The Traumatic Brain Injury Model Systems of Care

A project funded by the US Department of Education
National Institute on Disability and Rehabilitation Research

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Project Design

- The first prospective, longitudinal multi-center study ever conducted which examines the course of recovery and outcomes following the delivery of a coordinated system of acute neurotrauma and inpatient rehabilitation.

- Includes large scale follow-up to 20 years post-injury.

2012-2017 Project Priorities

Conduct research that contributes to evidence-based rehabilitation interventions and clinical and practice guidelines which improve the lives of individuals with TBI.

2012-2017 Project Priorities

- Improve long-term outcomes of individuals with TBI by conducting 1-2 site-specific research projects to test innovative approaches that contribute to rehabilitation interventions and evaluating TBI outcomes in accordance with the focus areas identified in NIDRR's Long-Range Plan.

- Improve outcomes for individuals with TBI by participating in at least one collaborative research module project, which may range from pilot research to more extensive studies.

- Successfully engage in multi-site collaborative research on TBI by demonstrating the capacity to access research participants. Also, Centers will demonstrate the ability to maintain data quality and the ability to adhere to research protocols.

- Continued assessment of long-term outcomes of TBI by enrolling at least 35 subjects per year into the longitudinal portion of the TBIMS database.

2012-2017 Project Priorities

- In carrying out research activities, each Center may select from the following research domains: Health and Function, Employment, Participation and Community Living, and Technology for Access and Function.

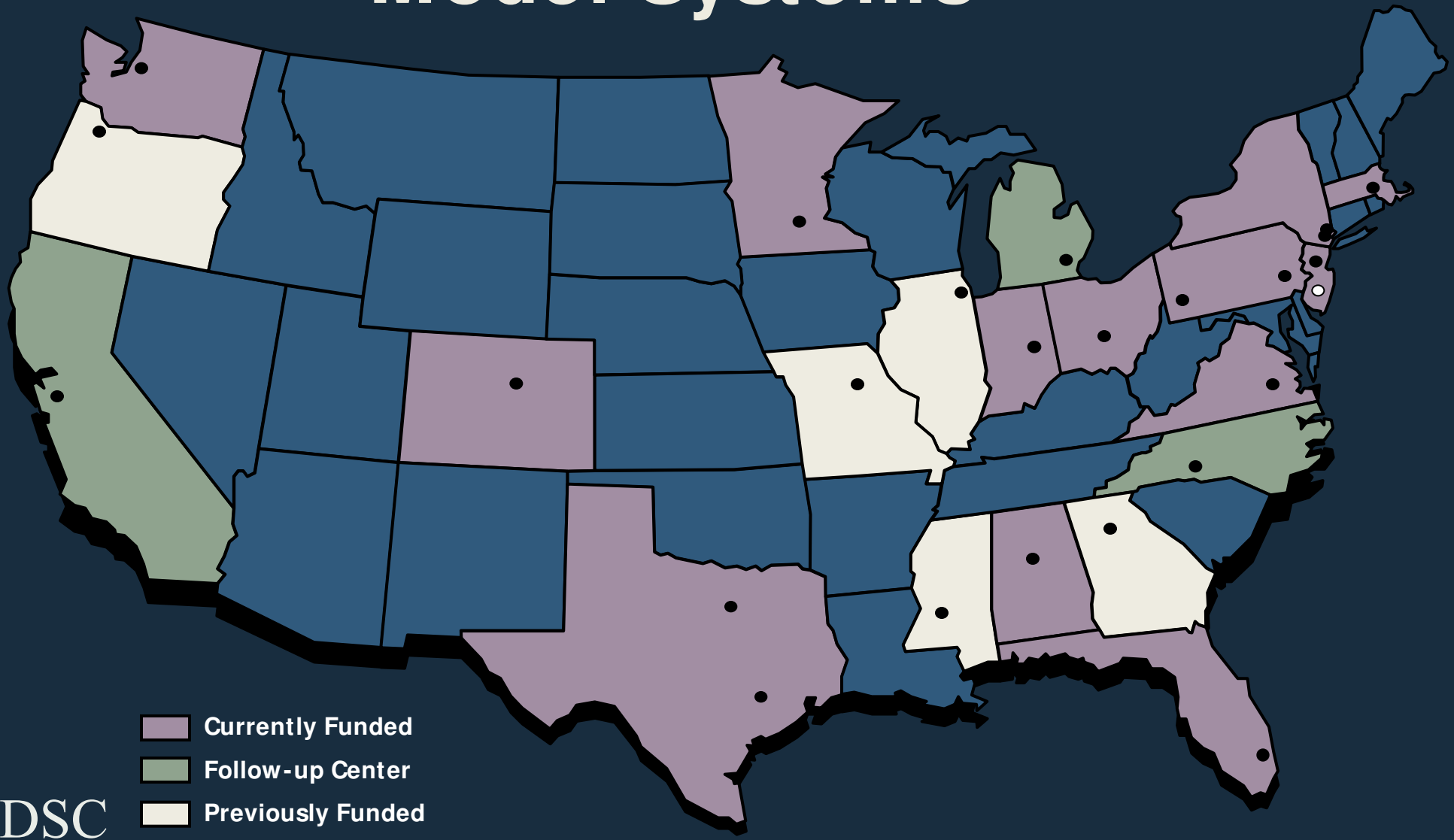
- In addition, each Center must:
  - Provide a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. The system must encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services; and

  - Coordinate with the NIDRR funded Model Systems Knowledge Translation Center to provide scientific results and information for dissemination to clinical and consumer audiences.

  - While addressing the needs of individuals with TBI, Centers must include individuals from one or more traditionally underserved populations. Also, the input of individuals with TBI will be used to shape TBIMS research.

  - Project Directors will participate in two annual face-to-face TBIMS Center Project Directors' meetings held in the Washington, DC area.

Current Traumatic Brain Injury Model Systems



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TBI Model Systems Leadership

- Federal Project Management
  - National Institute on Disability and Rehabilitation Research, Cate Miller, PhD, Project Manager
- National Data and Statistical Center
  - Craig Hospital, Englewood, CO, Cindy Harrison-Felix, PhD, Project Director
- TBI Model Systems Centers
  - Executive Committee Chair, John D. Corrigan, PhD

Centers and Key Personnel

- University of Alabama - Birmingham, AL - Thomas Novack , Ph.D.
- Craig Hospital - Englewood, CO - Cindy Harrison-Felix, Ph.D., Gale Whiteneck, Ph.D. and Don Gerber, PsyD
- University of Miami/Miller School of Medicine - Miami, FL - Douglas Johnson-Greene, Ph.D.
- Indiana University/Rehabilitation Hospital of Indiana - Indianapolis, IN - Flora Hammond, M.D.
- Spaulding/Harvard Medical School - Boston, MA - Joseph Giacino, Ph.D.
- Mayo Clinic- Rochester, MN - Allen Brown, M.D.
- Kessler Foundation- West Orange, NJ - Nancy Chiaravalloti, Ph.D.
- Rusk Institute of Rehabilitation Medicine - New York, NY - Tamara Bushnik, Ph.D. and Teresa Ashman, Ph.D.

Centers and Key Personnel (cont.)

- Mount Sinai School of Medicine - New York, NY - Wayne Gordon, Ph.D.
- The Ohio State University - Columbus, OH - John D. Corrigan, Ph.D.
- Moss Rehabilitation Research Institute - Elkins Park, PA - Tessa Hart, Ph.D.
- University of Pittsburgh Medical Center - Pittsburgh, PA - Amy Wagner, M.D.
- Baylor Institute for Rehabilitation/U of TX Southwestern Medical Center - Dallas, TX – Shahid Shafi, M.D., MPH and Michael Devous, Ph.D.
- TIRR Memorial Hermann - Houston, TX - Mark Sherer, Ph.D. and Angelle Sander, Ph.D.
- Virginia Commonwealth University - Richmond, VA - Jeffrey Kreutzer, Ph.D.
- University of Washington - Seattle, WA - Kathleen Bell, M.D.

Longitudinal Follow-up Centers

- The Rehabilitation Research Center/Santa Clara Valley Health and Hospital Systems - San Jose, CA - Stephanie Kolakowsky-Hayner, Ph.D.
- Rehabilitation Institute of Michigan - Detroit, MI - Robin Hanks, Ph.D.
- Carolinas Rehabilitation/Carolinas HealthCare System - Charlotte, NC – Tami Guerrier

Current Center-Specific Research Studies

Center	RCT	Questionnaire Correlative	Other Design	Topic
AL	X			Evaluation of a telehealth-based weight management treatment program
CO	X			Virtual reality intervention for balance deficits
CO	X			Structured volunteering intervention for well-being
FL	X			Evaluation and intervention of sleep disordered breathing (SDB)
FL		X		Evaluating assessment methods for pain
IN	X			Buspirone effectiveness for TBI irritability and aggression
IN		X		Developing a measure of irritability and aggression impact
MA			Neuroimaging	Validation of novel fMRI paradigms for detection of consciousness
MN			Randomized Pragmatic Trial	Multimedia use for remote clinical coordination - participation outcomes
NJ-Kessler Foundation	X			Speed of processing training to improve cognition in TBI: A randomized clinical trial
NY – Mt. Sinai	X			Management of post-TBI fatigue with light exposure
NY – Mt. Sinai			Intervention Development	Online emotional regulation group treatment
NY-NYU			Quasi-Experiment	Two-phase approach to improve health literacy and disparities among culturally diverse individuals with TBI
NY-NYU		X		Evaluating the sensitivity and responsiveness of the TBI-QOL CATs

Current Center-Specific Research Studies (cont.)

Center	RCT	Questionnaire Correlative	Other Design	Topic
OH	X			Brief intervention for substance misuse following moderate or severe TBI
OH	X		Secondary Data	The contribution of co-morbid conditions to deterioration 5 years following rehabilitation for TBI
PA - Elkins Park			Longitudinal Cohort Study	Dopamine dysfunction in TBI : A contextualized Rehabilomics© investigation using an ICF framework for assessing functioning, disability, and health.
PA - Moss	X			SMS delivery of implementation intentions to reduce depression & anxiety
PA - Moss			IRT Based Scale Dvlpmt	Development of pain scale for patients with TBI unable to communicate
TX-North			Comparative Effectiveness Study	Comparative effectiveness study of variations in clinical practices and patient outcomes across TBI MS rehab centers and to develop evidence-based practice guidelines for TBI rehabilitation
TX-North			Neuroimaging	To identify TBI patients that may benefit from early methylphenidate therapy utilizing single photon emission computed tomography (SPECT) imaging of dopamine transporter
TX-TIRR	X			Effectiveness of acceptance and commitment therapy for reducing emotional distress and improving participation outcomes after TBI
VA	X			Intervention to promote survivor resilience and adjustment
VA	X			Evaluation of a skill-building, supportive, and educational intervention for couples
WA	X			Sumatriptan to treat headache after moderate-severe TBI
Total	14	3	9	

2007-2012 Module Projects

- A Prospective Study of the Relationship between Post-TBI Fatigue and Insomnia.
  - NY (lead), CA, NC, NJ-KF, NJ-JFK
- The Natural History of Headache after TBI.
  - WA (lead), MN, AL, TX-North, VA, CO
- Enhancing the TBIMS Core Dataset to Expand Research on Environmental Influences Affecting Outcomes from TBI
  - OH (lead), all centers participating
- Sexuality after TBI.
  - TX-TIRR (lead), CO, MN, NC, MI, IL
- Statins and Outcome After TBI: An Observational Study
  - PA (lead), NY, CO, IL, OH, AL, TX-North, TX-TIRR, NJ-JFK

TBI MS Collaborative Studies

- TBI Model System Collaborative Study of Amantadine for Post TBI Irritability and Aggression
  - Approximately 29-71 percent of individuals with traumatic brain injury (TBI) experience the problem of irritability and/or aggression which can interfere with interpersonal interaction, relationships and function. The current medical literature does not support standards or guidelines for the management of TBI irritability or aggression. However, pilot research at Carolinas Rehabilitation has revealed that amantadine may reduce irritability and aggression severity and frequency. Flora Hammond, MD , Carolinas Rehabilitation, is the Principal Investigator

TBI MS Collaborative Studies

- Individualized Planning for the First Year Following Acute Rehabilitation Project
  - This Practice Based Evidence (PBE) study will identify individual differences in demographic characteristics, pre-morbid status, injury-related conditions and medical course that differentially predict the effectiveness of rehabilitation interventions on functional independence, participation and subjective well-being up to 1 year following traumatic brain injury (TBI). The proposal incorporates data being collected for an NIH-funded PBE study focusing only on acute rehabilitation and extends the scope to recovery processes occurring after discharge from rehabilitation. John D. Corrigan, PhD, Ohio State University, is the Principal Investigator.

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.

Database Inclusion Criteria

- Moderate to severe TBI (PTA > 24 hrs or LOC > 30 minutes or GCS in ED < 13 or intracranial neuroimaging abnormalities)
- Admitted to system's hospital emergency department within 72 hours of injury.
- 16 years of age or older at the time of injury
- Receives acute care and comprehensive inpatient rehabilitation within the model system hospitals.
- Informed consent is signed by patient, family or guardian.

Database Objectives

- Study the clinical course of individuals with TBI from time of injury through discharge from acute care and rehabilitation care.
- Evaluate the recovery and long-term outcome of individuals with TBI.
- Establish a basis for comparison with other data sources.

NIDRR TBI National Database

- Form I - Acute care: 254 variables
- Form II - Follow-up: 191 variables
- Follow-up conducted 1,2,5, and every 5 years thereafter
- Follow-up methods: in-person, phone, mail questionnaire

NIDRR TBI National Database

- Form I – 11058 cases (as of 3/31/2012)
- Form II – 35238 follow-ups* - 21% attrition (4%**)
  - Year 1 – 10,432 – 17% attrition (1%**)
  - Year 2 – 9,217– 18% attrition (4%**)
  - Year 5 – 6,502– 20% attrition (6%**)
  - Year 10 – 2,827 – 22% attrition (4%**)
  - Year 15 – 742– 18% attrition (8%**)
  - Year 20 – 228– 11% attrition (0%**)

*There are some follow-ups in database that were performed at 3, 4, and 6 years post-injury.

**Additional percent attrition due to loss of center funding.

Study Limitations

- Lack of control or comparison group
- Selection bias in sample: only patients treated in funded Centers
- Lack of uniformity in treatment across all Centers
- Attrition in follow-up
- Inability to systematically track post-acute service utilization
- No further follow-up evaluations if Center defunded

  [in 2007 NDSC began funding some defunded centers to continue follow-up]

Research Issues for Variable Selection

I. Premorbid history
II. Demographic characteristics of the population
III. Causes and severity of injury
IV. Nature of diagnoses
V. Types of treatment/services
VI. "Costs" of treatment/services
VII. Measurement and prediction of outcomes including impairment, disability and participation

I. Premorbid History

- Drug Use
- Alcohol use (NHSDA/BRFSS)
- Conditions and limitations
- Psychiatric History
- Arrests/felony incarcerations
- Learning/behavior problems
- Military History

II. Demographic Characteristics

- Age
- Gender
- Race
- Marital Status
- Residence
- Zip Code
- Living with
- Level of education
- Employment

III. Causes of Injury

- Date of injury
- ICD-9 external cause of injury codes
- Blood alcohol level (limited data)

III. Severity of Injury

- Glasgow Coma Scale Score
- Revised Trauma Score
- Duration of unconsciousness
- Duration of Post Traumatic Amnesia

IV. Diagnoses

- Spinal Cord Injury
- Intracranial CT scan findings
- Intracranial hypertension
- Neuropsychological assessment
- ICD-9 diagnosis codes
- Cause of death

V. Treatments

- Surgical procedures
- Rehospitalizations

VI. "Costs" of Treatment

- Length of stay
- Payer source

VII. Measure and Predict Outcome at Follow-up

- Impairment
  - Mortality
  - Lifetime History of TBI

VII. Measure and Predict Outcome at Follow-up

- Disability
  - Disability Rating Scale (DRS)
  - Functional Independence Measure (FIM)
  - Glasgow Outcome Scale-Extended (GOS-E)
  - Supervision Rating Scale (SRS)

VII. Measure and Predict Outcome at Follow-up

- Participation
  - Living with
  - Residence (e.g., private home, SNF, AFC, hospital)
  - Address
  - Marital Status
  - Level of education
  - Employment
  - Drug use
  - Alcohol use (NHSDA/BRFSS)

VII. Measure and Predict Outcome at Follow-up

- Participation (cont.)
  - Transportation
  - Arrests
  - Psychiatric problems
  - Generalized Anxiety Disorder Scale (GAD-7)
  - Patient Health Questionnaire (PHQ-9)
  - Satisfaction with Life Scale (SWLS)
  - Participation Assessment (PART)

Sources of Data

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

Guidelines for Follow-up

- Follow-up contact attempted with every patient 1st, 2nd, 5th years and then every five years.
- 4 month window for year 1 follow-up, 6 month window for year 2, 1 year window for years 5, 10, 15, . . .
- Patient is primary source of follow-up information; if patient cannot be interviewed, follow-up is attempted with a proxy.
- Methods of follow-up in order of priority: phone/in-person, mail questionnaire.

Data Quality Checks

- Data entry screens:
  - Checks for valid codes and correct range
  - Logical checks between variables
  - Consistency checks between variables across time

Data Quality Checks

- User-initiated database reports:
  - Identify cases with errors or blanks
  - Notify of follow-ups coming due
  - Warnings about overdue follow-ups
  - Calculate missing data rates
  - Calculate follow-up rates

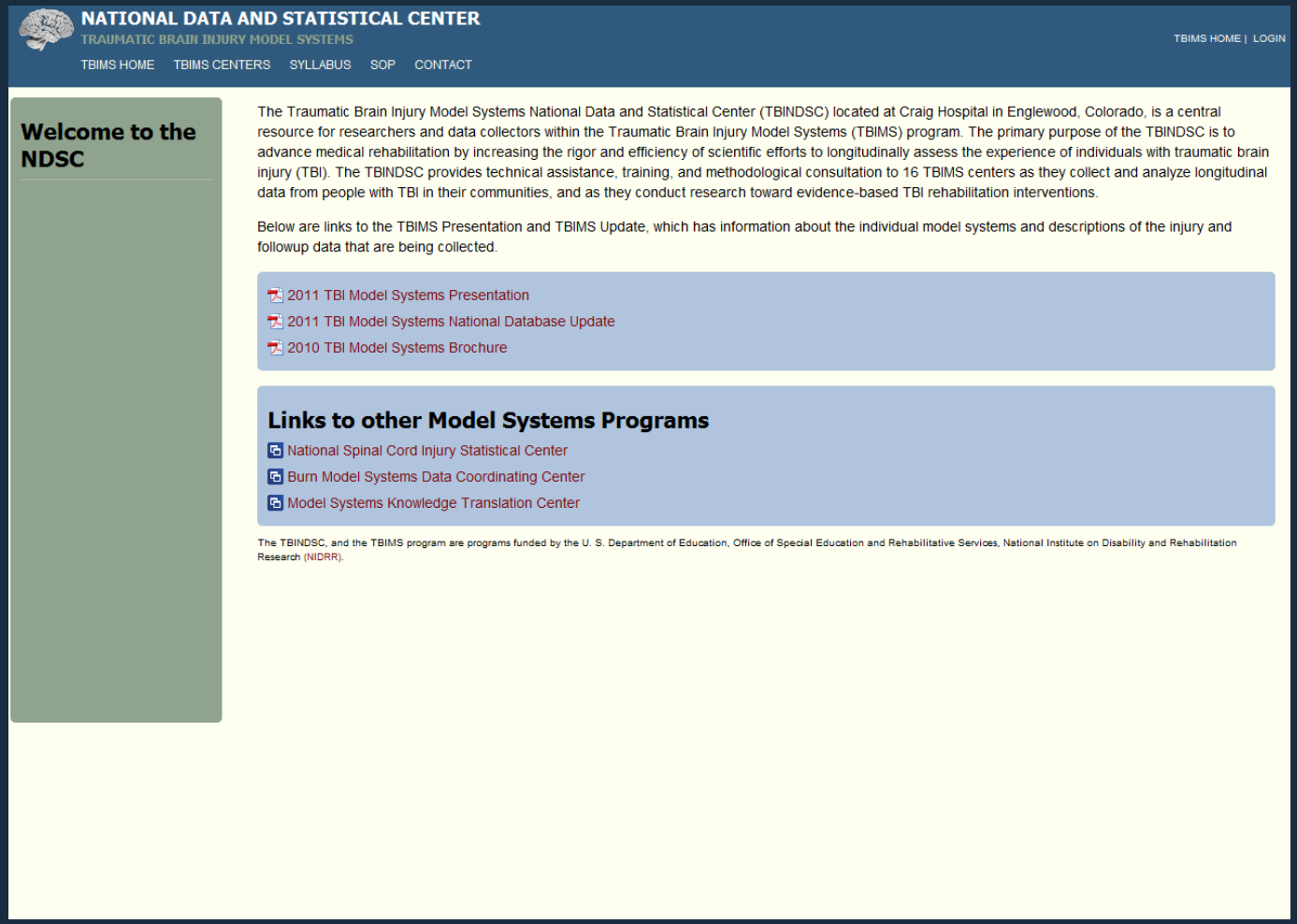
Internal Dissemination

- Annual Data Report
- Quarterly Enrollment and Follow-up Target Reports
- Semi-Annual Missing Data Reports

External Dissemination

- World Wide Web Site [www.tbindsc.org]
  - Online Database Syllabus
  - Annually updated TBI Model Systems PowerPoint Presentation
- National/International Presentations
- Journal Publications

TBI Model Systems National Data and Statistical Center Website www.tbindsc.org



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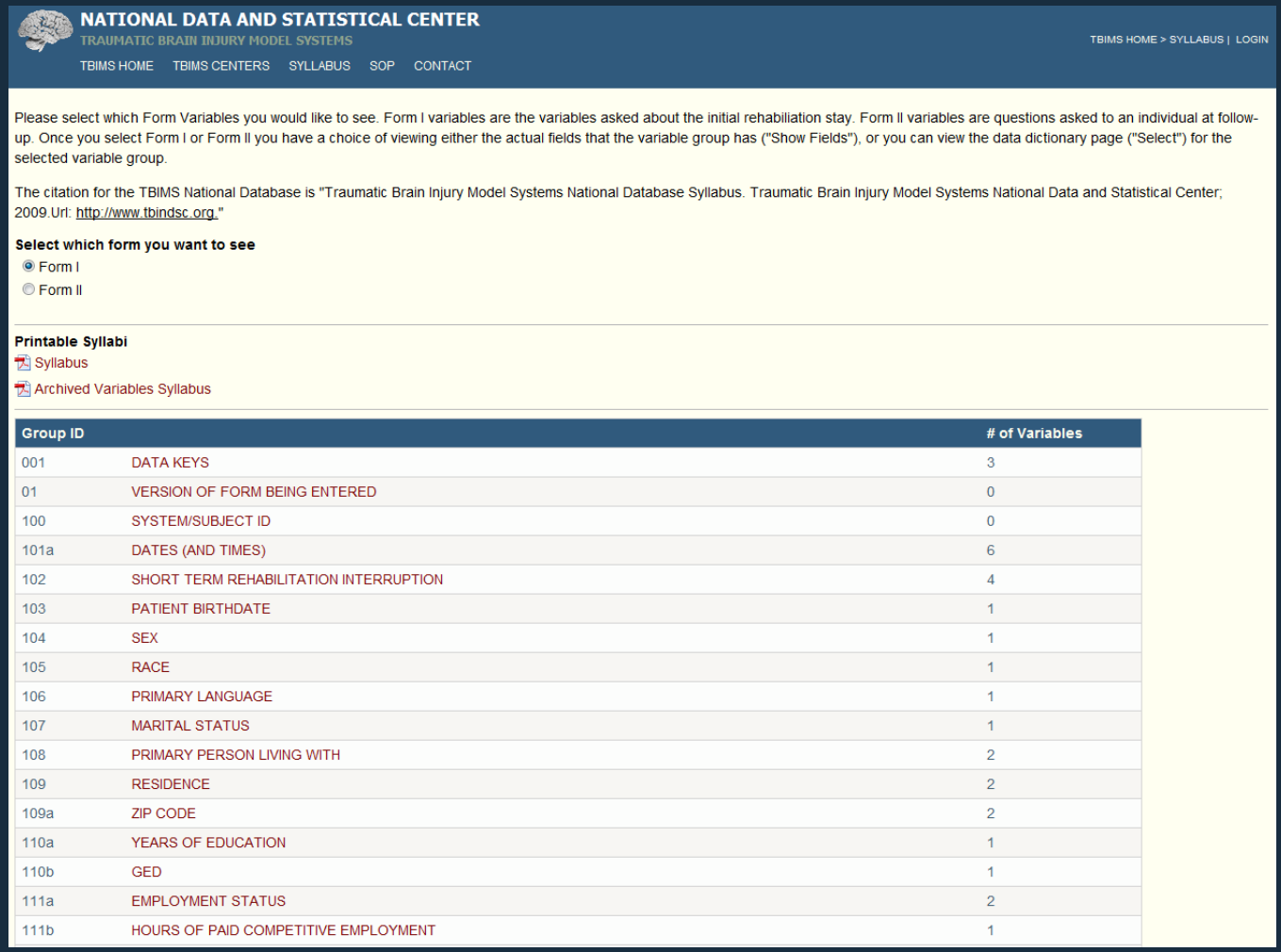
Online TBI Model Systems National Database Syllabus



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TBIMS HOME > SYLLABUS | LOGIN

TBIMS HOME TBIMS CENTERS SYLLABUS SOP CONTACT

Please select which Form Variables you would like to see. Form I variables are the variables asked about the initial rehabiliation stay. Form II variables are questions asked to an individual at follow-up. Once you select Form I or Form II you have a choice of viewing either the actual fields that the variable group has ("Show Fields"), or you can view the data dictionary page ("Select") for the selected variable group.

The citation for the TBIMS National Database is "Traumatic Brain Injury Model Systems National Database Syllabus. Traumatic Brain Injury Model Systems National Data and Statistical Center; 2009.Url: http://www.tbindsc.org."

Select which form you want to see

- (•) Form I
- ( ) Form II

Printable Syllabi

Syllabus

Archived Variables Syllabus

Group ID		# of Variables
001	DATA KEYS	3
01	VERSION OF FORM BEING ENTERED	0
100	SYSTEM/SUBJECT ID	0
101a	DATES (AND TIMES)	6
102	SHORT TERM REHABILITATION INTERRUPTION	4
103	PATIENT BIRTHDATE	1
104	SEX	1
105	RACE	1
106	PRIMARY LANGUAGE	1
107	MARITAL STATUS	1
108	PRIMARY PERSON LIVING WITH	2
109	RESIDENCE	2
109a	ZIP CODE	2
110a	YEARS OF EDUCATION	1
110b	GED	1
111a	EMPLOYMENT STATUS	2
111b	HOURS OF PAID COMPETITIVE EMPLOYMENT	1

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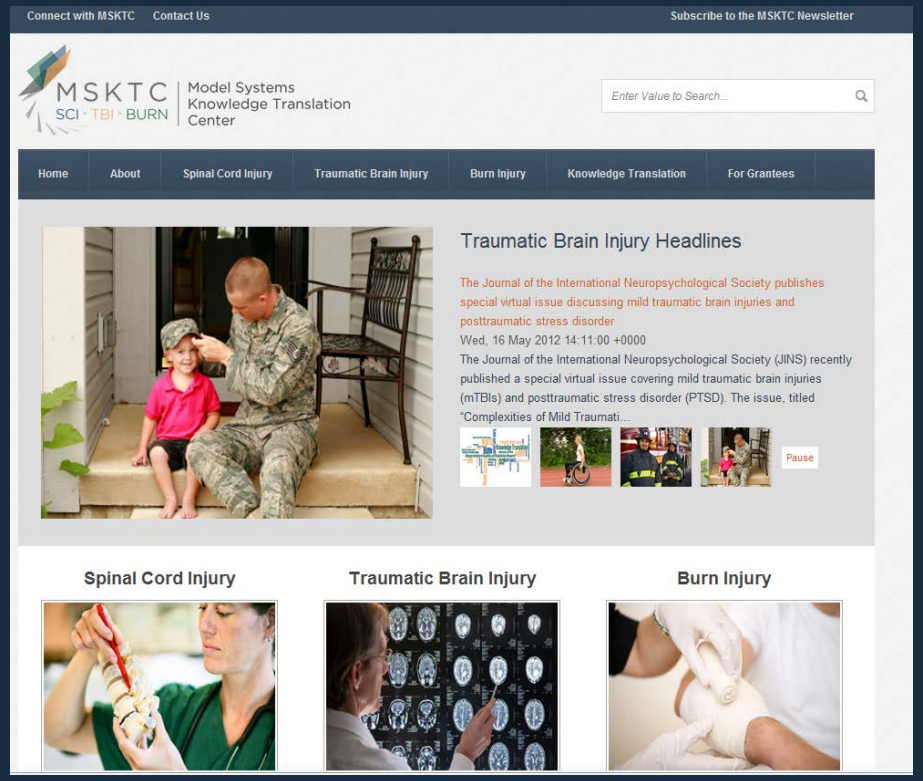
Model Systems Knowledge Translation Center (MSKTC)



- The Model Systems Knowledge Translation Center (MSKTC) aims to:
  - *Enhance* the relevance and visibility of Model Systems research
  - *Communicate* Model Systems research effectively to stakeholders
- The MSKTC is operated by American Institutes for Research in collaboration with WETA/BrainLine and George Mason University

www.msktc.org

MSKTC Goals

Three overarching goals guide the work of the MSKTC:

- **Goal 1:** Enhance the understanding of the quality and relevance of knowledge among researchers and multiple users on the topics of SCI, TBI, and Burn
- **Goal 2:** Enhance knowledge of advances in SCI, TBI, and Burn research among the diverse audience members who need this information
- **Goal 3:** Create a centralized repository of empirical information and resources on research in SCI, TBI, and Burn areas and actively conduct outreach and dissemination activities to communicate this knowledge

MSKTC Activities

2011-2012 Highlights

	Completed	In Process
Systematic Reviews		• TBI & Fatigue
Consumer Factsheets	Submitted Repackaged Factsheets to Archives of Physical Medicine & Rehabilitation: •TBI & Alcohol •TBI & Depression •TBI & Headaches	• TBI & Relationship • TBI & Vocational Rehabilitation • TBI & Vision Problems
Knowledge Translation Products	• Planning for Communities of Practice: A guide for Model Systems Grantees • Newsletter Template and Instructions • Press Release Template and Instructions	• Knowledge Translation Webinar • Communities of Practice Webinar • Additional tools for the Knowledge Translation Toolkit
Multimedia Products	• TBI and Alcohol Slideshow	• Hot Topics Module: Relationships after TBI

TBI MS National Database
Descriptive Data Summary

[Includes data from 01/01/1989 – 12/31/2011]

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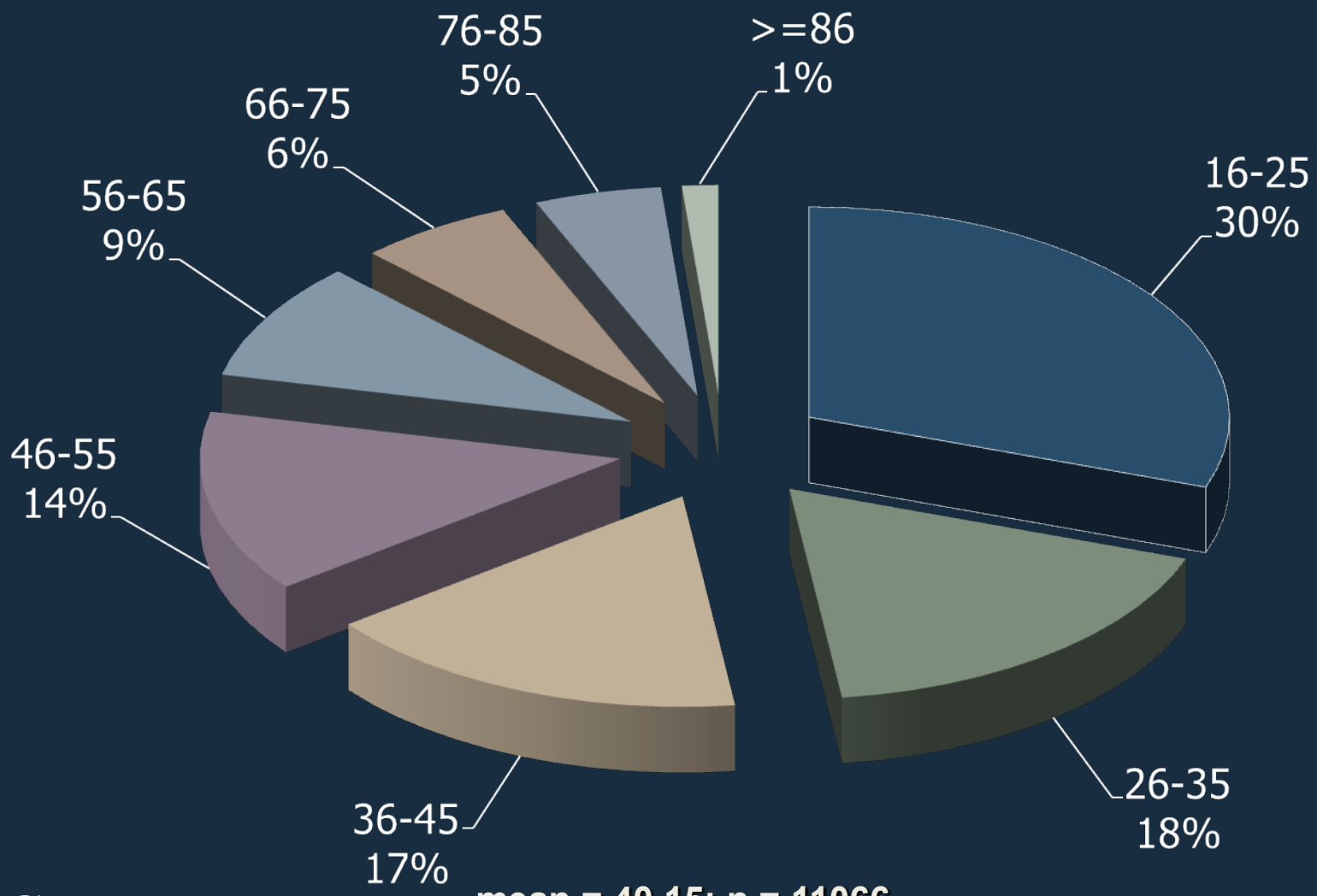
Age



mean = 40.15; n = 11066

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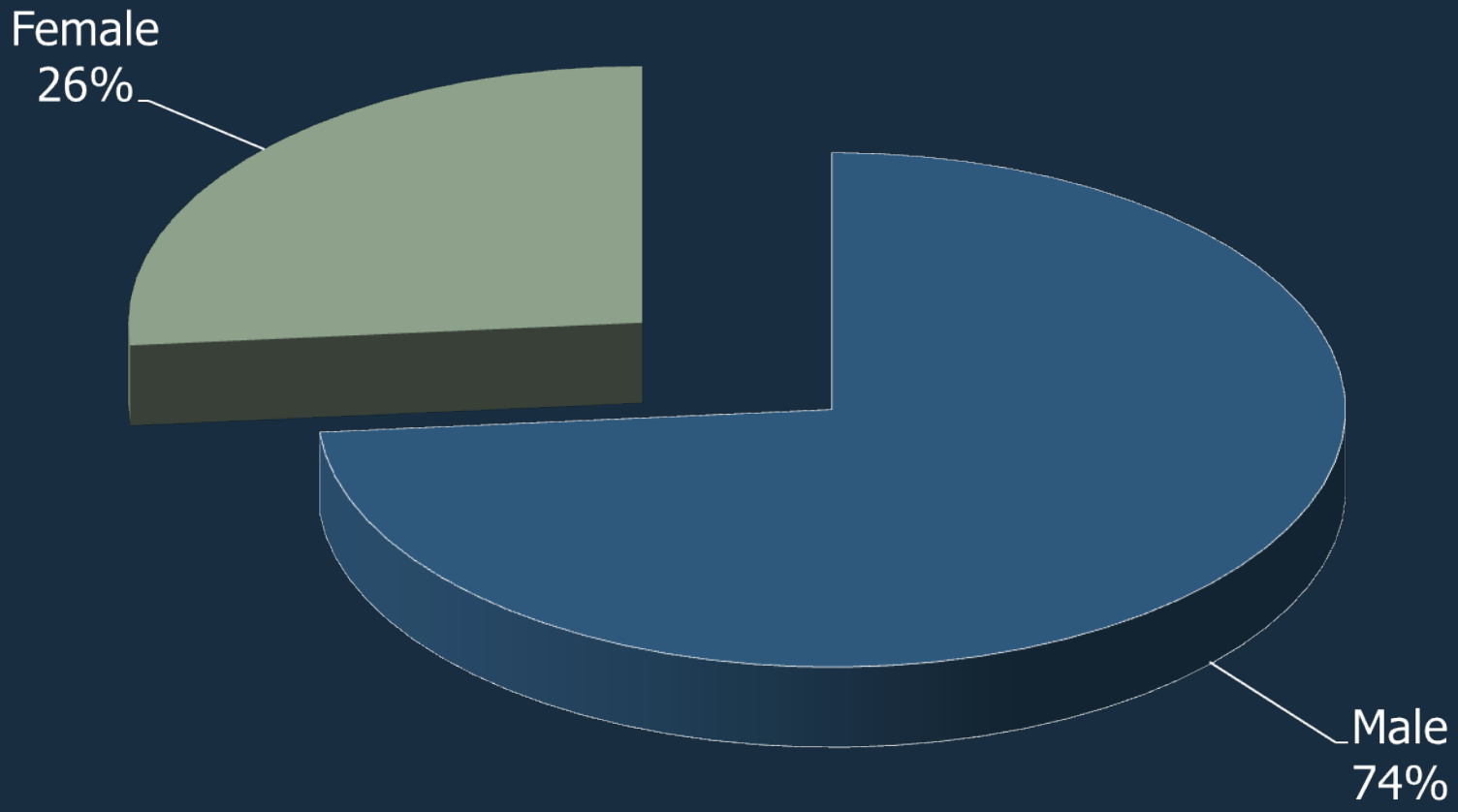
Gender



n = 11065

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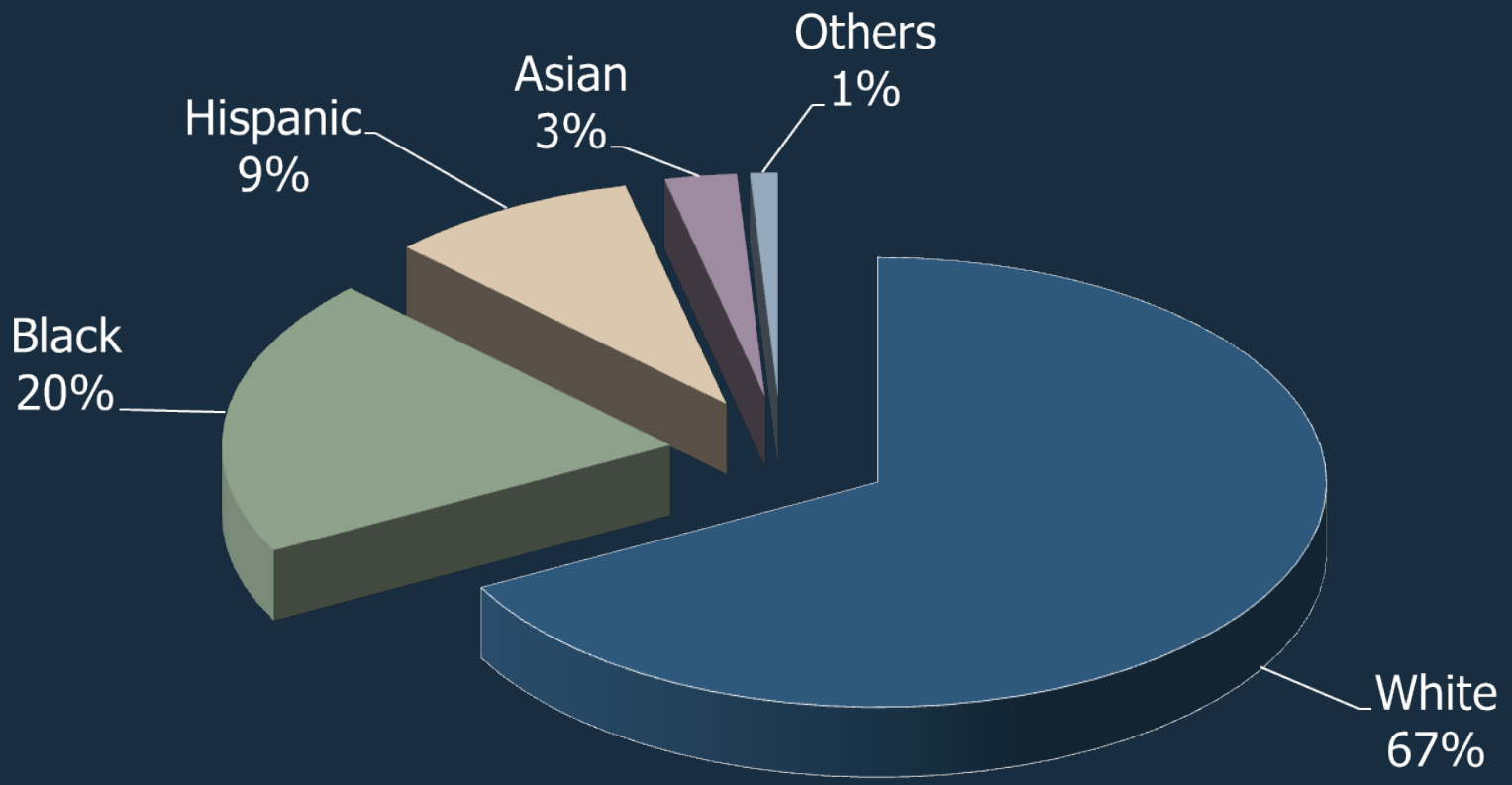
Race



n = 11064

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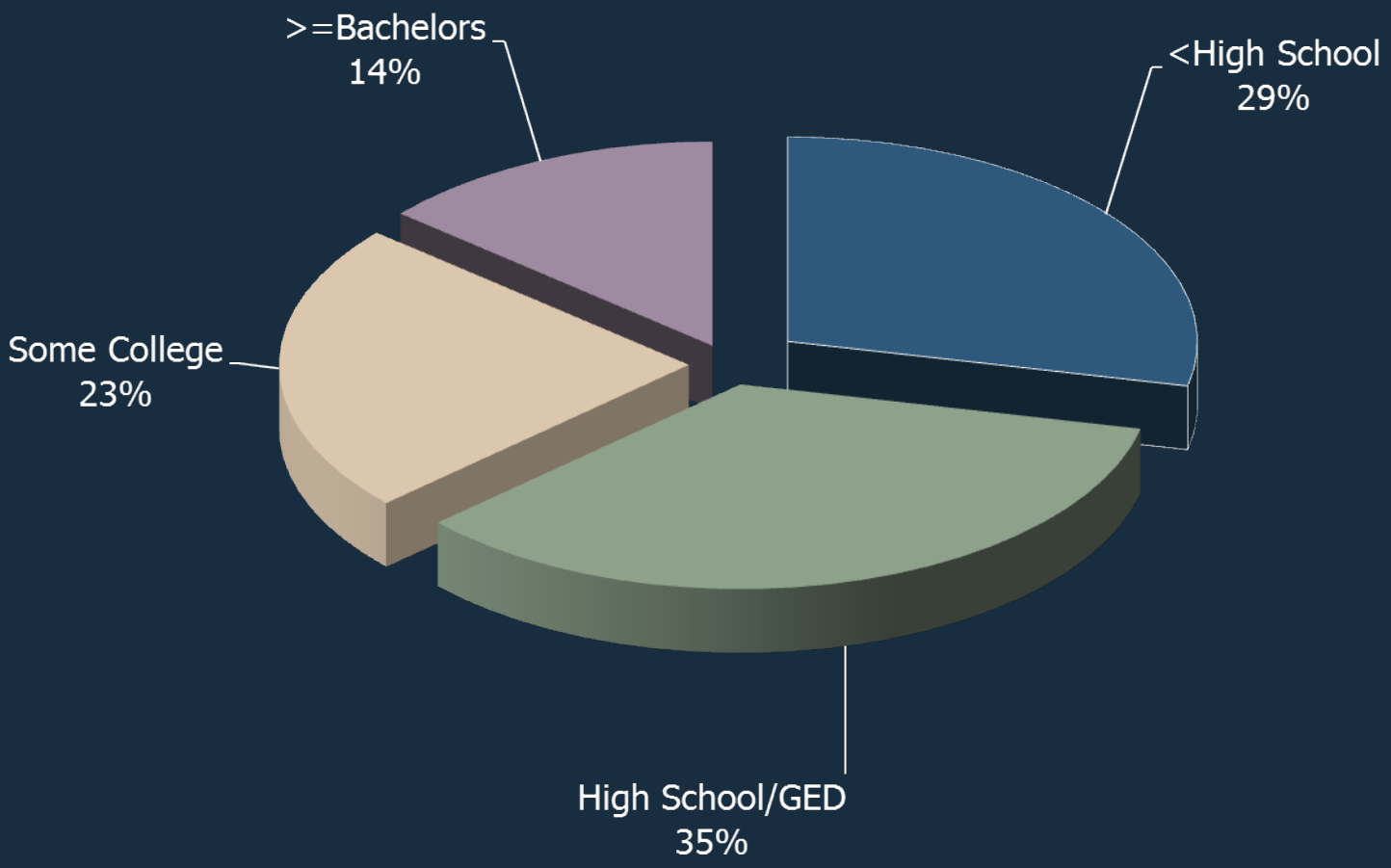
Level of Education At Injury



n = 10859

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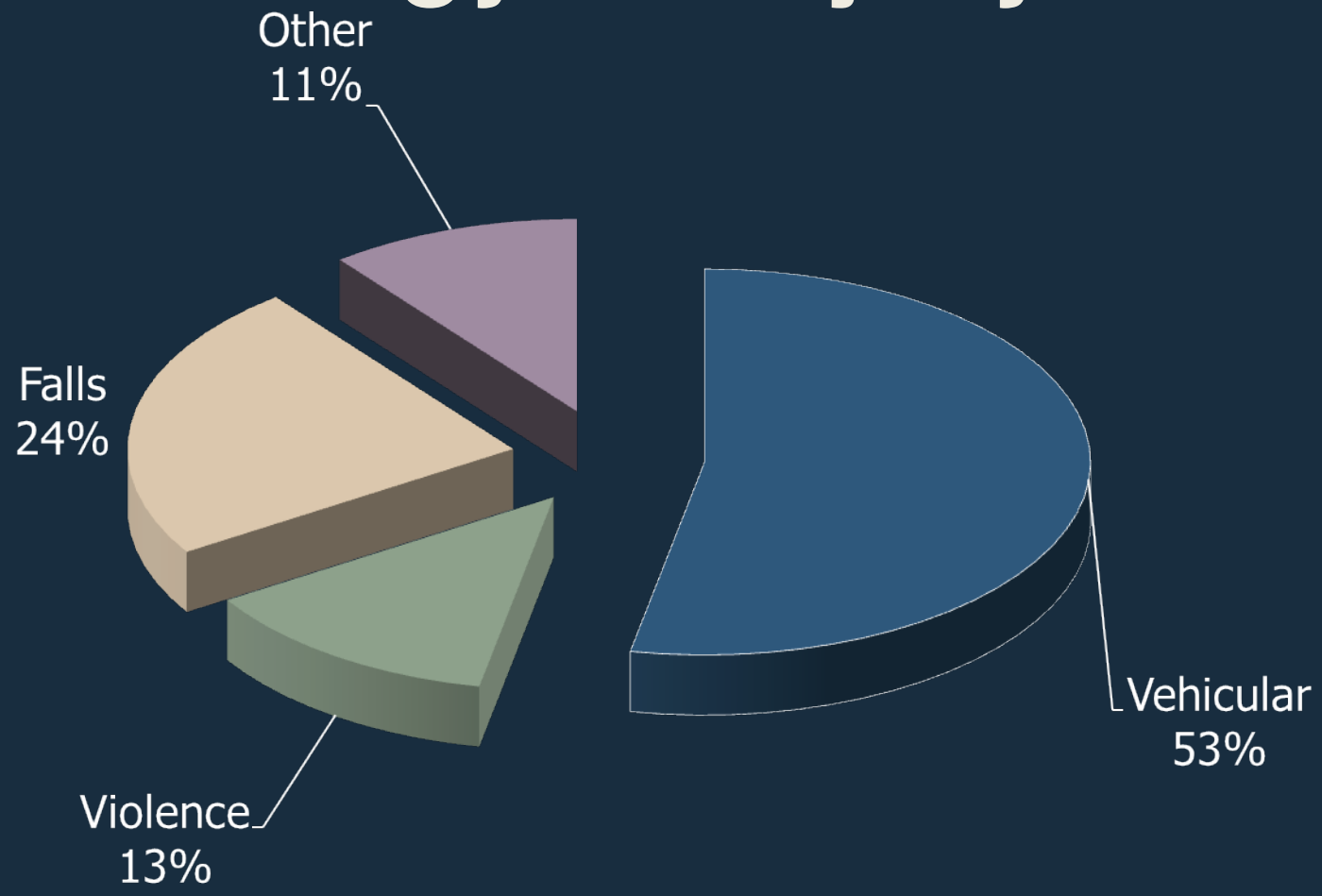
Summary

- Demographic Characteristics of the Population
  - Average age = 40.15
  - Male (74%)
  - Minority population (33%)
  - High school education or less (64%)

Etiology of Injury



n = 11034

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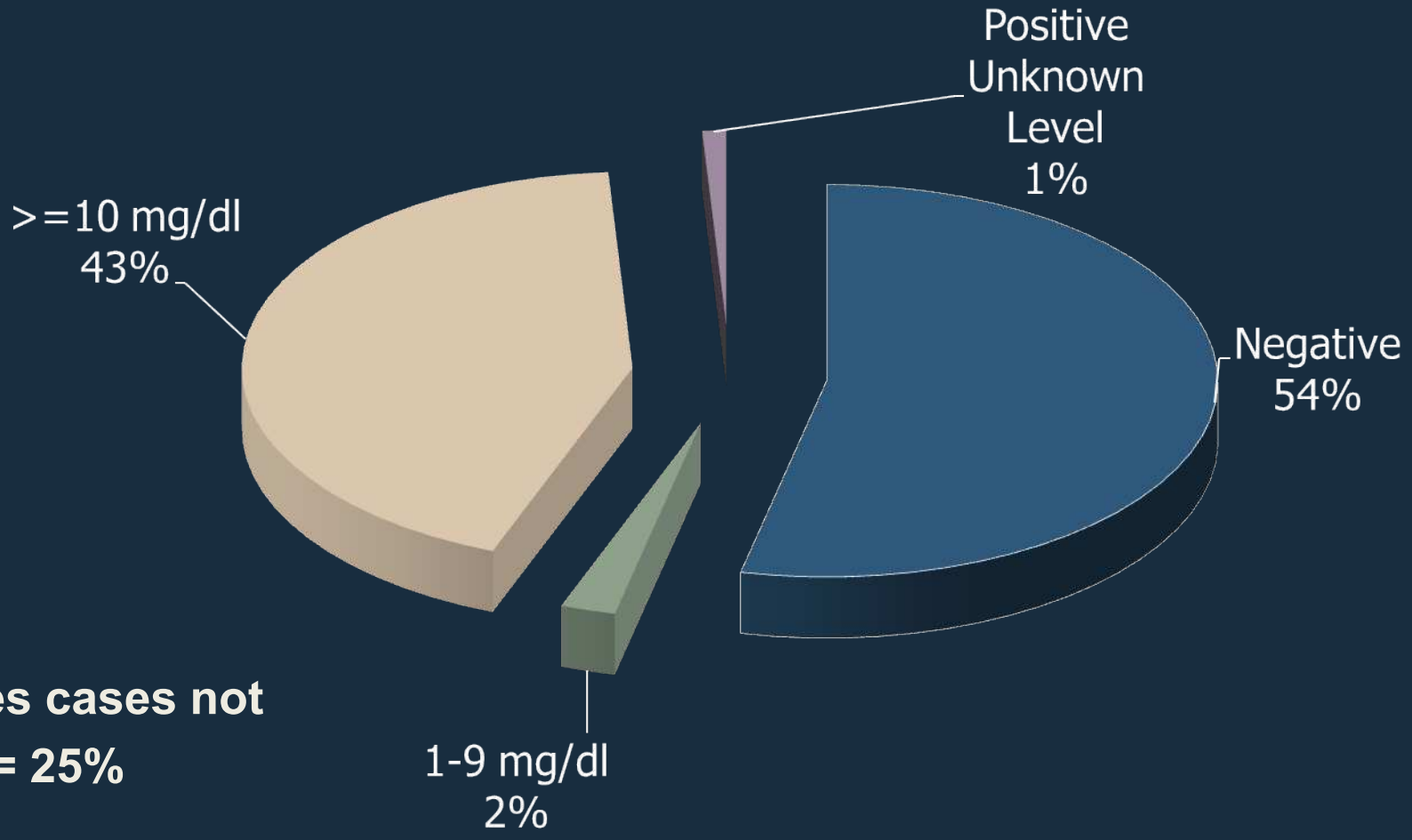
Blood Alcohol Level

At Emergency Department Admission*



*** excludes cases not tested = 25%**

mean = 69.71; n = 8007

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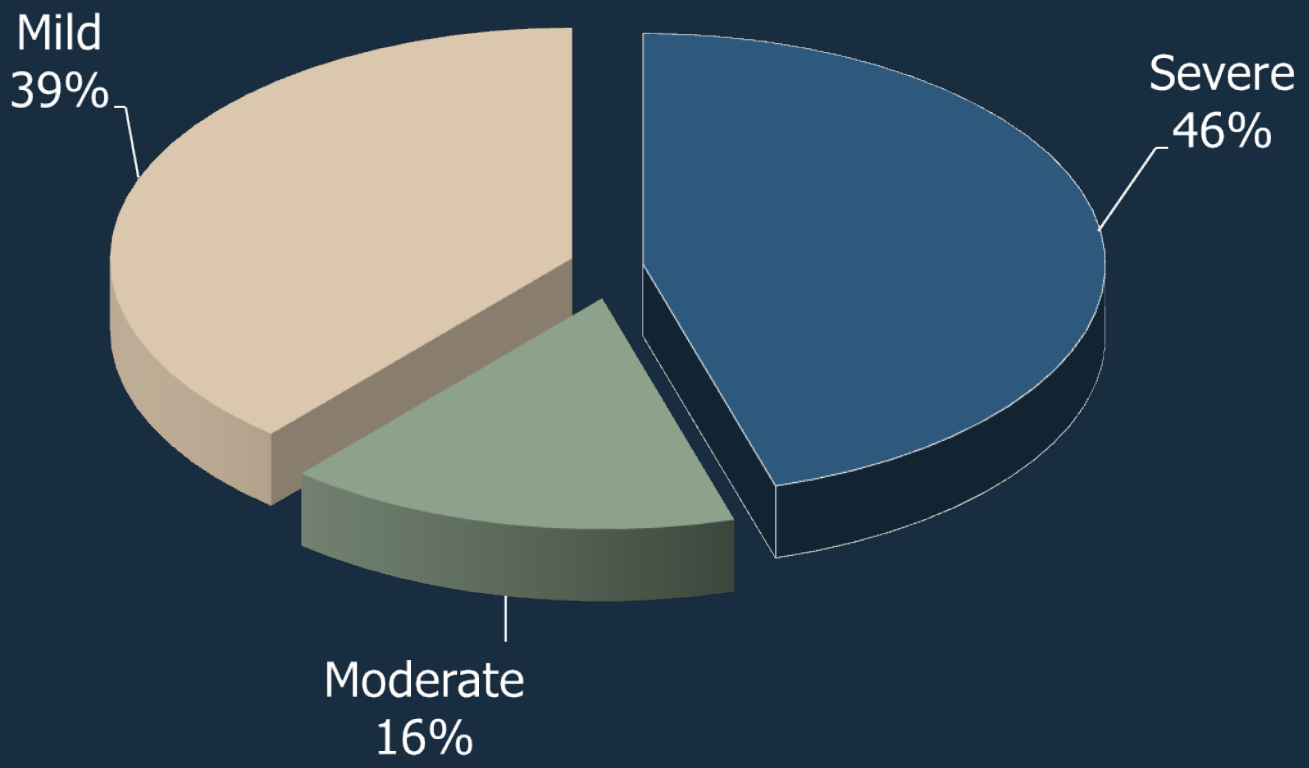
Summary

- Causes of Injury
  - Primary cause is vehicular (53%), followed by falls (24%) and violence (13%)
  - High incidence of alcohol-related injuries (46%)

Glasgow Coma Scale Score

At Emergency Department Admission*



mean = 9.50; n = 8375

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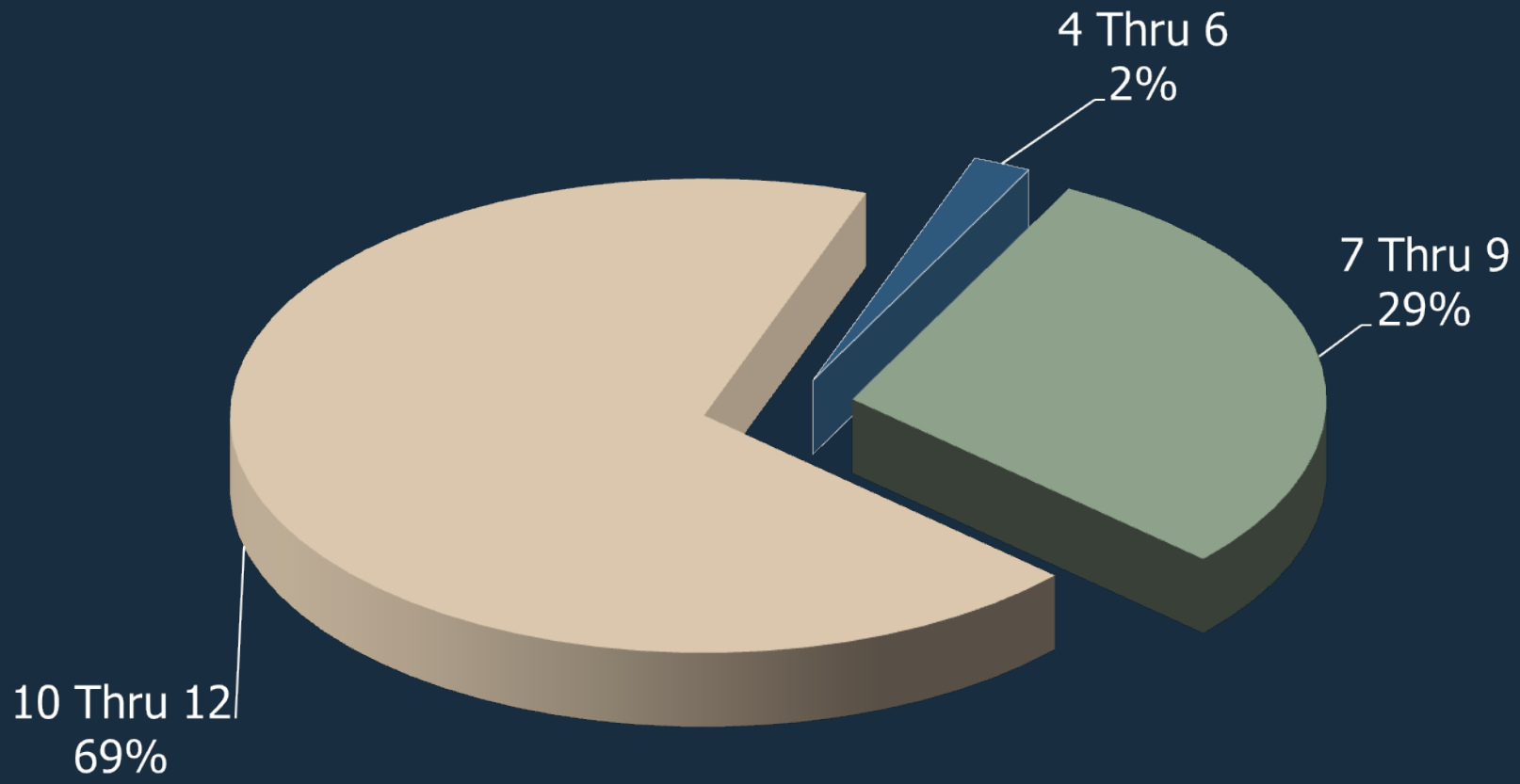
Revised Trauma Score

At Emergency Department Admission*



mean = 9.96; n = 6029

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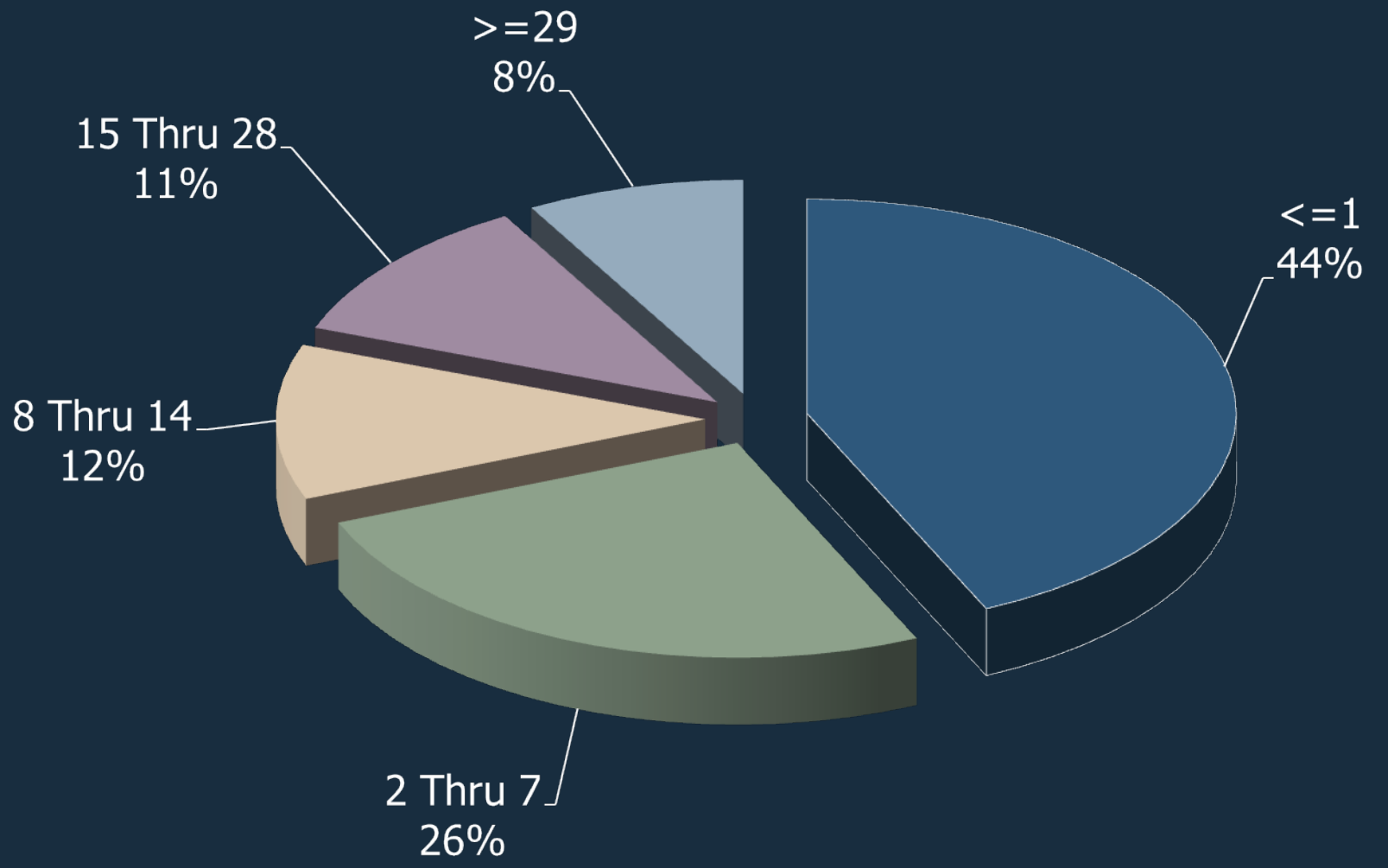
Duration of Unconsciousness



mean = 8.33 days; n = 10620

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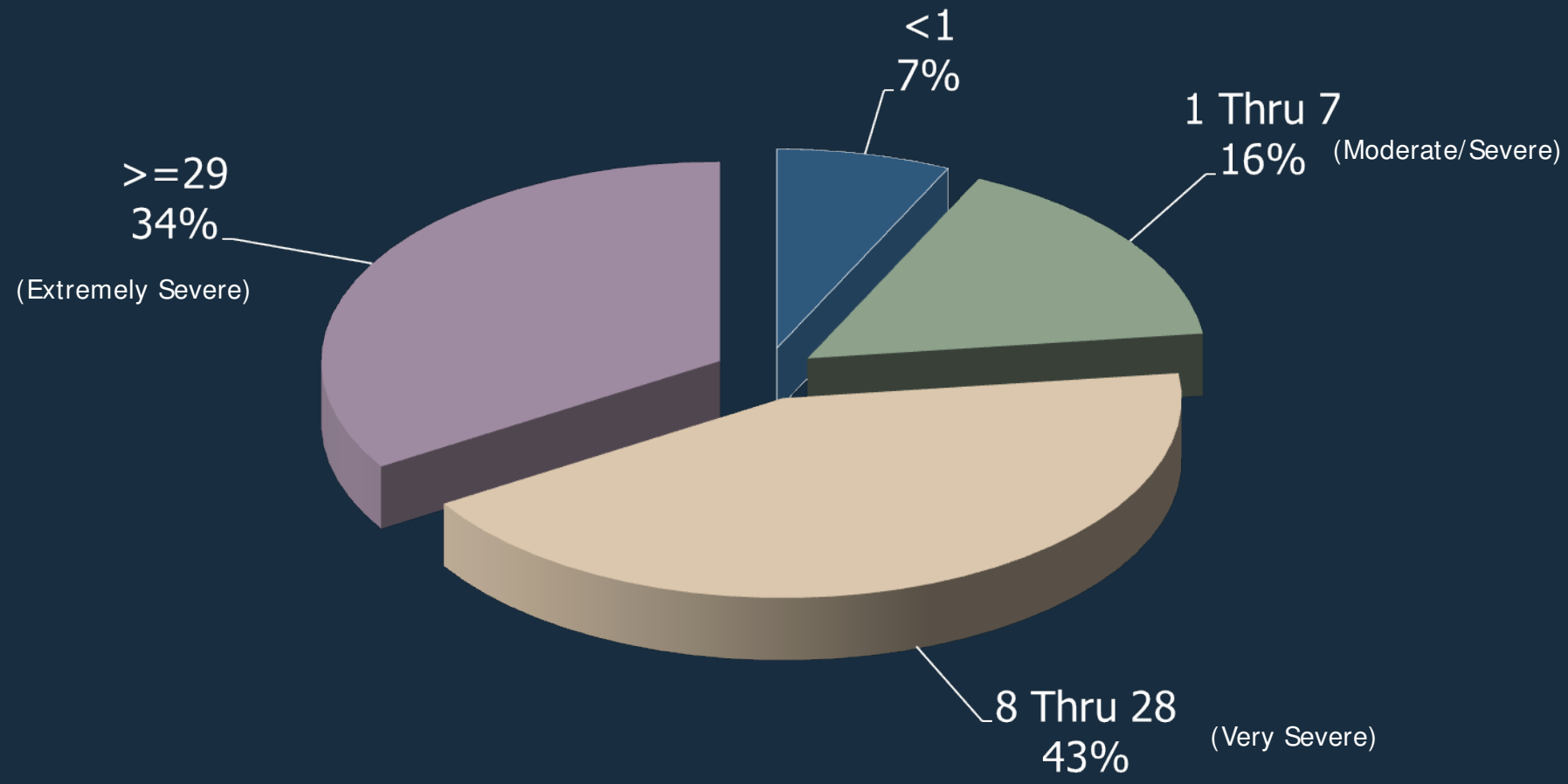
Duration of PTA



mean = 24.34 days; n = 8364

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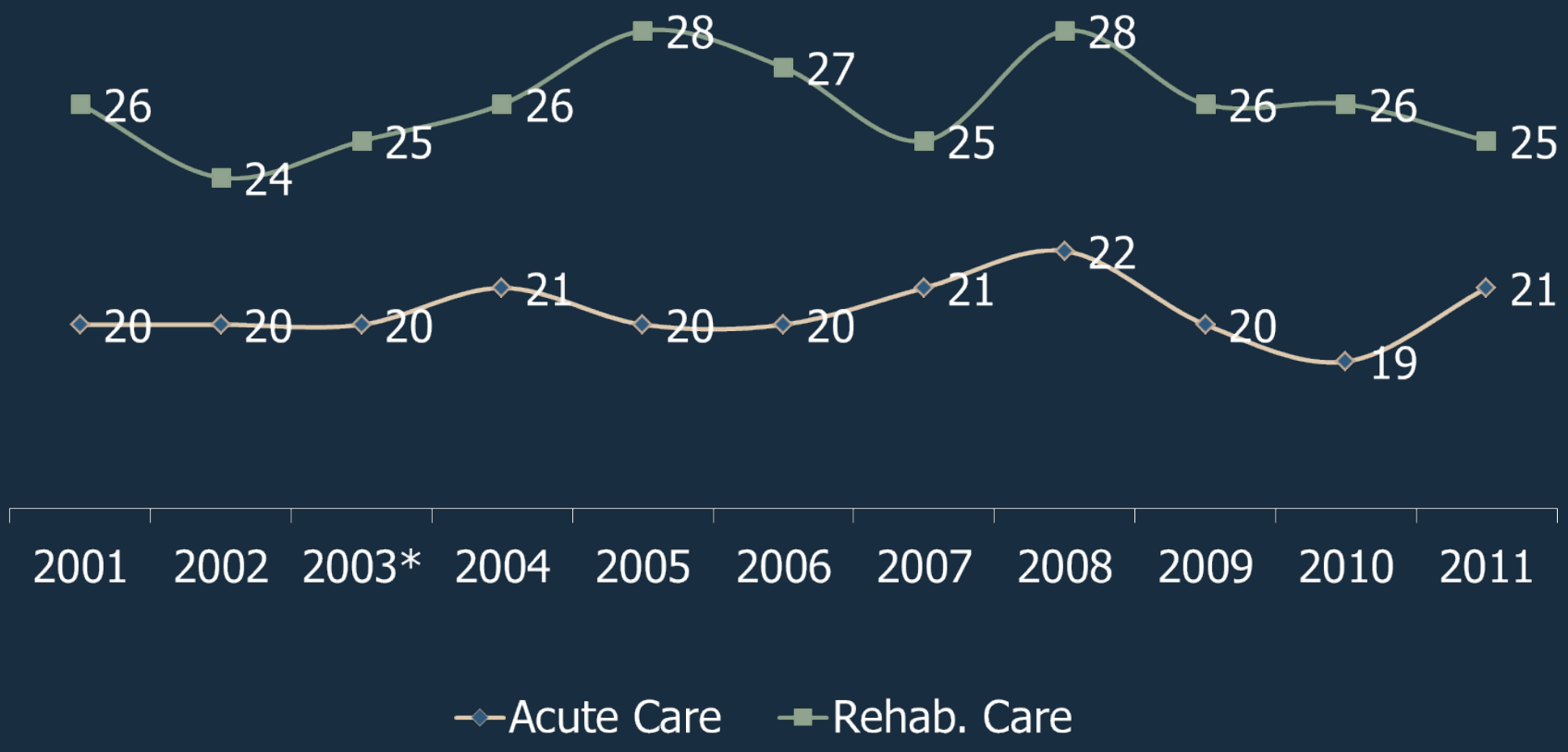
Summary

- Severity of Injury
  - Average duration of LOC is **8.33** days
  - Average duration of PTA is **24.34** days

Mean Length of Stay



* Did not capture leave of absences this year

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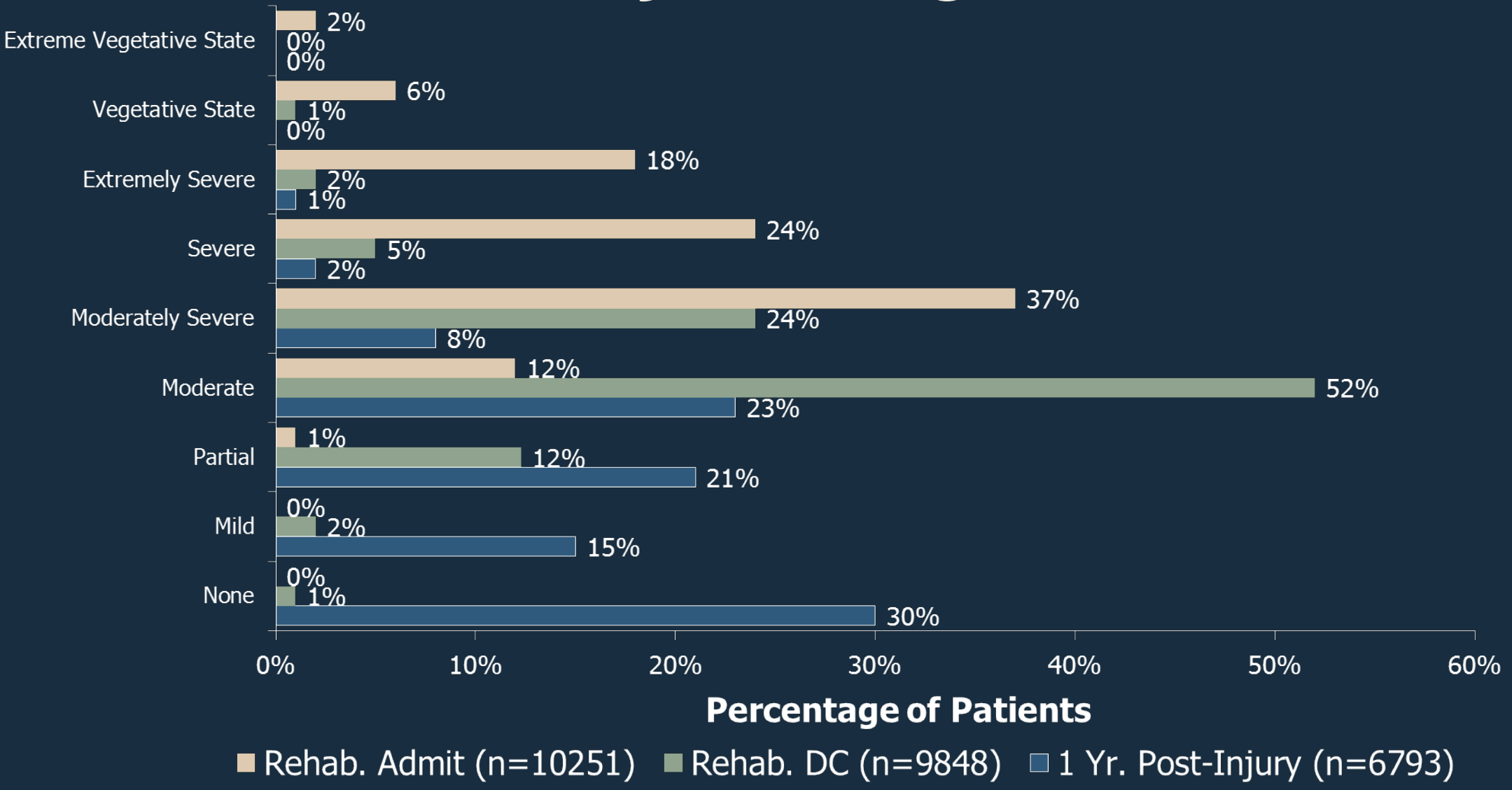
Summary

- Costs of Treatment
  - Acute care LOS has remained relatively stable (even increased a bit) and inpatient rehabilitation has declined but not consistently (1998-2008)
  - 37% have government-sponsored rehabilitation care (M'caid/M'care)

Disability Rating Scale



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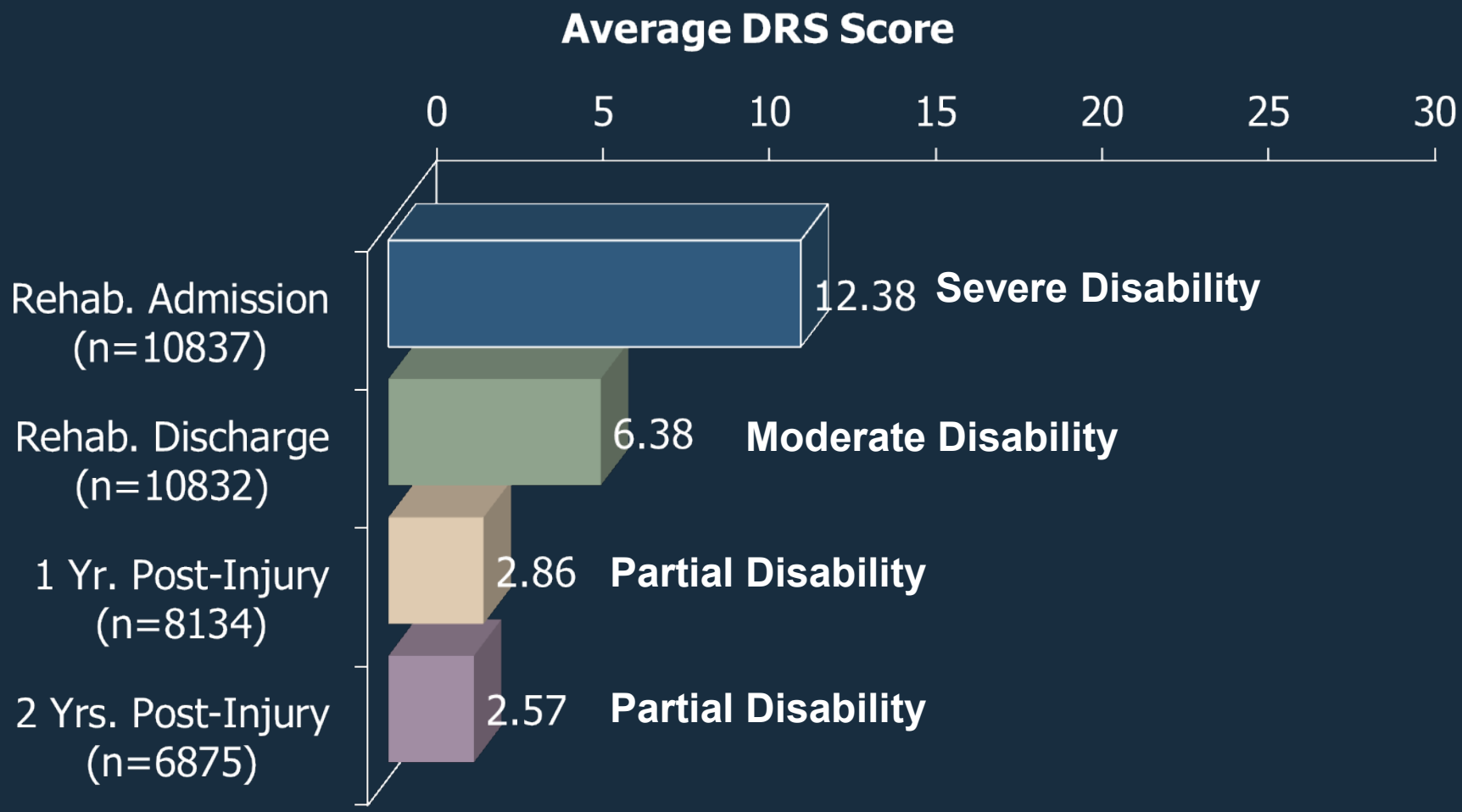
Disability Rating Scale



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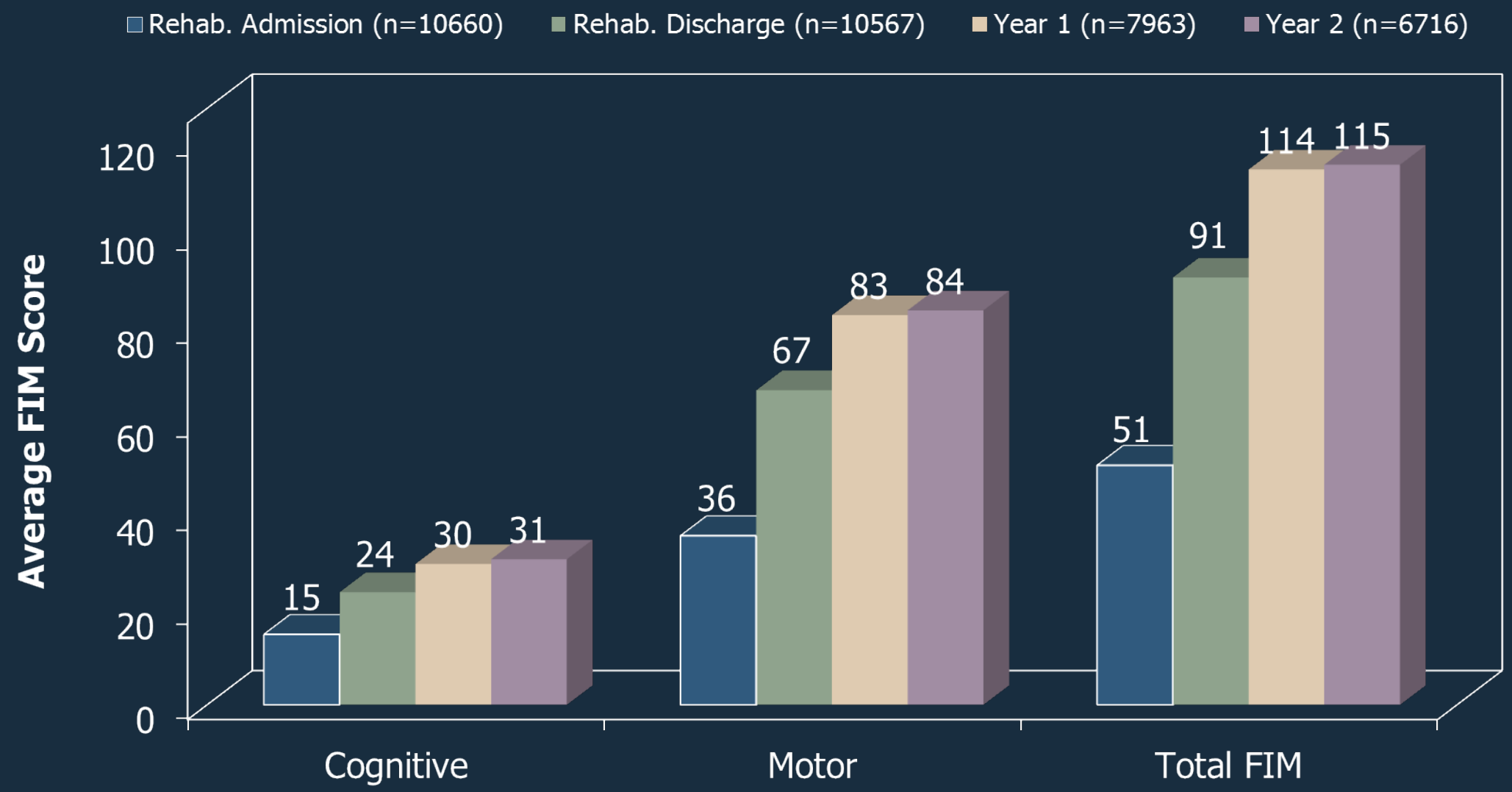
Functional Independence Measure



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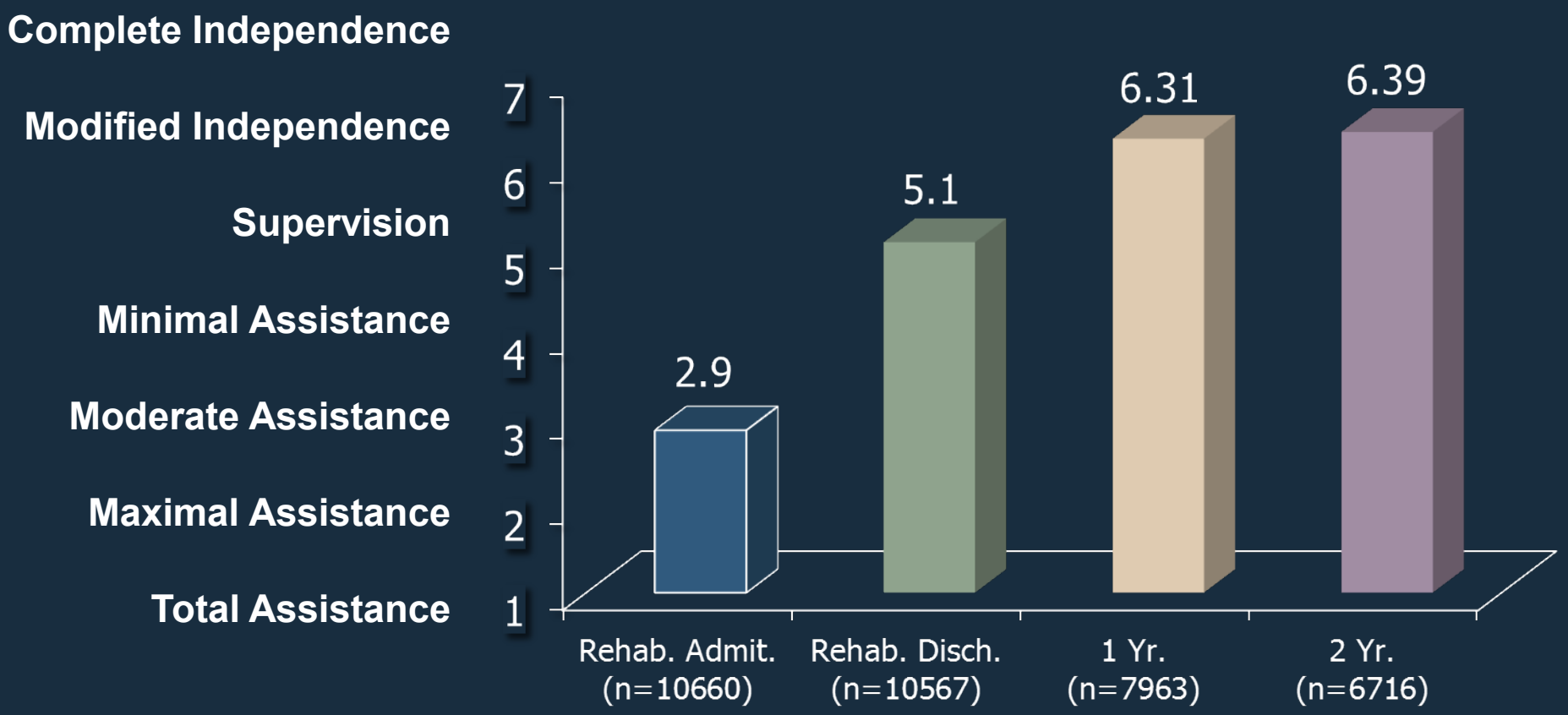
*Note: The value of n is reflective of Total FIM measure

Functional Independence Measure

Mean Scores converted to 7-point scale



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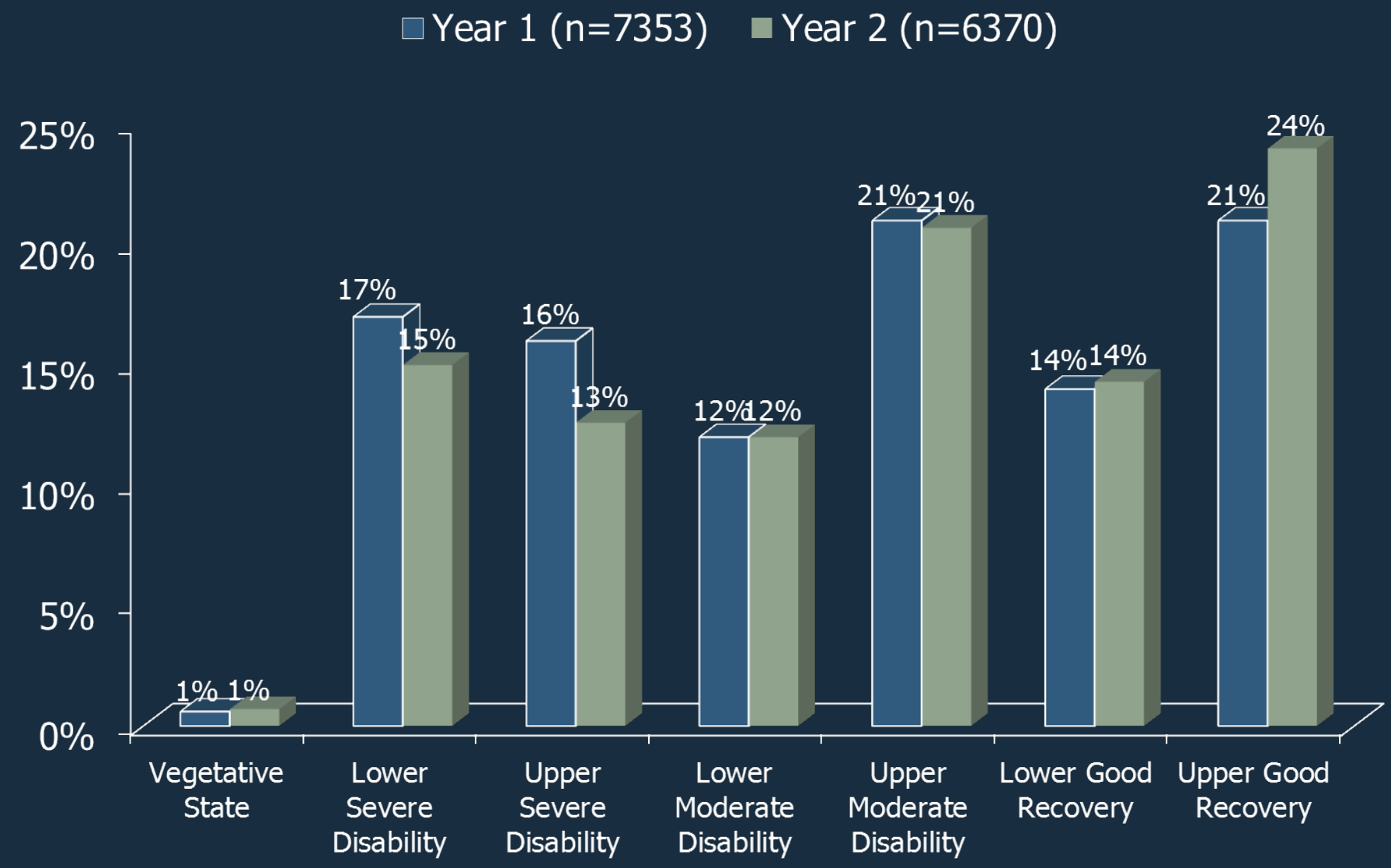
Glasgow Outcome Scale-Extended



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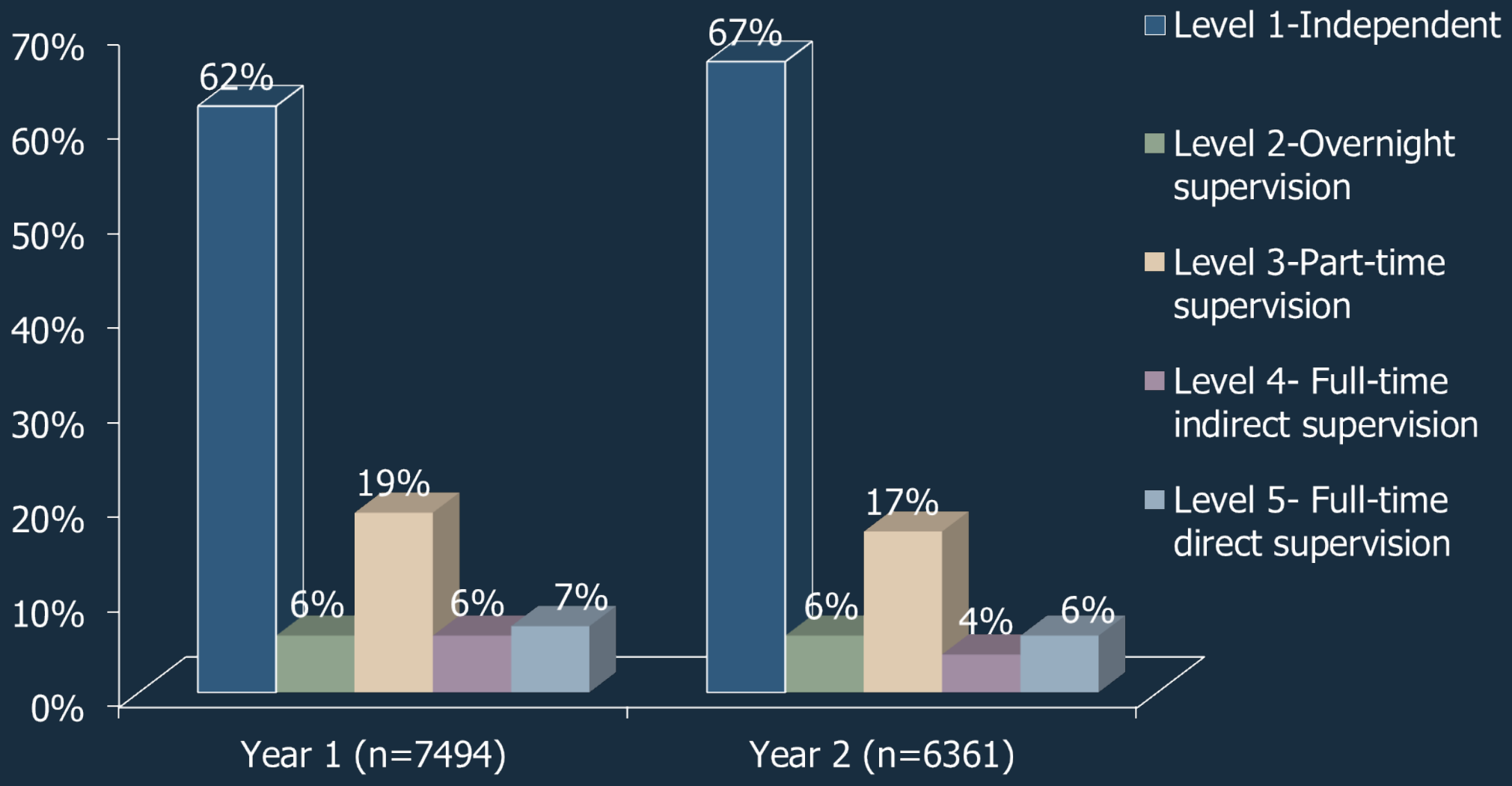
Supervision Rating Scale



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Satisfaction With Life Scale

	Year 1	Year 2
Number	6358	5442
Mean	21.10	21.50
SD	8.23	8.33
Min	5	5
Max	35	35

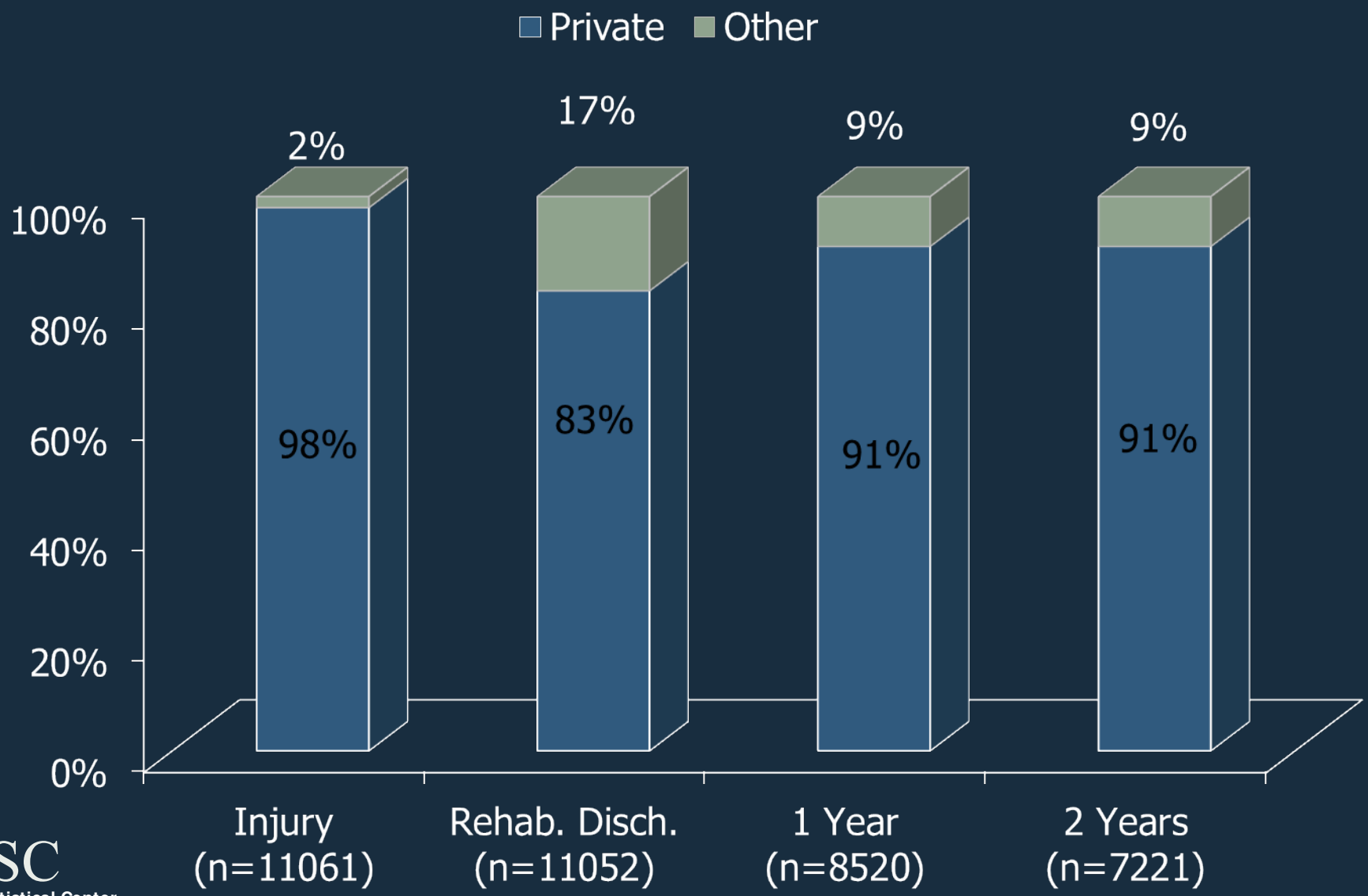
Summary

- Disability Outcomes
  - DRS indicates improvement in level of disability from SEVERE DISABILITY at rehab. admission to PARTIAL DISABILITY at 1 and 2 yrs. post-injury
  - FIM indicates improvement in functional ability from level requiring MODERATE ASSISTANCE at rehab. admission to MODIFIED INDEPENDENCE at 1 and 2 yrs. post-injury
  - SRS indicates that 38% of individuals require some level of supervision at 1 yr. post-injury and 33% at 2 yrs. post-injury.

Summary

- Disability Outcomes (cont.)
  - Most improvement in level of disability and functional ability occurs during inpatient rehabilitation
  - Continued improvement is seen at 1 yr. post-injury
  - Level of disability and functional ability appear to plateau between 1 and 2 yrs. post-injury

Residence



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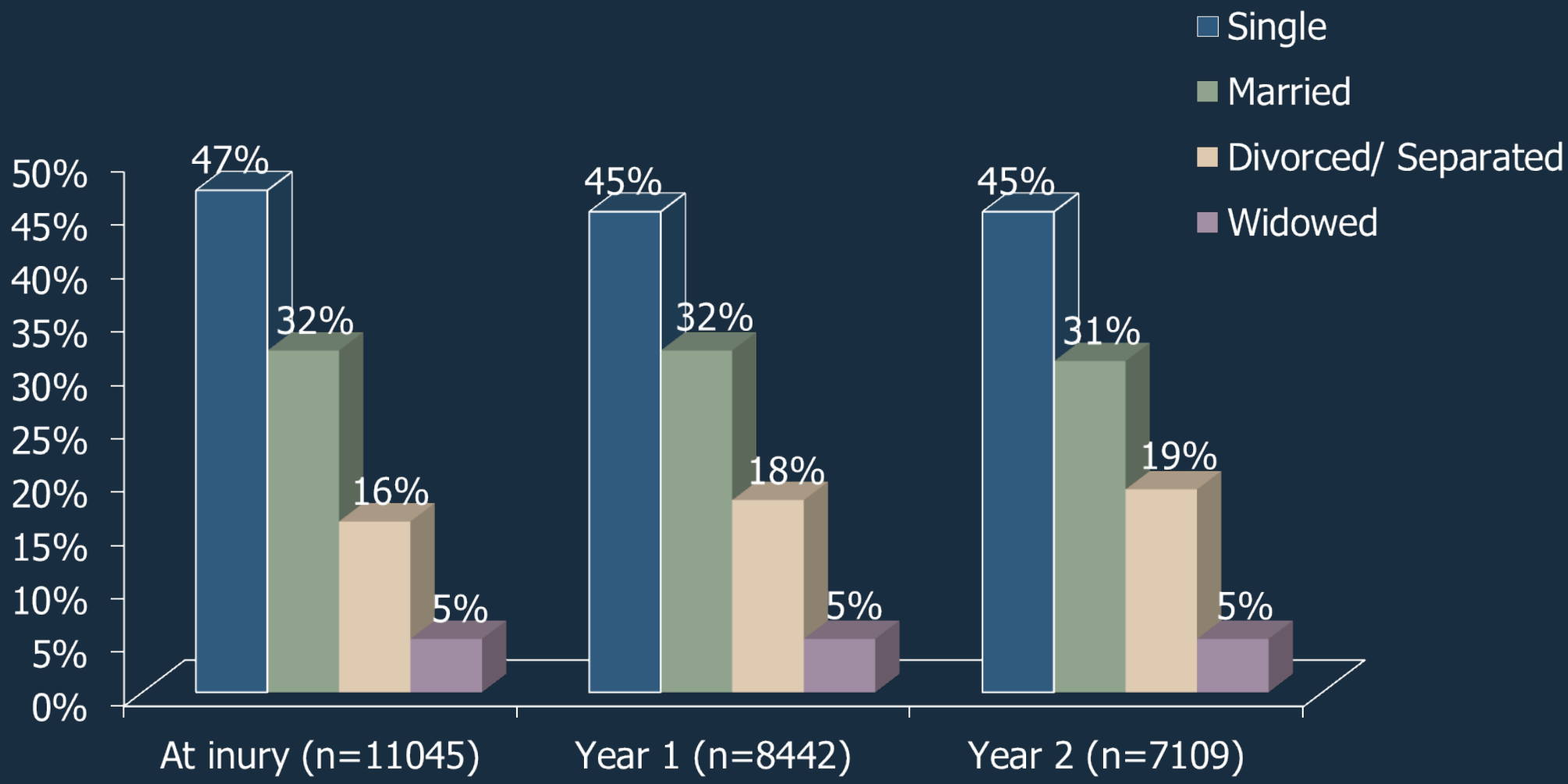
Marital Status



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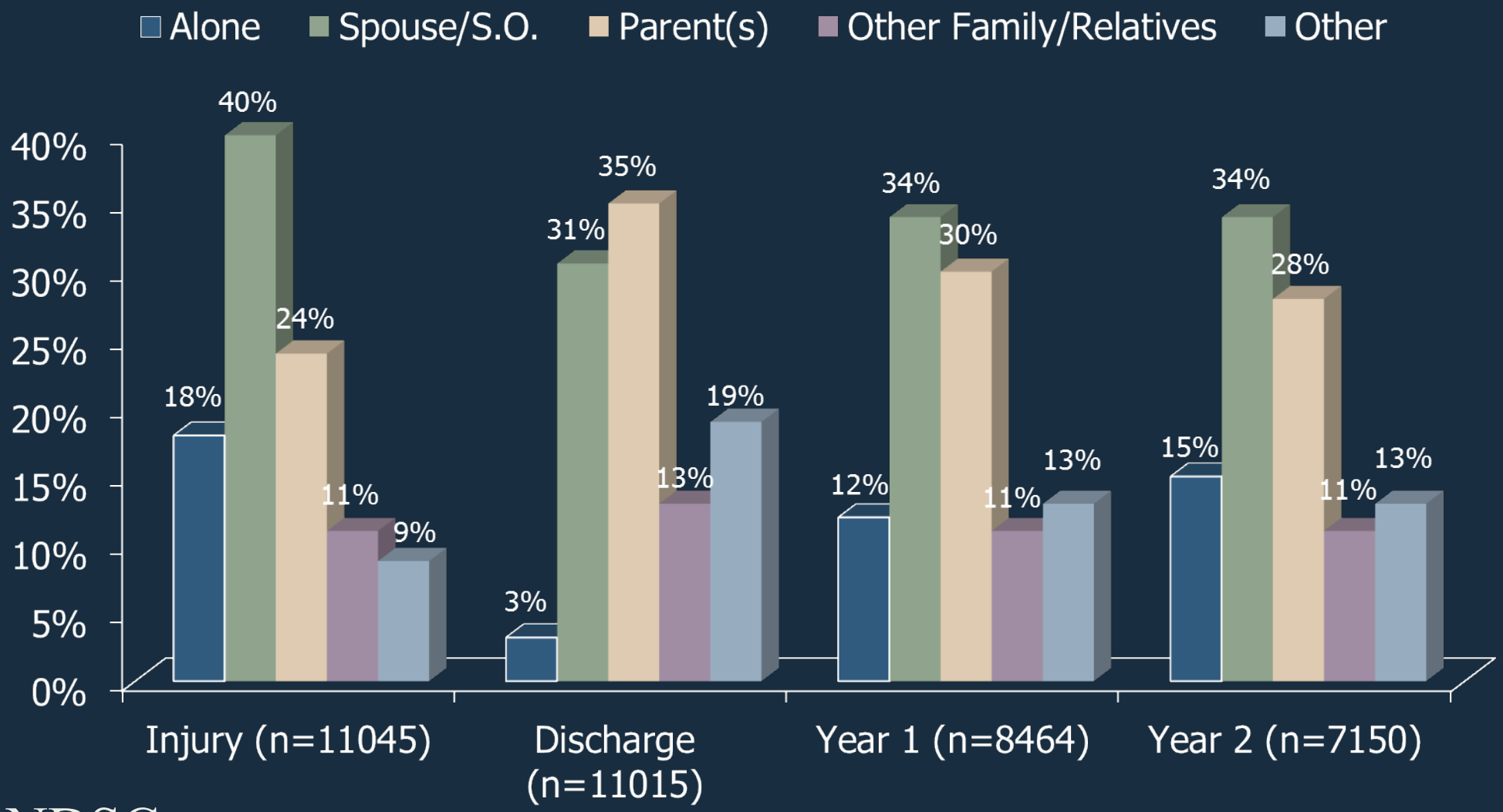
Living Situation



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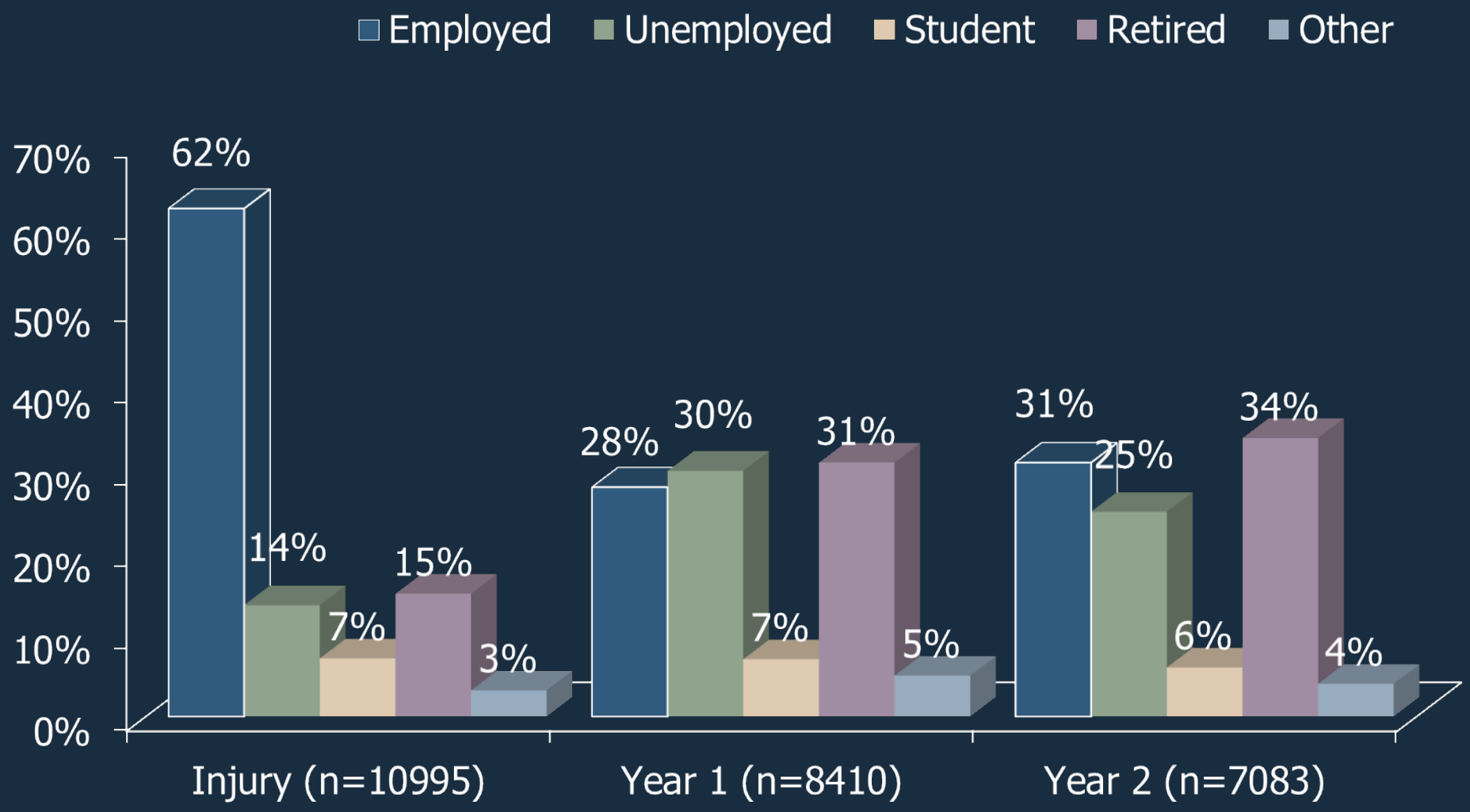
Employment Status



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Summary

- Participation Outcomes
  - Most live in a private residence following rehab. discharge (83%)
  - 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 yr. post-injury (62% employed at injury)

Conclusions

The TBI Model Systems Program:

- Demonstrates a system of care for TBI
- Performs several types of research
  - Several center-specific clinical trials and other types of studies
  - Innovative module (collaborative) studies
  - A comprehensive longitudinal database already containing over 10,000 cases with up to 20 years of follow-up.