CLUSTER RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFECTIVENESS OF A MULTIFACETED ACTIVE STRATEGY TO IMPLEMENT LOW BACK PAIN PRACTICE GUIDELINES; EFFECT ON COMPETENCE, PROCESS OF CARE AND PATIENT OUTCOMES IN PHYSICAL THERAPY

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CLUSTER RANDOMIZED CONTROLLED TRIAL TO EVALUATE THE EFFECTIVENESS OF A MULTIFACETED ACTIVE STRATEGY TO IMPLEMENT LOW BACK PAIN PRACTICE GUIDELINES; EFFECT ON COMPETENCE, PROCESS OF CARE AND PATIENT OUTCOMES IN PHYSICAL THERAPY

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The study was a cluster randomized controlled trial designed to evaluate the effectiveness of an active strategy to implement practice guidelines for low back pain in physical therapy. Physical therapy clinics (clinics=28, therapists=41) were randomized to receive a multifaceted active intervention (education, audit, feedback) (clinics=16, therapists=24) to increase awareness regarding key recommendations in guidelines or mailed guidelines (clinics=12, therapists=18). Primary outcome measures were change in pre to post intervention competence score (18 clinical vignettes), adherence to guidelines and change in patient Oswestry scores from first to last visit. The competence test was administered at baseline and on completion of the education course. Data on LBP patients treated by participating therapists in a 12-week pre (therapists=41, patients=50) and post (therapists=41, patients=107) intervention period (education, audit and feedback) was extracted from the UPMC electronic database. Patient care was classified as being adherent or non-adherent using 6 quality indicators developed to reflect recommendations in the guidelines. Overall percentage of adherence and adherence to individual criterion on the guidelines were also calculated. The results of the study indicated that education did not have an effect improving knowledge measured by change in total competence score. However, there were significant differences between groups on the ability to appropriately identify directional preference with movement testing, where the intervention group did better than the control. Adherence to guidelines and patient outcomes did not improve as a result of the active

intervention strategy. The groups were not significantly different when comparing overall adherence to guidelines or to individual criterion on guidelines. There was an underutilization of mobilization thrust (82.3%), traction (78.5%) and graded exercises (47.6%) for fear avoidant patients, while stabilization was over-utilized in 51% of patients. Although therapists demonstrated moderate to high scores on the competence test, they failed to apply this knowledge in clinical practice. Future research should focus on a qualitative inquiry into organizational and environmental barriers to adoption of clinical practice guidelines. These include evaluating if payment policies and reimbursement from providers are aligned with guidelines and also assessing the extent to which patient demands and compliance influences adherence to guidelines.

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PREFACE

I would first like to extend my heartfelt thanks to Dr. Anthony Delitto, my mentor and dissertation chair. It was a privilege to work with him and to have his guidance and support. Dr. Delitto has always helped me focus on finding solutions without splitting hairs, as he would say it. If anything kept me going in the end it was his trust and his faith in me. Thank you!

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A warm note of thanks to my brother Siddharth, his wife Kanan and Vedant, for having faith in me. I would most importantly like to thank my parents for their constant support, encouragement and wisdom. Mom, thank you for teaching me to always put my best foot forward. Dad, thank you for teaching me to always think big!

1.0 INTRODUCTION

1.1 STATEMENT OF PURPOSE

Numerous clinical practice guidelines for low back pain have been developed and published worldwide with the intention of improving the quality of care and reducing variation in practice patterns. However, several studies have demonstrated the failure to implement practice guidelines in both medical and physical therapy practice. This has resulted in patients receiving inappropriate, unnecessary, or even harmful care.

Patients with acute low back pain receive guideline concordant physical therapy care only about 50% of the time (Swinkels, van den Ende et al. 2005; Fritz, Cleland et al. 2007; Rutten, Degen et al. 2010). Guideline adherent care is associated with improved outcomes and lower cost of treatment in patients with low back pain (Fritz, Cleland et al. 2007; Rutten, Degen et al. 2010).

Fritz and colleagues (Fritz, Cleland et al. 2007) conducted a study to evaluate if patients with low back pain who received guideline concordant care, of active versus passive approach to treatment, had greater improvements in clinical outcomes (greater improvement in disability and pain status) and lower treatment cost. In this study adherent care was defined as use of greater proportion of active interventions per visit such as exercise and manual therapy compared to passive interventions such as ultrasound and TENS.

Only 40% of the patients with LBP received adherent care i.e. greater proportion of active treatment per visit. Patients who received adherent care demonstrated significantly greater reductions in disability and pain and had lower treatment charges when compared to patients who received non-adherent care. The results of this study indicate that although adherence to practice guidelines can potentially improve clinical outcomes and reduce cost associated with LBP, majority of the LBP patients continue to receive care inconsistent with guidelines.

One of the major limitations of the study by Fritz and colleagues was a narrow definition of adherent care. The authors did not include specific treatment sub-groups (stabilization, spinal mobilization, directional preference exercises etc) in their definition of adherent care, which is inconsistent with the most recent practice guidelines (Delitto, George et al. 2012)**.** Hence, it was not possible to determine treatment choices of physical therapists for patients with different profiles in this study.

There are several studies in medical literature that have evaluated the effectiveness of interventions to increase adoption of LBP practice guidelines, by general practitioners (Rossignol, Abenhaim et al. 2000; Shekelle, Kravitz et al. 2000; Robling, Houston et al. 2002; Schectman, Schroth et al. 2003; Dey, Simpson et al. 2004; Engers, Wensing et al. 2005; Jellema, van der Windt et al. 2005; McKenzie, French et al. 2008; Evans, Breen et al. 2010). In contrast, only 3 cluster-randomized controlled trials till date have evaluated the same in physical therapists, two in the United Kingdom (Stevenson, Lewis et al. 2006; Evans, Breen et al. 2010) and 1 in the Netherlands (Bekkering, Hendriks et al. 2005; Bekkering, van Tulder et al. 2005).

While 2 of these studies evaluated the use of active dissemination strategies like interactive workshops and reminders (Bekkering, Hendriks et al. 2005; Stevenson, Lewis et al. 2006), one studied impact of only printed practice guidelines compared to a no-intervention

control (Evans, Breen et al. 2010). The outcomes evaluated in all three studies measured impact of guidelines on changing practitioners' beliefs in a very broad context of introducing early activity, using active versus passive interventions, discouraging bed rest and advice on return to work. One study used a single clinical vignette to measure change in process outcome i.e. practice behavior (Evans, Breen et al. 2010)and the other two, used process of care data (Bekkering, Hendriks et al. 2005; Stevenson, Lewis et al. 2006). Process of care data used was extracted from discharge summary in one study (Stevenson, Lewis et al. 2006), and from forms developed for data collection in the other study which required therapists to fill in details regarding the patients evaluation and treatment procedures (Bekkering, Hendriks et al. 2005). Only one study evaluated the effect of implementation strategies on patient outcomes (Bekkering, van Tulder et al. 2005)and none evaluated its effect on knowledge gained.

In the study, by Bekkering et al, 113 physical therapists were randomized to either receive a multifaceted intervention that included education, feedback and reminders or to receive mailed guidelines only. Main recommendations in guidelines included; establishing treatment goals that aim at functional restoration, management with active versus passive approach to treatment, patient education, and limiting number of treatment sessions to 3 for patients with symptoms for less than 3 weeks.

The educational intervention included didactic overview of the evidence for treatment and diagnostic approaches in back pain with role-playing. There were 2 sessions, which lasted 2.5 hours each, followed by feedback and reminders. There was a moderate improvement in adherence in the intervention group when compared to the control group at 4 weeks following the education program (12% improvement).

The intervention provided in this study was short. Intervention delivered over a longer period with the flexibility to access information over time may lead to more favorable results. In addition evaluation of competence prior to and after delivery of educational intervention is important to assess if the educational intervention increased awareness / knowledge regarding guidelines. If skill or knowledge (competence) has not improved following educational intervention behavior cannot be expected to change. Alternatively, if a clinician demonstrates significant improvements in competence following an educational intervention and yet does not deliver guideline adherent care, further qualitative data collection could explore barriers to adherent care (e.g., lack of agreement with guideline, lack of motivation, patient demand for alternative treatment, etc.).

In a subsequent study the authors evaluated if the patients treated by the participating therapists who were assigned to the continuing education program demonstrated significantly greater improvements in clinical outcomes compared to those treated by non-participating therapists (Bekkering, van Tulder et al. 2005). The patient outcomes were measured as a self report of their coping strategies, belief about back pain and time taken off from work at 6, 12, 26 and 52 weeks after intervention.

The patients in the two groups did not differ significantly at any time point, which could mean that the effect the intervention had on changing clinical behaviors (12%) was possibly not enough to detect improvements in clinical outcomes. A greater percentage of adherences may be necessary before the effect of the educational intervention can be detected in clinical outcomes. Another reason for lack of differences in patient outcome could be that the recommendations on the guideline did not account for heterogeneity of patients with non-specific LBP and hence the guideline itself was not useful in improving outcomes.

The current study accounts for some on the limitations observed in the studies by Bekkering et al (Bekkering, van Tulder et al. 2005). This is the first study that has evaluated the effectiveness of a multifaceted intervention that includes education, audit and feedback on knowledge of and adherence to practice guidelines in addition to clinical outcomes of patients with LBP. The guideline used in this study is based on the Treatment Based Classification (TBC) approach to management of LBP, which is consistent with recently released practice guidelines (Delitto, George et al. 2012). This approach to treatment classifies patients into subgroups for management based on their clinical presentation and hence accounts for the heterogeneity of patients with LBP. The sub-groups targeted in this study included grade V thrust mobilization, stabilization, directional preference, traction and graded exercise for fear avoidance.

The education intervention was formulated following a needs assessment that assessed the current state of adherence to the practice guidelines within and across all included responder subgroups. Areas where adherence was poor were considered to be priority areas where additional intervention should focus upon.

The course includes web-hosted modules in management of LBP (based on the practice guidelines) delivered over a 5-week period. This was accompanied by bi-monthly audit and feedback that included chart audits and benchmarking of therapists over a period of 12 weeks following the educational intervention. A continuing education program administered over an extended period of time and that allows the learner flexibility in accessing the resources without a time constraint may enhance learning and change behaviors. Several systematic reviews of RCT's of continuing education programs have shown that multifaceted interventions that combine an interactive approach to teaching with extended follow-ups and periodic feedback through chart audits and benchmarking are most effective in increasing clinician's knowledge of

clinical practice guidelines and enabling change in clinician behaviors (Davis, Thomson et al. 1995; Davis, O'Brien et al. 1999; Bennett, Davis et al. 2000).

Measurement of effectiveness of the educational intervention was based on the Kirkpatrick's four-level model of evaluation for training programs (Kirkpatrick 1994). The four levels include evaluation of learner's satisfaction, knowledge gained, application of learnt skill at the workplace and improved *productivity. For purposes of this study, we will define productivity as greater positive patient outcome change per visit*. The modified version of the Kirkpatrick's model for evaluation of learning outcomes following continuing education for medical professions as described by Curran et al. is presented in Table 1.

Table 1. Evaluation of outcomes of continuing medical education

Learning outcome	Rationale
1. Learner satisfaction (reaction)	Intends to evaluate the student's satisfaction with the program. Student may be asked to rate his satisfaction with the programs content, instruction, delivery etc.
2. Training result with regard to knowledge or skill (clinicians competence)	Intends to measure change in skill, knowledge or attitudes.
3. Change in behavior at work place or application of learnt skill (Clinicians performance)	Intends to measure the extent to which learning has influenced behavior or performance in their practice. Have the newly acquired skills been implemented in the workplace through change in practice patterns?
4. Result or improvement in productivity at the work place	Intends to measure if the patient's health care outcome was influenced as a result of the health care provider's participation in a continuing education (CE) program. This level of performance measurement attempts to directly link the CE activity to improvements in health care outcome.

This approach to assessment of outcome of training program is based on the rationale that knowledge and application of skill are independent of each other. Gains in knowledge may not be reflected in behavior change, a necessary step in guideline adherence. If change in behavior (adherence) does not improve productivity then it is possible that the process of management (guideline) is itself not effective in improving productivity.

The outcomes of this study included assessment at level 2, 3 and 4 of the Kirkpatrick's model that is knowledge gained, change in clinician's behavior and patient outcome. We used a multiple choice question exam to assess competence. Results from our pilot study indicate that the test developed for competency assessment is highly reliable ($_{\text{chronbachs}}\ \alpha = .819$). Adherence to Fguidelines was assessed using electronic health care records, which is more reliable and valid than self-report of adherence. Patient outcome was evaluated using Oswestry LBP questionnaire, which has been previously validated in the LBP population.

The current study aimed to evaluate if participation in the educational intervention has an effect on improving clinician's knowledge of and adherence to evidence based practice guidelines in treatment of patients with LBP. The current study also evaluated the effectiveness of the educational program in improving clinical outcomes of patients treated by participating physical therapists when compared to those treated by non-participating therapists.

1.2 SPECIFIC AIMS AND HYPOTHESES

1.2.1 Specific Aim 1

To evaluate the effectiveness of education, in improving physical therapists knowledge of the practice guidelines for management of LBP.

1.2.2 Hypothesis 1

Physical therapists assigned to the active educational strategy will have significantly greater change in pre to post test competence exam scores when compared to the control groups.

1.2.3 Specific Aim 2

To evaluate the effectiveness of education, audit and feedback in changing practice patterns of physical therapists, in management of patients with low back pain. We specifically evaluated if education, audit and feedback improved adherence to the clinical practice guidelines for LBP.

1.2.4 Hypothesis 2

Patients with low back pain treated by physical therapists assigned to the active educational strategy will receive adherent care more frequently compared to those treated by therapists in the control group.

1.2.5 Specific Aims 3

To evaluate the effectiveness of education, audit and feedback in improving the health status of patients with low back pain as a result of receiving adherent care.

1.2.6 Hypothesis 3

Patients with low back pain treated by physical therapists assigned to the active educational strategy will demonstrate significantly greater improvements in self-reported disability status compared to patients treated by therapists in the control group.

2.0 REVIEW OF LITERATURE

In **Section 2.1, 2.2 and 2.3** we outline gaps in quality of health care in the United States, define inappropriate care and suggested methods for reform, respectively.

In **Section 2.4** we discuss strategies to translate evidence into practice with a focus on education, audit and feedback.

In **Section 2.5 and 2.6** we discuss the impact of LBP and the need for identification of treatment sub-groups.

In **Section 2.7** we outline gaps in quality of Physical Therapy for low back pain, define inappropriate care and barriers to change.

2.1 GAPS IN QUALITY OF HEALTH CARE IN THE UNITED STATES

Quality of health care has been defined as **"the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with *current professional knowledge*"** (Chassin and Galvin 1998). Good quality of health care ensures that the process of care is based on evidence and the treatment is proven to increase the likelihood of a positive outcome. Currently, there is a substantial gap between current recommended standards of care and actual care delivered to health care consumers in the U.S. In 2001, Institute of Medicine (IOM) issued its urgent call for improvements in health care quality

in a report; Crossing the Quality Chasm (IOM 2001). The IOM report stated that *"between the health care we have and the care we could have lies not just a gap, but a chasm"* (IOM 2001).

In 2003, McGlynn et al (McGlynn 2003) conducted a study to measure the extent to which recommended (evidence-based) process of medical care was delivered to the patients. The authors of the study evaluated the appropriateness of care delivered to a random sample of adults for 30 medical conditions. The results of the study indicated that only 54.9% of patients (N= 6059) in the study received process of care consistent with current standards. There was little difference between care recommended for prevention, and to address acute or chronic episodes of a condition. This was the first study to highlight the alarming gaps in quality of care in America.

More than a decade has passed since the IOM issued it urgent call for fundamental changes in the health care system to address sub-standard quality of care. Despite agreement by health care leaders and policymakers across the nation that improvements were required, action to initiate changes has been slow.In the United Stated more than 98,000 Americans die from medical errors annually and the costs associated with treating such errors reportedly exceed 2 billion dollars per year (IOM 2001). De Vries et al conducted a systematic review of 8 studies and a total of 74,485 patient records to evaluate the incidence of in-hospital adverse events (AE) (de Vries, Ramrattan et al. 2008). The authors found that 9.2% (IQR 4.6–12.4%) of the cases experienced adverse events, 7.4 % of these events led to death. The median percentage of preventability was 43.5% (IQR 39.4–49.6%). Of these adverse events 39.6% were due to operational errors and 15.1% were medication-related.

The consequences of substandard quality of care include poor treatment outcomes and prognosis, increased medical complications, and substantial increase in associated costs.

2.2 DEFINING INAPPROPRIATE CARE

In a consensus statement by the Institute of Medicine (IOM), Chassin and colleagues (Chassin and Galvin 1998) reported that the health care quality problems in the U.S fall under 3 categories, namely; underuse, overuse and misuse.

2.2.1 Underuse

Underuse is the failure to deliver a health care service when there is evidence to support its efficacy in improving patient outcome (Chassin and Galvin 1998). Underuse of evidence based interventions or diagnostic processes largely contribute to poor health care outcomes related to a disease. Sadly, there are countless, alarming examples of underuse of health care.

Through a 3-year prospective study Christenson et al. found a 57% reduction in all-cause mortality among elderly person who were given the pneumococcal vaccine when compared with those who were not. A study found that for administration of each pneumococcal vaccine the health care system saved $117 per year Nichol et al. Despite this evidence only 62.3% % of the elderly received the pneumococcal vaccine in 2011(MMWR 2013).

According to another study only 64% of patients received beta-blockers after a heart attack although it is known to significantly reduce mortality and re-infraction rates (Fernandes, Madhavan et al. 2005).

2.2.2 Overuse

Overuse of a health care service occurs when a treatment is recommended under conditions where its potential for harm exceeds any possible benefits (Chassin and Galvin 1998). Overuse occurs when a drug or treatment is given without medical justification. In health care, more does not translate to better care.

A classic example of overuse in medical literature is the routine use of antibiotics when it is not indicated. There has been a concern that a super strain of drug resistant bacteria could emerge as a result of indiscriminate use of antibiotics. Although evidence suggests that Acute Otitis Media in children resolves in 3 days without antibiotics it is prescribed in 80% (Williamson, Benge et al. 2006; Haggard 2011) of the cases especially with children < 2 years (Paradise, Rockette et al. 1997).

Overuse is also very often seen in prescription of diagnostic imaging. When used appropriately, MRI's and other imaging exams are valuable. However, MRI's often don't change the treatments prescribed or a patient's outcome, such as in back pain. In these cases use of MRI is unnecessary, exposes the patient to harm and greatly adds to cost of treatment (Chou, Deyo et al. 2012).

2.2.3 Misuse

Misuse is another very serious quality issue in health care with dire consequences. Misuse occurs when a preventable complication of a process of care is not treated with the appropriate intervention or when an intervention with proven ineffectiveness is continued to be used for management of a disease (Chassin and Galvin 1998).

Potentially inappropriate medications (PIMs) continue to be prescribed as first-line of drugs for older adults, despite evidence of poor outcomes determined by an explicit criteria (Beers Criteria) (Campanelli 2012). Caterino et al conducted a nationwide study to retrospectively determine the national rate and trend of inappropriate medication administered to elderly patients in the emergency department (ED) (Caterino, Emond et al. 2004). Appallingly, inappropriate medications were administered in an estimated 16.1 million (95% confidence interval (CI) =14.9-17.3 million) or 12.6% (95% CI=11.6-13.5%) of elderly ED visits from 1992 to 2000. Adverse drug reaction due to PIMs being the fourth to sixth leading cause of death among the elderly, this is a huge gap in health care quality (Lazarou, Pomeranz et al. 1998).

Reducing occurrences of overuse underuse and misuse of medical resources has the potential to improve health care outcomes while reducing cost associated with the health care services (Chassin and Galvin 1998). If overuse of a health care service is controlled, the health care benefit increases, as the patient is not exposed to a treatment that has no significant effect on the disease outcome. At the same time costs associated with the treatment decrease because the patient has potential to recover sooner with the appropriate service that is supported by evidence. Similarly health care outcomes improve with reduction in misuse and the associated costs also decrease, as there is a decrease in number of medical complications that could add to medical expenditure.

Reducing underuse of treatment although almost always results in better health care outcome, it may either lead to an increase or decrease in health care costs. There may be an increase in health care cost if this intervention is expensive. However the overall costs associated with treatment of the episode may decrease due to faster recovery and prevention of recurrence when the appropriate intervention is used.

2.3 STRATEGY FOR REFORM OF HEALTH CARE QUALITY

The IOM aptly states, “In its current form, habits, and environment, American health care is incapable of providing the public with the quality health care it expects and deserves” (IOM 2001). It is recommended that the health care system must be re-designed to provide care that achieves six national quality aims**: safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity.** The goals for achieving these six aims for quality in the U.S should include

1) Provision of effective care to those who could benefit

2) Avoidance of health care services that are proven to be ineffective and

3) Elimination of all preventable complications of health care services.

The IOM report from 2001 suggest that clinicians are not solely responsible for delivering substandard quality of care, the entire health care system is and needs to be redesigned to improve standards of health care delivery (IOM 2001). All units within the health care system should be held accountable for the standards of care delivered and this includes the health care provider, the organizations, insurance providers and the stockholders. Strategic and organized Quality Improvement (QI) initiatives are necessary to identify gaps in quality of care, identify barriers to delivering ideal quality of care and implement fundamental changes in the health care delivery system. The health care system has remained static in a dynamically changing research environment and maintaining status quo is no longer an option.

The strategy for reinventing the system is depicted in Figure 1.

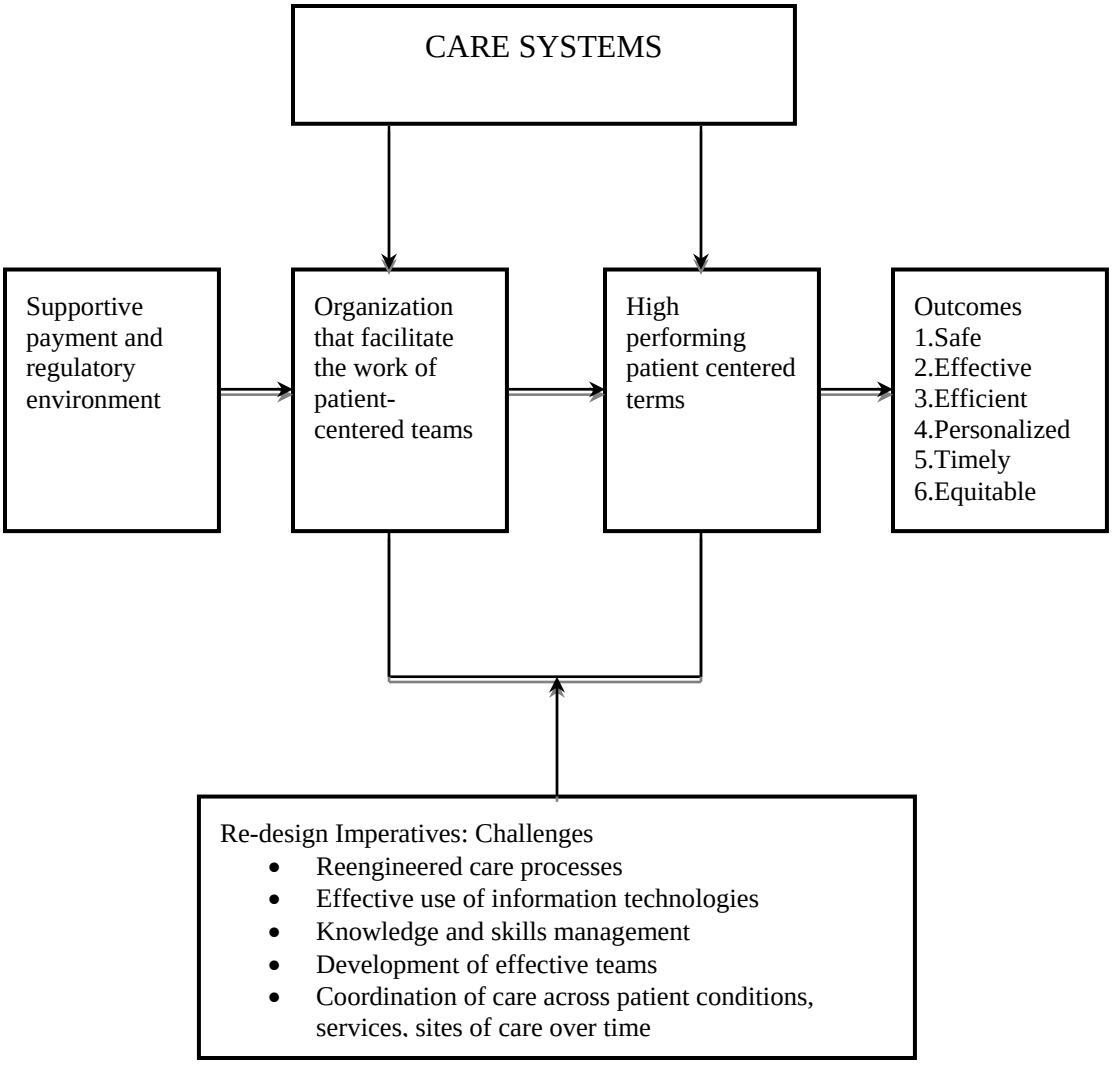

Figure 1. Strategy for reinventing the system, IOM 2001

2.4 TRANSLATING EVIDENCE INTO PRACTICE

It takes on an average 17 years to for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then there is wide variation in its adoption (Balas and Boren 2000). The Institute of Medicine stresses on the importance of improving quality of care by identification of best practices in healthcare, formulation and dissemination of specific practice guidelines, development of support tools to help clinicians in applying evidence, and development of measures for assessing quality of care (IOM 2001). Efforts to optimize translation of research into practice are most effective if barriers to change in practice patterns are considered.

Cabana et al (Cabana, Rand et al. 1999) summarized barriers to clinician's adherence to practice guidelines in a systematic review. Lack of adherence to guideline adherence may be due to internal or external factors. Internal barriers relate to individual characteristics and attitudes of the clinician and external barriers included factors that hinder the clinician from applying evidence based practice guidelines in the clinic. The sources of internal barriers could arise from:

Lack of awareness: The clinician may not be aware of the guideline or may not be familiar with the related research. The volume of research is large and the clinicians may lack time, resources or the knowledge to critically appraise the literature.

Lack of motivation to change practice: Some clinicians may lack motivation to stay abreast with current advances in medical literature or to implement changes in practice patterns despite of being aware of these advances.

Lack of agreement/ outcome expectancy: The clinician may not have faith in the evidence presented to him and may continue to deliver treatment based on his/her personal beliefs.

Lack of self-efficacy: The clinician may not have faith in his or her ability to perform interventions recommended by current standards in spite of being aware of the expected benefit of utilizing the treatment approach.

External barriers may be related to the guideline itself, organizational and environmental factors. The guideline may be overly complicated and difficult to apply in clinical situations. Lack of time in busy clinical settings, lack of resources at the clinic to apply guideline recommendations, insurance reimbursements, and patient demand and lack of compliance are examples of external barriers.

The barriers to adoption of clinical practice guidelines are summarized in Figure 2. Interventions that target change in clinician's behaviors must create a positive impact on internal factors such as lack of motivation, awareness and self-efficacy while decreasing the organizational barriers to change.

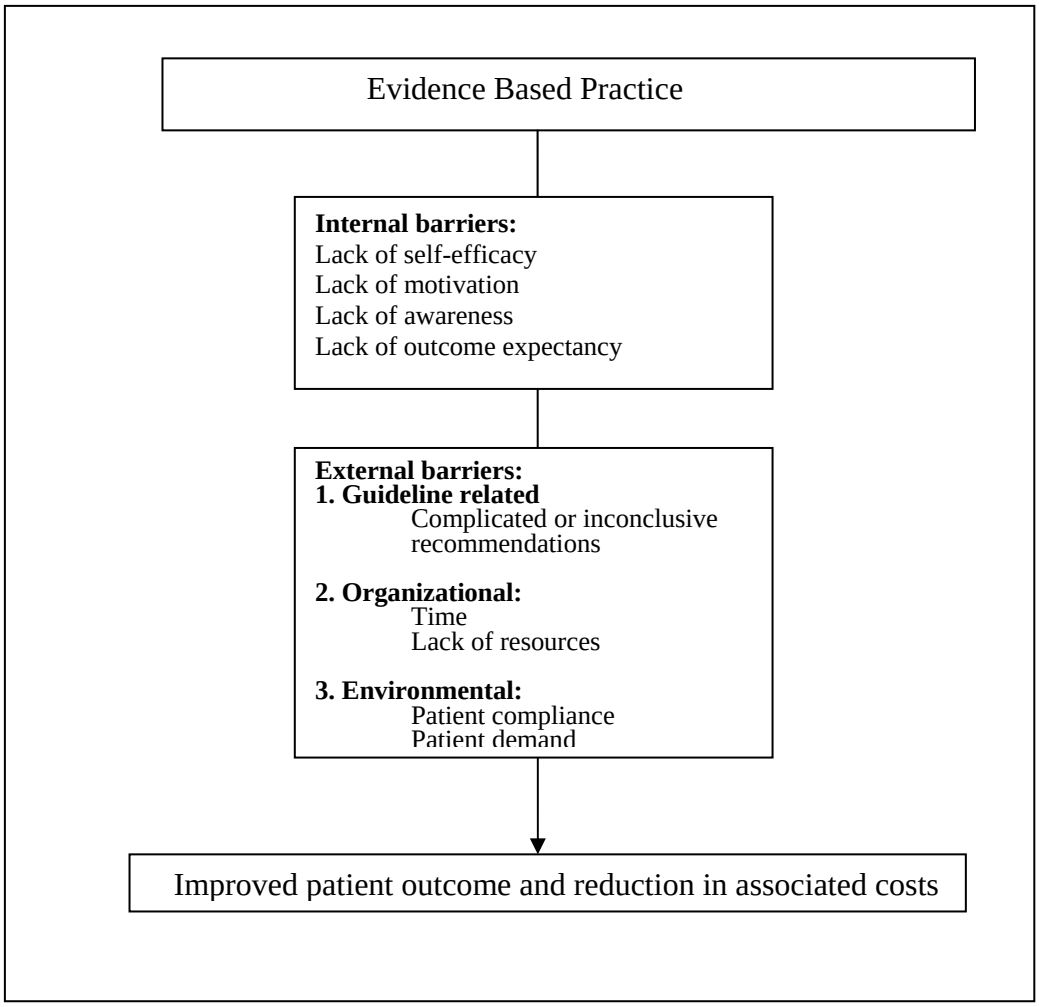

Figure 2. Barriers to adoption of clinical practice guidelines

Guideline implementation strategies should facilitate clinician's awareness, motivation, belief and clinical expertise while decreasing organizational barriers to change. Health care organizations should develop practice guidelines in order to make the current evidence easily accessible to the health care provider, as well as the consumer. Organizational strategies to implement practice guidelines could include regulatory changes that make guideline implementation an organizational priority, align the guideline with the organizations strategic plan, define specific measureable goal or outcomes for the guideline and assimilate the guideline through monitoring for quality assurance (Curry 2000). Health care insurers can encourage guideline implementation through restructuring of reimbursements and benefits for care given. Consumers of health care should be educated regarding best treatment options and the expected outcome with use of evidence based care. This approach can help increase patient compliance with evidence-based care (Curry 2000).

While development of evidence based practice guidelines can resolve the issues of information overload (magnitude of research being published), active educational strategies are required for guideline uptake. Passive diffusion models operate under the assumption that research and guidelines published in journals and presented at national conferences will positively influence clinician's attitude towards newer evidence and bring about change in their practice behaviors. This approach to changing clinician's behavior however is ineffective mainly due to the time constraints (Shojania and Grimshaw 2005). Active educational strategies that augment the clinician's awareness of and belief in the newer evidence, and provide feedback to the clinician regarding clinical performance are necessary to initial change in their behaviors.

A number of strategies and interventions to implement evidence into practice in a variety of clinical settings have been identified and investigated in the literature. These include

educational meetings and materials, use of opinion leaders, and educational outreach visits. Clinical decision aids, computerized reminder systems and chart audits serve as facilitators to change.

2.4.1 Continuing Education Programs

Continuing education programs are the most popular approach to translating evidence into practice (Brown, Belfield et al. 2002). Worldwide professional and regulatory bodies necessitate re-credentialing through continuing educational requirements (Peck, McCall et al. 2000). This is an effective approach for clinicians to keep abreast with new research findings that has the potential to help them in their practice.

Traditionally education interventions comprised of didactic lectures delivered at conferences or one-day workshops. Although attendance at conferences and day lectures may improve knowledge they seem to have little impact on health care professional practice behaviors and patient outcomes (Bloom 2005; Forsetlund, Bjorndal et al. 2009). In a systematic review of 50 randomized controlled trials evaluating the effect of continuing medical education interventions on physician performance, Davis et al. summarized that didactic courses had no impact on physician performance (Davis, Thomson et al. 1992).

Interactive workshops that include group discussions with practice sessions and role play had large effects on changing practice patterns and to a lesser extent on patient outcomes (Davis, Thomson et al. 1992). Multifaceted interventions that utilize both didactic and interactive approach, academic detailing, and reminder systems had the most significant effects on outcomes of education programs (Davis, Thomson et al. 1992). In 7 studies, sufficient data were available

for effect sizes to be calculated; overall, no significant effect of these educational methods was detected (standardized effect size, 0.34; 95% confidence interval [CI], -0.22 to 0.97).

In an updated review Davis et al analyzed the effect of formal continuing medical education (CME) interventions on physician performance and health care outcomes (Davis, O'Brien et al. 1999). The authors included randomized controlled trials from 1993-1999 of formal didactic and/or interactive CME interventions (conferences, courses, rounds, meetings, symposia, lectures, and other formats) in which at least 50% of the participants were practicing physicians. The findings were in line with the previous review where they found that didactic approach had no effect on practice behaviors. Interactive and mixed educational sessions with the opportunity to practice skills were associated with a significant effect on practice (standardized effect size, 0.67; 95% CI, 0.01-1.45).

A more recent Cochrane review investigated the effect of educational meetings and workshops in improving medical professional practice (Forsetlund, Bjorndal et al. 2009). A total of 81 RCTs were included in the review. The results of the review indicated a 6% improvement in professional practice (median adjusted risk difference (RD) 6%, Inter Quartile Range (IQR) 2.9% to 15.3%) and a 3% increase in attainment of treatment goals (median adjusted RD= 3%, IQR=0.1% – 4%), when educational meetings were compared with no intervention. However, this improvement in professional behaviors did not translate to similar improvements in patient outcome.

Forsetlund et al found additional factors such as rate of attendance and the use of multifaceted interventions influenced the effectiveness of educational sessions. A higher attendance at the educational meetings was associated with a larger adjusted risk difference ($p<0.01$) demonstrating improved compliance.

The authors reported that the use of multifaceted interventions, which included didactic and interactive (role playing, case discussion or skills practice) approaches were more effective (median adjusted RD=13.6) than using the didactic (median adjusted RD=6.9) or interactive approach (median adjusted RD=3.0) alone.

When educational meetings were included in multifaceted interventions (including educational meetings, reminders, educational outreach or audit and feedback), there was a 6% improvement in compliance with desired professional practice compared to no intervention (median adjusted RD= 6%, IRQ= 1.8% to 15.9%, 30 trials included).

Interestingly, when the multifaceted interventions were compared to educational meetings alone, there was no difference between groups (median adjusted RD of 6% for both conditions). This suggests that the small improvement in professional practice seen in the multifaceted interventions may be associated with the interactive educational meetings.

In conclusion, in order to be effective education programs must be interactive, sequenced, and multifaceted, including more than one method to facilitate adoption of guidelines (Davis, O'Brien et al. 1999). In addition to improving delivery methods, it has been suggested that assessment of educational needs is vital in developing effective continuing education courses and is an essential precursor to change (Mazmanian and Davis 2002).

2.4.2 Opinion leaders

Opinion Leaders are members within a social group with significant social influence over others (Hong, Ching et al. 1990). Some of the strategies used by opinion leaders for disseminating and implementing evidence-based practice are didactic lectures, community out-reach education,

small group teaching and academic detailing (Thomson O'Brien, Oxman et al. 2000; Ryan, Marlow et al. 2002). Opinion leader interventions have been utilized with mixed results to change health care practitioner's practice patterns (Thomson O'Brien, Oxman et al. 2000) however it is suggested that it may be beneficial to use this approach in combination with other interventions such as audits and feedback (Doumit, Gattellari et al. 2007). There are four main methods used to identify opinion leaders (Rogers 1995; Valente and Pumpuang 2007):

1. **Observation method**: An independent observer acts to identify opinion leaders amongst a group of professionals interacting with one another in a work environment
2. **Self-designating method**: Members of a professional network report their own roles as opinion leaders
3. **Informant method**: Individuals are asked to identify those individuals who act as principle sources of influence in their own experience
4. **Sociometric method**: Members of a network are asked to evaluate individuals via a standardized, self reported questionnaire using educational, influential, knowledgeable and humanistic measures.

In a Cochrane review in 2011, Flodgren et al investigated the effectiveness of local opinion leaders on improving the behavior of health care professionals and patient outcomes (Flodgren, Parmelli et al. 2011). Of the 18 RCT's included in the review, 14 studies used the Sociometric method and 2 studies used the informant method to identify the local opinion leaders. The remaining 2 studies used a combination of the informant and self-designation method.

The median adjusted RD for the main comparisons in the study were: 1) Opinion leaders compared to no intervention, +0.09, (IQR, -0.15 to +0.38); 2) Opinion leaders alone compared to a single intervention, +0.14 (IQR, +0.12 to +0.17); 3) Opinion leaders with one or more additional intervention(s) compared to the one or more additional intervention(s), +0.10 (IQR, -0.08 to +0.25); 4) Opinion leaders as part of multiple interventions compared to no intervention, +0.10 (IQR, -0.04 to +0.72). Overall, across all 18 studies the median adjusted RD was +0.12 representing a 12% absolute increase in compliance in the intervention group.

2.4.3 Educational outreach

Educational outreach is defined as "the use of a trained person who meets with providers in their practice settings to provide information with the intent of changing the provider's performance." (Yana and Jo 2004) The role of the person providing outreach visits may be to provide feedback regarding the practitioner's performance or to discuss approaches to evidence based care. Evidence from previous studies suggests that educational outreach visits (EOV) combined with additional interventions are effective in changing clinical behavior of health care providers (Thomson O'Brien, Oxman et al. 2000).

Interventions to reinforce knowledge and enable sustenance of practice patterns such as audit and feedback, bench marking and outreach visits have also been utilized with moderate success in changing clinician's behavior (Davis, Thomson et al. 1992; Davis, Thomson et al. 1995; Oxman, Thomson et al. 1995; Davis and Taylor-Vaisey 1997; Thomson O'Brien, Freemantle et al. 2001).

In a recent Cochrane review by O'Brien et al, 69 RCTs investigated the effects of EOV compared to no intervention on professional practice (O'Brien, Rogers et al. 2007). When EOVs were investigated alone compared with no intervention, a 5% improvement in professional practice was observed in the intervention group compared with the control (median adjusted RD=5%, IQR= 3% to 6.2%).

2.4.4 Chart audit and feedback

Chart audits and feedback (Surveillance) have been defined as "any summary of clinical performance of health care over a specified period of time", given in a written, electronic or verbal format (Jamtvedt, Young et al. 2003). Chart audits directly target measurement of clinician's performance and aim to changing practice behaviors through feedback. In an audit and feedback process, a clinician's professional practice or performance is measured and compared to professional standards or targets. This information is then provided to the clinician with the intention of encouraging the clinician to follow professional standards (Ivers, Jamtvedt et al. 2012).

Chart audits have been used as means of intervention to enforce guidelines, to evaluate gaps in quality of care as a form of needs assessment and also as an outcome to measure adherence to evidence based care. Behavior change theories suggest that feedback may work by changing clinician's awareness about current practice. Clinicians may not be able to self assess their performance and they may not be aware of their sub-optimal performance. They may be prompted to change their practice behaviors if given feedback that their performance is inconsistent with the recommended guidelines.

Van der Veer et al conducted a systematic review of 53 studies to evaluate the effectiveness of using medical registries to provide feedback to clinicians on improving quality of care (van der Veer, de Keizer et al. 2010). The authors found that quality of data provided, motivation and interest of clinicians and the organizational support for quality improvements were important effect modifiers in changing practice behaviors.

Hysong et al, re-analyzed articles from a previous review, using principles of the "feedback intervention theory" (Hysong 2009). They found greater effectiveness with increasing frequency of feedback, with written rather than verbal format, and with feedback that included information regarding the correct solution.

In a recent systematic review by Ivers et al, 140 studies were analyzed to evaluate the effect of audit and feedback on professional practice and patient outcomes (Ivers, Jamtvedt et al. 2012). The authors evaluated the studies with dichotomous and continuous outcomes for compliance separately. They also evaluated patient outcomes in a similar manner. The authors of the study found a 4.3% (IQR 0.5% to 16%) absolute increase in health care professionals compliance with desired practice with the studies featuring the dichotomous outcomes (82 comparisons from 49 studies). In all these studies audit and feedback was the core or essential aspect of the intervention. For articles with continuous outcomes the authors found a 16% absolute improvement in health professional compliance with desired behaviors. For patient outcomes the weighted median RD was -0.4% (IQR -1.3% to 1.6%) in articles with dichotomous outcomes and weighted median percentage change relative to control group was 17% (IQR 1.5% to 17%) in articles that included continuous outcomes.

Further meta-regression analysis demonstrated that baseline performance was inversely associated with effectiveness of audit and feedback. They also found that feedback is more

effective when a supervisor or senior colleague provides it, delivered at least monthly, efforts were targeted towards decreasing rather than increasing behaviors (such as reducing prescription of imaging) and when feedback offered explicit goals and an action plan.

In summary, audit and feedback leads to small but potentially important improvements in professional practice behaviors. The effective of feedback depends on baseline performance and how the feedback is provided.

2.4.5 Benchmarking

Benchmarking is a tool for health care providers to perceive their personal performance within the context of the performance of their peers (Kiefe, Allison et al. 2001; Kiefe, Allison et al. 2001). There is conflicting evidence regarding the effectiveness of benchmarking.

Kiefe et al conducted a RCT to evaluate the effectiveness of using achievable benchmarks to enhance physician performance feedback and improve care for patients with diabetes mellitus (Kiefe, Allison et al. 2001). Seventy community physicians were randomly assigned to receive a multimodal improvement intervention, including chart review and physician-specific feedback (comparison group; n = 35) or an identical intervention plus achievable benchmark feedback which was the mean score of the top 10% of peers (experimental group; n = 35). Achievable Benchmarks of Care (ABCs) are standards of excellence attained by top performers in a peer group and are easily and reproducibly calculated from existing performance data. The outcomes included administration of influenza vaccine; foot examination; and 3 blood tests measuring glucose control, cholesterol level, and triglyceride level.

They found that the achievable benchmark group had greater improvement in compliance to recommend care compared to control group (median adjusted RD = 3%, IQR = 2% to 4%). In

particular, statistically significant increases were observed for administration of influenza vaccination (OR 1.54, 95% CI 1.26 to 1.96), foot examination (OR 1.33, 95% CI 1.05 to 1.69) and for long-term glucose control measurement (OR 1.33, 95% CI 1.04 to 1.69). Cholesterol measurement (OR 1.20, 95% CI 0.95 to 1.51) and triglyceride measurement (OR 1.15, 95% CI 0.92 to 1.44) was had statistically significant additional adjustment for physician characteristics.

In contrast, Schneider et al found that benchmarked data presented in a quality circle (QC) (i.e. learning collaborative) did not lead to improvements in management of asthma (adjusted RD = -5%) (Schneider, Wensing et al. 2008). In the study 6 clinics were randomized to a traditional QC without benchmarking and 6 were randomly assigned to a QC working with an open benchmark and discussion of the results. The General practitioners (GP) in the benchmarking group received the name and information about the GP who performed best in their QCs. They also received information about the top 10% of GPs in the benchmark arm. Under the guidance of the moderator, the GPs discussed with the identified GP how the best practice was achieved. In addition, practice details of the 'overall best practice' of the benchmarking arm were given to enable a comparison with the benchmark.

The authors did not find significant differences between the two groups although there was a trend towards an increase of full adherence to guidelines and decrease of under dosing in the benchmarking group.

2.5 IMPACT OF LOW BACK PAIN

According to NHI Survey, conducted in 2002, approximately fifty-four million adults in the United States, reported to have low back pain and about twenty million health care visits were recorded for patients seeking care for LBP (Deyo, Mirza et al. 2006; Strine and Hootman 2007). A study conducted in 1991 by Frymoyer and colleagues (Frymoyer 1992) reported that the total annual expenditure in direct and indirect costs for LBP in the United States was 50-100 billion dollars. When projected to 2005, the total annual economic strain created by LBP was estimated to be 100 -200 billion dollars a year (Luo, Pietrobon et al. 2004; Katz 2006).

Most current guidelines emphasize on discouragement of bed rest and early activation with physical therapy for patients with back pain. However in most health-care systems where the PCP is the first contact for a patient with LBP referral to physical therapy is reserved for when the patients fails to recover after 4 weeks of bed rest and medication (Patel and Ogle 2000). Not only is this steeped care approach detrimental to the long-term outcome of back pain, it adds significantly to the cost of treatment (Pinnington, Miller et al. 2004). In addition, there is evidence that early treatment by physical therapists, for low back pain can reduce the amount of time people are on sick leave and can help to prevent an acute episode from becoming chronic (Pinnington, Miller et al. 2004).

Early access to physical therapy for back pain is also more cost effective. In a study by Mitchell et al the authors evaluated the cost effectiveness of direct access to physical therapy compared to physician referrals. The authors found that patients who received care by direct access had fewer number of services used, shorter duration and substantially lesser cost (difference of $1200) of treatment (Mitchell and de Lissovoy 1997).

As direct access to physical therapy has made early intervention for back pain possible it has become the physical therapists responsibility to identify patients eligible for physical therapy and refer those not eligible back to the appropriate health care provider. Physical therapists have to keep abreast with new research in literature and apply evidence based care to ensure delivery of best quality of care and outcomes. However adoption of evidence based practice in physical therapy has been slow to catch up because of several barriers to implementation such as lack of access to research databases or lack of clinical appraisal skills required to interpret study results. This has led to a know-do gap; the gap between what is known and what is done in practice (Jette and Delitto 1997; Scott, Moga et al. 2010).

2.6 NEED FOR SUB-GROUPING OF PATIENTS WITH LOW BACK PAIN

In primary care it is difficult to make an anatomical diagnosis of LBP and a very small proportion of patients have an identifiable cause for LBP. Only 2 % of the LBP cases have a true disc herniation and even fewer have an underlying life threatening condition. Hence majority (80%) of the patients that present to outpatient physical therapy clinics have a diagnosis of “non-specific LBP”.

Primary care guidelines worldwide recommend against prescribed bed rest and early imaging unless red flags are present during patient exam. Most guidelines also recommend early introduction of general exercises and to stay active. There are inconsistencies however in the recommendation for thrust mobilization, specific directional exercises and patients who demonstrate fear avoidance.

These inconsistencies stem from the fact that studies in literature have contradictory and incongruous findings regarding the effectiveness of these interventions in management of LBP. A reason for this lack of definitive findings could be because most studies have used very broad inclusion criteria to evaluate the effectiveness of one any one intervention. Most studies have included all patients with non-specific low back pain with very little exclusions such as pregnancy, absence of red flags and post-operative. Considering that non-specific LBP is an extremely broad label placed on almost 80% of all LBP cases it is unrealistic to expect any one treatment to benefit these patients. This one-size fit all approach in LBP research has lead to inconsistencies in study findings and in turn has led to a lack of standardization in physical therapy practice. This widespread variation in practice patterns in physical therapeutic management of LBP has led to poor PT outcomes.

Hence the alternative approach is to identify patients who are best suited for a particular intervention. Dr Anthony Delitto first described this approach of classifying patients with LBP into sub-groups that would benefit from different interventions in detail in 1995 (Delitto, Erhard et al. 1995). In a perspective article Delitto et al outlined a clinical decision making system or algorithm that would help therapists first screen patients for serious medical red flags and then use history and examination findings to place patients with low back pain into one of 4 treatment subgroups; spinal mobilization, specific-exercise, traction and stabilization. Very few studies in LBP literature have taken into consideration that specific groups of patients may benefit from a treatment approach. It is not surprising that those who have accounted for sub-groups have found more definitive results.

A multi-centre RCT conducted by Fritz and colleagues compared the effectiveness of a classification-based approach to treatment of patients with acute LBP with an approach based on

the AHCRP guidelines (Fritz, Delitto et al. 2003). Seventy-eight subjects were randomly assigned to either receive treatment based on clinical practice guidelines that emphasized on low stress aerobics and general muscle conditioning after 2 weeks of LBP incident or according to the classification scheme developed by Delitto et al. which assigned subjects to one of the four treatment groups i.e. mobilization (sacral/lumbar) immobilization, direction specific exercises (flexion, extension) and traction on basis of their clinical presentations.

Subjects who received treatment according to the classification based approach to treatment showed significantly greater changes in Oswestry and SF-36 scores compared to those subjects who received treatment according to current guidelines, thus favoring the classification based approach over the guidelines based approach to treatment. At one year changes in Oswestry scores continued to favor the classification group. At one year the relative risk of missing work was 2 times higher for those in guideline group compared to those in the classification based group. A cost analysis also demonstrated reduced costs for treatment of LBP subjects in the classification group compared to guideline based group with an average annual savings of $229.68 $ between groups.

In another study Brennan and colleagues assigned 123 patients to receive treatment according to stabilization, mobilization or specific exercise classification and compared them matched or unmatched to their treatment groups (Brennan, Fritz et al. 2006). Subjects who received treatment matched to the classification sub-group scored significantly better on the outcome measures and reported greater short-term (4 weeks) and long-term (1 year) reductions in disability compared to subjects who received treatment unmatched to the classification sub-groups.

2.6.1 Grade V thrust mobilization

The evidence to support use of thrust mobilization in treatment of LBP is inconclusive and inconsistent. Some studies have established that mobilization is more effective in treatment of LBP than placebo or other interventions while others studies have reported contradictory results (Godfrey, Morgan et al. 1984; Cherkin, Deyo et al. 1998; Assendelft, Morton et al. 2003; Aure, Nilsen et al. 2003; Childs, Fritz et al. 2004; Goldby, Moore et al. 2006; Hancock and Maher 2010; Bronfort 2012; Cruser d, Maurer et al. 2012; Goertz, Long et al. 2012; Rubinstein, Terwee et al. 2012; de Oliveira, Liebano et al. 2013; Rubinstein, Terwee et al. 2013). Majority of these studies have used broad inclusion criteria, such as non-specific low back pain. This would imply that all patients with low back pain would benefit from spinal mobilization. We know now that non-specific low back pain includes several subgroups of patients who may respond to different approaches to treatment. Hence using a one size fits all approach when planning a study would greatly limit the findings of the study.

Such inconsistent findings led to the idea that a subgroup of patients with low back pain may benefit from spinal mobilization. Traditionally the decision to manipulate patients would rely heavily on special tests based on biomechanical theories and movement testing. However many of these tests were found to have poor reliability and validity.

Since then researchers have shifted focus on trying to identify clinical examination findings and patient characteristics that may be associated with better outcomes with spinal mobilization. Based on this reasoning a CPR for identification of patients who were likely to improve with spinal mobilization was developed and validated (Flynn, Fritz et al. 2002; Childs, Fritz et al. 2004).

The CPR established by Flynn and colleagues was a first approximation of the variables that were likely to predict success or failure with mobilization (Flynn, Fritz et al. 2002). Seventy-one subjects with non-specific low back pain were included in the study. Patients who were pregnant, had nerve root compression, prior lumbar surgery or a history of osteoporosis or spinal fracture were excluded from the study. All patients were manipulated in 2 treatment sessions. Success with treatment was defined as a 50% reduction in self-reported disability (Oswestry scores).

All patients who demonstrated 50% reductions in Oswestry scores were classified as having successful outcome. Patients who did not have a minimum of 50% reduction in scores were considered treatment failures. The baseline characteristics and physical examination findings of patients (predictors) who improved with mobilization were then compared to those of patients who did not improve. Five variables were found to be most predictive of success with mobilization and constitute the rule.

These are:

1. Symptom duration less than 16 days
2. Fear avoidance beliefs questionnaire work subscale < 19
3. Hypo-mobility of lumbar spine with posterior anterior mobility testing
4. Internal rotation of hip < 35*
5. Back pain radiating up to but not beyond the knee

To be considered positive on the CPR, the patient should meet at least 4/5 criteria on the CPR. When the criteria is met, the likelihood of success with treatment increases significantly with a positive likelihood ratio of (LR+) of 24, meaning that if pretest probability of success with

mobilization is assumed to be 50%, then the post test likelihood of improvement with mobilization increases to 97%. Similarly, for prediction of failure, if 2 or fewer criteria on the rule are met, the post-test probability of success decreases to 9% with a negative likelihood ratio of 0.09. Change in probability of success when 4 out of 5 criteria on the CPR for spinal mobilization are met is pictorially depicted in Figure 3.

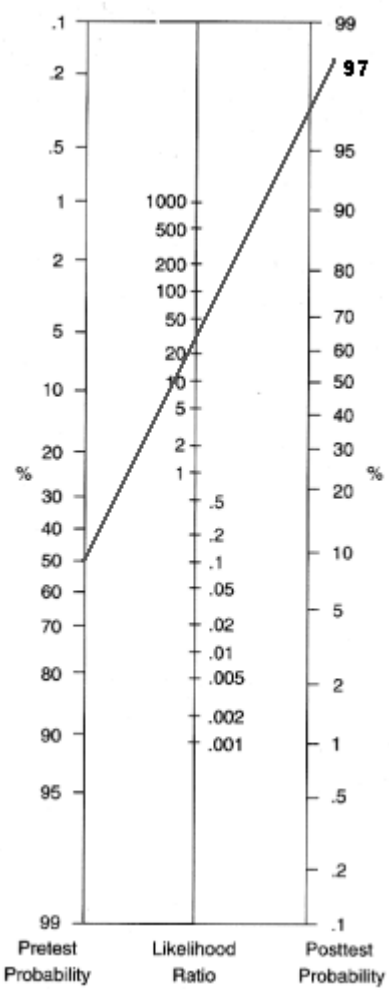

Figure 3. Change in probability of success when 4 out of 5 criteria on the CPR for spinal mobilization are met

In order to validate the finding in the study by Flynn et al, Childs and colleagues conducted a follow-up validation study (Childs, Fritz et al. 2004). In this prospective randomized controlled trial patients with LBP were assigned to one of two groups; standard exercise program with mobilization or without mobilization.

After treatment, the entire sample was then classified according to their status on the rule. These groups were then further divided into two groups. Those who received treatment matched to their status and those who received treatment unmatched to their status on the rule. Oswestry scores were compared for the two groups as reference standard. Fifty percent reduction in Oswestry scores following treatment was considered to be a successful outcome.

The authors found that patients who were positive on the CPR and received mobilization experienced greater improvements in pain ratings as well as disability scores in the short term (1and 4 weeks) and long-term follow up period (6 months) when compared patients who received unmatched treatments ($p<0.05$). This study validated the use of the CPR and provides very strong evidence for presence of a unique subgroup of patients who, when present with 4/5 criteria as defined by the CPR, are uniquely responsive to spinal manipulative intervention.

Fritz et al evaluated if a pragmatic application of the CPR rule would still lead to dramatic improvements in outcome. They found that if two factors were present; duration less than 16 days and not having symptoms distal to the knee, patients still had a moderate to large shift in probability of a successful outcome following application of thrust spinal mobilization (+LR= 7.2, 95% CI: 3.2, 16.1) (Fritz, Childs et al. 2005). Remarkably previous studies that have relied on biomechanical examination findings to identify manipulative candidates have also consistently found these 2 findings as most predictive of success, short duration of pain and absence of pain radiation into legs (Skargren and Oberg 1998; Axen, Jones et al. 2005).

2.6.2 Stabilization classification

Earlier efforts to identify patients with clinical instability were directed towards correlating clinical examination and radiographic finding of instability (Dupuis, Yong-Hing et al. 1985; Abbott, McCane et al. 2005; Fritz, Piva et al. 2005) or through the use of clinical signs and symptoms such as recurrent episodes of LBP, frequent mobilizations, trauma, pregnancy, oral contraceptive use, and positive response to immobilization of the spine. Overall all these strategies have been shown to be unreliable (Hayes, Howard et al. 1989; Boden, Davis et al. 1990; Boden and Wiesel 1990; Abenhaim, Rossignol et al. 1995). There have been several published randomized controlled trials that have investigated the benefits of spinal stabilization exercises for treatment of LBP and have found inconsistent results (to be inserted). The reason offered for these findings was that there might be a subgroup of patients who are likely to benefit from stabilization.

A clinical prediction rule for identification of patients likely to benefit from stabilization has been developed since then. The clinical prediction rule suggests that when a cluster of signs and symptoms are present the chances of success with stabilization are greatly increased.

Hicks et al. conducted a study to identify predictors of success with stabilization in patients with LBP. The authors of the study developed a CPR that can be used to assist the clinician to identify those patients most likely to benefit from treatment with stabilization. Patients with LBP with and without leg symptoms, over 18 years of age were included in the study. Patients, who were pregnant, had previous spinal fusion surgery, had red flags and neurological compromise were excluded from the study.

Findings from history and examination were recorded to identify predictors of success with treatment. All patients were provided with 8 weeks of stabilization training to the

multifidus, erector spinae, transverse abdominus, and oblique abdominal muscles. The outcome of treatment was considered successful if the patient demonstrated a 50% reduction in self reported disability scores on the Oswestry questionnaire (Reference Standard). The baseline characteristics and examination findings of patients who were classified as having improved with treatment were then compared to those who did not improve with treatment to identify predictor variables for success.

Of the variables assessed, 4 were found to be predictive of success with stabilization;

1. **Age less than 40**
2. **Average SLR range of motion > 91**
3. **Aberrant movements in sagittal plane Lumbar ROM**
4. **Positive prone instability test**

To be considered positive on the CPR, the patient should meet at least 3/4 criteria on the CPR. When at least 3 of the 4 predictors are present the positive likelihood ratio was observed to be 4.0. When the criteria is met, the likelihood of success with treatment increases significantly with a positive likelihood ratio of (LR+) of 4.0, meaning that if pretest probability of success with stabilization is assumed to be 50%, then the post test likely hood of improvement with stabilization increases to 80%. This change in probability when the criteria on CPR for success with stabilization are met is shown pictorially in Figure 4.

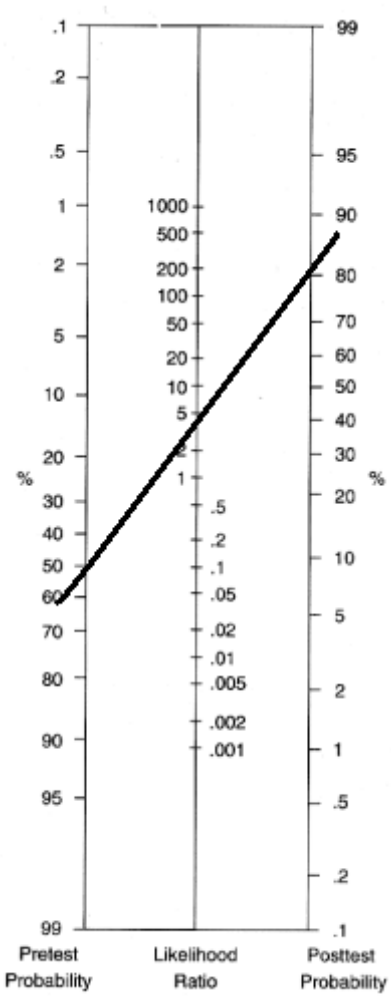

Figure 4. Change in probability of success when 3 out of 4 criteria on the CPR for success with stabilization are met

The CPR also identified predictors for failure with stabilization. Failure with treatment was predicted by presence of a:

1. ***Negative*** **prone instability test**
2. ***Absence*** **of aberrant movement during sagittal plane ROM**
3. ***Absence*** **of lumbar hyper mobility**
4. **FABQ score>9 (higher fear avoidance beliefs are associated with failure)**

The patient is said to have met the criteria for failure if he presents with 3 out of the 4 findings in the CPR. When the criteria is met the probability of failure with stabilization increases to 95% if the pretest probability of failure is assumed to be 50% and given the positive LR of 18.8.

If the CPR for predicting failure with stabilization is not met that is if two or fewer of the predictors are present [Negative prone instability test, Absence of aberrant movement during sagittal plane ROM, Absence of lumbar hyper mobility, FABQ score>9] the probability of failure with stabilization falls from 50% to less than 20%. This change in probability when CPR for failure with stabilization is met or not met is shown pictorially in Figure 5.

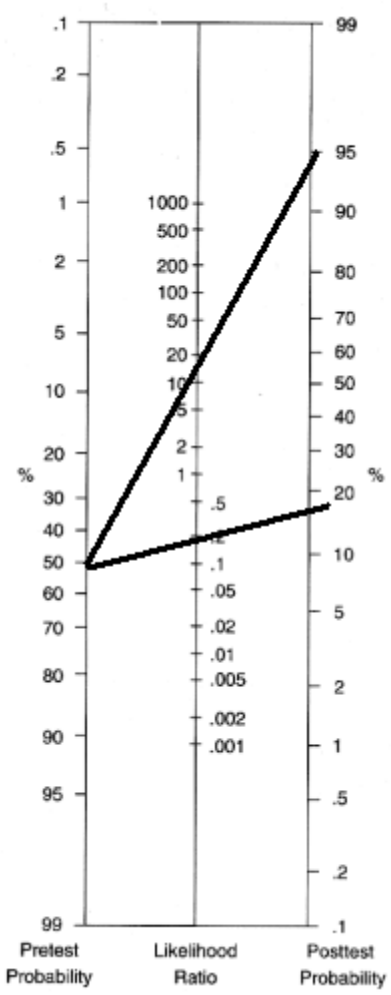

Figure 5. Change in probability of success when 3 out of 4 criteria for the CPR for failure with stabilization are met

2.6.3 Specific exercise

Mckenzie and colleagues first described centralization of back pain (McKenzie 1981). Centralization is the process by which, pain radiating from the spine is sequentially abolished, distal to proximal, in response to therapeutic positions or movements. The opposite response, that is, if the pain moves from the back further down into the legs in response to movement it is called peripheralization.

When a patient centralizes with one movement and peripheralizes with the opposite movement he is demonstrating a directional preference. Directional preference to movement is commonly encountered in the low back pain population. Directional preference is fairly common in the low back pain population. In a meta-analysis Aina et al found a prevalence rate of 70% in acute LBP cases and of 52% in Chronic LBP cases (Aina, May et al. 2004).

The inter-rater reliability of judgments for establishing a directional preference in LBP during movement testing is reported to be excellent (kappa = 0.7 to 1.0) and is not affected by years of clinical experience (Sufka, Hauger et al. 1998; Werneke, Hart et al. 1999; Fritz, Delitto et al. 2000; Kilpikoski, Airaksinen et al. 2002).

The presence of centralization has been shown to be a positive prognostic indicator, and its presence is associated with better outcomes (Werneke and Hart 2001). Due to its reliability and prognostic value it is a very useful tool in identification of patients who will benefit from specific exercises (Aina, May et al. 2004)

There is good quality evidence that when patients are treated with exercises matching their direction of preference they have better outcomes than when they receive unmatched exercises (Long, Donelson et al. 2004; Browder, Childs et al. 2007; Long, May et al. 2008).

In a randomized controlled trail, Long et al examined if direction specific exercises improved treatment outcomes in patients with LBP when compared to patients who received exercises opposite to the established directional preference and to those who received general exercises and stretches. The group that received exercises matched to their directional preference showed greater improvements in outcomes measured by improvements in pain and disability when compared to the other groups (Long, Donelson et al. 2004).

Long and colleagues conducted a secondary analysis of a previous RCT examining a range of factors that were predictive of a favorable outcome when patients were classified and treated according to their directional preference. Subjects with a directional preference/centralization who received matched treatment had a 7.8 times greater likelihood of a good outcome (defined as a minimal reduction of 30% on the Roland Morris Inventory) (Long, May et al. 2008).

Extension directional preference is established when patient reports centralization of pain with extension and peripheralization of pain with flexion. Extension directional preference is more commonly encountered in the clinic. There is definitive evidence supporting use of extension-biased exercises to treat patients with an extension directional preference.

Browder et al conducted a study to evaluate the effectiveness of an extension-oriented protocol in improving outcomes in patients with extension directional preference (Browder, Childs et al. 2007). The study included all patients who had pain in the lower back radiating below the buttock and also demonstrated an extension directional preference. Study subjects were randomly assigned to receive an Extension oriented treatment approach or a general strengthening program.

Patients who received extension based exercises demonstrated significantly greater improvements in disability status (Oswestry) at 1 week, 4 weeks and 6 weeks following treatment when compared to the control group. These patients also had significantly lower pain rating and centralization of pain at 1 week following treatment when compared to the control group. The authors suggest that those patients that centralize with lumbar extension movements may preferentially benefit from an extension-oriented treatment approach.

Flexion directional preference is established when patient reports centralization of pain with flexion, and peripheralization with extension. Patients in this category are often older and may possibly have a diagnosis of Lumbar Canal Stenosis (LCS).

Whitman et al conducted a randomized clinical trail to evaluate the effectiveness of flexion-based exercises to treat back pain when the patient presented with a flexion directional preference during clinical exam (Whitman, Flynn et al. 2006). The authors of the study randomized patients over 50 years of age with a diagnosis of LCS to receive either manual physical therapy, flexion exercise, general lower leg conditioning and a de-weighted ambulation program (MPTExWG) or lumbar flexion exercises, sub-therapeutic ultrasound, and a treadmill walking program without body weight support. (FExWG).

At both time points of outcome measurement, 6 weeks and 1 year, the group that received manual therapy, flexion exercises, general conditioning for lower extremities and body weight supported treadmill exercise reported significantly greater ratings on perceived recovery than those treated by flexion exercises, sub therapeutic ultrasound and walking program.

2.6.4 Traction

There is a lack of evidence to support the use of traction in management of LBP. Several randomized controlled trials have compared traction to sham traction with no significant differences between the groups (Beurskens, de Vet et al. 1995; Beurskens, de Vet et al. 1997; Clarke, van Tulder et al. 2007; Schimmel, de Kleuver et al. 2009).

In the Treatment Based Classification guidelines Delitto and colleagues have recommended that patients who have back pain radiating distally, signs of nerve root compression and absence of centralization with repeated movements would benefit from traction.

Fritz et al conducted a RCT to determine if a sub-group of patients with LBP would benefit from mechanical traction and extension-based exercise (Fritz, Lindsay et al. 2007). The authors included 64 patients having low back pain with radicular symptoms in the study. Patients were randomized to receive an extension-based treatment approach or an extension-based treatment approach with mechanical traction for 6 weeks. The traction group showed a greater reduction in disability and fear-avoidance beliefs at the 2- week follow up.

The authors also looked at predictors of success with treatment with traction. They found that patients who peripheralize with extension and have a positive crossed SLR test had a better likelihood of success. Of these subjects, 84.6% in the traction group had a successful outcome as compared to 45.5% that allocated to the extension group. The authors suggested that patients with sciatica, signs of nerve root compression, a positive crossed SLR test and those who peripheralize with extension are likely to benefit by traction.

2.6.5 Graded exercise for fear avoidance

A patient's fear of pain is sometime more disabling than the pain itself. Fear that activity or return could worsen back pain can lead to a vicious cycle of pain, inactivity and de-conditioning. Several studies have found that presence of elevated fear avoidance beliefs is predictive of chronic back pain, persistent disability and delay in return to work (Linton 2000; Fritz, George et al. 2001; Fritz and George 2002).

The Fear Avoidance Beliefs Questionnaire (FABQ) is a useful tool to identify patients in the clinic with elevated fear avoidance beliefs (Fritz, George et al. 2001; Cleland, Fritz et al. 2008; Calley, Jackson et al. 2010). The FABQ was originally described by Waddell and colleagues and is designed to identify beliefs of patients on how back pain affects their ability to do physical activity and work. It is a 16-item questionnaire, each item scored from 0-6; higher numbers indicate greater fear and avoidance beliefs (96 total points possible). The FABQ has two subscales: the Work Subscale (items 6-7, 9-12, 15), which amounts to 42 points possible, and the Physical Activity Subscale (items 2-5), which amounts to 24 points possible.

Fritz and colleagues conducted a study to evaluate the relationship of fear avoidance beliefs and future disability and return to work status (Fritz, George et al. 2001). The authors found that patients with elevated fear avoidance beliefs measured by the FABQ questionnaire (> 34 on the Work subscale and >14 on the Physical Activity subscale) was predictive of continued disability at 4 weeks and these patients were less likely to return to work. There was a greater association between FABQ status and disability and return to work than self-reported pain or depressive symptoms.

In the TBC guidelines first proposed by Delitto et al in 1995, the authors suggested that elevated fear avoidance behaviors should raise a Yellow Flag in the clinician's mind and that such patients would benefit from graded activity exercises along with counseling (Delitto, Erhard et al. 1995). The choice of intervention would then include strategies that enable confrontation of pain-avoidance behaviors on the part of the patient (such as graded exercises for fear avoidance) in addition to aerobic or general conditioning exercises in order to achieve maximum success with treatment.

Graded exposure treatment includes operant conditioning principles to gradually expose patients to perceived harmful situations or activities. There is some evidence to suggest that graded activity and graded exposure to activities that simulate movements the patient is fearful in daily life and in the work environment can help improve outcomes.

George et al conducted a randomized controlled trial to evaluate the efficacy of an intervention targeted towards alleviation of fear-avoidance behavior in improving outcomes for LBP when compared to standard care (George, Wittmer et al. 2010). Patients who had chief complaint of LBP or LBP and leg pain (onset, within 8 weeks) and were 18-55 years old were included in the study. Patients with nerve root compression, Red Flags or if pregnant were excluded from the study.

Sixty-six patients were randomly assigned to one of two treatment groups

1. **Physical Therapy targeting Fear Avoidance Beliefs:** Back Book educational pamphlet to target fear avoidance beliefs, graded exercises designed to enable the patient to confront the pain.
2. **Standard Care:** Handy hints educational pamphlet, exercises progressed on basis of reported pain intensity before and after exercise.

Outcomes measured were that of disability (Oswestry Disability Questionnaire), Pain (Numeric pain rating scale), Fear Avoidance Beliefs Questionnaire. At 4 weeks and 6 months both groups had significant improvements in pain and disability status. Patients who had High fear avoidance beliefs at baseline and were treated with Fear Avoidance Based PT demonstrated significantly greater reductions in disability and pain compared to patients who did not receive matched treatment. Patients who received fear avoidance based physical therapy also had a greater positive shift in fear-avoidance beliefs. This study demonstrates effectiveness for fear-avoidance directed patient education and emphasizes the importance of matching intervention to appropriate patients.

Leeuw et al demonstrated similar results for graded exposure and graded activity in patients with chronic low back pain. Effectiveness was maintained at short and long- term follow-up (Leeuw, Goossens et al. 2008).

The authors specifically evaluated the effectiveness as well as specific mediating mechanisms of graded exposure (GE) versus operant graded activity (GA) directly and 6 months post-treatment in a multi-centre randomized controlled trial. In total, 85 patients suffering from disabling non-specific CLBP reporting at least moderate pain-related fear were randomly allocated to GE or GA. The authors found that both groups had significant improvements in altering pain catastrophizing and perceived harmfulness of activities is clearly established but the groups were not significantly different.

This is line with other studies that have found behavioral intervention more effective than no treatment at all but there is no evidence that one is better than the other (Moseley 2002; Smeets, Vlaeyen et al. 2006; Smeets, Vlaeyen et al. 2006; Godges, Anger et al. 2008; Leeuw, Goossens et al. 2008; Vong, Cheing et al. 2011).

In a recent Cochrane Review, Henschke et al, concluded there is moderate evidence that operant therapy and behavioral therapy are more effective than waiting list or usual care for short term pain relief in patients with chronic low back pain, but no specific type of behavioral therapy was found to be superior than another (Henschke, Ostelo et al. 2010). In the intermediate to long term, there was no established difference between behavioral therapy and group exercise for management of pain or depressive symptoms in patients with chronic low back pain.

In another controlled trial Godges, et al specifically looked at the treatment of patients with occupational related acute low back pain having elevated fear avoidance beliefs (Godges, Anger et al. 2008). All subjects received standard physical therapy including strengthening and ergonomic exercise. One half additionally received ongoing education and counseling with emphasis on the positive natural history of low back pain and that activity helps decrease the duration of episode.

Results of the study demonstrated that all workers in the education group returned to work within 45 days. A third of the workers in the control group did not return to work at the 45-day time point. This study provides further evidence for the effectiveness of education and counseling for patients with low back pain with elevated fear avoidance beliefs.

2.7 GAPS IN QUALITY OF CARE OF LOW BACK PAIN

Low back pain has been identified as a priority condition for quality improvement initiatives by the Institute of Medicine (IOM 2001). In the management of low back pain “best care” delivered on the basis of evidence in literature should ideally increase the likelihood of functional restoration, reduce pain, and prevent incidence of recurrence. Providing good quality of care could also reduce costs associated with treatment by minimizing the number of required visits required per episode, reducing care seeking behavior, need for imaging, ensuring quick return to work and minimizing the number of days taken off from work.

Considering that LBP is a common condition that is very expensive to treat it is important to first characterize the quality of care delivered to patients with LBP in order to plan implementation strategies to improve quality. Several studies have documented delivery of sub-standard quality of care in management of LBP (Battie, Cherkin et al. 1994; Jette and Delitto 1997; Jette and Jette 1997; Mielenz, Carey et al. 1997; Li and Bombardier 2001; Swinkels, van den Ende et al. 2005; Fritz, Cleland et al. 2007; Rutten, Degen et al. 2010; Derghazarian and Simmonds 2011; Freburger, Carey et al. 2011; Hendrick, Mani et al. 2012).

If quality of low back pain were to be evaluated with the new definitions of quality we find several areas of misuse, overuse and underuse.

2.7.1 Over use of medical Imaging

Extensive research on back pain in the past has shown that the identification of the source of back pain may not necessarily guide treatment. In one study, MRI scans revealed herniated discs in 36%, spinal stenosis in 21% and degenerated or bulging disc in over 90% of asymptomatic

persons greater than 60 years of age. Also, 20% of the asymptomatic subjects less than 60 had herniated discs and 35% had degenerated discs (Boden, Davis et al. 1990). Clearly, the identification of structural abnormalities in the spine does not correlate with clinical symptoms.

Also, since the results of an MRI do not change the course of treatment its use simply adds to the economic burden of LBP. In fact, medical imaging like MRI is now only reserved in the presence of red flags such fever and back pain or back pain in an older adult with a past history of cancer (Flynn, Smith et al. 2011). Despite this a recent study in the Journal of the American College of Radiology found that 35% of the MRI scans ordered for back pain were inappropriate and unnecessary (Lehnert and Bree 2010).

2.7.2 Over use of stabilization exercises

An active approach to treatment of low back pain is recommended however many times physical therapists prescribe the same exercises irrespective of the patient's clinical presentation (Battie, Cherkin et al. 1994; Jette and Delitto 1997; Li and Bombardier 2001; Swinkels, van den Ende et al. 2005). Recent evidence suggests that some patients fit the profile for stabilization exercises while others may need exercises based on their directional preference to pain (Hicks, Fritz et al. 2005). Hence a one-size fit all approach to exercises would be considered an overuse of health care resources.

It could be argued that overutilization of stabilization is not harmful so why identify it as a quality issue. However not receiving appropriate treatment at the first visit and receiving general stabilization exercises without consideration to distribution of pain pattern and elevated fear avoidance beliefs could lengthen the episode of low back pain, lead to worsening symptoms and also increase associated expenditure for episode of care.

2.7.3 Misuse of passive modalities

Historically, management of LBP was based on the acute pain model, which attempted to identify the source of pain in the diagnostic process. The treatment was directed towards enabling tissue healing and enabling reduction of pain. The treatment recommendations included bed rest and use of passive modalities like heat and electrotherapy to manage pain.

The focus of treatment of back pain has made a paradigm shift away from the acute pain model. The numerous clinical practice guidelines for back pain published over the years have discouraged the use of passive modalities such as heat, ultrasound, TENS, Ice and IFT, which have no proven benefit in the management of low back pain. In fact some studies suggest that it is detrimental to patient recovery.

Several studies have documented frequent use of passive modalities in the management of low back pain (Battie, Cherkin et al. 1994; Jette and Delitto 1997; Mielenz, Carey et al. 1997; Li and Bombardier 2001; Derghazarian and Simmonds 2011; Freburger, Carey et al. 2011).

In a recent study that evaluated utilization of physical therapy services for low back pain in the United States, Freburger and colleagues reported that heat treatment was used in 50%, cold in 41.4%, electrical stimulation in 31.5%, Ultrasound in 25.5% and TENS in 27.4% of the low back pain cases (Freburger, Carey et al. 2011). While these percentages are lower than those reported by Mielenz et al in 1997 they are still very high (Mielenz, Carey et al. 1997).

Fritz and colleagues (Fritz, Cleland et al. 2007) conducted a study to evaluate if patients treated with active versus passive approach to treatment for LBP, resulted in improved clinical outcomes (greater improvement in disability and pain status) and lowered costs. Active treatment included use of exercise and manual therapy and passive included use of passive modalities such as physical agents, ultrasound and TENS. Only 40% of the patients with LBP received adherent

care i.e. active forms of treatment such as exercises and manual therapy, while most patients with LBP received passive modes treatment. Patients who received adherent care demonstrated significantly greater reductions in disability and improvements in pain status and had lower treatment charges when compared to patients who received non-adherent care.

Rest, and the use of passive treatment until recovery, is likely to lead to a vicious cycle of pain-inactivity and de-conditioning. This is believed to be the likely cause of chronic pain and continued disability. Continued use of passive modalities can be classified as a misuse of health care resources.

2.7.4 Underuse of grade V thrust mobilization

The current clinical practice guidelines recommend the use of thrust mobilization particularly in acute low back pain when onset of pain is less than 16 days and no symptoms beyond the knee (Delitto, George et al. 2012). Even back in 1994 when the AHCPR published guidelines for management of acute low back pain, although the same quality of evidence did not exist to support the use of spinal mobilization in a specific sub-group of patients with back pain the recommendation was that "Manipulation can be helpful for patients with acute low back problems without radiculopathy when used within the first month of symptoms" (Bigos S 1994). Despite this recommendation the reported use of spinal mobilization has been between 2-10% between 1997 and 2001 (Jette and Delitto 1997; Li and Bombardier 2001; Freburger, Carey et al. 2011).

Li et al conducted an exploratory survey to characterize physical therapists' reported management of acute and sub acute lumbar impairment (Li and Bombardier 2001). The authors used 3 clinical vignettes (acute, sub acute and acute with sciatica) to record the therapists

understanding of the patient profile and determine their treatment preferences for that profile. Although 30% of the therapists reported that spinal mobilization is an effective treatment for low back pain, less than 5% selected spinal mobilization to treat an acute case of low back pain without radiculopathy and no red flags.

2.7.5 Underuse of identification of yellow flags and bio-psychosocial approach to back pain

Current guidelines recommend identification of a yellow flags and moving away from the biomedical orientation that encourages fear avoidant behavior (Delitto, George et al. 2012). Studies have shown that physical therapists with elevated fear avoidance beliefs tend to make guideline discordant recommendations regarding return to usual activity and return to work (Linton, Vlaeyen et al. 2002; Derghazarian and Simmonds 2011).

Derghazarian et al conducted a study to characterize physical therapists attitudes and beliefs about the bio-psychosocial problem of low back pain (LBP), and the extent to which their advice and treatment is in line with practice guidelines (Derghazarian and Simmonds 2011). The bio-psychosocial and bio-medical orientation was measured in 108 physical therapists using 2 questionnaires; The Pain Attitudes and Beliefs Scale for Physiotherapists and the Attitudes to Back Pain Scale for musculoskeletal practitioners. In addition, participants responded to questions about treatment recommendations for patients in two clinical vignettes one with a moderate risk and the other with a low risk of developing disability based on the presence of fear avoidant behaviors.

The authors found that only 12% of the physical therapists in the study were aware of the recommendation for identification of yellow flags. Physical therapists with a stronger

biomedical orientation scored the severity of spinal pathology higher in the patient vignettes. A stronger biomedical orientation was also associated with disagreement with recommendations to return to usual activity or work.

All these examples in low back literature demonstrate that there exists a large discrepancy between what is considered to be “best practice” for management of LBP in physical therapy and “real practice”. Immediate steps are necessary to enable implementation and adoption of clinical practice guidelines into clinical practice to improve low back pain outcomes.

2.7.6 Barriers to LBP guideline adoption by physical therapists

In general, physical therapists seem to have a favorable attitude towards Evidence Based Practice (EBP) and believe that EBP can improve treatment outcomes (Jette, Bacon et al. 2003; Stevenson, Lewis et al. 2004). Despite this positive attitude clinical practice patterns do not reflect the use of evidence to guide treatment. Some of the most important reasons reported as barriers to implementation of EBP are lack of time (Jette, Bacon et al. 2003; Stevenson, Lewis et al. 2004), inability to generalize practice guidelines to individual patients (Jette, Bacon et al. 2003), lack of confidence in critically appraising literature and difficulties in interpreting journal articles due to statistical terminologies (Stevenson, Lewis et al. 2004).

In a study by Stevenson et al (Stevenson, Lewis et al. 2004), attitudes of physical therapists towards EBP were measured through self report at baseline and after an intervention targeted towards improving knowledge and skill in conducting evidence based literature searches and critical appraisal. A control group that received standardized information on the knee was used for comparison. Although physical therapists reported that EBP was useful and important in making clinical decisions there was no change observed in their management approach. Physical

therapists reported that they would prefer to attend training programs that delivered current evidence on management of specific conditions rather than “spend time during the working day” on performing literature searches.

McCluskey et al (McCluskey and Lovarini 2005) conducted a study to evaluate if teaching occupational therapists(OT) to procure evidence would lead to greater adoption of EBP. A hundred and six occupational therapists attended a 2-day workshop on evidence-based practice. The workshop include lectures practical sessions and group discussions on topics of evidence based practice, writing clinical questions, searching databases, critical appraisal of research, interpreting statistics and overcoming barriers in making change to evidence based practice. The workshop sessions were followed up with outreach visits, email and telephone. This study found significant improvements in knowledge/ competence, however there were no changes observed in behavior. The most important reasons for not being able to change behavior were documented as lack of time and lack of self-efficacy in appraising and searching literature.

These studies indicate that due to lack of time to conduct literature searches and difficulties with interpreting literature physical therapists need an alternative approach such as structured guidelines to keep abreast with current evidence. The AHCPR have developed and disseminated guidelines to aid health care practitioners in making evidence based clinical decisions, however these guidelines were prepared in 1994 which. Since these guidelines were released, there have been modest improvements in the reduction in use of diagnostic imaging and recommendation for bed rest by physicians. However the guidelines have had little impact on the practice behaviors of physical therapists (Li and Bombardier 2001). The lack of effect of the guidelines on PT practice was most likely because at the point of formulation of these guidelines there was limited and contradictory evidence for the use of therapeutic interventions.

Since then Delitto et al have published clinical practice guidelines for management of LBP that are specific to physical therapy and include evidence for identification of specific sub-groups of patients likely to respond to treatment. The primary goals of this study are to evaluate if an active intervention strategy to implement the recently released clinical practice guidelines can improve competence, adherence and also improve patient outcomes.

3.0 PILOT STUDIES

Section 3.1 presents results of a pilot study undertaken to characterize the quality of care delivered to patients with LBP. Specifically, we compare current practice to the ideal practice based on clinical decision-making rules in the practice guidelines. The results of this study served as a needs assessment for development of courses in the Educational Intervention.

In **Section 3.2** we present the results of a pilot study undertaken to assess the reliability and validity of a multiple choice competence exam developed as a measure of competence in the practice guidelines.

3.1 PILOT STUDY 1

A CROSS SECTIONAL STUDY TO CHARACTERIZE THE QUALITY OF CARE DELIVERED BY PHYSICAL THERAPISTS TO PATIENTS WITH LBP

3.1.1 Background

Low back pain has been identified as a priority condition according to the quality chasm report by the IOM for quality improvement initiatives. A number of studies have demonstrated significant variations in practice patterns in management of LBP (Battie, Cherkin et al. 1994; Jette and Jette 1997; Mielenz, Carey et al. 1997; Li and Bombardier 2001). A recent study by Fritz and colleagues (Fritz, Cleland et al. 2007) reported that only 40% of patients with LBP received care consistent with guidelines developed for management of LBP. Patients who received care consistent with guidelines demonstrated significant improvements in self-reported disability status and perceived pain and required fewer visits for the treatment episode when compare to those who received treatment inconsistent with the guidelines. The cost of care was significantly lower for the patients who received adherent care. The results from this study indicate that currently adherence to LBP guidelines is very poor. If patients are treated according to the recommendations in the guidelines there is a potential to improve treatment outcomes as well as reduce costs associated with management of LBP.

In a more recent study by Rutten et al, the authors found that guideline adherence was related to better improvement of physical functioning and to a lower utilization of care. Quality improvement initiative targeting the physical therapists that manage patients with LBP could

include outcome-based continuing education programs that provide an opportunity to actively disseminate practice guidelines for LBP.

In order to plan and implement such outcome based educational programs it is essential to measure the current clinical performance in management of LBP. **Needs assessment** entails identification of gaps between current practice behavior and accepted standard of practice (Norman, Shannon et al. 2004). These gaps in knowledge can be measured through competency examinations (Norman, Davis et al. 1993) or more data driven methods such as medical chart audits and benchmarking and these methods are considered to be more valid and reliable (Davis, Thomson et al. 1992; Davis, Thomson et al. 1995; Davis and Taylor-Vaisey 1997; Norman, Shannon et al. 2004). Assessment of therapist performance can help quantify the gaps in quality of care in management of LBP. The content and delivery of the educational program can then be designed to fill the gaps in quality of care. Thus measurement of the therapist's performance prior to planning the content of the course is essential to identify specific educational needs of the therapists with regards to management of LBP.

Few studies till date have utilized clinical data for assessment of educational need prior to planning the educational intervention. Several studies have utilized self-reports of perceived educational needs. Even fewer have used clinical vignettes as an assessment of educational need. Self-report is not accurate estimation of educational need and clinical vignettes measure knowledge. It is possible that knowledge is not necessarily reflected in behavior. Hence in order to plan outcome based continuing education course it would be useful to develop a measure of the clinicians performance. Surveillance and tracking of the clinician's performance in the clinic will allow us to quantify the gaps in quality of performance prior to planning the educational intervention. Areas where clinical performance is poor can be considered as priority areas where

additional coaching is required. In addition such data can also be used to develop benchmarks where the clinicians performance in compared to his peers. This strategy may serve as a motivating force for clinicians to improve their performance in the clinic.

In order to quantify the quality of PT care being delivered to patients with LBP we designed a cross sectional study to measure the degree to which patients with a chief complaint of LBP received care in accordance with practice guidelines for management of LBP.

3.1.2 Methods

3.1.2.1 Study subjects

Study subjects included a cohort of patients who were treated for LBP at the Centers for Rehab Services, in Pittsburgh, for a period of three months.

3.1.2.2 Data extraction

Patient records entered by physical therapists into the UPMC database were sampled for a period of three months. Demographic, history and physical examination data recorded at first and last visit for all patients treated for Low back pain from 06/01/2007 to 09/18/2007 were extracted from the database. The minimum data set used for extraction of patient data is attached in APPENDIX A. Patients were identified by the ID number, and by the treating physical therapist. Patients who were post surgical were excluded.

3.1.2.3 Determination of adherence to guidelines

For purpose of assessment of adherence to guidelines we developed quality indicators for PT management of LBP based on the TBC practice guidelines and is attached in APPENDIX B.

Based on the clinical information documented during the patient's first visit the patients were classified into treatment sub-groups (spinal mobilization, stabilization, directional preference, traction and bio-behavioral) according the practice guidelines. The classification of patients into the treatment sub-group was conducted by a trained physical therapist blinded to the treatment given to the patients. The treatment given to the patient during this first PT visit was then compared to the treatment they should have ideally received based on the guideline. If data on any of the variables of interest were missing and the status on rule could not be established for this patient then these data were not reported and were excluded from further analysis.

3.1.3 Data analysis

The patients were categorized into 6 classifications according to the guidelines. These were Grade V thrust mobilization, stabilization, flexion directional preference, extension directional preference, traction and graded exercises for fear avoidance. If the classification and treatment matched it was identified as on-protocol or adherent care, if not it was identified as off-protocol or non adherent care. On-protocol was defined as patients who received care appropriately and also those who did not receive treatment when it was not indicated.

Patients who received treatment appropriately (On protocol)

- Patients who received treatment when they should (appropriately received, OnP1)
- Patients who did not received treatment and did not need treatment (appropriately did not receive, OnP2)

Off-protocol was defined as patients who did not receive treatment when indicated and vice versa. Also, use of passive modalities such as ice, heat and TENS was classified as non-adherent care.

Patients who received treatment inappropriately (Off protocol)

- Patients who did not receive treatment when they should (Underuse)
- Patients who received treatment when they should not (Overuse)
- Patients who received treatment with passive modalities that are proven to be ineffective in management of LBP such as ice, heat, ultrasound, TENS. (Misuse)

We calculated the percentage of adherence to guidelines within each classification using the formula given below.

[OnP1+OnP2 /N]* 100

An overall adherence to guideline was calculated by computing a weighted mean (weighted by number of patients in each group) of the adherence across all 6 classifications.

3.1.4 Results

In the three-month period, 265 patients had received treatment for LBP. Of these 35 were post-surgical patients and were excluded from the study (13.2%). The final data set contained 220 patients. **Overall adherence to guidelines across the 6 groups in the classification scheme was 68.46%. When evaluated according to each classification subgroup percentage of**

adherence varied from 56%-86%. The number of patients in each cohort, the treatment given and the percentage of adherence to guidelines for each classification summarized in the Table 2.

Table 2. Summary of results of needs assessment: Pilot Study

		Should be given treatment			Should not be given treatment	
	Met criteria	Given On Protocol	Not Given **Underuse**	Did not meet criteria	Given **Overuse**	Not Given On Protocol
Grade V thrust	27	3	24 88%	183	4 2.18%	179
Stabilization	23	17	6 26.0%	189	149 78.83%	40
Flexion directional preference	22	17	5 22.7%	198	56 28.2%	142
Extension directional preference	14	13	1 7.14%	196	41 20.91%	155
Traction	30	2	28 93.3%	190	7 3.68%	183
Graded exercise for fear avoidance	64	0	64 100%	83	0 0%	83
Overuse: Given when not needed Underuse: Not given when not needed						

3.1.4.1 Grade V thrust

The overall percentage of adherence to the guideline for grade V thrust mobilization was 86.66% for all patients who received thrust mobilization appropriately and for those who did not receive it when it was not recommended. Of 220 patients, 27 were eligible for spinal mobilization. Of the 27 patients eligible for thrust mobilization only 3 received the appropriate treatment

(11.11%). Out of 183 patients who were non-manipulative candidates 4 patients received thrust mobilization (2.18%). Results indicated that within the proportion of non-adherent care thrust mobilization is mostly underused. Of 27 patients who were eligible for thrust mobilization 24 did not receive it (88%).

3.1.4.2 Stabilization

The overall percentage of adherence to the guideline for stabilization was 26.88% for all patients who received stabilization appropriately and for those who did not receive stabilization when it was not recommended. Of 220 patients, 23 were eligible for stabilization exercises. Of the 23 patients eligible for stabilization 17 received the appropriate treatment (73.91%). However a large number of patients also received stabilization even though it was not recommended (78.93%). This suggests that stabilization is overused as a treatment option for management of LBP.

3.1.4.3 Flexion directional preference

The overall percentage of adherence to guideline was found to be 72.27%. Of 220 patients, 22 demonstrated flexion directional preferences. Seventeen of the 22 patients received appropriate treatment (72.27). Proportions of underuse and overuse were relatively lower for this classification group, (22.72% and 28.27% respectively)

3.1.4.4 Extension directional preference

The overall percentage of adherence to guideline was 84.09%. Of 220 patients, 14 demonstrated extension directional preference. Thirteen of the 14 patients received appropriate treatment

(92.85%). Proportions of underuse and overuse were relatively low for this classification group, (7.14% and 20.91% respectively).

3.1.4.5 Traction

The overall percentage of adherence to guideline was found to be 84.09%. Of 220 patients, 30 were eligible to be treated with traction. Only 2 of these 30 patients received appropriate treatment (6.66). Traction was mostly underused, as 93.33% of the patients eligible for traction did not receive appropriate care.

3.1.4.6 Graded exercise for fear avoidance

The overall percentage of adherence to use of graded exercises when indicated was found to be 56.84%. This intervention was underused to a very large extent. In fact none of the patients eligible for this intervention received appropriate care.

3.1.5 Discussion

These results indicate that there is significant variation in practice patterns of physical therapists approach to management of LBP. This is consistent with previous studies that have demonstrated significant variation in practice pattern of PT in treatment of LBP. Fritz and colleagues reported that adherence to LBP guidelines was only 40.4%. The authors defined adherence as use of greater proportion of active interventions per visit without consideration to specific responder groups. The purpose of the current study was to characterize the degree to which patients received care consistent with current guidelines for management of LBP accounting for subgroups of patients who would respond to specific interventions.

We found the overall adherence to guidelines to be modest (68.46). We classified non-adherent care into three categories; Underuse, Overuse and Misuse. Our results indicate that spinal mobilization, traction and graded exercise for fear avoidance are most underused (88%, 93.33% and 100% respectively). Stabilization exercises were most commonly utilized for patients regardless of their clinical presentation and hence this approach to treatment was highly overused (73.83%). Directional preference exercises had a relatively lower rate of under/over use compared to other classifications, suggesting that therapists may be relatively competent in identifying patients who are likely to benefit or not benefit from this treatment approach.

Clinical guidelines are published with the intention to increase the clinician's awareness regarding recent evidence in literature and to decrease variation in practice patterns. It appears that in its current state the quality of care delivered to patients with LBP does not reflect the recommendations made in the practice guidelines for LBP. The results of this study indicate that there is a need for active dissemination of clinical practice guidelines for LBP. Active dissemination of practice guidelines can be accomplished by modeling a course to provide detailed information regarding the statement summaries contained in the practice guidelines.

This study also served as an assessment of the educational needs of physical therapists who manage patients with LBP in order to plan the course content. The results of this study indicate that the major sources of variation in practice patterns of physical therapists arise from underuse of spinal mobilization, traction and graded exercise for fear avoidance, an overuse of stabilization and misuse of passive modalities such as ice, heat, ultrasound and TENS. An educational course that aims at improving quality of care should provide the clinicians with detailed clinical decision rules to support use of each of these interventions and specifically outline the clinical characteristics of the patients who are expected to improve with each of these

treatments based on what current evidence defines. Measuring a decrease in the occurrences of non-adherent care following the educational intervention can assess effectiveness of the education program.

3.2 PILOT STUDY 2

EVALUATION OF THE FACE AND CONTENT VALIDITY OF THE COMPETENCE TEST

3.2.1 Background

The purpose of this pilot study was to develop a tool that measures competence in Physical Therapy professionals for the management of low back pain (LBP) based on the Treatment Based Classification approach to treatment of LBP.

The primary aim of the study was to develop two parallel forms that would measure the same constructs. This would allow us to administer one test as a baseline measurement of competence and the other as a posttest measurement following participation in a continuing educational program while avoiding the “practice” effect. Using separate forms that measure similar constructs for baseline and posttest measurement will eliminate any contamination due to recall bias on the posttest scores.

Since we are evaluating knowledge gained through a continuing education program we wanted to see if greater knowledge led to higher scores on the exam. So we also evaluated if

final year physical therapy students performed significantly better than first year students on the competence exam.

Final year students have taken advanced courses in the management of LBP. These courses include evidence-based management of LBP and principles of clinical decision making in management of LBP, similar to the continuing education course that will be developed for the physical therapists in our future study. Hence it was hypothesized that final year students would score significantly higher than first year students in the competence exam.

3.2.2 Hypothesis 1

Form A and Form B are equivalent

3.2.3 Hypothesis 2

Final year students would demonstrate significantly higher scores on the competence exam when compared to first year students

3.2.4 Methods

3.2.4.1 Subjects

Eighty-seven Physical Therapy students (first year=45, final year=42) from the School of Health and Rehabilitation Sciences at the University of Pittsburgh were given the exam on October 19th and 27th of 2007.

3.2.4.2 Test formulation

The competency examination tool was designed to measure knowledge in the classification-based approach to treatment of LBP. The competence exam included questions that targeted measurement of PT knowledge in screening of patients eligible for treatment, screening of patients who have neurological or hip involvement and classification of patients into treatment sub-groups defined in the classification scheme.

The first draft of the test included 38 multiple-choice questions with 4 answer choices for each question. The questions on the test were reviewed by two physical therapists for content and validity. The test was then reviewed by 10 physical therapy students for clarity and ease of comprehension of test questions. Minor changes to the test were made to improve the test for ease of comprehension and testing.

The test contained three sections:

Section 1 of the test, items, had 8 questions. These questions evaluated the therapist's ability to develop preliminary hypotheses during the patient interview with regards to *identification of patient's eligibility for physical therapy.* The first two items' (i=2) content domain were identification of Non-musculoskeletal causes of LBP. The rest of the section had items in the following areas: fear-avoidance behaviors (i=2), neurovascular compromise (i=2), and differential diagnosis of LBP and hip dysfunction (i=2).

Section 2, contained 6 questions that evaluated the therapist's ability to develop preliminary hypotheses regarding the appropriate clinical classification of patients likely to respond to spinal mobilization (i=2), stabilization (i=2), and directional preference (i=2).

Section 3 included 24 structured clinical scenarios that present information collected during a hypothetical patient history and physical examination. These questions evaluated the

ability to identify non-musculoskeletal causes of LBP (i=2), fear-avoidance behaviors (i=2), differential diagnosis of LBP and hip dysfunction (i=2), ability to interpret results of clinical diagnostic tests (i=10) and classification of patients into appropriate treatment groups; spinal mobilization (i=2), stabilization (i=4) and directional preference (i=2).

The initial draft of test items (n=38) were divided evenly into two parallel forms (A and B) containing 19 questions each (part 1= 4, part 2= 3 and part 3= 12). The content covered on both forms was designed to be equivalent. The development of two parallel forms will allow us to administer one for the pre-test and the other for the post-test.

3.2.4.3 Test scoring

Total score on test is calculated by summing the score on each part. No partial credit was given and the scoring was dichotomous (right or wrong).

3.2.4.4 Test administration

The tests (test A and B) were administered to 86 PT students from the first and final years of the physical therapy doctoral program. The days the test was administered for the first years was October 19 2007 and October 27 2007 for the final years. Both forms were administered at the same time in order to eliminate unreliability due to occasion. We did not attempt to control for students skipping questions in the exam. If a question were not answered then it would be marked as the wrong answer.

3.2.5 Data analysis

3.2.5.1 Hypothesis 1

Equivalence of forms A and B

The test was first evaluated for degree of internal consistency. This was conducted by computing the Cronbach's alpha for the test when administered at once (Form A + Form B, i=36). The test items were then separated into Form A (i=18) and Form B (i=18) and a measure of internal consistency for each was calculated. Equivalence between Form A and Form B was evaluated using a paired sample t-test (test variable1=scores on Form A, test variable2 =scores on Form B). A Pearson's correlation co-efficient was calculated between forms for all students.

3.2.5.2 Hypothesis 2

Final year students will demonstrate significantly higher scores on the competence test compared to the first year students.

An Independent sample t-test with the total score on the test (Form A+ Form B) as the test variable and the year (first or final) as the grouping variable was conducted to evaluate if final year students scored significantly higher than first year students in the competence exam. In addition we converted the raw scores on the exam to a percentage and assumed that if a student had received a score of 70% or greater on the competence exam he or she was competent in the required knowledge for management of LBP. The proportions of competent and non-competent students were compared for the two groups of students (first and final years) using a chi-square test.

3.2.6 Results

Eighty-seven students took the competence exam. Of these 45 were first year students and 42 were final year students. Only one student had left a question unanswered and this answer was marked as the wrong answer for the student. All other data were complete for the remaining students (98.8%).

Two items were removed from the test as students reported that they required them to apply statistical concepts to answer the question and this may not be practical for clinicians. Since the items tested equivalent content and each were on a different forms the sub-tests were still equivalent. The test now contained 36 items, 18 on each form. The effect of item removal is given in APPENDIX F. The composite reliability for both forms was high, ($_{\text{chronbachs}}\ \alpha = .819$). When the test was divided into two forms, Form A and Form B, the measure of internal consistency was still moderate for both forms, ($_{\text{chronbachs}}\ \alpha = .703$ and $_{\text{chronbachs}}\ \alpha = .692$ for Form A and Form B respectively).

Since the two forms, Form A and Form B, were developed to measure the same constructs we hypothesized that the students would score equivalently on each form. This hypothesis was confirmed. The mean scores on Form A and Form B were 11.07 and 11.03 respectively. The results of the paired samples t-test indicated that there were no significant differences between the results of each student on two forms (t (85) = .124, p = .902). The correlation between Form A and Form B was moderately high (r (85) = .665, $p < 0.001$).

The results of a independent samples t-test with the total score on the test as the test variable and the year (first or final) as the grouping variable indicated that final years (M = 27.21, SD = 2.15) had significantly higher scores than first year students (M = 17.22, SD = 3.59)

on the competence exam (t (84) = 15.527, p < 0.001, 95% CI: 11.25 - 8.71). These results confirm our second hypothesis that the final year students would demonstrate significantly higher scores compared to the first year students on the competence exam. When assessed in terms of competence (score>70%) a significant proportion of final year students were competent compared to the first year students (78.6% vs. 2.3%, p<0.001). Results of the competence exam in first and second year physical therapy students are graphically shown in Figure 6.

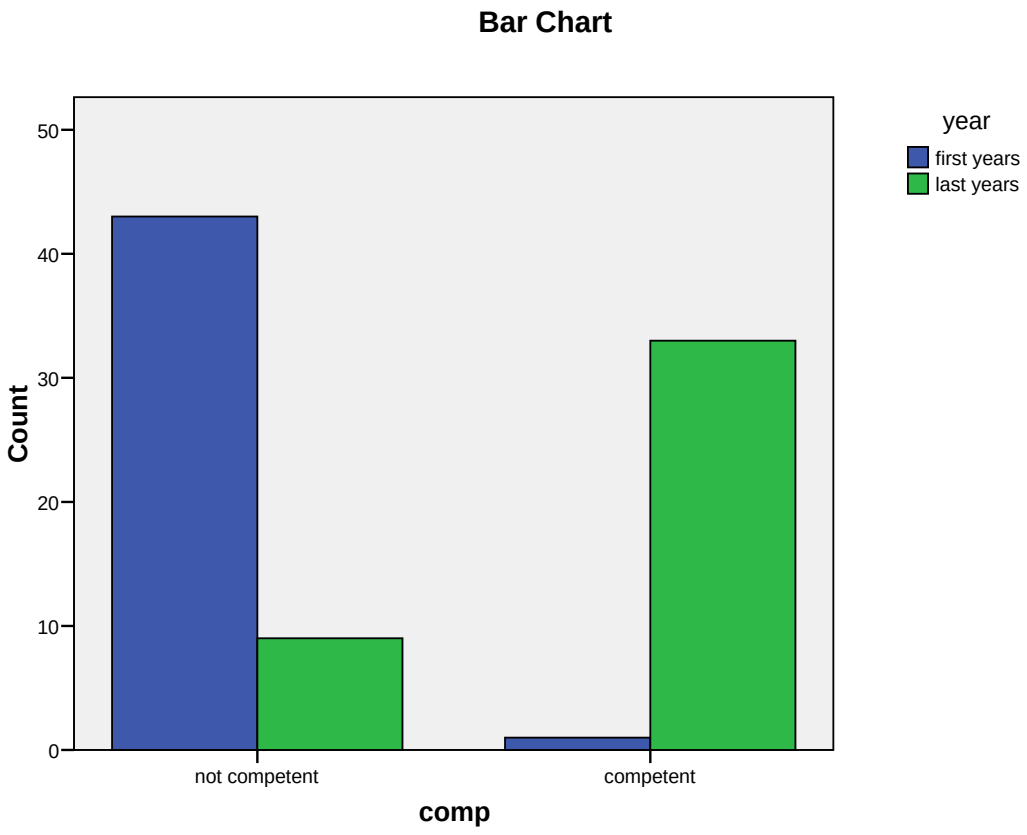

Figure 6. Competence in first and final year physical therapy students: Pilot study

3.2.7 Discussion

The results of the study indicate that the questions on the two competency assessment exams created are similar in content and can be used to measure similar constructs in assessment of knowledge of physical therapists in management of LBP. The final year students demonstrated significantly higher scores on the competency assessment exam. This is a reflection of greater knowledge in the content domains assessed after having completed an advanced course in management of LBP. The competence exam was also able to differentiate competent students from incompetent students with a cut off percentage of 70%.

Previous studies that have evaluated competence in physical therapists have done so using a single case scenario or a limited number of structured cases to assess competence in physical therapists knowledge in management of LBP. Knowledge is dynamic and hence results of newer research need to be incorporated into competency assessments. We have developed a competence tool that can be use to evaluate knowledge in physical therapists for management of LBP according to the current available evidence in literature.

3.3 SUMMARY OF CONCLUSIONS OF PILOT STUDIES

The pilot studies were undertaken to evaluate physical therapists' knowledge of evidence based interventions (competence test) and to characterize the extent to which physical therapists utilize evidence based interventions for management of LBP in the clinic (audit). The results of this study served as an assessment of needs for planning the content of the educational material in the current study. The competence test and quality indicators developed in the pilot were used as primary outcomes in the current study to measure knowledge and process of care of physical therapists in management of LBP.

4.0 METHODOLOGY

4.1 EXPERIMENTAL DESIGN AND SUBJECTS

4.1.1 Study design

The study had a cluster randomized multicenter design. ***Clinics (level 3)*** were randomized to the control or intervention arm of the study. The ***therapists (level 2)*** were nested within clinics and ***patients (level 1)*** were nested within therapists.

We used cluster randomization at the clinic level specifically to prevent cross-contamination within the study. For example, if two therapists from a clinic were to be randomized to different interventions they could share study material leading to contamination.

Also therapists working at the same clinic may have similarities in knowledge, choice of practice techniques and skills. Similarly patients clustered within a therapist, that is patients treated by a therapist may have similar outcomes. This is called the within group correlation and to account for this we chose to randomize by clinic rather than by therapist.

4.1.2 Recruitment of clinics

All outpatient physical therapy clinics at Centers of Rehab Services were invited to participate in the study. The clinical facility directors and the therapists who agreed to participate signed a consent form approved by the Institutional Review Board of University of Pittsburgh. The informed consent used in the study is appended in APPENDIX C.

4.1.3 Randomization

Since the randomization was done at the level of the clinic we assigned clinics to the treatment or control group after being blocked by cluster size. The clinics were randomized to either receive the active intervention (education, audit and feedback) or to receive mailed practice guidelines (control).

All study subjects (therapists) were required to complete the baseline competence test online prior to randomization. This competence test included a demographic questionnaire and 18 questions included in the competence test.

4.2 INTERVENTION

4.2.1 Standard dissemination

Therapists in the control group received mailed practice guidelines that included algorithm that defined the approach to patient care for low back pain.

4.2.2 Active strategy

The active strategy included education, audit and feedback.

4.2.2.1 Continuing education

Subjects in the intervention group completed an online continuing education course designed to implement the practice guidelines. The course consisted of 8 training modules, 3 of which were introductory and 5 of which were advanced. The modules were hosted at the University of Pittsburgh Health Sciences e-Learning Environment. The therapists were provided a username and password to login and complete the modules.

The modules consisted of PowerPoint presentations, recorded lectures, interactive case presentations and discussions of research articles that supported recommendations in the practice guidelines. Each module was preceded by a pre-test and followed by a post-test to evaluate learning. The pre-and post-test questions were the same for each module and were in the form of objective multiple-choice questions. The therapists were required to achieve a pass percentage of 80 on the posttest in order to have successfully completed the module. The therapists had 12 weeks to complete the modules.

The Pennsylvania State Board of Physical Therapy accredited the course for 8 continuing education credits (7 of which could be used towards direct access). A detailed description of the course content is outlined in Table 3.

Table 3. Description of web-based continuing education modules

Introductory Modules

Module 1: "Clinical Decision Making Paradigm" is an over view of the clinical decision making paradigm for management of LBP.

Module 2: "Key Elements in History" is a review of the key elements in history of patient episode of LBP that are helpful in development of preliminary hypothesis regarding presence of serious underlying pathology as a source of the LBP and establishing patients eligibility for PT treatment. A hypothetical case is presented to review this material.

Module 3: "Neurological Assessment" is an overview of assessments conducted to rule out neurological involvement in patients with LBP.

Advanced Modules:

Module 4: "Staging and Classification of patients with LBP" is an overview of the classification-based approach to treatment of LBP. Information regarding criteria for staging patients with LBP based on severity of symptoms and further classification of Stage I patients into sub-groups is presented.

Module 5: "**The Spinal Mobilization Classification"** presents criteria for identification of patients eligible for spinal mobilization. Strength of evidence to support use of spinal mobilization for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Module 6: "**The Stabilization Classification"** presents criteria for identification of patients eligible for spinal stabilization exercises. Strength of evidence to support use of for spinal stabilization the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Module 7: "**The Directional Preference Classification"** presents criteria for identification of patients eligible for directional preference exercises. Strength of evidence to support use of directional preference exercises for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Module 8: "**The Bio-behavioral Classification"** presents criteria for identification of patients eligible for bio-behavioral exercises. Strength of evidence to support use of bio-behavioral exercises for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

4.2.2.2 Audit and feedback

The therapists in the clinics that were in the intervention arm received feedback regarding their clinical performance in the form of a benchmarked report card. This audit and feedback was performed every 2 weeks for a period of 12 weeks.

4.2.2.2.1 Data extraction and collection

All new episodes of care at the participating clinics that were assigned an ICD-9 code defined under UPMC's Low Back Pan initiative were included for the audit. The patient data was collected using the Minimum Data Set (MDS) that has been in use at the UPMC CRS since 2006. The MDS is attached in APPENDIX A.

The MDS form is a paper based data collection tool that assists the therapist to collect critical demographic information, record historical and physical examination findings and define the treatment plan for patients with low back pain. The therapists at UPMC CRS complete the MDS for patients with a chief complaint of low back pain at every visit. This data is then entered into the CRS web-portal to be stored on the composite server as the Clinical Outcomes Database.

The patient data for the audit and feedback was extracted from the clinical outcomes database and de-identified by an honest broker. An honest broker is an individual, organization or system acting on behalf of the covered entity to collect and provide health information to the investigators in such a manner whereby it would not be reasonably possible for the investigators or others to identify the corresponding patients/subjects directly or indirectly. The data was provided to the PI in 2 excel spreadsheets. One included the patient history and demographic data and the other included physical examination findings and the treatment given at each visit.

The PI first merged the 2 data sets based on common identifier variables and then only retained data from the patient's first visit or initial visit for the audit.

4.2.2.2.2 Determination of adherence to guidelines

The determination of adherence to guidelines was performed, by analyzing the data in SPSS. Using the demographic data, patient history and physical examination findings at the first /initial visit the patients were classified into 6 treatment sub-groups (spinal mobilization, stabilization, flexion and extension directional preference, traction, and graded exercise for fear avoidance). A detailed description of the quality indicators used to determine adherence are listed in APPENDIX B.

4.2.2.2.3 Scoring performance and benchmarking

Once the patient was classified appropriately, the treatment actually given to the patient at the first visit was compared to the treatment they should have received based on the guideline. If the treatment received was the same as the treatment classification then this was marked as on-protocol. If not, it was marked as off-protocol. If data on any of the variables of interest were missing and the status on rule could not be established for this patient then these data were not reported and were excluded from further analysis.

Of the 6 classifications only 5 are mutually exclusive. These are spinal mobilization, stabilization, flexion and extension directional preference, and traction. The graded exercise for fear avoidance classification may present in addition to one of the other 5 classifications.

Due to this lack of mutual exclusivity we scored the therapist based on the number of correct treatment classifications. For example a therapist may have treated 10 patients in a 2-week period. Of these 5 may have been classified to receive one intervention and the other 5 may have

required 2 interventions (bio-behavioral and one other). In this case the number of classifications is 15. If the therapist had correctly classified and treated 10 out of 15 classifications then his adherence percentage was 66.6.

The therapists were then ranked based on their performance score. The final report to the therapists included a breakup of the number of classifications by patients account number, an adherence percentage score, and the therapists ranking in the intervention group. An example of the emails sent is attached in APPENDIX D.

4.3 OUTCOME MEASURES

4.3.1 Competence (knowledge)

All subjects completed the competence test at baseline and on completion of the online course. The competence test was administered through an online testing site called test.com. Therapists from the clinics that agreed to participate were sent a link to the competence test via email. Each therapist was given a unique username and password to log in and complete the test. The therapists could log into the test from any computer however they could only do so once. This helped prevent multiple entries and attempts to complete the test. Once the therapist had initiated the test they had 40 minutes to complete it before the session expired. An incentive of $25 was offered for timely completion of the pre-test and an additional $50 was offered for timely completion of the modules and the post-test.

The questions on the competence test were developed and tested for validity and reliability in a preliminary study. In this study 38 questions were tested of which 2 questions

were thrown out due to ambiguity. From the remaining 36 questions 2 parallel forms comprising of 18 questions each were formulated. Form A was used to measure baseline competency and Form B was used to measure competency after the education intervention had been administered.

The questions on the test were in the form of clinical vignettes that required the therapists to apply their knowledge of the practice guidelines to make appropriate clinical decisions. These questions were formulated to specifically measure knowledge in three main concepts that were addressed in the continuing education course.

- **Screening of Patients with Low Back Pain:** These questions evaluated the therapist's ability to identify red flags during patient interview and determine if the patient is eligible for physical therapy or requires a referral to another health care practitioner.

- **Classification of Patients with Low Back Pain:** This section contained questions that evaluated the therapist's ability to develop preliminary hypotheses regarding patient's treatment classification. Questions in this category included ability to interpret special tests that helped in decision-making regarding choice of treatment.

- **Treatment of Patients with Low Back Pain:** Questions in this section included clinical vignettes that evaluated selection of the appropriate treatment classification based on the practice guidelines. These included; spinal mobilization, stabilization, traction, graded exercises for fear avoidance, flexion and extension directional preference.

4.3.2 Adherence

Adherence to guidelines was measured for a 12-week pre and post intervention period. The data for the 12-week baseline and follow up period was de-identified and extracted from the UPMC database by an honest broker.

All patients with low back pain treated at the clinic in this period were first classified into the 6 treatment sub-groups based on the practice guidelines and is attached in APPENDIX B. Once the patients were classified the PI evaluated if the patients had been treated according to guidelines. If a patient's treatment sub-group matched the treatment given at the initial/first visit, the case was marked as On-Protocol or Adherent. If not, the case was marked as being Off-Protocol or Non-Adherent.

4.3.3 Patient outcome, change in Oswestry score

The Oswestry scores collected from the initial and final visit was used to calculate change in Oswestry scores. This was used as a measure of improvement in patient quality of life as a result of adherent care. The modified Oswestry Disability Questionnaire is a disease specific measure of disability among patients with LBP (Beurskens, de Vet et al. 1995). This measure has demonstrated excellent reliability and validity in assessment of disability status in patients with LBP compared to other measures of disability (Beurskens, de Vet et al. 1995).

The questionnaire comprises of a comprehensive self-reported assessment of functions covering the following domains; pain severity, lifting, sitting, standing, walking, sleeping, personal hygiene, social life and traveling. Scores range from 0 to 5 (higher scores represent

greater disability) for each question. The individual scores for each question are added; two then multiplies the total. The final score is reported as a percentage.

The percentage score documented at the last visit was subtracted from that documented at the first visit. This value; Change in Oswestry from first to last visit will be recorded as a measure of improvement in patient status as a result of the PT treatment received. A change in Oswestry score of 6 points or more is considered clinically significant.

5.0 DATA ANALYSIS

5.1 INTRODUCTION

The data analysis will have to take into consideration the effect due to clustering of therapists with the clinics. Standard fixed effect regression models, which assume that all observations are independent of each other, are not appropriate for clustered data. In clustered data observations within a cluster tend to me more alike than observations selected at random. There are 3 reasons for this:

1. The subject may choose the cluster to which they belong. People who choose a particular cluster may be similar in both measurable and other ways.

2. Cluster level variables may affect all members of the cluster to some degree. For example, patients treated by a particularly good therapist may generally have better outcomes.

3. Individuals within a cluster may interact and influence each other.

Since observations within clustered data are correlated, they are not stochastically independent. This violates the fundamental assumption of independence of observations required

for basic statistical techniques. Analyzing clustered data as though they are independent observations underestimate standard errors and thereby increases the likelihood of a type I error. Hence the effect of clustering needs to be taken into account for analysis of clustered data.

In clustered data there are 2 sources of variance; the variability between clusters (Inter) and the variability within clusters (Intra). Failing to account for clustering will result in CI that are too narrow and dubiously low p-values, thus risking a false positive outcome of data analysis.

In order to account for this effect of clustering we used a linear mixed model (LMM) for continuous outcomes and a generalized estimating equation (GEE) model for dichotomous outcomes. These analyses account for the intra-class correlation within each clinic attributable to clustering effect.

5.1.1 Linear Mixed Model

The Linear Mixed Model (LMM) incorporates fixed and/or random effects parameters, and assumes that a continuous outcome variable is linearly dependent on a set of (fixed) predictor variables and cluster specific random effects that influence all members of that cluster, much like a particularly good therapist's competence benefits all his/her patients. The random effects are assumed to approximately follow a normal distribution with mean 0 and its own variance component.

In summary, LMMs are basically extensions of the standard general linear model (which includes familiar models such as regression and analysis of variance) that include both the fixed and random effects thus allowing similar analyses in presence of clustering.

For example, in the present investigation, one employed model is given by

$$Y_{ij} = \beta_0 + \beta_1 X_i + Z_i + \varepsilon_{ij},$$

where Y_{ij} is the Oswestry score of the j^{th} therapist from the i^{th} clinic; β_0 is the estimated mean of the control group; β_1 is the estimated means difference between the intervention and control groups; X_i is an indicator variable identifying whether the therapist's clinic belongs to an intervention (=1) or control (=0) group; Z_i is the random effect for the i^{th} clinic expected to influence all therapists within the clinic; Z_i's are assumed to be independently, identically and approximately normally distributed with mean 0 and variance σ_c^2 ; and ε_{ij}'s are therapist specific random errors also assumed to be independently, identically and approximately normally distributed with mean 0 and variance σ^2 and uncorrelated with the random effects Z_i's.

5.1.2 Generalized Estimating Equations

Generalized Estimating Equations (GEE) are extensions of generalized linear models (such as logistic regression models) that allow for modeling data without requiring the standard independence of observations assumption. Measurements from providers and/or patients from the same facility tend to be more similar than those from different facilities, and this dependence is typically modeled with an exchangeable correlation structure within a GEE model.

For example, in the present investigation, one employed model is given by

$$log_e\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right) = \beta_0 + \beta_1 X_i,$$

where π_{ij} is the proportion of on-protocol patients for the j^{th} therapist from the i^{th} clinic; β_0 is the estimated log odds of the control group; β_1 is the estimated log odds ratio of the intervention group to the control group; X_i is an indicator variable identifying whether the therapist's clinic belongs to an intervention (=1) or control (=0) group; β_0 and β_1 are estimated by solving the system of estimating equations

$$\sum_{i=1}^{I} D_i^T V_i^{-1}(\underline{Y}_i - \underline{\pi}_i) = 0 \ ,$$

where D_i is an appropriate matrix of partial derivatives; V_i is an exchangeable working covariance matrix representing correlations among therapists from the same facility; and $\underline{Y}_i$ and $\underline{\pi}_i$ respectively are vectors of observed outcomes and corresponding estimated probabilities for clinic i.

5.2 BASELINE CHARACTERISTICS

5.2.1 Therapist baseline characteristics

Data for the following baseline characteristics were collected for therapists using a questionnaire administered along with the competence test prior to commencement of the study; age, gender, years of experience, highest degree earned (Bs. PT, Ms. PT, DPT), entry-level degree (Bs. PT,

Ms. PT, DPT). For baseline comparisons pre-test score on the competence test was also included for the therapists.

Age and years of experience were treated as continuous variables. Gender was treated as a categorical (dichotomous) variable (male / female). For the variables 'highest degree earned' and 'entry-level degree', there were 3 possible answer choices; Bs. PT, Ms. PT and DPT. We created a separate variable for each of the contained options and dichotomized the responses to yes /no.

5.2.2 Patient baseline characteristics

The following baseline data on the back pain patients treated by the participating therapists was extracted from the UPMC database: age, gender, initial Oswestry (OSW) score, and initial score on the Numeric Rating Scale (NRS). Age, OSW and NRS were treated as continuous variables and gender was treated as dichotomous (male/ female).

5.2.3 Comparisons of baseline characteristics between groups

Data for categorical variables (dichotomized) were analyzed using GEE to evaluate differences between groups. An odds ratio for intervention and a 95% confidence interval was computed as a measure of group differences, if any. The data for these continuous variables was plotted as a histogram with accompanying Q-Q plots and Shaprio-Wilk tests performed to access normality. In addition skewness was accessed by skewness-kurtosis tests.

Non-parametric tests that account for the effect of clustering have not yet been developed. Thus we decided to use LMM for comparisons between groups if the data did not deviate

significantly from normality. This is because the LMM is fairly robust against deviations from normality. Descriptive statistics computed included mean and standard deviation for continuous data and frequency counts and percentages in categorical data.

5.3 RESEARCH QUESTION 1

Can an active implementation strategy that includes education, audit and feedback increase Physical Therapists knowledge of Practice Guidelines for management of LBP?

Specific Aim: Evaluate the effectiveness of education in improving physical therapists knowledge of the practice guidelines for management of LBP.

Hypothesis: Physical therapists assigned to the intervention group will demonstrate significant greater change in pre to post test competence scores when compared to therapists who are assigned to the control group

The range of possible scores for the competence test administered at baseline and on completion of the CE intervention was 0-18. For purpose of analysis we first calculated a change in competence score by calculating the difference between the pre and posttest scores. We treated this outcome, ‘change in score’, as a continuous variable.

The data was plotted as a histogram with accompanying Q-Q plots and Shaprio-Wilk test was performed to access normality. In addition skewness was accessed by skewness-kurtosis tests. As aforementioned, non-parametric tests that account for clustering have not been

developed and hence if deviations from normality were not significant linear mixed model was used for analysis.

We fitted a linear mixed model using the SAS® MIXED procedure with 'change in score' as the response variable; the randomized arm (Group=intervention/control) as the main categorical fixed effect of interest; baseline competence test score as fixed effects covariates; and a clinic random effect to account for the clustering of therapists within clinics and the resulting non-independence of observations.

We had selected a priori a number of potential covariates like years of experience of therapists, highest degree earned by therapist, entry-level degree, age and gender to be included as fixed effect covariates in the model. However for every additional covariate entered in the model we would have to increase out sample size by 10. Since it was impossible to extend the study to include a larger sample size we used baseline competence test score as a summary marker to account for the potential effects of all the covariates. We used the therapist's baseline score on the competence test if they did not complete the posttest to account for the missing data in a last value carried forward approach.

5.3.1 Post Hoc analysis for research question 1

5.3.1.1 Post Hoc analysis 1

Research Question: Are there differences between groups for responses for each item on the competence test?

We hypothesized that the two groups would be significantly different on the responses for each item on the competence test. The response to an item on the competence test was marked as either correct or incorrect. The outcome was treated as dichotomous. We used a SAS® GENMOD procedure to account for clustering of therapists within clinics. Differences between groups for response for each item on the competence test (18 items) were tested for using Generalized Estimating Equations (GEE) analysis. Odds ratio and a 95% confidence interval were computed as a measure of intervention effect for each question.

5.3.1.2 Post Hoc analysis 2

Research Question: To what extent are physical therapists aware of the current recommendations in the practice guidelines for Low Back Pain?

On an exploratory basis we conducted a descriptive analysis of the responses to each question on the competence test. This allowed us to characterize the extent to which physical therapists adhere to guidelines recommendations when measured by clinical vignettes. For each item we frequency and percentage of each answer choice was calculated.

5.4 RESEARCH QUESTION 2

Can an active implementation strategy that includes education, audit and feedback improve adherence to practice guidelines for Management of LBP?

Specific Aim: To evaluate the effectiveness of education, audit and feedback in improving adherence to the clinical practice guidelines for LBP.

Hypothesis: Patients treated by physical therapists assigned to intervention group will receive greater guideline adherent care compared to patients treated by therapists who are assigned to the control group.

The PI was blinded to the therapist's group assignment. The patient data from the pre and post intervention period was de-identified and extracted from the UPMC database. These patients record were then classified into appropriate treatment subgroups based on their documented history and examination findings, using methods described in APPENDIX B. A separate variable was created for each of these classifications.

Adherence to guideline was determined to each by comparing the established treatment classification with the treatment they actually received (documented by the therapist). When a patient received treatment matched to its subgroup it was classified as adherent care. Patient record was also marked as adherent when a patient did not receive unnecessary interventions. That is when a patient was not classified to a subgroup and was appropriately not treated according to it. When a patient did not receive matched care it was marked non-adherent. When

a patient did not match a classification but was treated according to it, it was also marked as off protocol.

Thus, we had 2 possible instances of adherent care (On-Protocol)

1. Patient met the criteria on guideline and received appropriate treatment (On protocol 1)
2. Patient did not meet the criteria on the guideline and did not receive it (On Protocol 2)

Similarly we had 2 possible instances of non-adherent care (Off-Protocol)

1. Patient met the criteria on guideline but did not receive appropriate treatment- Underuse
2. Patient did not meet the criteria on the guideline but received it-Overuse

To be considered as being adherent the therapist had to be adherent across all 6 treatment subgroups for each patient. The therapist may give a treatment when required but to be considered adherent he must also not give a treatment when it is not needed.

In order to evaluate this we created ***3 operational definitions***:

1. **At least one on protocol**: The therapist was adherent across all treatment sub-groups that is gave treatment that was required and did not give treatment that was not required. (yes, no)
2. **Most on protocol**: The therapist was adherent for at least 4 of the 6 treatment subgroups. (yes, no)
3. **At least 1 on protocol**: The therapist was adherent for at least one treatment subgroup. (yes, no)

Since the outcome was dichotomous we used Generalized Estimating Equations (GEE) analysis to assess effect of intervention on each of the 3 operational definitions. We used a SAS® GENMOD procedure to account for clustering of patients within therapists and therapists within clinics. Differences between groups for each of the new variables computed were tested for using Generalized Estimating Equations (GEE) analysis. We used a logit link function and an exchangeable working correlation structure in GEE models accounting for clustering within clinics to test the hypotheses greater adherence to the practice guidelines in the intervention group compared to the control group. An odds ratio for intervention and a 95% confidence interval was computed as a measure of intervention effect.

5.4.1 Post Hoc analysis for research question 2

5.4.1.1 Post Hoc analysis 1

Research Question: Are there differences between groups when comparing adherence to each criterion on the guideline?

We evaluated if the groups were different on adherence to individual criteria on the guideline. For these comparisons adherence was defined as treatment given when indicated. Each variable was dichotomized as adherent or non adherent. We used a SAS® GENMOD procedure to account for clustering of patients within therapists and therapists within clinics. Differences between groups for adherence to each criterion on the guidelines were tested for using Generalized Estimating Equations (GEE) analysis. Odds ratio and a 95% confidence interval was computed as a measure of intervention effect for each question.

5.4.1.2 Post Hoc analysis 2

Research Question: To what extent does treatment delivered by physical therapists match recommendations in practice guidelines for Low Back Pain? What is the overall percentage of guideline adherence and to each criterion on the guideline?

On an exploratory basis we conducted a descriptive analysis of the overall percentage of adherence and for each criterion on the guideline (6 subgroups). This allowed us to characterize physical therapy choices for management of low back pain and how often they adhere to practice guidelines. We included all therapists who participated in the study. Frequency and percentage of adherence for each criterion and overall adherence was calculated.

5.5 RESEARCH QUESTION 3

Can an active implementation strategy that includes education, audit and feedback regarding adherence to practice guidelines improve outcomes of patients with low back pain?

Specific Aim: Evaluate the effectiveness of education, audit and feedback in improving the health status of patients with low back pain as a result of receiving adherent care.

Hypothesis: Patients treated by therapists assigned to the intervention group will have significantly greater improvements in Oswestry scores compared to patients treated by therapists in the control group.

We first computed a new variable for change in Oswestry scores from first visit to last visit for all patients. The change in Oswestry score was treated as a continuous variable. The data was plotted as a histogram with accompanying Q-Q plots and Shaprio-Wilk tests performed to access normality. In addition skewness was accessed by skewness-kurtosis tests. As aforementioned, non-parametric tests that accounts for clustering have not been developed and hence if deviations from normality were not significant linear mixed model was used for analysis.

Educational intervention was applied at the level of the clinic. The therapists were nested within clinic and the patients are nested with the therapists. To account for this clustering we used the SAS® MIXED to procedures assess differences between groups.

We fitted a linear mixed model using the SAS® MIXED procedure with pre- to post-intervention change in the average Oswestry score as the response variable; the randomized arm (intervention/control) as the main categorical fixed effect of interest; mean score per therapist as

a fixed effect covariate and a clinic random effect to account for the clustering of therapists within clinics and the resulting non-independence of observations.

A number of potential covariates like years of experience of therapists; highest degree earned by therapist and baseline characteristics of patients (gender, age) were selected a priori to be included as fixed effect covariates in the model. However due to the limitation of a small sample size we used mean change in Oswestry score per therapist as a summary marker to account for the potential effects of all the covariates. We carried the last value forward if Oswestry score was missing to account for the missing data.

6.0 RESULTS

6.1 SCREENING, ENROLLMENT AND LOSS TO FOLLOW-UP

Amongst the forty-two clinics invited to participate 31 consented to the study. The clinic size ranged from a maximum of 5 to a minimum of 1, with a total of 45 therapists in the 31 clinics. Fifteen clinics (Therapists=20) were randomized to the control arm and 16 clinics (Therapists=25) were randomized to the intervention arm of the study.

Before random allocation, 3 clinics, all from the control group, withdrew from study (Therapists n=3). The reason for withdrawal was lack of time due to busy clinic schedule. Because baseline data was not available for these therapists we did not include them in further analysis.

CONSORT diagram in Figure 7 depicts the progress of the clusters: the clinics, therapists and patients through the study. The final sample included 16 clinics (therapists=24), in the intervention group and 12 (therapists=18) in the control group.

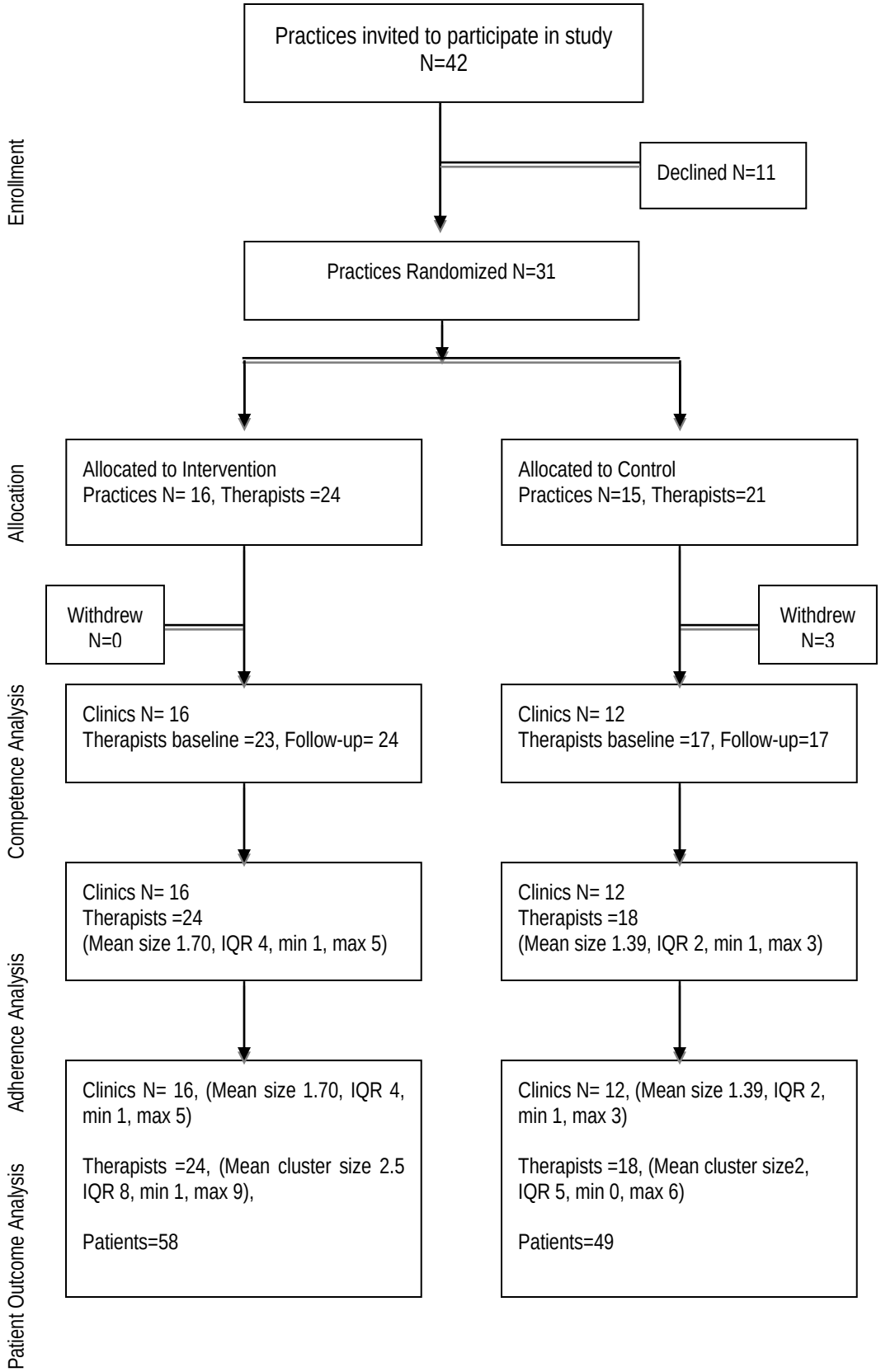

Figure 7. CONSORT Diagram depicting progress of clusters through study

6.2 BASELINE COMPARISIONS

We assessed if the intervention and control groups were equivalent by comparing the demographic characteristics of the therapists nested within the clinics and the patients nested in the therapists.

6.2.1 Therapists

6.2.1.1 Normality testing of baseline characteristics; Therapists

Normality of the continuous variables was assessed using the Shapiro-Wilk tests. Therapist age and years of experience had a p-value of < 0.05, therefore the null hypothesis for normal distributions were rejected. However when we looked at the Q-Q plots we found that the deviations from normality were minor. Since the linear mixed model procedure is fairly robust against minor deviations from normality we chose this test over a non-parametric test to account for the effect of clustering. The results of the Shapiro-Wilk tests for normality are summarized in Table 4. The Q-Q plots are presented in Figures 8, 9 and 10.

Table 4. Normal distribution testing for continuous baseline variables: Therapists

Baseline Variable	**Shapiro-Wilk Test Statistic**	**p-value**
Age*	0.931	0.017
Years of Experience*	0.928	0.013
Competence Test Score	0.92293	0.226
* = *Significant finding (Reject the null of normal distribution)*		

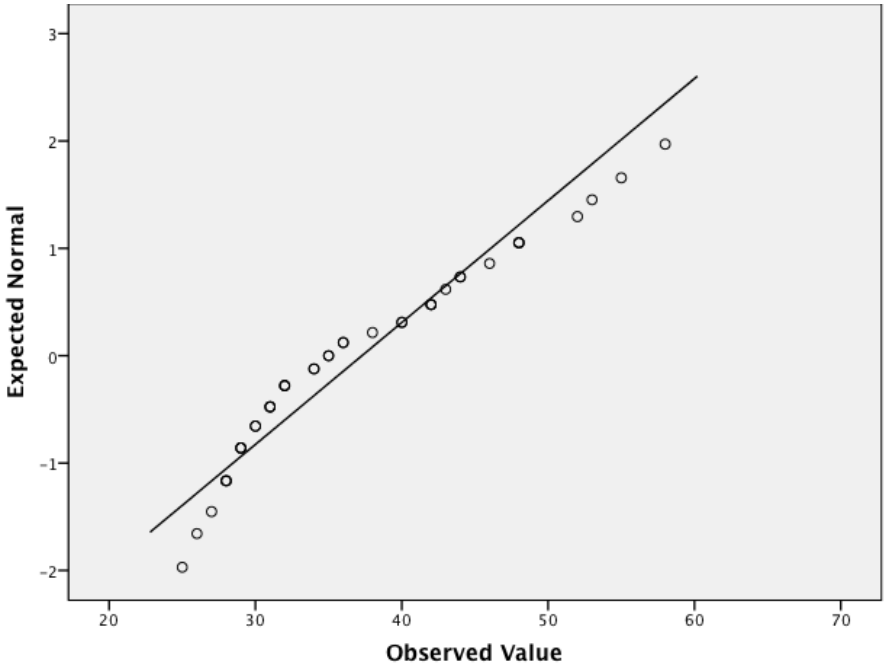

Figure 8. Normal Q-Q plot for age of therapists

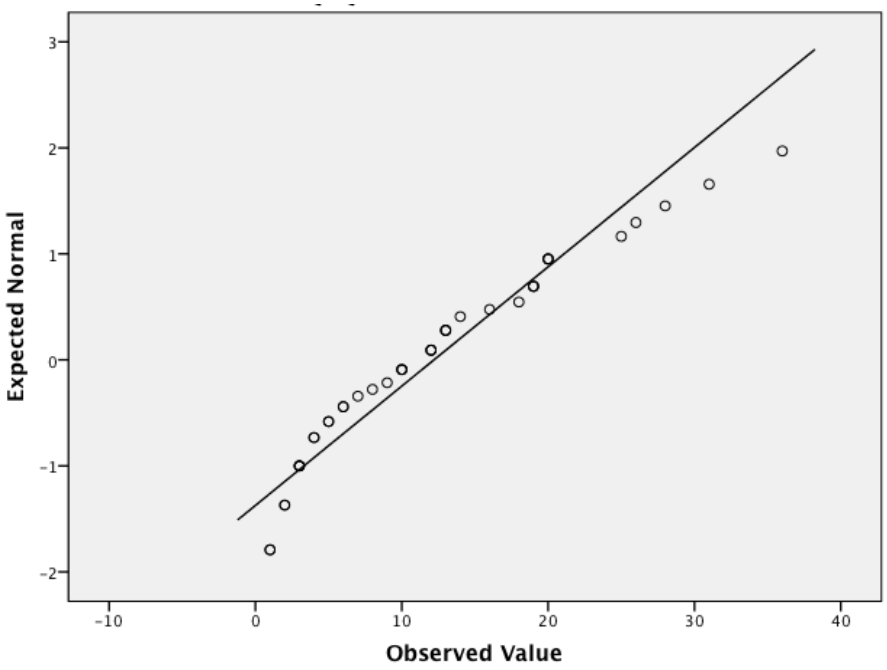

Figure 9. Normal Q-Q plot for years of experience of therapists

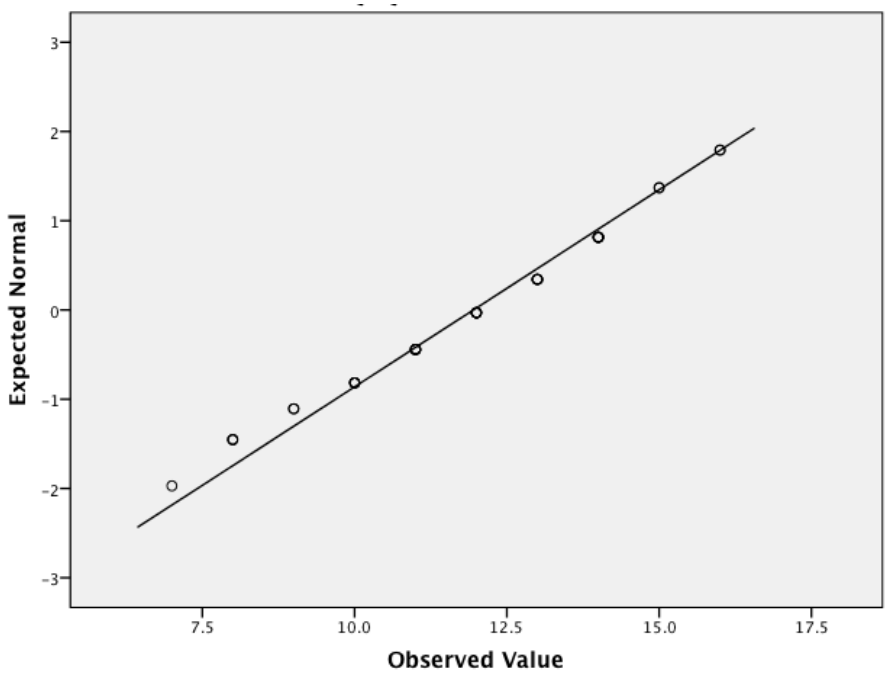

Figure 10. Normal Q-Q plot for competence test scores of therapists at baseline

6.2.1.2 Baseline comparison between groups; Clinics and Therapists

The intervention and control groups were homogenous as no statistically significant differences were found between the two groups for any of the baseline variables. The summary of the baseline comparisons between groups for clinics can be viewed in Table 5 and for therapists in Table 6.

Table 5. Comparison of baseline characteristic between groups for clinics

Clinics	Control (n=12)	Intervention (n=16)	p-value
Clinic Size (Mean)	1.33	1.52	0.89

Table 6. Comparisons of baseline characteristics between groups for therapists

Therapists	Control (n=18)	Intervention (n=24)	p-value
Age			
Mean	38.50	36.92	0.56
SD	9.03	8.63	
Range	29	33	
Missing	0	0	
Gender			
No.			0.68
(% Men)	58.8	54.2	
Missing	0	0	
Years of experience			
Mean	12.61	12.29	0.90
SD	8.45	9.12	
Range	30	35	
Missing	0	0	
Entry Level Bs.			
No.	4	5	0.74
%	22.2	20.8	
Missing	0	0	
Entry Level Ms./MPT			
No.	8	9	0.80
%	44.4	37.5	
Missing	0	0	
Entry Level DPT			
No.	6	10	0.39
%	33.3	41.7	
Missing	0	0	
Highest Degree Bs.			
No.	2	1	0.38
%	11.1	4.2	
Missing	0	0	
Highest Degree			
Ms/MPT	9	10	0.44
No.	50	41.7	
%	0	0	
Missing			
Highest Degree DPT			
No.	7	13	0.10
%	38.9	54.2	
Missing	0	0	
Baseline score			
(out of 18)			
Mean	12.29	11.70	
SD	2.28	2.26	0.41
Range	8	9	
Missing	1	1	

6.2.2 Patients

6.2.2.1 Normality testing of baseline characteristics; Patients

Normality of the continuous variables; age, initial Oswestry and pain score was assessed using the Shapiro-Wilk tests. The continuous variables were age, Initial Oswestry score, Initial Pain score, FABQ physical activity sub-scale and FABQ work subscale. All 5 variables had a p-value of < 0.05, therefore the null hypothesis for normal distributions were rejected. However when we looked at the Q-Q plots we found that the data deviation from normality were minor. Since the linear mixed model procedure is fairly robust against minor deviations from normality we chose this test over a non-parametric test to account for the effect of clustering. The results of the Shapiro-Wilk tests for normality are summarized in Table 7. The Q-Q plots are presented in Figures 11 through 15.

Table 7. Normal distribution testing for continuous baseline variables: Patients

Baseline Variable	**Shapiro-Wilk Test Statistic**	**p-value**
Age*	0.965	<0.01
Initial Oswestry Score*	0.954	<0.01
Initial Pain Score*	0.932	<0.001
FABQ physical activity*	0.943	<0.001
FABQ work*	0.869	<0.001
** = Significant finding (Reject the null of normal distribution)*		

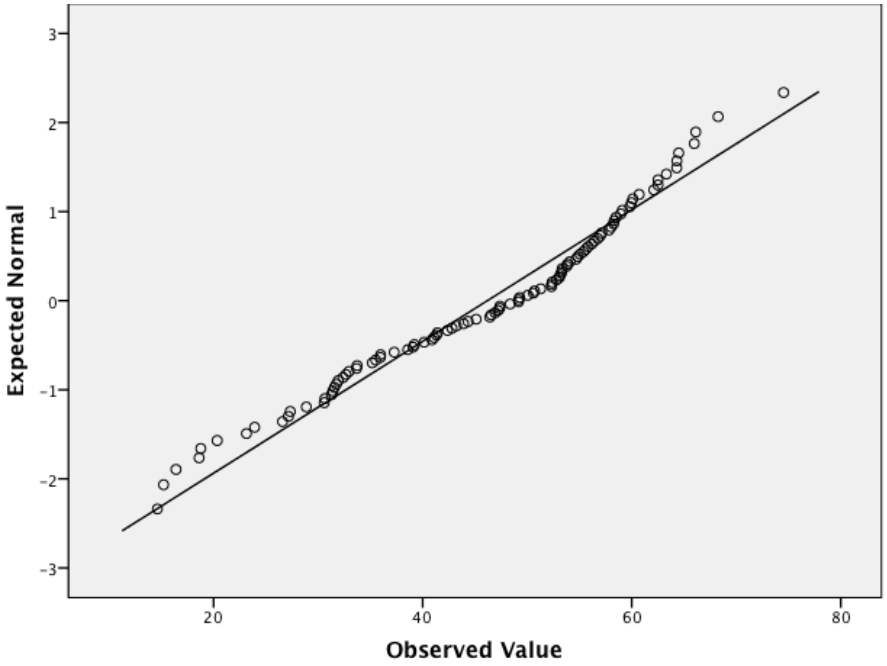

Figure 11. Normal Q-Q plot for age of patients

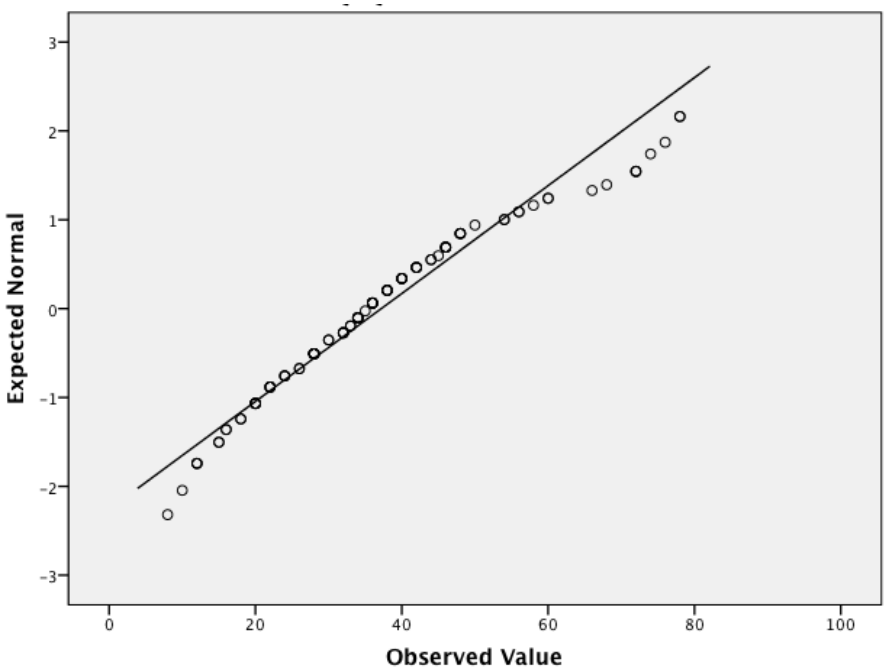

Figure 12. Normal Q-Q plot for initial Oswestry score of patients

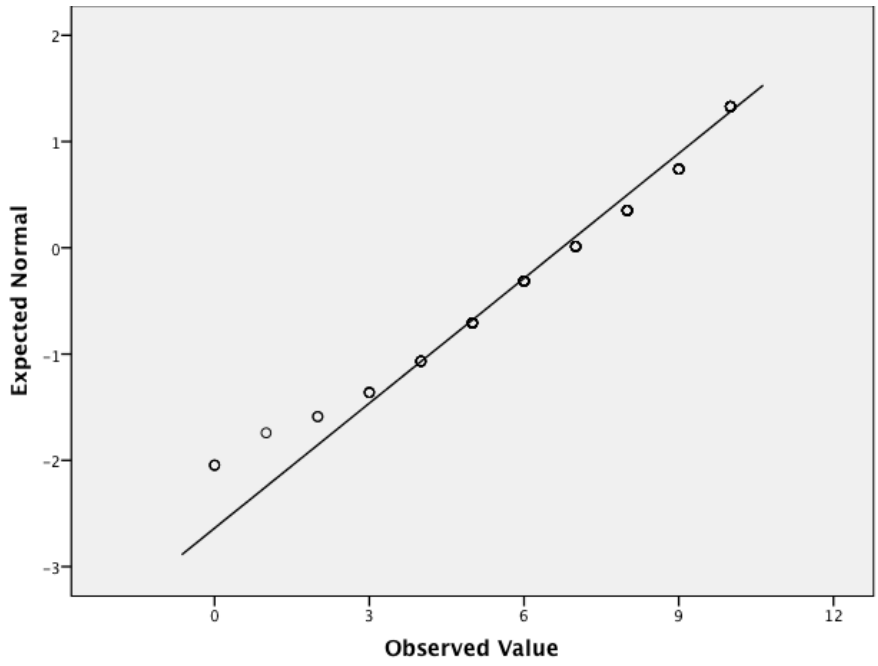

Figure 13. Normal Q-Q plot for initial pain score (VAS) of patients

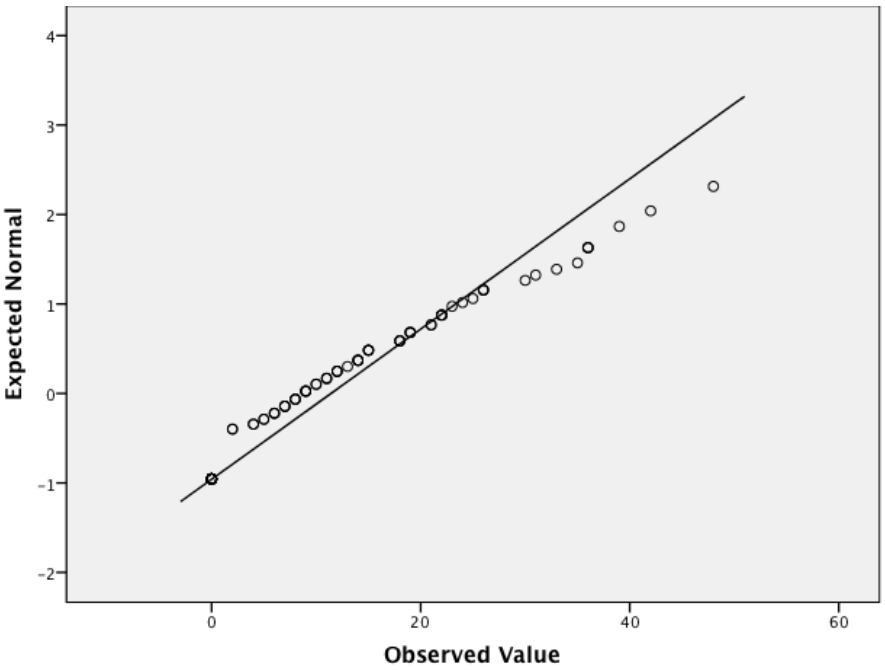

Figure 14. Normal Q-Q plot for initial FABQ work sub-scale score of patients

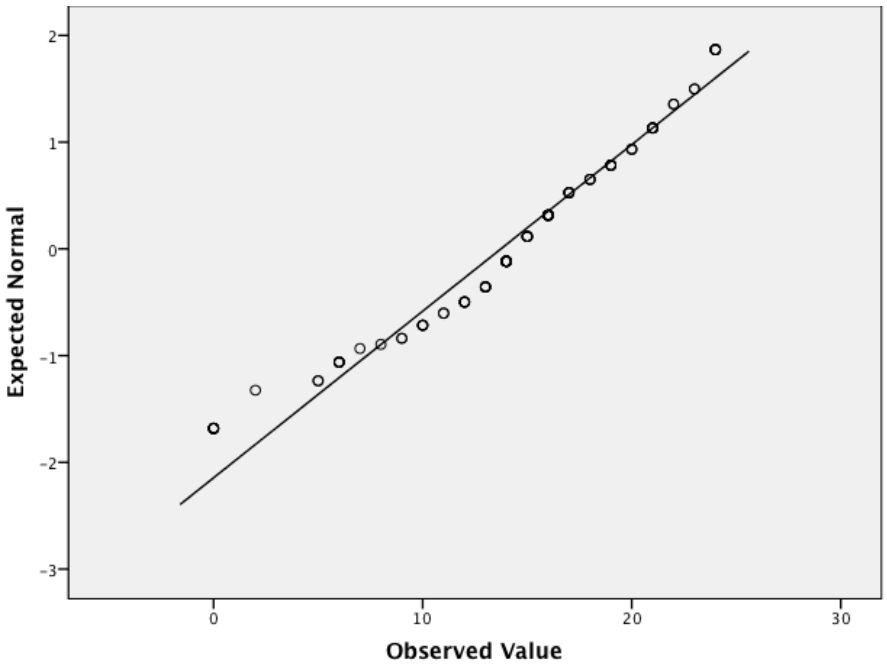

Figure 15. Normal Q-Q plot for FABQ physical activity sub-scale of patients

6.2.2.2 Baseline comparisons between groups; Patients

The demographics and baseline characteristics of the patients treated by the study therapists in the intervention and control are presented in Table 8. The two groups were not were not significantly different.

Table 8. Comparisons of baseline characteristics between groups for patients

Patients	Control (n=27)	Intervention (n=23)	p-value
Age			
Mean	47.16	45.29	0.33
SD	13.01	14.01	
Range	53.04	59.90	
Missing	0	0	
Oswestry			
Mean	38.65	34.98	0.57
SD	18.38	12.89	
Range	70	64	
Missing	1	0	
Pain VAS			
Mean	6.46	6.79	0.92
SD	2.74	2.44	
Range	10	10	
Missing	2	0	
FABQ Physical Activity			
Mean	14.35	12.96	0.081
SD	7.09	5.50	
Range	24	24	
Missing	3	2	
FABQ work			
Mean	9.28	13.74	0.865
SD	11.925	11.58	
Range	48	42	
Missing	4	2	
Gender (Men)			
No.	18	20	0.74
Percent	33.33	41.7	
Missing	0	0	

6.3 ANALYSIS OF RESEARCH QUESTION 1

Hypothesis: Physical therapists assigned to the intervention group will demonstrate significant greater change in pre to post test competence scores when compared to therapists who are assigned to the control group

Ninety-five percent (40/42) of the therapists completed the baseline competence test and 97.6% (41/42) completed the follow up test. When we compared the change in total competence scores from baseline to follow-up between groups we did not find significant group differences (Estimated mean difference 0.04, 95% CI: -1.22 to 1.31, p=0.56).

6.3.1 Post Hoc analysis of research question 1

6.3.1.1 Post Hoc analysis 1

Research question: Are there differences between groups for responses for each item on the competence test?

When we evaluated differences between groups on individual items or clinical vignettes on the competence test we found significant differences between groups for only one question (OR for Intervention vs. Control [95% CI]: 3.65[2.06 to 6.63], p<0.0001).

The results of the between group comparisons for each item on the competence test is summarized in Table 9. Table 10 includes a description of the vignette for which significant group differences were detected along with the p-value.

Table 9. Between group comparisons for each item on the competence test

Question	Intervention	Control	p-value
Q1	13/23 (56)	14/18(77.8)	0.15
Q2	16/23 (69)	17/18(94.4)	0.09
Q3	9/23(39.1)	8/18(44.4)	0.85
Q4	19/23(82.6)	17/18(94.4)	0.35
Q5	18/23(78.3)	15/18(83.3)	0.47
Q6	14/23(60.9)	12/18(66.7)	0.61
Q7	9/23(39.1)	7/18(38.9)	0.86
Q8	19/23(82.6)	14/18(77.8)	0.76
Q9	23/23(100)	17/18(94.4)	0.35
Q10	22/23(95.7)	14/18(77.8)	0.17
Q11	19/23(82.6)	16/18(88.9)	0.43
Q12	19/23(82.6)	14/18(77.8)	0.85
Q13*	19/23(82.6)	10/18(55.6)	<0.0001*
Q14	22/23(95.7)	16/18(88.9)	0.62
Q15	22/23(95.7)	17/18(94.4)	0.85
Q16	14/23(60.9)	9/18(50.0)	0.94
Q17	19/23(82.6)	14/18(77.8)	0.93
Q18	10/23(43.5)	6/18(33.3)	0.76
*=Significant differences			

Table 10. Description of vignette to which correct responses between groups were significant. Values represent frequency (percentage)

Question	Intervention	Control	p-value
Q13. Your patient has baseline pain in the low back that he rates as 5/10 on Visual Analogue Scale (VAS). The patient also reports pain down the leg at 5/10 on VAS and paresthesia along the lateral border of the foot. When he performs extension during movement testing, the VAS ratings for pain in the back and leg immediately reduce to 3/10 with no effect on the paresthesia. There are no red flags present. Given this brief clinical profile, what is the status change indicated as a result of extension movement? A. Improved, or better, because back pain decreases. B. Improves in the back, worsens in the foot. C. Worsens because there was no change in the paresthesia. **D. Status Quo, no change because there was no change in the paresthesia.**	19/23(82.6)	10/18(55.6)	<0.0001

6.3.1.2 Post Hoc analysis 2

To what extent are physical therapists aware of the current recommendations in the practice guidelines for Low Back Pain?

Due to its length descriptive analysis of responses to clinical vignettes for the entire sample (N=41) is presented in APPENDIX E. The table provides a summary of answer choices of the therapists to each vignette.

6.4 ANALYSIS OF RESEARCH QUESTION 2

Hypothesis: Patients treated by physical therapists assigned to intervention group will receive greater guideline adherent care compared to patients treated by therapists who are assigned to the control group.

The study therapists (n=42) treated 113 cases of LBP in the 12-week baseline period and 212 cases in the 12-week follow up period. 12/113 cases from baseline and 35/212 cases from follow-up were post-surgical and excluded from further analysis. The total sample then contained 101 cases (I=53, C=48) of LBP treated in the baseline period and 177 cases (I=99, C=78) in the follow up period. We could not determine status on rule due to insufficient data (intervention delivered not entered) for 5 out of 110 cases from baseline and 13 out of 177 cases from follow up. The status on the guideline criterions could not be established for 46 out of 101 cases from baseline and 56 of 177 from follow up.

Final sample for the study had 50 cases from baseline (I=23, C=27) and 107 subjects from follow-up (I=58, C=49). The distribution of patients in the baseline and follow-up period is given in Table 11.

Table 11. Distribution of patients in groups at baseline and follow-up

	Baseline			Follow-up		
	Total	Intervention	Control	Total	Intervention	Control
Total	113	58	55	212	122	90
Post-Surgical	12	5	7	35	23	12
Missing Intervention entry	5	3	2	13	11	3
Could not establish status on rule	46	27	19	56	30	26
Final	50	23	27	107	58	49

These cases were then classified into one of 6 treatment groups (spinal mobilization, stabilization, flexion directional preference, extension directional preference, traction, graded exercise for fear avoidance) based on criteria in APPENDIX B. The independently established classifications were then compared to the actual treatment given. The data was classified as adherent or non-adherent. We had 2 possible instances of adherent care (On-Protocol)

3. Patient met the criteria on guideline and received appropriate treatment (OnP 1)
4. Patient did not meet the criteria on the guideline and did not receive it (OnP2)

Similarly we had 2 possible instances of non-adherent care

3. Patient met the criteria on guideline but did not receive appropriate treatment- Underuse
4. Patient did not meet the criteria on the guideline but received it-Overuse

The proportion of patients who received adherent care per criterion on the guideline, in the intervention and control groups is summarized in Table 12.

Table 12. Proportions of patients who received adherent care per criterion in intervention and control groups

CRITERION	Intervention		Control	
	OnP1	OnP2	OnP1	OnP2
Spinal mobilization	3/17(17.64)	40/41(97.56)	3/11(27.27)	37/38(97.36)
Stabilization	11/13(84.61)	18/45(40.0)	10/14(71.42)	21/35(60.0)
Flexion directional preference	8/8(100.0)	45/50(90)	7/7(100.0)	38/42(90.47)
Extension directional preference	5/6(83.33)	44/52(84.61)	4/4(100.0)	38/45(84.44)
Traction	2/14(14.28)	43/44(97.72)	3/13(23.07)	33/36(91.66)
Graded exercise for fear avoidance	5/13(38.46)	39/45(86.66)	5/7(71.42)	36/42(85.71)

OnP1= Met criteria and given
OnP2= Did not meet criteria and not given

The proportion of patients who received non-adherent care per criterion on the guideline, in the intervention and control groups is summarized in Table 13.

Table 13. Proportion of patients who received non-adherent care per criterion in the guideline for intervention and control groups

CRITERION	Intervention		Control	
	Underuse	Overuse	Underuse	Overuse
Spinal mobilization	14/17(82.35)	1/41(2.43)	8/11(72.72)	1/38(2.63)
Stabilization	2/13(15.38)	27/45(60.0)	4/14(28.57)	14/35(40.0)
Flexion directional preference	0/8(0.0)	5/50(10.0)	0/7(0.0)	4/42(9.52)
Extension directional preference	1/6(16.66)	8/52(15.38)	0/4(0.0)	7/45(15.55)
Traction	12/14(85.71)	1/44(2.27)	10/13(76.92)	3/36(8.33)
Graded exercise for fear avoidance	8/13(61.65)	6/45(13.33)	2/7(28.57)	6/42(14.28)

Due to the lack of mutual exclusivity one patient could be classified to require more than one treatment. In this case the therapists should ideally give both treatments. To account for this we created 3 operational definitions (dichotomized as yes or no). The proportions of patients in each of these, “At least one on protocol”, “Most on protocol” or “All on Protocol”, is given in Table 14.

Table 14. Proportion of patients who received all, most, or at least one intervention per guideline.

Values represent proportions (percentage)

	Intervention	Control
All On	14/58(24.13)	14/49(28.57)
Most on	36/58(62.06)	30/49(61.22)
At least one on protocol	8/58(13.79)	5/49(10.20)

We then compared the 2 groups for differences on each of these 3 variables; we did not find significant group differences for any one. The odds ratio, 95% confidence Interval and p-value for each are outlined in Table 15.

Table 15. Between group comparisons for adherence to guidelines at follow-up

	Intervention Group Clinic=16 Therapist=24 Patients=58	Control Group Clinic=12 Therapist=17 Patients=49	OR*	95% CI	p-Value
At least 1 on	14	14	0.70	0.22 to 2.18	0.54
Most on	36	30	0.96	0.64 to 1.46	0.88
All on	8	5	1.33	0.63 to 2.68	0.53
**OR for Intervention vs. Control*					

6.4.1 At least one on protocol

The groups were not significantly different when we compared proportions of therapists who were on protocol for at least one of the 6 classifications according to protocol (OR for Intervention vs. Control [95% CI]: 0.70 [0.22 to 2.18], p=0.54).

6.4.2 Most on protocol

The groups were not significantly different when we compared proportions of therapists who were on protocol for 4 or more of 6 classifications (most) according to protocol (OR for Intervention vs. Control [95% CI]: 0.96 [0.64 to 1.46], p=0.88).

6.4.3 All on protocol

The groups were not significantly different when we compared proportions of therapists who were on protocol for all 6 criterions on the guideline (OR for Intervention vs. Control [95% CI]: 1.33 [0.63 to 2.68], p=0.53).

6.4.4 Post Hoc analysis of research question 2

6.4.4.1 Post Hoc analysis 1

Research Question: Are there differences between groups when comparing adherence to each criterion on the guideline?

When we compared differences between groups for each criterion on the guidelines we did not find significant differences between groups on any of the 6 criterions. We also included Failure with stabilization classification in these comparisons. Failure with stabilization is when the patient meets the criteria for failure with stabilization (not an ideal stabilization candidate) and receives these exercises. The results of the analysis for between group differences, per criterion are given in Table 16. The values represent frequency (number of patients given correct treatment/ number of patients eligible for treatment).

Table 16. Between group comparisons for each criterion on the guideline, Failure with stabilization added

Criterion	Intervention	Control	P-value
Spinal mobilization	3/17	3/11	0.15
Stabilization	11/13	10/14	0.72
Flexion Directional Preference	8/8	7/7	0.30
Extension Directional Preference	5/6	4/4	0.08
Traction	2/14	3/13	0.70
Graded exercise for fear avoidance	5/13	5/7	0.17
Failure with stabilization	27/45	14/35	0.72

6.4.4.2 Post Hoc analysis 2

To what extent does treatment delivered by physical therapists match recommendations in practice guidelines for Low Back Pain? What is the overall percentage of guideline adherence and to each criterion on the guideline?

In order to get a descriptive report of the utilization of physical therapy services and to what extent they match the current practice guidelines we completed descriptive analysis of the overall adherence to guideline for all 6 criterion and for each criterion. Overall adherence to guidelines was 51.97%. When we evaluated the adherence for each criterion we found that therapists adherence to guidelines for mobilization thrust (21.43%), traction (18.52%) and graded exercises (50%) for fear avoidant patients were very low. Stabilization was over utilized in 51.25% of the cases. Directional preference exercises were most often used appropriately.

The frequency and percentage of receiving adherent care for each criterion on the guideline for the combined sample is give in Table 17. The frequency and percentage of underuse and overuse of services for each criterion on the guideline for the combined sample is given in Table 18.

Table 17. Adherence to each criterion on the guidelines: combined sample

(Therapists=41, Patients=107)

Criterion	Met Criteria	Given	Percentage
Mobilization	28.00	6.00	21.43
Stabilization	27.00	21.00	77.78
Flexion Directional Preference	15.00	15.00	100.00
Extension Directional Preference	10.00	9.00	90.00
Traction	27.00	5.00	18.52
Graded exercise for fear avoidance	20.00	10.00	50.00
Failure with stabilization	80	38	48.75
Overall adherence	**127**	**66**	**51.97**

Table 18. Descriptive analysis of underuse and overuse of physical therapy resources for total sample

	Underuse	Underuse %	Overuse	Overuse %
Grade V Thrust	14/17	82.3	2/79	2.5
Stabilization	6/30	20	41/80	51.25
Flexion directional preference	1/17	5.8	9/92	9.78
Extension directional preference	1/11	9.09	15/97	15.46
Traction	22/28	78.57	4/80	5
Graded exercise for fear avoidance	10/21	47.61	12/87	13.79

6.5 ANALYSIS OF RESEARCH QUESTION 3

Hypothesis: Patients treated by therapists assigned to the intervention group will have significantly greater improvements in Oswestry scores compared to patients treated by therapists in the control group.

There were no differences between groups when comparing in change in Oswestry scores of patients with low back pain treated by the therapists in the control and intervention group. (Estimated mean difference -1.82, 95% CI: -7.37 to 3.72, p=0.49).

7.0 DISCUSSION AND CONCLUSION

We examined the effects of a multifaceted intervention strategy that included education, audit and feedback on increasing knowledge of and adherence to practice guidelines in physical therapists. We also, compared the outcomes of patients with back pain who were treated by therapists who received the multifaceted intervention with those treated by therapists in the control group. The results did not demonstrate significant improvements in knowledge of and adherence to practice guidelines by physical therapists or improvements in the patient's clinical outcome.

Although there were no differences between groups for change in the total test score from baseline to follow-up, the groups had significantly different responses for 3 of the individual items on the competence test. The descriptions of these questions are provided in Table 10. The results of these comparisons indicate that therapists in the intervention group were more likely to provide adherent care to patients with flexion directional preference compared to therapists in the control group. The education intervention seemed to have a positive effect of gain in knowledge for this classification alone.

When evaluating overall adherence to practice guidelines (N=41) we found that therapists were adherent in only 51.97% of the low back pain cases. Guideline adherence was particularly low for classifications of thrust mobilization (21.43%), traction (18.52%), fear-avoidant (50%) and failure with stabilization (48.75%). This is consistent with the conclusion of our pilot study

where we noted an underuse of thrust mobilization, traction and fear-avoidant intervention and an overuse of stabilization when the patient profile indicated they would not benefit from this treatment.

An interesting finding was a discrepancy between knowledge of guidelines and its application in the clinic; this is demonstrated in Figure 16.

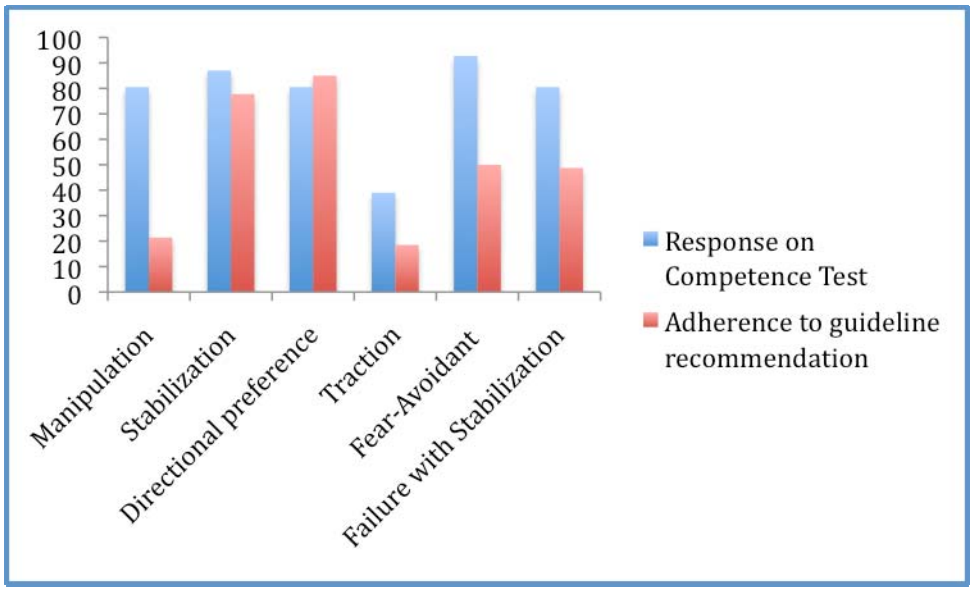

Figure 16. Discrepancy between knowledge of practice guidelines and its application in the clinic

For example, although 80.5% (33/41) of the therapists were able to correctly interpret the clinical prediction rule for thrust mobilization only 63% (26/31) chose to manipulate when presented with a clinical vignette for a patient that matched the CPR for thrust mobilization. An even lower percentage of therapists (21.43%) used thrust mobilization in the clinic in accordance

with the guidelines. This finding is consistent with a previous study that found a similar inconsistency between knowing and doing in physical therapy management of low back pain (Jette and Delitto 1997).

Adherence to stabilization was relatively high both in terms of knowledge and behavior. Eighty-seven percent of the therapists were able to correctly interpret the prone instability test required for identification of patients who would benefit from stabilization exercises on the competence test and 77.78% of the patients received stabilization exercises in accordance with the guidelines in the clinic. However stabilization was also used in a large number of cases when it was not recommended. Although 80.5% were able to correctly interpret the CPR for failure with stabilization in the competence test, 51.25% of the patients received stabilization exercises inappropriately.

Seventy percent of the therapists correctly interpreted the status change based on movement testing to identify presence or absence of directional preference and 80.5% of the therapists correctly identified presence of directional preference based on the clinical vignette. However there was some ambiguity in the response for choice of treatment in the management of a patient with flexion directional preference. According to the guidelines patients with flexion directional preference will benefit from flexion bias exercises and general lower extremity strengthening exercises. Fifty-six percent of the therapists chose the right answer and 41.5% chose only flexion exercises with end range flexed postures.

Adherence to the guideline recommendation of directional preference was high. Ninety-six percent of the patients eligible for directional preference exercise received appropriate treatment [flexion DP= 100%, extension DP=90%]. Both awareness to guidelines regarding traction (39%) and its use in the clinic were low (18.52%). Although 92.7% (38/41) of the

therapists were able to identify patients who were fear avoidant through the clinical vignettes only one half of the patients received it appropriately.

Since adherence to guidelines in this study was low in both groups it is not surprising that education did not have an impact on patient outcome. Previous studies have suggested that an adherence rate of at least 75% may be needed to detect effect of guideline on patient outcome (Fritz, Delitto et al. 2003). Since the adherence to guideline (51.97%) in this study was quite low, it would have not been possible to detect effect of education on the patient outcome even with an adequate sample size.

One of the major strengths of this study is the cluster randomized controlled design. A study by Cleland et al in found that education had a significant positive effect on outcomes of patients with neck pain (Cleland, Fritz et al. 2009). However this study did not utilize a cluster-randomized design and therapists from the same clinics were randomized to different arms of the trial. This is a significant threat to the internal validity of the study and can lead to inflated p-values and a type -1 error. A study by Bekkering and colleagues found that education had a moderate effect on changing clinician's behaviors and on improving patient outcomes (Bekkering, Hendriks et al. 2005; Bekkering, van Tulder et al. 2005). The sample size calculated in the study indicated that in-order to detect a 20% difference in adherence between groups a sample of 48 practices and 5 patients per practice or 284 patients (ICC =0.05, two sided alpha=0.05, Beta=0.20) is needed. In this study we fell short of achieving adequate power, as this study had 28 practices and 107 patients.

Another strength of this study was the outcomes used to evaluate the effectiveness of education. Previous researches have focused on changing clinician's attitudes or behaviors (Bekkering, Hendriks et al. 2005; Bekkering, van Tulder et al. 2005; van der Wees, Jamtvedt et

al. 2008) without including the more immediate plausible effects of education, which is gain in knowledge. Few studies in physical therapy literature have evaluated the effect of education on patient outcomes, only one of which targeted LBP (Bekkering, van Tulder et al. 2005; Brennan, Fritz et al. 2006; Cleland, Fritz et al. 2009). To our knowledge this is the first study that has evaluated the effect of education on all three desired outcomes; knowledge gained, application of learnt skill at the workplace and improved productivity defined as improvement in patient outcome.

While previous studies have evaluated knowledge using self-reported questionnaires and guideline adherence using hypothetical patient scenarios, this is one of the few studies that have evaluated knowledge using clinical vignettes and practice behaviors of therapists and patient outcomes using electronic health records, a gold standard for measurement of practice behaviors. We chose to include all three outcomes based on the rationale that gain in knowledge does not necessarily translate to behavior change and/ or improved patient outcomes.

Several barriers to guideline adherence must be discussed in light of the findings in this study. Cabana and colleagues have suggested that barriers to guideline adoption include those related to knowledge, attitudes and behaviors (of patient and therapist). In this study knowledge did not appear to be a significant barrier to guideline adherence. Even when therapists were aware of a specific recommendation in the guideline as demonstrated by their responses on the clinical vignettes they did not implement that knowledge in treatment of patients with LBP. There could be several barriers relating to therapists and/or patients that could be responsible for poor guideline adherence. Barriers related to attitudes and behaviors of therapists include lack of self-efficacy, lack of outcome expectancy and inertia of previous practice (or lack of motivation to change).

The lack of belief that one is capable of adequately performing the recommendation in practice guideline has been identified as a significant reason for non-adherence to guidelines. Lack of self-efficacy could be due to lack of skills, experience or training in the treatment approach. Lack of self-efficacy could be speculated to be the primary cause for lack of adherence to guideline recommendation related to grade V thrust mobilization. Although a large percentage of therapists in the study seemed to know what to do for patients who matched the criteria for thrust mobilization, adherence to this criterion was low (21.43%).

Lack of outcome expectancy, meaning clinicians do not believe that applying the recommendation would result in better patient outcomes is another cause for non-adherence to guidelines. Outcome expectancy for all criteria on the guideline in this study was clearly outlined in the education course. For each recommendation in the practice guidelines, supporting research articles were provided in the form of bottom lines. How the results of these studies could be applied to the clinical setting, was explained. We specifically provided outcome expectancies with treatments where possible, such as likelihood ratios for grade V thrust and stabilization exercises when criteria on the CPR were met. Despite this, physical therapists could be in disagreement with some guideline recommendations due to personal beliefs or experiences. For example overuse of stabilization may seem harmless, and therapists may continue to use these exercises although the patient profile suggests otherwise. However giving stabilization exercises to the patient regardless of the patient's presentation has the potential to worsen the patient's symptoms and lengthen the episode of care. Further research into qualitatively identifying barriers to implementation is necessary to identify why physical therapists do not adhere to guidelines for management of LBP despite being aware of the recommendations.

Inertia to change is probably the most difficult barrier to overcome. In this study we hypothesized that education and feedback regarding the clinician's performance in the audit report would help improve adherence to guidelines. This hypothesis was not supported by the results of the current study. We found that although therapists were aware of the guideline recommendations and were guideline concordant in their responses in clinical vignettes, they delivered adherent care only 51% of the time. Aligning payment policies to encourage and support quality improvement may have more promise in facilitating change in clinician's behaviors, especially those who lack motivation. Payment policies can help determine how health care organizations and professionals deliver care and how patients select and use that care (Hillman 1991). Current payment methods such as fee-for-service and capitation per case payment do not adequately encourage good quality of care.

Fee for service there is little or no incentive to provide efficient, evidence based care or to prevent unnecessary care (Miller 2009). This is especially so if the patients co-payments are low. This encourages the clinician to administer treatment that may not be needed and the patients do not mind receiving additional care at no expense.

Capitation and per case payment in contrast can lead to underutilization of services. Since there is a set payment for each patient (depending on associated co-morbidities) and providers receive reimbursements regardless of if the patient is treated or not, there is a concern for underutilization.

In Crossing the Quality Chasm, the IOM has suggested that purchasers should develop strategies to recognize and reward high quality of care to support quality improvement (IOM 2001). Implementing episode based bundled payment and comprehensive care payments, which are value-based payment methods, can help, improve quality and control cost. Value based

payment rewards quality of care through payment incentives and transparency of services provided. In these payment methods health care providers are reimbursed based on expected costs for clinically defined episodes of care (Miller 2009). In value-based payment methods value is a function of quality, safety, efficiency and cost where there are rewards for achieving pre-specified performance goals. Thus, providers are held accountable services provided and incentives discourage inappropriate, unnecessary, and costly care (Miller 2009).

Barriers related to patients include demand for outdated treatment because of lack of awareness of current standards of practice. Although patients are not expected to know what current practice standards are, educating the patient regarding new standards can help in creating a demand for evidence-based care.

In conclusion, education, audit and feedback did not have an effect on improving knowledge of or adherence to clinical practice guidelines or in improving patient outcomes. Future research should focus on identifying potential barriers to adherence of clinical practice guidelines. Efforts should also be directed towards aligning payment policies to encourage clinicians to be more guideline adherent and data from quality improvement studies should be made available to patients or the consumers to create a greater demand for improved quality.

APPENDIX A

MINIMUM DATA SET (MDS) AND WEB REPORTING INSTRUCTIONS

LOW BACK PAIN FORM

DEMOGRAPHICS (Initial Only)

Status: ☐ Licensed PT ☐ Student PT Date (Initial): _____

Patient ID: _____ Gender: ☐ Male ☐ Female

HISTORY (Initial Only)

Location (check one)
- ☐ LBP
- ☐ LBP and buttock/thigh symptoms (not distal to knee)
- ☐ LBP and leg symptoms distal to knee

Duration
- ☐ ≤ 15 Days
- ☐ > 15 Days

Location of other symptoms (check all that apply)
- ☐ N/A
- ☐ Head/Neck
- ☐ Thoracic Spine
- ☐ Upper Extremity (ies)
- ☐ Hip(s)
- ☐ Knee(s)
- ☐ Foot/Feet

FABQ
PA _____
WK _____

Post Surgical
- ☐ Yes
- ☐ No

Sought medical care for this same episode in the past?
☐ Yes ☐ No

Previous episodes of LBP ☐ 0 ☐ 1-2 ☐ 3-5 ☐ >5

Frequency Increasing ☐ Yes ☐ No

PHYSICAL EXAM: ☐ **Initial** ☐ **Follow-up** **Date:**_____

Avg SLR
- ☐ ≥ 91
- ☐ < 91

Prone Instability Test
- ☐ Positive
- ☐ Negative

Mobility Testing
- ☐ Hypo
- ☐ Normal
- ☐ Hyper

Directional Preference
- ☐ Extension
- ☐ Flexion
- ☐ No Directional Preference

Aberrant Movements
- ☐ Yes
- ☐ No

Pain (worst): _____ Flexion ROM: _____ Oswestry: _____

TREATMENT CLASSIFICATION (Initial & Weekly)

Stage I (check one)
- ☐ Thrust Manipulation (Grade V)
- ☐ Non Thrust Manipulation (Grade I-IV)
- ☐ Stabilization
- ☐ Flexion Directional Preference
- ☐ Extension Directional Preference
- ☐ Traction

Stage II (check all that apply)
- ☐ Aerobic
- ☐ General Conditioning

FABQW Status (check one)
- ☐ Negative (<29)
- ☐ "At Risk" (29-34)
- ☐ Positive (>34)

FABQPA Status
- ☐ Positive (>14)
- ☐ Negative (≤14)

NOTE: You must check
1. One Stage I category ***or*** one or more stage II categories ***and***
2. One FABQ status (initial only; weekly optional)

INTERVENTIONS (Initial & Weekly) (check all that apply)
- ☐ Patient Education/Instruction
- ☐ Flexion Exercises
- ☐ Extension Exercises
- ☐ Flexibility Exercises
- ☐ Stabilization Exercises
- ☐ General Conditioning Exercises
- ☐ Thrust Manipulation (Grade V)
- ☐ Non Thrust Manipulation (Grade I-IV)
- ☐ Aerobic Exercise
- ☐ Functional Training
- ☐ Heat Modalities
- ☐ Cold Modalities
- ☐ Traction – Mechanical
- ☐ Traction – Autotraction
- ☐ De-weighting / Unloading
- ☐ Behavioral Exercise Approach
- ☐ NMES (Strengthening)
- ☐ NMES (Pain Control)
- ☐ Soft Tissue Massage
- ☐ Myofacial Release
- ☐ Craniosacral Therapy
- ☐ Other

Demographics

- Fill out this section at the initial visit only
- **Status**: Licensed PT or Student PT – check only one box based on who is the primary therapist for the patient
- **Date**: Fill out date in the following format: dd / mm / year (for example, 25/03/2008)
- **Age**: Fill in the patient's age in years
- **Gender:** Check either male or female for the patient's sex

HISTORY

- **Location:** You must check only 1 of the 3 boxes.
  - **LBP** – This represents symptoms that can extend from T 12 down to the lumbo-sacral junction (L5/S1).
  - **LBP and buttock/thigh symptoms** –Symptoms extend below the lumbo-sacral junction, as far as the popliteal crease of the knee.
  - **LBP and leg symptoms distal to the knee** – Symptoms extend below the popliteal crease of the knee.
- **Duration**
  - You must check only one box: "≤ 15 days" or "> 15 days".
  - This represents the duration of symptoms for this episode of LBP.
  - **Location of other symptoms**
  - Check boxes representing all areas where the patient is currently experiencing symptoms, even if unrelated to his/her LBP.
  - **FABQ**
  - This is where you will report the scores of the Fear Avoidance Beliefs Questionnaire.
  - Insert the score from the Physical Activity subscale after the letters "PA" (the range of scores is 0-24)
  - Insert the score from the Work subscale after the letters "WK" (the range of scores is 0-42)
  - **Post-Surgical**
  - Check "Yes" if the patient has had surgery to the lumbar spine. Do not check "yes" if he/she has had surgery to the thoracic or cervical spine regions.
  - **Sought medical care for this same episode in the past?**
  - You must check only one box. Check yes only if the medical care was for THIS EPISODE of LBP. If care was sought for a prior episode only, you should check "no".
  - **Previous episodes of LBP**
  - The patient is asked about the number of prior episodes of LBP that have caused him/her to miss work or reduce his functional activity level. Check the appropriate box to represent this number.
  - **Frequency Increasing**
  - You must check only one box. Check "yes" if the frequency of episodes of LBP (that cause the patient to miss work or reduce functional activity levels) is increasing.

PHYSICAL EXAM

– Fill this section out at the initial visit and at follow-up visits. For follow-up visits, enter the date of the visit (in dd / mm / year format), and the visit number.

– **Visit number:**
  - You fill out the actual visit number for the patient. Include the initial visit. For example, if a patient has been to your clinic for an initial visit and 3 follow-up visits, you would enter "4" for the visit number. If there was ever an occasion where the patient came to your clinic and was billed for care, but you did not see the patient, this would still count as a visit.

– **Avg SLR**
  - The patient is supine with the head relaxed. The examiner holds the foot with one hand to maintain the hip in neutral rotation. The inclinometer is positioned on the tibial crest just below the tibial tubercle. The leg is raised passively by the examiner, whose other hand maintains the knee in extension. The leg is raised slowly to the maximum tolerated straight leg raise (not the onset of pain). The maximum straight leg raise is recorded in degrees. The opposite leg is then tested in the same manner. Average straight leg raise is computed by adding the maximum straight leg raise of the left and right legs and dividing by two.

– **Prone Instability Test**
  - The patient lies prone with the body on the examining table and legs over the edge and feet resting on the floor. While the patient rests in this position, the examiner applies posterior to anterior pressure (PA) to the lumbar spine. Any provocation of pain is noted. Then the patient lifts the legs off the floor (the patient may hold table to maintain position) and posterior compression is applied again to the lumbar spine.
  - Positive Test - If pain is present in the resting position but <u>subsides</u> substantially (either reduces in severity/intensity, or resolves) in the second position, the test is positive. Mild improvement in symptoms does not constitute a positive test.
  - Negative Test – If pain is present in the resting position, but <u>does not subside substantially</u> in the second position, the test is negative. Further, if the patient did not have any pain provocation with PAs, then you should mark "negative".

– **Mobility Testing**
  - Mobility or spring testing is performed by placing the hypothenar eminence (just distal to the pisiform) of the hand over the spinous process of the segment to be tested. With the elbow and wrist extended, the examiner applies a gentle but firm, anteriorly-directed pressure on the spinous process. Interpretation of whether a segment is hypomobile, normal, or hypermobile should be based on the examiner's anticipation of what normal mobility should feel like at that spinal level and compared to the mobility detected in the spinal segments above and below the segmental level of interest.
  - The following options are available for each level tested:
    - Hypomobility – Passive mobility is judged to be hypomobile at <u>≥</u> 1 lumbar spine segmental level
    - Normal - Passive mobility is judged to be normal throughout the lumbar spine (L1-L5)

- Hypermobility - Passive mobility is judged to be hypermobile at $\geq$ 1 lumbar spine segmental level

- Note that you are able to check both "Hypo" and "Hyper" if you find $\geq$1 lumbar spinal segment that is hypermobile and $\geq$1 lumbar spinal segment that is hypomobile. However, if you check "normal", this implies that all segments (from L1-L5) exhibited normal mobility.

– **Directional Preference**
  - This term focuses on selecting a particular direction of exercise that exhibits a centralization of symptoms with lumbar movement testing during the initial examination and can include extension, flexion, or no directional preference. Note that centralization is defined as when a movement or position results in the migration of symptoms from an area more distal or lateral in the buttocks and/or lower extremity to a location more proximal or closer to the midline of the lumbar spine.
  - Extension – Mark this if your patient's symptoms centralize with repeated extension movements/exercises
  - Flexion – Mark this if your patient's symptoms centralize with repeated flexion movements/exercises
  - No Directional Preference – Mark this if your patient's symptoms do not centralize with either repeated flexion or repeated extension movements/exercises
– **Aberrant Movements**
  - Check "yes" if you observe any of the following **aberrant movement** (as defined below) during sagittal plane motion:
    - Instability catch: An instability catch is defined as any trunk movement outside of the plane of specified motion during that particular motion i.e., lateral sidebending during trunk flexion).
    - Painful arc (on descent or return): Symptoms felt during the movement at a particular point in the motion (or through a particular portion of the range) that are not present before or after this point.
    - Thigh climbing: Using the hands on thighs (or some other external support) to push up on when returning from flexion to the upright position.
    - Reversal of lumbopelvic rhythm: The trunk being extended first, followed by extension of the hips and pelvis to bring the body back to upright position.
– **Hip IR ROM**
  - The patient lies prone. The examiner places the opposite leg of the leg to be measured in 30° of hip abduction to enable the tested hip to be freely moved into external rotation. The lower extremity of the side to be tested is kept in line with the body (ie neutral abduction/adduction), and the knee on that side is flexed to 90° with the ankle in the neutral position, and the leg in the vertical position. The inclinometer is placed on the distal aspect of the fibula in line with the bone and zeroed. Measurement of hip IR (hip rotated in a lateral direction [leg moved toward the edge of the plinth) is recorded at the point in which the pelvis first begins to move. The measurement should be recorded bilaterally. When measuring hip

rotation, be sure that the knee remains in the same place (does not slide inward toward the opposite knee or outward away from the opposite knee).
    - Check whichever box is applicable: "≥ 1 hip IR > 35°" or "No hip IR > 35°.
- **Pain (worst)**
    - Record the worst pain the patient has experienced in the past 24 hours (0-10 scale, 0 = no pain, 10 = worst pain imaginable)
- **Flexion ROM**
    - Lumbar range of motion is measured with a fluid-filled inclinometer. The patient stands erect. The inclinometer is held at T_{12}-L_1 and the patient is asked to reach down as far as possible towards the toes while keeping the knees straight. The measurement of total flexion is recorded in degrees.
- **Oswestry**
    - Simply insert the actual percentage score (0-100). Do not enter the raw points obtained out of 50. Use the procedure below to score the Oswestry.

Scoring the Oswestry

a. Assign a score to each section. Each section can be scored from 0-5, based on the selection chosen by the subject. If the subject marks the first response, assign a score of 0, the next response a 1, the next response a 2, and so on, with the final response being assigned a score of 5. Below is an example of the section called "Pain Intensity" with the corresponding score that should be assigned if that response is selected.

- **Pain Intensity**
- I can tolerate the pain I have without having to use pain medication. **(0)**
- The pain is bad but I can manage without having to take pain medication. **(1)**
- Pain medication provides me complete relief from pain. **(2)**
- Pain medication provides me with moderate relief from pain. **(3)**
- Pain medication provides me with little relief from pain. **(4)**
- Pain medication has no affect on my pain. **(5)**

b. Add up the individual scores for each section.
c. Divide this result by 50, and report as a percentage (ex. 30/50 = 60%). In the event a subject does not complete each section adjust the denominator accordingly. For example, if the subject does not answer the question with respect to "Social Life", divide by 45 instead of 50. Divide by 40 if they leave 2 sections blank, 35 if they leave 3 sections blank, and so on. **(Note: Therapists should always check to ensure all items are completed to minimize having to adjust the score.)**
d. Mark the score on the form and circle it.

TREATMENT CLASSIFICATION

- Fill out at the initial visit and follow-up visits.
- **<u>You must check</u>**:
  - One Stage I category OR one or more stage II categories <u>AND</u>
  - One FABQ status (initial entry for FABQ status is mandatory, weekly entries optional)
- **Stage I – Check only one box (Thrust Manip, Non-Thrust Manip, Stabilization, Flexion Directional Preference, Extension Directional Preference, Traction)**
  - Selection of Stage I is based on the patient meeting the following criteria:
    - Patients with higher levels of disability (Oswestry scores generally greater than 30%) and substantial reported difficulty with basic daily activities such as sitting, standing, and walking.
    - Management goals are to improve the ability to perform basic daily activities, reduce disability, and permit the patient to advance in his or her rehabilitation.
  - Thrust spinal mobilization (Gr V) – Primary initial intervention approach is to improve mobility / decrease pain / decrease disability through the use of thrust spinal mobilization to the lumbo-pelvic region
  - Non thrust Spinal mobilization (Gr I – IV) - Primary initial intervention approach is to improve mobility / decrease pain / decrease disability through the use of non-thrust spinal mobilization to the lumbo-pelvic region
  - Stabilization – Primary initial goal for therapy is to work on lumbo-pelvic stabilization / re-education / "core stability"
  - Flexion Directional Preference – Primary initial focus of intervention is to have the patient perform repeated flexion movements / exercises. For patients in this classification, symptoms peripheralize with lumbar extension; symptoms centralize with lumbar flexion
  - Extension Directional Preference - – Primary initial focus of intervention is to have the patient perform repeated extension movements / exercises. For patients in this classification, symptoms centralize with lumbar extension; symptoms peripheralize with lumbar flexion
  - Traction - Signs and symptoms of nerve root compression, but no movements centralize symptoms
- **Stage II – Check one or both boxes as applicable: Aerobic or General Conditioning**
  - Selection of Stage II is based on the patient meeting the following criteria:
    *Individuals in the Stage II Classification include those whose symptoms are not acute and who are only having moderate difficulty with ADLs or work activities
    Management goals are to improve strength, flexibility, and conditioning, or with a work-reconditioning program.
  - Aerobic – Check this box if aerobic conditioning is a primary management goal
  - General Conditioning – Check this box if management goals include working on improving strength, flexibility, or work reconditioning.
- **FABQW Status (check one box only)**
  - Negative – Mark this if the FABQW subscore is < 29 pts

- At Risk – Mark if FABQW subscore is between 29 and 34 pts
- Positive – Mark if FABQ subscore is > 34 pts

– **FABQPA Status (check one box only)**
- Positive – Mark if the FABQPA subscore is >14
- Negative – Mark if the FABQPA subscore is $\leq$ 14

INTERVENTIONS

– Check all boxes that apply at the initial visit and weekly

– **Patient Education/Instruction –** Includes verbal or written education/instruction provided to the patient

– **Flexion Exercises** – Includes any exercises designed to repeatedly flex the spine, such as double-knee-to-chest and single-knee-to-chest exercises

– **Extension Exercises–** Includes any exercises designed to repeatedly extend the spine, such as prone press ups or repeated extension exercises in standing

– **Flexibility Exercises -** Includes any exercises designed to improve muscle lenghth or flexibility. Also includes self-mobilization and general mobility exercises (ie. Pelvic tilts, hand-heel rocks, etc).

– **Stabilization Exercises** – Includes exercises designed to specifically strengthen the trunk musculature (ie, transversus abdominus, multifidus, lateral abdominal muscles, etc.)

– **General Conditioning Exercises** – Includes general strength and conditioning exercise such as calisthenics, general resistance training (ie, lifting weights), etc.

– **Thrust Spinal mobilization (Gr V)** – Includes only thrust, or grade V, spinal mobilization (also called small amplitude, high velocity spinal mobilization)
- **Check all regions that apply:** thoracic spine, lumbo-pelvic region, hips

– **Non Thrust Spinal mobilization (Gr I-IV)-** Includes all forms of joint mobilization/spinal mobilization that doesn't include thrust, or high velocity, technique
- **Check all regions that apply:** thoracic spine, lumbo-pelvic region, hips

– **Aerobic Exercise** – Exercise geared to improve the aerobic capacity of the patient (walking, jogging, running, cycling, stairstepper, etc)

– **Functional Training** – Exercises that are designed specifically to improve certain functional or job-related tasks

– **Heat Modalities** – Includes any physical modalities designed to increase the tissue temperature, such as ultrasound (include both pulsed and continuous here), moist heat packs, diathermy, etc

– **Cold Modalities** - Includes any physical modalities designed to decrease tissue temperature

– **Traction – Mechanical** – Includes traction that is performed to the lumbo-pelvic region through the use of mechanical traction device.

– **Traction – Autotraction** – An autotraction device must be used to check this box.

– **De-weighting / Unloading** – Check this box if you use some form of body-weight support / deweighting / unloading device. Typically, these devices support the patient in a harness and "unload" a portion of the patient's body weight. These are typically arranged over a treadmill so that the patient can walk while a portion of his/her body weight is unloaded, or supported, by the unloading device.

- **Behavioral Exercise Approach** – Includes use of principles of cognitive behavioral therapy in a physical therapy setting (graded exercise approach, use of quotas for exercise, focus on function > pain, focus on remaining active during episode of LBP, practicing/confronting fearful activities, etc.
- **NMES (strengthening) –** Any form of electrical stimulation that is selected / designed for strengthening
- **NMES (Pain control) –** Any form of electrical stimulation that is selected / designed to reduce pain
- **Soft Tissue Massage –** Includes soft tissue techniques that are not myofascial release or Craniosacral therapy techniques
- **Myofascial Release** – Includes any techniques used to improve the mobility of the skin and fascia
- **Craniosacral Therapy** – Includes any techniques specifically designed to target the craniosacral system
- **Neural Mobilization** – Includes any techniques specifically designed to "mobilize" or "tension" the neural system (ie slump stretching, "neural flossing", etc).
- **Other** – Check this box if you used a form of intervention that does not fit into any of the above categories

APPENDIX B

QUALITY INDICATORS FOR LOW BACK PAIN GUIDELINES

Clinical Presentation	Treatment Given	On/off protocol
IF	AND	THEN
1. Mobilization Thrust A. Oswestry scores>=30, Pain duration<15 days, LBP is in back only OR radiates up to the knee OR B. Oswestry score >=30 AND 3 of 4 criteria positive Pain Duration<15 days Pain in low back or up to knee, Hypo-mobility with spring testing FABQ work score <19	Mobilization Thrust	On protocol for Mobilization Thrust
	Mobilization Thrust NOT given	Off protocol for Mobilization Thrust
2. Stabilization A. Prone Instability test (PI) is positive OR B. 3 of 4 criteria are positive on Stabilization CPR Prone Instability test positive Aberrant movements present Average SLR>91 Age<40 years	Stabilization exercises given	On protocol for Stabilization
	Stabilization exercises not given	Off protocol for Stabilization
3. Flexion Directional Preference: Location of pain distal to knee and directional preference flexion	Flexion exercises given	On protocol for Flexion Directional Preference
	Flexion exercises not given	Off protocol for Flexion Directional Preference
4. Extension Directional Preference: Location of pain distal to knee and directional preference extension	Extension exercises given	On protocol for Extension Directional Preference
	Extension exercises not given	Off protocol for Extension Directional Preference

APPENDIX B (continued)

5. Traction Location of pain distal to knee and No directional preference	Traction given	On protocol for Traction
	Traction not given	Off protocol for Traction
LBP only	Directional preference exercises given Or Traction given	Off protocol for Traction
6. Graded exercise for fear avoidance: FABQ work score>29 OR FABQ Physical activity score >19	Bio-Behavioral exercises given	On protocol for graded exercise for fear avoidance
	Bio-Behavioral exercises not given	Off protocol for graded exercise for fear avoidance

APPENDIX C

INFORMED CONSENT DOCUMENT

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Effect of Continuing Education on Quality of Care Delivered to Patients with Low Back Pain.

PRINCIPAL INVESTIGATOR: **Sonali Shenoy,** Ms. PT
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SOURCE OF SUPPORT: None

Why is this research being done?

You are being asked to participate in a quality improvement research study in which we evaluate if education and feedback can improve and optimize quality of physical therapeutic care delivered to patients with Low Back Pain. In this study a web-based educational module will be used to disseminate evidence based treatment decision-making approaches (Clinical Practice Guidelines) to physical therapists for management of Low Back Pain. We will specifically

evaluate if education and feedback can improve adherence to practice guidelines and if adherence to practice guidelines has a potential to improve treatment outcomes for Low Back Pain.

In this research study, we will randomly assign your clinical practice to the experimental or control group. The therapists from the clinical practice assigned to the treatment group will complete a web-based educational module and those in the control group will not receive any educational interventions beyond that required in normal practice (that is any educational program taken for continuing education credits as a part of routine employment practice).

Who is being asked to take part in this research study?

You are being invited to take part in this research study because you are a Physical Therapists practicing at Centers for Rehab Services, who is likely to provide treatment patients with Low Back Pain.
People invited to participate in this study must be between licensed Physical Therapists. The study is being performed on a total of 40 clinical practices at the Centers for Rehab Services.

What procedures will be performed for research purposes?

Baseline Measure:
You will be required to take a short multiple choice exam with 19 questions prior to the randomization procedure. The exam will contain questions directed towards clinical decision making for management of various presented cases of Low Back Pain.

Educational Program:

If you decide to take part in this research study and are randomized to the educational intervention group, you will take a web-based educational program that will include 10 short educational modules. The learning objectives for the course and educational modules are described briefly below.

Learning Objectives: The learning objectives for the course emphasize that on completion of the course the therapists would be able to identify patients eligible for management with manipulation, stabilization, bio-behavioral intervention, traction or directional preference exercises and tailor treatment protocols for patients classified to each of these treatments.

Introductory Module 1: "Clinical Decision Making Paradigm" is an over view of the clinical decision making paradigm for management of LBP.
Introductory Module 2: "Prior to First Encounter." is a review of medical forms used in the Physical therapy clinic to collect information regarding the patient prior to the patient interview.
Introductory Module 3: "Key Elements in History" is a review of the key elements in history of patient episode of LBP that are helpful in development of preliminary

hypothesis regarding presence of serious underlying pathology as a source of the LBP and establishing patients eligibility for PT treatment. A hypothetical case is presented to review this material.

Introductory Module 4: "Neurological Assessment" is an overview of assessments conducted to rule out neurological involvement in patients with LBP.

Advanced Module 5: "Staging and Classification of patients with LBP" is an overview of the classification-based approach to treatment of LBP. Information regarding criteria for staging patients with LBP based on severity of symptoms and further classification of Stage I patients into sub-groups is presented.

Advanced Module 6: "**The Manipulation Classification"** presents criteria for identification of patients eligible for spinal manipulation. Strength of evidence to support use of manipulation for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Advanced Module 7: "**The Stabilization Classification"** presents criteria for identification of patients eligible for spinal stabilization exercises. Strength of evidence to support use of for spinal stabilization the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Advanced Module 8: "**The Directional Preference Classification"** presents criteria for identification of patients eligible for directional preference exercises. Strength of evidence to support use of directional preference exercises for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Advanced Module 9: "**The Bio-behavioral Classification"** presents criteria for identification of patients eligible for bio-behavioral exercises. Strength of evidence to support use of bio-behavioral exercises for the identified subgroup is presented. A hypothetical case is presented to review this material and a protocol for use of the technique is suggested.

Summary Module 10

<u>Follow up exam:</u>

You will be required to take a short multiple-choice exam with 19 questions on completion of the educational program. The exam will contain questions directed towards clinical decision making for management of various presented cases of Low Back Pain.

What are the possible risks, side effects, and discomforts of this research study?

There are no medical risks, or side-effects from participating in this study. You may experience test anxiety or anxiety related to completion of an educational program.

What are possible benefits from taking part in this study?

You will not receive any direct benefits from participation in the study. There is a potential to improve quality of patient care and improve standards of care delivered to patients with Low Back Pain.

Will I be paid if I take part in this research study?

You will receive the educational program free of cost and continuing education credit for completion of the educational program. You will also receive two educational days leave from work.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of five years after final reporting or publication of a project.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if

you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future employment at a UPMC hospital.

You are not under any obligation to participate in this research study.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future employment at a UPMC hospital.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____	_____	_____
Participant's Signature	Printed Name of Participant	Date

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise."

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

APPENDIX D

SAMPLE OF EMAILS TO THERAPISTS REGARDING CLINICAL PERFORMANCE

D.1.1 EMAIL TO THERAPISTS REGARDING CLINICAL PERFORMANCE

Dear Therapist,

Thank you for participating in the Low Back Pain study.

We will be providing you with periodic feedback regarding your clinical performance in the management of patients with Low Back Pain. We will be analyzing all patients with Low Back Pain and through the low back minimal data set inputted by you establishing the treatment classification for each of these patients. We will then check to see if the treatment given to the patient at the **first visit** corresponds with the treatment classification of the patient.

This mail contains a summary of your performance in the management of Low Back Pain for the period of xx/xx/xxxx through xx/xx/xxxx.

You treated a total of x patients with Low Back Pain. You adhered to the guidelines for management of patients with Low Back Pain **x/x or xx%** of the time. You did not adhere to the guidelines for management of Low Back Pain in **x/x or xx%** of these cases. Outlined below is a summary of adherence to clinical guidelines for the time period specified above.

Classification	Number of Classifications	On-Protocol	Off-protocol	Percentage On-protocol	Percentage Off-protocol
Grade V Thrust					
Stabilization					
Flexion Directional Preference					
Extension Directional Preference					
Traction					
Graded exercise for fear avoidance					
Total					

The attached word file includes the account numbers for each of the patients you treated and their established classifications. Please download and review both attachments sent with this email.

Please email me if you have any questions or need any clarifications regarding this information and your adherence to clinical guidelines.

Thank you,

D.1.2 BENCHMARKED EMAIL TO THERAPISTS

Dear Therapist,

This document includes the account numbers for each of the patients you treated and their established classifications.

No	Account No.	Visit Date	Post-Surgical	Classification	Appropriate Treatment Given

I have attached the clinical decision making rationale behind these classifications along with the email. Please review these as well.

Please email me if you have any questions or need any clarifications regarding this information and your adherence to clinical guidelines.

Thank you,

APPENDIX E

ITEMIZED RESPONSES TO QUESTIONS ON THE COMPETENCE TEST (CORRECT ANSWERS IN BOLD)

RULE OUT RED FLAGS				
Q2. A 17-year-old male patient complains of severe LBP. He has had several such episodes of LBP in the past 2 years. There is no history of trauma. He is unable to go to school or play sports because of this current episode of pain. Given the clinical profile what are your initial concerns about this patient? A. Rule out Fear-Avoidance behavior B. Rule out Neurovascular compromise **C. Rule out non-musculoskeletal cause of pain**	6(14.6)	2(4.9)	**33(80.5)**	0
Q9. A 65-year-old female developed LBP after falling in the shower 2 days ago. The patient presents to the clinic in a wheel chair and is reluctant to stand because this worsens the pain considerably. Her body diagram markings indicate that the pain is felt in the left sacral area, extending into the groin and down her entire left leg. She scores a 32/42 on the FABQ. Given this brief clinical profile, please choose the most appropriate preliminary hypotheses for this patient: A. This patient is demonstrating fear- avoidance belief behavior and should be referred for psychological consultation to address this **B. This patient has possible sustained a fracture and should be referred to a health care practitioner for further diagnostics** C. The patient demonstrates some fear-avoidance and is most likely benefit from graded exercises to address pain and dysfunction D. This patient may have lumbar spinal stenosis and should be started on an exercise program.	0	**40(97.6)**	1(2.4)	0

APPENDIX E (continued)

DIFFERENTIAL DIAGNOSIS FOR HIP INVOLVEMENT				
Q3. A 65-year-old male patient complains of a gradual onset of stiffness and aching in the low back, buttocks and left anterior thigh. Given the clinical profile what is your preliminary hypothesis? A. Mechanical Low Back Pain B. Neurovascular compromise **C. Possible hip involvement** D. Non-musculoskeletal condition	19(46.3)	4(9.8)	**17(41.5)**	1(2.4)
Q18. A 45-year-old female complains of pain in the low back that extends into her right buttock and anterior thigh. She reports that the pain is worse in the evenings than in the mornings. The pain is aggravated when she bears weight on the right leg or when walking and is relieved when she sits. Her positions of maximum comfort are leaning back in a reclining chair or lying down (supine) because the pain persists when she sits erect. There are no red flags present. Given this brief clinical profile, what is the most probable hypothesis? A. Lumbar stenosis B. Sacro-iliac dysfunction C. Dysfunction at the L4 vertebral level **D. Hip osteoarthritis**	0	**15(36.6)**	7(17.1)	19(46.3)
Q11. A 65-year-old male patient complains of pain in the low back that extends into his left buttock and groin. He reports that the pain has been there for quite some time however he did not seek medical help for it before, as it did not bother him that much. In the past month his pain has worsened and he cannot stand for too long (over 30 minutes). He has started walking with a cane for the past three weeks, because this seemed to help decrease the pain. During the standing exam you notice that his left PSIS is higher than the right PSIS. When you re-examine this in sitting the PSIS seem leveled. There are no red flags present. His Oswestry score is 65 and FABQ physical activity sub-score is 14/24. Given this information what is the most probable hypothesis? A. This patient has a posteriorly rotated left innominate and further tests should be conducted to rule in/out this hypothesis. B. This patient has an anteriorly rotated right innominate and further tests should be conducted to rule in/out this hypothesis. C. **This patient has hip arthritis and further tests should be conducted to rule in or rule out this hypothesis**. D. This patient has a dysfunction at the L4 vertebral level and further tests should be conducted to rule in/out this hypothesis.	3(7.3)	3(7.3)	**35(85.4)**	0

APPENDIX E (continued)

Q4. A 28-year-old woman reports LBP that extends into the back of her calf, which is 8/10 on Visual Analogue Scale (VAS). The pain is present in sitting and standing. She is unable to perform her daily household chores. Given this brief clinical profile, please choose the most appropriate preliminary hypotheses for this patient: A. Fear-Avoidance behavior B. Neurovascular compromise **C. Rule out hip involvement** D. Non-musculoskeletal condition	1(2.4)	36(87.8)	**0**	4(9.8)
THRUST MOBILIZATION				
Q17. You are evaluating a patient who complains of LBP with radiation down to the leg and calf following a fall on the buttocks 3 days ago. He scores 34/42 on the FABQ Work subscale. On further examination you find that this patient meets 2/5 criteria on the Clinical Prediction Rule for spinal mobilization. Assuming a pre-test probability of 44% with a negative likelihood ratio of 0.01, what is the post-probability of success with spinal mobilization for this patient? A. **Less than 10%** B. Between 10-20% C. Between 20-30% D. Still around 45%	**33(80.5)**	2(4.9)	5(12.2)	1(2.4)
Q6. A patient complains of pain in the low back for the past 4 days. He is a tennis player and first experienced a sharp pain when playing a game 4 days ago. He described several episodes of LBP in the past. He does not have radicular symptoms but the pain is worse when he extends and is relieved when flexing during movement testing. The symptoms are localized to the low back during testing. What treatment would you give this patient on the first visit? A. Traction followed by electrical stimulation B. Stabilization exercises to strengthen the core abdominal muscles C. Directional Preference exercises **D. Thrust Spinal mobilization**	0	2(4.9)	13(31.7)	**26(63.4)**

APPENDIX E (continued)

STABILIZATION EXERCISE				
Q10. In this picture, a physical therapist is performing a special test on a patient. In the first part of the test the physical therapist performs spring testing of the vertebral segment. After, spring testing, the patient is instructed to assume the position in the picture. The therapist will consider the test to be positive when the patient reports that: **A. Pain is present during the spring test of the vertebral levels but disappears when the patient raises her legs off the ground.** B. Pain is present during the spring test of the vertebral levels but disappears when the patient lowers her legs to the ground. C. Pain is present during the spring test of the vertebral levels and also when the patient extends her legs off the ground. D. Pain is not present on spring testing of the vertebral levels but appears when the patient extends her legs off the ground.	**36(87.8)**	2(4.9)	3(7.3)	0
Q8. A patient reports a history of long standing low back pain (over 2 years). The pain is recorded as 4/10 on Visual Analogue Scale (VAS).. She is unable to sit or stand for a long time (over 30 minutes) and feels the need to "stretch out" her back every now and then. There are no symptoms of radiation or referred pain. Given this clinical profile what is your preliminary hypothesis according to the practice guidelines for LBP? A. Traction category **B. Stabilization category** C. Directional Preference category D. Spinal mobilization category	2(4.9)	**33(80.5)**	2(4.9)	4(9.8)
Q15. A 30-year-old male patient reports recurrent episodes of LBP. He rates his pain as 4/10 on Visual Analogue Scale (VAS). Pain is localized to the low back without radiation, and worsens in the evenings. There are no red flags present and on examination the patient demonstrates a positive prone instability test. Which type of treatment would he respond most favorably based on the Clinical Predication Rules for LBP? A. Spinal mobilization **B. Stabilization** C. Extension exercises D. Traction	1(2.4)	**39(95.1)**	1(2.4)	0

APPENDIX E (continued)

Q12. When performing an assessment on a patient with LBP you recognize that your patient has a positive test in 3 of the 4 predictors in the Clinical Prediction Rule for failure Stabilization. Assume that the patient has a pre-test probability of failure using stabilization exercises of 45%. Given that the positive likelihood ratio when 3 of 4 criteria are met is 18.8% what will be the post-test probability of failure? A. Over 95% B. Between 70-80% C. Greater than 95% D. Below 50%	0	33(80.5)	**7(17.1)**	1(2.4)
DIRECTIONAL PREFERENCE				
Q13. Your patient has baseline pain in the low back that he rates as 5/10 on Visual Analogue Scale (VAS). The patient also reports pain down the leg at 5/10 on VAS and paresthesia along the lateral border of the foot. When he performs extension during movement testing, the VAS ratings for pain in the back and leg immediately reduce to 3/10 with no effect on the paresthesia. There are no red flags present. Given this brief clinical profile, what is the status change indicated as a result of extension movement? A. Improved, or better, because back pain decreases. B. Improves in the back, worsens in the foot. C. Worsens because there was no change in the paresthesia. **D. Status Quo, no change because there was no change in the paresthesia.**	12(29.3)	0	0	**29(70.7)**
Q5. A 65-year-old male patient complains of LBP radiating into both low extremities. The pain in his legs worsens when walking and moving around and is better if he rests. Given this brief clinical profile, please choose the most appropriate treatment classification for the patient according to the the practice guidelines for low back pain: A. Traction B. Stabilization **C. Directional Preference** D. Spinal mobilization	8(19.5)	0	**33(80.5)**	0

APPENDIX E (continued)

Q16. At baseline, your Stage I LBP patient has pain in the low back (Visual Analogue Scale (VAS). Rating of 3/10) and along the lateral border of the calf (VAS rating 9/10). The patient also reports paresthesia in the calf. When he is asked to perform lumbar flexion during movement testing, the pain in the back is reported as 1/10, the pain in the calf area as 2/10 and the paresthesia disappears. There are no red flags present. Recent evidence suggests that clinical management of this patient should include: A. Flexion-oriented program emphasizing end-range flexed postures, having established flexion as the direction of preference. B. Extension-oriented program with emphasis on walking and running, having established extension as the direction of preference. C. Flexion-oriented program emphasizing flexion and general lower extremity strengthening exercises. D. Extension-oriented program with emphasis on prone extension exercises having established extension as the direction of preference.	17(41.5)	1(2.4)	**23(56.1)**	0
TRACTION				
Q7. A 35-year-old male patient comes to the clinic complaining of LBP that he has had for a week. The patient's pain radiates from the back into the left posterior-lateral thigh. He rates the pain in the leg as a 5/10 on the Visual Analogue Scale. When performing a straight leg raise test on the left you notice that the pain is reproduced along the back of the right leg. He has no red flags present at initial screening. He is a factory worker and is eager to get back to work as soon as possible. Which type of treatment would he be most likely to respond to? A. Extension exercises B. Spinal mobilization **C. Traction** D. Stabilization	13(31.7)	12(29.3)	**16(39)**	0

APPENDIX E (continued)

GRADED EXERCISES FOR FEAR AVOIDANCE				
Q1. A patient complains of severe low back pain (LBP) that has affected his ability to perform basic Activities of Daily Living for over six months. Given this brief clinical profile, please choose the most appropriate preliminary hypotheses for the patient: A. **Fear-Avoidance behavior** B. Neurovascular compromise C. Rule out hip involvement D. Non-musculoskeletal condition	**27(65.9)**	0 (0.0)	4(9.8)	10(24.4)
Q14. A patient revisits your clinic 7 days after discharge. You originally treated him for a back injury that he sustained while lifting a heavy box at work. You gave this patient Extension Principle treatment for two weeks after which the patient reported that his symptoms had subsided. He now reports that the back pain has worsened since his discharge and he is reluctant to return to work and resume physical labor. At this visit, his medical screening questionnaire has no significant findings, his Oswestry score is 55%, and FABQ Work subscale score is 34/42. Given this brief clinical profile, what can you conclude about this patient? A. This patient does not need further treatment because he is exhibiting signs of malingering. B. This patient probably requires further psychological assessment followed by psychological treatment for fear-avoidance belief behavior. C. This patient is demonstrating fear-avoidance beliefs and will benefit from treatment after this has resolved on its own. **D. This patient is demonstrating fear-avoidance belief behavior and treatment should include bio-behavioral exercises and counseling to address the fear associated with return to work.**	1(2.4)	2(4.9)	0	**38(92.7)**

APPENDIX F

EFFECT OF ITEM REMOVAL ON COMPETENCE TEST: PILOT DATA

Total Group			Before	After
	Composite	Mean	22.97	22.104
		StD	5.91	5.83
		p-value	0.812	0.819
	Form A	Mean	11.52	11.07
		StD	3.16	3.24
		p-value	0.67	0.703
	Form B	Mean	11.45	11.03
		StD	3.36	3.17
		p-value	0.71	0.692
First years	Composite	Mean	18.09	17.22
		StD	3.66	3.59
		p-value	0.46	0.464
	Form A	Mean	9.13	8.61
		StD	2.21	2.19
		p-value	0.25	0.305
	Form B	Mean	8.96	8.61
		StD	2.47	2.38
		p-value	0.41	0.413
Final years	Composite	Mean	28.19	27.21
		StD	2.27	2.16
		p-value	0.05	0.037
	Form A	Mean	14.07	13.57
		StD	1.68	1.65
		p-value	0.18	0.109
	Form B	Mean	14.12	13.64
		StD	1.73	1.57
		p-value	0.17	0.083

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