Research in the TBI Population

Traumatic Brain Injury Model System

Denise Consoli
October 16, 2012
Research in the TBI Population
Carolinas Rehabilitation Research

Presenters
• Denise Consoli, Project Assistant Coordinator & Family Education
• Will Setzer, Research Analyst
• Carla Kingsbury, Senior Research Tech
• Sheri Bartel, Senior Research Tech
• Sally Rickard, LRT/CTRS, CBIST

Our presentation focus is on traumatic brain injury research at
Carolinas Rehabilitation
• Traumatic Brain Injury Model System Study
• Site specific and national summary data on TBI
• Site specific and collaborative research projects derived from the TBIMS study
• Project STAR community resources
What is TBI?

• Definition of TBI

TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by medically documented loss of consciousness or post traumatic amnesia (PTA) due to brain trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination.

NDSC
National Data and Statistical Center
Traumatic Brain Injury (TBI)

- Late 1970s noticeable increase in survivors of moderate or severe TBI patients
- TBI units and OP programs followed
- Institutions related to TBI care and research were established
  - Rehabilitation for TBI began
  - 1980 - National Head Injury Interdisciplinary Foundation of America (now BIAA) was founded
  - 1986 – *Journal of Head Trauma Rehabilitation* first published
WHAT IS TBI MODEL SYSTEMS?

A Research Grant
Funded Through Department of Education’s
National Institute on Disability and Rehabilitation Research (NIDRR)

Purpose:
to improve care and outcomes for individuals with TBI through a national database and collaborations that allow us to learn about problems facing individuals with TBI.
TBI Model System Study
A Little History

• Began in 1987
• On going for 25 years
• Continuously funded by NIDRR and the Dept of Ed
• Originally there were 5 centers
• Presently 16 Centers
• Grant is a 5 Year cycle
• Competitive renewal at end of each cycle
• Started as a demonstration program – focus is now on research
• Research studies and collaborative research projects are supported and required
• Collaborative research projects include “module” projects and multi-site interventional studies
• Database is the largest longitudinal study of TBI in the world
• The TBI Model Systems are called "model systems" because they are national leaders in TBI-related care and research
WHEN DID CAROLINAS REHABILITATION BECOME A TBI MODEL SYSTEMS CENTER?

- In 1997, Dr Flora Hammond, MD applied for a TBI Model System Grant
- October, 1998 – Carolinas Rehabilitation becomes a TBIMS site
- Largest grant funding ever received by all of CHS
- First federal grant funding for CR
- January, 1999 – our first patient is enrolled in the study
Dr Flora Hammond
PRINCIPLE INVESTIGATOR

Flora Hammond, MD

• Residency and fellowship at Model System sites
• Research and publications focused on medical complications and predicting outcomes following TBI.
• Carolinas Rehabilitation Research Director, Brain Injury Program Director, and Brain Injury Fellowship Director. (1995 – 2009).
• Present Position: Covalt Professor of Physical Medicine & Rehabilitation Chair, Indiana University Department of Physical Medicine & Rehabilitation Chief of Medical Affairs, Rehabilitation Hospital of Indiana
Carolinas Traumatic Brain Injury Rehabilitation & Research System

OUR MISSION

Improve care and outcome for survivors of TBI through a model system of care using research, demonstration and dissemination to expand and enhance services throughout their lifetime.
Subject Identification

• Review daily census for CR admissions with TBI diagnosis
• Visit patient and family
• Distribute TBI educational material, HEADS UP Newsletter, BIANC information and information on weekly education meeting for families
• Approach 100% of the inpatients with moderate to severe TBI
• Invite participation in TBIMS if inclusion criteria is met
Inclusion Criteria for TBIMS

• Moderate to severe TBI
  - PTA>24 hrs or
  - LOC>30 minutes or
  - GCS in ED <13 or
  - Intracranial neuroimaging abnormalities

• Admitted to ED within 72 hours of injury

• 16 years of age or older

• Acute care and comprehensive inpatient rehabilitation within the model system hospital

• TBI is the primary diagnosis

• Informed consent signed by patient, family or guardian
What About Those Who Do Not Meet The Inclusion Criteria?

- The Carolinas Research Registry
  - Confidential database containing contact and health information of prospective research candidates
- Enrollment is not automatic. A consent to participate must be signed
- All those who sign the consent to participate are part of the registry
- Only those who meet the eligibility requirements are part of the TBIMS study and the National Database
- Registry enrollment is open to anyone who suffered a TBI. (it is not necessary to have been a patient at either CR or CHS)
- Benefits of Registry Participation
  - Ability to contact our staff at any time
  - Notification of research studies for which they may be eligible
  - Receive quarterly Heads Up Newsletter
Enrollment

- The consent to participate is voluntary
- Consent can be withdrawn at any time
- There are no risks to this study
- Due to the nature of the injury, in most cases, the next of kin or guardian signs the consent
- Once a consent is signed, a TBIMS ID number is assigned and all identifying information is removed from questionnaires, tests and forms
- All patient files are kept in locked cabinets in locked rooms.
- CR consistently surpasses the required benchmark enrollment of 35 subjects per year.
- In 2010, our center won 4 out of 6 National Excellence Awards for most participants enrollment and Form I data.
What is Form I?

• Form I data is the information which is collected while the subject is an inpatient

• Information for Form I includes data on:
  - Pre-injury
  - Injury
  - ED
  - Acute Care
  - Acute Rehabilitation
  - Discharge information
Form I

- Over 240 items or variables are collected on each patient for Form I
  - Demographics
  - Cause and severity of injury
  - Alcohol level
  - Military service
  - Incarceration
  - Employment
  - Nature of diagnoses
  - Treatment services
  - Cost
  - Duration of PTA

- Our physicians and therapists assist us in gathering the necessary information. For example:
  - CT forms
  - DRS at admission and discharge
  - FIM scores
  - GOAT scores – reliability GOAT scores
Multidisciplinary System of Rehabilitation
What is Form II?

- Post discharge collection and submission of participant data is known as Form II. Form II is follow-up data.
- Over 150 Form II variables are collected primarily through phone follow-up.
- Variable focus on objective and subjective outcomes. Example: employment, life satisfaction, depression, function and community participation, measure of living independently.
- Every TBIMS participant is called at one, two and five years post-injury and every five years thereafter.
- Form II is entered into the national TBIMS database and submitted on a quarterly basis.
- Every effort is made to follow our subjects throughout their lifetime.
Some Outcomes

• Identification of long term problems that follow TBI
  - Research studies and clinical trials

• Description of how people with TBI recover in the first years post injury

• Over 500 Publications

• Knowledge Translation Center
  • MSKTC is a national center that works to put research into practice to serve the needs of people with traumatic brain injuries (TBI), spinal cord injuries (SCI), and burn injuries
  • Consumer Fact Sheets
  • Informational/Educational slideshows
References


TBIMS Descriptive Data Summary

Includes data from 01/01/1998 – 09/30/2012

Will Setzer
Carolinas Rehabilitation
Sources of Data

• Abstract from medical records
• Pre-existing database
• Specialized data collection forms
• Patient examination/interview/testing
• Family interview
Age

n=1027

16-25: 319
26-35: 192
36-45: 194
46-55: 136
56-65: 78
66-75: 61
76-85: 36
86 and older: 11
Gender

- Male, 724, 70%
- Female, 303, 30%

n=1027
Race

- White: 770
- Black: 206
- Asian: 9
- Hispanic Origin: 35
- Other: 7

n=1027
Level of Education at Injury

- High School/GED, 317, 37%
- <High School, 270, 32%
- Some College, 173, 21%
- >=Bachelors, 88, 10%

n=848
Summary

- Demographic Characteristics of Population
  - Average age=38.67
  - Male (70%)
  - Minority population (25%)
  - High school education or less (69%)
Etiology of Injury

- Vehicular: 66%
- Falls: 18%
- Violence: 7%
- Other: 9%

n=1027
Blood Alcohol Level
at Emergency Department Admission

- >=10 mg/dL: 44%
- 1-9 mg/dL: 5%
- Negative: 51%

n=760
Excludes cases not tested =25%
Summary

• Causes of Injury
  • Primary cause of is vehicular (66%)
  • High incidence of alcohol-related injuries (44%)
Duration of Unconsciousness

- <=1: 30%
- 2-7: 28%
- 8-14: 16%
- 15-28: 15%
- >=29: 11%

n=1008; mean=11.13 days
n=679; mean=26.55 days
Summary

• Severity of Injury
  • Average duration of LOC is 11.13 days
  • Average duration of PTA is 26.55 days
- Mean Length of Stay
  - Acute=20.81 days
  - Rehab=22.66 days
- 43% have government-sponsored rehabilitation care (Medicaid & Medicare)
National
DRS - Total

12.39
6.32
2.84
2.53

Admission (n=10050) Discharge (n=10043) Year 1 (n=7420) Year 2 (n=6156)

*Data from 01/01/1989 – 12/31/2010
FIM - Cognitive

- Admission: 14.56
- Discharge: 23.00
- Year 1: 29.82
- Year 2: 30.02

n=652
FIM - Motor

Admission: 34.13
Discharge: 66.94
Year 1: 82.53
Year 2: 83.57

n=652
National FIM Scores

*Data from 01/01/1989 – 12/31/2010*
Summary

Disability Outcomes

- DRS indicates improvement in level of disability from SEVERE DISABILITY at rehab. admission to PARTIAL DISABILITY at 1 and 2 years post-injury
- FIM indicates improvement in functional ability from level requiring MODERATE ASSISTANCE at rehab admission to MODIFIED INDEPENDENCE at 1 and 2 years post-injury
- Most improvement in level of disability and functional ability occurs during inpatient rehabilitation
- Continued improvement is seen at 1 year post-injury
- Level of disability and functional ability appear to plateau between 1 and 2 years post-injury
Marital Status

- Single
- Married
- Divorced / Separated
- Widowed

At injury:
- Single: 50.44%
- Married: 34.81%
- Divorced / Separated: 11.80%
- Widowed: 2.95%

Year 1:
- Single: 46.46%
- Married: 32.74%
- Divorced / Separated: 16.81%
- Widowed: 3.98%

Year 2:
- Single: 45.56%
- Married: 31.51%
- Divorced / Separated: 19.08%
- Widowed: 3.85%

n=678
Summary

Participation Outcomes

- Most live in a private residence following rehab discharge (79%)
- Few live alone at rehab. discharge (3%), with the highest proportion living with parent(s) (35%), or spouse/SO (31%)
- 28% are employed at 1 year post-injury (62% employed at injury)
Other Research Studies

• Closed Enrollment
• Open Enrollment
Studies with Closed Enrollment

- Fatigue and Insomnia
- Sexuality
- TBI-Practice Based Evidence
TBI Model Systems: Fatigue and Insomnia

A Prospective Study of the Relationship Between Post-TBI Fatigue and Insomnia

Principal Investigator: Flora Hammond, MD

Purpose: The aim of this study is to provide new information to support the development of improved treatment for post-TBI insomnia and fatigue.

Enrolled: Carolinas Rehabilitation: 40
Total Enrollment: 531

- 5 sites participated
- Ages 18 and older
- Prevalence of insomnia and fatigue in individuals with mod-sev TBI
- Follow up calls at 1, 2, and 5 years
TBI Model Systems: Sexuality After TBI

Investigators: Flora Hammond, MD and Lori Grafton, MD

Purpose: To determine the frequency, type and severity of changes in sexual functioning associated with TBI.

Enrolled: Carolinas Rehabilitation: 99 subjects, 41 partners
Total Enrollment: 260 (subjects only)

- 6 sites participated
- Ages 18 and older
- Information collected at 6 mths and 12 mths post injury
- Phone interviews and self-report questionnaires
Traumatic Brain Injury- Practice Based Evidence (PBE)

Principal Investigator: Dr. Flora Hammond
Sub-Investigator: Dr. Lori Grafton

Purpose: To learn which elements are most associated with better outcomes and to improve TBI rehabilitation with that knowledge.

Enrolled: Carolinas Rehabilitation: 268
Total Enrollment: 2220

- 10 sites participating
- Ages 14 and older
- Enrolled patients from October 2008-November 2010
## Participating Centers

- Ohio State University
- Intermountain Medical Ctr.
- Shepherd Center
- Loma Linda Univ. Med. Ctr.
- Carolinas Rehabilitation
- Mt. Sinai Medical Ctr.
- Brooks Rehab. Hospital
- Toronto Rehab. Institute
PBE Process

Consent for Study

POC Forms

Follow Up Calls

Chart Abstraction
PBE Process

Consent for Study

POC Forms

Follow Up Calls

Chart Abstraction
PBE Process

Consent for Study → POC Forms → Follow up Calls → Chart Abstraction
PBE Process

Consent for Study

POC Forms

Follow Up Calls

Chart Abstraction
What information is entered into the database?
### Point-of Care (POC) documentation - Physical Therapy

**Session Info**
- **Clinician ID:** 123
- **Start Time:** 9:00 AM
- **Date:** 09/08/08

**Documenting For:**
- Aide
- Student
- Other PT

**Missed Session:**

**# of Session Participants:**
- Patients: 1
- PTA: 0
- PT: 1
- Aide: 0
- Other Therapist: 0
- Supervisors/Contact People: 0

**Interventions/Devices**

<table>
<thead>
<tr>
<th>Activities</th>
<th>Minutes</th>
<th>Neuroumbular:</th>
<th>Cognitive/Perceptual/Sensory:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Functional Activity</td>
<td></td>
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<tr>
<td>Therapeutic Exercise</td>
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<td></td>
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<tr>
<td>Developmental Sequencing</td>
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<td></td>
<td></td>
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<tr>
<td>Equipment Management</td>
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<td></td>
<td></td>
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<tr>
<td>Bed Mobility</td>
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<td></td>
<td></td>
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<tr>
<td>Sitting</td>
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<td></td>
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<tr>
<td>Standing</td>
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<tr>
<td>Transfers</td>
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<td></td>
<td></td>
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<tr>
<td>Wheelchair Mobility</td>
<td></td>
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<tr>
<td>Pre-Gait</td>
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<tr>
<td>Gait</td>
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<tr>
<td>Advanced Gait</td>
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<tr>
<td>Stairs</td>
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</tr>
<tr>
<td>Community Mobility</td>
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<td></td>
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<tr>
<td>Preparation Time</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Casting/Splint</td>
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<td></td>
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<tr>
<td>Evaluation at Patient Home</td>
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</tr>
<tr>
<td>Formal Assessment</td>
<td></td>
<td></td>
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<tr>
<td>Resting</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interventions/Devices</th>
<th>Environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROM (for serial casting)</td>
<td>Knee</td>
</tr>
<tr>
<td>Dorisflexion Knee Extended</td>
<td>Dorisflexion Knee Flexed</td>
</tr>
</tbody>
</table>

**Assistive Devices**
- Ambulation Devices:
  - 37 Ankle Assistive Device
  - 38 Unilateral Ambulation Device
  - 39 Bilateral Ambulation Device
  - 40 Knee Extension Assistance
  - 41 Swedish Knee Cage
  - 42 Wheelchair
  - 43 Body Weight Support
  - 44 Parallel Bars/Handrail
  - 45 PETO Frame
  - 46 Step Ladder
  - 47 Steps (Various Heights)
  - 48 Trendmill
  - 49 AROO Walker
  - Other Devices:
    - 50 Automobile
    - 51 Floor
    - 52 Gym Equipment
    - 53 Lift
    - 54 Mirror
    - 55 Standing Frame
    - 56 Swiss Ball
    - 57 Tilt Table
    - 58 Transfer Devices
    - 59 Upper Extremity Sling
    - 60 UE Support/Handed Assist
    - 61 Other

**Environment Key**
- 1 Quiet
- 2 Minimally Stimulating
- 3 Moderately Stimulating
- 4 Maximally Stimulating

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*Carolinas HealthCare System
Uncompromising Excellence. Commitment to Care.*
Auxiliary Data Module (ADM) Elements

Patient information

- Age
- Gender
- Ethnicity
- Height
- Weight
- BMI
- Level of Education
- Payer Information
- Marital Status
Auxiliary Data Module (ADM) Elements

Patient information

- History of Psychological Issues
- History of Substance abuse
- History of Previous Brain Injury
- Employment status
- Pre-morbid Drug/Alcohol abuse
- Pre-albumin Levels
Auxiliary Data Module (ADM) Elements

Injury information
- Cause of Injury
- Location
- Blood Alcohol content
- Presence of Drugs
- Restraint/safety gear
- Concomitant Injuries
- GCS
- Length of PTA (Olog/GOAT scores)
- Pain Logs (FLACC and Verbal)
- Ataxia
Auxiliary Data Module (ADM) Elements

**Injury information**
- Aphasia
- Dysphagia
- Admission CSI total
- Admission Motor and Cognitive FIM
- BI and non-BI CSI scores
- ROM measures
- Berg Score
- Ashworth Scale Score
Auxiliary Data Module (ADM) Elements

Injury information

• Strength Measures
• Disability Rating Scale
• Rancho De Los Amigos Score
• Family Coping Style
• Days from Injury to Rehab Admission
• BIA (Spasticity, Coordination)
Severity Questions

- Questions based on ICD-9 Codes
- Number of questions varied
- Admission, Maximum, Discharge
1-Year Patient Follow-up Survey Data Elements

Current living situation
- Private home
- Nursing home
- Hotel
- Hospital
- Other

Living with
- Alone
- Spouse
- Parent/Sibling
- Children
- Other

Marital status

Years of education completed

Employment
- # weeks worked
- # hours/week
- Total annual salary
- Kind of work
1-Year Patient Follow-up Survey Data Elements

Current employment or educational status
- Student
- Employed
- Retired
- Volunteer work
- Other

Vocational Services received

Non-employment income
- Social Security disability income
- Worker’s compensation
- Other

Satisfaction with life
1-Year Patient Follow-up Survey Data Elements

Weekly activities
Amount of time engaged in activities
  • Home maintenance
  • School
  • Working
  • Public transportation/Private transportation

Frequency spent in activities
  • Socialize with friends/family
  • Give emotional support
  • Use the Internet
  • Get out of the house
1-Year Patient Follow-up Survey Data Elements

Monthly activities
Frequency spent in activities
  • Eating in a restaurant
  • Shopping
  • Sports or exercise outside home
  • Volunteer work
  • Movies
  • Attend sports events
  • Attend religious or spiritual services
1-Year Patient Follow-up Survey Data Elements

- Relationship status
- Method of transportation
- Had another head injury
- Rehab experience
- Visits to ER
- Admission to a nursing home, a transitional living facility, or a long term care facility
- Outpatient or day program rehabilitation services received
- Changes to medications
- Health issues
  - Seizures, headaches, fatigue, depression, anger, dizziness, apathy, sleeping, etc.
1-Year Patient Follow-up Survey Data Elements

Feelings about injury
Feelings about religious beliefs or spirituality
Use of illegal drugs/alcohol
Incarceration
Attempted suicide
Functional Independence Measures
Disability Rating Scale
Glasgow Outcome Scale
## Summary

<table>
<thead>
<tr>
<th>Under 65</th>
<th>65 Plus</th>
</tr>
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<tbody>
<tr>
<td>N = 1198</td>
<td>N = 373</td>
</tr>
<tr>
<td>Most injuries – vehicle</td>
<td>Most injuries – fall</td>
</tr>
<tr>
<td>Less ADL assistance pre-injury</td>
<td>More ADL assistance pre-injury</td>
</tr>
<tr>
<td>Admit TBI – severe</td>
<td>Admit TBI – moderate</td>
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<tr>
<td>Severe concomitant injuries</td>
<td>Min concomitant injuries</td>
</tr>
<tr>
<td>Few comorbidities</td>
<td>More comorbidities</td>
</tr>
<tr>
<td>Longer acute LOS</td>
<td>Shorter acute LOS</td>
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<tr>
<td>Greater CSI gain</td>
<td>Less CSI gain</td>
</tr>
</tbody>
</table>
Top 5 Most Common PT Treatment Activities

(Ranked by mean hours/week)

<table>
<thead>
<tr>
<th>Activity</th>
<th>% of Total Hours/Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait</td>
<td>23%</td>
</tr>
<tr>
<td>Therapeutic Exercise</td>
<td>18%</td>
</tr>
<tr>
<td>Formal Assessment</td>
<td>9%</td>
</tr>
<tr>
<td>Standing</td>
<td>8%</td>
</tr>
<tr>
<td>Resting</td>
<td>7%</td>
</tr>
</tbody>
</table>

Total 65%
Top 5 Most Common OT Treatment Activities

(Ranked by mean hours/week)

- Lower Body Dressing
- Pre Functional Activity
- Assessment Total
- Upper Extremity Activity
- Cognitive Activity

% of Total Hours/ Week
- 5%
- 8%
- 9%
- 12%
- 22%

Total 56%
Top 5 Most Common SLP Activities

(Ranked by mean hours/week)

- Group Other: 9%
- Group Swallowing: 11%
- Group Problem Solving: 15%
- Group Memory Orientation: 16%
- Group Assessment: 18%

Total: 69%
Top 5 Most Common PSY Treatment Activities

(Ranked by mean hours/week)

- **Cognitive Remediation**: 7%
- **Information and History Gathering**: 7%
- **Psychotherapeutic and Behavioral Therapy**: 14%
- **Neurobehavioral Status Assessment**: 17%
- **Neuropsychological Testing**: 22%

Total: 67%
Top 5 Most Common TR Treatment Activities

(Ranked by mean hours/week)

- **Cognitive Activity**: 46%
- **Other**: 20%
- **Sports**: 9%
- **Arts**: 5%
- **Music**: 1%

Total: 81%
Now what?

- Data cleaning
- Data analysis
- Articles and publications based on outcomes
Studies with Open Enrollment

- Tegretol
- Amantadine
- Mild Traumatic Brain Injury Registry
- Mild TBI PAR Study
Tegretol

Carbamazepine for the Treatment of Chronic Post-TBI Irritability and Aggression: A 42 day Single Site, Forced-titration, Parallel Group, Randomized, Double-blind, Placebo-controlled Trial

Principal Investigator: Flora Hammond, MD
Sub-Investigators: Lori Grafton, MD
Shilpa Kasuganti, MD

Enrollment Goal: 74

- Ages 16-75 years old
- Moderate-severe level of irritability
- Initial dose 400mg with titration up to 800mg daily
- Evaluated at baseline, Day 28, and Day 42
- Physician, subject, and informant complete assessments
Amantadine

A Multi-center, Parallel-Group, Randomized, Double-blind, Placebo-controlled Trial of Amantadine Hydrochloride in the Treatment of Chronic TBI Irritability and Aggression: A Replication Study

Principal Investigator: Flora Hammond, MD
Sub-Investigator: Lori Grafton, MD
Shilpa Kasuganti, MD

Enrollment Goal: Carolinas Rehabilitation: 28
Total Enrollment: 168 (6 sites)

- Ages 16-75 years old
- Moderate-severe level of irritability
- TBI >6 months ago
- 100mg twice a day
- Evaluated at baseline, Day 28, and Day 60
- Physician, Subject, and Informant complete assessments
- After Day 60, a 30 day open label phase is offered free of charge
Mild Traumatic Brain Injury Registry

Co-Principal Investigators: Lori Grafton, MD  
Michael Gibbs, MD

Purpose: To gather information about patients with Mild Traumatic Brain injury (mTBI) in order to develop guidelines for evaluation and treatment.

Enrollment Goal: 400

- Ages 16-60 years old
- Negative CT scan
- Diagnosis of mild TBI
- Blood Sample (optional)
- Patient seen in CMC ED for baseline, then at CR for 2 follow-up visits
- Follow-up calls at 3 months, 6 months, and 12 months
Mild Traumatic Brain Injury Registry

- Biomarkers
- Cognitive and Balance assessments
- ACE symptom checklist

Can the results help us with the prognosis of mTBI?
Mild TBI PAR Study

Health Information Needs after mTBI: A Participatory Research Exploration

Principal Investigator: Mark Hirsch, PhD
Co-Investigators: Lori Grafton, MD       Jeffrey Kline, MD
                    Rachel Seymour, PhD       Tami Guerrier
                    Rashmi Pershad

Purpose: To describe the experience of receiving health information from the perspective of the person with the brain injury, their caregiver(s), and family members. Another purpose of this study is to learn more about what health information is given by physicians and others in the community who are involved with caring for persons with mTBI.
Mild TBI PAR Study

- Ages 18 and over

- Three groups of people:
  - People with mTBI
  - Family members/spouses/significant others of people with mTBI
  - Health care professionals that work with people with mTBI

- Focus groups, interviews, surveys
Brain Injury and Emotions

- Brain Injury can have direct impact on interpersonal skills
- Interpersonal skills are important part of functioning in the community and at home
- Affect Recognition Study
- Emotional Film Clips Pilot Study
Affect Recognition Study

- Controlled Study of Affect Recognition Training
- Purpose: to evaluate the effectiveness of three (3) therapy programs to improve skills related to emotion and cognition in adults with TBI
- Multi-site, international study
- Drs. Hammond, Neumann, Grafton at Carolinas Rehabilitation
Affect Study Screening/Testing

- Participants identified through TBIMS registry, inpatient, outpatient clinics, therapists, flyers, support groups, etc.
- Screening included family (informant) questionnaires
- Screening computer-based, standardized tests and pictures of faces
- Participants paid $30 per screening/test session
Affect Recognition Treatment

- Qualified participants randomly assigned to one of three programs – pictures of faces (FAR), short stories (SEI), cognitive “brain games”
- Treatment 3 times/week for 3 weeks
- Follow testing within 4 days, 3 and 6 months post treatment
- Informant questionnaire continued at each testing session
Film Clip Pilot Study

- Use new and old methods to test ability to understand and respond to emotional information
- Participants with and without TBI
- More “real-life” movie clips and standardized still pictures of faces
Why is emotional research important?

- Long-term goal: learn more about emotional problems that develop after brain injury
- Develop therapies and interventions to increase emotional skills
Factors Related to Community Integration and Relationship Quality after Traumatic Brain Injury

Sheri W. Bartel, Med, CBIS Carolinas Rehabilitation, Charlotte, NC
Dawn Neumann, PhD, Indiana University, Indianapolis, IN
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Community Integration and Relationships after TBI

Community integration involves going back into the home, family, workplace and neighborhood, all of which include social interaction.

- Re-integrating back into the community can often be challenging after TBI

- Quality of relationships are often compromised

Social integration is key to Successfully reintegrating back Into the community!
Affect Recognition and Empathy

- Success of interpersonal interactions is influenced by our ability recognize and empathize with others’ feelings.
  - **Affect recognition**: ability to recognize how others are feeling (facial or vocal expressions)
  - **Empathy**: capacity to care about, understand, and share emotional experiences of others.
    - Present in both moderate and severe TBI (Babbage, Yim, Neumann, Zupan, Tomita and Willer, 2011)
    - Immediately following injury and many years post (Borgaro, 2004)
Impaired affect recognition and loss of empathy are common after TBI

- 50% of people with TBI have a difficult time picking up on social cues and inferences
- 13–39% of people with moderate to severe TBI have significant difficulties with facial affect recognition (Babbage, Yim, Neumann, Zupan, Tomita and Willer, 2011)
- Knox & Douglas (2009) found that recognition of facial emotion remained closely related to social function.
- Problems with facial affect recognition are partly related to communication difficulties and impoverished social relationships (Radice-Neumann, Zupan, Babbage & Willer, 2007).
Rationale

Identifying factors that contribute to poor community integration and relationship quality after TBI will help guide the development of more effective treatments.
OBJECTIVE 1

Affect recognition

Empathy

Community Integration
OBJECTIVE 2

Affect recognition

+ 

Empathy

Perceived Relationship Stress and Support

+ 

Community Integration
Participants

- N=191 Participants with moderate to severe TBI
- N=151 family/friends were recruited (Informants)

Part of a larger, multi-site treatment study – participants recruited from USA, Canada and New Zealand for *Controlled Study of Affect Recognition Training for Individuals with Traumatic Brain Injury.*

*National Institute on Disability and Rehabilitation Research Grant #H133G080043*
### Outcome Measures

<table>
<thead>
<tr>
<th>TBI</th>
<th>Informants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida Affect Battery, Naming facial affect</td>
<td>Relationship Support and Stress (LISRES)</td>
</tr>
<tr>
<td></td>
<td>Empathy (Interpersonal Reactivity Index)</td>
</tr>
<tr>
<td></td>
<td>Empathic concern</td>
</tr>
<tr>
<td></td>
<td>Perspective–taking</td>
</tr>
<tr>
<td></td>
<td>Community integration (CIQ)</td>
</tr>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td></td>
<td>Home Integration</td>
</tr>
<tr>
<td></td>
<td>Social Integration</td>
</tr>
<tr>
<td></td>
<td>Productivity</td>
</tr>
</tbody>
</table>
Inclusion/Exclusion Criteria

**Inclusion:**
- Age between 18 and 65 years old
- At least 8 years old at time of injury
- Minimum one year post injury
- GCS $\leq 12$; or PTA $\geq 24$ hrs

**Exclusion:**
- Premorbid dx of mental illness (except depression or anxiety)
- Uncorrected visual or hearing impairment
- Severe expressive or receptive language impairment
### Demographics and Injury Statistics

<table>
<thead>
<tr>
<th></th>
<th>TBI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Participant Age</td>
<td>40</td>
</tr>
<tr>
<td>Years post-injury</td>
<td>10 (range 1–42; s.d.=8.9)</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 74% Female 26.2%</td>
</tr>
<tr>
<td>GCS</td>
<td>Mild=6.9% Mod=11.1% Severe=81.9%</td>
</tr>
<tr>
<td>PTA</td>
<td>7+ days=86.3% 1–6 days=12.5% &lt;24 hrs=1.2%</td>
</tr>
<tr>
<td>Cause of Injury</td>
<td>MVA=62% Fall=14% Assault=17% Other=17%</td>
</tr>
</tbody>
</table>
## Demographics and Injury Statistics

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
</table>
| **Education**            | 22% did not finish high school  
                          | 33.3% finished high school  
                          | 43.9% higher education   |
| **Marital Status**       | Single=49.5%               
                          | Married=25%                
                          | Partner=9.4%               
                          | Divorced/Separated=13.4%   
                          | Widowed=2%                 |
| **Informant Relationship** | Sign.Other/Spouse=39.9%  
                          | Other Family=41.9%         
                          | Friend=9.4%                
                          | Careworker=7%              
                          | Other=1.8%                 |
### Results- Total Community Integration

<table>
<thead>
<tr>
<th>Linear Regression (Enter)</th>
<th>$R^2$</th>
<th>Adjusted $R^2$</th>
<th>$F$</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>15.8%</td>
<td>14.1%</td>
<td>9.08</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>• Facial Affect</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Perspective Taking</td>
<td></td>
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<tr>
<td>• Empathic Concern</td>
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</tr>
</tbody>
</table>

- Facial affect recognition, perspective-taking, and empathic concern significantly accounted for 14% of the (adjusted) Community Integration variance.

- Age, gender, time post-injury, injury severity and education were NOT significantly correlated with Community Integration.
## Results - Social Integration

<table>
<thead>
<tr>
<th>Linear Regression (Enter):</th>
<th>R^2</th>
<th>Adjusted R^2</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>19.4%</td>
<td>17.6%</td>
<td>10.66</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Facial Affect</td>
<td></td>
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<tr>
<td>Perspective Taking</td>
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<td></td>
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<tr>
<td>Empathic Concern</td>
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</tr>
</tbody>
</table>

- Facial affect recognition, perspective-taking, and empathic concern significantly accounted for 18% of the (adjusted) Social Integration variance.

- Age, gender, time post-injury, injury severity and education were NOT significantly correlated with Community Integration.
## Results - Relationship Stress

<table>
<thead>
<tr>
<th>Linear Regression (Enter):</th>
<th>$R^2$</th>
<th>Adjusted $R^2$</th>
<th>F</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>32.0%</td>
<td>29.5%</td>
<td>11.77</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>• Facial Affect</td>
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<tr>
<td>• Perspective Taking</td>
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<tr>
<td>• Empathic Concern</td>
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<td></td>
</tr>
<tr>
<td>• Home Community Integration</td>
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<tr>
<td>• Social Integration</td>
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</tbody>
</table>

- The model significantly explained 29.5% of (adjusted) perceived relationship stress
- Age, gender, time post-injury, injury severity and education were NOT significantly correlated with Relationship Stress
## Results - Relationship Support

<table>
<thead>
<tr>
<th>Linear Regression (Enter):</th>
<th>( R^2 )</th>
<th>Adjusted ( R^2 )</th>
<th>( F )</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Model</strong></td>
<td>39.6%</td>
<td>37.2%</td>
<td>16.28</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>- Facial Affect</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>- Perspective Taking</td>
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<tr>
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<tr>
<td>- Home Community Integration</td>
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<tr>
<td>- Social Integration</td>
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</tbody>
</table>

- The model significantly explained 37.2% of (adjusted) perceived relationship support
- Perspective-taking explained most of the variance
  - Age, gender, time post-injury, injury severity and education were NOT significantly correlated with Relationship Support
Conclusions

Facial Affect Recognition

Perspective Taking (Empathy)

Empathic Concern

Total and Social Community Integration
Conclusions

Facial Affect Recognition

Perspective Taking (Empathy)

Empathic Concern

Home and Social Integration

Relationship Stress & Support
The ability to recognize and empathize with others’ emotions is important for community integration. Treatments should be developed to improve affect recognition and empathy impairments. Family education should be integral part of therapy. Community re-entry therapy should include social re-training in addition to functional training.
Questions?

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Project STAR
at Carolinas Rehabilitation

Carolinas Rehabilitation
Funding

• Grant 1: North Carolina Department of Health and Human Services-Division of Mental Health, Developmental Disabilities, and Substance Abuse Services

• Grant 2: Health Resources Services Administration (HRSA)

• Grant 3: Brain Injury Association of NC
TBI Project STAR
704-355-1502

• Information and Referral Service to Community Resources
• Educational Materials
• Trainings and In-services
• Publications
• Prevention/ Brain Injury Awareness
• Community Program Development: Technical Assistance, Community College Classes, Support Groups
• Substance Use/Abuse and TBI
• Family and Community Support Office of the Brain Injury Association of North Carolina
• Ombudsman Program---Referral Line: BIANC 1-800-377-1464
We help individuals with brain injury and their families get connected with community resources

- Brain Injury Association of America
- Brain Injury Association of North Carolina
- Division of Mental Health, Developmental Disabilities and Substance Abuse Services
- Carolinas Rehabilitation
- Day Programs

- Vocational Rehabilitation
- Vocational Rehabilitation-Independent Living
- Social Security Benefits Specialist
- Residential Services
- Volunteer Work Locations
- Support Groups
- Centers for Independent Living
How can we help you?

Project STAR can:

- Consent to the TBI Registry
- Provide Community Resources
- Provide Educational Information on General and Specific Issues Related to Brain Injury
- Provide BI Prevention Resources/Materials
- Provide Resources on Starting Support Groups
- Provide Complementary Memberships to the Brain Injury Association of NC
What Project STAR can’t do:

• Coordinate D/C Needs, such as Equipment or Placement

• Assist with Applying for Benefits such as Social Security, Medicaid, etc.

• Provide Funding for Therapy, Equipment, etc.
Project STAR Staff

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- Volunteers—Barbara Westphal, John Simon, and Peggy Philbrick
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Carolinas Rehabilitation
www.carolinasrehabilitation.org