Part 2: Steps Required to Develop a Foundation for Practice-Based Evidence (PBE) Designed Observational Study

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Faculty Affiliation and Disclosure

• Affiliation
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• Disclosure
  – No financial relationships with FOTO
  – No affiliations which may bias data presentation
  – Our research group (PBERN) uses FOTO software to collect and manage outcomes data on our patients on a routine basis
Background: APTA’s “2020” Vision

A competent rehabilitation professional (i.e., first-contact clinician in a direct access environment), demonstrates:

1) *evidence-based practice* for physical therapy differential diagnosis & intervention, and
2) leadership by collecting data during routine care documenting patient outcomes demonstrating *efficient & effective treatment choices*
Background: Strength of Evidence

Strong evidence

- RCT
- Qualitative
- Case Study or Case-series

Weak evidence

Stories: "Expert Opinion" Information

Research = Outcomes! Finding the Right Treatment for the Right Patient?
Background: Right RX for Right Patient

- Practice guidelines: randomized control trial
- RCT is the traditional gold standard for determining best evidence for guiding medical care and intervention
- RCT methodology is ideal for isolating treatment effect or establishing treatment efficacy by minimizing patient differences and unmeasured confounders through “blinded randomization processes”
Background: RCT Design

- RCT methodology
  - Strict inclusion & exclusion criteria
  - Treatment is performed under tightly controlled protocols conducted by experts in large academic/medical settings

- Example: Childs et al. Annals Intern Med 2004
  Validating CPR for spinal manipulation
  - Patients & clinical setting
    - 24% of all patients with LBP screened were eligible
    - Average age 34 years
    - 58% males
    - Average duration of symptoms = 2 ½ weeks
    - Military health care facilities
Background: RCT & PBE Designs

• Generalizability of the evidence? For examples:
  – Does the patient in the treatment room match the patient described in the RCT?
  – Are outcomes from efficacious treatments enhanced or diminished when such treatments are rendered in combination with other interventions?

• Alternative research design: compliments RCT
  – Practice-Based Evidence (PBE): observation, standardized data documentation & reporting driven by the clinician at the patient bedside reflecting actual practice

Horn, S et al. Another look at observational studies: Going beyond the holy grail of RCT APMR 2005
Practice-Based Evidence Research

• The advantages of PBE design
  – 1) reflects actual clinical practice
  – 2) research: clinical-driven i.e. clinician informs research
  – 2) examines generalizability for everyday clinical care
  – 3) examines associations between patient outcomes & interventions while controlling for confounders
  – 4) generates hypotheses for future testing in RCT
Practice-Based Evidence Research

• Supports APTA’s mandate to enhance delivery of care by vitalizing clinical practice-informed research through:
  – Development of a national clinical research network creating large outcome database with core set of outcome measures
  – Develops an organized system that uses observational study design to collect data in a standardized manner to evaluate clinical effectiveness and efficiency
  – Process allows knowledge translation through publication and presentations
Specific steps for implementing an observational PBE designed study using a “standard data & outcome documentation process”
A PBE Research Design Study

• Step-by-step implementation process:
  – Step 1: Forming a national clinical research network
  – Step 2: Developing a uniform outcome database
  – Step 3: Programming software
  – Step 4: Initiating data collection
  – Step 5: Checking data quality
  – Step 6: Identifying additional needs using PBE
PBE Implementation: Step 1

• Develop a clinical team

• PBE Research Network
  – 14 physical therapists in 9 states
  • 11 full time clinicians from 3 different practice settings: hospital-based, private practice, and military
  • 3 statistical consultants

• Outcome measurement tool: FOTO
  – Large national database (3 million patients)
  – Risk adjustment for CER analyses
PBE Implementation: Step 2

• Developing a database - 4 important criteria:
  – Patient characteristics
  – Outcome measures/questionnaires
  – Standardized and quantified physical examination tests
  – Standardized & reliable treatment choices
Criterion 1: Patient Characteristics

- Identify important patient characteristics or prognostic factors which influence FS & pain outcomes beyond RX rendered
- Important known prognostic factors
  - Intake functional status & intake pain intensity
  - Body part, age, symptom duration, and gender
  - Surgical and exercise histories
  - # Medical co-morbidities and payer
  - Psychosocial factors, clinician & practice type
  - Classification based on signs and symptoms
Criterion 2: Outcome Surveys

• Measurement & outcome tools selection guide:
  – *Patient self-report surveys* i.e. central role of patient in process of care is driving motivation to research
  – All tools selected must be supported with strong published psychometric data (e.g., reliability, sensitivity to change, responsiveness & validity)
  – Computerized data collection to improve efficiency & feasibility for using multiple screening questionnaires during busy everyday clinical care
Criterion 2: Outcome Surveys

- **Functional status measure (IRT-based)**
  - reliable, valid, sensitive, and responsive (Hart et al 2006 & 2010)

- **Pain intensity (NRS)**
  - 11 point numeric scale reliable & valid (Jensen et al 1999)

- **Global Rating of Change (GROC) by patient & clinician**
  - External measure to assess FS change (Stratford et al Phys Ther 1996)

- **Fear-Avoidance Belief Questionnaire (IRT-based)**
  - Two subscales (PA & work) reliable & valid (Waddell Pain 1993; Hart 2011)

- **Depression & Somatization (both IRT-based)**
  - Subscales from the SCL-90-R questionnaire (Derogatis Psychol Med 1983)
Depressive symptoms (paper vs. computer)

- SCL-90-R Depression subscale
  - Paper & Pencil version
    - 10-item scale
    - Example: “Feelings of worthlessness” with responses Not at all, A little bit, Moderately, Quite a bit, Extremely (Derogatis 1983)
  - Reliable & valid survey
Depressive symptoms (paper vs. computer)

• SCL-90-R Depression subscale (IRT-based)
  – DEP was assessed using a single triage item from SCL-90-R developed using item response theory methods designed to dichotomize patients into low vs. elevated depressive symptoms
  – “Feelings of worthlessness” with responses Not at all, A little bit, Moderately, Quite a bit, Extremely (Derogatis 1983)
  – Responses: “moderately” or greater = positive.

• Diagnostic accuracy strong (Sn 0.97, Sp 0.90, +LR 10.07, -LR 0.04) (Hart, Werneke et al. QURE 2011 online first 6/10/11)
Criterion 3: Clinical Tests

- Standardized and quantified physical exam
- Program all identified tests in software
- Spine classification methods
  - McKenzie syndromes & Quebec Task Force,
  - Clinical prediction rules for manipulation, stabilization, & cervical radiculopathy
  - Patient response criteria
    - Pain Patterns (3 levels, i.e., CEN, Non-CEN, N/C)
    - Directional preference (2 levels, i.e., DP or No-DP)
Criterion 3: Clinical Tests

• Example of test item:
  – Directional preference
    • Patient self-report
      – Extension (e.g., walking, standing, descending stairs, and/or hanging out wash)
      – Flexion (e.g., sitting, bending forward, gardening and/or vacuuming)
      – No movement/positional preference
  • From objective exam
    – Extension, flexion, lateral, rotation, no preference
Criterion 3: Clinical Test

Example

- Items used to judge directional preference
  - Centralization
  - Pain intensity (> 2/10 most distal pain location)
  - Increase trunk AROM (single inclinometer)
  - Patient’s report: ability to bend move
  - LE Break test
  - Aberrant trunk motions
  - Neural tension Sign
Criterion 3: Clinical Test

- Example
  - Items used to judge centralization
    - Change in pain location only
    - Pain diagram & overlay template as recommended by Aina et al 2004
    - Therapist records pain location scores before and after physical examination tests following MDT methods during the initial visit
Example: Change in Pain Location

Centralization vs Non-centralization

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Criterion 4: Interventions

- Standardized operational definitions
  - Therapeutic exercise (19 techniques)
    - Core stabilization, specific exercise (DP), aerobics
  - Manual (22 techniques)
    - Lumbar extension mobilization & manipulation
  - Education (13 techniques)
    - Sitting posture, bending/stooping
  - Function (5 techniques)
    - Lifting, ADL & work tasks
  - Pain (5 techniques)
    - Passive modalities, bed rest, pain management
  - Cognitive behavioral (6 techniques)
    - Graded exposure, graded operant program
Reliability Study

- Clinician's ability to identify neck and low back interventions: An inter-rater chance-corrected agreement pilot study (JMMT 2011;19:172-181)
  - Developed standardized operational definitions for 6 major intervention groups: therapeutic exercise, manual, education, functional, modalities, & cognitive behavioral
  - 7 therapists identified interventions presented within 52 videos and 5 written case studies describing 72 intervention techniques
  - Generalized kappa coefficients ranged from 0.73 to 1.00
Criterion 4: Initiate Data Collection

- Program FOTO software to collect all data and to develop the PBE database
- Survey utilization criteria:
  - Administer all surveys at regular intervals, i.e., intake, during the treatment episode, & discharge
  - Use the data & results of surveys to assist in ongoing daily management and discharge planning of each patient
  - Standardized instructions to the patient before completing each survey
Criterion 4: Initiate Data Collection

• Data collection process
  – Patient’s burden to complete all surveys
    • Patient scheduled to come in 15 minutes early
    • Practical/clinical stopping rule ≤ 15 minutes
    • Pen light & touch screen technology
  – Clinician’s burden and time constraints
    • physical examination protocol required practice
      – ≤ 45 minutes feasible
      – data documentation approximately 5 minutes
Criterion 5: Ongoing Data Quality

• Identify any data irregularities that might represent differences in how therapists are examining patients or interpreting variables used in the study

• Enhance completeness of data
  • Track reasons (non-participation audits)
    – why patients did not complete intake survey (participation rate) &
    – at least 1 follow up status survey (completion rate)
Criterion 6: Additional PBE Needs

• Reliable descriptions of all tests & treatment components is an important step in conducting PBE to assess associations between treatments and outcomes

• Reliability studies
  – Judging specific interventions used by therapists in our group
  – Judging directional preference
Reliability Study (ongoing)

• The Inter-rater Reliability Study of Clinician’s Ability to Identify Directional Preference for Patients with Lumbar Impairments (ongoing)
  – Reliability for judging DP in absence of CEN is unknown
  – 120 patients examined by 4 pairs of raters
    • Examiner & observer; videotaped
  – Analyses: Cohen’s kappa adjusted for chance, prevalence & bias indices
Questions & Answers?

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Part 3: Clinical Data and Initial Results of Multi-Clinic PBE Research Studies: Investigating Outcomes for Patients with Low Back Pain Managed by a Patient-Response Classification Method

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Anaheim, CA 2011
Prevalence of Classification Methods for Patients with Lumbar Impairments using the McKenzie Syndromes, Pain Pattern, Manipulation and Stabilization Clinical Prediction Rules

Evidence supports classifying patients with LBP into homogeneous subgroups based on clinical signs and symptoms to improve patient outcomes,

Identifying methods for classifying patients with LBP is an important research priority,

There is lack of agreement on classification methods currently recommended in the literature for managing patients with LBP.
Purposes

• To determine the proportion of patients who could be classified by McKenzie syndromes & pain pattern using MDT methods and clinical prediction rules for manipulation (Man CPR) and stabilization (Stab CPR),

• Within each Man & Stab CPR subgroup, determine classification prevalence rates using McKenzie syndromes and pain patterns
Materials/Methods

• Eight physical therapists practicing in 8 diverse outpatient physical therapy settings (i.e., 2 military, 3 hospital-based, 3 private practice),
• Therapists classified at intake all patients with low back pain referred to the participating clinics by: McKenzie syndromes, pain pattern subgroups, and subgroups determined by CPRs for manipulation and stabilization,
• Therapists were experienced with all classification methods
Sample

- 618 patients approached
  - 34 patients not started with outcomes (8 system down, 6 cognitive, 5 language, 4 visual, 3 one visit)
  - Participation rate 95%

- 584 patients with low back syndromes
  - Age: mean 50 years old (SD 18) min 18, max 92
  - Gender: 44% male
  - Acuity: 20% acute, 27% subacute, 53% chronic (> 3 months)

- 481 patients with complete intake & discharge FS outcomes
  - Completion rate 82%
Results: Prevalence

Pain Pattern Categories

- **Centralization**: 43%
- **Non-CEN**: 39%
- **Not classified**: 18%

Subgroups
Results: Prevalence

Manipulation CPR Classification

Prevalence (%)

Subgroups

Fritz  n=79 (13%)
Results: Prevalence

Stabilization CPR Classification

Subgroups

Prevalence (%)

Hicks n=41 (7%)

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Prevalence: Cross Tabulation

McKenzie Syndrome & Pain Pattern by Manip Subgroup

Fritz n=79 (13%)
Prevalence: Cross Tabulation

McKenzie Syndrome & Pain Pattern by Stab Subgroup

![Bar Chart]

Prevalence (%)

Hicks' CPR

83 (Derangement)
80 (Centralization)

Hicks n=41 (7%)
Conclusions

- Man & Stab CPRs may not represent a discrete RX subgroup but may include patients who can be managed in other ways.
- Recognition of the reality that overlap does exist within and between popular classification paradigms
- Further research is recommended to clarify the generalizability of classification methods applied to diverse patient populations seen in a variety of physical therapy outpatient clinics
Effect of adding McKenzie syndrome and patient-response classification methods with pain and psychosocial variables to risk-adjusted models predicting functional status outcomes for patients with lumbar syndromes

Werneke MW, Hart DL, Stratford PW, & Deutscher D (manuscript 2011)
Background

- One common treatment-based classification method is Mechanical Diagnosis and Therapy (MDT), i.e., McKenzie
  - McKenzie classification
    - McKenzie main syndromes: derangement, dysfunction, posture, & other
    - Within McKenzie system evidence supports the clinical value for classifying patients by patient-response method
      - Centralization
      - Directional preference
Background

• The prognostic and discriminative ability of classifying patients into the main McKenzie syndromes is unknown.

• There are no data comparing the clinical utility for differentiating patient outcomes between classifications following the main McKenzie syndromes and patient- response criteria.
Purpose

• To determine the effect of adding classification variables including 1) McKenzie syndromes, i.e., derangement, dysfunction, posture, and other, and 2) patient-response criteria, i.e., directional preference and/or centralization data at intake to biopsychosocial explanatory models predicting risk-adjusted functional status (FS) outcomes at discharge from rehabilitation.
Methods

• Design: prospective, longitudinal, observational, cohort study

• Sample 958 patients with LBP (mean 52 yrs old, SD 17, min 18, max 93 yrs, 43% male) referred to physical therapy services and treated by 10 clinicians participating in our research group
Methods

• All patients completed a battery of questionnaires gathering information on 9 known risk-adjusted variables influencing FS outcomes: intake FS, age, symptom duration, surgical & exercise history, payer, gender, use of medication, # of medical co-morbidities, in addition

• Pain intensity 11-point numeric pain scale 0-10

• SCL-90-R depression and somatization subscales
Methods

• After patient completed intake surveys on pain, functional status, psychosocial and demographic data, patients were evaluated by the participating therapist using MDT methods and classified 2 ways by McKenzie syndromes and by patient response criteria
McKenzie Syndrome (McK)

• Derangement
  – Subdivided into reducible and irreducible subgroups based on prior studies suggesting that the 2 groups are clinically & meaningfully different

• Dysfunction

• Posture

• Other
  – mechanically inconclusive, sacroiliac joint, hip, spinal stenosis, symptomatic spondylolisthesis, surgical, red flags, systemic arthritis (e.g., RA AS), chronic pain syndrome, trauma
Patient-Response Criteria (PRC)

- Centralization (CEN) & directional preference (DP)
  - Recent data suggest CEN and DP should be considered independent variables for analyzing FS and pain outcomes (Werneke et al JOSPT 2011)

- Patients were classified into 5 clinical patient-response categories
  - DP and CEN (reference standard), DP/Non CEN, or DP/NC
  - No DP/Non CEN, or No DP/NC (Werneke et al JOSPT 2011)
Data Analyses: Iterative Process

• Discharge FS was the dependent variable
• 5 multivariable linear regression models were developed by sequentially adding variables for pain intensity, SOMAT & DEP, McK and PRC while controlling for:
  – intake FS, age, symptom acuity, surgical & exercise histories, payer, gender, medication use, # comorbid conditions
• Model power ($R^2$) and beta coefficients for each variable level (t-statistic & 95% confidence intervals) for all models were calculated
Results: to be presented

- Prevalence rates
- Model Power & Important Variables
Future PBE Projects

• Investigating which treatment type or combination of interventions are associated with best patient FS outcomes when patients with low back pain are managed by MDT-trained clinicians

• Comparing treatment effectiveness & efficiency between therapists trained in different classification paradigms, e.g., MDT vs. EIM
Methods: Treatment Model

• Model developed for explaining FS outcomes
• Independent variables
  • Previous models: intake FS, age, symptom duration, surgical & exercise history, payer, gender, use of medication, # of medical co-morbidities, PRC, & somatization
  • In addition
    • Treatment groups: (6 levels: exercise, manual, education, functional, cognitive- behavioral, passive mod
Initial Results: to be presented

- Treatment variation despite similar MDT training
- Percentage of patients receiving different treatment
- Model Power & Important Variables
Specific Interventions:

- With 72 interventions and almost countless interactions, analyses are complex and only just begun
- Preliminary results to be presented
Intervention Analyses: Next Steps

- Examine each intervention
- Recheck data entry methods (branching)
- Begin to identify which treatment interventions are important within each main treatment group
- Build model iteratively
- Look for and investigate interactions
- Make the final model parsimonious and clinically relevant
Thank You
Questions & Answers?

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