SCIRehab: A Collaborative Investigation of the Process of Spinal Cord Injury Rehabilitation

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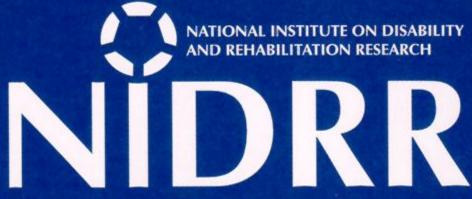
Objectives

- Describe the multidisciplinary approach of Practice Based Evidence research methodology in rehabilitation research as demonstrated in the SCIRehab project
- Describe importance of detailed patient and treatment data
- Discuss associations of treatments, controlling for patient characteristics, with outcomes at discharge and 1-year post injury

Disclosures

The author has no disclosures

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Evidence-based Medicine

Cochrane 1972 Guyatt 1992 Sackett 1996

- "De-emphasizes intuitions, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and..."
- Stresses the examination of evidence from clinical research"

Evidence-based Medicine

Cochrane 1972 Guyatt 1992 Sackett 1996

- The "Gold Standard": Randomized Parallel Group Double Blind Placebo Controlled Trial
 Great for examining specific singular treatments
 - □ At its best, allows some inference of cause and effect
- The challenge—the development of high-quality evidence for complex treatments (e.g. Rehab)
 - Multiple interacting treatment components that contribute to outcomes

The "Black Box" Dilemma

"...a device, system or object which can be viewed solely in terms of its input and output without any knowledge of its internal workings, that is, its implementation is "opaque"..."



- Rehabilitation is a complex "system" composed of many plausible independent variables
 - Patient characteristics
 - □ Clinician/Institutional characteristics
 - Individual discipline-specific treatments
 - Team processes
 - □ How much of *what* initiated *when* for *how long*...
- How can we study the *internal workings* of the Black Box of Rehab?
 - RCTs are not well-suited—too many interacting variables
 - □ <u>Practice Based Evidence (PBE)</u>—designed for study of complex systems

A Caveat...

Demonstration of: Association (A is associated with B) Vs. Causal Relationship (A causes B)

Evidence-Based Practice

- Much of medicine has little evidence for why we do most of what we do
- This is particularly true of rehabilitation
- Every review of literature decries the lack of strong evidence for rehabilitation interventions

Practice-Based Evidence (PBE)

- A methodology that offers a rigorous complement to RCTs to build the evidence necessary for the scientific practice of rehabilitation
- Particularly appropriate when investigating complex multifaceted interventions in natural settings
- Strives to identify interventions most strongly associated with positive outcomes

Recent PBE Studies in Rehabilitation

- Post-Stroke Rehabilitation Study first PBE study in rehabilitation
 - Identified importance of early & aggressive Tx
 - Supplement issue of APM&R & 11 other papers
- The JOINTS Study
 - Multiple papers in APM&R
- Traumatic Brain Injury PBE Study funded September 2007 and ongoing

SCIRehab – funded 2006

Collaborators:

- Craig Hospital, Englewood, CO
- Carolinas Rehabilitation, Charlotte, NC
- Mt. Sinai Medical Center, New York, NY
- National Rehabilitation Hospital, Washington, DC
- Rehabilitation Institute of Chicago, IL
- Shepherd Center, Atlanta, GA
- Institute for Clinical Outcomes Research, Salt Lake City, UT

The need for treatment taxonomies

- In order to describe rehabilitation processes, we need to
 - Understand that each treatment session may involve many interventions ("activities")
 - Identify the most salient ones
 - □ Identify the "active ingredient(s)" in each
 - Differentiate them from one another based on active ingredient(s): a treatment taxonomy
 - □ Find a way to quantify the active ingredients (time, dose per unit time, repetitions, etc.)

Engage Your Clinicians!

Necessary for the "Bottom-up" Approach

Grass Roots Perspectives of

- Care that is provided
- Content of traditional documentation
- Information needed to advance their fields of specialty as well as rehabilitation as a whole

Want to help!

Clinicians Develop Ideal Treatment Documentation

- Captures the most important interventions thought to be related to outcomes
- Carefully balances the amount of detail to be collected with the burden placed on clinicians to record it
- Always consider: Is it important? Is it related to outcomes? Can it be collected easily?

SCIRehab Detailed Data Sources Patient, Process Outcomes

Point-of-care documentation (PDA)
 7 disciplines/7applications
 PT, OT, SLP, TR, NSG, Psych, SW/CM

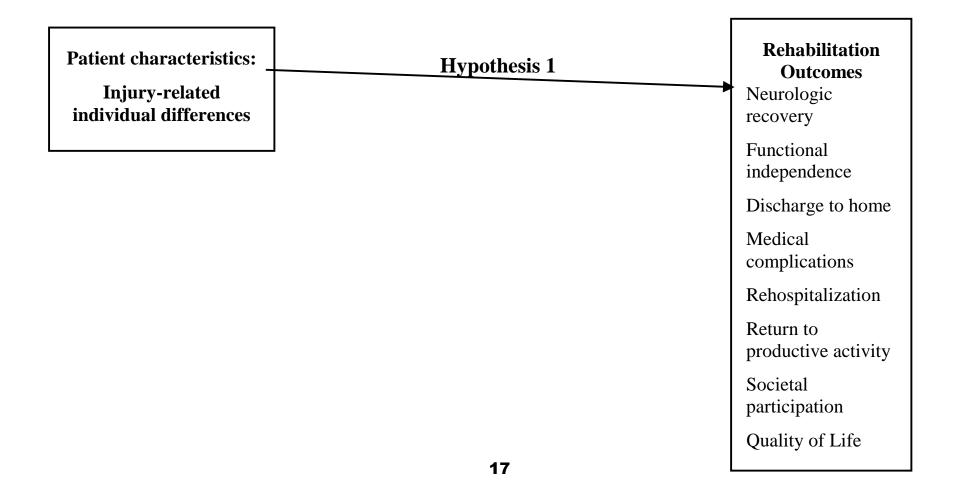


- Medical record
- Electronic files: medication and physician billing
- SCI Model System database Forms I & II
- Follow-up interviews (Form II + project-specific)
 - Outcomes and post-discharge process data

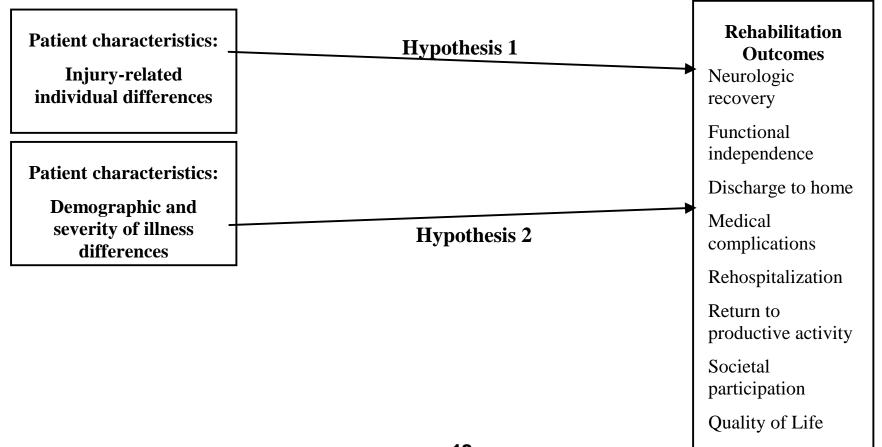
Early Major Contributions of SCIRehab

- A comprehensive, multidisciplinary taxonomy for describing the details of the SCI rehabilitation process
- A technology for efficiently documenting the elements of the rehabilitation process by all clinicians in all disciplines after each treatment session or patient encounter

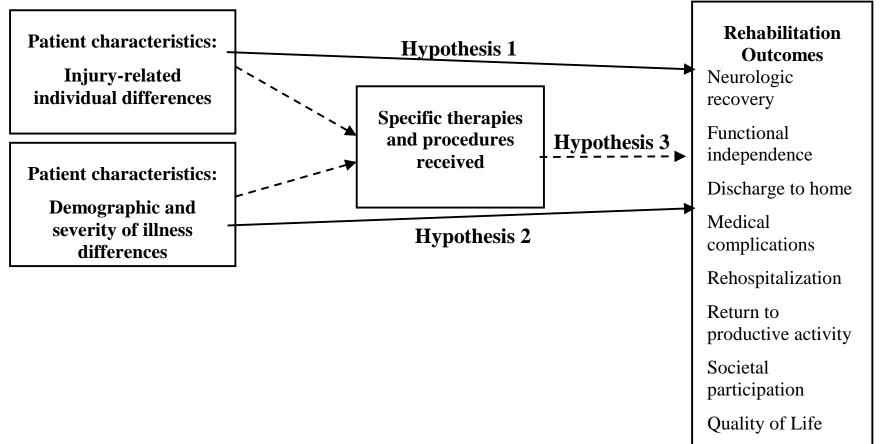
Hypothesis 1: Individual patient differences in severity of injury explain variation in outcomes



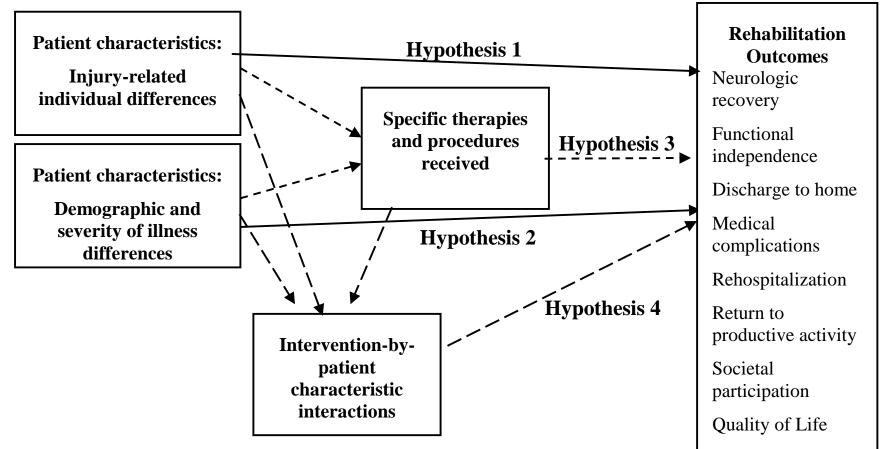
Hypothesis 2: Patient differences in demographic characteristics and severity of illness (complications, comorbidities) explain variation in outcomes



Hypothesis 3: Controlling for patient characteristics, specific and identifiable medical procedures and therapy interventions are associated with better outcomes



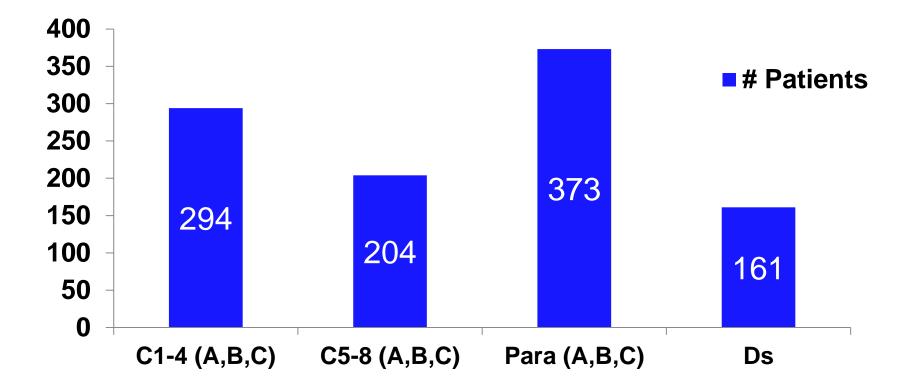
Hypothesis 4: Specific interactions of levels of impairment with treatment activities are associated with better outcomes, controlling for patient characteristics



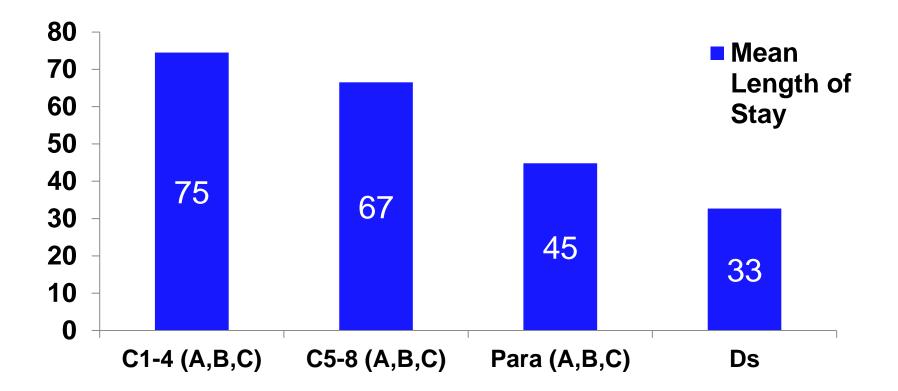
SCIRehab Dataset

- 6 centers; enrollment: Fall 2008-Dec 2010
- 1378 cases:
 - □ 1032 in analytic dataset
 - 346 in validation dataset
- 255,236 total hours of documented interventions
- 282,999 treatment sessions/shifts
- 462,455 activities within treatment sessions
- 1094 clinicians

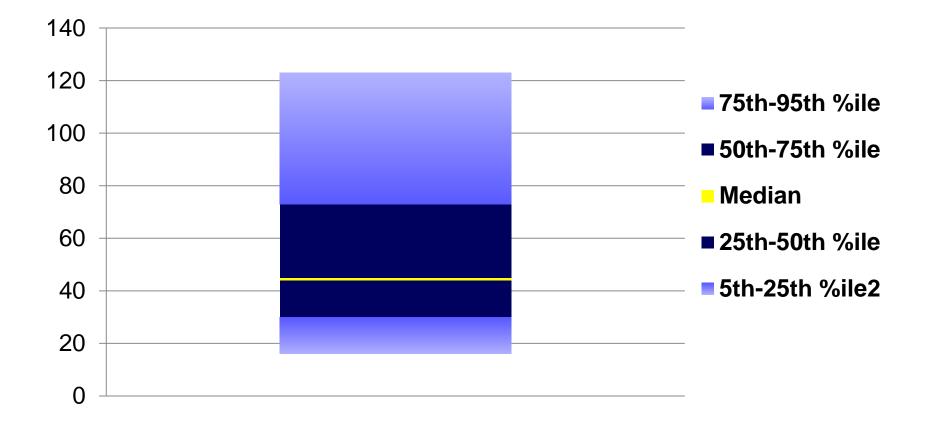
SCIRehab Injury Groups



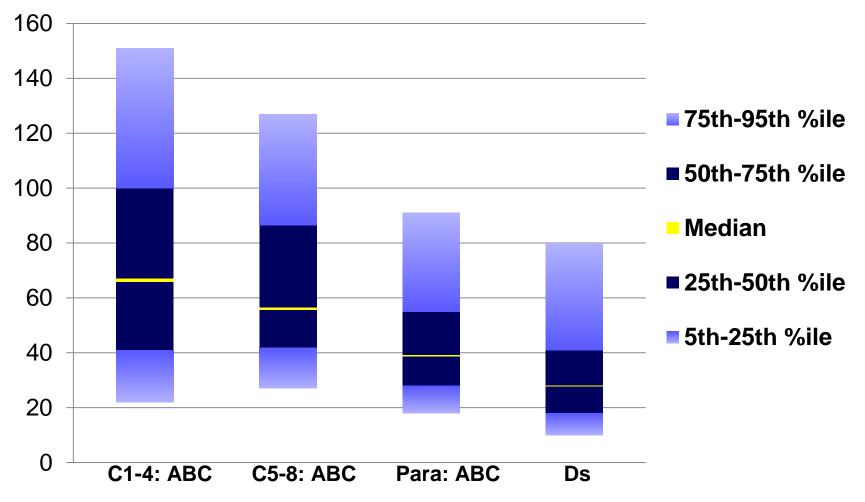
SCIRehab LOS



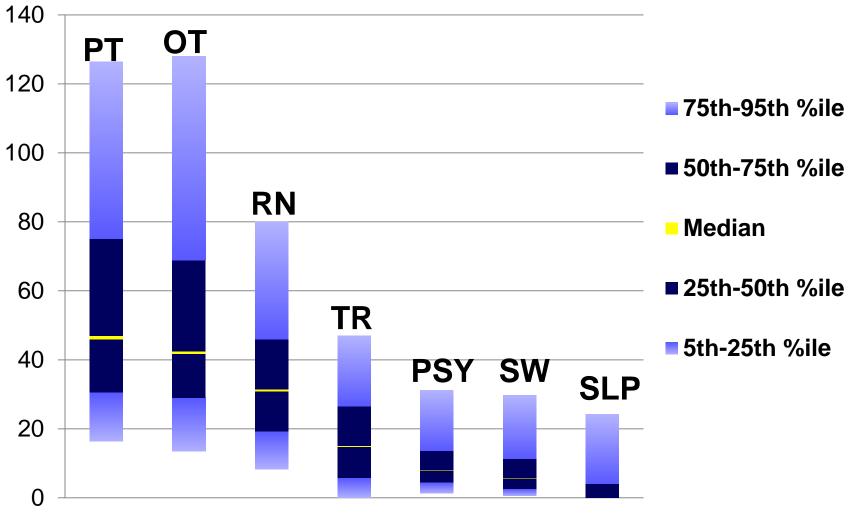
Length of Rehabilitation Stay



Length of Rehabilitation Stay by Impairment Group



Total Hours (mean) Spent on Rehabilitation Activities



Descriptive Summary

- Wide variation in total intervention time
 Total hours during rehabilitation stay
 Minutes per week
- Wide variation in time spent in each discipline
- Natural variation is important to PBE success
- What patient/injury characteristics and then treatments explain variation in outcomes?

Patient Characteristics

Demographic

- 🗆 Age
- 🗆 Gender
- 🗆 Race
- Education completed
- Married or not
- Employment status
- English primary language
- 🗆 BMI
- Payer

Injury

- Etiology of injury (vehicular, falls, sports, violence, other)
- □ Work related or not
- AIS group (C1-4 ABC, C5-8 ABC, Para ABC, All Ds
- □ CSI severity (13-82, M=24)
- □ FIM (motor, cognitive)
- Vent use at rehab admit

Treatment Variables

- Rehabilitation Length of Stay
- Total Time in Each Rehabilitation Discipline
 - □ PT, OT, TR, ST
 - □ Psychology, SW/CM
 - Nursing bedside education and care mgmt

Time Spent in Discipline- specific Activities

- □ PT: gait, strengthening, WC mobility, transfers, etc.
- OT: lower body dressing, toileting for clothing mgmt and hygiene, WC mobility, etc.
- Psychology: psychotherapeutic and psycho-educational interventions
- SW/CM: discharge planning, financial planning, etc.

Understanding the Statistics

- Stepwise Regression Models
- Independent variables are patient characteristics and treatments
- Adjusted R² amount of variance explained
 Range 0-100
 - □ Larger values better strength of model
- P Values strength of predictor variable
 *** = <0.001 ** = <0.01 * = <0.05</p>

	Patient Variables only	
Adjusted R-square	0.650	
Independent Variables	Parameter Estimate	P value
ASIA Group		***
C1-4 ABC	-12.890	***
C5-8 ABC	-9.872	***
Para ABC	-4.765	***
All Ds (Reference)	0.000	
Admission FIM motor score-Rasch-transformed	0.439	***
Admission FIM cognitive score-Rasch-transformed	-0.025	**
# days from trauma to rehabilitation admission	-0.042	***
Age at Injury	-0.064	***
Injury is work related	1.446	*
BMI ≥30	-1.614	**

Treatment variables = LOS and total time in each discipline

		Patient plus Treatment Variables	
	Adjusted R-square	0.702	
Independ	ent Variables	Parameter Estimate	P value
Rehabilita [.]	tion length of stay	-	**
Occupatio	nal therapy total hours	-	**
Physical th	nerapy total hours	+	***
Therapeutic recreation total hours			ns
Speech therapy total hours			ns
Psycholog	y total hours		ns
Nursing (b	edside education and care mgmt) total hours		ns
Social wor	k/case management total hours		ns

Treatment variables = time in Physical Therapy activities

	Patient plus Treatment Variables	
Adjusted R-squar	e 0 ,	.769
	Parameter	
Independent Variables	Estimate	P value
Patient participation score (mean) in PT	+	***
Airway/respiratory management hours	-	***
Aquatic exercises hours	+	*
Assessment hours	+	***
Classes hours	-	***
Equipment evaluation/provision/educ hours	-	*
Gait hours	+	***
Musculoskeletal treatment modalities hours	-	*
Pre-gait hours	+	***
Range of motion/stretching exercises hours	-	*
Strengthening exercises hours	+	***
Upright hours	-	**
Wheelchair mobility-manual hours	+	***
Wheelchair mobility-power hours	-	**

Treatment variables = time in Occupational Therapy activities

Patient Plus Treatment Variables 0.738 **Adjusted R-square** P value **Independent Variables Parameter Estimate** *** Rehabilitation length of stay + *** Patient participation score (mean) - OT Airway/respiratory management hours ** ** Assessment hours + *** Assistive technology hours **Balance** hours ** * Bowel management hours ÷ Classes hours *** ** Dressing-lower body hours * Dressing-upper body hours ** Education (not in other activities) hours * Self-feeding hours Home management skills hours ** ÷ Range of motion/stretching hours *** Transfers hours ***

Can we attribute improvement in outcomes to rehabilitation treatments?

Need to minimize the influence of natural recovery

Can we make our patient groups more homogeneous?

Complete Thoracic Injuries

- 🗆 T1-9
- □ AIS A or B
- No change in AIS from admission to discharge

Complete Low Cervical Injuries

- 🗆 C5-8
- □ AIS A or B
- No change in neuro level or AIS from admission to discharge

Can we make our outcomes more specific to the homogeneous groups?

Discharge Motor FIM

- Transfer Component
- Self-Care Component
 - Lower body items (lower body dressing, bathing, toileting)
 - Upper body items (feeding, upper body dressing, grooming)

Motor Complete Thoracic Injuries (T1-9) Discharge Motor FIM

Treatment variables = time in Physical Therapy activities

N= 158	Patient variables			
Adjusted R-square	0.295			
Independent Variables	Parameter estimate	P Value		
Admission FIM motor score-Rasch transformed	+	**		
Gender = male	+	***		
Marital status = married	-	*		
BMI ≥30	-	**		

Motor Complete Thoracic Injuries (T1-9) Discharge Motor FIM

Treatment variables = time in Physical Therapy activities

N= 158	Patient variables	Patient plus Treatment Variables				
Adjusted R-square	0.295	0.641				
	Parameter					
Independent Variables	estimate	P Value				
Admission FIM motor score-Rasch transformed	+	**				
Gender = male	+	* * *				
Marital status = married	- *					
BMI ≥30	-	**				
Patient participation score (mean) in PT	+	***				
Assessment hours	-	*				
Bed mobility hours	-	***				
Classes hours	-	***				
Endurance exercises hours	+	**				
Wheelchair mobility-manual hours	+	**				

Lower-body Self Care - Discharge Motor FIM

Treatment variables = time in Occupational Therapy activities

	N=158	Patient variables	
	Adjusted R-square	0.256	
Independe	ent Variables:	Parameter estimate	P Value
Admission	FIM Motor Score	+	***
CSI (severi	ty of illness) score	-	*
# Days fror	n Trauma to Rehab Admit	-	**
Male		+	***
BMI ≥30		-	*

Motor Complete Thoracic Injuries (T1-9)

Lower-body Self Care - Discharge Motor FIM

Treatment variables = time in Occupational Therapy activities

N=158	Patient variables	Patient plus Treatment Variables			
Adjusted R-square	0.256	0.540			
	Parameter				
Independent Variables:	estimate	P Value			
Admission FIM Motor Score	+	***			
CSI (severity of illness) score	-	*			
# Days from Trauma to Rehab Admit	-	**			
Male	+	***			
BMI ≥30	-	*			
Rehab LOS	+	***			
Education Total Hours	-	**			
Grooming Total Hours	-	***			
Interdisciplinary Conferencing Total Hours	-	**			
Strengthening/Endurance Total Hours	-	***			
Toileting - Clothing Mgmt/Hygiene Total Hours	+	*			

Motor Complete Low Tetraplegia (C5-8) Transfer Score - Discharge Motor FIM Treatment variables = time in Physical Therapy activities											
N=78	Patient variables										
Adjusted R-square	0.365										
Independent Variables	Parameter estimate	P Value									
ASIA Group		***									
C5	-	***									
C6	-	*									
C7-8 (Reference)											
Admission FIM Transfer Score-Rasch transformed	+	**									
# Days from Trauma to Rehabilitation Admission	-	*									

,88

Motor Complete Low Tel	traplegia	(C5-8)									
Transfer Score - Discharge Motor FIM											
Treatment variables = time in Physi	cal Therapy	activities									
N=78	Patient variables	Patient plus Treatment Variables									
Adjusted R-square	0.365	0.607									
Independent Variables	Parameter estimate	P Value									
ASIA Group		***									
C5	-	***									
C6	-	*									
C7-8 (Reference)											
Admission FIM Transfer Score-Rasch transformed	+	**									
# Days from Trauma to Rehabilitation Admission	-	*									
Assessment hours	-	**									
Wheelchair mobility-manual hours	+	***									

Motor Complete Low Tetraplegia (C5-8)

Upper-body Self Care - Discharge Motor FIM

Treatment variables = time in Occupational Therapy activities

	N=78	Patient variables	
	Adjusted R-square	0.451	
Independe	ent Variables	Parameter estimate	P Value
ASIA Grou	р		***
	C5	-	***
	C6	-	**
	C7-8 (reference)		
Admission	FIM Self Care Upper Score	+	***
Age at Inju	ry	-	***

Motor Complete Low Tetraplegia (C5-8)

Upper-body Self Care - Discharge Motor FIM

Treatment variables = time in Occupational Therapy activities

N=78	Patient variables	Patient plus Treatment Variables		
Adjusted R-square	0.451	0.644		
Independent Variables	Parameter estimate	P Value		
ASIA Group		***		
C5	-	***		
C6	-	**		
C7-8 (reference)				
Admission FIM Self Care Upper Score	+	***		
Age at Injury	-	***		
Clinician Experience Index OT	-	*		
Classes Total Hours	-	***		
Home Management Skills Total Hours	+	**		
Therapeutic Activities Total Hours	+	*		
Toileting - Clothing Mgmt/Hygiene Total Hours	+	**		

Full sample regression modeling

Discharge from rehabilitation

- □ Motor FIM
- Discharge destination (to home)

1-year injury anniversary

□ Motor FIM

- □ CHART: Physical Independence
- □ CHART: Social Integration
- □ CHART: Occupation
- □ CHART: Mobility
- □ PHQ-9 (low less depression)
- □ Life Satisfaction (SWLS)
- Residential location
- □ Work/school
- □ No rehospitalization
- □ No pressure sore

Influence of LOS and discipline treatment time

	D/C Motor FIM	1-year Motor FIM	CHART: Phys Ind	CHART: Soc Integ	CHART: Occup	CHART: Mobility	Low PHQ9 Score	Life Satisfaction	D/C to Home	Reside Home 1 Yr	Work/School 1 Yr	No Rehosp Yr 1	No Press Sore Yr 1
Rehab LOS	-					-							
Clin exp index								+	+	-	+		
PT hours	+	+	+	+		+						+	+
OT hours	-									-			-
TR hours				+	+	+		+		+	+	+	+
PSY hours			-					-			-		
ST hours							-						+
RN hours									+			-	
SW/CM hours		-			47	7							

Physical Therapy Treatment Activities

Primarily positive relationships	D/C Motor FIM	1-year Motor FIM	CHART: Phys Ind	CHART: Soc Integ	CHART: Occup	CHART: Mobility	Low PHQ9 Score	Life Satisfaction	D/C to Home	Reside Home 1 Yr	Work/School 1 Yr	No Rehosp Yr 1	No Press Sore Yr 1
Clin Exper								+	+		+		
Participation	+	+	+	+	+	+		+	+		+	+	+
Aquatic exer	+												
Assessment	+	+	+										
Education				+					+	+		+	
Gait	+	+			+	+						+	+
Pre-gait	+	+	+										
Endurance				+									
Strengthening	+		+			+				-		+	+
Manual WC	+				48	3							

Physical Therapy Treatment Activities, con't

Negative/mixed relationships	D/C Motor FIM	1-year Motor FIM	CHART: Phys Ind	CHART: Soc Integ	CHART: Occup	CHART: Mobility	Low PHQ9 Score	Life Satisfaction	D/C to Home	Reside Home 1 Yr	Work/School 1 Yr	No Rehosp Yr 1	No Press Sore Yr 1
Airway mgmt	-	-	-			-							
Classes	-		-	-						-			
Equip eval	-	-				+			+				
TX modalities	-												-
Skin mgmt			-	-									
Balance													-
ROM/ stretching	-	-	-			-			-	-		+	
Upright	-												+
Power WC	-	-	-		-		-	-		-		-	

Occupational Therapy Treatment Activities

Primarily positive relationships	D/C Motor FIM	1-year Motor FIM	CHART: Phys Ind	CHART: Soc Integ	CHART: Occup	CHART: Mobility	Low PHQ9 Score	Life Satisfaction	D/C to Home	Reside Home 1 Yr	Work/School 1 Yr	No Rehosp Yr 1	No Press Sore Yr 1
Rehab LOS	+											+	
Participation	+	+		+	+	+					+	+	
Assessment	+	+	+									+	
Balance	+												
Bathing							+		+				
Bladder mgmt												+	
Bowel mgmt	+												
Dressing-lower	+		+										+
Home mgmt skills	+	+	+		+	+							+
Modalities						+							
Skin mgmt					+								
Strengthening		+	+					-					
Toileting clothing mgmt hyg				50						+			

Occupational Therapy Treatment Activities

Negative/ mixed relationships	D/C Motor FIM	1-year Motor FIM	CHART: Phys Ind	CHART: Soc Integ	CHART: Occup	CHART: Mobility	Low PHQ9 Score	Life Satisfaction	D/C to Home	Reside Home 1 Yr	Work/School 1 Yr	No Rehosp Yr 1	No Press Sore Yr 1	
Clin exper				-						-				
Airway/ mgmt	-			-		-	-							
Assist tech	-	-												
Bed mobility		-		+										
Classes	-		-								-			
Communication		-	-		-									
Dressing-upper	-		-											
Education	-								+					
Self-feeding	-	-				-			-		-			
ROM /stretch	-		-					-		-				
Ther activities										-				
Transfers	-				51									

	_	_							
Variance Explained by Patient Char and Treatments									
Continuous Outcome Variables:	D/C Motor FIM	1 yr Motor FIM	CHART: Phys Ind	CHART: Soc Int	CHART: Occup	CHART: Mobility	Low PHQ9	Life Satisfaction	
% Explained by Pt Characteristics 65% 51% 41% 12% 24% 27% 6% 8%									
% Additional Variance Explained by Treatment Variables:									
Overall Hours by Discipline	5%	1%	2%	2%	1%	3%	1%	2%	
PT treatments	12%	11%	7%	4%	5%	6%	<1%	2%	
ОТ	9%	5%	6%	4%	3%	6%	1%	1%	
TR	2%	1%	2%	1%	1%	2%	0%	1%	
PSY	3%	1%	2%	<1%	1%	1%	0%	2%	
ST	2%	<1%	0%	1%	<1%	1%	<1%	0%	
NSG	5%	2%	3%	2%	3%	5%	1%	1%	
SW/CM	<u>3</u> %	1%	2%	5%	2%	2%	2%	<1%	

Occupational Therapy

Influence of Treatment Variables Increases With

More Homogeneous Sample and More Specificity of Outcome

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		Percent of	Percent of
		Variance in FIM	Additional
	Rasch Transformed	Explained by	Variance
	Discharge FIM	Patient	Explained by
Description of the	Outcome Measure	Characteristics	Treatment
Sample	Analyzed	Alone	Variables
Total Sample, n=1032	Motor FIM at discharge	65%	9%
C5-8 AB at admission and discharge, n=78	Motor FIM at discharge	39%	22%
C5-8 AB at admission and discharge, n=78	Self-care component of Motor FIM at discharge	44%	25%
C5-8 AB at admission and discharge, n=78	Lower body items of self-care Motor FIM at discharge	37%	28%

Conclusions

What Did We Learn?

- PBE studies can be implemented with POC electronic data gathering technology
- Patient/injury characteristics are powerful predictors of outcome
- Treatment variables often add to explained variance but not always

□ And not always "positive" associations

Limitations

- The SCIRehab Centers were not a probability sample of SCI Treatment Facilities
 - □ Treatment philosophies, emphasis
 - Patient population
 - □ Can these findings be generalized?
- Treatment after Rehab discharge not included
- Choice of routine clinical dependent variables (e.g. FIM) may be limiting, insensitive
 SCIM, QIF, WISCI, 10mw, 6mw, GRASSP, etc.

Conclusions

What Did We Learn?

- Interpretation of Positive and Negative Associations between Treatment Variables and Outcomes may be challenging and counterintuitive
 Negative associations do not necessarily mean harm
 Possibly a surrogate for:
 - a need not adequately captured
 - an outcome not adequately measured
- For some patient subgroups, treatment was as powerful as patient variables in predicting outcome
 - Association between treatment and outcomes is stronger when patient subgrouping and treatments more homogeneous

Conclusions

What Did We Learn?

SCI is not a homogeneous disorder

Different patient subgroups may benefit from a different "mix" of rehabilitation treatments

"one size" does not "fit all"

- SCIRehab has not provided a "prescription" standard of care
- SCIRehab has provided some guidance for SCI rehabilitation treatment planning

Questions... Answers

SCIRehab Project