial Medical Services Plan. Therefore, if a claim is not accepted, the injured worker is required to pay 'out of pocket' for services. Couple the costs of therapy with the loss of wages/benefits if the claim is denied and the injured worker suffers significant financial hardship. Injured workers, therefore, choose to forgo treatment and wait until coverage for therapy is secured to reduce their financial risks. WSBC's current policy is therefore considered a financial barrier to the access of early physiotherapy services.

Once the claim is adjudicated and if accepted, private physiotherapy services are paid for by WSBC according to a negotiated agreement between WSBC and the PABC.

Q: How do BC's physicians manage within this system?

A: Physicians in BC are covered under the provincial Medical Services Plan. Therefore, when a physician provides services for an injured worker whose claim may be denied, the physician is able to invoice the MSP for reimbursement of the service. Injured workers are not liable for payment of physician services if their claim is denied and therefore do not inappropriately limit their participation in physician-rendered services as a result.

Q: Are there examples of institutions that have allowed injured workers/citizens to access early and direct physiotherapy services?

A: Newfoundland's equivalent to WSBC (the 'Commission') has recognized the benefits of early intervention by physiotherapists and has instituted policy to reduce the barrier. The Commission's policy allows an injured worker to attend physiotherapy within two weeks of an injury; the Commission will cover the costs up to 12 visits. If the injured worker wishes to attend physiotherapy two weeks after the injury, a physician's referral is required. If an injured worker attends physiotherapy and a claim has not been initiated, a claim number is automatically assigned and labeled 'invoice only' while other evidence is gathered to adjudicate the claim. Provision of a 'temporary' claim number allows the injured worker to access insured physiotherapy services. In cases where the claim is ultimately denied, physiotherapy services up to and including the date of the denial of claim are approved (<http://www.whscc.nf.ca/default.htm>).

In Ontario, the Workplace Safety and Insurance Board (WSIB) follows legislation that considers physiotherapists as regulated health professionals, and so has policy that allows the injured worker direct access to insured physiotherapy services following an injury (<http://www.wsib.on.ca/wsib/wsibsite.nsf/public/homepage>). Because a physician's referral is not necessary, the injured worker has access to expedited physiotherapy care.

Saskatchewan's Worker's Compensation Board acknowledges physiotherapists as primary care practitioners allowing direct access for injured workers and utilizing physiotherapy reports in the initial adjudication of the claim. When a claim is disallowed, healthcare providers not covered under the provincial medical services plan are paid by the WCB for services rendered that were previously authorized (<http://www.wcbsask.com/>).

The Province of British Columbia removed the need for a physician referral for patients to access physiotherapy services in 1989 (http://www.bcma.org/public/news_publications/publications/policy_papers/EnsuringExcellence/AppendixA.htm). A majority of BC residents no longer are eligible for coverage of physiotherapy services through the MSP as physiotherapy was de-listed in 2002. Approximately two thirds of residents who access physiotherapy services utilize an extended health benefits plan which is subsidized by their employer. The writer is not aware of any insurance companies that underwrite these plans that require a physician's referral to access physiotherapy.

Implications of early and direct access to physiotherapy services.

Q: Is it safe and effective for an injured worker to see a physiotherapist without first seeing a physician? (i.e. Are physiotherapists adequately trained and competent to provide direct access care to manage an injured worker safely (without initial physician assessment and referral)?)

A: Yes. Physiotherapists in BC are university-trained and governed by the College of Physiotherapists of BC (CPTBC). The CPTBC operates within the framework of the Health Professions Act (HPA) and enforces established uniform requirements to ensure physiotherapy intervention is in the public's best interest. In addition to being accountable, a physiotherapist is trained to be able to assess a client's physical and psychosocial status, functional abilities, and needs and goals. This includes screening for medical red flags that may contraindicate the use of physiotherapy treatments. The physiotherapist is also trained to analyze the collected data to determine an accurate diagnosis/clinical impression. Further to the assessment the physiotherapist is specifically trained to develop and carry out an effective client centered intervention plan.

Q: What are the financial risks and benefits of improving accessibility to physiotherapy for injured workers in BC?

A: The financial risk of allowing direct access and insuring physiotherapy services for injured workers is directly related to the number of claims that are ultimately declined whilst having undergone physiotherapy. It is the writer's understanding that less than 2 percent of claims are declined (not all of which would attend therapy) minimizing the potential risk greatly.

The financial benefit is related to the benefit of early intervention. If early intervention can reduce the length of time a worker is absent from the workplace, the cost savings can be calculated via the total amount of wage loss benefits, and medical and rehabilitation costs that are saved. The insurer should consider policy and legislative changes to influence process adjustments representing a positive net present value. Physiotherapists in BC manage approximately 26,000 claims per year, and studies suggest that early access has the potential to shorten the length of disability.

Q: Are there other non-direct implications of early and direct access to physiotherapy?

A: According to the policy paper 'Ensuring Excellence': Renewing BC's Primary Care System (2002), there is strong concern about the ability of BC's physicians to manage the primary care needs of BC residents. In an attempt to reduce the burden, the provincial government removed the need for a physician's referral for a resident to access private physiotherapy. Physicians continue to

be the primary care practitioner in WSBC's model and as a result, often find themselves the 'gatekeeper' to the return to work plan with limited first-hand knowledge of their patient's functional abilities and confirmed work demands. Return to work recommendations are often made based on estimations of what a patient could typically do with this type of injury at this point in the recovery (Talmage, James B., Melhorn, J., Mark, 2005). Physiotherapists have the training, skills, equipment and resources to collect objective functional information and confirm accurate job demands to make safe return to work recommendations. Also, physicians have acknowledged the expertise of physiotherapists and embraced the shift in role of the physiotherapist in direct access (http://www.bcma.org/public/news_publications/publications/policy_papers/EnsuringExcellence/AppendixA.htm).

Relevance of Early Access to the Model of Care

Early and direct access to physiotherapy has potentially significant clinical and financial benefits and relatively minimal risks to the management of the injured worker within WSBC. WSBC's current policy may have been based on traditional roles for physicians and physiotherapists. However, physiotherapists have become increasingly focused on skills and education for the management of orthopedic conditions and are easily accessible. WSBC's policy may also have been perceived as a way to manage costs. However, as described, the costs of delaying the start of physiotherapy can outweigh the benefits of reduced wage loss benefit costs. It is recommended that WSBC consider a policy change that would result in direct and early access for injured workers requiring physiotherapy. It is recommended that a policy change to this effect be monitored for clinical and cost effectiveness and include a significant awareness campaign to facilitate the change in culture (worker awareness) required for engaging physiotherapists in primary care.

3.2.8 Communication

Communication at the outset and throughout therapy between the physiotherapist and WSBC, the employer, injured worker and physician is an essential component of the MoC. The role of the physiotherapist in the primary care model is different from the physiotherapy role in the MoC. When considering the results of the literature the reader is encouraged to consider the results related to the population within the MoC versus those utilized in much of the evidence available. There is limited evidence that confines the population to the injured worker with LBS receiving wage loss benefits within a policy framework similar to WSBC's. A close comparison was found with Lemstra & Olszynski (2004) where the authors recognized that injured workers receiving benefits within the Saskatchewan Worker's Compensation system achieved lower injury claim incidence, duration, and costs with 'occupational management' versus 'early intervention program (EIP)' or 'standard care' models. Occupational management was defined as including injury education and reassurance, simple exercises, work site assistance with a neutral health care provider, union and management involvement and support, utilization of modified and gradual return to work programs, and collaboration between all stakeholders. Standard care was not well defined but alluded to the presence of a physician, and physical therapist or chiropractor. The early intervention program (EIP) was defined as immediate and intensive physical therapy and work hardening with a multidisciplinary assessment at 6 weeks (which could result in a referral to a psychologist for hurt versus harm education). The EIP included no onsite assistance and the WCB was responsible for initiating, monitoring and reviewing the status of the worker while only utilizing functional information alone to determine work readiness. The study was confined to companies with strong modified work availability and a positive culture between the union and employer related to this practice. Employers in BC do not all fit this description, which challenges possible movement to a strict 'occupational management' design. However, strong consideration for the strategies within the occupational management design (strong emphasis on education and reassurance, and return to work coordination with a neutral health care provider) within the MoC may result in improved outcomes. The rationale for the role of education and reassurance is highlighted within a recent American College of Occupational and Environmental Medicine (ACOEM) guideline. The guideline recommends that return to work models include the handling of 'the normal human emotional reactions that accompany temporary disability to prevent it becoming permanent. Encourage payers to devise methods to provide these services or pay for them.' The guideline also comments on the return to work process by recommending strong communication among all stakeholders. The role of a return to work facilitator is described as facilitating face-to-face discussions between the worker and the first line supervisor. The other parties act as resources and the outcome is a resolution-focused process including high worker and supervisor satisfaction and overall demedicalization.

Within WSBC there is an increasing effort to improve communication with the employer. WSBC has initiated resources both internally and externally in recent years. The addition of nurse advisors (NA) to build relationships with employers and be directly involved in return to work coordination is consistent with the intent of the literature recommendations. WSBC and the PABC have attempted to further facilitate this communication by agreeing to a fee for physiotherapists to communicate with the NA or claim owner (CO). The CO is expected to be similarly involved as an internal resource in the return to work process. The nature of the phone communication between the NA or CO and the physiotherapist is understood to include treatment and return to work plans, functional capacity information, and medical and non-medical barriers to return to work. The external use of resources includes the development of fee schedules for physicians and chiropractors to coordinate return to work plans and for therapists (occupational therapists, physiotherapists, kinesiologists) to provide return-to-work support services. Despite generous fees, physicians and chiropractors have not readily participated in the direct coordination of return to work plans. Return-to-work support services (ROWSS) requires a referral from a CO and was intended to facilitate return to work coordination for those workers not appropriate for OR1 (previously Work Conditioning) or when return to work was

complicated at any point in the life of the claim where a specific program did not have this service (e.g. Hand Therapy agreement). Return to work services have most commonly been performed by kinesiologists and occupational therapists with some familiarity of functional capacity and psychosocial factors related to return to work. Physiotherapists have not embraced the direct provision of this service. The research suggests that the treating therapist is a necessary part of the return to work process (Lemstra & Olszynski, 2004) and to overcome the lack of direct physiotherapy communication, PABC and WSBC have agreed to a fee to reimburse physiotherapists for communication with the RTWSS provider. Utilization characteristics of RTWSS can help shed light as to the prevalence during the initial acute physiotherapy services. From 2006 Q3 data, the median and mean time from date of injury to date of referral (calendar days) is 150 and 322.90 days respectively. Given these time frames, it may be unlikely that these services are being widely utilized in the early stages (pre-OR1). The presumably limited referral volume during the acute therapy stage may represent a lack of communication between the physiotherapist and the CO, a heavy reliance on OR1 to take over this task (potentially prolonging claim duration (Lemstra & Olszynski, 2004), or a lack of confidence in and initiation of RTWSS by CO's.

One published work by the WCB of Ontario concerning a population that very closely resembles the population in the MoC (Program of Care for Low back injuries: one year evaluation Report June 2004) generated some conclusions after evaluating their program of care. Among these, they noted that the low 'percentage of providers that contact employers must be increased, outcome measures of pain and function in ALBI POC enhance understanding of worker progress, and employers are dissatisfied with limited contact and information from health care providers.

From the employer's perspective, ongoing communication of the injured worker's functional capabilities is integral to coordinate the earliest modified work return to both increase productivity and reduce time loss penalties. The employer is also interested in timelines for return to work, so they can better plan substitution. When a return to work is imminent, this communication may prevent the injured worker's termination.

Alday & Fearon (1997) completed a cohort study examining a 'spinal protocol' that included not only therapeutic interventions for the physician and physiotherapist but also protocols for the case manager. These included: 1. Weekly communication with the employer, and 2) 'progressive' RTW facilitated with updated limitations modified weekly or biweekly, and the worker not left on 'limited' duty' without specific definition or advancement. The results of the cohort undergoing the 'spinal protocol' were far superior to the usual care (no communication or return to work management protocols). The superior outcomes related to utilization and return to work were confounded by non-similar groups in this study. The 'protocol' group had much shorter timelines from injury to therapy initiation. However, the timeliness of referral was in itself a desirable outcome and achieved by increasing accountability of the CM regarding treatment initiation.

Recommendations

Create a process for early communication whereby the physiotherapist communicates with:

- the Employer to determine accurate job demands and potential temporary accommodations,
- the Case Manager/Nurse Advisor to advise as to the functional status in relation to the job demands, prognosis for functional recovery and return to work, and barriers to the potential successful outcome,
- the Attending Physician, as necessary, where medical closure and consensus is presenting as a barrier to return to work.

Relevance of Communication to the Model of Care

Communication is recognized within the MoC as the intervention by which the injured worker's functional status is appropriately compared to the available job demands. Communication amongst the stakeholders allows the sharing of identified barriers and the collaborative minimization of the effect on the barriers on the return to work effort. Early and collaborative communication amongst the stakeholders is expected to shorten the length of time loss from work.

4.0 OTHER CONSIDERATIONS

4.1 Outcome Measures

This section identifies the tests and measures indicated by the structure of the MOC, as supported by the evidence-based clinical reviews (EBCR) and offer a selection of measures that are both reliable and valid for the stated purposes.

Measurement of health care interventions can be classified as discriminative, evaluative, or predictive in purpose (Streiner & Norman, 1995). Virtually all clinical measures are discriminative in nature. Diagnostic tests are classic examples where the objective of the test is to differentiate persons with a health state or condition from those without. Additionally, tests or measures may also be validated for ability to evaluate change over time, and/or to predict a future event. All of these objectives are present in the MoC. Although the developmental state the MoC precludes making extensive decisions on specific measurement instruments at this time, some specific measures indicated by the EBCRs. Also, framing the MoC in a health model will provide a context for common understanding of various stakeholder groups.

General Clinical Measurement Recommendations

The general recommendations include consideration of a framework for measurement, and of general measurement issues.

Much confusion exists in the definition of the term “disability” with competing models using conflicting terms.(Altman, 2001). In workers’ compensation settings, a common conflict arises between clinical and administrative definitions of disability. Disability in clinical models can refer to deficits at the body part, whole-person, or societal levels, and may or may not address interactions between levels. In workers’ compensation systems, disability typically has an administrative definition of reduced earnings capacity. (Altman, 2001 ; WSBC, 2007) In order to avoid this conflict, an acceptable framework with neutral terminology may be beneficial.

The International Classification of Functioning, Disability, and Health (ICF) (World Health Organization, 2001) as defined by the World Health Organization (WHO) uses disability as an encompassing term. Health states can then be defined in positive or negative terms at each of three levels. These include impairments of Body Function and Structure (BFS), Activity limitations, and Participation restrictions. Under this model, a back strain injury would be classified as an impairment, a deficit in ability to meet a work demand such as lifting 20 kg floor-to-counter would be a limitation, and the loss of earnings capacity due to being off work would represent a restriction. In addition, each of these can be modified by Personal Factors and Environmental Factors. In conjunction with the ICF model, WHO has defined a system to classify impairments, limitations and restrictions, and environmental factors.(World Health Organization, 2001) This classification system has been developed as a partner to the International Classification of Diseases (ICD-10).(World Health Organization, 2001)

Health status measures can also be classified by their purpose under the ICF. Measures of impairment used in physical therapy include joint range of motion (ROM), muscle strength, and limb segment girth for swelling or atrophy. Activity-level measures include whole-body tasks, and participation-level measures include evaluation of work status. Measures can also be grouped into performance or self-report measures. Both of these can be either standardized or non-standardized. Although performance tests are often considered to be “objective” and self report “subjective,” standardized self-report questionnaires have been widely demonstrated as valid and reliable

Since physical therapists have interests in recovery of bodily injury and the performance of activity and participation impacted by the injury, all three levels will be of value although the most immediate clinical concern may be for reduction of impairment. As insurers have a vested interest in minimizing both loss of earnings and impairments, (WSBC, 2001) arguably they also have an interest in measurement at all levels, although the early objective may be to minimize loss of earnings through early safe return to work. (WSBC, 2001) Therefore, incorporating measures at all three ICF levels is recommended.

Due to the wide variation of impairment type and severity associated with back injury, there is no simple, meaningful way to measure, report, and aggregate detailed data at this level. Options include using a measure of attainment (e.g., goal attainment scale) or a generic scale of impairment status (e.g., a rank-ordered scale from severe to resolved, with parameters for applying each rank to various impairments). Under the MoC, this would provide a summary index of either achievement of treatment goals or impairment reduction over the episode of care.

The activity level provides both a meaningful connection between BFS and participation, and the level at which most reliable, valid, and interpretable data can be gathered.

Performance measures can provide an indication of current ability compared to documented or reported job demands. Standardized measures can provide scores for evaluation of individuals and groups at various points in time including on admission, during, upon discharge, and following physical therapist (PT) intervention under the MoC. Clinically, comparison of performance and self-report can identify psychosocial components to the worker's presentation, facilitate communication between the physical therapist, worker, employer, and insurer, and guide administration of early, safe return-to-work strategies.

Measurement of work status represents an aspect of participation for all injured workers, as well as an important outcome for both physical therapists and WSBC. However, the general term RTW can be confused with specific levels of work status, such as full duties, modified hours, modified duties, and not at work. Clear distinction between the general concept and specific levels of work status is recommended.

Regardless of level, measures that have been demonstrated as reliable and valid for their intended purpose(s) are recommended. Selection of measures with other measurement properties relevant to the client population (e.g., responsive to change for the stage of the injury timeframe(s) of most interest) may also be important, especially for self-report questionnaires used to assess change. Measures with lower levels of respondent and administrative burden are desirable, except where doing so compromises measurement properties of the test that are critical to assessment of the individual worker or of the MoC. Measures that are familiar to stakeholders, and/or can be easily interpreted with minimal training are also more desirable. Where possible, use of strategies that further minimize administrative burden or enhance response/completion rates (e.g., online vs. paper administration) are recommended.

Specific Clinical Measurement Recommendations

In addition to these general recommendations, two measures have been specifically implicated within the BSTF recommendations. They are the Fear Avoidance Beliefs Questionnaire (FABQ) and an activity-level back pain-related self-report questionnaire.

The Clinical Practice Rule for the use of manipulation as an intervention strategy requires administration and scoring of the FABQ work subscale (FABQ-W). It is one of five criteria for assessing potential for benefit from spinal manipulation as a treatment for non-specific acute low

back pain. (Childs & Cleland, 2006) Also, when administered within 3 weeks of injury, the FABQ-W has been demonstrated a significant predictor of continued disability after 4 weeks of PT intervention.(Fritz, George, & Delitto, 2001) This may provide an important link between the MoC and subsequent WSBC rehabilitation programs.

Of the wide range of self-report questionnaires developed to measure Activity limitations associated with back pain, two have been more frequently evaluated in research and clinical practice literature. They are the Roland-Morris Questionnaire (RMQ)(Riddle, Stratford, & Binkley, 1998 ; Roland & Fairbank, 2000) and the Oswestry Disability Index (ODI).(Fairbank, Couper, Davies, & O'Brien, 1980; Roland & Fairbank, 2000) The RMQ tends to be more responsive to change and less affected by ceiling effects than ODI in acute and subacute back pain populations.(Roland & Fairbank, 2000) The ODI tends to be better at discriminating more severe levels of disability, especially with increasing chronicity.(Roland & Fairbank, 2000) Considering the population of interest in the MoC, the RMQ may provide a better measure of change over the episode of care if measured pre- and post-MoC for all clients. The ODI may provide a better measure for those workers who do not recover fully and whose claims continue to subacute or chronic stages, with first administration following the MoC.

Summary

This section reviews some of the general and key specific measurement issues associated with implementation and evaluation of the MoC. Three models were suggested to help frame the MoC in the context of health and disability, to promote adoption of the MoC by practitioners, and to structure the implementation process. Measurement issues were considered in the context of internal validation of the MoC, and external validation in the WSBC system.

Table 3. Sample of process variables derived from the Model of Care

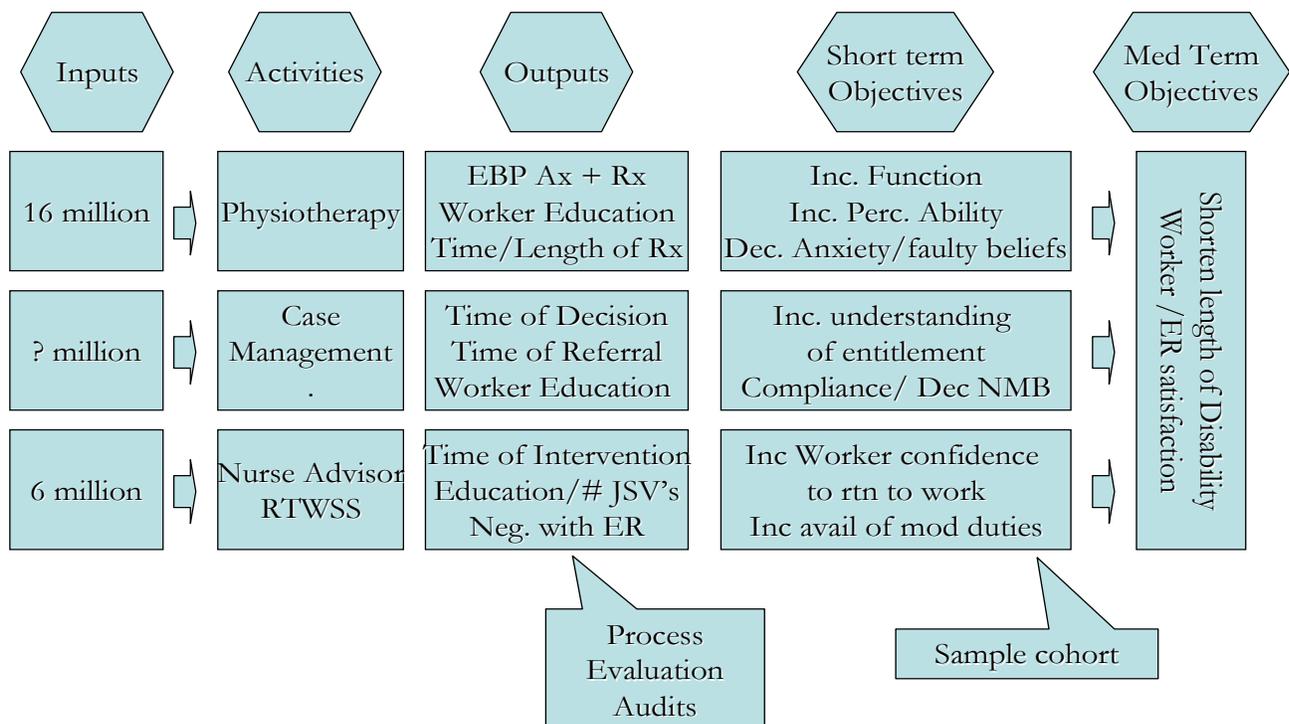
Variable Name	Date Variable	Type Variable
Injury	Yes	Injury code
Initial assessment date	Yes	
Key subsequent visits		
	Yes	Red flag assessment result/recommendation
	Yes	Advice/reassurance/education
	Yes	RTW planning/employer contact
Triage assessment		
	Yes	Function
	Yes	Psychosocial
	Yes	Typical/Atypical recovery
Discharge	Yes	
		Result/Recommendation

4.2 MoC Evaluation

The purpose of recommending specific MoC evaluation strategies is to highlight the need for appropriate evaluation of the MoC such that the decision makers and stakeholders can accurately determine how the MoC is performing and how it may be improved. The current physiotherapy agreement has a limited evaluation strategy and includes information such as utilization and overall

costs. In the writer's opinion, these outcomes do not allow the stakeholders and decision makers to create a more effective and/or efficient program. A draft logic model for evaluation of the MoC (Figure 3) is provided as a starting point to conceptualize the activities and the outputs of these activities. As well, the model demonstrates the link between the outputs and the final objective. This model is a 'draft' - as the development of such a model requires the input from stakeholders within WSBC to be as relevant as possible.

Figure 3: Draft Logic Model for the Evaluation of the MoC



The evaluation strategy may take on any of the outputs or objectives within the model. As an example, a process evaluation audit of physiotherapy files from an individual or group of physiotherapists may be completed. This evaluation would expose the level of adherence to the practice guidelines in place and highlight training needs or other barriers to their successful implementation. Another example of a process audit could include evaluation of a certain file(s) to determine whether the outputs of all the activity members (physiotherapists, NA, CO) are occurring as per the guidelines.

The evaluator may be satisfied that completion of the appropriate activities is resulting in the optimal achievement of the objectives because the evidence in the literature suggests this is the case. However, if the evaluator chose to confirm this assumption, he/she could choose to follow a cohort of workers and measure outcome measures of interest within the MoC and/or evaluate the return to work and satisfaction success of the MoC overall.

It is recommended that the evaluation information be collected and analyzed by the stakeholders. This analysis is the beginning of designing changes to the activities, their outputs or to other details within the MoC, with the overall goal being to enhance the efficiency and effectiveness of the MoC.

4.3 Cost Benefit and Cost Effectiveness Analysis

The final section of this report considers the potential for cost savings as a result of implementing the outlined strategies. There does not appear to be a consistent model within the disability management literature regarding the evaluation of a new intervention strategy with respect to cost savings. In the literature reviewed, a number of variables have been considered, including wage loss benefits paid, days lost due to disability, modified work days, medical costs, rehabilitation costs, etc.

It is recommended that the economic evaluation take both an insurer perspective and a social perspective to be consistent with the nature of program evaluations within the current WSBC rehabilitation philosophy. The cost benefit analysis (CBA) is the analysis of costs alone and considers the extra costs (if any) of implementing the new intervention strategy and the change in costs of wage loss benefits paid, change in medical costs and the change in other directly-related expenditures. The cost effectiveness analysis (CEA) examines the change in outcome (e.g. worker satisfaction) against the extra costs (if any) for the new strategy.

Within the evidence reviewed, there has been little economic evaluation of early intervention strategies to satisfy any decision maker that the simple replication of an existing program would result in a cost savings. However, there is evidence suggesting the characteristics of the recommended MoC can result in significant cost savings.

5.0 FINAL CONCLUSIONS

Based on a thorough review of research and evidence-based best practices related to the treatment of low back strain, the Physiotherapy Back Strain Task Force recommends the following guidelines for treating low back strain:

1. Therapeutic exercise: A patient-specific classification-based system to inform the prescription of exercise in the acute and sub-acute phases of recovery to facilitate early functional recovery.
2. Manual Therapy and Manipulation: Spinal manipulation in the first 8 weeks of recovery of nonspecific low back pain, and the effectiveness of intervention based on the Clinical Practice Rule.
3. Education: In-person education with focus on the content and delivery of a positive message which includes the critical advice to stay active even in the presence of pain.
4. Electrophysical Agents: Evidence on electrophysical agents is challenged by inconsistencies in classification and lack of control over parameters and dosages. Usage should be based on the relevant evidence and within the context of other evidence-based interventions available.
5. Acupuncture: There is limited published research regarding the effectiveness of acupuncture or intramuscular stimulation, and the physiotherapist is advised to use clinical judgment in each case.
6. Predictive factors: Assessment of the worker's pain beliefs, cognitions and attitudes to recovery, presence of leg pain, perceived disability, and pain intensity in order to determine the appropriate treatment to optimized timely functional recovery.
7. Early access: There are potentially significant clinical and financial benefits when workers have early access to a physiotherapist's assessment, clinical management, and education.
8. Communication: Physiotherapist-led collaborative communication among worker, employer, case manager and physician regarding the worker's functional abilities and barriers to return to work is expected to shorten time loss from work.

To implement a new approach to treating LBC among injured workers, physiotherapists and WSBC must partner on adopting Model of Care whereby:

- Physiotherapists evaluate, reevaluate, and treat as recommended by the evidence based practice presented in this paper;
- WSBC endorse early access to Physiotherapy services;
- WSBC and Physiotherapists collaboratively engage in communication focussed on the function of the injured worker relative to the available job demands;
- Physiotherapists and WSBC engage the Employer in early return to work planning and the identification and minimization of non-medical barriers to return to work

BIOGRAPHIES OF THE EXPERT PANEL TASK FORCE MEMBERS

PERRY STRAUSS

Hons.BSc.Kin, BHSc.PT, MHA candidate

Education:

University of Waterloo BSc – Kinesiology
McMaster University BSc – Physiotherapy

Areas of Expertise:

- Disability Management

Committees/Task Forces in the past 5 years

- WSBC – PABC liaison
- Business Affairs Committee member
- Negotiation Team Member
- Back Strain Task Force

Practice Experience relevant to back strain:

- Experience in WSBC programs including Medical Rehabilitation, Occupational Rehabilitation, Work Conditioning (OR1), Chronic Pain Program, Acute Physiotherapy.
- Experience in the practice and development of policy for the management of workplace disability with a large insurer.
- In final stages of MBA in Health Administration

NEIL PEARSON

MSc(RHBS), BScPT, BA-BPHE, Cert MDT, CYT

Education:

Queen's University Bachelor of Arts, Bachelors of Physical and Health Education
 BSc – Physiotherapy
 MSc – Rehabilitation Science

Areas of Expertise:

- Pain Sciences, Chronic Pain and Pain Management
- McKenzie Mechanical Diagnosis Therapy
- Yoga Therapy

Committees/Task Forces in the past 5 years

- Co-founder and Co-Chair Canadian Physiotherapy Pain Sciences Group
- Continuing Competence Committee – College of Physical Therapists of BC
- Back Strain Task Force

Practice Experience relevant to back strain

- Ten years working in WSBC programs: Acute Physiotherapy to Chronic Pain Program

Other:

- Clinical Faculty UBC – since 1997.
- Post graduate Education Instructor - Pain Science and Prevention & Treatment of Chronic Pain
Consultant Orion Health Pain Clinics

MATTHEW WRIGHT-SMITH
BSc. PT

Education:

La Trobe University, Melbourne Australia BSc - Physiotherapy

Areas of Expertise:

- Orthopaedics
- Manual therapy/manipulation
- Industrial rehabilitation: work conditioning
- Sports physiotherapy

Committees/Task Forces in the past 5 years:

- Whiplash Associated Disorders
- Best Practice Task Force
- Business Affairs Committee
- Liaison to WSBC Liaison Committee
- Back Strain Task Force

Practice Experience relevant to back strain:

- Owner Healthx Physical Therapy: Langley and Whistler OR 1 programs,
 - Owner Squamish Physiotherapy Sports & Spinal Manipulation Centre: OR 1 & 2 programs for Squamish.
 - 14 years running Work Conditioning/OR 1 programs
 - Experience in WorkSafe BC programs including Medical Rehabilitation, Occupational Rehabilitation, Work Conditioning (OR1), Chronic Pain Program, Acute Physiotherapy.
 - Experience in the practice and development of policy for the management of workplace disability with a large insurer.
-

ALLAN J. KOZLOWSKI
B.Sc. PT, PhD Candidate

Education:

University of British Columbia BSc. Physiotherapy

Areas of Expertise:

- Work Disability Prevention

Committees/Task Forces in the past 5 years:

- Back Strain Task Force

Practice Experience relevant to back strain:

- Recipient, Senior Graduate Studentship cofunded by WSBC and the Michael Smith Foundation for Health Research, 2007 – 2009
- Trainee, CIHR Strategic Training Program in Work Disability Prevention, 2007 – 2009
- Doctoral candidate, Rehabilitation Sciences, University of British Columbia, 2004 – 2009
- WSBC Employee October 1991 – February 2003: employed as Staff Physical Therapist, Senior Physical Therapist, Manager Occupational Rehabilitation Programs, Manager Private Physiotherapy Services Agreement.

Other:

- Clinical Instructor, Department of Physical Therapy, Faculty of Medicine, University of British Columbia, 2005 - 2007

TRACY BARBER
RPT, FCAMT, IFOMT

Education:

Manchester Royal Infirmary Graduate Diploma of Physiotherapy

Areas of Expertise:

- Diploma of Advanced Manual and Manipulative Physiotherapy
- Licensed Intramuscular Stimulation Practitioner
- Sports Injury

Committees/Task Forces in the past 5 years:

- National Canadian Physiotherapy Association (CPA) Orthopaedic Division Executive
- Co-editor of the National Orthopaedic Journal (CPA Orthopaedic Division Review)
- Back Strain Task Force

Practice Experience relevant to back strain:

- 20 years experience working in musculoskeletal physiotherapy
-

BIANCA MATHESON
BSc PT

Education:

Lincoln School, La Trobe University BSc - Physiotherapy

Areas of Expertise:

- Spinal Manipulation: FCAM
- Sports Injury: SPC Diploma
- IMS: CGIMS

Committees/Task Forces in the past 5 years:

- Invited speaker at the IOC medical council congress Greece 2004

Practice Experience relevant to back strain:

- Experience and special interests in Spinal manipulative therapy and spinal stabilization work
- Extensive experience with Sports therapy including Physiotherapist to Olympic Teams at the last two winter and summer games:
 - Sydney Games: Sports Physiotherapist for Beach volleyball
 - Physiotherapist to Australian winter Olympic team for Salt Lake 2002 and Torino 2006 competitions.
 - Contract Physiotherapist with Australian Institute of Sport: elite triathlon program.
- Extensive work with local whistler and BC/Canadian mountainbiking, BC Alpine, Alpine Canada, Whistler mountain ski club and triathlon
- Currently completing an Executive MBA.

PHILIPPE DE CLERCK

MPT, MBA Candidate

Education:

Ghent State University – Belgium	Scientific Degree of Master in Rehabilitation Sciences and Physical Therapy
Higher Institute for Allied Health Professions, Ghent, Belgium	Diploma in Physiotherapy

Areas of Expertise

- Active rehabilitation and chronic pain management.

Committees/Task Forces in the past 5 years:

- Exercise Therapy Task Force
- Back Strain Task Force

Practice Experience relevant to back strain:

- Physical therapist on a multi-disciplinary team working with persons with chronic pain, mostly as a result of low back 'strain'.
- Workshops/Courses on: Medical Exercise Therapy (MET), Evidence-based Rehabilitation. Canada, Norway, Sweden, Denmark, Belgium, Spain. Ongoing since 1998.
- Guest Speaker: Chronic Pain, back pain, workplace injury for WSBC, Canadian Physiotherapy Association, Norwegian Physiotherapy Association

ALISON M HOENS

BScPT, PG Sports PT, MSc

Education:

University of British Columbia	BSc Physiotherapy
Curtin University, Australia	PG Sports Physiotherapy
Curtin University, Australia	MSc

Areas of Expertise:

- Electrophysical Agents – Prelicensure (UBC Department of Physiotherapy) & Continuing Education
- Consultant on EPA malpractice for College of Physical Therapists and VANOC 2010 Therapy Service
- Evidence-Based Practice – Knowledge broker for knowledge translation of research into practice
- Dynamometric Evaluation of Muscle Function

Committees/Task Forces in the past 5 years

- Founding member International Association of EPA in Physiotherapy
- Member, Rehabilitation Aimed At Muscle Performance (RAMP) research group UBC/VCH
- Back Strain Task Force

Practice Experience relevant to back strain:

- Master's Research Project: The influence of age and gender on trunk muscle strength and endurance
- Current research project with Dalhousie University (Drs. K Harman and A. Fenety) on physiotherapeutic management of subacute Low Back Pain

EUGENE BARSKY
BA, MLIS

Education:

Ben Gurion University, Beersheba, Israel
University of British Columbia

BA in Psychology and Behavior Sciences
Master of Library and Information Studies

Committees/Task Forces in the past 5 years:

- Back Strain Task Force Committee

Practice Experience

- Outreach Librarian for the Physiotherapy Association of BC
- Regulatory Intelligence Specialist for QLT inc.

REECCA B TUNNAcliffe
BA, MA

Education:

University of British Columbia
Queen's University, Kingston

Bachelor of Arts, English Literature
Master of English Literature

Chief Executive Officer of PABC since 2001.
Ex Officio on all committees and task forces.

TYPE OF LOW BACK PAIN – EVALUATION RECOMMENDATIONS

(from Rosignol, Arsenault, Dionne, Poitras, Tousignault, Truchon, Allard, Cote & Neveu, (2007))

A. Simple Low Back Pain

General Characteristics:

- Lumbar or lumbosacral pain with no neurological involvement
- “Mechanical” pain, varying over time and with physical activity
- Patient’s general health is good

B. Back Pain with Neurological Involvement

-The patient must have one or more neurological symptoms and signs indicating possible neurological involvement:

Symptoms

- Pain radiating below the knee, which is as intense or more intense than the back pain
- Pain often radiating to the foot or toes
- Numbness or parathesia in the painful area

Signs

- Positive sign for radicular irritation as tested, for example, by straight leg raising
- Motor, sensitivity, or reflex signs supporting nerve root involvement

C. Back Pain with suspected serious spinal pathology (Red Flags)

General Characteristics

- Violent trauma (such as a fall from height or an automobile accident)
- Constant, progressive, non-mechanical pain
- Thoracic or abdominal pain
- Pain at night that is not eased by a prone position
- History of or suspected cancer, HIV or other pathologies that can cause back pain
- Chronic corticosteroid consumption
- Unexplained weight loss, chills or fever
- Significant or persistent limitation of lumbar flexion
- Loss of feeling in the perineum (saddle anaesthesia), recent onset of urinary incontinence

The risk of a serious condition may be higher in those under 20 or over 55 years of age. Particular attention must be paid to the previously mentioned signs and symptoms in these age groups.

**GENERAL SEARCH STRATEGY FOR EACH SPECIFIC RESEARCH TOPIC IN LOW BACK PAIN
IN THREE DATABASES USED FOR THIS REVIEW:**

OID MEDLINE

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. clinical trial.pt OR clinical trials.sh OR ('clinical trial'.tw)
8. ((singl?.tw OR doubl?.tw OR trebl?.tw OR tripl?.tw) AND (mask?.tw OR blind?.tw)) 9. "latin square".tw OR placebos.sh OR placebo?.tw OR random?.tw
10. or/1-9
11. animal/ not human/
12. 10 not 11
13. back pain.sh.
14. exp *Low Back Pain/
15. back pain.ti,ab.
16. backache.ti,ab.
17. dorsalgia.ti,ab.
18. lumbago.ti,ab.
19. (lumbar adj pain).ti,ab.
20. or/13-19
21. 20 and 12
22. (acute or subacute or sub-acute).ti,ab.
23. 22 and 21

OID EMBASE

1. Randomized Controlled Trial/
2. Clinical Trial/
3. Randomization/
4. Double Blind Procedure/
5. Single Blind Procedure/
6. clin\$ adj10 trial\$.ti,ab.
7. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj10 (blind\$ or mask\$)).ti,ab.
8. (placebo\$ or random\$).ti,ab.
9. or/1-8
10. ANIMAL/ not Human/
11. 9 not 10
12. Backache/
13. Low Back Pain/
14. (back pain or backache or (dorsalgia adj5 pain) or (lumba? adj5 pain)).ti,ab.
15. or/12-14
16. 15 and 11
17. (acute or subacute or sub-acute).ti,ab.
18. 16 and 17

EBSCO CINAHL:

1. (ZT "CLINICAL TRIAL")
2. (MH "Clinical Trials+"), explodes to include Double-Blind Studies, Single-Blind Studies, etc
3. (MH "Random Assignment")
4. clin* W10 trial*
5. ((singl* OR doubl* OR trebl* OR tripl*) W25 (blind* OR mask*))
6. (MH "Placebos")
7. S1 OR S2 OR S3 OR S4 OR S5 OR S6
8. (MM "Back Pain+") or (MM "Low Back Pain")
9. backache or (dorsalgia w5 pain) or (lumba* w5 pain)
10. S8 OR S9
11. S10 AND S7
12. AB (acute OR subacute OR sub-acute) OR TI (acute OR subacute OR sub-acute)
13. S11 AND S12

A total of 382 papers were retrieved by the Librarian and were reviewed by the Task Force Members.

A FULL EXAMPLE OF ONE DATABASE (OVID MEDLINE) SEARCH STRATEGY FOR ONE PARTICULAR PICO QUESTION THE EFFECTIVENESS OF INTRAMUSCULAR STIMULATION FOR ACUTE / SUBACUTE LOW BACK PAIN:

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. Randomized Controlled Trials/
4. Random Allocation/
5. Double-Blind Method/
6. Single-Blind Method/
7. clinical trial.pt OR clinical trials.sh OR ('clinical trial'.tw)
8. ((singl?.tw OR doubl?.tw OR trebl?.tw OR tripl?.tw) AND (mask?.tw OR blind?.tw)) 9. "latin square".tw OR placebos.sh OR placebo?.tw OR random?.tw
10. or/1-9
11. animal/ not human/
12. 10 not 11
13. back pain.sh.
14. exp *Low Back Pain/
15. back pain.ti,ab.
16. backache.ti,ab.
17. dorsalgia.ti,ab.
18. lumbago.ti,ab.
19. (lumbar adj pain).ti,ab.
20. or/13-19
21. 20 and 12
22. (acute or subacute or sub-acute).ti,ab.
23. 22 and 21
24. intramuscular stimulation.ab,ti.
25. (intramuscul\$ adj5 stimulat\$).ab,ti.
26. dry needling.ab,ti.
27. (dry adj5 needl\$).ab,ti.
28. or/24-27
29. 23 and 28

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