Evidence Report on Rehabilitation of Persons with Traumatic Brain Injury

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AHCPR Contract
#290-97-0018
July 1998

Acknowledgments

The authors thank the members of the Brain Injury Support Group of Portland for their support and the use of their library. They also thank the Portland State University Capstone students who volunteered their time to help with the project: Heather Brooks, Samantha Cohen, Justin Davis, Cynthia Davis-O'Reilly, Julie Geil, Cheryl Matsumura, and Jeana Schoonover.

The American Academy of Family Practice provided the model, its Clinical Policy Review Form, on which the authors based their review form for this report.

Abstract

Objective

To examine the evidence for effectiveness of rehabilitation methods at various phases in the course of recovery from traumatic brain injury (TBI) in adults. Specifically, we addressed five questions about the effectiveness of (1) early rehabilitation in the acute care setting, (2) intensity of acute inpatient rehabilitation, (3) cognitive rehabilitation, (4) supported employment, and (5) care coordination (case management).

Search Strategy

A MEDLINE search (1976 to 1997), supplemented by searches of HealthSTAR (1995 to 1997), CINAHL (1982 to 1997), PsycINFO (1984 to 1997), and reference lists of key articles.

Selection Criteria

Broad inclusion criteria were defined for screening eligible abstracts. Two reviewers read each abstract to determine its eligibility. Full articles were included if they met methodologic criteria and were relevant to one of the causal links identified for each major question. Specifically, we included all comparative (controlled) studies, as well as uncontrolled series that had information about the short- or long-term outcomes associated with rehabilitation for traumatic brain injury.

Data Collection and Analysis

We developed an instrument to record data abstracted from each eligible article. The instrument includes items for patient characteristics, interventions, co-interventions, outcomes, study methods, relevance to the specific research questions, and results of the study. We used a three-level system to rate individual studies. Well-designed randomized controlled trials (RCTs) were rated as Class I. RCTs with design flaws, well-done, prospective, quasiexperimental or longitudinal studies, and case-control studies were rated as Class II. Case reports, uncontrolled case series, and expert or consensus

opinion were generally rated Class III. Comparative studies that met inclusion criteria were critically appraised and summarized in evidence tables.

Main Results

A total of 3,098 references were specified for inclusion. After removal of duplicates, 569 applied to questions 1 and 2, 600 applied to question 3, 392 applied to question 4, 975 applied to question 5. Eighty-seven articles pertaining to Questions 1 and 2, 114 articles for Question 3, 93 articles for Question 4, and 69 articles for Question 5 passed the eligibility screen. Sixty-seven additional articles were recommended for inclusion by experts, or were obtained from reference lists of review articles.

There was weak evidence from Class III studies that early rehabilitation during the acute admission reduces the rehabilitation length of stay. Studies of the intensity of acute inpatient rehabilitation had inconsistent results and used study designs that, despite appropriate use of statistical methods to adjust for severity, had serious limitations because of confounders. Controlled trials of cognitive rehabilitation had mixed results, with the strongest evidence (Class I) supporting the use of prosthetic aids to memory. Well-done, prospective observational studies (Class II) support the use of supported employment within the context of well-designed, well-coordinated programs. From one Class II clinical trial, there was no support for case management, but two well-done Class II studies supported the use of case management to produce functional improvements.

Conclusions

Population-based studies are needed to examine the overall impact of TBI and the differences in outcome associated with different rehabilitation strategies. Future studies of cognitive rehabilitation and case management should focus on health outcomes of importance to persons with TBI and their families.

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Summary

Advances in medical technology and improvements in regional trauma services have increased the number of survivors of traumatic brain injury (TBI), producing the social consequences and medical challenges of a growing pool of people with disabilities. Wider awareness of the scope of the problem and its consequences for society has led to rapid growth in the rehabilitation industry. Because of this growth, and particularly because clinical rehabilitation strategies vary widely, many groups are interested in the effectiveness of rehabilitation for TBI.

Three questions about the status of brain injury research underlie uncertainty about the effectiveness of rehabilitation services. First, how should fundamental concepts such as recovery, functional status, and disability be defined? Because brain function is highly complex, TBI has an extremely wide range of potential outcomes, including, for example, cognitive deficits, motor disabilities, emotional and social dysfunction, personality changes, and changes in appearance. As a result, therapeutic aims and perspectives vary widely among studies, as do definitions of outcome, making valid comparisons across studies difficult.

Second, how should the type and severity of the injury itself be measured? Variation in methods to assess the severity of injury in patients entering rehabilitation make it difficult to estimate the effectiveness of different rehabilitation methods.

Third, which therapies are effective, and how can patients best be matched to treatment approaches likely to be effective for them? Today, a person’s path to rehabilitation after sustaining brain injury may be determined by the mechanism of injury, the resources of the community, the person’s employment or financial status, the consent of the family, or the accuracy of emergency department diagnosis. While a few metropolitan areas have organized referral systems that connect patients with resources and rehabilitation programs, systematic methods for evaluating the needs of persons who have sustained brain injury and referring them to appropriate programs are unusual. Without knowing the efficacy of rehabilitation methods in their specific applications, systematic referral that produces the desired result is not possible.

Injury is the leading cause of mortality among Americans under 45 years of age; TBI is responsible for the majority of these deaths. An estimated 56,000 lives are lost in the United States each year to TBI. Motor vehicle accidents, followed by firearms and falls, are the leading causes of death from TBI. Males are 3.4 times as likely as females to die of TBI. About 50 percent of people who sustain TBI are intoxicated at the time of injury.

In a recent analysis based on hospital discharge data and vital statistics, the annual incidence of TBI in the United States was estimated as 102.8 per 100,000. In males, the incidence peaks between the ages of 15-24 (248.3 per 100,000) and again above 75 years of age (243.4 per 100,000). The incidence in females peaks in the same groups, but the absolute rates are lower (101.6 and 154.9, respectively). These rates underestimate the true incidence of head trauma because patients with milder symptoms at the time of injury are usually not hospitalized.

About three-quarters of traumatic brain injuries that require hospitalization are nonfatal. Each year, about 80,000 survivors of TBI will incur some disability or require increased medical care needs. Direct medical costs for TBI treatment have been estimated at $48.3 billion per year, including the costs of acute care hospitalization and the costs of various rehabilitation services. In the years 1988-1992, reports of average length of stay (LOS) for the initial admission for inpatient rehabilitation range from 40-165 days. In one multicenter study (the Model Systems study), the average rehabilitation LOS was 61 days and the average charge was $64,648 exclusive of physician fees. Total charges averaged $154,256. In more recent studies performed in the early 1990s, rehabilitation LOS and charges were lower, ranging from 19 days and $24,000 for patients with milder injuries to 27 days and $38,000 for those with severe injuries. In the Medicare population in 1994, mean charges for patients admitted for brain injury (excluding stroke) were $42,056.

To focus attention on important questions, we characterized the life of an adult survivor of TBI in terms of five phases. The first phase is “pre-injury.” “Medical treatment” is divided into the acute (or immediate) treatment phase and the intensive treatment phase, lasting days to weeks. The “rehabilitation” phase may last months to years. The “survivor” phase implies the remaining life of the person with TBI and involves continual development and adjustment. This division into phases clarified the three challenges to assessing the efficacy of rehabilitation discussed above. For each phase, we identified patient populations, interventions, and outcome measures and reviewed the literature to answer key questions identified by technical experts.

Reporting the Evidence

Two panels of experts worked with the research team to identify key questions in the rehabilitation and survivor phases for adults with TBI. The first panel was composed of two physiatrists, a survivor of TBI, the wife of a survivor of TBI, a state vocational rehabilitation counselor, a neuropsychologist, a psychologist, a clinical coordinator of an outpatient TBI rehabilitation program, and a rehabilitation clinical nurse specialist, all from the Portland, OR area. The second panel was composed of nationally recognized experts in rehabilitation.

The panels formulated five questions pertaining to the phases of recovery described above. These questions addressed the effectiveness of (1) early rehabilitation in the acute care setting (timing), (2) intensity of rehabilitation, (3) cognitive rehabilitation, (4) supported employment, and (5) care coordination (case management). For each of these questions, members of the research team worked with panelists to write a brief rationale for the question, define key terms, and specify the relevant patient populations, interventions, and outcome measures that should be examined in the literature review. The questions were:

1. Should interdisciplinary rehabilitation begin during the acute hospitalization for traumatic brain injury?

2. Does the intensity of inpatient interdisciplinary rehabilitation affect long-term outcomes?

3. Does the application of cognitive rehabilitation enhance outcomes for persons who sustain TBI?

4. Does the application of supported employment enhance outcomes for persons with TBI?

5. Does the provision of long-term care coordination enhance the general functional status of persons with TBI?

Methodology

A MEDLINE search (1976 to 1997), supplemented by searches of HealthSTAR (1995 to 1997), CINAHL (1982 to 1997), and PsycINFO (1984 to 1997), produced a total of 3,098 references to be considered for inclusion; of these, 569 applied to questions 1 and 2, 600 applied to question 3, 392 applied to question 4, and 975 applied to question 5.

Abstracts of each article retrieved by these searches were reviewed independently by two members of the research team, who applied predefined, broad eligibility criteria. When the two reviewers disagreed, a third reviewer read the abstract and cast the deciding vote on whether it should be included. In the event a reference did not have an abstract, and the title for the reference was not sufficient for determination of status, the article was retrieved and reviewed to determine its eligibility. The two reviewers examined each abstract and indicated whether it met the inclusion criteria and, if not, the reason for exclusion. If the abstract was eligible, or if it did not contain sufficient information to determine eligibility, the full text of the article was retrieved for review in the next phase of the selection process.

Eighty-seven abstracts pertaining to questions 1 and 2; 114 articles for question 3; 93 articles for question 4; and 69 articles for question 5 passed the eligibility screen. Sixty-seven additional articles were recommended for inclusion by experts or by review of reference lists of review articles. In all 363 articles were retrieved from the library for review and abstraction.

Additional criteria for inclusion were defined separately for each of the five questions; these criteria are described in the results sections concerning each question. The criteria varied because the types of studies required varied from question to question. Articles that applied to more than one question were maintained as duplicates (or triplicates, etc.) in each question-specific file, so they could be considered for inclusion based on their relevance to each question.

Data Abstraction

We designed an instrument to record data abstracted from each eligible article. The instrument includes items for patient characteristics, interventions, cointerventions, outcomes, study methods, relevance to the specific research questions, and results of the study. The instrument has two components: the first four pages of the instrument apply to all articles specified for inclusion in the study. The remaining pages are individual instruments that apply to one of the five questions. To abstract an article, a reader used the initial abstraction instrument plus one or more of the five question instruments.

The first few questions of the initial abstraction instrument allowed the reviewer to determine if the article actually met the eligibility criteria for inclusion in this report. If an article was determined to be ineligible, it was passed to a second reader for confirmation. The remaining articles were subjected to the full abstraction protocol.

Specification of Level of Evidence

We used a three-level system to rate individual studies. Well-designed randomized controlled trials (RCTs) were rated as Class I. RCTs with design flaws, well-done, prospective, quasiexperimental or longitudinal studies, and case-control studies were rated as Class II. Case reports, uncontrolled case series, and expert or consensus opinion were generally rated Class III. A well-done, prospective, multicenter or population-based case series can provide valuable information that, in some ways, is more reliable than data from a randomized trial done in a highly selected sample of patients. However, when used to make inferences about effectiveness, an uncontrolled case series is generally classified as Class III, indicating the lowest level of confidence.

A “gray zone” exists between Class II and definite Class III articles. Much of the research in rehabilitation uses quasi-experimental designs. In these observational study designs, control subjects are sometimes identified from a separate patient population. For instance, Aronow and colleagues compared patients undergoing inpatient rehabilitation to a sample of persons with TBI who had been treated in a region of the country where formal inpatient TBI rehabilitation was not available. This was an entirely separate patient group and all the data except outcome measures came from an independent database.

The main difficulty with the quasi-experimental design is lack of control over the constitution of the compared groups. Because there is no randomization and generally no control over the details of the selection process through which the patients received their separate therapies, the groups are likely to differ in the frequency of characteristics that are associated with the outcomes of interest. Even when significant efforts are made to match the experimental and the quasi-control groups, significant differences between the groups are still likely to be present.

Much of the literature relevant to the five questions addressed in this effort falls into the "gray zone" between Class II and Class III.   For this reason, critical appraisal of key studies played a particularly important role in this review.   A number of characteristics of these studies were considered relevant to all rehabilitation questions and were recorded in the data abstraction form. Evaluation of the following factors played a major role in critically appraising these articles:

- Prospective collection of data.
- Complete description of parent study population.
- Large study population size (driven by hypothesis, power, type I error threshold).
- Study setting—a single center, many centers, or population-based.
- Description of reasons for referral to service being studied.
- Methods described completely enough to allow study replication.
- Complete description of rehabilitation technique in question (independent variable).
- Complete and adequate description of differences between control" and "experimental" groups.
- Conditions determining whether they did or did not receive the rehabilitation technique in question.

- Information about potential confounders, including types and severity of injury, age, and others (including, in some cases, economic status, educational level, lack of family support).
- Measurement of confounding variables using instruments validated as accurate, sensitive, and reliable.
- Payer group.
- Choice of outcome variables that are meaningful to patients as well as caregivers.
- Use of functional status and other health outcomes rather than surrogate (intermediate) outcomes.
- Measurement of outcome variables using instruments validated as accurate, sensitive, and reliable.
- Timing of outcome measurements.
- Assessment of patient characteristics and outcomes by blinded observer.
- Use of multivariate statistical analysis: Were interactions sought and controlled for? Were risk estimates calibrated? Were all relevant confounders included as candidate variables?

The criteria used to classify articles and the features to be considered in critically appraising them were discussed at the subcommittee, committee, national expert panel, and Aspen Neurobehavioral Conference levels with the goal of maintaining consensus at least on the relative stratification of individual articles.

Construction of Evidence Tables

Evidence tables were constructed to summarize the best evidence about effectiveness pertaining to each question. No randomized trials and only a few quasi-experimental studies were available for questions 1 and 2. There were a large number of relevant observational studies of important relationships (for example, the relation of patient characteristics to outcome); we chose not to summarize studies that concerned individual causal links or relationships in evidence tables. For question 3, addressing cognitive rehabilitation, 15 randomized controlled trials and comparative studies that met specified inclusion criteria were placed into evidence tables. All comparative studies located for the last two questions, which addressed supported employment and care coordination, were included in evidence tables.

Critical Appraisal of Key Articles

For each of the five questions, we formed subcommittees of one or two members of the research team and one or two members of the local technical panel. Each subcommittee was chaired by a member of the research team. Key articles relevant to the assigned question were reviewed in-depth by all members of the subcommittees. These reviews were discussed among the various members of the subcommittees, and the results summarized by the chair. This was an effort to ensure that the summary statements on the research questions reflected the expertise and experience of a variety of technical experts with relevant skills and training. These interpretive efforts addressed the methods and results of individual studies, their rating, and their scientific importance.

All of the critical articles for the five questions were individually read by the principal investigator. Summaries were presented and discussed with national experts at the Aspen Neurobehavioral Conference in April 1998.

Findings

1. One small, retrospective, observational study from a single rehabilitation facility supports an association between the acute institution of formalized, multidisciplinary, physiatrist-driven TBI rehabilitation and decreased LOS (acute hospital and acute rehabilitation) and some measures of short-term physiologic (non-cognitive) patient outcome. The level of evidence is Class III. This study concerned adult patients with severe brain injury (Glasgow Coma Scale [GCS] 3-8); there is no evidence from comparative studies for or against early rehabilitation in patients with mild and moderate injury.

2. When measured as the hours of application of individual or grouped therapies, there is no indication that the intensity of acute, inpatient TBI rehabilitation is related to outcome. Because of methodological weaknesses, however, previous studies are likely to have missed a significant relationship if one exists (a Type II error). These studies contained insufficient information about severity of injury and baseline function to ensure the comparability of compared groups. Also,

these studies did not consider the quality of individual treatments, their lack of autonomy in the cognitive realm, and the delivery milieu. One or more of these factors may affect the outcome of care more than the time spent in each modality. Therefore, future research into efficacy of acute inpatient TBI rehabilitation must more adequately measure such factors and include them in their predictive models. Future studies must also employ a wider spectrum of outcome measures, including measurement of outcomes longer after discharge.

From a clinical aspect, the evidence does not support equating different TBI rehabilitation delivery systems based on equivalent times of patient exposure to various therapeutic modalities. For example, this analysis would not support predicting that patient benefit would be equal if an equal time spectrum of rehabilitation therapies were delivered at a rehabilitation center as compared to a skilled nursing facility. More detailed analysis of factors involved in predicting response to rehabilitation modalities must be considered in approaching such questions.

Additionally, mandating a minimum number of hours of applied therapy for all TBI patients is not supported by the present state of scientific knowledge. The issue of how much of which interventions optimizes recovery in a given type of patient remains inadequately studied. It is certainly reasonable to avoid situations in which patients do not receive potentially beneficial treatment. Based on the above studies, however, defining a minimal rehabilitation program in terms of time of applied therapy is not likely to optimize either therapists' time or patient recovery. It is probable that specific basic programs will have to be related to individual patient groups. Developing such algorithms requires further research.

Many patients who suffer TBI do not enter acute inpatient rehabilitation. Only one study of the effectiveness of inpatient rehabilitation included a comparison group of patients who did not undergo inpatient rehabilitation. Future studies should compare acute, inpatient rehabilitation to commonly used alternatives to inpatient rehabilitation, such as care in a well-staffed skilled nursing facility or in less intense variations of acute rehabilitation. Very little is known about the outcome of TBI in these settings.

3. There is evidence from two small studies (Class I and Class III) that a personally-adapted electronic device and a notebook with alarm wristwatch reduce everyday memory failures for persons with TBI. There is evidence from one study (Class II[a]) that compensatory cognitive rehabilitation (CCR) reduces anxiety and improves self-concept and relationships for persons with TBI. Evidence from two studies (Class I and Class II[b]) supports the use of computer-aided cognitive rehabilitation (CACR) to improve immediate recall on neuropsychological testing, but the clinical importance of this finding has not been validated.

4. Class II evidence indicates that supported employment can improve the vocational outcomes of TBI survivors. Nearly all information about supported employment comes from two bodies of work, each of which used different experimental designs and different models of supported employment. The findings have not been replicated in other settings or by other centers, so the generalizability of these programs remains untested.

5. Very few studies exist on the effectiveness of case management, and the results of these studies are mixed. The only outcome for which there were results in the same direction from two or more studies pertained to changes in vocational status. This was associated with the single case-manager and insurance approach, as well as with the combined nurse and vocational case-manager model. There were conflicting results about the effects of case management on disability or functional status, living status, family impact and other aspects, and some findings were mentioned in only one study. The clinical trial resulted in no functional status changes among case managed subjects, despite an extended period of rehabilitation. However, when two forms of case management were compared, both the single and multiple case-manager/insurance approaches showed significant functional improvements.

Future Research

1. Randomized trials of the timing and intensity of early and acute rehabilitation would be useful. Because the patient characteristics that affect outcome also affect the type and level of rehabilitation services delivered, it may be unlikely that any observational study can provide decisive evidence about

effectiveness. Moreover, assigning patients to different levels of intensity, or to early versus conventional initiation of rehabilitation, in a prospective trial may be ethically acceptable, since these different levels represent a range of current practice rather than a deviation from it.

2. Population-based studies of all patients with TBI, including those who do not enter inpatient rehabilitation facilities, are imperative. Important questions about the effectiveness of rehabilitation and its component disciplines require the development of regional or national registries, with standardized data collection and identification and followup of all patients with head injury.

3. Research designs for future studies should incorporate health outcomes of importance to persons with TBI and their families. Commonly used measures should be more strongly linked to health outcomes. Future studies should address the effect of spontaneous recovery, systematize criteria for entering cognitive rehabilitation, and differentiate between the effects of general stimulation and specific techniques.

4. The greatest overall need for the evaluation of supported employment programs is a series of trials with adequate controls and with unbiased allocation of clients to the conditions compared.

5. Future research should focus on improving the outcome measures used to examine the results of case management in TBI rehabilitation. In addition to outcomes of changed patient functionality, there should be outcomes of changed family functionality. Since much of case management communication is directed toward helping family members learn what to expect and where to obtain services, relevant outcomes would include family use of community and rehabilitation services and indicators of family assertiveness about care expectations. While case management may only indirectly affect a patient's functional outcomes such as level of disability, vocational status, and living status, it is possible that case management can directly affect family knowledge of TBI rehabilitation needs and services, level of psychosocial anxiety, and family competency in coping with TBI.

Introduction

An estimated 4.5 million United States citizens are disabled as a result of traumatic brain injury (Centers for Disease Control and Prevention [CDC], 1998). Advances in medical technology and improvements in regional trauma services have increased the number of survivors[1] of traumatic brain injury (TBI), producing the social consequences and medical challenges of a growing pool of people with disabilities (Annoni, Beer, and Kesselring, 1992; Ewing, Thomas, Sansces et al., 1983). Lifelong disability is the consequence for 80,000 to 90,000 individuals each year (CDC, 1998). As a result, answers to questions about recovery are being pursued through a multitude of research projects by various communities with distinct objectives.

Wider awareness of the scope of the problem and its consequences for society has led to rapid growth in the rehabilitation industry. Because of this growth, and particularly because clinical rehabilitation strategies vary widely, many groups are interested in the effectiveness of rehabilitation for TBI:

- Rehabilitation experts have recognized the inadequacy of applying traditional models, effective with broken arms or legs, to the task of recovery from brain injury and cerebral tissue damage.
- Payers have also begun to recognize the inadequacy of current standards for funding rehabilitation from brain injury; they want to know what long-term outpatient programs are most likely to return a person to functional independence; when specific types of rehabilitation should start, and when they should end; and which components of complex, multidisciplinary rehabilitation programs are effective.
- Congress has raised questions about unmet needs for rehabilitation services, the adequacy of care in existing facilities, and the relative costs and effectiveness of the wide variety of rehabilitation services offered to survivors of TBI.

[1] Use of language in reference to persons with TBI is based on a survey of current usage. “Survivor” is used through the course of a person’s life. “Patient” is used when the person is an inpatient. “Client” is used in general outside the patient setting. Otherwise, “persons with TBI” is the preferred term.

- A strong and growing advocacy movement of survivors of TBI and their families has a research agenda that includes defining recovery and functional status in terms of quality of life as well as financial independence.

With the current interest in the effectiveness of rehabilitation for TBI, the Agency for Health Care Policy and Research (AHCPR) selected this topic as one to be investigated by an Evidence-based Practice Center (EPC). AHCPR selected Oregon Health Sciences University (OHSU) to produce the evidence report. The OHSU EPC found a partner in the planning committee for the Consensus Development Conference on Rehabilitation of Persons with Traumatic Brain Injury, sponsored by the National Institutes of Health and to be held in October 1998. In addition, the Brain Injury Association, Inc., an organization with a mission to support research leading to better outcomes for people who sustain a brain injury, indicated a willingness to serve as a partner with the OHSU EPC.

Three questions about the status of brain injury research underlie uncertainty about the effectiveness of rehabilitation services. First, how should fundamental concepts such as recovery, functional status, and disability be defined? Because brain function is highly complex, TBI has an extremely wide range of potential outcomes, including, for example, cognitive deficits, motor disabilities, changes in emotional and social function, personality changes, and changes in appearance. As a result, therapeutic aims and perspectives vary widely among studies, as do definitions of outcome, making valid comparisons across studies difficult.

Second, how should the type and severity of the injury itself be measured? Variation in methods to assess the severity of injury in people entering rehabilitation make it difficult to estimate the effectiveness of different methods of rehabilitation.

Third, which therapies are effective, and how can patients best be matched to treatment approaches likely to be effective for them? Today, a person's path to a rehabilitation program after sustaining brain injury may be determined by the mechanism of injury, the resources of the community, the person's employment or financial status, the consent of the family, or the accuracy of emergency department diagnosis. While a few metropolitan areas have organized referral systems that connect persons with TBI with resources and rehabilitation programs, systematic methods for evaluating the needs of those who have sustained brain injury and referring them to appropriate programs are unusual. Without knowing the efficacy of rehabilitation methods in their specific applications, systematic referral that produces the desired result is not possible.

Another major theme in the literature, and in public discourse, concerns the costs associated with traumatic brain injury and the cost-effectiveness of its treatment. The clinical economic problem posed by persons with TBI is how much to invest in their rehabilitation after it is clear they will survive their injuries. Our ability to maximize the return on this investment is limited by a lack of accurate information about the costs of TBI and the costs and benefits associated with various treatments.

In this report, we examine available evidence about the effectiveness of rehabilitation for adult survivors of TBI. Specifically, we report the results of a systematic effort to identify the best available evidence about the various strategies to improve the outcome of traumatic brain injury in the most common rehabilitation settings. The main virtue of a systematic review is the application of methods designed to avoid the biases inherent in less formal approaches to reviewing the literature. For example, to avoid bias in the identification and selection of articles, a systematic review uses predefined search strategies and explicit criteria for inclusion or exclusion of studies. This approach can uncover published evidence that might be ignored in an informal review, in which studies that are widely known or that support a particular viewpoint are more likely to be identified. Similarly, a systematic review applies methods to reduce bias in interpreting studies, such as review by more than one investigator and the use of a data abstraction form.

In addition to being systematic, this report employs methods to assess the methodologic strength of individual studies and the strength of evidence supporting assertions about the effectiveness of interventions. The strongest evidence for effectiveness comes from experimental studies, in which subjects are randomly assigned to alternative interventions. In many cases, inferences about effectiveness are drawn from the results of uncontrolled, or poorly controlled, cohort studies. In these observational studies, a group of subjects is followed over time. Such studies are particularly useful for describing the incidence of certain outcomes over time, and for analyzing the relationship between risk factors and those outcomes. However, observational studies often provide weak or flawed evidence about effectiveness, because it is not clear if the observed outcomes resulted from specific interventions, or if they would have occurred anyway in the absence of the intervention.

How should the information in this report be used? Our main goal is to provide a guide to the strengths and limitations of the evidence about these interventions that organizations can use to develop evidence-based practice guidelines for rehabilitation. Another goal is to identify information gaps and controversies that can be addressed in future research studies. A finding that a particular treatment is proven effective, or proven ineffective, may dominate a discussion about what should be done. Most findings, however, are in between—"not proven," rather than "proven not." In these situations, factors other than the strength of evidence should be considered in deciding on a clinical recommendation. Patient and societal preferences and values such as equity, attitudes about risk, and evidence about the relative benefits and harms need to be considered in making a recommendation about practice.

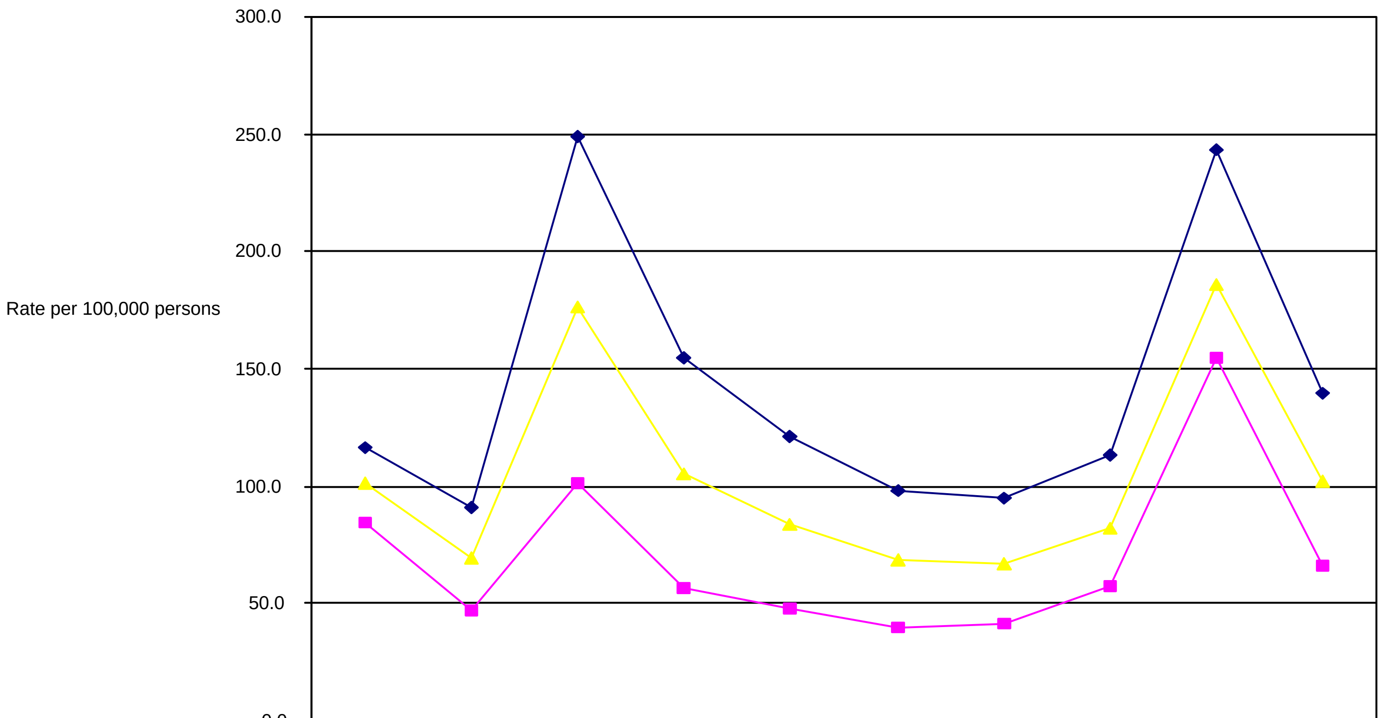
The Course and Lifetime Burden of TBI

Incidence and Costs of TBI

TBI is the leading cause of death and disability among children and young adults in the United States (CDC, 1998). An estimated 56,000 lives are lost in the United States each year to TBI (Kraus and McArthur, 1995). Motor vehicle accidents, followed by firearms and falls, are the leading causes of death from TBI (Sosin, Sniezek, and Waxweiler, 1995). Males are 3.4 times as likely as females to die of TBI (National Institute of Neurological Disorders and Stroke). About 50 percent of people who sustain TBI are intoxicated at the time of injury (Ruff, Marshall, Klauber et al., 1990; Kreutzer, Doherty, Harris et al., 1990).

In a recent analysis based on hospital discharge data and vital statistics, the annual incidence of TBI in the United States was estimated as 102.8 per 100,000 (CDC, 1997). Figure 1 shows TBI incidence rates by age group and sex. In males, the incidence peaks between the ages of 15-24 (248.3 per 100,000) and again above 75 years of age (243.4 per 100,000). The incidence in females peaks in the same age stratum, but the absolute rates are lower (101.6 and 154.9, respectively). These rates may underestimate the true incidence of head trauma because people with milder symptoms at the time of injury are usually not hospitalized.

Figure 1. Incidence of traumatic brain injury per 100,000 U.S. population



	<5	5 to 14	15 to 24	25 to 34	35 to 44	45 to 54	55 to 64	65 to 74	>75	Total
Male	116.5	91.1	249.3	154.7	121.2	98.3	95.1	113.4	243.4	140.0
Female	84.6	47.1	101.6	56.9	47.7	39.7	41.3	57.1	154.9	66.0
Total	101.0	69.7	176.7	105.7	84.1	68.4	67.0	82.2	186.2	102.1

Source: MMWR – Morbidity and Mortality Weekly Report. 46(1) : 8-11, 1997 Jan 10.

About three-quarters of traumatic brain injuries that require hospitalization are nonfatal. Each year, about 80,000 survivors of TBI will incur some disability or require increased medical care (Kraus and Sorenson, 1994). From an economic viewpoint, the problem posed by survivors of TBI is how much to invest in their rehabilitation after it becomes clear they will survive. The type, intensity, and duration of rehabilitation services affect the total economic impact associated with TBI. For example, investing in rehabilitation services to help a survivor become independent or return to work may reduce the lifetime economic burden of illness. To date, no study has comprehensively examined the lifetime costs of TBI. As shown in Table 1, the total economic impact includes many types of costs besides direct medical costs. A starting point for estimating these costs would be information about the prevalence of chronic TBI in the general population, but such data are lacking.

Table 1. Direct medical care and rehabilitation costs

Type of costs	Cost definitions
Direct personal care costs	All additional costs of supported living arrangements required by the person with TBI relative to independent community living.
Direct family out-of-pocket costs	Copayments and deductibles for covered health care services, expenses for uncovered health care services, child care expenses while attending rehabilitation, child care costs due to inability of patient to care for child, transportation to/from rehabilitation, cost of home renovation to adapt to the needs of the person with TBI (e.g., wheelchair access, installing a bathroom on a main floor).
Indirect medical care and rehabilitation costs	Travel time receiving rehabilitation treatment, waiting time, time caregivers, family members or friends spend in providing care.
Lost productivity	Lost productivity for the person with TBI and caregiver(s) because of the person with TBI.
Friction costs	Transaction costs (e.g., hiring, training) associated with replacement of a worker.
Insurance	Loading fees (profit and claims administration costs) for health and liability insurance, increase in experience-rated health insurance premiums for persons with TBI subsequent to their injuries.
Education	Costs of formal retraining of workers with TBI into former or new jobs because of their disabilities.
Social welfare	Administrative costs of social welfare system to determine eligibility and set up transfer payments for income maintenance, direct publicly-financed treatment (rehabilitation and sheltered living arrangements), and health insurance
Consumer auto modifications	Costs of modifications to automobiles driven by persons with TBI to install adaptive devices to compensate for impairments.
Legal/justice system	Costs of the tort liability system for determining the compensatory damages for TBI resulting from negligence; costs of the tort system for appealing decisions from the social welfare system relating to income maintenance for persons with TBI.
Pain, suffering, bereavement	Bodily pain and unobservable psychological and emotional distress for the persons with TBI and their families caused by the injury, its treatment, and the associated loss of functioning. Note that these costs are separate from the lost productivity effects associated with chronic pain and emotional distress. Ideally, these effects would be valued by a persons' willingness to pay to avoid these TBI symptoms.

Note: All health care services for the TBI episode and its complications and sequelae, including hospital care, skilled nursing care, home health services, drugs, tests, durable medical equipment, mental health, physical therapy, speech therapy, occupational therapy. We will include all medical care costs starting with the time of the injury to be inclusive of all potential rehabilitation services. We will then attempt to separate the TBI care episode into two phases, medical stabilization and rehabilitation.

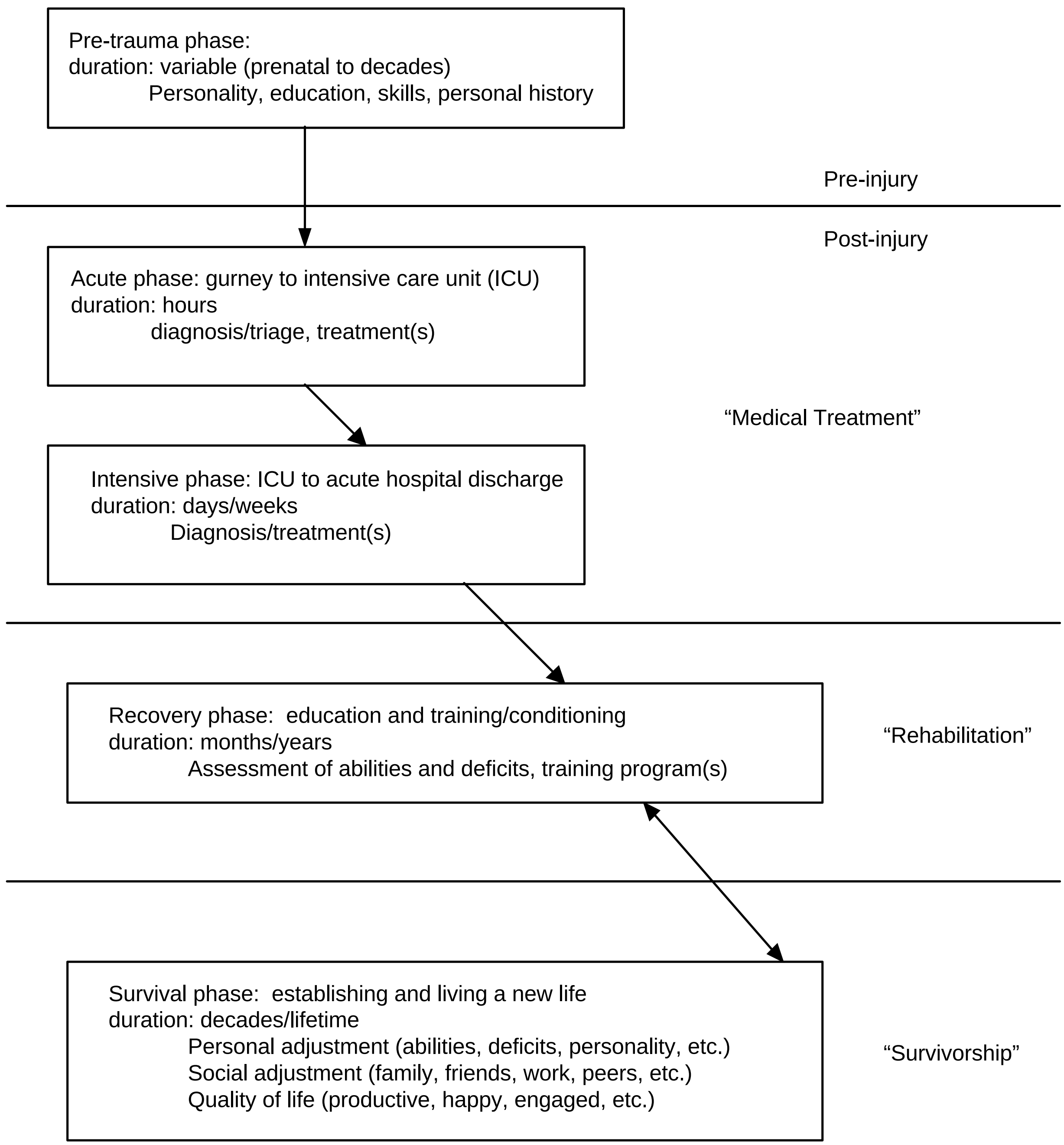
Although it is difficult to precisely quantify costs, useful information can be gleaned by studying charge data from published studies in various settings. The total cost of traumatic brain injuries in the United States is estimated to be $48.3 billion annually. Hospitalization accounts for an estimated $31.7 billion, whereas fatal brain injuries cost the nation approximately $16.6 billion (Lewin, 1992).

In recent years, LOS and inpatient costs for rehabilitation have decreased. In the years 1988-1992, reports of average LOS for the initial admission for inpatient rehabilitation range from 40-165 days (Blackerby, 1990; Carey, Seibert, and Posavac, 1988; Giacino, Kezmarsky, DeLuca et al., 1991; Mackay, Bernstein, Chapman et al., 1992; McMordie and Barker, 1988; Rappaport, Herrero-Backe, Rappaport et al., 1989). In one older multicenter study (the Model Systems study), the average rehabilitation length of stay (LOS) was 61 days and the average charge was $64,648 exclusive of physician fees. Total charges averaged $154,256 (Lehmkulh, Hall, Mann et al., 1993). In more recent studies, performed in the early 1990s, rehabilitation LOS and charges were lower, ranging from 19 days and $24,000 for patients with milder injuries to 27 days and $38,000 for those with severe injuries (Cowen, Meythaler, DeVivo et al., 1995). In the Medicare population in 1994, mean charges for patients admitted for brain injury (excluding stroke) were $42,056 (Chan, Koepsell, Deyo et al., 1997).

Conceptual Model of the Lifetime Burden of Illness

To focus attention on important questions, we characterized the life of a person with TBI in terms of five phases, as presented in Figure 2. The first phase is “pre-injury.” “Medical treatment” is divided into the acute (or immediate) treatment phase, and the intensive treatment phase, lasting days to weeks. The “rehabilitation” phase may last months to years. The “survivor” phase signifies the remaining life of the person with TBI, and involves continual development and adjustment. This division into phases clarifies the three challenges to assessing the efficacy of rehabilitation discussed above. Patient populations are defined generally in terms of the phases, and interventions and outcomes must be specific to the phase being evaluated.

Figure 2. The career of a TBI survivor



Mechanisms of Brain Injury

In TBI, the disease process begins at the moment of impact and extends thereafter for a protracted period of time. In strictly biological aspects, the brain injury disease process can be divided into primary and secondary insults. The primary insult initiates with the physical trauma to the brain. The secondary insults occur thereafter and, in many cases, are the primary determinants of outcome.

Beginning at impact and continuing for a generally brief period, primary insults to the brain include formation of intracranial hematomas (subdural or epidural), intracerebral hematoma, cerebral parenchymal contusions, cerebral swelling, or diffuse axonal injury. Intracranial hematomas such as subdurals and epidurals occur outside of the brain parenchyma and exert much of their pathological effects via increasing pressure on the brain (elevation of intracranial pressure [ICP]). Particularly with respect to epidural hematomas, if this pressure is avoided or rapidly reversed through expedient surgery, there may be no damage to the underlying brain and no residua. In instances with a period of protracted intracranial hypertension, the ICP elevation may result in herniation of the brain tissue through orifices of the skull and/or cerebral ischemia due to interference with cerebral blood flow. Depending on magnitude and duration, such insults can produce deficits that vary from subtle to mortal.

Subdural hematomas can also cause significant intracranial hypertension and have a high likelihood of damaging underlying brain. This damage is often the primary determinant of long-term recovery.

Similar concerns about ICP are also relevant to cerebral swelling. Intracranial processes such as increased extracellular or intracellular fluid or elevated intracranial blood volume can raise ICP and impair adequate blood flow to the brain. In addition, some of these processes can cause primary cellular damage or ischemia by interfering with oxygen transport of between vessels and cells.

Injuries such as intracerebral hematomas and cerebral contusions result in blood intermixed with brain. In the case of contusions, the pathology includes primary damage to neuronal cells. In both instances, the presence of blood within brain tissue appears to have significant toxic effects which can produce profound secondary insults to the injured tissue.

Diffuse axonal injury is a somewhat different disease entity. In this injury type, the physical forces the brain sustains during an injury characteristically consist of linear as well as angular acceleration or deceleration. These forces disrupt axons within the cerebral white matter, and these are called shear injuries. In this injury type, there may be no herniation or intracranial hypertension and, indeed, computer tomographic (CT) studies may often be normal or remarkably benign in appearance. Unfortunately, the widespread damage to the white matter will produce a recovery that is characteristically slow and incomplete.

Primary brain injuries occur at the time of injury and, by definition, must be treated *post hoc*. Secondary brain injuries are initiated sometime after injury and are often due to systemic factors. Their generally delayed onset allows them to be treated when they occur and also to be forestalled. This aspect of prevention has stimulated many of our trauma protocols and drives significant ongoing pharmaceutical research efforts.

The best known and possibly most devastating secondary brain insult is that of cerebral ischemia due to systemic hypotension. Systemic hypotension is extremely common, occurring in about one-third of patients with TBI during the period of injury through the end of resuscitation. A single hypotensive episode is associated with a doubling of mortality (Chesnut, Marshall, Klauber et al., 1993). Systemic hypotension illustrates the profound influence secondary brain insults can have on recovery and strongly supports the potential benefits of optimal trauma care.

Secondary brain insults may be due to intracranial processes that are initiated by:

- Primary brain injury.
- Secondary systemic insults such as hypoxia or hypotension.
- Injuries to extracranial organ systems.

- Systemic complications directly or indirectly related to the initial traumatic incident.

Secondary brain insults arising from the initial trauma include a number of toxic cellular and subcellular biologic processes. These include:

- Cerebral edema.
- Alterations in intracranial ionic homeostasis (e.g., calcium, chloride).
- Free radical formation.
- Alterations at the molecular biology level.

These processes may result in ongoing and self-perpetuating brain injury in various fashions. Cerebral edema will interfere with transport of nutrients, oxygen, and waste products and cause injuries to cells surrounding the area of primary injury as well as impair the healing of the initially damaged cells. Alterations in ionic homeostasis will disrupt the transmission properties of the neuronal and neighboring cells. Free radical formation can initiate a self-perpetuating cascade of toxic elements that may damage cells initially untouched by the injury. Finally, alterations at the molecular biology level will interfere with the primary genetic cellular control processes.

Secondary brain insults due to hypoxia or hypotension have become very well-recognized over the past two decades and are a primary target of resuscitation protocols. The magnitude of importance of these insults is illustrated by the data on hypotension. Because we now have several tools to effectively recognize and treat such insults that are so devastating, intense interest is currently focused on managing them.

Secondary insults may also occur from systemic trauma to extracranial organ systems. Although much of the influence of such extracranial trauma is mediated through hypoxia or hypotension, some aspects are unique to the individual organ system. For instance, long bone fractures may produce fat emboli to cerebral vessels that interfere with cerebral circulation. Alterations in timing and techniques of managing such fractures may improve cerebral outcome by decreasing the risk of embolism.

Finally, cerebral injury can be influenced by systemic complications occurring during the acute phase of management. The most well-established of these complications as determinants of outcome include hypotension, pneumonia, sepsis, and coagulopathy. The importance of such factors in determining outcome supports the necessity of excellent critical care in managing patients with TBI.

The biologic aspects of repair or recovery are of primary importance during the early post-injury period, while the cognitive/psychological/behavioral issues become increasingly predominant over time. The primary processes involved in biologic neuronal recovery are 1) reparative and 2) adaptive or plastic processes. Scientists believe that, except under extremely unusual circumstances, new neurons are not formed in the mature human brain, and thus when a neuron dies, its contribution to brain function is irreparably lost. Since neuronal death can apparently be induced not only by direct trauma but also by traumatic activation of inherent biological processes of programmed cell death (apoptosis), the question of cessation or reversal of such processes is an active focus of research.

Neurons have somewhat limited capabilities of self-repair, but the physiologic underpinnings of this regeneration are not completely understood. Although some clinical evidence suggests that neuronal repair can be facilitated pharmacologically in the injured spinal cord, no clinical evidence suggests that we can favorably influence such processes in the brain.

Research in animals suggests the existence of critical periods during recovery wherein interventions may be particularly beneficial. The existence of similar periods has been postulated for the injured human brain both for biological and behavioral interventions. To date, however, no clinical evidence supports the existence of such critical periods in the human.

Another biologic recovery mechanism is adaptation. In a biologic sense, this involves the formation of new circuitry to replace that lost from trauma. There is a great deal of plasticity in the nervous system, some of which continues throughout the organism's life, for example, learning of new information. At the more macroscopic level of altering neuronal circuits to directly replace those lost, however, abilities seem to be significantly limited in the adult human brain. In the immature nervous system, such plasticity is commonplace. A primary example is the alteration of laterality of language function resulting from very early injury to the left cerebral hemisphere. Unfortunately, the ability to make adaptations of such magnitude is lost early in life and the degree to which plasticity of lesser magnitude persists or can be induced in a more mature brain remains unclear. The question of such plasticity is fundamental to the concept of restorative cognitive therapy as well as to the concept of critical periods.

Social, Behavioral, and Emotional Factors in Recovery from TBI

Neither traumatic brain injury nor its recovery can be described in purely biologic terms. The sudden onset of TBI combines with extreme changes in behavior, personality, memory, and general function to produce a catastrophic perturbation in the social system of the person (Goldstein,1995; Johnston and Hall, 1994). Memory deficits and inappropriate behavior limit the ability to return to work (Treadwell and Page, 1996). Personality changes and behavioral problems mimic other pathologies such as mental retardation or psychiatric disorders. These behaviors in turn elicit negative reactions from family and friends that operate to impede the recovery process. Long-term consequences include financial dependence, social isolation (Dikmen, Machamer, and Temkin, 1993), divorce (Lezak, 1995), and various forms of incarceration such as lockup care facilities, state hospitals, or prisons.

The recovery course is partially determined by the presence or absence of factors in the survivor's social context (Goldstein, 1995). Size and strength of immediate and extended family (Kozloff, 1987), access to social services, and adequate resources (both money and programs) (Johnston and Hall, 1994) contribute to the recovery process. Aspects of the survivor's psychology, such as premorbid modes of behavior, may persist after injury (Dikmen, Machamer, and Temkin, 1993), influencing how the survivor engages in the present task of recovery. Drug or alcohol abuse (Sparadeo, Strauss, and Barth, 1990) may provide an alternative to the discomfort of persistent disorientation, confusion, and physical pain.

During the initial phase of recovery, the patient will manifest behaviors that are an immediate attempt to become oriented (Goldstein, 1995). These behaviors are often inappropriate to the context, unexpected, and may appear to be maladaptive. They are a consequence of the patient's sudden reduction in perception of the environment and ability to respond effectively to stimuli. This phase is of primary importance in rehabilitation, in that the milieu must be designed to accommodate the behaviors, and not impede them. Attempts to suppress these behaviors may operate to slow the recovery process, and keep a patient from engaging a new orientation. However, resistance to odd behaviors is usually a natural response from family and friends. The newly injured patient will often focus on the familiar, usually a family member, to achieve orientation; training the family to respond appropriately is an important component in establishing a context in which the patient can recover (Rosenthal and Young, 1988).

Chronic Complications of TBI

TBI can cause severe cognitive, physical, and psychosocial/behavioral/emotional dysfunction. The most important cognitive sequelae are memory loss; difficulties with concentration, judgment, communication and planning; and spatial disorientation. Physical problems include abnormalities of muscle tone, vision, hearing, smell, taste, and speech, as well as reduced endurance, headaches, and seizures. Frequently encountered psychosocial/behavioral/emotional problems arising from TBI include anxiety and depression, mood swings, denial, sexual difficulties, emotional lability, egocentricity, impulsivity and disinhibition, agitation, and isolation. A recent review examined papers describing the psychosocial and emotional sequelae for survivors of TBI (Morton and Wehman, 1995). The results of those studies demonstrated that survivors of severe TBI often lose friendships and social support, have limited opportunities to develop new social contacts and friends, have few leisure activities, and have high levels of anxiety and depression for prolonged periods of time. In addition to the psychosocial problems described above, categories of functional status used to describe outcome from TBI include memory, mobility and independence, organization and productivity, physical disabilities, and inappropriate behavior.

Memory

Brain injury can cause deficits in memory that range from mild, intermittent forgetfulness to profound inability to recall anything from the past or to integrate new information. Cognitive scientists and clinicians have made distinctions in mechanisms of memory that reflect modes of memory loss. Implicit memory records information that occurs nonconsciously; explicit memory is a function of active work such as repetition. Some brain injury depletes implicit memory but not explicit, or vice versa. Semantic memory allows for understanding of the meaning of words; episodic memory records time- and place-specific experiences. Procedural memory is reflected in behavioral routines; declarative memory is reflected in the ability to explicitly report.

The burden of illness with respect to memory loss depends on the scope and degree of deficit, and is also context-specific. For example, loss of procedural memory may result in devastating occupational consequences to a person whose work tasks are routine. However, if that is the only affected mechanism, other intact modes of memory may substitute for the deficit, and the person may be able to learn a new skill and regain independence.

The inability to integrate new information can result in global loss of independence, especially when accompanied by intact pre-morbid memory. The individual clearly remembers profession, life circumstances, and family from before the injury, but nothing thereafter. Because they do not remember, they do not know that they do not remember, which leads them to insist on a daily, sometimes hourly basis that they are who they used to be. A reminder of the injury may last a minute or a day, but will fade with other post-morbid information. These people cannot work, and the burden of their illness is evidenced in the consequences to family and caregivers.

Mobility and Independence

Limitations in mobility and independence may cause inability to drive or ride a bus, work and earn a living, balance a checkbook, or prepare meals. Mobility will also be affected by physical impairment, and independence by degree of memory deficit. The burden is also affected by the individual's social milieu. For example, for one person the presence of family to facilitate mobility may mediate the impact of the trauma. For someone else, dependence on family may be abhorred, and compound the burden of illness.

Organization and Productivity

Many survivors of brain injury exhibit an obsession for orderliness. Some are capable of servicing the obsession to varying degrees. For example, one person's home may be cluttered and disorganized, with one room (a computer room or tool shop) in meticulous order. The burden of illness can be observed in the amount of time and energy devoted to the orderly space and the confusion and lack of productivity experienced in the disorderly environments. Often, on a daily basis, a person never disconnects from the obsessional tasks in order to engage in other productive activities.

Physical Limitations

Physical deficits include difficulty with ambulation, hearing, vision, speaking, fatigue, and use of hands. They may result from injuries sustained at the same time as, but distinct from, the head injury, or they may be directly result from brain and spinal column nerve damage.

Inappropriate Behavior

Persons with traumatic brain injury often lose the ability to monitor and control behavior (Lezak, 1995). They may say whatever comes to their mind at inappropriate times. They may misunderstand the meaning of a situation or conversation, and respond according to their misunderstanding. This problem can have profound effects on a person's life, resulting in loss of work, friends, and family.

Interventions

Rehabilitation methods differ in setting, level, and range of provided therapeutic interventions, durations of treatment, and overall expenses. Lack of standard classification and different aims of therapies are problems in evaluating rehabilitation as an intervention.

Three issues complicate classification of interventions:

1. General versus specific modes of classification. A very general mix of therapies constitutes the protocol of some rehabilitation programs. In contrast, other programs use intricate evaluations to identify deficits and then design interventions specific only to those deficits.
2. Discipline-driven classification. Another approach to classification of intervention is to stratify according to the discipline that generates the treatment, such as cognitive rehabilitation, occupational therapy, or physical therapy.
3. Comparison of intervention categories. In evaluating the effectiveness of a treatment, to what should the treatment be compared? Should inpatient rehabilitation be compared to outpatient; vocational to cognitive? Or should rehabilitation be compared to no rehabilitation?

The specific aims of therapy also vary widely, encompassing interventions aimed at an extremely wide range of potential outcomes, including, for example, cognitive deficits, motor disabilities, changes in emotional and social function, personality changes, and changes in appearance. As a result, therapeutic aims and perspectives vary widely among studies, as do definitions of outcome, making valid comparisons across studies difficult.

Another problem is variation in practice. Allocation of interventions appears to be arbitrary, and not necessarily dictated by established standards of practice. A substantial minority (30-40 percent) of severely injured patients do not enter rehabilitation, while about 30 percent with mild head injury do. In one study (Dombovy and Olek, 1997), of 48 patients assessed 6 months after discharge from acute care, only 8 had received any post-acute rehabilitation.

On a population basis, only a selected subset of patients with TBI undergo inpatient rehabilitation after discharge from the acute care hospital (Wrigley, Yoels, Webb, et al., 1994.)
Patients seen by a physiatrist during the acute hospitalization were more likely to be provided post-acute rehabilitation. The presence or absence of a physiatrist at the hospital was a stronger

determinant of referral to inpatient rehabilitation than clinical factors and patient characteristics that would seem to be reasonable criteria for referral (Wrigley, Yoels, Webb et al., 1994).

In Table 2, interventions are mapped onto the phases from Figure 2 to illustrate what practice settings and techniques are most relevant to each specific phase of recovery.

Table 2. Distribution of practice settings and techniques in TBI treatment phases

	Phases of treatment in TBI			
Practice settings	Acute	Intensive	Recovery	Survival
Coma treatment centers				
Acute rehabilitation programs				
Long-term rehabilitation programs				
Transitional living programs				
Behavior management programs				
Day treatment programs				
Extended intensive rehabilitation				
Late rehabilitation				
Independent living programs				
Life-long residential				
Techniques of treatment				
Physical therapy				
Standard rehabilitation (OT, PT, Speech)				
Speech and language therapy				
Cognitive therapy				
Occupational therapy				
Behavioral therapy				
Psychotherapy				
Social skills training				

Note: Shading in the cells denotes the settings of treatment phase or application of techniques in that phase. Grid shading denotes greater co-relation of phase with setting or technique.

Practice Setting

The following are practice settings. Although they are presented separately here, they often overlap to varying degrees.

- (Coma) Treatment Centers. A small number of people with head injuries will remain in a minimally responsive state for months or longer after injury. A few centers will accept such individuals once they are medically stable and attempt to achieve improvement by the use of various stimulation techniques. Skilled nursing care and physical therapy are also important elements of these programs.

- Acute rehabilitation programs are prepared to treat patients as soon as they are medically stable and are discharged from the acute hospital. Most of these are located in rehabilitation hospitals. Their primary emphasis is to provide intensive physical and mental restorative services in the early months after injury. Many will have specialized head injury units with an interdisciplinary team composed of physicians, nurses, speech and occupational therapists, and neuropsychologists. These programs are relatively short term, but longer stays may occur.

- Long-term rehabilitation programs provide extended rehabilitation and management services. They may provide a full range of rehabilitation services for the person with brain injury who is in need of a structured environment and who is making slow improvements. They generally are not permanent placement facilities, although they may have this service available. Usually a person may remain in the program as long as there continues to be some improvement.

- Transitional Living Programs. The goal of a transitional program is to prepare individuals for maximum independence, to teach the skills necessary for community interaction, and to work on pre-vocational and vocational training. Specialized programs stressing cognitive, memory, speech, and behavioral therapies are usually structured to the needs of the individual. Programs of this type are being established in a variety of settings—small group homes, special educational institutions as part of a continuum of care in rehabilitation centers.

- Behavior Management Programs. Severe maladaptive or aggressive behavior will limit an individual’s participation in most rehabilitation settings. While these programs treat the common behavioral problems following head injury, many of them cannot handle destructive behavior to self or others (e.g., sexual aggression).

- Day treatment programs are non-residential facilities that emphasize services to upgrade functional skills. These services are similar to those described above under transitional living programs. Some offer day-care (supervision) services for those unable to benefit from an active program.

- Extended Intensive Rehabilitation. The more seriously injured person may require extended therapies in a structured program that has all the elements found in the acute rehabilitation center. Emphasis will usually be on cognitive and memory retraining, speech therapy, activities of daily living (ADLs), restructuring lost social behaviors and continued physical therapies. Prevocational and vocational training, recreational therapy, and community reentry are usually part of each program. Patients will remain in these programs as long as progress is being made—usually 6 to 12 months.

- Late rehabilitation. After discharge from the acute rehabilitation center, many people with head injury will need extended rehabilitation either in a residential or inpatient setting or in outpatient programs. Admission requirements may vary and may be defined by a specific time after head injury.

- Independent living programs (ILPs) are community-based services that assist people with severe disabilities living in their own homes to increase personal self-determination and independence. ILPs provide both direct and indirect services ranging from residential/transitional programs to resource referral.

- Life-long residential programs. For those individuals unable to live at home or independently, a residential program may be the only alternative. There are very few programs of this type specifically set up for people with head injuries. Some facilities that have had experience with other populations of people with disabilities are beginning to explore this possibility.

- The home. For some, the home environment provides the most productive setting for therapy. In addition to in-home nursing care, rehabilitation professionals may come to the client's home on a routine basis to conduct therapy sessions.

- TBI Social Clubs. Although not necessarily a setting for formal rehabilitation, the social clubs provide an environment in which persons with TBI associate with each other, form friendships, and instruct each other in how to manage life with a disability.

Techniques

Therapies discussed here may be provided on an individual basis or in group settings.

- Physical therapy. Treatment designed to restore normal physical function: walking, use of hands, arms, and so forth. A physiatrist may specify the course of treatment, integrating physical therapy with other programs.

- Therapeutic recreation targets resuming leisure activities, community skills, and social skills.

- Speech and language therapy. Language disruption is common with TBI, and is specifically addressed in speech therapy. Speech therapy encompasses relearning appropriate methods of communication, verbal and nonverbal, as well as relearning communication of abstract thought.

- Cognitive therapy offers retraining to learn to think, use judgment, make decisions. Focus is on correcting deficits in memory, concentration and attention, perception, learning, planning, sequencing, and judgment. A neuropsychologist, aided by other specialists (for example, Occupational Therapists [OT], Speech and Language Pathologists [SLP]), may be asked to evaluate the level and kind of cognitive dysfunction following TBI, and may reassess the individual over time to measure recovery.

- Occupational therapy offers retraining to enable the person with TBI to cope with the routine demands of a work environment. Often the occupational tasks are at a level below that of pre-injury status.

- Behavioral therapy involves modification of maladjusted, asocial, or socially inappropriate behaviors.

- Psychotherapy targets emotional issues, social adaptation, and self-awareness. Group psychotherapy is useful for feedback, support, and confrontation by peers. Family members may participate in therapy to assist them in coping with the stress of being a caregiver, and to build their ability to provide appropriate in-home support.

- Social skills training may be provided as a separate program, or integrated into any of the methods described above.

Measures of Injury Severity and Disability

Table 3 lists measures that are commonly used to assess or predict the outcome of TBI. As shown in the table, the choice of outcome measure or predictor depends on the individual's phase of treatment and recovery.

Table 3. Use of measures of injury and disability in phases of recovery from TBI

	Phases of treatment and recovery			
Scale or Measure	Acute	Intensive	Recovery	Survival
Intra-cranial pressure (ICP)				
Brain scans (CT, MRI)				
Duration of coma (DOC)				
Duration of post-traumatic amnesia (PTA)				
Glasgow Coma Scale (GCS)				
Galveston Orientation and Amnesia Test (GOAT)				
Rancho Los Amigos Scale (RLAS)				
Physical impairment measures				
Injury Severity Scale (ISS)				

Bond Neurophysical Scale (BNS)				
Glasgow Outcome Scale (GOS)				
Disability Rating Scale (DRS)				
Functional Independence Measure (FIM)				
Functional Assessment Measure (FAM)				
Portland Adaptability Inventory (PAI)				
Community Integration Questionnaire (CIQ)				

Note: A shaded cell denotes use of the scale or measure in phase(s) of recovery. See Figure 2 for description of phases of recovery.

Outcome Measures

The validation of TBI rehabilitation systems and the study of neurobehavioral outcomes measurement are in states of evolution. Currently there is no consensus on which measures of outcome should be used to assess long-term recovery.

The Glasgow Outcomes Scale (GOS) has commonly been used in the acute care literature to measure outcome from TBI. It is widely felt to be too simple to be useful as a single indicator of outcome. The GOS (Jennett and Bond, 1975; Jennett, Snoek, Bond et al., 1981) may be used to rate outcome during any phase of recovery, and is often a part of a patient's acute hospital record (Marshall, Bowers-Marshall, Klauber et al., 1991; Braakman, Gelpke, Habbema et al., 1980; Choi, Narayan, Anderson et al.,1988). It has five levels: (1) death, (2) persistent vegetative state (absence of cortical function), (3) severe disability (conscious but disabled), (4) moderate disability (disabled but independent), and (5) good recovery (resumption of "normal life"). Many studies group the various levels into poor outcome (GOS 1-3) or good outcome (GOS 4 or 5). The simplicity of the scale does not lend itself to accurate prediction of future performance, particularly for people categorized as moderately disabled (Brooks, Campsie, Symington et al., 1986).

The Rancho Los Amigos Scale (RLA) (Hagen, 1984) is also used by acute care staff to categorize a patient's status and determine placement at discharge. It consists of eight levels of cognitive functioning: (1) no response, (2) generalized response, (3) localized response, (4) confused-agitated, (5) confused-inappropriate, (6) confused-appropriate, (7) automatic-appropriate, and (8) purposeful-appropriate.

The Functional Independence Measure (FIM) is an 18-item scale that evaluates self-care, sphincter control, mobility, communication, psychosocial adjustment, and cognitive function. (Granger, Hamilton, and Sherwin, 1986). Because it serves as the outcome measure in the Uniform Data System for Medical Rehabilitation, it has been applied by inpatient rehabilitation programs to a large population of patients with diverse problems, including TBI (Guide for the Uniform Data Set for Medical Rehabilitation [Adult FIM], 1993; Fiedler, 1997).

The FIM is considered to be the best single outcome scale for use during inpatient rehabilitation. However, a high score on the FIM does not necessarily mean a return to full function. For example, by FIM scores, about one-quarter of people with TBI are independent at the time of discharge from inpatient rehabilitation, and one-half by 1 year after injury. Followup studies, however, suggest that people with moderate or severe traumatic brain injury are unlikely to return to competitive employment (High, Boake, and Lehmkuhl, 1995).

Attempts to circumvent this "ceiling effect" by adding more cognitive/psychosocial information to the scale (FIM + FAM [functional adaptability measure]) have met with limited success (Hall, Mann, High et al., 1996). Judging by FIM or FIM + FAM scores, a typical survivor's goals for recovery are almost completely achieved by 1 year after injury; little change is achieved thereafter. Since it is rather strongly felt that this is incorrect, these scales are probably not optimal for long-term followup. This limitation of the FIM (or FIM+FAM) is not surprising, since these indices were designed to describe progress during rehabilitation, not functional status after discharge. In fact, therapists sometime use the attainment of threshold performance on items that are contained within the FIM as criteria for discharge.

The Disability Rating Scale (DRS) was developed to improve on the GOS as a global disability outcome tool (Rappaport, 1982). Questions on the DRS span the recovery phases, so the instrument can be used beginning in acute care through outpatient rehabilitation to track individual progress. It has has been shown to have validity, high reliability, and good utility

(Eliason and Topp, 1984; Hall, Cope, and Rappaport, 1985; Fryer and Haffer, 1987; Gouvier, Blanton, LaPorte et al., 1987). The DRS has also been shown to predict employment well (Rappaport, Herrero-Backe, Rappaport et al., 1989; Rao and Kilgore, 1992; Cope, Cole, Hall et al., 1991) and to interact with measures of severity of injury (Thatcher, Cantor, McAlister et al., 1991). The DRS appears to have less ceiling effect than the FIM or FIM+FAM (Hall, Mann, High et al., 1996) but probably is not as useful as the FIM for inpatient assessment.

High scores on functional measures do not necessarily predict a successful return to the community. In response, tools to evaluate reintegration have been developed. The Community Integration Questionnaire (CIQ) is a 15-item survey that evaluates home integration, social integration, and integration into productive activities. The questions are about practical, everyday tasks that are markers of independence, such as shopping, finances, meal preparation, and leisure time. Another scale used to evaluate deficits that may impede reintegration is the Portland Adaptability Inventory (PAI) (Lezak, 1987), a set of three scales that measure temperament and emotionality, activities and social behavior, and physical capabilities.

How well do these measures predict what happens after discharge from the rehabilitation unit? One study compared estimated working capacity as evaluated at discharge with actual employment at 6 months follow up (N = 147) (McLaughlin and Peters, 1993). As measured by assessment at the time of discharge, 11 percent were classified as unemployed; the actual outcome at 6 months was 39 percent. Other studies (McLaughlin and Peters, 1993, Najenson, Groswasser, Mendelson et al., 1980; Olver, Ponsford, and Curran, 1996) found that some survivors of TBI regress as a function of their transition from one phase of treatment to the next. These observations suggest that measures taken at the time of discharge from the inpatient unit may not be valid shortly thereafter. Repeating the FIM or other standard measures some time after discharge from the inpatient rehabilitation facility might improve prediction and counteract the “ceiling effect” described earlier.

Because standard measures may fail to predict outcome for a large cross-section of survivors

(Sbordone, Liter, and Pettler-Jennings, 1995), many clinics and rehabilitation programs have developed their own instruments for tracking patient progress. These instruments may be useful within their specific milieu, but their use hinders comparisons among centers and among published studies.

Long-Term Outcome of Traumatic Brain Injury

Only a few population-based studies have been done to examine the long-term outcomes of individuals who survive traumatic brain injuries (Dawson and Chipman, 1995; Edna and Cappelen, 1987; Pentland and Miller, 1986; van Balen, Mulder, and Keyser, 1996). In a Canadian study of survivors 13 years after injury, 66 percent reported the need for ongoing assistance with some ADLs, 75 percent were not working, and 90 percent reported some limitations or dissatisfaction with their social integration. In a study performed in the Netherlands, 67 percent of the population with major TBI had long-term situational, cognitive and behavioral disabilities, and only 10 percent received any rehabilitation services after the acute-care period (van Balen, Mulder, and Keyser, 1996).

Comparable population-based information from the United States is sparse. In a study of 520 Vietnam War veterans 15 years after surviving penetrating head trauma, 56 percent were employed (Kraft, Schwab, Salazar et al., 1993; Schwab, Grafman, Salazar et al., 1993). A registry study, the Traumatic Coma Data Bank, found that two-thirds of survivors who were employed or in school before their injury returned to work within a year of injury (Ruff, Marshall, Crouch et al., 1993). A few small U.S. studies have used acute hospital discharge abstracts to identify patients with TBI. In one of these, one-third of patients were cognitively impaired and 60 percent were unemployed 6 months after discharge. Only 8 of the 48 located at followup received any rehabilitation services (Dombovy and Olek, 1997). In a study of 31 patients identified from discharge records of acute care hospitals and surveyed after 2 years, many people with moderate-to-severe head injuries remained unable to work, support themselves financially, live independently, or participate in pre-injury leisure activities (Dikmen, Machamer, and Temkin, 1993).

Rehabilitation programs designed for populations of survivors of TBI with all levels of deficit can achieve about 50 percent employment (Ben-Yishay, Silver, Plasetsky et al., 1987; Prigatano, 1986). The main trends of employment post-injury are summarized by Wehman and colleagues (Wehman, Sherron, Kregel et al., 1993) as follows: (a) unemployment rates soar in survivors of TBI post-injury; (b) unemployment stays at very high rates of 50-80 percent for long periods of time, even with vocational rehabilitation services provided; (c) wages are greatly reduced from pre-injury levels; and (d) there is high job turnover among survivors post-injury.

Most information about the long-term outcome of persons with traumatic brain injury comes from followup studies of patients who underwent inpatient rehabilitation. While they are useful in understanding what to expect from inpatient rehabilitation in the long run, these studies are of limited usefulness in estimating the long-term burden of TBI in the general population for two reasons. First, these studies exclude the large numbers of survivors who do not undergo acute inpatient rehabilitation. As noted above, patients with mild or severe injuries who enter inpatient rehabilitation units are not necessarily representative of patients generally.

Second, because survivors of TBI who have a poor outcome are relatively difficult to follow up, the studies may overestimate the likelihood of a good outcome. In one study, for example, the investigators vigorously tried to contact 88 people who had TBI 1 year after discharge from acute rehabilitation (Corrigan, Bogner, Mysiw et al., 1997); 34 (38.6 percent) of these individuals could not be reached. People intoxicated at time of injury and those with history of substance abuse were more likely to be lost to followup. The authors noted that, among those who were contacted, these characteristics were associated with a lower probability of return to work. They concluded that "systematic bias in longitudinal studies may result from subjects with substance se problems being lost to followup. Population estimates for return to work or school will be overestimated if those lost who have substance use problems resemble those followed."

Fourteen studies concerned long-term outcomes of unselected patients with TBI after acute inpatient rehabilitation (Asikainen, Kaste, and Sarna, 1996; Corrigan, Bogner, Mysiw et al., 1997; Dombovy and Olek, 1997; Eames, Cotterill, Kneale et al., 1996; Fearnside, Cook, McDougall et al., 1993; Greenspan, Wrigley, Kresnow et al., 1996; Hawkins, Lewis, and Medeiros, 1996; High, Hall, Rosenthal et al., 1996; Rappaport, Herrero-Backe, Rappaport et al., 1989; Sander, Kreutzer, Rosenthal et al., 1996; Spatt, Zebenholzer, and Oder, 1997; Tennant, MacDermott, and Neary, 1995; Whitlock, 1992; Whitlock and Hamilton, 1995). Four studies were multicenter (Greenspan, Wrigley, Kresnow et al., 1996; Sander, Kreutzer, Rosenthal et al., 1996; Tennant, MacDermott, and Neary, 1995; Whitlock and Hamilton, 1995). The sample size for eight studies was under 100, and ranged between 181 and 525 for six studies. Followup measures were taken at < 2 years for seven studies and at > 2 years for six studies. In these studies, between 13 percent and 40 percent of subjects could not be reached for followup.

In general, patients show substantial improvements in physical, cognitive, and other functions between the time of admission to a rehabilitation facility and the time of discharge or at long-term followup. At the same time, continued morbidity and disability is common. Eight of the studies addressed post-injury return to productive activity. Post-injury unemployment ranged from 28 percent to 75 percent across these studies (Asikainen, Kaste, and Sarna, 1996; Dombovy and Olek, 1997; Fearnside, Cook, McDougall et al., 1993; Greenspan, Wrigley, Kresnow et al., 1996; Hawkins, Lewis, and Medeiros, 1996; Rappaport, Herrero-Backe, Rappaport et al., 1989; Sander, Kreutzer, Rosenthal et al., 1996; Spatt, Zebenholzer, and Oder, 1997). Employment in a job below pre-injury level or with reduced hours and demand ranged from 7 percent to 34 percent.

Studies differed widely in the methods used to measure return to work. Accounting for differences in measurement and the impact of injury severity on the probability of returning to work, it appears that more than half of survivors of TBI become unemployed as a consequence. For example, some samples combined survivors who retired with those who were unemployed or placed on disability. Also, some studies did not account for pre-injury unemployment. At 1 year followup, one study reported 75 percent unemployment; pre-injury unemployment for that sample was 19 percent (Hawkins, Lewis, and Medeiros, 1996). Forty-one individuals had an initial GCS of 3 to 8, suggesting a group with severe impairements, which could account for the high unemployment ratio. The study with the lowest post-injury unemployment ratio retrospectively evaluated 496 survivors up to 20 years after injury (Asikainen, Kaste, and Sarna, 1996). In that sample, 285 (58 percent) had an initial GCS of 3 to 8; post-injury unemployment was 28 percent, with an additional 14 percent working at jobs below the pre-injury standard.

Seven studies used long-term followup to assess community reintegration (Eames, Cotterill, Kneale et al., 1996; Fearnside, Cook, McDougall et al., 1993; Hawkins, Lewis, and Medeiros, 1996; Rappaport, Herrero-Backe, Rappaport et al., 1989; Tennant, MacDermott, and Neary, 1995; Whitlock, 1992; Whitlock and Hamilton, 1995). Type of placement at discharge from inpatient rehabilitation is often used as an indictor of community reintegration. It is difficult to compare the results of different studies because the categories for disposition at discharge vary. Also, a post-injury living status of "alone" may indicate a high level of independence and a successful recovery, or it may indicate social isolation and a decrease in quality of life, so post-injury status without a measure of change from pre-injury may not be an accurate indicator of the effect of the trauma.

To estimate the impact of TBI on community integration, we categorized disposition as either discharged to home or to an institution such as a skilled nursing facility, long-term rehabilitation center, hospital, prison, etc. In six studies that measured this outcome, the proportion of people institutionalized after discharge from inpatient rehabilitation ranged from 6 percent to 52 percent (Eames, Cotterill, Kneale et al., 1996; Fearnside, Cook, McDougall et al., 1993; Hawkins, Lewis, and Medeiros, 1996; Rappaport, Herrero-Backe, Rappaport et al., 1989; Whitlock, 1992; Whitlock and Hamilton, 1995).

A study performed in New South Wales, Australia, had the lowest proportion of institutionalized survivors (6 percent) (Fearnside, Cook, McDougall et al., 1993), perhaps reflecting national, cultural differences that would result in a greater number of people being discharged to home rather than an institution. The highest proportion of institutionalized survivors of these studies was 52 percent (Whitlock, 1992). Of 23 respondents, 11 had returned home and 12 were in skilled nursing facilities at 1 year followup. Comparing the results of these studies, it appears that institutionalization of roughly half of TBI patients persists beyond 1 year.

Injury severity and pre-admission disability affect the probability that a patient will eventually go home as opposed to being institutionalized. In the studies cited above, initial injury severity and pre-admission disability were measured by a wide variety of methods, including FIM scores, GCS scores, length of stay in acute care, PTA (post-traumatic amnesia) duration, coma duration, and novel measures designed by the researchers conducting the investigation, and each sample contained its own mix of severity levels. Given the inconsistencies in measurement and categorization, and differences due to culture and resources, the probability of being in a long-term care facility cannot be estimated from these studies.

One study used the FIM to evaluate outcome at 1 year after discharge from rehabilitation (Hawkins, Lewis and Medeiros, 1996). As measured by the FIM at 1 year after discharge, 43 of 51 survivors (84 percent) were independent in Self Care, 42 (82 percent) in Locomotion, 27 (53 percent) in Communication, and 21 (41 percent) in Cognition. In another study (Whitlock, 1992), 20 of 23 patients improved on FIM scores from admission to discharge. However, for this same group, only 5 improved on the GOS between 6 months and 1 year post-discharge. Seventeen stayed the same (1 was not included in the 1 year assignment). Other studies that used the GOS to estimate functional status present sample proportions with good outcomes ranging from 24 percent to 79 percent (Hawkins, Lewis and Medeiros, 1996).

Predictors of Outcome

A large number of studies have examined the predictive ability of patient characteristics known at the time of admission to inpatient rehabilitation units (Cowen, Meythaler, DeVivo et al., 1995; Lehmann, Steinbeck, Gobiet et al., 1996; Malec, Smigielski, De Pompolo et al., 1993; Saneda and Corrigan, 1992; Spatt, Zebenholzer, and Oder, 1997; Torkelson, Jellinek, Malec et al.,1983; Vilkki, Ahola, Holst et al., 1994; Zafonte, Hammond, Mann et al., 1996). Variables that have been associated with long-term outcomes include a) pre injury characteristics such as diseases, psychological conditions, and social and economic issues; b) age and sex; c) severity of brain injury (site, severity, mechanism of injury, secondary insults such as hypotension or hypoxia, etc);

d) severity and influence of extracranial injuries and complications of acute-care hospital care; and e) the time between the initial injury and the initiation of rehabilitative treatment.

The Glascow Coma Scale (GCS) score is the instrument most intensively studied (Teasdale and Jennett, 1974). This scale, ranging from 3-15 points, reliably and repeatably describes the level of consciousness of the patient with TBI. When it is carefully scored at the completion of resuscitation, it is highly predictive of outcome measured by the Glasgow Outcome Scale (GOS) (Jennett and Bond, 1975) at 3, 6, and 12 months after injury (Braakman, Gelpke, Habbema et al., 1980; Choi, Narayan, Anderson et al., 1988; Levin, Gary, Eisenberg et al., 1990; Marshall, Gautille, Klauber et al., 1991). However, emergency departments vary in who performs the assessment (neurosurgeon versus emergency department staff) and when it is performed (before or after blood pressure and hypoxia are stabilized) (Marion and Carlier, 1994); these variations can affect the ability of the GCS to predict outcome (Bullock, Chesnut, Clifton et al., 1998). Attention to these details has been lacking in the literature to date, even in quasi-experimental studies that use the GCS as a covariate.

In addition to the GCS, four other indicators are useful. A recent evidence-based literature analysis done for the World Health Organization as part of the Guidelines for the Management of Severe Head Injury has outlined the operating definitions of these variables and the optimal methods for their collection and has suggested that they be controlled via multivariate analysis in all subsequent TBI outcome prediction studies (Bullock, Chesnut, Clifton et al., 1998).

Pupils

The status of the pupils (an indicator of intracranial pressure or herniation) helps predict outcome (Marshall, Gautille, Klauber et al., 1991).

Age

Age is usually (Jennett, Teasdale, Galbraith et al., 1979; Vollmer, Torner, Jane et al., 1991; Waxman, Sundine, and Young, 1991; Braakman, Gelpke, Habbema et al., 1980; Choi, Narayan, Anderson et al., 1988) but not always (Reeder, Rosenthal, Lichtenberg et al., 1996) found to predict GOS and function (FIM) after rehabilitation. Age appears to be a primary predictor independent of age-related factors such as systemic illnesses (Vollmer, Torner, Jane et al., 1991).

Systemic Hypotension

The presence of severe systemic injuries is also correlated with worse outcome (Bowers and Marshall, 1980; Klauber, Marshall, Luerssen et al., 1989; Mayer, Walker, Shasha et al., 1981). However, when systemic hypotension occurring during the period between injury and the end of resuscitation is controlled, the influence of systemic trauma drops out (Chesnut, Marshall, Klauber et al., 1993). This suggests that the influence of injuries to extracranial organ systems on outcome from TBI is primarily mediated by the associated hypotension.

Intracranial Computer Tomographic (CT) Diagnosis

It would seem logical that the location, extent, and severity of damage to the brain would be predictive of outcome from TBI. Although prediction studies have correlated outcome with various parameters consistent with severity of brain injury such as skull fracture, intracranial hematoma, or presence of surgical mass lesions (Bergman, Rockswold, Haines et al., 1987; Braakman, Gelpke, Habbema et al., 1980; Jennett, Teasdale, Galbraith et al., 1979; Waxman, Sundine, and Young, 1991), no one has yet demonstrated the expected degree of anatomic specificity in predicting recovery or residual deficits. This may be largely a question of defining the extent of brain injury based on the rather limited technology of computed tomography and magnetic resonance imaging. To date, the Traumatic Coma Data Bank classification of the CT imaging of the brain during the acute-care course is the most promising method of incorporating the anatomical nature of the brain injury into a predictive model (Marshall, Bowers-Marshall, Klauber et al., 1991).

Other variables that have been suggested as predictive of outcome, as measured by GOS, include mechanism of injury (Waxman, Sundine, and Young, 1991), brainstem reflexes (Born, Albert, Hans et al., 1985), evoked potentials (Anderson, Bundlie, and Rockswold, 1984), CSF catecholamines (Woolf, Hamill, Lee et al., 1987), degree and severity of intracranial hypertension (Alberico, Ward, Choi et al., 1987; Jones, Andrews, Midgley et al., 1994; Marmarou, Anderson, Ward et al., 1991), jugular venous desaturation (Gopinath , Robertson, Contant et al., 1994; Jones, Andrews, Midgley et al., 1994; Robertson, Contant, Gokaslan et al., 1992), cerebral perfusion pressure (Gopinath , Robertson, Contant et al., 1994; Jones, Andrews, Midgley et al., 1994; Robertson, Contant, Gokaslan et al., 1992), fever (Jones, Andrews, Midgley et al., 1994), and in-hospital hypotension (Chesnut, Marshall, Piek et al., 1993; Jones, Andrews, Midgley et al., 1994). The statistical independence of these various factors remains to be clearly delineated. It cannot be presently suggested that they be included as potential injury severity confounding variables in rehabilitation studies. When planning such investigations, however, the present state of the literature must be assessed since some of these indices, or variations thereof, may develop as mandated covariables.

Two other indices, duration of PTA and coma, are frequently used in quasiexperimental studies to adjust for severity of injury. Both of these are determined some time following the injury.

The use of PTA originated with Russell and colleagues in the 1930s (Russell, 1932; Russell, 1935; Russell, 1971; Russell and Nathan, 1946; Russell and Smith, 1961). Russell classified injuries with PTA < 5 minutes as very mild; 5-60 minutes as mild; 1-14 hours as moderate; > 24 hours as severe; > 1 week as very severe; and > 4 weeks as extremely severe. In a study of 1,766 patients in 1961, Russell and Smith found the duration of PTA to be the single best predictor of neurological outcome (Russell and Smith, 1961).

In many studies, PTA is measured retrospectively by reviewing patient charts. Unfortunately, retrospective PTA is unreliable (Gronwall and Wrightson, 1980). PTA is best determined prospectively using as an index the attainment of a criterion score (e.g. 85 percent) on the Galveston Orientation and Amnesia Test (GOAT) (Levin, O'Donnell, and Grossman, 1979).

It is difficult to reconcile PTA with the more commonly used GCS score as an index of TBI severity. Using a PTA of > 24 hours as their criterion for the diagnosis of severe TBI, Bishara and colleagues found that 81 percent of such patients attained a good outcome (GOS 4-5) at 1 year (Bishara, Partridge, Godfrey et al., 1992). This contrasts with only 43 percent of patients achieving such an outcome in the Traumatic Coma Data Bank (TCDB) where severe head injury was defined as a post-resuscitation GCS = 8 (Marshall, Gautille, Klauber et al., 1991). Such a discrepancy suggests that these two indices cannot be used interchangeably as they will be predictive of markedly different courses of recovery.

Duration of coma has been used to quantify the severity of brain injury and to predict outcome. Patients in coma for < 20 days frequently regain independence in functional activities whereas those who remain in coma > 20 days are usually profoundly disabled (Jones, 1981; Pazzaglia, Frank, Frank et al., 1975). Like the PTA, duration of coma is unreliable when determined retrospectively and is not interchangeable with the GCS score. In addition, its determination can be confounded by the use of medications which are commonly administered during the care of TBI patients.

Average LOS in acute care after TBI has been used as a gross indicator of the "sickness" of the patient during the immediate, posttraumatic period. More recent studies have reported acute care stays ranging from 20 to 60 days (Lehmkulh, Hall, Mann et al., 1993; Mackay, Bernstein, Chapman et al., 1992; Sakata, Ostby, and Leung, 1991; Sparadeo and Gill, 1989). Unfortunately, this variable is sensitive to socioeconomic issues, which may be difficult to control when using it as an indicator of trauma severity.

The above considerations reveal that the prediction of outcome based on physiologic indicators of TBI remains in a state of active development. At present, a credible attempt to control for (or match on) severity of illness should include the five best physiologic indicators described above. Older studies frequently do not use these indicators, the importance of which was not clearly established until recently. Even today, retrospective analyses are hampered by the lack of reliability and absence of the necessary data in patient charts. Properly approaching this problem in the future will require a coordinated effort in data collection beginning at admission and continuing through rehabilitation wherein common definitions are used throughout.

Methods

Topic Assessment and Refinement

Two panels of experts worked with the research team to identify key questions in the Rehabilitation and Survivor phases for adults with TBI. The first panel was composed of two physiatrists, a survivor of TBI, the wife of a survivor of TBI, a state vocational rehabilitation counselor, a neuropsychologist, a psychologist, a clinical coordinator of an outpatient TBI rehabilitation program, and a rehabilitation clinical nurse specialist, all from the Portland, OR area. The second panel was composed of nationally recognized experts in rehabilitation.

The local panel met twice to establish the scope of the literature review, develop a common understanding of the main concepts bearing on questions of effectiveness in rehabilitation, and identify key questions for investigation. Prior to the first local panel meeting, members were sent a document describing the prevalence, incidence, and burden of illness of TBI and a list of treatment settings and techniques. At the first meeting, one of the investigators explained the use of a causal pathway diagram (Woolf, Battista, Anderson et al, 1990) to enumerate causal links and identify key clinical questions about an intervention. Causal pathways highlight the role of intermediate measures of outcomes, which are often used as proxies for health outcomes in clinical studies and in practice. The format of the meetings was semi-structured to promote free interaction aimed at surfacing issues with respect to TBI rehabilitation among representatives of the various disciplines. Proposed questions and elements of causal pathways were documented and synthesized for review by the national panel.

Prior to the first meeting of the national panel, members were provided the same briefing given the local panel, along with a summary of material generated from that panel's meetings. During the national panel meeting members were asked to consider the proposed questions, add to or delete from the list, and elaborate the revised list of questions. The research team synthesized this second level of input, and distributed draft questions for study to both panels. Panel members submitted revisions to the Task Order Manager, who coordinated input, and continued to distribute new iterations of the questions until consensus was reached.

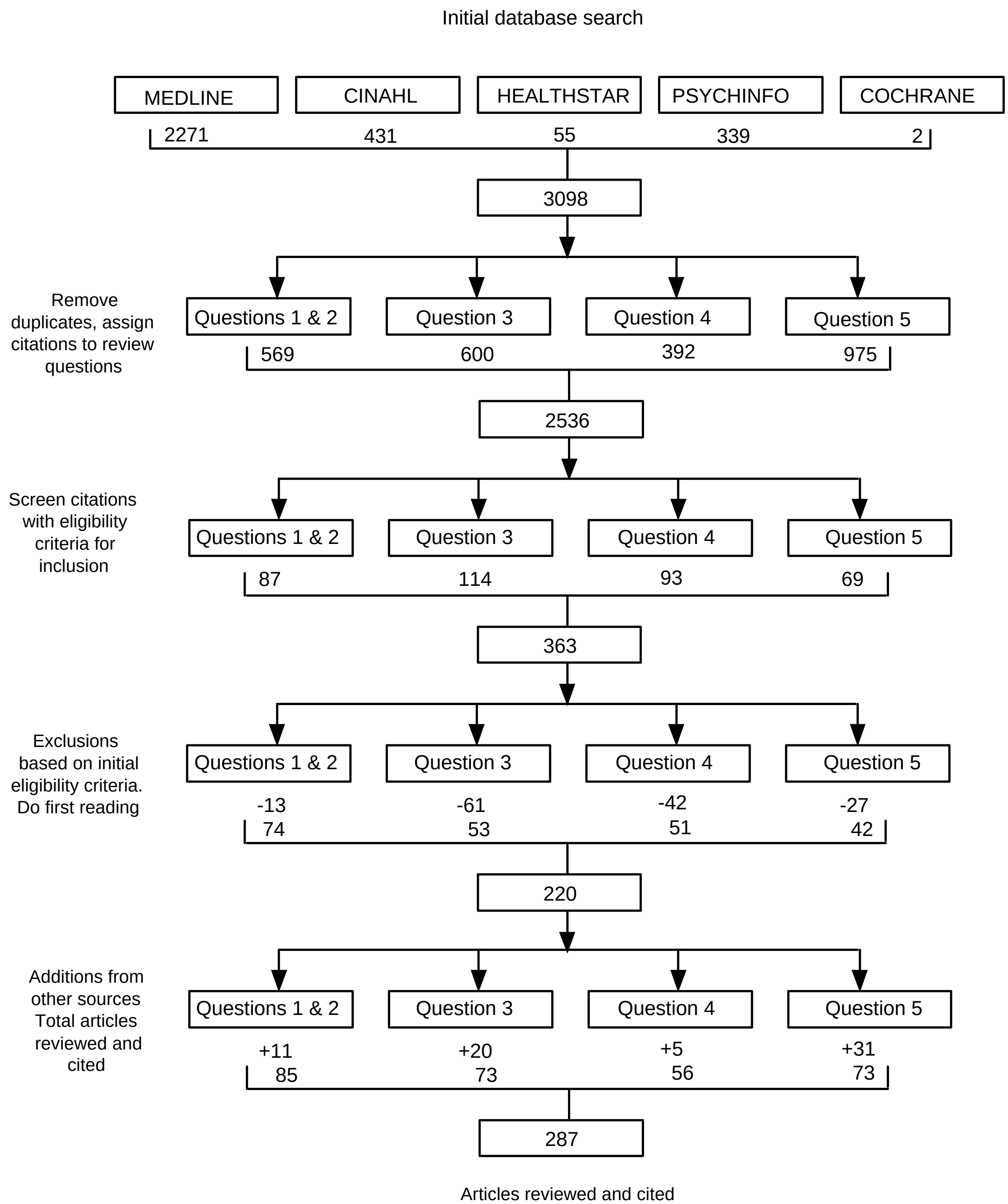
The panels formulated five questions pertaining to the phases of recovery described in Figure 2. These questions addressed the effectiveness of (1) early rehabilitation in the acute care setting (timing), (2) intensity of rehabilitation, (3) cognitive rehabilitation, (4) supported employment, and (5) care coordination (case management). For each of these questions, members of the research team worked with panelists to write a brief rationale for the question, define key terms, and specify the relevant patient populations, interventions, and outcome measures that should be examined in the literature review (Appendix 1). Detailed information for each question is provided in results sections addressing each question.

Literature Retrieval

Literature was searched using MEDLINE, CINAHL, HealthSTAR, and PsycINFO. In addition, the Cochrane Collaboration made available a database of about 500 articles on brain and spinal cord injury. Four MEDLINE search strategies were written. A single strategy was designed to seek references regarding the timing and intensity of acute care rehabilitation (questions 1 and 2). Three additional search strings were used to find articles on the remaining questions (3, 4, and 5). The full MEDLINE database was searched for randomized controlled trials; otherwise, MEDLINE was searched from 1976 to 1997. One additional search strategy, designed to capture literature for all 5 questions, was written for each of the remaining databases used (CINAHL from 1982 to 1997, HealthSTAR from 1995 to 1997, and PsycINFO from 1984 to 1997). The search strings are given in Appendix 2. Finally, we searched the Cochrane database for articles about rehabilitation. We referred to the Current Contents database on a monthly basis between November 1997 and May 1998 to ensure we did not miss new literature that might be relevant.

Figure 3 shows the results of the search. The MEDLINE search retrieved a total of 2,271 references. The CINAHL search retrieved 431 articles, HealthSTAR 55, and PsycINFO 339. Members of the research team read the abstracts from CINAHL, HealthSTAR, and PsycINFO and assigned them to one or more of the five questions. Two Cochrane references were also retrieved (the Cochrane database contained primarily pharmaceutical studies). After removal of duplicates, 2,536 citations remained.

Figure 3. Chart of search and selection of articles for review



Two members of the research team read the 2,536 abstracts and applied the eligibility criteria, which are listed in Table 4. The criteria were designed to be broad and generally inclusive of studies with data from at least a series of persons undergoing rehabilitation for traumatic brain injury. When the two reviewers disagreed, a third reviewer read the abstract and cast the deciding vote on whether to include it. For citations without abstracts or when the title of the abstract was not sufficient to determine its status, the full article was retrieved and reviewed to determine its eligibility. The reviewers examined each abstract and indicated whether it met the inclusion criteria and, if not, the reason for exclusion. Appendix 3 shows the results of a reliability test between reviewers.

Table 4. Exclusion criteria for review of abstracts

General review criteria
Not traumatic brain injury (e.g., carbon monoxide poisoning)
Pediatric
Pharmacology study
Case study
Instrument development
Alcohol/drug use
Stroke
Editorial
Acute care
Foreign language
Question specific review criteria
No data
Methods
Not rehabilitation
Wrong independent variable
Wrong dependent variable

Eighty-seven abstracts pertaining to questions 1 and 2, 114 for question 3, 93 for question 4, and 69 for question 5 passed the eligibility screen. The full text of these articles was retrieved and the articles were reviewed using the data abstraction instrument described below. Each article was assigned one or more categories, such as “longitudinal,” “effectiveness,” “interventions,” etc. (Table 5) Categories were noted in the database for each article, to allow for electronic search of subsets of articles containing specific information.

Table 5. Topics addressed by reviewed articles

Article subject	Review questions				All questions
	Questions 1 and 2	Question 3	Question 4	Question 5	
Population-based study	3	0	1	1	5
Longitudinal study	23	9	17	21	70
Intervention	17	47	27	14	105
Effectiveness	11	7	2	3	23
Measures	22	15	12	25	74
Predictors	10	4	16	10	40
Followup	2	1	9	21	33
Outcomes	0	0	5	3	8
Totals:	88	83	89	98	358

Note: Entries in cells show number of articles dealing with each subject for each review question. Articles may address more than one subject or appear in more than one review question.

Literature Synthesis

Data Abstraction

We designed an instrument to record data abstracted from each eligible article (Appendix 4). The instrument includes items for patient characteristics, interventions, cointerventions, outcomes, study methods, relevance to the specific research questions, and results of the study. The instrument has two components: the first four pages of the instrument apply to all articles specified for inclusion in the study. The remaining pages are individual instruments that apply to one of the five questions. To abstract an article, a reader used the initial abstraction instrument plus one or more of the five question-specific instruments.

The first few questions of the initial abstraction instrument allowed the reviewer to determine if the article actually met the eligibility criteria listed in Table 4. If an article was determined to be ineligible, it was passed to a second reader for confirmation. As shown in Figure 3, 143 articles were eliminated at this phase based on initial eligibility criteria. The remaining 220 articles, plus an additional 67 articles recommended by technical experts or found in the reference lists of reviewed articles (total 287), were subjected to the full abstraction protocol.

Managing the Database of Abstracts and Articles

Retrieved abstracts were kept in an electronic database (EndNotes Plus™). User-defined fields were used to record results of the eligibility screen, review for inclusion, and number of reviews performed. Paper copies of the articles were maintained in a master file. Throughout the literature review process, any articles identified from sources such as bibliographies or reference lists, manual searches of journals not contained in electronic databases, or references recommended by outside parties were added to the electronic databases.

Specification of Level of Evidence

We used a three-level system to rate individual studies:

Class I

• Properly designed randomized controlled trials.

Class II

(a) • Randomized controlled trials that contain design flaws preventing a specification of Class I. An example of a design flaw is failure to blind raters or lack of followup data.

• Multicenter or population-based longitudinal (cohort) studies.

(b) • Controlled trials that were not randomized.

• Case control studies.

• Case series with adequate description of the patient population, interventions, and outcomes measured.

Class III

• Descriptive studies (uncontrolled case series).

• Expert opinion.

• Case reports.

• Clinical experience.

A well-done, prospective, multicenter or population-based cohort study can provide valuable information that, in some ways, is more representative of results in actual practice than are data from a randomized trial done in a highly selected sample. However, an uncontrolled case series is generally classified as Class III, indicating a low level of confidence for inferences about effectiveness.

Why is a control group needed to make inferences about effectiveness? Information about the long-term natural history of TBI provides too little certainty about the outcome to forego the use of a control group. If the consequences of brain injury in the absence of rehabilitation could be predicted accurately, a control group would not be needed. Some evidence suggests a natural course of recovery from TBI in both basic and complex functions (Dikmen, Reitan, and Temkin, 1983), especially in the first 6 months after injury (Bond, 1979; Levin, Benton, and Grossman, 1982; Levin, Gary, Eisenberg et al., 1990). After 6 months, survivors of TBI recognize their disabilities as they stabilize and often maximize their functional status, but major deficits in social and leisure activities tend to persist (Oddy and Humphrey, 1980).

A "gray zone" exists between Class II and definite Class III articles. Much of the research in rehabilitation uses quasiexperimental designs. In these observational study designs, control groups are sometimes identified from a separate population of people with TBI. One study compared patients undergoing inpatient rehabilitation to a sample of persons with TBI who had been treated in a region of the country where formal inpatient TBI rehabilitation was not available (Aronow, 1987). This was an entirely separate patient group and all the data except outcome measures came from an independent database.

The main difficulty with the quasiexperimental design is lack of control over the constitution of the compared groups. Since there is no randomization and generally no control over the details of the selection process through which the study participants received their separate therapies, the groups are likely to differ in the frequency of characteristics that are associated with the outcomes of interest. Even when significant efforts are made to match the experimental and the quasi-control groups, groups are still likely to differ significantly.

Quasiexperimental designs rely heavily on multivariate statistical analysis and matching to counter this problem. While this is common practice, making inferences about effectiveness from statistically controlled data is controversial, because these methods do not necessarily guarantee that the results are reliable or that serious bias and confounding have been eliminated. There are at least three major barriers to accuracy in the practice of statistical adjustment for risks. First, all of the confounding variables must be recognized and be associated with accurate and reliable measurement instruments. Second, data on all of these confounding variables must be available in comparable formats in the compared groups. For example, in the study mentioned earlier, baseline data, such as admission functional status scores, may be available for patients who entered inpatient rehabilitation, but missing for patients who did not. Third, statistical methods must be selected and applied properly.

Since the first two barriers are virtually never overcome, and the third remains somewhat controversial, the execution of a statistically valid quasi-experimental study is a daunting and generally unrealized task. Most studies using retrospective data suffer from the absence of well-measured data on a number of important confounding variables. The few prospective studies generally suffer from a lack of consensus on the proper measurement instruments for many of these variables. Finally, while the standard of practice for use of statistical methods to remove confounding is not completely defined, many studies do not use, or fail to report, available methods to improve the reliability and robustness of these methods.

Much of the literature relevant to the five questions addressed in this effort falls into the "gray zone" between Class II and Class III. For this reason, critical appraisal of key studies plays a particularly important role in this review. A number of characteristics of these studies were considered relevant to all rehabilitation questions and were recorded in the data abstraction form. Evaluation of the following factors played a major role in critically appraising these articles:

- Prospective collection of data.
- Complete description of parent patient population.

- Large study population size (driven by hypothesis, power, type I error threshold).
- Study setting—a single center, many centers, or population-based.
- Descriptions of reasons for referral to service being studied.
- Methods described completely enough to allow study replication.
- Complete description of rehabilitation technique in question (independent variable).
- Complete and adequate description of differences between “control” and “experimental” groups.
- Conditions determining whether they did or did not receive the rehabilitation technique in question.
- Information about potential confounders, including types and severity of injury; age; and others (including, in some cases, economic status, educational level, lack of family support).
- Measurement of confounding variables using instruments validated as accurate, sensitive, and reliable.
- Payer group.
- Choice of outcome variables that is meaningful to survivors as well as caregivers.
- Use of functional status and other health outcomes rather than surrogate intermediate outcomes.
- Measurement of outcome variables using instruments validated as accurate, sensitive, and reliable.
- Timing of outcome measurements.
- Assessment of survivor characteristics and outcomes by blinded observer.
- Use of multivariate statistical analysis: Were interactions sought and controlled for? Were risk estimates calibrated? Were all relevant confounders included as candidate variables?

The criteria used to classify articles and the features to be considered in critically appraising them were discussed at the subcommittee, committee, national expert panel, and Aspen Neurobehavioral Conference levels with the goal of maintaining consensus on at least the relative stratification of individual articles.

Construction of Evidence Tables

Evidence tables were constructed to summarize the best evidence about effectiveness pertaining to each question. For questions 1 and 2, there were no randomized trials, and only a few quasiexperimental studies. There were a large number of relevant observational studies of important relationships (for example, the relation of survivor characteristics to outcome); while we discuss these results, we chose not to summarize studies that concerned individual causal links or relationships in evidence tables. For question 3, addressing cognitive rehabilitation, 15 randomized controlled trials and comparative studies that met specified inclusion criteria (see the section on question 3) were placed into evidence tables. All comparative studies located for the last two questions, which addressed supported employment and care coordination, were included in evidence tables.

Critical Appraisal of Key Articles

For each of the five questions we formed subcommittees of one to two members of the research team and one to two members of the local technical panel. A member of the research team chaired each subcommittee. The principal investigator also led subcommittees consisting of members of the national expert panel. All members of the subcommittees reviewed key articles relevant to the assigned question. These reviews were discussed among the various members of the subcommittees, and the results summarized by the chair. This was an effort to ensure that the summary statements on the research questions reflected the expertise and experience of a variety of technical experts with relevant skills and training. These interpretive efforts addressed the methods and results of individual studies, their rating, and their scientific importance.

The principal investigator individually read all of the critical articles for the five questions. Summaries were presented and discussed with national experts at the Aspen Neurobehavioral Conference in April 1998 (see Appendix 6).

Results

The results are presented in five sections, one for each of the questions listed in Appendix 1. When neccesary, we provide additional information about background and methodology before the discussion of results for each section.

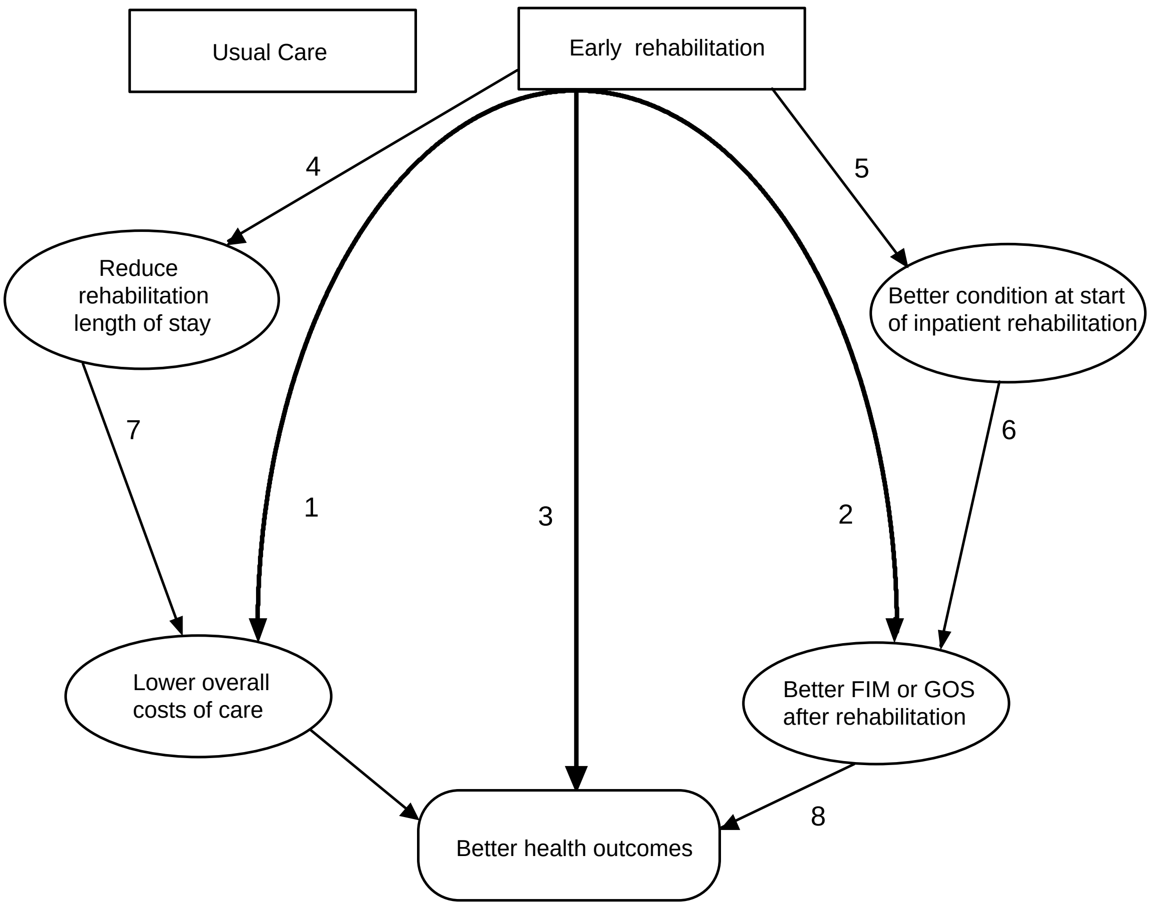
Question 1: Should interdisciplinary rehabilitation begin during the acute hospitalization for traumatic brain injury?

It is widely accepted that patients with severe head injury should undergo a course of inpatient rehabilitation immediately after discharge from the acute care hospital. A retrospective study demonstrated that patients admitted to rehabilitation units less than 35 days after injury required less rehabilitation than patients admitted more than 35 days after injury to achieve the same functional level (Cope and Hall, 1982). This study raised the question of whether interdisciplinary rehabilitation should be started earlier than was customary.

Early neurological rehabilitation means starting rehabilitation of brain damaged patients as soon as possible during the acute phase of the trauma or illness, often while the patient is still unconscious. The components of early rehabilitation might include a multidisciplinary family conference, and a baseline assessment by a physiatrist, an occupational therapist, a physical therapist, and, when the patient is conscious or has a tracheotomy, a speech therapist (Sherburne, 1986).

Figure 4 shows a causal pathway linking early rehabilitation to potential benefits. Direct comparisons of early rehabilitation to usual care in randomized trials (represented by arcs 1, 2, and 3) would provide the strongest evidence about costs and effectiveness. Because such evidence is not available, the effect of early rehabilitation on costs and outcome must be inferred from indirect, observational studies of each causal link. In general, the opportunities for bias and confounding make it hazardous to make inferences about effectiveness from observational studies (High, Boake, and Lehmkuhl, 1995).

Figure 4. Causal pathway for early neurological rehabilitation in the acute hospital setting



Note: FIM = Functional Independence Measure
GOS = Glasgow Outcome Scale

The remaining arcs represent indirect evidence. On the left of the figure, the first link in the causal chain is that early rehabilitation might reduce the total length of stay for the acute admission and rehabilitation combined (arc 4). The next link is that a lower length of stay would reduce the total costs of care (arc 7). On the right, the first link is that, after early rehabilitation, patients will be discharged to the inpatient rehabilitation service in better condition than in usual care (arc 5). The next link is that, as a result, scores on functional assessment instruments at the end of rehabilitation will be the same or better as in usual care, despite the lower length of stay (arc 6). An implicit assumption, indicated by arc 8 in the figure, is that better scores on these assessments translates into better health outcomes after discharge from the rehabilitation unit.

While such evidence cannot ever be as strong as evidence from a well-conducted experimental trial, certain methods of study design or of analysis can improve the reliability of the findings. First, the baseline characteristics of the patients in the compared groups should be described in detail using reliable measures of severity, comorbidity, and other information that might be associated with the outcome of interest. At a minimum, these measures are age, GCS scores and indicators of severity and mechanism of injury, of multiple injuries, and pre-injury function. Second, matching, stratification, or statistical adjustment for these risk factors should be used to minimize the influence of confounders on the study's observed results. We used these study characteristics as inclusion criteria to identify high quality studies of the relations depicted in the causal pathway. Third, the study must report at least one relevant outcome measures, such as

- Presence or absence of complications.
- Length of stay in the hospital.
- Immediate care costs and long term financial burden.
- Health status at discharge from the acute care hospital.
- Long-term measure of impairment.
- Long-term measure of disability.

Of the 87 abstracts that passed the eligibility screen and were assigned to Questions 1 and 2, 14 were potentially relevant to the timing of intensive rehabilitation. Of these, two were review articles, three were studies that contained no original data (Johnson and Roethig-Johnson, 1989, Kock and Fuhrmann, 1992, Kosubek, Feldmann, and Schwendemann, 1996), and one was a case report (Sherburne, 1986). The eight articles remaining are discussed below.

Direct Evidence

There is no direct evidence from randomized trials about the effect of early neurological rehabilitation on health outcomes.

Indirect Evidence

Comparative studies. No prospective, randomized controlled trials of the effects of early rehabilitation on length of stay, condition at the time of entry into a rehabilitation unit, or long-term costs have been done. Moreover, no nonrandomized (observational) controlled study fully met the criteria described above.

Mackay and colleagues (Mackay, Bernstein, Chapman et al, 1992) conducted the premier study of integrating formal rehabilitation into the acute-care setting. While the study has serious limitations, it is the only study to compare groups that clearly received different rehabilitation interventions during the acute phase of TBI (see Evidence Table 1). The authors looked retrospectively at 38 severely injured patients (GCS 3-8 on admission at the trauma center) consecutively discharged from impatient rehabilitation between 1984-90. These patients had been transferred from 11 different acute care hospitals. “Non-formalized acute rehabilitation” was performed at 10 hospitals. Acute, formalized early rehabilitation was performed at a single hospital. Formalized trauma rehabilitation was described as:

> "...evaluation and treatment on admission to the acute hospital by a physiatrist, physical therapist, occupational therapist, and speech and language pathologist. This intervention, which continued throughout the acute admission, involved structured multisensory stimulation, orientation, exercise, and positioning to decrease posturing and help prevent contractures and sensory deprivation. Goal-oriented treatment was provided by using a variety of early intervention approaches from both a rehabilitative and preventive framework.”

This program was initiated very early at the formalized rehabilitation hospital, uniformly beginning while patients were in coma an average of two days after admission. At the 10 “non-formalized acute rehabilitation” hospitals, therapy was started during coma in 42 percent, an average of 23 days after admission. For the “non-formalized" group, 14 percent received only physical therapy, 65 percent received no speech therapy, and 14 percent received no rehabilitation at all.

Severity of injury was rated using GCS score, injury severity score (ISS), RLA score, pupillary and pain responses, CT scans, associated injuries, and surgical interventions. The main outcome variables were length of stay at the trauma and rehabilitation hospitals and condition on discharge from the rehabilitation unit (length of coma, RLA at discharge from acute care and rehabilitation).

The authors found that the patients in the formalized treatment group had coma durations and rehabilitation stays about one-third the length of patients in the non-formalized group. There was no difference in acute hospital LOS. The acute LOSs were 50 to 60 days. The rehabilitation LOSs were 106 days for the formal system and 239 days for the non-formal system, giving rather long total mean LOSs of 158 days and 303 days respectively. Physical/motor, sensory/perceptual, and cognitive/language outcome were better for the formalized group. These were scored using a specified but non-standardized rating system. The differences in length of coma, rehabilitation LOS, total LOS, and RLA at discharge from the acute hospital remained large and statistically significant after statistical adjustment for the initial GCS and RLA scores.

Is it plausible that the provision of comprehensive rehabilitation during coma could reduce the average length of coma by 35 days? The patients in the compared groups were similar in age, associated injuries and initial GCS, ISS, and RLA scores. However, other predictors of a long length of stay in rehabilitation, such as more detailed head CT findings (Cowen, Meythaler, DeVivo et al., 1995), extremity fracture, and FIM scores (High, Hall, Rosenthal et al., 1996), were not recorded. As others have pointed out (High, Boake, and Lehmkuhl, 1995), the sample consists of 38 patients recruited over 6 years.   It is not clear whether the 38 patients in the study are representative of patients with severe head trauma generally.

A major weakness of the paper is that the results are reported only as means for the compared groups, making it impossible to determine how many patients in the formal early rehabilitation benefited. Because of the small sample size, it is possible that the very large difference in length of stay reflects the influence of one or more outliers in the group that did not receive formal early rehabilitation. Moreover, no information is provided about the reasons for the longer LOS in this group, so the mechanism by which early rehabilitation might have affected rehabilitation LOS is not clear.

Does earlier transfer to a rehabilitation unit affect rehabilitation LOS (arc 4)? A number of studies have examined whether early initiation of rehabilitation during the acute hospitalization for TBI is associated with a shorter rehabilitation LOS. The evidence presented in these studies is indirect, because early transfer to a rehabilitation unit is not the same, or even necessarily similar, to initiating rehabilitation in the days immediately following stabilization after injury.

As mentioned earlier, Cope and Hall (1982) retrospectively analyzed the influence of early rehabilitation on hospital LOS and costs. They arbitrarily defined the threshold dividing early and late as 35 days based on the median interval between injury and admission for their overall patient group. They matched two groups of patients (16 early and 20 late patients) for length of coma and analyzed other variables between groups including age, acute GCS (assigned retrospectively), DRS and GOS at entry to rehabilitation, evoked potentials, continence, social status, and physiological impairment (rated on an unspecified set of tests). None of these differences were statistically significant by t-statistics but they did not use multivariate analysis.

Acute hospitalization days, acute-rehabilitation days, and total hospital days were all statistically significantly longer in the delayed-rehabilitation group. Total hospital stay was over twice as long. Of interest, when they looked at outcome measures at the time of discharge, both the DRS and the GOS appeared similar, suggesting that the patients reached a comparable level of recovery at the time of discharge.

As the authors noted, the most important limitation of this study is that the ability to match the compared groups is very limited. It seems likely that rehabilitation was started earlier in some patients because they were doing better to begin with. In addition, as in Mackay's study, only mean LOSs were reported, so it is possible that a few outliers were responsible for the large differences observed. In general, most patients who have a shorter acute hospital LOS go home, while those who have a longer LOS are more likely to enter a rehabilitation unit (Andersen, Sharkey, Schwartz et al., 1992). This raises a question of a potential bias (the "Will Rogers phenomenon") that, among patients who have similar admission GCS scores, those who are discharged early are likely to be healthier than those who are not.

Five studies have used multivariate analysis methods to identify factors associated with a long rehabilitation LOS (Andersen, Sharkey, Schwartz et al., 1992; Cowen, Meythaler, DeVivo et al., 1995; High, Hall, Rosenthal et al., 1996; Rappaport, Herrero-Backe, Rappaport et al., 1989; Spettell, Ellis, Ross et al., 1991). Four of these studies found an association between early initiation of rehabilitation and a shorter rehabilitation LOS. In one study of 59 patients with severe injuries from a single rehabilitation facility, gender, GCS motor score, and acute LOS provided the best prediction of rehabilitation LOS, accounting for 34 percent of the total variance in a stepwise regression model (Spettell, Ellis, Ross et al., 1991). After controlling for acute LOS, duration of coma was no longer an independent predictor of rehabilitation LOS. A study of 91 patients admitted to a single university inpatient rehabilitation center had similar findings (Cowen, Meythaler, DeVivo et al., 1995). In that study, which included patients with mild, moderate, and severe injuries, admission FIM motor score and the length of the acute hospitalization were the strongest predictors of rehabilitation LOS.

A larger, prospective study of 525 patients in the TBI Model Systems sample confirmed some of these findings. The study examined the association between initial severity of TBI, rehabilitation admission FIM, neurologic and extracranial medical complications, mechanism of injury, and payer source in predicting hospital LOS and charges (High, Hall, Rosenthal et al., 1996). Patients' initial presentations ranged from mild to extremely severe and were generally skewed toward the severe end of the scale. Patients with lower GCS scores reached rehabilitation later, stayed longer, and generated higher charges than less severely injured patients. For patients within a given TBI severity, rehabilitation LOS and costs increased as acute hospitalization LOS and rehabilitation admission FIM increased. The effect of the admission FIM score was a very powerful predictor of rehabilitation LOS. For example, patients who had a GCS of 8 or less and an average FIM score ≤ 2.5 had an average rehabilitation LOS of 70 days, while patients who had a GCS of 8 or less and an average FIM score ≥ 4.5 had an average LOS of 21 days. In a regression analysis, acute care LOS was an independent predictor of rehabilitation LOS, along with GCS, average admission FIM, duration of coma, and medical complications. Together these variables explained 50 percent of the variance in rehabilitation LOS. However, because the portion of explanatory power attributable to acute care LOS was not reported, it is not clear how strongly these results support the view that acute care LOS is a major determinant of rehabilitation LOS.

In this study, age did not correlate with rehabilitation LOS and was not included in the regression models. However, another study performed in the same group of patients found that older patients had much longer rehabilitation LOS than younger patients (89 days versus 55 days), even though acute LOS was not significantly different in the two groups (Cifu, Kreutzer, Marwitz et al., 1996). These observations suggest that the relation between acute LOS, admission functional status, GCS scores, age, and other factors are complex. As a result, the relation between acute LOS and rehabilitation LOS may apply only within certain subgroups of patients. As mentioned before, the complexity of these relationships makes it difficult to interpret the results of Mackay's observational comparative study. For example, inclusion of only a few severely injured, older patients with a low admission average FIM could substantially skew the results in one of the compared groups.

Does early rehabilitation reduce total costs (arc 7)? No studies have examined the relationship between acute hospital LOS and the long-term costs of rehabilitation. In two of the studies discussed above (Cowen, Meythaler, DeVivo et al., 1995; High, Hall, Rosenthal et al., 1996), longer acute care LOS was associated with higher inpatient rehabilitation charges, but these studies did not examine direct costs or costs of care after discharge from the rehabilitation unit.

Does early intervention affect outcome (arcs 5 and 6)? Only a few studies have examined the association between acute hospital LOS and short- or long-term outcomes of rehabilitation. Two of the studies discussed above addressed whether a acute hospital LOS predicts short- or long-term outcomes of rehabilitation. In one study, after adjustment for other risk factors, a longer acute hospital length of stay was mildly associated with a lower GOS score within 11 months of injury (Spettell, Ellis, Ross et al., 1991). This association was statistically significant but was too small to be considered clinically important. In the other study (Cowen, Meythaler, DeVivo et al., 1995), a longer acute hospitalization was associated with a lower FIM motor and cognitive scores at the time of admission to rehabilitation. A longer acute hospitalization and a lower admission FIM motor score were also associated with lower discharge FIM scores.

Does early rehabilitation improve decisionmaking about transfer to a rehabilitation facility? Hospital bed days in the acute trauma hospital are frequently used by patients waiting for transfer to an appropriate rehabilitation or chronic care facility (Andersen, Sharkey, Schwartz et al., 1992). Apart from its effect on LOS and condition on admission or discharge from a rehabilitation unit, early involvement of a physiatrist into the acute-care trauma team might have other benefits. In theory, early involvement by a physiatrist could improve the process of initiating and supervising the application rehabilitation techniques as the indications arise for such interventions. As mentioned earlier, in a large, regional retrospective study, patients seen by a physiatrist in the acute-care setting were much more likely to be provided post-acute rehabilitation than patients whose discharge planning team did not include a physiatrist (Wrigley, Yoels, Webb et al., 1994). While it is not known whether this influence has a positive effect on outcome, it does suggest that formalized early neurological rehabilitation in the acute care setting might have the benefit of optimizing rehabilitative care after discharge.

Conclusions

One small, retrospective, observational study from a single rehabilitation facility supports an association between the acute institution of formalized, multidisciplinary, physiatrist-driven TBI rehabilitation and decreased length of stay (acute hospital and acute rehabilitation) and some measures of short-term physiologic (non cognitive) patient outcome. The level of evidence is Class III. This study concerned patients with severe brain injury (GCS 3-8); there is no evidence from comparative studies for or against early rehabilitation in patients with mild and moderate injury.

Some indirect evidence also confirms that early rehabilitation is associated with a shorter inpatient rehabilitation LOS, but this association rests on important assumptions that have not been examined in prospective studies. Most importantly, the association of acute LOS with rehabilitation LOS and greater rehabilitation costs does not directly imply that shortening acute LOS will result in favorable changes in these outcome measures. A common confounding variable in these studies is the inability to control for the possible correlation between the velocity of recovery and the acute hospital LOS. Patients with TBI who have similar GCS scores on admission may recover at markedly different rates. If a patient evidencing rapid recovery reaches threshold for rehabilitation admission and continues to recover quickly thereafter, his acute, rehabilitation, and total LOS days will be less than someone who reaches the same landmark at a slower rate. Because present indicators of TBI severity do not measure rate of recovery, this oversight might explain why the relation between acute LOS and rehabilitation LOS persists even after statistical control for severity of illness on admission.

These studies also found that rehabilitation admission FIM and acute care LOS are strongly associated with rehabilitation LOS and outcome. This finding suggests that acute hospitalization LOS is not simply a proxy for injury severity or level of recovery on transfer to rehabilitation.

Future Research

In essence, this question addresses the efficacy of starting formal rehabilitation efforts very early during the acute-care stay at the trauma center as opposed to “filling in” until the patient is transferred to a rehabilitation program. Certain therapeutic modalities such as physical therapy are generally felt to be properly started soon after admission because of the known rapidity with which complications such as contractures begin. Although the details of the proper techniques, timing, and intensity of such treatment remain to be determined, it is unlikely that a control group of patients that would receive no acute physical therapy could be ethically formed. Although the indications for early application of other rehabilitation-oriented therapeutic modalities are less clear, similar ethical constraints will likely prevent the development of pure control groups for any specific discipline.

The ability to study the efficacy for a formalized program, however, is not subject to such constraints at the present time. The concept of the acute initiation of formal rehabilitation should be defined as an attempt to begin rehabilitation independently of the patient's location or other extraneous constraints such as medical complications, bed availability, etc. Such a formalized system is an attempt to "blur the line" between the stay at the trauma center and the time at a rehabilitation center. It would attempt to divorce the treatment from the milieu and drive it directly based on the patient.

As such, the integration of such a formalized program into an acute care centers operating procedures could be effected in a prospectively randomized fashion without ethical constraints. Since such rehabilitation efforts properly come under the aegis of a physiatrist, the primary independent variable would be the involvement of a physiatrist overseeing explicit formalized application of rehabilitation techniques to the "experimental" group as compared to continuation of the status quo in the "control group." The dependent variables would be acute care and rehabilitation LOSs, outcome at time of discharge from acute care (admission to inpatient rehabilitation), outcome at discharge from rehabilitation, and cost-effectiveness of resource utilization.

For such an investigation to work, patients would have to be classified into working categories at a very early stage so that formalized and standardized rehabilitation protocols that meet their needs could be applied to them. If every patient is treated differently, it will not be possible to control for the resultant confounding of treatment variables with the independent variable. On the other hand, since different patients need different spectra of therapeutic modalities (differing in terms of treatments, timing, and intensity), managing all patients in the same fashion would not be proper. Therefore, if such research is to be useful, such issues must be addressed prior to onset of the investigation.

It will also be necessary to strictly define the applied therapies since these will be confounding variables in the analysis. Issues such as timing, intensity, modalities, therapist training, milieu, etc.

will need to be standardized within and between treatment groups. This will be especially critical if multiple centers are included in such a study and combined in the data analysis.

Such a study will not address which modalities should be applied at what point during the acute care stage. These are separate questions addressing the efficacy of rehabilitation modalities in general. The above suggested investigation will, however, address the present, seemingly artificial dependence of the initiation of formal rehabilitation on extraneous variables that commonly occur during the early postinjury period.

Question 2: Does the intensity of inpatient interdisciplinary rehabilitation affect long-term outcomes?

After discharge from an acute care hospital, many persons with TBI are admitted to an inpatient facility for intense multidisciplinary rehabilitation. It is widely acknowledged that the evidence supporting the effectiveness of inpatient rehabilitation is weak. A recent review identified eight studies published between 1984 and 1994 on the benefit of inpatient rehabilitation immediately or soon after discharge from an acute care facility (not including studies of "early" rehabilitation discussed in the preceding section) (Hall and Cope, 1995). Of the eight studies, three had control groups. Only one study used a control group that did not undergo inpatient rehabilitation. Two studies compared patients who underwent inpatient rehabilitation to those who underwent inpatient rehabilitation plus an additional intervention. Of the five uncontrolled studies, two compared measures of patients' function before and after rehabilitation, and three examined the relationship between the intensity of rehabilitation services and outcomes.

A large number of older uncontrolled case series document that patients who participate in a comprehensive, multidisciplinary rehabilitation program after TBI improve on a variety of measures, including independence in ADLs (Cope and Hall, 1982), language skills (Basso, Capitano, and Vignolo, 1979; David, Enderby, and Bainton, 1982; Lomas and Kertesz, 1978; Sarno, 1976), vocational functioning (Dresser, Meirowsky, Weiss et al., 1973), and neuropsychological functioning and emotional adjustment (Pazzaglia, Frank, Frank et al., 1975).

The methodologic limitations of these studies have been reviewed elsewhere (High, Boake, Lehmkuhl et al., 1995).

Do these observational studies provide sufficient evidence that inpatient rehabilitation is an effective intervention? Because they are uncontrolled, these studies cannot prove that the improvements observed would not have occurred anyway, in the natural course of recovery from injury. Older series of untreated survivors of TBI strongly suggest that avoidable complications occur frequently among candidates for rehabilitation who are not admitted to an inpatient rehabilitation unit following discharge from an acute care hospital. A study performed in 1969, for example, followed 102 persons with TBI whose average length of coma was three weeks and whose entry into rehabilitation was delayed an average of 20 months post-injury. These individuals exhibited 30 frozen shoulders, 40 major decubitus ulcers, and approximately 200 other major joint deformities. Rehabilitation efforts in these patients produced significant reversals of these deficits. As the authors argued, however, it is likely that these complications could have been prevented by appropriate admission to a rehabilitation unit following discharge from the hospital (Rusk, Block, and Lowman, 1969).

While it is widely accepted that "doing nothing" is neither a reasonable nor ethical option, many questions remain about the effectiveness and cost of inpatient rehabilitation. How does inpatient rehabilitation compare with modern alternatives, such as outpatient rehabilitation or rehabilitation in a skilled nursing facility? Which components of multidisciplinary rehabilitation are actually responsible for the observed effects? What are the characteristics of the patients that have better results with the application of intensive, interdisciplinary rehabilitation? Does the intensity of rehabilitation services affect long-term outcomes? When should a course of inpatient rehabilitation end?

Challenges in Assessing the Effectiveness of Inpatient Rehabilitation

A precise knowledge of the natural, untreated prognosis of brain injury could reduce uncertainty about the effectiveness of inpatient rehabilitation, but such knowledge is lacking. Because experimental trials of inpatient rehabilitation are unlikely to be performed, investigators have relied on statistical methods to adjust for differences in the baseline characteristics between the groups of patients compared in studies. These groups might be patients who received different intensities of rehabilitation services, who received rehabilitation services relatively early or late, or who did not receive rehabilitation in the usual course of care. The validity of these methods depends in large part on the predictive ability of the risk factors measured in these studies.

As discussed below, the likelihood of a good outcome depends on many patient characteristics. For this reason, it is impossible to interpret studies which fail to describe the baseline characteristics of the sample under study. In such studies, it is not clear whether the results were due to the interventions under study or to unreported selection factors. Two extremes characterize these studies with respect to the description of populations and samples. On one hand, it is common to have a sample described as "patients who were considered ready for (the intervention) by their occupational therapists" or "consecutive referrals to a vocational rehabilitation program who were considered employable under the right circumstances." On the other hand, the inclusion criteria for the sample may be a lengthy list of narrow parameters, including scores falling within a specific range on a series of neuropsychological tests. In one case, there is no description of the patients. In the other, the description is so specific that the results do not apply to the greater proportion of patients.

The nature of rehabilitation makes it difficult to evaluate its effectiveness. Multidisciplinary rehabilitation is a complex intervention. Even in studies which provide evidence that patients undergoing rehabilitation improved, it usually is not possible to determine which specific components of rehabilitation are effective. In general, little description of the precise components of multidisciplinary rehabilitation programs is available. Some studies use the number of hours of performance of individual treatment modalities (e.g., physical therapy, occupational therapy, speech therapy, etc.) as a measure of the intensity of rehabilitation. However, additional hours of specific treatments may be provided to patients who enter rehabilitation with more severe deficits.

In addition, their control for the confounding variables that they collected would have been considerably strengthened by the use of multivariate statistical methods such as regression analysis. Even without this confounding, an aggregate measure like time spent with the patient cannot capture the social factors and relationships that can be important components of the therapeutic process.

At present there is no reliable method to measure the effect of exposure to the milieu of the rehabilitation program—the interactions between patients and other patients, nurses, therapists, and physiatrists during the course of an inpatient TBI rehabilitation stay—or to separate their effects from the content of the actual therapy provided. Such information may be critical when attempting to determine whether an inpatient rehabilitation unit or a skilled nursing facility may be interchangeable for a given patient.

Most studies do not provide even descriptive information about the components of rehabilitation and the content of specific interventions.   In these studies, rehabilitation is somewhat of a black box—it is defined, by default, as whatever happens between admission to and discharge from a rehabilitation unit. The lack of detail about what constitutes rehabilitation reduces the generalizability of each study's findings, and makes it difficult to compare the results of different studies of the effectiveness of rehabilitation.

In formulating a strategy for reviewing the literature, we focused on whether information was available to examine the actual mechanisms by which inpatient TBI rehabilitation affects outcomes. Specifically, we sought to examine whether the results of rehabilitation vary with (1) whether the intervention was directed and managed by a physiatrist and (2) the number, kinds, and frequency of methods applied. Secondarily, we sought to examine what factors predict a good outcome and how these factors may be used in decisions about how and when patients might benefit from inpatient rehabilitation.

The population for this question consists of persons who sustained TBI between the ages of 18 and 65 years whose injury severity warranted admission to a hospital emergency department, transfer to acute care, and subsequent transfer to in-patient rehabilitation. We also intended to focus most attention on studies that included or measured the following patient characteristics:

- Age.
- Glasgow Coma Scale score.
- Severity of injury.
- Multiple injuries.
- Premorbid data.
- Mechanism of injury (kind of trauma).
- Intracranial diagnosis.
- Functional status.

Finally, studies had to report one or more of the following outcome measures:

- Length of stay in rehabilitation facility.
- Immediate care costs and long term financial burden.
- Health status at discharge from inpatient rehabilitation.
- Long-term measure of impairment.
- Long-term measure of disability.
- Independence, relationships, family life, satisfaction.

Of the 87 papers included for review of questions 1 and 2 (see Figure 3), 57 had some relevance to question 2. Of these, 10 primarily addressed predictors of outcome, 22 were uncontrolled followup studies of inpatient rehabilitation, and 20 examined the usefulness or validity of various measures of outcomes. Five studies, which were controlled or quasiexperimental studies that addressed the effectiveness or the intensity of inpatient rehabilitation, are discussed in detail in the following sections.

How effective is acute inpatient TBI rehabilitation in general?

Before addressing whether the intensity of inpatient TBI rehabilitation is associated with improved outcome, we examined the more general question of the effectiveness of TBI rehabilitation itself. A large number of uncontrolled case series show that people with brain injuries generally improve by the time of discharge from the acute inpatient rehabilitation facility (Ashley, Persel, and Krych, 1993; Basso, Capitani, and Vignolo, 1979; Ben-Yishay, Silver, Piasetsky et al., 1987; Cope, Cole, Hall et al., 1991; Cope and Hall, 1982; David, Enderby, and Bainton, 1982; Dresser, Meirwosky, Weiss et al., 1973; Eames and Wood, 1985; Evans and Ruff, 1992; Johnston, 1991; Jones and Evans, 1992; Lomas and Kertesz, 1978; Malec, Smigielski, DePompolo et al., 1993; Mills, Nesbeda, Katz, et al., 1992; Panikoff, 1983; Pazzaglia, Frank, Frank, et al., 1975; Prigatano, Fordyce, Zeiner et al., 1984; Sarno, 1976; Scherzer, 1986; Tuel, Presty, Meythaler et al., 1992). Because of imperfect knowledge of the natural history of TBI, and the nearly complete absence of data about the results of alternative methods of rehabilitation after discharge from the acute care hospital, these Class III studies provide only weak evidence that inpatient rehabilitation is effective. Comparing these studies, and aggregating their results into a systematic examination of results, was not possible because data were too incomplete to discern the relationship between types of population or interventions and outcomes.

One quasiexperimental study used an unmatched control group to assess the effectiveness of acute inpatient TBI rehabilitation (Aronow, 1987). Sixty-eight patients were selected from 107 consecutively discharged patients treated at a single inpatient brain injury rehabilitation center. Their long-term outcomes were compared with those of 61 patients selected from 1,400 cases consecutively entered into an epidemiologic TBI database of inpatients at a neurosurgical unit in an area of the country with no comprehensive rehabilitation available for severe TBI. These two groups were termed “rehabilitation” and “non-rehabilitation,” respectively. The selection criteria were TBI (>1 hour of unconsciousness and >24 hours of altered consciousness), age at injury between 5 and 80, acute hospital LOS >15 days, and not comatose at the time of acute hospital discharge.

Measures of TBI severity were PTA, acute hospital LOS, presence or absence of open brain injury, and number of skull fractures. Age, sex, race, and years post injury were measured as confounding variables. TBI severity and the other potentially confounding variables were controlled for by using regression analysis, entering the confounding factors into the model prior to adding the rehabilitation versus no rehabilitation variable. The outcome measure was a 13-variable measure that included vocational status, living arrangement, number of recent inpatient treatment episodes, number of recent outpatient episodes, hours of daytime care required, functional status in self-care, mobility, and residential skills, number of home and outside social contacts, and number of physical cognitive, and emotional symptoms. This standardized outcome measurement was developed unique to this study and has not been otherwise tested. Outcome data were obtained via telephone interview with the person with TBI or caregiver/relative during a set study period not indexed to time after injury or rehabilitation. Chi square analysis was used to examine differences in PTA between groups and linear multiple regression modeling to control for confounding variables in determining the relationship between rehabilitation and outcome.

At baseline, the rehabilitation and non-rehabilitation groups differed significantly in PTA, the major index of TBI severity used in the study. Seventy percent of the rehabilitation group had PTAs > 4 months while the non-rehabilitation group had PTAs ≤ 1 month in 74 percent. The nonrehabilitation group was also less impaired in self-care activities and memory.

In a multiple regression model adjusting for age, sex, race, injury severity (PTA, acute-hospital LOS, open brain injury, number of skull fractures), and years post injury, rehabilitation was associated with a better long-term outcome. The overall R2 value was 0.551, suggesting that about one-half of the variance in this group was accounted for by the nine predictors plus rehabilitation. Days in acute hospital, duration of post-traumatic amnesia, age at onset, sex, and whether rehabilitation was performed were statistically significant predictors of outcome. However, the correlation coefficient (Pearson r) for rehabilitation was only 0.159, suggesting that only about 3 percent of the variance was related to whether or not rehabilitation was done.

This study mildly supports the hypothesis that acute inpatient TBI rehabilitation improves outcome. The finding of a benefit despite worse initial severity in the rehabilitation group lends some credence to the results. The study has important weaknesses that have been enumerated by others (High, Boake, and Lehmkuhl, 1995). The obvious baseline differences between the two groups means that the attempt to identify a suitably comparable control population failed. While the statistical analysis was well-done, this method of control works best when there is good reason to believe that the two groups being compared are similar. The differences also reflect the underlying problem that the subset of patients admitted to a rehabilitation unit are not representative of the population thought to benefit from it.

Because this was a retrospective study, the authors were limited to information that had been recorded in the patients' charts or (in the case of the control group) data recorded in an epidemiologic study, although all records were abstracted using the same protocol and all followup interviews were conducted using an identical instrument and process. Data on the timing of followup (how long after injury, acute hospital discharge, and rehabilitation discharge the outcome data were collected) were not available. GCS data were also unavailable. Finally, the use of a proprietary outcome instrument prevents comparison of their data to other studies.

Is the intensity of acute inpatient TBI rehabilitation services related to outcome?

There are no prospective randomized controlled trials of different levels of intensity of acute rehabilitation. Four observational studies, three of which are retrospective, addressed the relationship between the intensity of rehabilitation services and outcomes for persons with brain injury not due to stroke (Blackerby, 1990; Heinemann, Hamilton, Linacre et al., 1995; Spivack, Spettell, Ellis et al., 1992) (see Evidence Table 2).

A retrospective multicenter study of 140 patients admitted between 1990-1991 to one of eight rehabilitation hospitals was the best of these studies (Heinemann, Hamilton, Linacre et al., 1995). Although the study was retrospective, all of the participating hospitals were prospectively collecting data using the Uniform Data Set for Medical Rehabilitation (Granger, Hamilton, and Sherwin, 1986). Claims were used to estimate the mean number of billed hours of application of individual therapeutic modalities (physical therapy, occupational therapy, speech and language services, and psychological services) or all services combined as their definition of intensity of therapy. They examined whether a higher level of services was associated with better motor and cognitive FIM scores, achievement of motor or cognitive potential ((D/C FIM - admit FIM)/(100-admit FIM)), and efficiency of change ((D/C FIM - admit FIM)/ln(LOS)) at the time of discharge.

An analysis of the interrelationships between intensity and severity of injury or other descriptors revealed that they were not independent. Intensity of treatment covaried with functional status at admission, patient demographics, and medical characteristics. This suggests that the functional status on admission is actually related to the therapy intensity the patient receives. It appears that the patients received more therapy if they were admitted with less cognitive function, had uninterrupted stays, had a longer delay to admission, were younger, and so forth.

Investigation of the relationship between intensity of therapy and their various outcome measures (discharge motor and cognitive FIM scores, achievement of motor or cognitive potential, and efficiency of change) did not reveal any significant relationship for occupational, physical, or speech therapy intensities. There was also no significant intensity:outcome relationship for intensity of all therapies combined. Only the number of hours of psychologic work per day, usually delivered as cognitive therapy, were associated with any alterations in outcome. These alterations were improvements in discharge cognitive, FIM score, achieved potential gains in cognitive FIM score, and efficiency of cognitive recovery.

The major weaknesses of this paper are the absence of a specific definition of TBI and lack of control for severity of injury as a confounding, predictive variable. It is unlikely that the admission FIM will cover all of the variance otherwise subsumed by GCS, PTA, and/or duration of unconsciousness (coma). There was no control over or description of differences in treatment between the involved hospitals. Also, the use of billing hours as their index of therapeutic intensity probably included time not spent directly in patient care. Finally, they only used one outcome measure (FIM) and there is no long term followup. Despite these weaknesses, however, the use of prospective data collection and credible analytic techniques makes this the most important paper to address the issue of the relationship between intensity of therapy and outcome. It is the only Class II study in this category.

A retrospective study (Spivack, Spettel, Ellis, et al., 1992) examined the influence on outcome measured at rehabilitation discharge of therapeutic intensity during the first treatment month and over the entire stay on 95 patients with TBI. The cohort consisted of patients with a complete set of records who had been admitted to a single inpatient rehabilitation unit between 1988 and 1990. A definition of TBI was not given. It was noted that not all patients were comatose on admission. LOS ranged from 20 to 412 days with a median of 58 days.

Intensity of treatment was calculated as hours of actual treatment performance measured in 15-minute intervals for PT, OT, ST, cognitive remediation, vocational services, neurophysiology, respiratory therapy, therapeutic recreation, and medical services. Intensity of treatment during the first month was the total hours of treatment during that month. Subjects were separated into high and low intensity groups based the median split of month one treatment hours. The median was 76 hours with a range of 18-196 hours. Average daily intensity of treatment over the entire stay was calculated and subjects were again classified into high and low intensity groups based on the median split. The median was four hours per day with a range of 1.4-12.25 hours. The authors felt that the true time spent per weekday was probably about one-third higher, since these estimates did not take account of days when therapy could not be administered (passes, holidays, weekends, etc.).

GCS was measured within 24 hours of admission to the trauma hospital. Head AIS score, duration of coma, severity of extracranial injuries (highest non-head AIS), and time since TBI were also measured. The statistical method used to control for these confounding variables was unclear.

The independent variables were intensity of treatment during the first month of rehabilitation, average daily intensity of treatment over the entire LOS, and LOS. All of these independent variables were made binary using the median split method as described above.

The dependent variables were outcome measures. RLA scores were measured on admission and discharge. In addition, therapy-specific outcomes on admission and at discharge were assessed using a seven-point functional status scale developed by clinicians within each rehabilitation discipline. A principal components analysis was used with a varimax rotation conducted on the matrix of correlations among functional scale scores at admission to group the scores on various axes. This resulted in grouping along axes of physical performance, higher-level cognitive skills and cognitively mediated physical skills. In addition, patients were rated on their RLA scores on admission and discharge.

The statistical methods for assessing the relationships between the independent and dependent variables were analyses of variance and covariance controlling for multiple comparisons.

ANCOVA with repeated measures analysis was used to investigate treatment intensity and LOS on the dependent variables of admission and discharge scores on physical performance, higher level cognitive skills, cognitively mediated physical skills and RLA level. In doing this analysis, LOS and intensity of treatment during the first month of rehabilitation and LOS and average daily intensity of treatment over the entire LOS were separately analyzed.

LOS significantly influenced outcome across all outcome groups. With respect to either intensity of treatment during the first month of rehabilitation or average daily intensity of treatment over the entire LOS, the only statistically significant relationship was between discharge RLA and one month treatment intensity. They found a borderline non-significant relationship ($p=0.06$) between higher level cognitive skills and average daily treatment intensity. They also found a borderline non-significant relationship ($p=0.07$) for the triple interaction of RLA, LOS, and average daily treatment intensity. Based on this borderline relationship, they performed univariate ANOVA analysis on this interaction. This revealed a significant effect of high intensity treatment during the entire stay on RLA scores on patients with LOSs. This relationship did not hold for patients with short lengths of stays. ANOVA analyses of age and LOS as confounding variables suggested that these variables could not explain this correlation.

There are a number of weaknesses in this paper. A strict definition of TBI was not provided, consequently it is difficult to determine the parent population. Additionally, the focus of the analyses was on outcome measures that were derived in the unit and are, therefore, of unestablished validity and reliability. The major weaknesses in this study, however, are the use of the median split method to dichotomize the independent variables and the lack of powerful multivariate statistical methods.

In this case, the median split method is a dichotomizing method of convenience and does not necessarily reflect any underlying physiologic basis. The distribution of intensity times may be influenced by confounding influences of various origins, including brain and extracranial injury characteristics, patient personality, payer characteristics, etc. One method to force independent variables into binary distributions would be to determine split thresholds recursively in terms of their influence on outcome. Alternatively, intensity of treatment could have been analyzed during the first month of rehabilitation and average daily intensity of treatment over the entire LOS as continuous variables. The use of the median split method in dividing independent variables might have increased the likelihood of a type II error.

The other major weakness is the lack of powerful, multivariate control for confounding variables. As was demonstrated (Heinemann, Hamilton, Linacre et al., 1995), it is not proper to assume independence between intensity of therapy and severity of injury or other patient descriptors. The analysis would have been considerably strengthened by using regression-type analysis.

In the analysis of results, several inferences were made from the non-significant but borderline interactions between higher level cognitive skills and average daily treatment intensity ($p=0.06$) and the triple interaction of RLA, LOS, and average daily treatment intensity ($p=0.07$).

Based on the latter borderline relationship, a significant effect was found of intensity of treatment during the entire stay on RLA scores on patients with long lengths of stay. Based on this interaction, suggestions were made on managing the intensity of treatment for patients with more severe injuries. Given that the interaction underlying the analysis that supported such statements had a p value of 0.07, however, the precise weight of their interpretations remains undetermined.

In one retrospective study (Blackerby, 1990) the influence on outcome from brain injury of a change in mean daily therapeutic intensity that accompanied a major programmatic change at the study institution was investigated (Blackerby, 1990). The study took place at two commercial inpatient head injury rehabilitation provider units run by Rebound, Inc., a commercial provider of head injury rehabilitation services. The charts of all 149 patients with brain injury in the program between 1986-1988 were evaluated, 97 percent of whom were admitted with a diagnosis of TBI. There was no description of TBI provided. Patients were either in a coma treatment program or an acute treatment program. For the pre-change group, 55 percent were in the coma treatment program (54 of 98 patients) whereas in the post-change group only 27 percent were in the coma treatment program (14 of 51 patients).

There was no precise measure of TBI severity. Confounding variables quoted in this study included age, level of function on admission, and time post-injury measured on admission. The measure of function on admission was not specified. It was reported that the two groups did not differ with respect to these variables, although the method of handling them as confounding variables is not stated and the raw data are not provided.

The independent variable was intensity of therapy measured as mean number of daily therapy hours for all types of therapy combined. The two groups were formed in 1986 when they altered the structure of their rehabilitation service delivery system. At this time, the intensity of inpatient rehabilitation was increased from an average of 5.5 hours per day to an average of 8 hours per day.

The dependent variable was inpatient rehabilitation LOS. The relationship between the independent and dependent variables was analyzed using t statistics, separately analyzing the coma treatment and acute treatment groups.

The results demonstrated a large change in average length of stay in both the coma and acute treatment programs following the programmatic changes. The variability in the LOS also decreased after the programmatic change. The only statistical examination was a t-test between pre- and post-change LOS for both the coma treatment program and the acute treatment programs. Both of these changes were statistically significant as tested.

The differences between these groups in terms of cost was evaluated. The average daily cost for the rehabilitation programs was $785 per day with $350 representing the fixed costs.
For the patients in the coma treatment program, the average savings would be $16,950 per patient. For the patients in the acute treatment program, the average savings would be $18,504. It was noted that such cost savings as well as the decreased variability in LOS that appeared to accompany the change in mean daily therapeutic intensity would be of use to insurance carriers in predicting and controlling costs.

There are a number of weaknesses in this paper. A strict definition of TBI was not provided, making it difficult to determine the parent population. In addition, there was a lack of control for severity of TBI or other confounding variables. No data on these variables were provided.

The major weakness, however, was the lack of statistical controls for a number of potentially significant confounding variables that are intrinsic to this experimental design. There appears to have been major changes in this rehabilitation delivery system that accompanied the increase in mean daily therapy intensity. The paradigm change was described as a change to a “naturalistic activity, total therapeutic day model” that apparently involved adaptations of those activities of interest to the individual before head injury. It was suggested that implementation of internal case management was part of the new system and that “senior clinical staff were added to the programs in the roles of clinical consultants and case managers, which increased staff experience and personnel." The occurrence of programmatic changes of such magnitude will, almost by definition, alter patient management in ways outside of those resulting from the increase in mean daily therapy intensity. If all of these changes could be described and quantified, their confounding influences could be addressed using multivariate statistics. In the absence of these data and such statistical analyses, it is difficult to interpret the results of this report.

Conclusions

Based on the current literature, there appears to be little evidence that therapeutic intensity, measured as hours of treatment, is related to the beneficial effects of acute, inpatient TBI rehabilitation when the analysis controls for confounding variables. The only Class II study (Heineneman, Hamilton, Linacre et al., 1995) found no correlation between intensity of individual or grouped therapeutic interventions and outcome. The second study found statistically significant correlations only for discharge RLA and 1-month treatment intensity (Spivack, Spettell, Ellis et al., 1992). Non-significant trends were reported toward associations between higher level cognitive skills and average daily treatment intensity and for a triple interaction of RLA, LOS, and average daily treatment intensity, but the interpretation of these trends is unclear in the absence of statistical significance or other supporting evidence. The third report (Blackerby, 1990) appears to have been so highly confounded by uncontrolled variables to render questionable any comparative interpretation of findings.

There are a number of possible reasons why various intensities of rehabilitation do not appear to correlate with functional improvements. First, the effect of specific comorbidities was underinvestigated in these papers. Second, there is a lack of long-term followup in all three studies. Third, these studies did not examine the quality of treatments or the reasons the various therapies were applied.

Another potential explanation for the demonstrated lack of correlation between therapeutic intensity and outcome is that all patients were receiving enough therapy and that added hours did not make a difference. Similarly, the ranges of intensities of treatment (lack of treatment variability) may have been too limited to show differential effect. As Heinemann, Hamilton, Linacre and others (1995) noted, the Health Care Financing Administration (HCFA) mandated 3 hours per day of therapy for each patient starting in 1983. The legislation might have decreased practice variation that, prior to the regulations, might have been wide enough to affect patient outcomes. Future studies should either consider suspending such constraints or including the influence of such mandated decreases in variation in therapeutic effort into the power calculations used to determine the minimal size of their patient populations.

Overall, however, it must also be questioned whether hours of applied therapy is the proper index for therapeutic intensity. The impact of individual therapeutic disciplines may not be independent or even separable, and the time spent in each might not be the best index of their intensity.

The use of hours of applied therapy as the index for therapeutic intensity also raises the question of how to measure the "milieu effect" of comprehensive rehabilitation. The potential contributions to recovery that might arise from formal and/or informal patient-patient, patient-nurse, patient-therapist, and patient-TBI rehabilitation environment are not addressed in any study to date. Particularly in units devoted to TBI, such a milieu effect should be taken into account in attempting to determine the mechanism of efficacy of the present rehabilitation efforts. This is particularly relevant to such questions as whether delivery of rehabilitation disciplines to a similar group in a setting outside of a formal inpatient rehabilitation unit (i.e., a less expensive setting) is an equally efficacious and, therefore, acceptable alternative method of care delivery.

Future Research

Future research into the question of intensity of inpatient rehabilitation must deal specifically with the limitations highlighted in the present body of literature. These deal specifically with the way the question has been asked and generally with the details of describing the patient population and the therapies applied.

The present unidimensional definition of intensity as hours of application appears to be neither an appropriate definition of intensity nor an adequate descriptor of the therapies. In order to examine the importance of hours of application, there must be description of and control for the other aspects that comprise each therapy. These include modalities used, therapist training, interactions between therapeutic disciplines and so forth, as well as the milieu in which the therapies are delivered. For instance, it is questionable if it is valid to compare two separate physical therapy sessions solely in terms of time spent without addressing what is done within those sessions, who performs the therapies, what aspects of other treatment modalities (for example, cognitive therapy) might be imbedded, etc. Such confounding variables need to be either standardized (preferable) or described in a fashion amenable to subsequent statistical control.

It is also necessary to better describe the patient population being treated. It is highly unlikely that all persons with TBI will receive optimal benefit from the same general therapeutic approach. It is critical that the types and magnitudes of impairments resulting from the TBI be described for the patient population, including both the severity of injury and the resultant degrees of physical and cognitive dysfunction. If adequate descriptions are provided, it will be possible to determine the interaction of the various facets of the individual treatment modalities with the types of impairments demonstrated by the persons being studied. In addition, it will facilitate subsequent focussed studies addressing matching treatment protocols to patient subtypes.

If treatments can be standardized and the patient population be adequately described, it is possible that RCTs could be performed addressing hours of therapy as the independent variable and outcome as the dependent variable. With the proper standardization, the influence of general milieu could also be addressed by adding it as a second independent variable. Such investigations, if performed in fashions that are replicable and comparable between studies, should prove extremely valuable in furthering our understanding of optimizing types and intensities of treatments for persons with specific, defined spectra of TBI-induced impairments.

Question 3: Does the application of cognitive rehabilitation improve outcomes for persons who sustain TBI?

TBI-induced cognitive dysfunction manifests in a spectrum of changes in memory, language, concentration, physical problems, and various behavioral disorders. Several longitudinal studies serve to characterize the nature and extent of cognitive problems following TBI. In a study of United States servicemen discharged for medical and behavioral TBI sequelae (n = 2243 of total discharge population of 1,879,724), 80 percent were discharged with mild dysfunction, 8 percent with moderate TBI, and 12 percent with severe TBI on the Abbreviated Injury Score for head injury (Ommaya et al., 1996). Servicemen who had mild TBI were 1.8 times as likely as other servicemen to be discharged because of behavioral problems. They were also 2.6 times as likely to be discharged for drug and alcohol problems and 2.7 times as likely to be discharged for criminal activities. The relative risks of discharge for medical reasons ranged from 7.5 for servicemen with mild TBI to 40.4 for servicemen with server TBI. Longitudinal studies in Sweden (Schalen and Nordstrom, 1994) and Scotland (Brooks, McKinley, Symington et al., 1987) found outcomes in TBI victims at 5 and 8 years and 7 years, respectively, that include persistent neurophysical pathology, language disorders, dependence on relatives, and myriad mental or behavioral problems, such as hostility, childish behavior, anger, distractedness, and fatigue.

Seeking a theoretical foundation for development of effective interventions, scientists and clinicians have generated a number of models of cognition. These models differ by discipline, but generally include the concept that cognition operates as an integrated system consisting of performance fields and various functions within these fields (Goldstein, 1995). The fields include attention, memory and learning, thinking or mental organization, affect and expression, and executive functions. Brain injury will affect overall performance and, depending on the nature and severity of the injury, may have differential effects on performances within these fields. Various strategies are used to help improve damaged intellectual, perceptual, psychomotor, and behavioral skills (Wehman, West, Fry et al., 1989). These systems of interventions are designed to increase daily functional abilities by improving or augmenting deficits in processing and interpreting information (Coelho, DeRuyter, and Stein, 1996).

One general distinction that serves to classify therapeutic strategies is that between restorative and compensatory cognitive rehabilitation. Restorative cognitive rehabilitation (RCR) is based on the theory that repetitive exercise can restore lost functions (Coelho, DeRuyter, and Stein, 1996). RCR targets internal cognitive processes, with the goal of generalizing improvements to real-world environments. Techniques used in RCR include auditory, visual, and verbal stimulation and practice, number manipulation, computer assisted stimulation and practice, performance feedback, reinforcement, video feedback, and meta-cognitive procedures such as behavior modification. Refinements in RCR methods involve extensive clinical evaluation to identify specific cognitive processes which are damaged, and individual remediation protocols targeting those processes (Sohlberg and Mateer, 1989).

Compensatory cognitive rehabilitation (CCR) strives to develop external, prosthetic assistance for dysfunctions (Wehman, Kreutzer, Sale et al., 1989). It does not rely on the ability to generalize learning, and does not depend upon restoration of lost abilities. CCR uses visual cues, written instructions, memory notebooks, watches, beepers, computers, or other electronic devices to trigger behavior. Therapists assist by simplifying complex tasks, obtaining the patient's attention, reducing distractions, and teaching self-monitoring procedures. CCR also includes jingles, mnemonics, verbal rehearsal, and paraphrasing. The concept of CCR has been expanded to include modification of the behavior of family members, teachers, and other support people present in the life of a person with TBI (Ylvisaker and Feeney, 1996). The adapted behavior of communication partners combines with the technical assistance of prosthetic devices and external cues to provide an environment of supported cognition.

RCR and CCR are not mutually exclusive and are commonly mixed in therapeutic programs for TBI. Restorative training is often enhanced by cues, mnemonics, and other compensatory prosthetics. In the absence of evidence for the differential effectiveness of these interventions, clinicians are compelled to combine and provide protocols according to their experience.

Some insurance programs do not pay for cognitive therapy as a stand-alone treatment, or as a clearly defined component of a treatment protocol. Therefore, RCR and CCR techniques may be components of a rehabilitation program that is more traditionally defined and thus eligible for payer reimbursement. For example, many inpatient and TBI day treatment programs use speech and language pathology treatment principles to provide cognitive remediation within a broad, and more widely accepted, program context of occupational therapy, physical therapy, speech therapy, community integration, and vocational rehabilitation. As a consequence, it is difficult to distinguish the effect of the cognitive strategy from that of the other interventions being applied.

Experts in cognitive rehabilitation have developed specific measures for many of the functions impaired by brain injury. These measures, frequently used by researchers in published studies, are also used by clinicians to diagnose deficits, and to make decisions about treatment planning. Many are also aimed at testing whether results in patients are consistent with various theories of cognition.

Table 6 shows tests and scales commonly used in practice and the frequency of their use in studies of cognitive rehabilitation. While practitioners agree the desired outcome of cognitive rehabilitation is improvement in daily function, many of the commonly used scales are intermediate measures rather than health outcomes. For example, the Paced Auditory Serial Attention Task, or PASAT (Gronwall, 1977) is a test of attention in which subjects are presented with a string of digits and are required to add each number to the one preceding. A cognitive rehabilitation study may identify attention as the primary dysfunction for a patient, apply an intervention designed to improve attention, and use the PASAT as a measure of improvement. The rehabilitation program at Auckland Hospital in New Zealand transitions clients from one phase to another when a specific score on the PASAT (mean time scores < 4 seconds) is achieved (Gronwall, 1996). This example raises important questions about published studies of cognitive rehabilitation. First, is the observed improvement on the PASAT greater than that of natural recovery or of other interventions? Related questions are, can the improvement on the PASAT be attributed to the specific intervention selected for the study, or would general stimulation produce the same effect? Does the evidence justify the need for complex, sometimes expensive therapeutic techniques, or would simpler, less expensive techniques work as well?

Table 6. Summary of results of intermediate measures of cognitive function (please see text for explanation)

	Number of tests found to have a positive effect or association			**Number of tests done without a positive effect or association**			**Proportion of positive effects found**	
Cognitive Domain and Associated Tests	RCTs (a)	Comparative studies (b)	Correlational studies (c)	RCTs (d)	Comparative studies (e)	Correlational studies (f)	RCTs & Comparative $\frac{a+b}{a+b+d+e}$	Correlation Studies $\frac{c}{c+f}$
Attention and orientation								
Digits	0	1	1	3	3	3	.14	.25
Mental Control	0	0	0	1	0	0	0	0
Trails A & B	0	0	3	1	1	1	0	.75
PASAT	0	1	2	1	2	0	.25	1.0
Test d2	0	0	0	1	0	0	0	0
Continuous Test of Attent.	0	0	1	0	0	0	0	1.0
Divided Attention	0	0	0	1	0	0	0	0
Ruff 2 & 7	0	0	0	1	0	0	0	0
Letter Cancellation	0	0	0	0	1	0	0	0
Time Estimation	0	0	0	0	1	0	0	0
Attention to Task	0	1	0	0	0	0	1.0	0
Attention Rating Scale	0	1	0	0	0	0	1.0	0
WMS Attent./Concentr.	0	0	0	0	0	2	0	0
Digit Symbol	0	0	1	0	1	1	0	.50
Ruff-Light Trail	0	0	0	2	0	0	0	0
Tactual Performance	0	0	1	0	1	0	0	1.0
Choice Reaction Time	0	1	0	0	0	0	1.0	0
Simple Reaction Time	0	0	0	0	1	0	0	0
Vigilance	0	0	0	0	1	0	0	0
Totals	**0**	**5**	**9**	**11**	**12**	**7**	**.18**	**.56**
Memory								
WMS General	0	0	0	0	0	2	0	0
WMS Verbal	0	0	0	0	0	2	0	0
WMS Visual	0	0	2	2	1	0	0	1.0
WMS Delayed Recall	0	0	1	0	0	1	0	.5
WMS Memory Quotient	0	1	0	0	0	0	1.0	0
WMS Logical Memory	0	0	2	3	2	0	0	1.0
WMS Paired Associates	0	0	1	0	1	0	0	1.0
Rivermead Beh. Mem. Test	0	0	0	1	0	0	0	0
Everyday Memory Quest.	0	0	0	1	0	0	0	0
Calif. Verb. Learn. Test	0	0	0	0	0	1	0	0
Rey Complex Figure	0	0	1	1	1	0	0	1.0
Rey Audit. Verb. Learn.	0	0	0	1	0	0	0	0
Block Span Learning	0	0	0	1	0	0	0	0
Benton Vis. Memory Test	0	0	0	1	0	0	0	0
Taylor Complex Figure	0	0	0	1	1	0	0	0
Buschke Select. Remind.	0	0	1	0	1	0	0	1.0
Recalling Sentences	0	1	0	0	0	0	1.0	0
Totals	**0**	**2**	**8**	**12**	**7**	**6**	**.10**	**.57**

Note: Tests were placed into categories consistent with taxonomy provided by Lezak (1995)

Table 6. Summary of results of intermediate measures of cognitive function (please see text for explanation)

	Number of tests found to have a positive effect or association			**Number of tests done without a positive effect or association**			**Proportion of positive effects found**	
Cognitive Domain and Associated Tests	RCTs (a)	Comparative studies (b)	Correlational studies (c)	RCTs (d)	Comparative studies (e)	Correlational studies (f)	RCTs & Comparative $\frac{a+b}{a+b+d+e}$	Correlation Studies $\frac{c}{c+f}$
Verbal & Language								
WAIS-R Information	0	0	0	0	0	1	0	0
WAIS-R Vocabulary	0	0	1	0	1	0	0	1.0
Language Competence	0	1	0	0	0	0	1.0	0
Word Fluency	0	0	0	0	1	2	0	0
Mill Hill Vocabulary	0	0	0	0	0	1	0	0
Token Test	0	0	0	0	0	1	0	0
Totals	**0**	**1**	**1**	**0**	**2**	**5**	.33	.17
Construction								
Parquetry Block Design	1	0	0	0	0	0	1.0	0
WAIS-R Block Design	0	2	1	1	0	0	.67	1.0
Object Assembly	0	0	0	0	0	1	0	0
Rey Complex Figure Copy	0	0	1	0	1	0	0	1.0
Totals	**1**	**2**	**2**	**1**	**1**	**1**	.60	.67
Concept Formation & Reasoning								
WAIS-R Similarities	0	0	0	0	1	1	0	0
WAIS-R Picture Arrangem.	0	0	1	0	0	0	0	1.0
WAIS-R Picture Complet.	0	1	0	0	0	1	1.0	0
WAIS-R Arithmetic	0	1	1	0	0	0	1.0	1.0
Making Inferences	0	0	0	0	1	0	0	0
Raven's Progress. Matrices	0	1	0	0	0	0	1.0	0
Category Test	0	0	1	0	0	2	0	.33
Wisconsin Card Sorting	0	0	0	0	1	1	0	0
Comprehension	0	0	1	0	1	0	0	1.0
Totals	**0**	**3**	**4**	**0**	**4**	**5**	.43	.44
Executive Functions & Motor Performance								
WISC-R Mazes	0	0	1	0	0	1	0	.50
Austin Maze	0	0	0	0	1	0	0	0
Hals. Reit. Finger Tapping	0	0	0	0	2	1	0	0
Grooved Pegboard	0	0	1	0	0	0	0	1.0
Grip Strength	0	0	0	0	0	1	0	0
Totals	**0**	**0**	**2**	**0**	**3**	**3**	0	.44

Note: Tests were placed into categories consistent with taxonomy provided by Lezak (1995)

Table 6. Summary of results of intermediate measures of cognitive function (please see text for explanation)

	Number of tests found to have a positive effect or association			Number of tests done without a positive effect or association			Proportion of positive effects found	
Cognitive Domain and Associated Tests	RCTs (a)	Comparative studies (b)	Correlational studies (c)	RCTs (d)	Comparative studies (e)	Correlational studies (f)	RCTs & Comparative a+b / a+b+d+e	Correlation Studies c / c+f
Batteries & Global Tests								
WAIS-R Full Scale I.Q.	0	0	1	0	0	1	0	.5
WAIS-R Verbal I.Q.	0	0	1	0	2	1	0	.5
WAIS-R Performance I.Q.	0	1	3	0	1	1	.33	.75
Russell Neur Av. Imp. Rat.	0	0	0	0	1	0	0	0
San Diego Neuro. Test Bat.	0	0	0	1	0	0	0	0
Wide Range Achiev. Test	0	0	0	0	0	1	0	0
Hals. Reit. Impair. Index	0	0	1	0	0	0	0	1.0
Totals	**0**	**1**	**6**	**1**	**4**	**4**	**.17**	**.60**
Miscellaneous & Clinic-Specific Tests								
Adolescent Word Test A	0	1	0	0	0	0	1.0	1.0
Adolescent Word Test B	0	0	0	0	1	0	0	1.0
Adolescent Word Test C	0	1	0	0	0	0	1.0	1.0
Adolescent Word Test D	0	0	0	0	1	0	0	1.0
Picture Vocabulary Test	0	1	0	0	0	0	1.0	1.0
Word Association Subtest	0	1	0	0	0	0	1.0	1.0
Understanding Metaphors	0	0	0	0	1	0	0	1.0
Peabody Picture Vocabulary	0	0	0	0	1	0	0	1.0
Ambiguous Sentences	0	1	0	0	0	0	1.0	1.0
Listening to Paragraphs	0	0	0	0	1	0	0	1.0
Neale Analysis of Reading	0	0	0	0	1	0	0	1.0
Pursuit Rotor	0	0	0	0	1	0	0	1.0
Sentence Assembly	0	0	0	0	1	0	0	1.0
Recreating Sentences	0	0	0	1	0	0	0	1.0
Single Reaction Time	0	0	0	1	0	0	0	1.0
Choice Reaction Time	0	0	0	1	0	0	0	1.0
NYUMT Acq. Rec. Scaled	1	0	0	0	0	0	1.0	1.0
NYUMT Acq. Rec. Stand.	0	0	0	1	0	0	0	1.0
Memory Index Scaled	1	0	0	0	0	0	1.0	1.0
Memory Index Standard	1	0	0	0	0	0	1.0	1.0
VerPa	1	0	0	0	0	0	1.0	1.0
VisPa	1	0	0	0	0	0	1.0	1.0
TeachWare Screen. Module	0	1	0	0	0	0	1.0	1.0
Name Writing	0	0	1	0	0	0	0	1.0
Totals	**5**	**6**	**1**	**4**	**8**	**0**	**.48**	**1.0**

GRAND TOTALS	**6**	**20**	**33**	**29**	**41**	**31**	**.27**	**.52**

Note: Tests were placed into categories consistent with taxonomy provided by Lezak (1995)

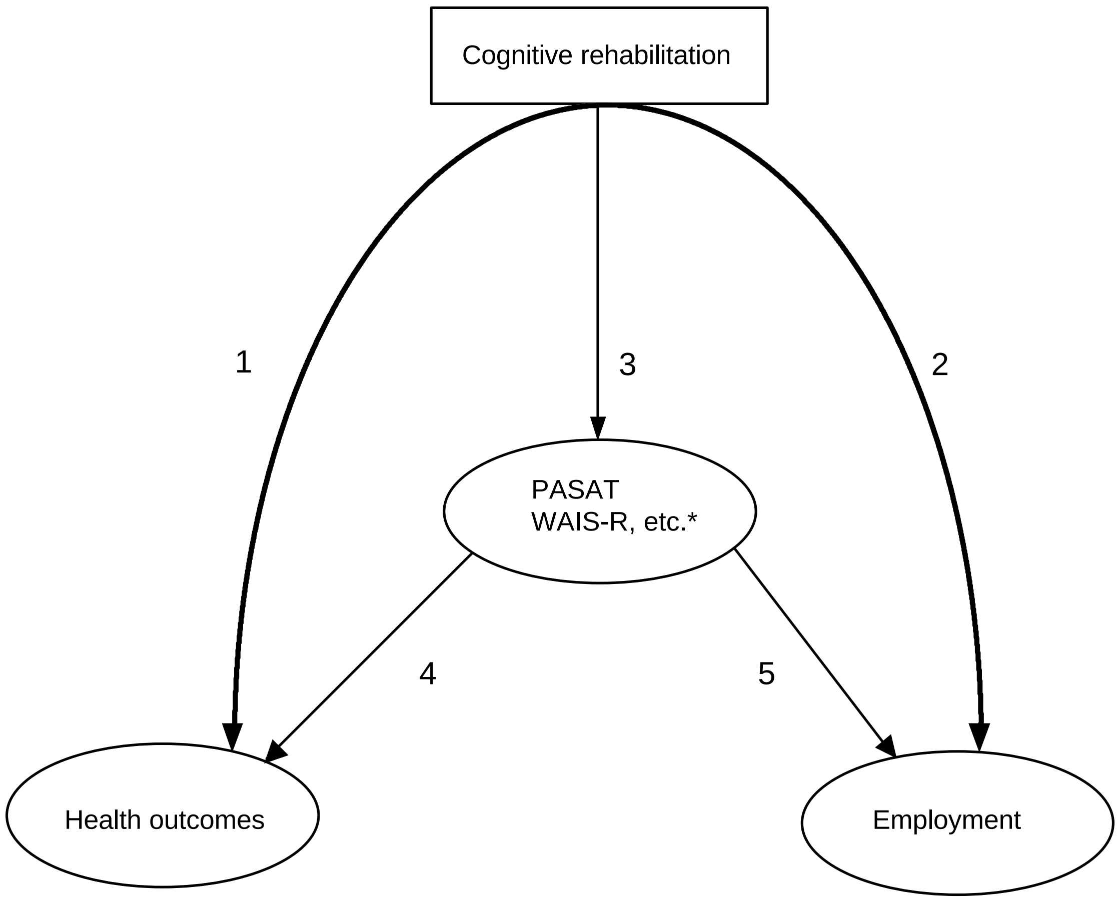
Second, in this example, do high scores on the PASAT accurately predict whether the patient's attentional performances will function adequately in the context of work or social situations in which distraction and other demands are present? More generally, do the measures used to assess the effectiveness of cognitive rehabilitation predict improvement in real life function?

The causal pathway we used to address these questions is shown in Figure 5. Arc 1 represents the direct effect of cognitive rehabilitation on health outcomes – outcomes that can be felt or experienced by the patient in daily life. A panel of technical experts identified the relevant health outcomes of cognitive rehabilitation for persons with TBI (see Methods, Topic Assessment and Refinement, earlier in this report.) The panel, which included a psychologist, a neuropsychologist, and a cognitive rehabilitation therapist, listed the following outcomes:

- Activities of Daily Living (ADLs)
- Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being)
- Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function)
- Independence, relationships, family life, satisfaction
- Long-term financial burden

In the context of a systematic review, “direct” evidence comes from comparative studies that examine the effect of cognitive rehabilitation on measures of these outcomes. Arc 2 represents the direct effect of cognitive rehabilitation on measures of employment such as return to work and job retention.

Figure 5. Causal pathway for cognitive rehabilitation



Note: * PASAT = Paced Auditory Serial Additional Task
WAIS-R = Wechsler Adult Intelligence Scale - Revised
See Table 6 for measures of cognitive abilities.

"Indirect" evidence refers to a causal chain that relies on intermediate measures. In Figure 5, the first link in this chain is between the intervention and intermediate measures of improvement (Arc 3); this link corresponds to the question, "does cognitive rehabilitation improve scores on intermediate measures of cognitive function, such as the PASAT, WAIS-R, etc.?" The next links in the causal chain correspond to the question, “do intermediate measures used to assess the effectiveness of cognitive rehabilitation predict improvement in real life function (Arc 4) and employment (Arc 5)?”

Of the 114 potential references identified for inclusion by the literature search, 53 met the predetermined eligibility criteria (see Table 5). Reference lists of reviewed articles and peers identified 20 additional articles, resulting in a total of 73 full-text articles that were retrieved and read. Of those, 41 were excluded. Of these, 3 were review articles 5 were studies with fewer than 5 subjects, 1 was retrospective, and 25 studies were descriptive. Five studies measured independent or dependent variables outside the scope of this research question, and 2 studies compared clients who were referred for treatment with those referred for testing. While excluded as evidence about effectiveness, the descriptive and observational data from these research efforts provided a foundation for understanding and interpreting the evidence.

The remaining 32 articles were abstracted and are presented in the following categories:

1. 10 randomized controlled trials
    - 5 measuring relevant health outcomes (Evidence Table 3)
    - 5 measuring intermediate outcomes (Evidence Table 5)
2. 5 comparative studies
    - 1 measuring employment outcomes (Evidence Table 4)
    - 4 measuring intermediate outcomes (Evidence Table 6)
3. 8 studies of the relationship between intermediate tests and employment
    (Evidence Table 7)
4. 9 observational studies
    - 1 measuring relevant health outcomes (Evidence Table 8)
    - 8 measuring intermediate outcomes

Direct Evidence

Does cognitive rehabilitation improve health outcomes (Arc 1)?

Randomized controlled trials. Five randomized controlled trials (Helffenstein and Wechsler, 1982; Neistadt, 1992; Novack, Caldwell, Duke et al., 1996; Ruff and Niemann, 1990; Schmitter-Edgecombe, Fahy, Whelan et al., 1995) used measures of relevant health outcomes to compare the effects of specific forms of cognitive rehabilitation to other treatments (see Evidence Table 3). Two studies, examined CCR, one examined RCR, and two used a combined program of RCR and CCR. Comparison groups were provided unstructured sessions, computer game sessions, and nontherapeutic attention. In one study (Neistadt, 1992) two specific restorative trainings were provided. Each group was trained in one of the skills, and was tested for both. Treatment time for four of the studies ranged from 10 to 20 hours; the fifth (Ruff and Niemann, 1990) provided 96 hours of treatment. Followup for one study (Schmitter-Edgecombe, Fahy, Whelan et al., 1995) occurred at 6 months, and for a second study (Helffenstein and Wechsler, 1982) at 1 month for 6 of the subjects; the other studies did not have followup testing.

As seen in Evidence Table 3, the studies varied in setting, populations, size, client chronicity and measures of severity of injury. One-hundred thirty-seven clients were observed in these trials; 69 received the targeted treatments.

Measures used in these studies which approximated important health outcomes were the Functional Independence Measure (FIM) ((Novack, Caldwell, Duke et al., 1996), Observed Everyday Memory Failures (EMFs) (Schmitter-Edgecombe, Fahy, Whelan et al., 1995), the Rabideau Kitchen Evaluation Revised (RKE-R) (Neistadt, 1992), the Katz Adjustment Scale (KAS) (Ruff and Niemann, 1990), and a variety of inventories designed to measure anxiety, communication, and relationships (Helffenstein and Wechsler, 1982). In addition, these studies used neuropsychological test batteries and other intermediate measures of cognitive function to evaluate treatment effect.

In two studies treatment produced statistically significant effects on relevant outcome measures. In one (Schmitter-Edgecombe, Fahy, Whelan et al., 1995), individuals trained in the use of notebooks and equipped with wristwatch alarm cues had fewer EMFs than those who did not have the compensatory devices . However, the effect was not present at 6 month followup. In the second study (Helffenstein and Wechsler, 1982) clients who received compensatory training had better results than those given nontherapeutic attention on one variable from an anxiety scale and three variables from a communication scale, and had better performance on the Interpersonal Relationship Rating Scale and Independent Observer Report Scale. Six scales were used in this study, and the number of variables per scale, as well as group means, were not provided.

In the other four studies described in Evidence Table 3, the cognitive rehabilitation intervention was not more effective than alternatives. The predominantly negative results of these small, Class I and II(a) trials may be mitigated by three important factors. First, in general both groups in these studies improved from pre to posttreatment, producing no treatment effect in the statistical analysis. This raises questions about what is operating to cause general improvement, stimulation or spontaneous recovery, or both? In each study the comparison group received equal hours of some form of stimulation, some of which was therapy of an unstructured nature. Second, four of the five studies provided 20 hours or less of treatment time. With the pervasive and life-long cognitive deficits that result from TBI, results from interventions of such limited duration should not be generalized to more sustained interventions. Third, it isn’t clear whether the patients included in these studies are representative of patients who might undergo cognitive rehabilitation in current practice. Along with the small size of studies and the narrow range of interventions studied, the lack of information about the representativeness of included patients makes it difficult to apply the findings of these studies to cognitive rehabilitation practice generally.

Does cognitive rehabilitation improve employment outcomes (Arc 2)?

There is no direct evidence from randomized trials of the effect of cognitive rehabilitation on employment.

Comparative Studies. One study (Prigatano, Fordyce, Zeiner et al., 1984) compared employment outcomes for clients of an intensive cognitive rehabilitation program (NRP) with those of people who were referred to the program but who did not participate (see Evidence Table 4). The intervention involved RCR and CCR in a coordinated multidisciplinary program. Participants were provided a minimum of 624 hours of treatment; 4 days a week for 6 hours a day, over 6 months. The treatment group consisted of patients who entered NRP between February, 1980 and August, 1982 who stayed in the program at least 6 months. Files for referrals to NRP during the same time period who did not enter the program were retrospectively evaluated to provide control group data. Followup took place approximately 3 months after the last client was discharged; consequently followup varies from between 3 months to 33 months. Eighteen people received the treatment; 17 were the non-client referrals. Chronicity for the control group was shorter (13.6 months) than that of the treatment group (21.6 months). Severity was not specified.

Participants were evaluated with 13 neuropsychological tests, the KAS relative scale, and a measure of employment. People who were gainfully employed either part-time or full-time, or who were actively engaged in a realistic school program, were considered employed. There were treatment effects on 3 of the 13 neuropsychological tests. Client attrition resulted in a reduction of participants at the time of followup. Of 18 people in the treatment group, 9 were employed at followup (50 percent). Of 13 in the control group, 5 were employed (38 percent). The statistical significance of this difference was not reported.

Because of the potential and unknown differences between treatment and control groups, interpretation of these results is difficult. Authors did not specify why clients in the control group, although referred to NRP, did not participate. It is possible that the same factor or factors that caused them not to participate in NRP operated to influence their employment outcomes (in either direction). This Class II(b) study does not provide evidence for or against the effect of cognitive rehabilitation on employment. However, it provides limited evidence of the effect of the intervention on some intermediate measures of cognitive function.

Indirect Evidence

Does cognitive rehabilitation improve performance on intermediate measures of cognitive function (Arc 3)?

Randomized controlled trials. Five randomized controlled trials (Kerner and Acker, 1985; Niemann, Ruff, and Baser, 1990; Ruff, Baser, Johnston et al., 1989; Ryan and Ruff, 1988; Twum and Parente, 1994) used a variety of neuropsychological tests and other intermediate measures to compare the effects of different forms of cognitive rehabilitation to each other, and to other forms of therapy and stimulation (see Evidence Table 5). Two studies combined RCR and CCR techniques; the other three used RCR exclusively in the interventions. Duration of treatment ranged from a single training session to a total of 160 hours of intervention. Two studies (Kerner and Acker, 1985; Niemann, Ruff, and Baser, 1990) conducted followup testing at 2 weeks. The other studies did not follow up participants. The studies varied in setting, client populations, size, client chronicity and measures of severity of injury. One-hundred seventy clients were observed; 100 received the targeted treatments.

Twenty individual tests of cognition, such as the PASAT were used in the 5 RCTs. In addition, two of the studies also used the full battery of subtests contained in the San Diego Neuropsychological Test Battery (SDNTB). Two studies produced treatment effects. Outcomes for one (Twum and Parente, 1994) were number of words and colors recalled immediately after practicing mnemonic techniques with the words and colors. No followup testing was conducted. Outcomes for the second study (Kerner and Acker, 1985) were a Memory Index (MI) task and an Acquisition Recall (AR) task, measured in scaled and standard forms. The treatment group received CACR targeting memory retraining. A control group used computers to create graphics, and a second control group had no intervention. With 3 groups and 2 forms of measuring each of the 2 tests, 12 effects were possible. Treatment effects were produced on 5 of the 12 measures at posttreatment. Improvement by the treatment group was not maintained at 2 week followup; however, the two control groups did not receive a followup test, so group differences in the decline were not measured.

Two of the three studies for which there was no treatment effect (Ruff, Baser, Johnston et al., 1989; Ryan and Ruff, 1988) compared equal amounts of structured cognitive rehabilitation programs with unstructured activities, providing the greatest number of treatment hours among the RCTs in this review. The third (Niemann, Ruff, and Baser, 1990) compared equal hours (36 total) of attention remediation with memory remediation. For all 3 studies, clients in both treatment and comparison groups improved from pre to posttreatment. This result underlines the previous suggestion that more may be learned about treatment effects by comparing intervention to no intervention, rather than comparing one form of intervention (i.e., structured) with another form (unstructured) in a design that provides equal amounts of time and stimulation. Also, this result suggests there may be a general effect of stimulation, perhaps interacting with spontaneous recovery, that exceeds the effect of the intervention.

To conclude, there is evidence from two small Class I trials that the restorative technique of practice, both with and without the aid of a computer, operates to improve short-term recall on laboratory tests of memory for persons with TBI.

Comparative Studies. Four studies with comparison groups to which participants were not randomly assigned used laboratory tests to evaluate the effect of cognitive rehabilitation on cognition (Batchelor, Shores, Marosszeky et al., 1988; Gray, Robertson, Pentland et al., 1992; Thomas-Stonell, Johnson, Schuller et al., 1994; Wood and Fussey, 1987) (see Evidence Table 6). The intervention for one (Thomas-Stonell, Johnson, Schuller et al., 1994) combined RCR and CCR. All four used computers (CACR) to enhance the intervention. One (Gray, Robertson, Pentland et al., 1992) compared the effect of CACR with that of recreational computing; the other three compared CACR to therapy that did not make use of computers. Treatment time ranged from 16 to 20 hours. Two studies (Gray, Robertson, Pentland et al., 1992; Wood and Fussey, 1987) performed followup testing at 6 months and 20 days, respectively. Samples included both inpatients and outpatients; the populations from which they were drawn varied. One-hundred seven people were observed in these studies; 50 received the targeted interventions.

Measures used to evaluate treatment effect included tests developed by the clinic or research project as well as established neuropsychological tests such as the PASAT, WAIS-R, Taylor Figure, and Digit Symbol. Of 54 intermediate tests performed, 3 of the 4 studies produced treatment effects on 17 tests. Group means were not presented, preventing an assessment of the magnitude of improvement. As with the RCTs for this category, equal amounts of stimulation were provided treatment and control groups. Improvements from posttreatment to followup suggest the presence of spontaneous recovery. These small, Class II(b) studies provide limited evidence that CACR improves performance on laboratory tests of cognition for persons with TBI.

Table 6 summarizes the results of the studies, reviewed above, that used laboratory tests of cognition to measure treatment effects. The first column lists all the laboratory-based tests that were used, within categories as defined by Lezak (1995): Attention and Orientation, Memory, Verbal and Language, Construction, Concept Formation and Reasoning, and Executive Functions and Motor Performance. Two additional categories are Batteries and Global Tests, and Miscellaneous or Clinic-Specific Tests. Column (a) shows the number of RCTs in which cognitive rehabilitation had a statistically significant effect on the test listed for that row; column (b) presents the same information for comparative studies. Column (c) gives the number of correlational studies in which there was a significant correlation between the test and a health outcome or employment. Columns (d), (e), and (f) list numbers of studies for each test for which there was no effect or association. Column (g) is the proportion of times the test was used in controlled studies (RCTs and other comparative) that the intervention produced an effect on the test. Column (h) is the proportion of times the test was used in correlational studies that there was a positive correlation between the test and a health outcome or employment. Ninety-one different laboratory-based tests of cognition were used in 160 distinct evaluations in the studies presented in evidence tables for this research question. For RCTs, the research design most capable of providing evidence for effectiveness, there was an effect of treatment 6 of 35 times (17 percent). Other comparative studies produced a treatment effect 20 of 61 times (33 percent). For correlational studies, there was a significant association between intermediate tests and health ourcomes or employment 33 of 64 times (52 percent). Thus, as the strength of evidence decreased, the effect increased. In addition, as the strength of research design decreased, the number of studies increased.

As discussed earlier, although the evidence is limited, there is some suggestion that certain cognitive rehabilitation methods improve performance on neuropsychological tests and other laboratory-based methods of evaluating cognitive function. The next question addresses the second link in the indirect path from intervention to relevant outcome.

Do intermediate measures of cognitive function associate with health outcomes (Arc 4) or employment (Arc 5)?

No studies meeting the criteria for this review reported an association between laboratory-based measures of cognitive function and health outcomes such as functional independence, ADLs, or measures of everyday memory.

Evidence Table 7 presents eight studies that measured the cognitive function of persons with TBI using a variety of neuropsychological tests, and also measured postinjury employment status or productivity and activity level (Brooks, McKinlay, Symington et al., 1987; Cicerone, Smith, Ellmo et al., 1996; Ezrachi, Ben-Yishay, Kay et al., 1991; Fabiano and Crewe, 1995; Fraser, Dikmen, McLean et al., 1988; Girard, Brown, Hashimoto et al., 1996; Ip, Dornan, and Schentag, 1995; Najenson, Grosswasser, Mendelson et al., 1980). Each used some correlation-based method to analyze the relationship between the laboratory tests and employment status. While specific research methods varied, in general these studies retrospectively gathered hospital and inpatient rehabilitation chart data to establish test scores, then interviewed clients and/or relatives to establish employment status. Sample sizes ranged from 20 to 152 participants; a total of 724 people was observed. Chronicity and severity varied within and across samples.

One-hundred twenty-three tests of cognition were administered. Two studies (Ezrachi, Ben-Yishay, Kay et al., 1991; Girard, Brown, Hashimoto et al, 1996) used numeric scales to measure productivity from 1 (worst) to 10 and 6, respectively. Four studies (Brooks, McKinlay, Symington et al., 1987; Cicerone, Smith, Ellmo et al., 1996; Fraser, Dikmen, McLean et al., 1988;

Ip, Dornan, and Schentag, 1995) used dichotomous measures of return to work or former level of productive activity. Two (Fabiano and Crewe, 1995; Najenson, Grosswasser, Mendelson et al., 1980) placed clients into 5 and 4 categories of employment, respectively. Methods of analysis included regression, t-tests, chi-square, Wilcoxon rank sum, discriminant analysis, and factor analysis.

Approximately half the time clients with higher intermediate test scores had returned to work or productivity, full or part time, but not necessarily to the pretrauma level. In one study that used a regression analysis (Girard, Brown, Hashimoto et al., 1996), 9 of 28 test scores, combined with 3 demographic characteristics, accounted for 30 percent of the variance in outcome; 19 of the tests did not help explain the difference in employment outcomes. In another study (Fabiano and Crewe, 1995) intermediate test scores were used in a discriminant analysis to derive a formula for predicting employment status. With this method, high scores on tests accurately predicted full-time employment 62 percent of the time, and low scores on tests accurately predicted unemployment 67 percent of the time. These proportions indicate that, while there appears to be some relationship between intermediate measures of cognition and employment, the association is not strong.

Observational Research

While research designs without control groups are limited, they can be a source of hypotheses which could be tested in controlled trial settings. This section highlights insights from studies with uncontrolled research designs identified in our literature search.

Nine observational studies of clients before and after cognitive rehabilitation fulfilled the criteria for inclusion in this review (Cicerone and Giacino, 1992; Deacon and Campbell, 1991; Glisky, Schacter, and Tulving, 1986; Goldstein, McCue, Turner et al., 1988; Middleton, Lambert, and Seggar, 1991; Ponsford and Kinsella, 1988; Ruff, Mahaffey, Engel et al., 1994; Scherzer, 1986; Wilson, Evans, Emslie et al., 1997). One used a measure of a relevant health outcome, everyday memory failures (EMFs) to evaluate treatment effect, and is presented in Evidence Table 8 (Wilson, Evans, Emslie et al., 1997).

The other eight studies either compared clients' performance from baseline phase to treatment phase, provided the same or similar treatments to different matched groups, or combined group and individual methods of measurement. In general, results indicate that for the selected clients treated in these clinical studies, one-on-one interaction with therapists in a rehabilitation environment is likely to improve individual performance on targeted laboratory tasks. Because the studies are not comparative, the improvement observed does not contribute to the body of evidence about the intervention being provided. However, the fact that clients do in fact improve gives rise to innovations in rehabilitation technology that may be useful to persons with TBI, and that warrant further evaluation.

For example, in the study presented in Evidence Table 8 (Wilson, Evans, Emslie et al., 1997) 15 clients were provided an electronic device, programmed to assist them in remembering to do routine daily tasks. Prior to the intervention, they were interviewed to identify targets for memory remediation unique and important to the them. Thus the intervention was individually adapted. The score for Everyday Memory Failures (EMFs) was the number of times a target was forgotten. EMFs were measured for 2 to 6 weeks during baseline. During the treatment phase, which lasted 12 weeks, each person in the study wore and used the device. The return-to-baseline phase was 3 weeks.

All participants had significant decreases in EMFs during treatment. During return-to-baseline, EMFs increased for 11 of the 15 participants; 5 increases were statistically significant. The results of this study suggest that the use of an electronic cueing device decreases EMFs for some people with TBI, and contribute to the evidence for the link represented by Arc 1 of the Causal Pathway. The observational design of this study weakens its value as evidence of effectiveness. However, in considering that the nature of most of the interventions reviewed here are not individually adapted, and on face value do not appear to be as pragmatic as an effective reminder device, this study is useful in that it generates a hypothesis about an intervention that may have potential to prosthetically improve memory for person with TBI.

Conclusions

Very few controlled studies of cognitive rehabilitation have examined health outcomes or employment. One small randomized controlled trial and one observational study provide evidence of the direct effect of compensatory cognitive devices (notebooks, wristwatch alarms, programmed reminder devices) on the reduction of EMFs for persons with TBI. A second randomized controlled trial provides evidence that compensatory cognitive rehabilitation reduces anxiety, and improves self-concept and interpersonal relationships for persons with TBI.

In the absence of strong and sufficient evidence for a direct effect of cognitive interventions on health and employment, we examined a causal pathway linking cognitive rehabilitation to intermediate measures of cognition, and subsequent associations between those measures and health or employment. One small randomized controlled trial and one comparative study provide limited evidence that practice and CACR improve performance on laboratory-based measures of immediate recall. However, no studies evaluated the link between cognitive tests and health outcomes, and associations between performance on cognitive tests and posttrauma employment and productivity were inconsistent.

Future Research

Identifying and evaluating outcomes that are relevant to people with TBI and their families is the first priority of a research agenda. Among the studies we reviewed, perhaps the most pragmatic outcome measure used was that of everyday memory failures. It is possible that the absence of treatment effect in these studies could be a function of the study's lack of relevance in the lives of the people being evaluated, represented in outcome measures and interventions that have little meaning to those people.

It is also important to identify the laboratory tests that are strongest and most reliable in their ability to measure cognitive function in relevant contexts, and to standardize their use across research projects and hospital and clinical settings.

Another question for future research not specifically addressed in this review is, when is the client ready for the intervention, and what are the markers of that readiness? Large, multicenter comparisons may provide initial information for a research design to investigate this question.

In general the studies in this review that did not produce a treatment effect compared one form of cognitive rehabilitation to another form, CACR to non-CACR practice, and specific to unstructured rehabilitation methods. Treatment effects were not observed when one kind of remediation was compared to another, with equal levels of stimulation for both treatment and comparison groups. What are the differential effects of general stimulation and technology? As TBI rehabilitation technology grows, costs proliferate. Consequently, certain subsets of the total population of survivors, those with liberal insurance policies and private money, will receive the intervention. It is important for clients as well as payers to know if the new technology causes improvement, or whether the increased level of stimulation used to deliver the technology causes improvement.

Question 4: Does the application of supported employment enhance outcomes for persons with TBI?

The goal of supported employment is to enable persons with severe long-term or permanent deficit to resume a productive life by providing on-site aid and advocacy at the place of employment. Programs in supported employment began in the late 1970s as university-based demonstration projects and then became a part of government-sponsored rehabilitation programs. They have been applied to a wide range of populations who were previously considered unemployable, particularly people with mental retardation, but also including persons suffering from neural, psychiatric, and physical disabilities (Wehman, Revell, Kregel et al., 1991). More recently, the techniques have been applied to help survivors of TBI resume a productive life.

Chronic unemployment has both a personal and a social cost. For the person, regular work is an important source of personal satisfaction and social identity (Partridge, 1996). It not only may provide financial resources, but it forms the basis of self-image and a claim on social recognition and reward (Shepherd, 1981). Work and a sense of vocation can contribute to a personal sense of worth and competence, of belonging and well-being, and to other psychological states essential to mental health (Pettifer, 1993). The fundamental value of work is illustrated by Roe's (1956) suggestion that it is the only social role that can fulfill all the stages of Maslow's (1987) hierarchy of needs, ranging from safety, through esteem, to self-actualization. Chronic unemployment, especially beginning early in life, is an important threat to personal mental health. Survivors of TBI are often injured just as they approach or reach their full potential as workers. The social cost is evident when we consider that more than 60 percent of survivors of TBI are men under 35 years of age (Wehman, West, Fry et al., 1989). This is precisely the population who tend to be highly skilled workers, at the peak of their powers, with 30 years or more of productive life remaining. That contribution to society is foreclosed by their absence from the work force or by the greatly diminished roles they must play after injury. And it is not only gainful employment that is lost to the person and the society, but the whole variety of productive work as students, homemakers, and other important social contributions which the person might have made (Sander, Kreutzer, Rosenthal et al., 1996).

Definitions

There are at least five models of supported employment: (1) individual placements, (2) work enclaves, (3) apprenticeships, (4) small businesses, and (5) mobile work crews (Powell, Pancsofar, Steere et al., 1991). The most common model is individual placement, which provides training and ongoing support individually to each survivor, in settings where fewer than 5 percent of the workers are disabled. The aim is to provide a quality match between worker and job requirements, including high job satisfaction by both worker and employer and decent wages (Ellerd and Moore, 1992). This is the model usually recommended for survivors of TBI (Wehman, Kreutzer, Stonnington et al., 1988), though a variation of the apprenticeship model has also been tried (Curl, Fraser, Cook et al., 1996). One of the most detailed definitions of the individual placement model is by Kreutzer and his associates (Kreutzer, Wehman, Morton et al., 1988). They identify four essential components, all of which must be tuned to the type of deficit of the client (in this case, the client with TBI):

- Job placement. This includes (a) matching job needs to client abilities and potential, (b) facilitating employer and client communications, (c) facilitating caretaker communications, (d) arranging travel arrangements or training, and (e) analyzing the job environment to detect potential problems.
- Job site training and advocacy. This emphasizes the active role of the employment specialist, job coordinator, or job coach, who is often cited as the key professional in supported employment programs (Wehman, West, Fry et al., 1989; Ellerd and Moore, 1992). The job coach serves functions usually left to the employer in conventional vocational rehabilitation (e.g., training), and also is proactive in identifying problems and designing solutions in cooperation with all the parties involved.
- Ongoing assessment. Continuous monitoring of key aspects of the client's work performance. There is an intense intervention by the job coach at the beginning, but this is expected to diminish, or "fade," as the client settles into a successful work adjustment (Ellerd and Moore, 1992; Wehman, Sherron, Kregel et al., 1993). This process is well-illustrated in Figure 1 of Wehman, Kreutzer, West et al., 1990.

- Job retention and follow-along. A continuing, proactive process in which the job coach tries to anticipate problems and intervene early to prevent crises from disrupting the client's adapted job placement. This assistance to the client is of indefinite duration, although it is expected to diminish over time (Wehman, Sherron, Kregel et al., 1993).

The hallmark of supported employment methods is that they are applied on the job, in the actual work environment, to help the client succeed. Off-job training and practice to prepare the client for work may be an important prelude to supported employment in some programs, but the job coach always accompanies the client to the job site to work out on-the-spot solutions to problems as they arise and to mediate between employer and client. This problem-solving-in-situ is a defining principle of the method of supported employment (Kreutzer, Wehman, Morton et al., 1988). Finally, these programs usually aim at competitive employment, usually defined as employment in a setting about 95 percent occupied by workers without disabilities and paying at least the official minimum wage (Wehman, Kreutzer, West et al., 1990; Ellerd and Moore, 1992). They do not aim at placement in sheltered workshops or other settings designed primarily to accommodate to disabled workers. There is a strong commitment to placing the client in the highest job position possible and to approach or exceed the pre-injury level of work.

Supported employment is necessary only in cases where standard vocational rehabilitation is not sufficient to secure the desired level of employment for a survivor of TBI. In this respect, supported employment could be considered an extension of vocational rehabilitation into the actual job site as the final stage of helping a particular survivor resume a productive life. Studies of post-injury employment in which survivors are sorted by severity of injury show that not all survivors of TBI require this extra step. Persons suffering mild injury (GCS = 13) are usually re-employed at high rates: from about 60-85 percent within 1 year post-injury, and maintaining this high rate up to 15 years later (Dikman, Temkin, Machamer et al., 1994; Schwab, Grafman, Salazar et al., 1993; Edna and Cappelen, 1987; Fraser, Dikman, McLean et al., 1988). In those same studies, persons suffering from moderate or severe injury do not fare as well. The re-employment rates for moderate injury (GCS = 9 to 12) for the same periods are 50-60 percent and for severe injury (GCS = 8) re-employment ranges from 20-30 percent.

The GCS alone may not always be the best predictor of employment success in multivariate analyses including other severity measures (Abrams and Toms Barker, 1991), but it seems evident that supported employment is most necessary for severe injury because regular vocational rehabilitation programs are insufficient, and even a variety of other interventions before job placement—like cognitive training, with and without occupational trials, and behavior modification—show only limited success (Wehman, Kreutzer, West et al., 1990). In addition, about one-half of survivors with moderate TBI and at least 15-20 percent of survivors with mild cases might also benefit from supported employment programs.

Ideally, as an extension of vocational rehabilitation, supported employment would address the problems that lead to lost jobs. Devany and her colleagues at the Medical College of Virginia (Devany, Kreutzer, Halberstadt et al., 1991) found that survivors of TBI who had trouble with re-employment suffered from four kinds of difficulties:

1. Somatic problems, like debility, loss of balance, and motor deficiencies.
2. Cognitive problems, like loss of memory, inability to focus attention, obsessions, and indecisiveness.
3. Behavioral problems, like inertia, restlessness, depression, and impatience.
4. Communication and social problems, like contentiousness and various disorders of speech and writing.

They also found that the survivors' scores on the Minnesota Multiphasic Personality Inventory (MMPI) showed peaks on scales 8 (Schizophrenia), 4 (Psychopathic Deviate), and 2 (Depression), in that order of magnitude. Valid MMPI scores might be problematic with this population, but the pattern found seems to match the common clinical impression. A configuration of 8-4-2 on the MMPI indicates a depressed person with severe interpersonal and social deficits who could easily alarm or offend others. Add this to the various motor and cognitive deficits already noted, and we have a formidable set of obstacles to placing and maintaining a person with a severe TBI in a job setting. The underlying assumption of the supported employment model is that all persons referred to the program are employable under suitable conditions (Wehman, Sherron, Kregel et al., 1993). Successful programs focus on finding or making those conditions in support of client success at work.

Of the 93 articles retrieved for review, 42 were excluded based on initial exclusion criteria, reducing the total number of articles to 51. Two investigators read all articles retrieved through the database search, as well as 5 additional articles acquired from reference lists and recommendations from peers, for a total of 56 articles.

Direct Evidence

There is no direct evidence from randomized trials about the efficacy of supported employment.

Indirect Evidence

No Class I or IIa studies of supported employment were found in the literature. In one prospective, controlled, observational study, Haffey and Abrams (1991) measured job placement and retention rates of 130 participants in a program of supported employment, the "Work Reentry Program" or WRP. These results were compared with those of 35 clients in a day-treatment program and 76 individuals who had received no post-acute rehabilitation (the "comparison group"). Participants in the WRP program were recontacted every 6 months for up to 3 years. Other subjects were followed for varying amounts of time over 3 years, depending on when they entered the study. A total of 87 (67 percent) of the 130 participants entering the program were placed in employment. Followup for the 87 placements was as follows:

Months of followup:	1-6	7-12	13-18	19-24	>24
N:	18	23	17	15	14

The second series has been reported in a number of publications (Wehman, West, Fry et al., 1989; Wehman, Kreutzer, West et al., 1989; Wehman, Kreutzer, West et al., 1990; Wehman, Sherron, Kregel et al., 1993;). These studies evaluated the outcomes of supported employment in a prospective registry study. In the first article cited, the sample included five survivors followed for 75 weeks (1.4 years); by the last article in the series the sample had increased to 115 consecutive referrals followed for up to 60 months (5 years). These individuals passed through two consecutive phases of vocational rehabilitation: first, the standard postrehabilitation services, then a supported employment program.

For convenience in the remainder of this report, we will refer to the first study as Haffey and Abrams, and to the second series of studies, taken as a group, as the Virginia series, after the home of the researchers in the Medical College of Virginia.

Post-trauma vocational success in the Virginia series was compared with the rates of pre-injury employment success of each client, who served as his or her own control in the study. Pre-injury employment is thus taken as a baseline control for results in the two subsequent phases of intervention—the last of which was supported employment—as each client passed through the following history:

Pre-injury employment =>	Post-trauma employment =>	Supported employment
(Baseline)	(1st phase intervention)	(2nd phase intervention)

Measures of employment success in the Virginia series were (1) number of jobs held per client, (2) mean hourly wage, (3) mean monthly wage, (4) mean annual wage, (5) monthly employment ratio (MER). The last is an index of vocational success developed by the Virginia group. It is the ratio (with specific definitions of the two variables): number of months client employed/number of months client could have been employed (Wehman, Sherron, Kregel et al., 1993).

Results were measured over 5 years of operation with measures of outcome taken weekly (Wehman, Kreutzer, West et al., 1989). During that time, 80 of the 115 entering clients were placed in jobs, but it is not clear how many of the 115 were followed up for all 5 years. In the whole series of studies, we have reports on 5 clients in 1989 (Wehman, West, Fry et al., 1989) and 20 clients later in the same year (Wehman, Kreutzer, West et al., 1989). In 1990, there is report of 53 clients (Wehman, Kreutzer, West et al., 1990) and in 1993 the total of 115 (Wehman, Sherron, Kregel et al., 1993). From this pattern in the reports, we may infer that about five clients were followed for a full 5 years, 15 clients for between 4 and 5 years, 33 clients for at least 3 years, and 62 for less than 3 years**.**

Selection and allocation of clients. There was no random selection or allocation to groups in either one of the studies reviewed. In the Haffey and Abrams study, assignment to the two treatments and one "comparison group" was "determined by factors that ordinarily lead to referral to rehabilitation services." (1) Clients in the WRP (supported employment program) were referred by the state rehabilitation department if they had employment potential "under the right circumstances" (which perhaps meant a program like the WRP). Clients believed to have "absolutely no employment potential" by rehabilitation counselors, client, or family were not admitted to the WRP. (2) The second treatment group (the day-treatment program) contained survivors for whom "competitive employment was not a current goal" because of medical problems, personal and family preference, economic disincentives (pension, social security), and other engagements (homemaker, student). (3) The comparison group was made of consecutive discharges from inpatient TBI rehabilitation who did not elect to attend the WRP because they (a) thought the services unnecessary, (b) believed they were too disabled to work, (c) played a dependent role with caregivers, (d) feared jeopardizing benefits, or (e) were active substance abusers.

In the Virginia series, the sample was 115 consecutive referrals by clients' supervising physiatrists to the supported employment program. All met the following criteria: (1) age between 18 and 64 years, (2) severe TBI: GCS ≤ 8 for ≥ 6 hours, (3) strong evidence that person cannot work successfully without ongoing job support, like previous post-injury failure, client doubts, or doubts by physician, family, or counselors. No client was excluded simply for having cognitive, physical, or psychosocial deficits. Some of the studies in the series (1990) say that clients were also excluded on evidence of active substance abuse.

Models of supported employment tested. Both studies used some variant of the individual placement model of supported employment, but the two versions differed significantly. Both programs had extensive analysis of client characteristics, preferences, abilities, and deficits to guide optimum placement of the clients, the active participation of the job coach at the work site, and continuing, but "fading," support for the client on the job. The analyses of client need and capacities and job requirements are extremely detailed in both programs, but Haffey and Abrams appear to use more behavioral criteria (like simulated work samples), and the Virginia group seems to rely more on screening and respondent information (see Wehman, Kreutzer, West et al., 1989 for the screening form used). But the program used in Haffey and Abrams had a component of pre-employment training available to the clients which was not a feature of the Virginia program. Haffey and Abrams included two pre-employment trainings for the clients: (1) work hardening, using real and simulated work activity to develop "stamina, work competencies, work behaviors, and productivity levels;" and (2) the Transitional Employment Program (TEP), placing the client, on salary, in the hospital dietary or environmental service departments with a job coach for 3 to 4 months. These features are in contrast to the Virginia model, which is predicated on the "assumption...that...cognitive retraining, work adjustment, work hardening and social skills training, may be best provided at the job site while the person is already employed." This is a fundamental difference in approach which is made explicit by a later statement in the same place: "Supported employment does not promote job readiness training, but instead emphasizes using a person's current abilities and strengths" (Wehman, Sherron, Kregel et al., 1993).

Outcomes. The outcomes are summarized in the evidence tables. In the Haffey and Abrams study, 68 percent of the WRP clients secured competitive employment and only 18 percent were considered chronically unemployed. Only 39 percent of the day-treatment group and 34 percent of the comparison group reported any employment after discharge. At the last followup period reported, 71 percent of the WRP clients placed were still working, but no retention rates for the day-treatment and comparison groups were reported. The Virginia studies produced the following results, derived from Table 3 of the 1993 article:

	Pre-injury	No SE	SE

Employment outcome	(n = 62)	(n = 37)	(n = 80)
Mean number of jobs/client	2.04	1.24	1.49
Mean hourly wage earned	$4.19	$1.55	$4.90
Mean monthly wage earned	$508	$107	$658
Mean annual wage earned	$6101	$1290	$7899
Monthly employment ratio	0.40	0.13	0.67

Conclusions

There is Class IIb evidence that supported employment can improve the vocational outcomes of survivors of TBI. Almost all information about supported employment comes from two bodies of work, each of which use different experimental designs and different models of supported employment. The findings have not been replicated in other settings or by other centers, so the generalizability of these programs remains untested.

In the Virginia studies, the clients all have severe cases of TBI as rated by the GCS. In the Haffey and Abrams experiment no GCS scores are given, but the data provided on severity of injury show median length of coma in the three groups ranging from 6 to 7 days, with the median value for the entire sample of 199 cases at 7 days and the overall range from 0 to >30 days. In the 80 job-placed survivors of the Virginia series (Wehman, Sherron, Kregel et al., 1993), the average length of coma is 48 days and the range from 0 to 182 days. Clearly, the Haffey and Abrams sample contained many persons with moderate or even mild injuries, while the Virginia sample consists entirely of persons with severe injuries. We have already noted, in the Introduction to this report, that severity of injury has an important effect on vocational success.

There are also difficulties of interpretation deriving from problems with the individual study designs, and with confounded variables and biases in the groups being compared. In both studies, the prospective data collection avoids the hazards of retrospective inference, but the lack of a control condition in the Virginia studies and the highly biased allocation of clients to the groups being compared in the Haffey and Abrams research make it impossible to clearly interpret results. In the Haffey and Abrams study there are so many differences among the groups being compared that comparisons are almost meaningless. The supported employment group is heavily biased toward better vocational outcomes, containing only clients specially selected by vocational counselors as likely prospects for work. The day-treatment group, however, is filled with clients for whom "competitive employment was not a current goal," and the comparison group made up of clients who had rejected a chance at supported employment and had multiple motives to avoid work altogether. Then, when the three groups were tested for differences in client characteristics (see Table 1, Haffey and Abrams, 1991), the only difference found was that the comparison group was significantly less likely to have been employed at the time of injury. With a stacked deck, no one is surprised when the dealer wins the hand, and the superior vocational performance of the supported employment group in this experiment is likewise an anticlimax.

The problems with the Virginia series are of another sort. They arise from the inherent limitations of the design itself, since case-control studies without separate control groups and unbiased allocation of participants are not able to untangle confounded variables. Repeated measures on a single group are bound to be confounded with variables for which there are no controls. An observation made by Wehman, Sherron, Kregel et al. (1993) will illustrate the problem. They note that during the economic recession of 1990 to 1992—the worst in the United States since the 1970s—nearly 20 percent of their program participants lost their jobs due to layoffs. The design of the Virginia studies compares baseline levels of employment pre-injury with subsequent performance under two levels of vocational rehabilitation, including supported employment as the final stage.

In the Virginia sample, the average age at injury was 24.8 years and the average age at referral to the program was 30.9 years, making the average interval from injury to entry in the program 6.1 years. The average time to job placement after program entry is about 1 year more, and the subsequent followup in the series of studies under review ranges up to 5 years, with a substantial proportion of the clients at least 3 years into followup. Simple arithmetic discloses that the average time from pre-injury employment to post-injury followup is on the order of 10 to 12 years and for about half the clients the interval will be even longer. This is the time elapsed between baseline measures of pre-injury vocational success and post-injury outcome measures under supported employment. It is a significant possibility that economic changes over a 10- to 12-year period (or more, for half the sample) would have significant effects on employment. Those economic effects will be confounded with the effects of supported employment programs running at the same time, and there is no way to separate the two kinds of effects unless a control group of clients, without supported employment, were measured over the same interval. Likely, there are many other confounded variables at play in the same way, including unknown ones.

In spite of the problems mentioned, it remains true that all the programs of supported employment reviewed showed better rates of vocational success than the baseline expectations of survivors of TBI with only standard post-acute rehabilitation or even with special kinds of pre-employment vocational counseling and training (see Problems Addressed section in the Introduction to this report). The success documented by the Virginia series with survivors with severe injuries is especially convincing in this respect. Supported employment appears to be a promising way to increase the vocational success of survivors of TBI, but the present literature does not give definitive proof of its effectiveness and does not provide enough clarity on why it works or guidance to the best applications of the method.

Future Research

Experimental designs. The greatest overall need for the evaluation of supported employment programs is a series of trials with adequate controls and with unbiased allocation of clients to the conditions compared. The prototype of this kind of evaluation is the randomized, controlled trial (RCT), in which a representative sample from a population of survivors of TBI is randomly assigned to programs in supported employment and to various control conditions, which may include alternate interventions, no interventions, or both. These experiments may be very difficult or impossible to do because of the conditions under which rehabilitation programs operate. There may not be access to representative samples of survivors of TBI, for example, or it may be difficult or impossible to insulate the different experimental conditions from each other when the clients and caregivers from the different groups live in the same community and have informal social exchanges with each other. The same may be true for professional staffs. Sometimes ideal experimental conditions must be approximated and sufficient measures taken to allow supplementary regression analyses to clarify confounded variables, or covariance analyses to control for unavoidable allocation biases. These are the realities of field research. But we need better studies than we now have to clarify the effects of supported employment.

Independent variables. Beside the main independent variables of intervention and control groups, a number of measures of client characteristics may be reconsidered in light of past research. On the matter of injury severity, for example, the general rule holds that clients with moderate-to-severe TBI injuries (GCS <10) are most at risk for poor vocational outcomes in unsupported work settings (see Introduction to this review). Stambrook, Peters, Deviaene et al. (1990) found that admission GCS scores, low pre-injury vocational status, greater age, and physical and psychological problems were the best discriminators of post-injury success.

The Virginia studies focus entirely on clients with severe injuries (GCS <8) because that is where most of the problem lies. However, the link between severity of injury and unemployment is not perfect and a substantial group of survivors with even mild injuries (15-40 percent) fail at work. In a study of predictors of vocational success one year after injury (Cifu, Keyser-Marcus, Lopez et al., 1997), the Virginia group found several effective measures, including injury severity (admission GCS, highest GCS, length of coma, and length of PTA); acute measures of physical functioning (admission FIM, admission DRS, discharge DRS); cognitive functioning (logical memory delay); and behavioral functioning (admission RLAS, discharge RLAS, NRS excitement factor). But very long intervals can elapse between injury and re-employment: an average of 5 to 7 years or more is common, with half the clients waiting longer times (Wehman, Sherron, Kregel et al., 1993; Courtney, 1992; Roessler, Schriner, and Price, 1992). There is a need for finer discrimination among the states of deficit at the time of entry into employment programs than is afforded by GCS scores in the acute phase.

One possibility is to use more proximate assessments of deficit which assess abilities needed in the workplace. If supported employment programs are aimed at clients with greatest risk of vocational failure—as in the Virginia series—post-acute measures may be better predictors of post-injury work success. For example, some cognitive deficits (executive function/flexibility), emotional disturbances (aggressiveness, depression), and low ADL ratings appear to be better predictors of employment after TBI than severity of injury (Crepeau and Scherzer, 1993). The research done by the Virginia group on "easy" and "difficult" groups of clients to place and train in employment settings (Wehman, Kregel, Sherron et al., 1993) may be another basis for better discrimination of client characteristics and better matches between clients and work settings, as is the work done on the kinds of problems leading to job loss in supported employment programs for clients with TBI (Sale, West, Sherron et al., 1991).

Another class of independent variables might be called co-interventions and concurrent variables. Co-interventions are the unprogrammed interventions made by family, co-workers, employers, etc. which may affect success or failure on the job. These are difficult to identify and measure, but it is unrealistic to assume that the job coach is the only helper or advocate of the client, and these other interventions may have powerful effects on outcome. An example of concurrent variables is the observation (Wehman, Sherron, Kregel et al., 1993) that, in one instance, 20 percent of clients in a supported employment program lost their jobs to layoffs during an economic recession.

Dependent variables. One important issue of outcome variables is length of followup and frequency of measurement of outcomes. Some studies take weekly measures (the Virginia series), and others longer periods, such as every 6 months (Haffey and Abrams, 1991). Generally, frequency of measure depends on how detailed the knowledge of job adjustment needs to be for effective job coaching. In the early stages, close monitoring is necessary; as the job coach "fades" the measures may be more spaced. More important for assessing the efficacy of supported employment is the length of followup. We recommend that followup be an integrated part of all supported employment programs, as a built-in component, and that it go on indefinitely. The play of variables that determine vocational success may act over long periods of time and adequate length of followup approximates the entire work career of the client. The example of the Virginia series, which made periodic updates on a cumulating sample, shows the value of this strategy.

Another issue of outcome is the criterion of vocational success. If a broader criterion is adopted, it would extend the range of the methods of supported employment into those of supported activity. The list of primary areas of activity (Sander, Kreutzer, Rosenthal et al., 1996), which includes homemaker, student, volunteer, and retired, as well as competitively employed, and specially employed (including supported employment), is one approach to a set of criteria for vocational success which is broader than simply work-for-wages. Another approach is age-appropriate activity, as proposed by Prigatano, Fordyce, Zeiner et al. (1984), which gives due weight to homemaking and schooling as successful vocations.

Some of the methods designed for supported employment (on-site aid and advocacy, the activity coach) might be extended experimentally to settings in the home and school. The Monthly Employment Ratio (MER), a measure of vocational success developed by the Virginia group (Wehman, Kreutzer West et al., 1989), has gained some currency in the field and is worth adopting as a standard outcome measure for supported employment. It could easily be extended into a more general measure, a Monthly Activity Ratio (MAR), based on similar principles of definition, for studies adopting a wider set of criteria of vocational success.

Strategies of evaluation. The main focus of the works reviewed is what may be called outcome evaluation. This strategy is entirely appropriate in medicine when seeking a basis for treatment in evidence, but there might be some utility to other modes of evaluation as well. Observations of process, participant perspectives on the programs (by clients, staff, employers, family, etc.), and assessment of client empowerment could add entirely new dimensions to our knowledge of how programs work. These approaches to "unpacking the black box" of a supported employment program would aim to show how successful programs produce their effects and why unsuccessful programs fail. This is the kind of detailed information we need to improve the design of interventions. It is likely that much remains to be discovered about how individual differences among clients interact with aspects of the programs serving them. Johnson (1987) found that factors like ability to return to one's previous job, being provided a work trial or easier work, and long periods of support were more important in determining successful re-employment than the client’s state of deficit. These are typical benefits provided by supported employment. But what makes for easier work, what is support, and what variations in both answer the needs of particular survivors? Many details remain obscure. In many instances, alternate approaches to evaluation will require qualitative methods in combination with the quantitative measures of job retention and success. Models of these other types of evaluation are available from a wide variety of applications and there is a developing set of methods for applying them (Chelimski and Shadish, 1997). Some work along the suggested lines is already being done—the studies of client characteristics cited in the discussion of independent variables are examples—but an expanded effort to measure the operating details of the programs might be useful in the design and implementation of new or improved programs.

Models of supported employment. Most of the work found in our search was done on one model of supported employment. The individual placement model is most favored because it is the most flexible and appropriate one for returning individual survivors to their pre-injury workplace, or to new settings where their particular abilities and deficits allow a successful adjustment. The practical nature of this model of supported employment is its own justification. However, its success has perhaps obscured some good reasons for more work on other models. Recently, a variant of the apprentice model has trained supervisors and co-workers to act as on-site "job coaches) with workers with TBI (Curl and Chisholm, 1993; Curl, Fraser, Cook et al., 1996). Even with provision of salary subsidies to the "job coaches," this model offers a potentially effective and relatively low-cost method of providing supported employment. Some co-workers refused payment for their services and the ones paid cost only about 10 percent of the salary of a professional job coach (see Table 2, Curl, Fraser, Cook et al., 1996). Even if co-workers were paid for as long as the average professional job coach it would still be much cheaper to provide this service. This may be an especially effective model in settings of professional and highly skilled work forces, where the co-worker has the knowledge and skill to be the most effective helper.

Another model which may be worth considering is a revised concept of the work enclave as a work setting designed to fit the abilities and deficits of survivors of TBI, perhaps in company of persons with complementary deficits, like other physical disabilities, or with family caregivers.

Although departing from the trend to integration and normalization of TBI survivors at work, this approach may have certain benefits, especially for the most severely disabled. All models of supported employment were first applied to non-TBI populations, and this modified version of a work enclave is proven effective with some of the same populations served by early programs of individual placement, like persons with chronic mental illness (Fairweather, Sanders, Maynard et al., 1969).

This different version of the work enclave might offer some of the same resources of natural support as other social settings—like community support groups—which enhance and enable the survivor's life: the camaraderie of fellow survivors and the intrinsic interest and help of family and friends. The combination of work and social relations available in this kind of milieu may have some potential to increase both vocational success and quality of life for survivors of TBI in the same setting and the same program. If effective, it could provide a powerful combination of benefits to relieve that part of the burden of illness in TBI which is linked to vocation and work, providing a personal sense of worth and competence, a sense of belonging and well-being, and other psychological states essential to mental health (Pettifer, 1993).

Question 5. Does the provision of long-term care coordination enhance the general functional status of persons with TBI?

Some long-term functional setbacks and disturbing psychosocial sequelae may not become apparent in survivors of TBI for several years. Some consequences are even preventable, but time is often critical to maximize treatment and forestall secondary effects. One response to issues of how and when to access TBI rehabilitation has been case-management programs designed to monitor survivors and match them with appropriate services. The various impairments that survivors experience often give rise to secondary problems of vocational failure, social isolation, and extended functional dependency that can increase over time at various rates (Brooks, Campsie, Symington et al., 1986; Goering, Farkas, Lancee et al., 1988; Kaitaro, Koskinen, and

Kaipio, 1995; Olver, Ponsford, and Curran, 1996; Schalen and Nordstrom, 1994; Spatt, Zebenholzer, and Oder, 1997; Van Balen, Mulder, and Keyser, 1996).

TBI impairments present three major survivor- and family-adjustment issues for which case management is a recommended solution. One problem is that survivors may not receive appropriate post-acute clinical rehabilitation services, or they may enter programs too early or too late to benefit. There is growing evidence that some effects of TBI can be ameliorated by post-acute rehabilitation as late as 10 years post-injury (Hall and Cope, 1995; Johnston and Lewis, 1991; Spatt, Zebenholzer, and Oder, 1997). In spite of this knowledge, survivors and their families may not be entering functional improvement and/or psychosocial support programs at strategic post-injury points. This has been attributed to fragmented responsibility for screening, lack of clarity about how to identify rehabilitation readiness, and lack of accountability among program providers (Greenwood and Brooks, 1994). One reason for the lack of extended rehabilitation could be that programs are either not locally available or are not supported with incoming clients as reported in Europe (McMillan, Morris, Brooks et al., 1988; Van Balen, Mulder, and Keyser, 1996).

However, other explanations pertain to the nature of the population needs. As the post-injury time increases, the difficulties experienced by survivors of TBI tend to be increasingly subtle and diverse, and informal caregivers fail to recognize and determine what their needs are. Professionals in primary and specialty care services can also experience confusion about what should be done at what points in the post-injury continuum by which disciplines in which types of service agencies. Unless an advocate is available to maintain interagency relationships and awareness of program improvements and opportunities, it is difficult for survivors of TBI, their families and their professional caregivers to create a timely recovery agenda and facilitate access.

A second problem for which case management is a projected solution is the relatively low re-employment rate among survivors of TBI. According to Malec, Buffington, Moessner et al. (1995), the long-term unemployment rate among patients with moderate to severe injuries without vocational intervention is low—about 50 percent— and only one-third resume independent competitive employment. Studies have also shown that the period between brain injury and return to work or initiation of vocational services is long-- about 5 to 7 years (Wehman, Sherron, Kregel et al., 1993; Courtney, 1992; Roessler, Schriner, and Price, 1992).

Without appropriate employment support, survivors may experience additional psychosocial problems because of misinterpretation or lack of understanding about the symptoms. For instance, concentration and memory problems may be perceived as lack of motivation, insensitivity or mental illness. Most survivors need assistance developing career goals, learning work skills and seeking and maintaining employment. This is based on evidence of improvement with declining long-term unemployment and underemployment rates being attributed to employment support and work re-entry programs for greater numbers of survivors of TBI (Sample and Rowntree, 1995). Because vocational rehabilitation programs that support employment entry or re-entry are not a standard feature of TBI clinical rehabilitation programs, case managers or vocational coordinators are considered one means of bridging the agency gap between rehabilitation and re-employment.

A third TBI-related problem for which case management is recommended is the issue of family burden. Studies of head injury effects on family life have shown that cognitive impairments and personality changes are more disruptive than physical disabilities (Cavallo, Kay, and Ezrachi, 1992; Gleckman and Brill, 1995; Godfrey, Knight, and Bishara, 1991; Hendryx, 1989; Kreutzer, Marwitz, and Kepler, 1992; Kwasnica and Heinemann, 1994; Leathem, Heath, and Woolley, 1996; Livingston, 1987) and that parents are better able to withstand such stresses than spouses (Panting and Merry, 1972; Thomsen, 1974). Rosenbaum and Najenson (1976) found that wives of survivors of brain injury experienced more strain, sense of isolation and loneliness than did wives of paraplegics. Others also report evidence of subjective family strain and friction (Brooks, Campsie, Symington et al, 1986; Weddell, Oddy, and Jenkins, 1980). The burden on families is so widely recognized that programs aimed specifically at support or assistance of the relatives of survivors of TBI are being developed (Carnevale, 1996; Peters, Gluck, and McCormick, 1992; Ragnarsson, Thomas, and Zasler, 1993; Sanguinetti and Catanzaro, 1987). This problem of family difficulty in coping with the effects of TBI merits a broad effort to identify antecedents and effective approaches, including case management.

Definitions

Case management has emerged as a possible solution because it systematically monitors client needs over time and facilitates access to services in various institutions and programs across communities. Case managers usually serve persons with long-term or chronic conditions because they have complex needs and find it difficult to navigate the health and/or social care systems. According to the Commission for Case Manager Certification (1996), case management is:

> A means for achieving client wellness and autonomy through advocacy, communication, education, identification of service resources and service facilitation while ensuring that available resources are being used in a timely and cost-effective manner in order to obtain optimum value for both the client and the reimbursement source.

The role typically includes admission or intake assessment, care-plan development, service referral, coordination of service details, and collaboration with care providers, informal caregivers and the client (Goering, Farkas, Lancee et al., 1988; Goodwin, 1994), and may also include authorization of service payments (Ashley, Krych, Persel et al., 1994; Evans and Watke, 1995). The domain is to determine service needs and to access service elements with a sequence and timing that will result in desired outcomes for the client and family as well as desired outcomes such as cost control for the service organization.

Case Management Characteristics and Desired Outcomes

One characteristic of case management is the adopted mission of the employing organization. Since case managers are found in hospitals, rehabilitation programs, health departments, aging services departments, mental health services, insurance companies, and managed care organizations (Gerber, 1994), the focus can vary from acute-care disposition planning to long-term patient advocacy to service cost control. As the orientation and purpose of case management programs vary, outcomes may reflect the differences. In order for case management interventions to be compared and tested for effectiveness, it is important to define the specific purposes and aspects of case management that are provided.

Case managers also focus on helping clients move across institutional or organizational systems and across provider disciplines. Managing these boundary issues calls for a collaborative approach around a common focus-the client and family. Understanding case management role specifications and the extent of boundary work is also critical for comparing programs and interpreting research that tests case management effects.

Within this context of TBI incidence and long-term effects, problems experienced by clients and their families, and the definition and role of case management, our study was conducted to identify evidence of case management effectiveness. The purpose was to review the literature for controlled clinical studies of the influence of care coordination on targeted outcomes among TBI rehabilitation populations of clients and their families.

Of the 69 articles retrieved for review, 27 were excluded based on the initial exclusion criteria, reducing the total number of articles reviewed to 83. Two investigators read all retrieved articles from the database search, as well as relevant articles found on reference lists of the retrieved articles and those obtained from colleagues, for a total of 73 articles. The only criterion for study selection in this phase was that case management was an independent variable. By mutual agreement three studies were critically analyzed and entered into Tables 1 and 2 to report evidence of case management effectiveness in TBI rehabilitation.

Results

Does the provision of long-term care coordination enhance the general functional status of persons with TBI? The search strategies yielded three controlled studies of case-management effectiveness in TBI rehabilitation. Two studies compared case-management with non-case-management and one study compared two types of case management. Two studies were completed trials (Ashley, Krych, Persel et al., 1994; Greenwood and Brooks, 1994), and one article (Malec, Buffington, Moessner et al., 1995) presented preliminary results after 1 year of data collection.

Although all the studies addressed case management effectiveness, they differed in most of the design characteristics, as reported in Table 1. Regarding study purpose, Ashley, Krych, Persel et al. (1994) focused on the level of independence following rehabilitation, while Greenwood and Brooks (1994) addressed the rehabilitation process, client employment and quality of life, and family burden; and Malec and colleagues (Malec, Buffington, Moessner et al., 1995) measured employment outcomes. Two designs were group comparisons, while one design compared outcome rates with previously established baseline rates (Malec, Buffington, Moessner et al., 1995). In the only clinical trial that tested the effects of case management on client outcomes (Greenwood and Brooks, 1994), the intervention was allocated to sequentially admitted clients in randomized sites. In the other two studies sequential admission for eligible subjects was also the intervention allocation method, but the subjects were at different stages of recovery. The number of subject withdrawals and exclusions were reported in two papers; in the third, the subjects were all clients who met the inclusion criteria and could be matched to the control group. The sample sizes were moderately high (> 100) in two studies (Greenwood and Brooks, 1994; Malec, Buffington, Moessner et al., 1995), and small (n = 39) in one (Ashley, Krych, Persel et al., 1994).

Each selected study focused on a different subpopulation. In two studies the subjects were homogeneous for level of disability: either moderate disability (mean Disability Rating Scale (DRS) scores of 4.95 and 5.17 (Ashley, Krych, Persel et al., 1994); or severe disability (mean DRS scores of 16.2 and 18.3, and mean Glasgow Coma Scale (GCS) scores of 6.6 and 5.5 (Greenwood and Brooks, 1994). In the third study, the sample at 1 year consisted of clients with mild injuries (79 percent), as rated with the GCS, and moderate or severe injuries (21 percent; Malec, Buffington, Moessner et al., 1995). Comparison-group differences made it necessary to control for aspects that may have affected the outcomes, but no controls were mentioned in the preliminary report by Malec, Buffington, Moessner et al., 1995.

The studies also tested different models of case management intervention. Ashley, Krych, Persel et al. (1994) evaluated two insurance-coverage models in which the key aspects were the authority to approve disability payment and rehabilitation service claims, although this was not defined, and differences between the two groups for this characteristic were not reported. Also, the report did not include any other behavioral or role descriptors to compare and contrast the two intervention models. In fact, although a key independent variable was same versus different case managers, it is not clear from the description whether all subjects in one group had the same case manager or whether each subject in the group had one case manager for the entire post-TBI period. Greenwood and Brooks (1994) tested a medical model of case management, defined as clinical needs assessment during acute hospital care, formulation of a proactive rehabilitation plan and facilitation of rehabilitation cooperation and involvement among patients, family and professionals.

Malec, Buffington, Moessner et al. (1995) evaluated a medical-plus-vocational model of case management. They defined it as assessment and rehabilitation planning during acute hospital care for the provision of medical outpatient rehabilitation services and for vocational counseling and planning related to employment services available in the community. Although there were presumably common role behaviors in these two models, there were not enough details offered in the Greenwood and Brooks (1994) report to determine whether the case manager referrals had led to subsequent care coordination by vocational counselors and others. If so, the Greenwood model would have been similar to the Malec model. Only one study identified the discipline or training that the case managers had received (Malec, Buffington, Moessner et al., 1995). Also, the intervention periods varied by study and by client need, which no doubt influenced the results.

In addition, other design aspects differed among the studies. The data collection points ranged from 1 month to 24 months, with only two studies measuring outcomes at 12 months. In two projects the research spanned 2 years, but subjects were followed for less than 2 years if they had not entered the study at the beginning. Also, due to the team-oriented nature of case management and the close institutional quarters of the subjects, blind assessments of the subjects were not possible. Therefore, care delivered by the case managers and other team members could have differed among groups and influenced the outcomes. Additionally, there was almost no information about possible co-interventions such as other service providers who may have offered care coordination and continuity, and there was very limited information about the other types of rehabilitation services that may have influenced client outcomes.

There are very few studies of the effectiveness of case management. The results of these studies are mixed (Evidence Table for case management, 2). There is evidence from Class III studies that case management improved vocational status. This was associated with the single case-manager and insurance approach (Ashley, Krych, Persel et al., 1994), as well as with the combined nurse and vocational case manager model (Malec, Buffington, Moessner et al., 1995).

There were conflicting results about the effects of case management on disability or functional status, living status, family impact and other aspects, and some findings were mentioned in only one study. The clinical trial resulted in no functional status changes among case managed subjects, despite an extended period of rehabilitation (Greenwood and Brooks, 1994). However, when two forms of case management were compared, both the single and multiple case-manager/insurance approaches showed significant functional improvements (Ashley, Krych, Persel et al, 1994).

Findings also conflicted on the effect of case management on subjects' living arrangements. Greater independence was demonstrated with the single case-manager and insurance approach (Ashley, Krych, Persel et al., 1993), while greater dependence was found with the general case-manager model (Greenwood and Brooks, 1994). In the only study that measured case management effect on families, the result was that families sought more medical care and they changed their amount of leisure time (although the direction was not identified) (Greenwood and Brooks, 1994). A modest majority of respondents in the Malec, Buffington, Moessner et al. (1995) study found the case manager helpful, but the report did not mention whether this rating referred to the nurse case manager and/or the vocational case manager. Single-study findings included lower rehabilitation costs and higher disability payments for the single-case-manager model (Ashley, Krych, Persel et al., 1993) and identification of unmet case management needs among adolescents, seniors and alcoholic clients (Malec, Buffington, Moessner et al., 1995).

Conclusions

From our review we conclude that there is no clear evidence that case management is effective with survivors of TBI and their families, but neither is there clear evidence that it is ineffective. Further research is warranted to resolve this question. It is not possible to directly compare the three studies reviewed because there were almost no similarities in design, sampling or outcome measures that would provide a basis for comparison. Although all 312 subjects had been diagnosed with brain injury and had evidence of impairment, the samples represent different sub-populations based on injury severity level: moderate, severe and mixed. For the latter sample, results were not reported by level of injury. Similarly, although there was a controlled intervention of case management provided in each study, there were key differences in the definitions and case-management-model characteristics. In addition, there were few, if any, specifications about the case managers' training, discipline, experience, and roles. Only one report (Greenwood and Brooks, 1994) mentioned the number of case managers who had provided the intervention (three) and it was also the only report that mentioned the number of clients that were managed by each case manager at a time (20). In no case was there any evidence of reliability or validity testing of the case management approach.

In addition, there are other weaknesses that contribute to the inability to draw conclusions from this small group of studies. One potential source of bias is the lack of control for co-interventions that may have provided service referrals, care continuity, and client and/or family support that simulated case management. This might have occurred, for example, when a study case manager referred the client to another program or service, and it may have also occurred within the family support system. Without controlling for such an effect, it is not possible to attribute any results to formal case management. Another problem is that the studies each provided case management for different amounts of time and at different stages of recovery. Moreover, they utilized different periods of time to measure the outcomes, and the measures did not continue longitudinally for all subjects. This had the statistical effect of reducing the number of subjects who were likely to benefit from the intervention. That is, even if the intervention had had a positive effect, the difference may not have been apparent. Also, because of the team-oriented nature of case management coordination, none of the researchers was able to arrange blind assessments of the subjects. For this reason, it is not possible to know whether there are provider biases associated with care provided for particular subjects or subject groups.

Finally, nothing is known about the quality of the rehabilitation programs associated with the case-management models demonstrated in the reviewed studies. Greenwood and Brooks (1994) point out that since the experimental subjects did not progress despite greater rehabilitation service contact time, the cause may have been that the case manager did not have the authority to improve the quality of rehabilitation. Since client and family outcomes may be related only to rehabilitation program benefit, it would be useful to know how to control for rehabilitation program quality to identify confounding factors. Another consideration for possible effect on the targeted outcomes is the ability to access the rehabilitation programs. Since rehabilitation access depends on program availability in the community, economic feasibility for the patient and the knowledge of others, such as family physicians and emergency care teams, it would be useful to have measures of those environmental conditions as additional outcome analysis controls.

Despite these methodological weaknesses and the incompatible findings, however, there are some observations that can be made from the collective findings of these three studies. First, two of the three studies found significant improvements associated with case management in at least one type of functional outcome (Ashley, Krych, Persel et al., 1994; Malec, Buffington, Moessner et al., 1995). This suggests that perhaps the model of case management that was employed in the Greenwood and Brooks (1995) study was simply the wrong model. Second, in the Greenwood and Brooks (1995) study the dropout rate among subjects without a case manager was higher, which suggests that subjects may have found the service useful in a subjective way. These glimmers of evidence from three controlled studies provide substantive implications for continued research that can improve upon the methods described above.

Future Research

Research studies in the future need to test for possible effects of case management that have not yet been identified. We believe it is important to conduct clinical trials that specify and test the extent of contact with the client and family, role training and competence, service-approval authority, screening/re-screening frequency, and influence within the rehabilitation community network. Reliability and validity testing are also recommended for measuring case management. In addition, controls should be in place for isolating possible co-interventions that simulate care coordination. The control variables should include post-injury rehabilitation elements such as settings, types of therapies, amount of contact times, goal achievement records, and other aspects that may directly affect client outcomes.

We suggest that there be improved outcome measures used in case management clinical trial studies for TBI subjects. In addition to outcomes of changed client functionality, there should be outcomes of changed family functionality. Since much of case management communication is directed toward helping family members learn what to expect and where to obtain services, relevant outcomes would include family use of community and rehabilitation services and indicators of family assertiveness regarding care expectations. While case management may only indirectly affect a client's functional outcomes such as level of disability, vocational status, and living status, it is possible that case management can directly affect family knowledge of TBI rehabilitation needs and services, level of psychosocial anxiety and family competency in coping with TBI.

We also recommend separate measures and analyses for subjects with mild, moderate, and severe disability. Greenwood and Brooks (1994) interpreted their findings that more case-managed-group relatives reported a major TBI effect on the family and had more use of prescribed drugs and medical services by attributing the differences to a more severely ill sample in the case-managed group. However, this could not be verified because they had not controlled for severity of illness. Third, if family members were measured at pre- and post-intervention points, the case management intervention effects should become more apparent. Finally, for purposes of study comparability, outcomes could be measured at 12-month post-injury intervals.

General Report Conclusions

The purpose of this document was to provide an exhaustive, evidence-based approach to the problem of traumatic brain injury rehabilitation. In order to make this a feasible undertaking, five specific topics were selected from among the many aspects of TBI rehabilitation. These aspects were closely defined and then subjected to rigorous and explicit evidence-based literature review and analysis.

In producing a “conclusions” section to this work, two issues need to be addressed. First, the results of the literature investigations into the five topics should be summarized. Second, their implications should be discussed. Because of the nature of the evidence-based medicine process and the overall weakness of the literature, however, these processes must be undertaken with care.

Although formulated around specific questions, evidence-based medicine is driven by the literature. For instance, the questions that are initially formulated are almost never directly reflected in any one individual study much less in a body of literature. Therefore, the results of evidence-based medicine efforts will be strongly influenced by the approaches to individual topics taken in the body of relevant literature and by the strength of those studies. Because of these constraints, it is hazardous to separate a synopsis of the conclusions of an evidence-based medicine analysis from the studies that specifically drive those conclusions. Unless there is a large body of Class I literature, separating summary statements from the strength of their supporting evidence vastly increases the risk of their misinterpretation. For that reason, the summary statements contained in this section with respect to the five questions are strictly limited to reflections of the statements made in their individual sections. The reader is strongly encouraged to study those sections prior to interpreting these summary statements.

In addition, because of the overall weakness of the literature as reflected in this work, clinical interpretation is hazardous. It must be remembered that the absence of evidence is not evidence of absence. Although none of the issues involved in TBI rehabilitation that are addressed in this work is supported by Class I evidence, it must be recognized that there is also not a similarly strong body of evidence standing in disproof. Therefore, because something has not been definitively proven as effective must not be interpreted to mean that is does not have clinical utility, should not be continued, or should not be funded. The proper interpretation would be that, in the presence of a need for treatment and the absence of clearly superior alternatives, choices must be made between therapies without proven superiority over others based on clinical pragmatism.

From a funding viewpoint, it must also be recognized that there is a vast difference between making a choice between alternate therapies based on less than optimal evidence and denying an entire category of therapeutic management based on the absence of strong scientific proof of efficacy. The application of evidence-based medicine techniques to the current body of clinical literature over the past several years has effectively raised the scientific bar much higher than it has ever been before. Although it is expected that the new height of the bar will be recognized by clinical researchers and result in significantly better design and more powerful studies in the future, the application of this new degree of rigor to studies done in even the recent past must be seen as an attempt to improve medicine, not paralyze it.

SUMMARY OF FINDINGS

Question 1: Should interdisciplinary rehabilitation begin during acute hospitalization for traumatic brain injury?

One small, retrospective, observational study from a single rehabilitation facility supports an association between the acute institution of formalized, multidisciplinary, physiatrist-driven TBI rehabilitation and decreased LOS (acute hospital and acute rehabilitation) and some measures of short-term physiologic (non-cognitive) patient outcome. The level of evidence is Class III. This study concerned patients with severe brain injury (GCS 3-8). There is no evidence from comparative studies for or against early rehabilitation in patients with mild and moderate injury.

Deriving clinical implications from the single Class III study that directly addresses this question must be done with trepidation. It is generally felt that the application of modalities such as physical therapy as early as possible following TBI is beneficial. In addition, the transition from acute stay at the trauma hospital to a rehabilitation facility for severe TBI patients is almost always driven by issues that are peripheral to the proper timing of rehabilitation efforts (e.g., systemic complications, bed availability, etc.). Since the one study did suggest that the institution of formalized, multidisciplinary, physiatric-driven TBI rehabilitation efforts early in the post-traumatic period was favorably associated with issues of short-term outcome as well as logistics, it would seem reasonable, based on the present body of literature, to include a physiatrist in the acute care team in as expedient a fashion as possible.

Question 2: Does the intensity of inpatient interdisciplinary rehabilitation affect long-term outcomes?

When measured as the hours of application of individual or group therapies, there is no indication that the intensity of acute-inpatient TBI rehabilitation is related to outcome. Because of methodological weaknesses, however, previous studies are likely to have missed a significant relationship if one exists (a Type II error). These studies contained insufficient information about severity of injury and baseline function to ensure the comparability of the compared groups. These studies also did not consider the quality of individual treatments, their lack of autonomy in the cognitive realm, and the delivery milieu. One or more of these factors might affect the outcome of care more than the time spent in each modality. Therefore, future research into efficacy of acute inpatient TBI rehabilitation must more adequately measure such factors and include them in their predictive models. Future studies must also employ a wider spectrum of outcome measures including measurement of outcomes longer after discharge. Such an analysis would be an ideal application of a universal uniform data set.

With respect to the clinical aspect, the evidence does not support equating different systems of TBI rehabilitation delivery based on equivalent times of patient exposure to various therapeutic modalities. For example, this analysis would not support the assumption that patient benefit would be equal if an equal time spectrum of rehabilitation therapies were delivered at a rehabilitation center as compared to a skilled nursing facility. More detailed analysis of factors involved in predicting response to rehabilitation modalities must be considered in approaching such questions.

Additionally, mandating a minimum number of hours of applied therapy for all TBI patients is not supported by the present state of scientific knowledge. The issues of how much intervention optimizes recovery in a given type of patient remains inadequately studied. It is certainly reasonable to avoid situations in which patients do not receive potentially beneficial treatment. Based on the above studies, however, defining a minimum rehabilitation program in terms of time of applied therapy is not likely to optimize either therapist time or patient recovery. It is probable that a specific basic program will have to be related to individual patient groups. Developing such algorithms requires future research.

Many persons who suffer TBI do not enter acute inpatient rehabilitation. Only one study of the effectiveness of inpatient rehabilitation included a comparison group of patients who did not undergo inpatient rehabilitation. Future studies should compare acute, inpatient rehabilitation to commonly used alternatives to inpatient rehabilitation, such as care in a well-staffed, skilled nursing facility or in less intense variations of acute rehabilitation. Very little is known about the outcome of TBI in these settings.

Question 3: Does the application of compensatory, cognitive rehabilitation enhance outcomes for persons who sustained TBI?

One small randomized controlled trial (Class I) and one observational study (Class III) provide evidence of the direct effect of compensatory cognitive devices (notebooks, wristwatch alarms, programmed reminder devices) on the reduction of everyday memory failures for persons with TBI. A second randomized controlled trial provides evidence that compensatory cognitive rehabilitation reduces anxiety, and improves self-concept and interpersonal relationships for persons with TBI. The level of evidence is Class II[a].

One small randomized controlled trial (Class I) and one comparative study (Class II[b]) provide limited evidence that practice and computer aided cognitive rehabilitation improve performance on laboratory-based measures of immediate recall. No studies evaluated the link between such cognitive tests and health outcomes, and the associations between performance on cognitive tests and employment in the literature were inconsistent.

Current practice in cognitive rehabilitation lacks a firm basis in experimental clinical studies. It is unlikely that the studies we reviewed, designed to address effectiveness, accurately describe the totality of techniques, stimulation, and human effort and ingenuity that constitute cognitive rehabilitation programs, particularly if the programs are multi or transdisciplinary. Therapists observe that their patients improve; what is causing the improvements is not understood. In making decisions about the course of treatment, clinicians are compelled to follow their experience and observations until strong research designs provide evidence from which guidelines and standards can be derived.

Question 4: Does the application of supported employment enhance outcomes for persons with TBI?

There is some Class II evidence that supported employment can improve the vocational outcomes of survivors of TBI. Most of the evidence on the effects of supported employment comes from two programs of research, each of which used different experimental designs and different models of supported employment. Both designs used prospective data collection, but one compared the treatment group to an independent control while the other was a case-control study comparing pre-injury employment with post-iinjury employment without and then with supported employment. The findings have not been replicated at other centers, so the results cannot be generalized t the general population of survivors of TBI. Most of the studies of supported employment in TBI research is of the individual placement model, but some evidence also supports the use of the apprenticeship model.

The evidence for improvement of vocational outcomes with supported employment is sufficient to warrant its use in practice, while further research continues. However, much remains unknown about the amount of improvement which is actually gained by these programs and what components of the programs contribute most to the improved outcomes. It may also be improtant to explore other models of supported employment, like the apprenticeship model or some variations of the work enclave model.

Question 5: Does the provision of long-term care coordination enhance the general functional status of person with TBI?

Very few studies of the effectiveness of case management have been done, with mixed results. The clearest demonstration of improvement due to case management is in vocational status, where at least two studies, using different models of case management, both showed similar improvements. One of these two programs showed superior results when a single case manager administered all the insurance benefits of each patient; the other showed results in the same direction using a combination of nurse and vocational case manager to select and time the interventions. There were conflicting results on other effects of case management, including disability or functional status, living status, and effects on the family, and some outcomes were mentioned in only one study. The clinical trial, using separate hospital systems randomly assigned to a case management condition, showed that there was no functional status changes among case management participants, despite an extended period of rehabilitation and followup. But, when two forms of case management were compared, both the single and multiple case manager/insurance models showed significant functional improvements.

Although the present evidence is mixed, it seems warranted to continue the use of several case management models to select and time interventions in cases of TBI, and it may also be of benefit to survivors to have the benefits of advocacy by the case manager in finding and obtaining treatments. There is a certain face validity to the basic idea of case management, which is simply a matter of careful planning of the choice, sequence and timing of interventions, and some variation of it is really a standard component of most clinical practice. There is also probably some value to the person with TBI of an advocate able to obtain benefits which would otherwise be missed by an unaided survivor. The extent of the benefit of case management, however, remains undemonstrated, and more studies using control groups would be very beneficial in clarifying the actual improvement in outcomes due to case management. It is also unclear whether some models of case management are better than others and for what kinds of clients they might be best suited. These questions give the agendas of future research.

Due to the methods through which the above five topics have been approached in the literature and the relative absence of powerful studies in these areas, the conclusions reached by this evidence-based approach and the clinical implications drawn there from are extremely limited. As a direct result, the utility of this document in driving profound alterations in TBI rehabilitation based on the scientific literature is very restricted. As the product of an exhaustive review of the literature in these five areas, however, this work is in an ideal position to summarize the shortcomings of the studies in these fields and to make generalizable recommendations regarding how future efforts could be improved. Because the five topics addressed in this work spend the temporal gamut from acute-care through long-term survivorship, this document also serves as an ideal conduit for suggesting means for optimizing continuity and consistency of research efforts spanning the spectrum of recovery from TBI. Because the ability to suggest improvements in research efforts in a knowledgeable fashion is probably the most valuable result of this work, special attention was directed to this area. This resulted in the analyses of research shortcomings and sets of recommendations contained in the accompanying Aspen Consensus Conference document (see Special Attachment).

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List of Abbreviations

ADL	Activities of daily living
AHCPR	Agency for Health Care Policy and Research
AIS	Abbreviated injury score
ANCOVA	Analysis of covariants
BVRT	Benton Visual Retention Test
CACR	Computer-aided cognitive rehabilitation
CCR	Compensatory cognitive rehabilitation
CFT	Complex Figure Test
CIQ	Community Integration Questionnaire
CT	Computerized tomography
D/C	Discharge
DRS	Disability rating scale
EMF	Everyday memory failure
EPC	Evidence-based Practice Center
FAM	Functional Adaptability Measure
FIM	Functional Independence Measure
GCS	Glasgow Coma Scale
GOS	Glasgow Outcomes Scale
HCFA	Health Care Financing Administration
ICP	Intracranial pressure
ILP	Independent living programs
ISS	Injury severity score
KAS	Katz Adjustment Scale
LOS	Length of stay
MANOVA	Multivariate analysis of variants
MAR	Monthly activity ratio
MER	Monthly employment ratio
MMPI	Minnesota Multiphasic Personality Inventory
OHSU	Oregon Health Sciences University
OT	Occupational therapy
PAI	Portland Adaptability Inventory
PASAT	Paced Auditory Serial Addition Task
PT	Physical therapy
PTA	Post-traumatic amnesia
RBMT	Rivermead Behavioral Memory Test
RCR	Restorative cognitive rehabilitation
RCT	Randomized, controlled trial
RKE	Rabideau Kitchen Evaluation
RLA	Rancho Los Amigo
RLAS	Ruff Language Assessment Scale
RT	Reaction time
SRT	Selective Reminding Test

ST	Speech therapy
TBI	Traumatic brain injury
TCDB	Traumatic Coma Data Bank
TEP	Transitional employment program
TLT	Trail Learning Test
VerPa	Verbal Paired Associated Task
VisPa	Visual Paired Associates Task
WAIS	Wechser Adult Intelligence Scale
WMS	Wechser Memory Scale
WRP	Work reentry program

Evidence table 1. Study - MacKay, 1992

Design	Patients	Setting	Sampling	Grouping	TBI severity measure	Confounding variables	Method of handling confounding variables	Definition of acute, formalized rehabilitation
Retrospective	38 severe TBI patients (admission GCS 3-8)	Single inpatient rehabilitation facility	Consecutively discharged from inpatient rehabilitation between 1984 - 1990	Formalized, physiatrist driven multidisciplinary rehabilitation program at the acute care facility (N=17) vs “non formalized” acute care rehabilitation at 10 hospitals (N=21)	GCS, ISS, RLA on admission to rehabilitation, pupillary & pain responses, CT scan	TBI severity, associated injuries (ISS), surgical interventions. Admission GCS and RLA on admission to rehabilitation included in ANOVA analysis.	t-test	Evaluation and treatment on admission to the acute hospital by a physiatrist and specialists in PT, OT, and ST. Rehabilitative and preventive intervention involved structured multisensory stimulation, orientation, exercise, and positioning.

Independent variables	Dependent variables	Statistical methods
Formalized rehabilitation at acute care hospital vs “non formalized” rehabilitation (much less regular time of onset and intensity therapy [14% received only physical therapy, 65% received no speech therapy, and 14% received no rehabilitation at all]	Duration of coma, rehabilitation LOS, specific outcome parameters in terms of physical/motor, sensory/perceptual, cognitive/language outcome.	ANCOVA

Results	Analysis	Caveats
• The formalized treatment group had approximately 1/3 the duration of coma and rehabilitation stays. • Length of coma, rehabilitation length of stay, total length of stay, and RLA at acute and rehab discharge were significantly associated with type of acute rehabilitation when controlling for GCS using ANCOVA analysis. When controlling for admission RLA using ANCOVA analysis, only RLA at discharge from the acute facility remains significantly different between groups. • Physical/motor, sensory/perceptual, cognitive/language outcome parameters were better for the formalized group.	Formalized multidisciplinary physiatrist-driven rehabilitation should be instituted as soon as possible following trauma center admission.	• Lack of multivariate statistical handling of potential confounding variables. This particularly weakens the data for recovery of physical/motor, sensory/perceptual, cognitive/language outcome parameters where there was no control for confounding variables. Multivariate regression analysis would be a more powerful method than ANCOVA in analyzing the relative predictive power of type of acute rehabilitation program vs other confounding factors. • Lack of long term follow-up

Evidence table 2. Study 1 - Aronow, 1987

Design	Patients	Setting	Sampling	Grouping	TBI severity measure	Confounding variables	Method of handling confounding variables	Definition of acute, formalized rehabilitation
Retrospective	Rehabilitation group N=68; Non rehabilitation (control) group N=61. Selection criteria = TBI (•1 hour of unconsciousness and •24 hours of altered consciousness), age at injury 5 -80, acute hospital LOS •15 days, not comatose at acute hospital discharge.	• Rehabilitation group = specialized inpatient brain injury rehabilitation program • Non rehabilitation (control) group = general neurosurgical unit at large teaching hospital in area of country with no comprehensive rehabilitation available for severe TBI	• Rehabilitation group-107 consecutive rehabilitation discharges. • Non rehabilitation (control) group-1400 cases consecutively entered into an autonomous epidemiologic TBI database	• Rehabilitation group inpatient, physiatrist driven comprehensive, multidisciplinary rehabilitation program • Non rehabilitation group-no comprehensive rehabilitation program (many received some informal, ancillary rehabilitation therapies)	PTA, acute hospital LOS, open brain injury, number of skull fractures	Age, sex, race, years post injury	Entered into regression analysis prior to independent variables; Chi square for PTA differences between groups	Inpatient, physiatrist driven comprehensive, multidisciplinary rehabilitation program

Independent variables	Dependent variables	Statistical methods
Rehabilitation vs. no rehabilitation	13 variable standardized measure (vocational status, living arrangement, number of recent inpatient treatment episodes, number of recent outpatient episodes, hours of daytime care required, functional status in self-care, mobility, and residential skills, number of home and outside social contacts, and number of physical cognitive, and emotional symptoms)	Multivariate linear regression

Results	Analysis	Caveats
• Rehabilitation was positively associated with outcome (total model R2=0.551, r=0.159) • When patients were grouped according to severity as indexed by post traumatic amnesia, there was a trend toward better outcome for rehabilitation patients of comparable severity in terms of cost • When average dollar costs were examined for patients with grouped post traumatic amnesias there appeared to be an overall net savings favoring the rehabilitation	When injury severity is considered, however, rehabilitation appeared to provide markedly better gains and the “unit cost” of these gains was less than for patients who received no rehabilitation	• Injury severity indexed by PTA differed significantly between groups (70% of the rehabilitation group had PTA’s •4 months while the non-rehabilitation group had PTA’s •1 month in 74% • Little actual data presented in paper • GCS was not used to index injury severity (due to missing data points) • Timing of long term outcome (telephone interview) not specified

group for a given level of post traumatic amnesia			• The long-term outcome measurement tool was a unique, non-validated scale • Poor correlation coefficient (0.159) for overall prediction model.

Evidence table 2. Study 2 - Heinemann, 1995

Design	Patients	Setting	Sampling	Grouping	TBI severity measure	Confounding variables	Method of handling confounding variables	Definition of acute, formalized rehabilitation
Prospectively collected data set (UDSMR)	140 patients with TBI	Eight UDSMR rehabilitation hospitals.	All patients admitted between 1990 1991.	None (0bservational study)	None	Age, admission FIM, rehabilitation LOS, interval between TBI and admission	Multivariate regression analysis	Average daily intensity = number of hours billed divided by LOS

Independent variables	Dependent variables	Statistical methods
Average daily intensity for PT, OT, ST, and Psychological services Average daily intensity for all services combined	• Discharge motor and cognitive FIM scores • Achievement of motor or cognitive potential ([D/C FIM - admit FIM]/[100 admit FIM]) • Efficiency of change ([D/C FIM - admit FIM]/ln[LOS])	Linear regression with forced entry of predictor variables (confirmed by backwards elimination linear regression analysis)

Results	Analysis	Caveats
• Treatment intensity is not independent of functional status at admission, demographics, or medical characteristics • Intensity measured as hours per day of PT, OT, or ST are not related to outcome as measured by the FIM at discharge from inpatient rehabilitation • Intensity of psychological services (generally delivered as cognitive therapy) is positively related to cognitive FIM recovery as measured by the FIM at discharge from inpatient rehabilitation	The lack of interaction between treatment intensity (other than psychological services) and outcome may be due to the choice of choice of outcome measures, lack of control of treatment quality or indications at the included hospitals, mismatch in timing of application of these therapies, or the HCFA mandate of a minimum 3 hours per day of treatment for each patient that was in place during this study. This mandate may have decreased the overall variation within therapies and weakened their correlations with outcome.	• Unspecified definition of TBI • No control for severity of injury • No control over treatments at the involved hospitals • Billing hours contain time not spent directly in patient care • Lack of long term follow-up

Evidence table 2. Study 3 – Spivak, 1992

Design	Patients	Setting	Sampling	Grouping	TBI severity measure	Confounding variables	Method of handling confounding variables	Definition of acute, formalized rehabilitation
Retrospective	95 patients with TBI	Single inpatient rehabilitation unit.	Patients with complete records admitted between 1988 1990	None (0bservational study)	GCS within 24 hours of acute admission, head AIS, duration of coma	TBI severity, severity of extracranial injuries (highest non head AIS), age, time since TBI	Unclear	Hours of treatment measured in 15 minute intervals of actual treatment performance

Independent variables	Dependent variables	Statistical methods
• Intensity of treatment during the first month of rehabilitation = total hours of treatment during the first month. Patients split into high and low groups using median value (76 hours). • Average daily intensity of treatment over entire LOS. Patients split into high and low groups using median value (4 hours/day). Corrected for off time by dividing all values by 0.66. • LOS. Patients split into high and low groups using median value (58 days).	Clinical outcome (in-house rating scales for each discipline grouped along 3 axes [physical performance, higher-level cognitive skills, and cognitively-mediated physical skills]). Also RLA at discharge.	ANCOVA with multiple comparisons/ANOVA with multiple comparisons

Results	Analysis	Caveats
ANCOVA analysis with multiple comparisons of 2 independent variables (1 month treatment intensities or full stay treatment intensity plus LOS) on each of the 3 dependent variables: • Statistically significant relation between discharge RLA and 1 month treatment intensity. • Borderline significance (p=0.06) between higher-level cognitive skills and average treatment intensity. • Borderline significance (p=0.07) for the triple interaction of RLA, LOS, and average treatment intensity. Further univariate ANOVA analysis of this	• Authors argued that treatment intensity can play a significant role in improving outcome, especially in patient with poorer presentation and longer LOS's. • Reason for weak role of treatment intensity could include: 1) ceiling effect due to most patient getting sufficient treatment such that more is not advantageous; 2) range of treatment too limited to show effect; 3) intensity results only relevant to higher cognitive functions. • Rehabilitative treatment in TBI should include 5-6 hours/day once patients are out of coma.	• Unspecified definition of TBI • Clinical outcome dependent variables other than RLA measured using proprietary, non-standardized scale. • Median split method of dividing independent variables into two groups may not provide physiologically meaningful groups. • Unclear methods of controlling for confounding variables. • Over emphasis on interactions that are of "borderline" significance (p values of 0.06 and 0.07) • Lack of lack of multivariate statistical handling of

borderline interaction revealed that there was a significant effect of high intensity treatment during the entire stay on rancho scores in patients with long lengths of stays. This was not true for patients with short lengths of stays.	potential confounding variables. • Lack of long term follow-up

Evidence table 2. Study 4 – Blackerby, 1990

Design	Patients	Setting	Sampling	Grouping	TBI severity measure	Confounding variables	Method of handling confounding variables	Definition of acute, formalized rehabilitation
Retrospective	149 brain injury patients (97% with TBI	Two commercial inpatient head injury rehabilitation provider units	All patients in program between 1986-1988	Number of patients pre vs post major programmatic changes including increase in mean daily therapy hours from 5.5 to 8 in patients in coma stimulation (54/14) and acute rehabilitation (44/37)	None	Age, level of function on admission (measure not specified), time post injury at admission	None (groups stated to not be different	Mean daily therapy hours

Independent variables	Dependent variables	Statistical methods
Intensity of therapy	Inpatient rehabilitation LOS	T-statistics for pre vs post programmatic change LOS for coma treatment and acute treatment groups

Results	Analysis	Caveats
Statistically significant decrease in rehabilitation LOS in both groups after the increase in intensity of treatment.	• decreased LOS correlated with increased intensity of treatment • Projected an average cost savings of 16,950 for coma treatment and $18,504 for acute treatment patients.	• Unspecified definition of TBI • No control for confounding variables • Change in treatment program vastly greater than simply the increased therapeutic intensity • Treatment differences between the two hospitals involved.

• Lack of long term follow-up

Evidence table 3. Randomized controlled trials of cognitive rehabilitation – Health outcomes [arc 1]

Source	Intervention/ treatment group	Comparison Group/ 2nd treatment grp.	Duration of intervention	Followup	Setting/population
Novack (1996)	Restorative and Compensatory Hierarchical, structured CACR with therapist support and external cues.	Unstructured. Memory/reasoning tasks, games, computer games.	30 min. sessions 5 days/week 20 sessions 10 hours total	None	Acute inpatient rehabilitation Consecutive admissions over 3 years
Schmitter-Edgecombe (1995)	Compensatory Notebook training with wristwatch alarm cue	Group sessions for problem solving, discussion of social isolation, frustrations	60 min. sessions 2 days/week 8 weeks 16 sessions 16 hours total	6 months	Outpatient volunteers
Neistadt (1992)	Restorative Functional Skills Group (T1) trained in food preparation.	Perceptual Skills Group (T2) trained in parquetry block assembly. Each group trained in one skill, tested for both skills.	30 min. sessions 3 days/week 6 weeks 9 hours total	None	Boston School of Occupational Therapy, Tufts University. Subjects recruited from 10 head-injury programs, 8 residential, 2 outpatient
Ruff (1990)	Restorative and Compensatory CACR and external aids (notebooks, calendars, schedules, timers, etc.)	Psychosocial Functioning and ADLs	3 hours/day 4 days/week 8 weeks 96 hours total	None	University of San Diego Outpatients Population not specified

Helffenstein (1982)	Compensatory Interpersonal Process Recall (IPR) Videotape of social interaction, viewing of tape, feedback, corrections and practice	Nontherapeutic attention (with no feedback on interpersonal functioning)	1 hour/day 20 days 20 hours total	1 month (on 6 subjects)	Brain Injury Project Woodrow Wilson Rehabilitation Center

Evidence table 3. Randomized controlled trials of cognitive rehabilitation - Health outcomes [arc 1 continued]

Source	N	Chronicity	Severity	Outcomes/analysis	Results	Level
Novack (1996)	T - 22† C - 22	T - 5.9 wks (3.3)* C - 6.4 wks (4.9)	21-GCS ≤ 8 3-moderate GCS + positive CT 20-8 days coma + positive CT	Digit Span & Mental Control subtests of WMS, Computer-based measures of reaction time (RT), Neuropsych. Batter, FIM on 24 of 44 subjects MANOVA/ANCOVA's, t-tests	No Treatment Effect for FIM ADLs T = 29.3 C = 29.2	I
Schmitter-Edgecombe (1995)	T - 4 C - 4	T - 77.7 mos (46.8) C - 86.8 mos (67.7)	T - 139.3 DRS (2.2) C - 140.5 DRS (2.6)	Laboratory Recall (Index from WMS Logical Memory 1 & 2, Visual Reproduction 1 & 2) RBMT profile score Everyday Memory Questionnaire Observed Everyday Memory Failures (EMFs) Symptom Checklist 90 ANCOVAs	No treatment effect on 4 of 5 measures. Treatment group had fewer EMFs than control group at posttreatment. for mean # of EMFs T = -23.37 C = -7.75 No treatment effect at followup	I
Neistadt (1992)	T1 - 23 T2 - 22	7.9 years (6.6)	≤ 10 WAIS-R Block Design scaled score Less than perfect score on pretest RKE-R	Parquetry Block Design Rabideau Kitchen Evaluation Revised (RKE-R) WAIS-R Block Design Subtest ANOVAs, t-tests	No Treatment Effect on RKE-R • for RKE-R T1 = 7.92 T2 = 2.68 Perceptual Skills Group (T2) scored significantly higher than Functional Skills Group (T1) on Parquetry Block Design	I
Ruff (1990)	T - 12 C - 12	T - 44.3 months (25.6) C - 52.2 months (19.2)	T - 25.5 coma days (16.4) C - 48.3 coma days (28.3)	Katz Adjustment Scale (KAS) Self-Report and Family-Report MANOVA/ANCOVA	No Treatment Effect • for means on KAS global scale scores ranged from: T = 4, C = 1 (Social Obstreperousness, Self-Report) to: T - -0.6, C = -0.4 (Acute Psychoticism, Family-Report)	I

Helffenstein (1982)	T - 8 C - 8	Not specified	Estimated to be mild to moderate	State Trait Anxiety Scale (STAS) Tennessee Self-Concept Scale (TSCS) Interpersonal Communication Inventory (ICI) Interpersonal Relationship Rating Scale (IRRS) Independent Observer Report Scale Videotape Analysis ANCOVAs	Treatment effect on 1 variable from STAS and 3 variables from TSCS. Treatment effect on IRRS scale, and Independent Observer Report Scale (group means not provided)	II (a)

† T = Treatment Group, C = Control Group
* Numbers in ( ) are standard deviations
Note: Refer to List of Abbreviations for key to severity and outcome measures.

Evidence table 4. Comparative study of cognitive rehabilitation – Employment [arc 2]

Source	Intervention/target	Comparison	Duration of intervention	Followup	Setting/population
Prigatano (1984)	Restorative and Compensatory Intensive, coordinated, multidisciplinary CR. Stresses awareness of deficits, compensatory skills development. Staff includes clinical neuropsych., speech pathologist, O.T., P.T., research psychologist.	No Neuropsych. rehab. progam (NRP) Other interventions not specified	4 days/week 6 hours/day 6 months 624 hours total	Between 33 months and 3 months, depending on when the person entered the program and was discharged	Treatment Group: TBI clients who entered Presbyterian Hospital NRP between 2/80 and 8/82 who stayed at least 6 months. Control Group: TBI files of referrals to NRP between 2/80 and 8/82 who did not enter the program were retrospectively examined.

Source	N	Chronicity	Severity	Outcomes/Analysis	Results	Level
Prigatano (1984)	T = 18 C = 17	T - 21.6 months C - 13.6 months	Not specified	1. WAIS-R Verbal IQ, Performance IQ, Vocab., Block Design, Digit Symbol. WMS Memory Quotient, Logical Memory, Visual Reproduction, Assoc. Learning. Halstead Reitan Trail Making Test, Finger Tapping, Tactual Performance Test. Russell-Neurenger Average Impairment Scale 2. KAS Relative Scale 3. Employment ANCOVAS	Treatment Effect: 1. WAIS-R Performance I.Q. • T = 8.7, C = 4.8 2. Block Design • T = 2, C = 1.4 3. WMS Memory Quotient • T = 9.5, C = 2	II(b)

† T = Treatment Group, C = Control Group
Note: Refer to List of Abbreviations for key to severity and outcome measures.

Evidence table 5. Randomized controlled trials of cognitive rehabilitation - Intermediate outcomes [arc 3]

Source	Intervention/treatment group	Comparison group 2nd treatment group	Duration of intervention	Followup	Setting/population
Twum (1994)	Restorative Imagery Training specific to Verbal Task outcome measures; verbal Labeling Training specific to Visual Task outcome measures. Test stimuli presented until recall was perfect or until 6th trial. Delayed recall tested at 30 min.	Four groups: No training, verbal training, imagery training, both trainings	Single training session	None	Towson State University Referral sources not specified. All had neuropsych. evaluations by State DVR
Niemann (1990)	Restorative Computer and non-computer attention remediation	Restorative and compensatory memory training	2 hours/day 2 days/week 9 weeks 36 hours total	2 weeks	Outpatients - U.C. San Diego Head Inj. Center. Contacted through hospitals, community colleges, and S.D. Head Injury Foundation
Ruff (1989)	Restorative and Compensatory CACR and external aids (notebooks, calendars, schedules, timers, etc.)	Computer and video games, coping skills, health, discussion, independent living, art	5 hours/day 4 days/week 8 weeks 160 hours total	None	University of San Diego Population not specified
Ryan (1988)	Restorative and Compensatory External mnemonics, encoding strategy practice, personalized emotional techniques, rehearsal, CACR, synthesis of all in group practice	Games, psychosocial support, art, group discussions, self-expression, relaxation exercises	5.5 hours/day 4 days/week 6 weeks 24 sessions 132 hours total	None	Univ. Virginia School of Medicine & Woodrow Wilson Rehab. Center Population not specified

Kerner (1985)	Restorative CACR Computer Memory Retraining Group (CMRG)	Two comparison groups: 1. Computer Control Group (CCG) Used computers to create graphics. 2. No Exposure Control Group (NECG)	45 min. sessions 12 sessions 4.5 weeks 9 hours total	15 days CMRG only	DeAnza College Population not specified

Evidence table 5. Randomized controlled trials of cognitive rehabilitation - Intermediate outcomes [arc 3 continued]

Source	N	Chronicity	Severity	Outcomes/analysis	Results	Level
Twum (1994)	T1 - 15† T2 - 15 T3 - 15 T4 - 15	Average 13.2 months from return to consciousness to treatment	≥ 3 weeks coma Average WAIS-R IQ = 80	Verbal Task Mean # Words Recalled, Delayed Recall, & Trials to Perfect Visual Task Mean # Words Recalled, Delayed Recall, & Trials to Perfect MANOVA	Treatment Effect Imagery Group scores higher than Verbal on all verbal tasks. Verbal Group scores higher than Imagery on all imagery tasks. Difference in means between Imagery and No Imagery Group on: 1. Immediate recall: +8 2. Delayed recall: +1.5 3. Trials to criterion: -2.5 Difference in means between Verbal Labeling and No Verbal Labeling Group on: 1. Immediate recall: +5 2. Delayed recall: +.75 3. Trials to criterion: -2.25	I
Niemann (1990)	T - 13 C - 13	T - 41.0 C - 37.1	Coma T - 15 days C - 20 days GOAT T - 94.4 (5.5)* C - 90.7 (6.8) DRS T - 132.9 (9.0) C - 135.2 (7.0)	Attention Test d2 PASAT Divided Attention Test Trails B RAVLT Block Span Learning SDNTB subtests MANOVA	No Treatment Effect	I
Ruff (1980)	T - 20 C - 20	Ranged from 1 to 7 years	T - 32.1 coma days (21.4) C - 48.8 coma days (26.4)	San Diego Neuropsych. Battery Forms A and B MANOVA	No Treatment Effect	I
Ryan (1988)	T - 10 C - 10	T - 54.5 months C - 57.3 months	Each group had 5 milds (DRS > 134/144) and 5 moderates (DRS ≤ 134/144)	BVRT, Rey CFT, Taylor Complex Figure, Selective Reminding Test, Ruff Trail, WMS Logical Memory subtest MANOVA	No Treatment Effect	I

Kerner (1985)	CMRG - 12 CCG - 6 NECG - 6	$\geq$ 3 months	Memory Index rating severe to mild	Memory Index (MI) scaled & standard scores Acquisition Recall (AR) scaled & standard scores t-tests	Treatment Effect on 5 of 12 measures •; • AR (scaled) for CMRG = -4.33, for CCG = 0.00 • MI (scaled) for CMRG = -5.92, for CCG = 0.50, for NECG = 0.66 • MI (standard) for CMRG = -5.58, for CCG = 0.50, for NECG - 0.33 Significant increase for CMRG was not maintained at fullowup	I

† T = Treatment Group, C = Control Group
* Numbers in ( ) are standard deviations
• Negative values indicate gain
Note: Refer to List of Abbreviations for key to severity and outcome measures.

Evidence table 6. Comparative studies of cognitive rehabilitation - Intermediate outcomes [arc 3]

Source	Intervention/Treatment Group	Comparison Group/2nd Treatment Group	Duration of Intervention	Followup	Setting/Population
Thomas-Stonell (1994)	Restorative and Compensatory CACR with therapist intervention <u>Teachware</u>	Traditional therapy, community school programs	1 hour/day 2 days/week 8 weeks 16 hours total	None	Hugh MacMillan Rehab Cen Toronto Population not specified
Gray (1992)	Restorative CACR Tasks selected that make demands on alerting, working memory, alternating attention and divided attention. Used feedback, reinforcement, visual stimuli, and cuing.	Recreational Computing	T - 75 min. sessions 14 sessions over 3 - 9 weeks 17.5 hours total C - 60-90 min. sessions over 3 - 9 weeks Mean 12.7 hours total	6 month	Newcastle General Hospital, Cambridge Univ., U.K. Psychologists in outpatient clinics, staff of social service and support groups in Edinb solicited for names of people attention deficits due to brair injury.
Batchelor (1988)	Restorative CACR directed toward remediation in recent memory, attention/speed of information processing, and higher cognitive functioning	Restorative Cognitive Therapy, directed toward remediation consistent with Treatment Group, but delivered without computers	4 - 6 weeks 20 hours total	None	Westmead Hospital, Australi Consecutive referrals to rehabilitation medicine unit c month
Wood (1987)	Restorative Visual training of information processing using CACR	C1 - Clients in same inpatient rehabilitation center as Treatment Group, who did not receive the CACR intervention C2 - Persons without TBI	1 hour/day 20 days 4 weeks 20 hours total	20 days	Inpatient rehabilitation cente St. Andrew's Hospital, U.K.

Evidence table 6. Comparative studies of cognitive rehabilitation - Intermediate outcomes [arc 3 continued]

Source	N	Chronicity	Severity	Outcomes/Analysis	Results	Level
Thomas-Stonell (1994)	T - 6† C - 6	Ranged from 3 months to 4 years	Recovered to 7 or 8 on Rancho Scale	TeachWare Screening Module Standardized Neuropsych. Test Battery ANCOVAS used to test group differences	Treatment Effect on 8 of 18 neuropsych. subtests. Group means not presented.	II(b)
Gray (1992)	T - 17 C - 14	T - 79 weeks (151)* C - 84 weeks (152)	T - 8 mild to moderate, 9 severe C - 8 mild to moderate, 6 severe	PASAT # Correct, Longest String, and Information Processing Rate (IPR) WAIS-R subtests Neuropsych. Battery 22 Total Tests ANCOVAS used for analysis	Treatment Effect on 2 of 22 tests at posttreatment Treatment Effect on 6 of 22 tests at followup Group means not presented	II(b)
Batchelor (1988)	T - 17 C - 17	T - 72.7 days (66.5) C - 96.3 days (104.1)	T - 7.3 coma days (6.3) C - 7.0 coma days (8.7)	WAIS-R Russel's WMS Buschke Selective Reminding Test Taylor Figure PASAT Austin Maze ANCOVAs and t-tests used for analysis	No Treatment Effect	II(b)
Wood (1987)	T - 10 C1 - 10 C2 - 10	T - 27.5 months (5.8) C1 - 36.5 months (15.6)	PTA T - 2.4 months (0.5) C1 - 2.7 months (0.4) All required full time care	Pursuit Rotor, Digit Symbol, Choice Reaction Time, Simple Reaction Time, Visual and Choice Reaction Time for vigilance, Attention to Task, Attention Rating Scale	Treatment Effect for Attention to Task and Attention Rating Scale from baseline to first followup. Treatment Effect for Choice Reaction Time from baseline to second followup. Group means not presented.	II(b)

† T = Treatment Group, C = Control Group
* Numbers in ( ) are standard deviations
Note: Refer to List of Abbreviations for key to severity and outcome measures.

Evidence table 7. Studies of the relationship between intermediate tests and employment [arcs 4 and 5]

Source	Setting/population	N	Chronicity	Severity
Girard (1996)	Current and former clients of a hospital-based, interdisciplinary outpatient TBI program	Initial - 152 6 month followup - 114 12 month followup - 69	3 years (range 6 months to 12 years)	Not specified
Cicerone (1996)	Referrals to neuropsychology clinic of brain injury rehabilitation program. Selected on basis of having participated in neurorehabilitation, having neuropsych. evaluation, and being available for followup.	20	7.8 months (range 3 to 20 months)	Mild
Ip (1995)	Consecutive referrals for rehabilitation to Brain Injury Unit of a hospital between 1988 and 1994	70	3.1 years	20% mild 27% moderate 53% severe (based on GCS)
Fabiano (1995)	Consecutive referrals to 3 post-acute rehabilitation facilities Minimum length of coma 24 hours, minimum chronicity 1 year	94	59 months (42.6)*	Severe 20 days average length of coma (20.2)

Ezrachi (1991)	Consecutive participants in NYU Head Trauma Program over 4 years Sample chosen on basis of not being able to return to work for 1 year postinjury, and willingness to participate in program	59	34.65 months (27.49)	Moderate to Severe 36.2 days in coma (31.42)

Evidence table 7. Studies of the relationship between intermediate tests and employment [arcs 4 and 5 continued]

Source	Setting/population	N	Chronicity	Severity
Fraser (1988)	Consecutive outpatient referrals who were employed prior to injury	48	Not specified	Average GCS for 35 who returned to work = 13 Average BCS for 13 who did not return to work = 11
Brooks (1987)	Consecutive admissions to Department of Neurosurgery, Institute of Neurological Sciences, Glasgow, UK	134	Ranged from 2 to 7 years	Coma duration $\geq$ 6 hours, or PTA > $\underline{2}$ days, or surgery for intracranial hematoma
Najenson (1980)	Consecutive discharges from Lowenstein Rehabilitation Hospital, Ra'anana, and Tel Aviv University School of Medicine, Israel from 1/11/74 to 1/4/77	147	Not specified	Coma duration ranged from $\leq$ 1 day (n = 21) to $\geq$ 30 days (n = 21)

Numbers in ( ) are standard deviations.

Evidence table 8. Observational study of cognitive rehabilitation - Health outcomes [arc 1]

Source	Intervention	Duration of intervention	Followup	Setting/population	N
Wilson (1997)	Compensatory device programmed to provide reminders of daily activities <u>neuropage</u>	baseline 2 - 6 weeks treatment - 12 weeks baseline - 3 weeks	none	Cambridge Univ., u.k. referrals from hospital, therapists, psych. clinics, support group	15

Source	Chronicity	Severity	Outcomes/Analysis	Results	Level
Wilson (1997)	Ranged from 6 months to 13 years	RBMT ranges from severe to moderate or mild	Everyday Memory Failures (EMFs) maximum score individually determined, based on number of target reminders Mean % Success used to measure effect	Significant increase in scores for all subjects during treatment. Scored decreased for 11 of 15 during second baseline. Mean % Success: Baseline - 37.08% (24.86)* Treatment - 85.56% (18.58) Baseline - 74.46% (28.23)	III

* Numbers in ( ) are standard deviations
Note: Refer to List of Abbreviations for key to severity and outcome measures.

Evidence table 9. Comparative studies of supported employment: Study characteristics

Source	StudyRating/Comment	Design/Allocation	Outcome Measures	Follow-up
Haffey & Abrams, 1991	Class IIb study. Highly biased assignment to groups under comparison. T1 group (WRP) contained clients selected as good job prospects by rehab. counselors. T2 & C full of poor job prospects.	Retrospective initial data collection for clients whose injury predated 1/88. Prospective, non-randomized comparison of three groups: **T1:** Supported employment (WRP) **T2:** Day Treatment **C:** Comparison Group	% Job placements % Job retention Monthly Employment Ratio (MER)	Every 6 months. Clients entering at the beginning followed up for 3 years, others less time <u>N Months follow up</u> 18 1 to 6 23 7 to 12 17 13 to 18 15 19 to 24 14 >24
Wehman, et al., 1989 to 1993 (Cumulating sample, reported in 4 articles from 1989 to 1993)	Class III study. Excellent measures and follow-up. Study focused on difficult population. Prospective data collection. Weakness of case-control study with no independent control groups and random assignment to conditions.	Prospective, case-control study with each consumer moving through 3 consecutive Phases of employment history: 1. Pre-trauma employment 2. Post-trauma employment 3. Supported employment (SE) (Post-trauma employment Phase designated as -SE)	% Job placements Monthly Employment Ratio (MER) Number of jobs held Hourly wages Monthly wages Annual wages Hours/week of work Intervention hrs/wk required	Weekly job assessment on-site. Follow-up assessment every 6 months. <u>N Years follow-up</u> 5 5 15 4 to 5 33 >3 62 .5 to 3

Evidence table 10. Comparative studies of supported employment: Selection and allocation of clients

Source	Population/Selection	Allocation to Comparison Groups	N	Severity/Chronicity	Exclusions/Attrition
Haffey & Abrams, 1991	*Supported Employment (WRP)* All referrals from 1/88 to 8/90 by State Rehabilitation Program or State Worker's Compensation as unable to find or keep jobs but suitable for work "under the right circumstances." *Day Treatment Group* Cases treated from 1/88 to 8/90 for whom competitive employment was not a current goal because of: medical problems, personal & family preference, economic disincentives, other activities (homemaker, student) *"Comparison Group"* Consecutive discharges from inpatient rehabilitation program from 4/88 to 8/90 who did not enter WRP because: believed unnecessary, perception of severe functional limits, dependency reinforcement, threat to potential benefits, or substance abuse.	130 clients in WRP, all recommended by state vocational rehab as candidates for work, compared to... 35 clients in a Day Treatment program for whom competitive employment was not a goal for various reasons, and to... "Comparison Group" of 76 clients who received no formal post-acute rehabilitation	T1: WRP: n = 130 T2: Day Treat. n = 35 Comparison: n = 76 N = 241	Group Md days coma T1 6 T2 7 C 7 All 7 Chronicity not specified.	Potential clients with current substance abuse or disabling conditions were referred to other treatment. Clients believed to have no potential for employment by State rehabilitation counselors, or by self or family, were excluded.
Wehman, et al., 1989 to 1993 (Cumulating sample reported in 4 articles from 1989 to 1993)	Referrals for supported employment from physicians (physiatrists), psychologists, rehabilitation counselors, and families. Inclusion criteria: 1. Between 18 and 64 year age. 2. Severe TBI (GCS•8 for •6h). 3. Strong evidence cannot work without job support. No exclusion merely for cognitive, physical, or psychosocial deficit.	3 work consecutive work phases compared for same group of 115 consumers: Phase 1: Pre-trauma Employment Phase 2: Post-trauma Employment Phase 3: Supported Employment	Cumulating sample over 5 years, reported as follows: 1989 n = 5 1989: n = 20 1990: n = 53 1993: N = 115	All consumers severe TBI (GCS•8 for •6h). Av. coma: 68 days. Range: 3-233 days. Mean scores on neuro-psych. tests below 50th percentile; range 10%-50%. Mean chronicity 7.75 years. Range 1-19 years.	Potential clients with current substance abuse were excluded.

Evidence table 11. Comparative studies of supported employment: Models of supported employment tested and outcomes

	Models of supported employment tested			Outcomes	
Source	Setting	Intervention	Duration	Analysis	Results
Haffey & Abrams, 1991	Community Re-Entry Services, Work Re-Entry Program (WRP), Sharp Memorial Center, San Diego, CA	Transitional Employment Work Entry Program (WRP): Includes intake, vocational assessment, work hardening, job development, job analysis, transitional employment program, job placement, short-term support, and long-term follow-up. On-the-job support by a job coach for first 60 days—intense at first, then fading at the end.	2 hours intake 26 hours initial assessment 6 hrs job preparation 12 hrs job development 10 hrs job placement and support 3 hrs post-placement employer contact 60 hrs total of staff assistance 60 days on-the-job support	Descriptive statistics Percentages	*Placement* as of 10/90: T1: 68% (88/130) T2: 39% C: 34% *Retention* at most recent follow-up: T1: 71% (62/88) T2: Not reported C: Not reported
Wehman, et al., 1989 to 1993 (Cumulating sample reported in 4 articles from 1989 to 1993)	Department of Rehabilitation Medicine, Medical College of Virginia, Richmond, VA	Transitional employment. Job coach provided at each site. Training and counseling support. Intake and home visits. Intense analysis of potential jobs for fit with consumer deficits, needs, and other characteristics. Consumer's Screening Form matched to Job Screening Form, providing criteria for referral.	No specific duration. Job support to continue, at diminishing levels, indefinitely.	Descriptive statistics ANOVA in one study (1989)	Placement: 70% (80/115) Measure Preinj -SE SE Mean MER .40 .13 .67 # Jobs held 2.04 1.24 1.49 Mean $/hr 4.19 1.55 4.90 Mean $/mo $508 $107 $658 Mean $/yr $6101 $1290 $7899 Intervention hours required: 1st 4 weeks: 80% of time After 14 weeks: 3 hrs/week After 30 weeks: <3 hrs/week

Evidence table 12. Case management studies in traumatic brain injury rehabilitation: Design characteristics

Publication	Study Purpose (Target/Problem - Hypotheses/Goals)	Design Features	Intervention Allocation Method	Population Characteristics	Group Sizes	Group Differences	Case Management Intervention Model	Intervention Duration	Measurement Period	Co-interventions Described
Ashley et al. (1994)	Target: pt progress & level of independence at end of rehab	retrospective, comparison of two CM conditions, case-control study: Grp 1 selected then Grp 2 matched	Grp 1 subjects covered by same insurance carrier with a single CM; Grp 2 subjects covered by different insurance carriers with different CMs	~ 350 TBI patients of one post-acute rehab clinic treated from 1980-90, Disability Rating Scale score < 10 (moderately severe) & in vocational rehab Grp 1 Inclusions: admitted by a single carrier & single CM Grp 2 Matches: males; 20 yrs + at in	Grp 1 (same CM) = 21 Grp 2 (different CMs) = 18	Grp 1 = more pts w/ permanent disability claim advances & more autonomous CMs (authority to approve both disability payment & rehab services)	insurance coverage models: Grp 1 = 1 CM & 1 insurer, Grp 2 = >1 CM & >1 insurer; CM variable = either or both disability-claims-approval authority & rehab authority	inpatient rehab stay: means: Grp 1 = 230 days, Grp 2 = 276 days	at rehab discharge (8 - 9 mos)	insurance coverages: number & type
Greenwood et al. (1994)	Problem: lack of rehab after acute period; Hypotheses: CM would: 1) decr hosp stay, 2) incr number of pts into rehab, 3) incr rehab duration, 4) not alter cognitive impairment, 5) improve employment & QOL, 6) reduce relatives' burden	prospective, comparison of sequential pts in randomized matched settings (2 sets of 3 hospital units); intervention group (CM) = normal hospital services + case management; control group (NON-CM) = normal hospital services	by sequential hospital admissions	Inclusions: TBI treatment from 3/88 - 11/90; 16-60 yrs, < 7 days post-injury, > 6 hrs in coma or > 48 hrs amnesia = severe injuries; family consent;local resident Exclusions: hosp tx for substance abuse; psych or	CM = 56 pts at entry 48 at 6 mos 37 at 12 mos 31 at 24 mos NON CM = 70 pts at entry	CM = more severity than NON CM: i.e. longer coma, lower Glasgow coma scores, more respiratory complications & tracheostomies, less conservative management, longer post-injury amnesia & DRS 18.3 compared with DRS 16.2 in NON CM Grp	care-continuity model: advice, support, goal-planning, advocacy & referral; Tasks: assessed pt; developed rehab plan; facilitated cooperation & involvement of pt/fam & professionals; provided general info re head injury & informal counseling & support	up to 2 yrs post-injury maximum	at 6, 12, 24 mos post-injury; 2-yr study	care settings: neuro hospital, general hospital, rehab unit, outpt, daycare, home; services: physical therapy, occup therapy, speech therapy, psychology, social work, psychiatry, vocational rehab

Malec et al. (1995)	Goals: reduce time between brain injury & community reintgration from 7 yrs to 9 mos with 70% employment or education at level > 3 on Vocational Outcome Scale (VOS) & 45% employment at level 5 on VOS	prospective, one setting, comparison of CM & non-CM via benchmarks	by sequential pt screenings	509 TBI patients of one emergency room treated from 10/94 - 10/95: Inclusions (n = 147): 18 - 55 yrs, primary dx of TBI & if receiving appropriate treatment for psychiatric or substance abuse comorbidities; Exclusi	CM = 147; 25 mild injury pts lost to followup; total = 122	CM Grp = 79% mild injury, 21% moderate or severe injury	care-continuity + vocational coordination model: nurse case coordinator (NCC) tasks: screen; advise; support & reassure re emotional sx; monitor status; direct to medical, neuropsych & rehab services & to vocational case coordinator (VCC); VCC tasks: as	no sx = 1 month w/ sx = 1 mo & 12 mos after subjects complete program	at 1 & 12 mos post-rehab; 2-yr study	medical center services, home & community services

Note: CM = case management

Evidence table 13. Case management studies in traumatic brain injury rehabilitation: Results

Publication	Outcome measures	Outcomes: Functional status	Vocational	Living arrangements	Family	Other	Overall
Ashley et al. (1994)	changes in Disability Rating Scale (DRS), Living Status, Occupational Status, treatment costs	Grp 1 = more disability (DRS) improvement (moderate to mild); Treatment effect: DRS mean improvement difference = .58; DRS at rehab discharge: Grp 1 = 1.14, Grp 2 = 1.94	Grp 1 = most improved occupational status (*not working* to *part-time at former job or equal position*); Treatment effect: Occupational Rating mean improvement difference = 7.04	Grp 1 = most improved living status (*private qrtrs w/ professional help* to *private qrtrs w/o help*); Treatment effect: Living Rating mean improvement difference = 1.83	NA	Grp 1 = greater use of pre-settlement permanent disability advances; CM had both claims & rehab authority; lower rehab costs ($40,000 less per pt)	Both groups had signif differences in adm-discharge scores on Disability, Living & Occupational Status; Grp 1 made signif more improvements in Disability, Living & Occupational status
Greenwood et al. (1994)	number of referrals to inpt/outpt facilities/services; time in rehab services; physical & cognitive impairment (including DRS); changes in affective, behavioural, social functioning & personality; global impairment; changes in pt's & relatives' housing, f	at 24 mos: DRS difference = 1.24 (higher for CM group), (not reported for 6 & 12 mos); no signif differences in other measures; DRS at 24 mos post-injury: 2.0 CM pts; 0.76 non-CM pts	NR	more CM patients needed a caretaker at 12 & 24 months	more CM families sought medical care, changed their use of leisure time, and rated the effect on the family as major; most (62%) families rates CM as helpful	NR	no significant differences in functional improvements; all trends favored control group, accounted for by difference in severity of injury; CM increased chance & range of contact with services (esp psychology, social work, speech therapy), but not duratio
Malec et al. (1995)	change in BI-related disability (Mayo-Portland Adaptability Inventory) per pt & staff; level of employment function (Vocational Outcome Scale); job type, job setting, pay rate, type & cost of voc supports; independent living	NA	at 1 yr: 34% went to nonsheltered work or training; 100% had retained a job for 90 days; 73% had been placed within 9 mos	NA	NA	identified new service needs for adolescents, seniors & alcoholic pts	

level; satisfaction of pts & S

Appendix 1. Question text and characteristics

Question 1

1. Does the application of early, interdisciplinary rehabilitation improve outcomes for persons with traumatic brain injury?

Rationale:
- The use of interdisciplinary rehabilitation varies in when it is applied.
- The purpose of this question is to find out if there is evidence that the application of this intervention during treatment in the acute care hospital improves outcomes.

Definitions:
- Early applies to the phase of treatment after discharge from the emergency department and prior to discharge from the acute care hospital.
- Interdisciplinary rehabilitation is an intervention that utilizes a variety of methods, usually including but not limited to physical therapy, occupational therapy, and speech therapy.

Patient population:
- Persons who sustained traumatic brain injury between the ages of 18 and 65 years whose injury severity warranted admission to a hospital emergency department and subsequent transfer to acute care.

Patient characteristics:
- Age, severity of injury, pre-morbid data, mechanism of injury (kind of trauma and intracranial diagnosis) and functional status measure. Measures of injury severity include Glasgow Coma Scale Score and multiple injuries.

Studies must include or measure:
- Age
- Glasgow Coma Scale Score
- Severity of injury
- Multiple injuries
- Pre-morbid data
- Mechanism of injury (kind of trauma)
- Intracranial diagnosis
- Functional status measure

Outcome measures:
- Presence or absence of complications (i.e., skin problems, pneumonia)
- Length of stay in hospital.
- Immediate care costs and long-term financial burden.
- Health status at discharge from the acute care hospital (ADLs, locomotion, and short-term functional status measure such as Disability Rating Scale).
- Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function).
- Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being).

Question 2

2. Does the intensity of in-patient rehabilitation affect outcomes for persons with traumatic brain injury?

Rationale:

- The application of in-patient rehabilitation varies in intensity.
- The purpose of this question is to find out if there is evidence that a particular level of intensity of in-patient rehabilitation optimizes outcomes.

Definitions:
In-patient rehabilitation applies to the phase of treatment after discharge from the acute care hospital into an in-patient rehabilitation facility.

Intensity - Levels of the intervention vary in intensity based on:
1. Whether the intervention was directed and managed by a physiatrist.
2. Number, kinds, and frequency of methods applied.

Patient population:

- Persons who sustained traumatic brain injury between the ages of 18 and 65 years whose injury severity warranted admission to a hospital emergency department, transfer to acute care, and subsequent transfer to in-patient rehabilitation.

Patient characteristics:

- Age, severity of injury, pre-morbid data, mechanism of injury (kind of trauma and intracranial diagnosis) and functional status measure. Measures of injury severity include Glasgow Coma Scale Score and multiple injuries.

Studies must include or measure:

- Age
- Glasgow Coma Scale Score
- Severity of injury
- Multiple injuries
- Pre-morbid data
- Mechanism of injury (kind of trauma)
- Intracranial diagnosis
- Functional status measure

Outcome measures:

- Length of stay in rehabilitation facility.
- Immediate care costs and long-term financial burden.
- Health status at discharge from in-patient rehabilitation (ADLs, locomotion, and short-term functional status measure such as Disability Rating Scale).
- Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function).
- Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being).
- Independence, relationships, family life, satisfaction.

Appendix 1. Question text and characteristics (continued)

Question 3

3. Does the application of compensatory cognitive rehabilitation enhance outcomes for persons who sustain traumatic brain injury?

Rationale:
- The efficacy of cognitive rehabilitation is being questioned. In addition, the application of the intervention may be based on patient resources; the availability may be based on regional differences.
- The purpose of this question is to find out if there is evidence that compensatory cognitive rehabilitation is an effective intervention.

Definitions:
- Cognitive Rehabilitation - Treatment to increase or improve the capacity to process and use incoming information so as to allow increased functioning in everyday life.
- Focus is correcting deficits in memory, concentration and attention, perception, learning, planning, sequencing, and judgment. The broad definition includes both methods to restore cognitive function and compensatory techniques, such as use of memory aids.

Patient population:
- Persons who sustained traumatic brain injury between the ages of 18 and 65 years whose functional status level allows for employment and/or community integration, but who require an intervention to facilitate success.

Patient characteristics:
- Age, severity of injury, pre-morbid data, mechanism of injury (kind of trauma and intracranial diagnosis), application and methods of in-patient rehabilitation, and chronicity at time of entry to out-patient program.

Outcome measures:
- ADLs.
- Return to work/school, maintenance of job/school, long-term financial burden.
- Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being).
- Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function).
- Independence, relationships, family life, satisfaction.

Question 4

4. Does the application of supported employment enhance outcomes for persons with traumatic brain injury?

Rationale:
- For persons who have sustained traumatic brain injury, the ability to maintain employment may be compromised by cognitive deficits and behaviors not normally accepted in the workplace.
- The purpose of this question is to find out if there is evidence that the intervention of supported employment operates to facilitate job maintenance and success.

Definitions:
- Supported Employment - An intervention in which the occupational tasks and environment are modified specific to the needs of the patient, where training is modified according to the patient's deficits, and where responsibility for attendance and performance at a job are shared by a professional.

Patient population:
- Persons who sustained traumatic brain injury between the ages of 18 and 65 years whose functional status level allows for employment, but who require an intervention to facilitate success.

Patient characteristics:
- Age, severity of injury, pre-morbid data, mechanism of injury (kind of trauma and intracranial diagnosis), application and methods of in-patient rehabilitation, and chronicity at time of entry to supported employment program.

Outcome measures:
- Job maintenance.
- Job success.
- Efficiency.
- Types of work held relative to that of pre-injury.
- Income level relative to that of pre-injury.
- Immediate care costs and long-term financial burden.
- Independence, relationships, family life, satisfaction.

Question 5

5. Does the provision of long-term care coordination enhance the general functional status of persons with traumatic brain injury? What is the cost-effectiveness of the provision of this intervention?

Rationale:
- As persons with traumatic brain injury move through their recovery process they may be particularly vulnerable during periods of transition.
- Case management by a certified individual may not always be available or optimal; a family member may provide the service.
- This question asks if there are benefits to continuity of care, and if so, what are the costs relative to those benefits.

Definitions:
- Care coordination - Service provided by someone other than the patient throughout phases of recovery that:

(1) considers alternative interventions and venues relevant to the patient's needs,
(2) considers available resources and/or identifies and secures new resources to fund the interventions,
(3) provides information to patient and family about alternatives,
(4) facilitates selection and implementation of the intervention that best represents the needs and desires of the patient and family, and
(5) monitors and communicates about the progress of the patient and family while the patient is participating in the intervention.

- A care coordinator may be a private contractor, representative of an agency, family member or friend, medical professional, or rehabilitation professional.

Patient population:
- Persons with traumatic brain injury between the ages of 18 and 65 years.

Patient characteristics:
- Age, severity of injury, pre-morbid data, mechanism of injury (kind of trauma and intracranial diagnosis, application and methods of in-patient and/or out-patient rehabilitation. Identification of care coordinator.

Outcome measures:
- Return to work/school, maintenance of job/school, long-term financial burden.
- Long-term measure of disability (restriction or lack [resulting from an impairment] of ability to perform an activity in the manner or within the range considered normal for a human being).
- Long-term measure of impairment (loss or abnormality of psychological, physiological, or anatomical structure or function).
- Independence, relationships, family life, satisfaction.

Appendix 2. Search strings

1. MEDLINE search string

MEDLINE Initial Strategy (Identical for all questions) – 1976 to 1997

1. Explode Head Injuries/Rehab
2. Explode Head/Injury
3. rh.fs.
4. 2 and 3
5. Head injur$.tw
6. Brain injur $.tw
7. 5 or 6
8. 7 and 3
9. 1 or 4 or 8

MEDLINE Questions 1 and 2 Strategy

10. Limit 9 to human
11. Exp hospitals/
12. Accute.tw.
13. Exp intensive care units
14. Early.tw.
15. Length of stay/
16. Exp emergency medical services/
17. Emergency medicine/
18. Exp hospitalization/

19. Interdisciplinary rehabil$.tw.
20. Speech therapy/
21. Physiatry.tw.
22. Exp physical therapy/
23. Physical therapy department, hospital/
24. Occupational therapy/
25. Occupational therapy department, hospital/
26. Exp rehabilitation/
27. Exp rehabilitation centers/
28. Rehabilitation.tw.
29. 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
30. Exp head injuries/
31. 29 and 30
32. 10 or 31
33. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28
34. 32 and 33
35. Exp clinical trials
36. 32 and 35
37. From 36 keep 1-4
38. From 34 keep 1-5, 8-12, 14, 18, 20-22, 25, 27-28

MEDLINE Question 3 Strategy

10. Limit 9 to human
11. Exp cognition/
12. Exp cognition disorders/
13. Cognit$.tw
14. Exp memory/
15. Exp memory disorders/
16. Attention/
17. exp perception/
18. exp learning
19. exp learning disorders/
20. judgement/
21. 1102 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
22. 10 and 21
23. from 22 keep 2-3, 8, 11, 14-15, 17-18,20-21,23

MEDLINE Question 4 Strategy

10. Limit 9 to human
11. Exp employment/
12. Work capacity evaluation/
13. Exp work/
14. absenteeism/
15. Employment.tw.
16. Employed.tw.

17. Vocational education/

18. Exp rehabilitation, vocational/

- sheltered workshops/
- 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19
- 10 and 20
- from 21 keep 1-10,12-13, 15-16,18-26,28-38,40
- exp brain injuries/
- 20 and 23
- 24 not 21
- limit 25 to human
- from 26 keep 7-9,19,22,29

Medline Question 5 Strategy

10. case management/

11. exp home nursing/

12. forecasting/

13. follow-up studies/

14. long term.tw.

15. longterm.tw.

16. social work/

- 10 or 11 or 12 or 13 or 14 or 15 or 16
- exp *brain injuries/
- 9 or 18
- 17 and 19
- limit 20 to human

- 10 or 11 or 16
- 22 and 21
- from 23 keep 1-2, 4-8
- 21 not 23
- from 25 keep 5-8,11-13, 15, 20,23,32,35-36,38

2. HealthSTAR search strings

<u>HealthSTAR strategy (identical for all questions)</u> 1993 to 1997

1. Explode Head Injuries/Rehab
2. Explode Head/Injury
3. rh.fs.
4. 2 and 3
5. Head injur$.tw
6. Brain injur $.tw
7. 5 or 6
8. 7 and 3

- 1 or 4 or 8

3. CINAHL search strings

<u>CINAHL general search strategy (all questions)</u> 1982 to 1997

- american journal of occupational therapy.jn
- archives of physical medicine and rehabilitat
- clinical rehabilitation.jn.
- disability & rehabilitation.jn.
- international journal of rehabilitation res
- journal of rehabilitation research & develo

- physical therapy.jn.
- quality of life research.jn.
- rehabiliation nursing.jn.
- rehabiliation.jn.
- 9 or 10
- scandinavian journal of rehabiliation medi
- scandinavian journal of rehabiliation medi
- 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10
- exp brain injuries/
- brain injur$.tw.
- 15 or 16
- exp rehabiliation/
- rh.fs.
- 18 or 19
- 17 and 30
- 21 not 14
- from 22 keep 1-7,9-10,12-13,15-20,22-24,26
- from 22 keep 6,12-13,15-16,20-22,24,29-30,33
- 23 or 24
- brain injury.jn.
- 22 not 26
- 25 not 26
- 27 not 28
- from 29 keep 6-7,14,17,20,22,25,32-33,35-36
- 28 or 30
- 22 not 31

4. PyschInfo search string

PsycInfo search strategy (all questions) 1982 to 1997

- exp brain damage/
- exp head injuries/
- 2 not 1
- brain.tw.
- 3 and 4
- 1 or 5
- exp cognitive rehabilitation
- exp rehabilitation
- exp rehabilitation centers/
- exp vocational rehabilitation/
- exp employment status/
- exp case management/
- clinical trials.tw.
- 7 or 8 or 9 or 10 or 11 or 12 or 13
- 6 and 14

5. Current Contents search string

Current Contents search strategy (all questions) Week 01, 1998 to Week 21, 1998

- head injur$.ab,ti,kw,kp.
- Brain injur$.ab,ti.kw,kp.
- 1 or 2

Appendix 3. Computations of Cohen's Kappa

	Number in agreement	Number in disagreement	K computation	Confidence interval of Kappa				Probability of total independence of judges	
Questions 1 and 2 (combined)	204	17	0.8209	$\alpha = .05$	0.754	< K <	0.888	$K/\sigma =$	23.255 $p < .0001$
				$\alpha = .01$	0.727	< K <	0.915		
Question 3	221	10	0.8792	$\alpha = .05$	0.818	< K <	0.940	$K/\sigma =$	26.862 $p < .0001$
				$\alpha = .01$	0.793	< K <	0.965		
Question 4	132	4	0.9382	$\alpha = .05$	0.888	< K <	0.988	$K/\sigma =$	21.583 $p < .0001$
				$\alpha = .01$	0.868	< K <	1.009		
Question 5	559	34	0.7851	$\alpha = .05$	0.729	< K <	0.842	$K/\sigma =$	45.741 $p < .0001$
				$\alpha = .01$	0.705	< K <	0.865		
All questions, all judges	1,116	65	0.8438	$\alpha = .05$	0.813	< K <	0.874	$K/\sigma =$	58.747 $p < .0001$
				$\alpha = .01$	0.801	< K <	0.887		

Initial Abstraction Instrument

Please read paper before beginning abstraction process

Paper ID: 0 Reviewers Initials: Question Number:

Paper Title: xc

First Author (Last Name): Year Paper Published: 0

1) Was cost to patient or cost of intervention reported in the paper?:

2) Is the paper suitable for the research question?:

If "yes", skip question 3 and continue data abstraction If "no", answer question 3 and end abstraction

3) If no, give reason paper was not suitable for the research question:

Specify, if other:

4) Study setting (check all that apply):

A. Acute Care Hospital: ☐ In-patient Rehab: ☐ Out-patient: ☐

B. University/Tertiary Center (Referred): ☐ Primary Setting (Non-referred): ☐

C. Population-based Study: ☐ Multicenter Study: ☐ Single-Center: ☐

5) Was there a control/comparison group?:

If "yes", continue questions 6-9 If "no", complete questions 10-13

6) Was the study: 7) Was the study blinded?:

8) What was method used to allocate to groups (check all that apply)?:

Random assignment to conditions: ☐ Historical Controls: ☐ Case-control: ☐

Case is own control or crossover design (pre-post): ☐ Concurrent Controls: (tabled comparisons) ☒ Statistically Controlled: (regression model) ☐

9) If assignment was not random, what method was used to control for baseline differences in the intervetion and control groups?

Stratification: ☐ Severity of Illness Indices: ☐ None: ☐ Specify, if other:

Statistical Comparisons: ☐ Matching: ☐ Other: ☐

10) What type of observational study is it?

Cross-sectional: ☐ Longitudinal: ☐ Retrospective: ☐ Prospective: ☐

11) How was the population chosen for the study?:

12) What characterisitcs describe the sampled population?:

13) Type of population sampled?:

14) Type of criteria used for inclusion (check all that apply):

Age: ☐ Gender: ☐ Injury severity measure: ☐ Neuro/pshyc measure: ☐

15) What measure was used to select/stratify patients?:

16) Number initially screened for study (in pop): 17) Number eligible for the study:

18) Number who participated in the study: 19) Total number of dropouts during study:

20) Final number of patients in analysis:

21) Final number of patients in each group:

Treatment 1: 0 Treatment 2: 0 Control 1: 0 Control 2: 0

22) Did analysis take into account missing data? : Check "NO", if term "missing data" is not mentioned in the study

23) Age of Sample:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

24) Gender of Sample: 25) Characteristics of Injury:

Percent male: Proportion of sample with open head injury :

Proportion of sample treated neuro-surgically:

26) Elasped Time From Injury to Study Evaluation (months):

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

27) Glasgow Coma Scale:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

28) AIS assigned for "head" body region:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

29) Injury Severity Score:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

30) Days in Coma:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

31) Did subjects have multiple injuries?:

32) Days in Acute Care:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

Range: Mean: Standard Deviation: Median: Choose One:

33) Were premorbid data collected?:

34) What other characteristics were used to describe the sample (check all that apply)?:

Income: ☐ Insurance: ☐ Education: ☐ Occupation: ☐

35) Which of the following phrases were discussed in the results/methods sections or tables?:

Analysis of Variance (ANOVA): ☐ Bivariate Analysis: ☐ Multivariate: ☐ Others: ☐

Analysis of Covariance (ANCOVA): ☐ Multiple Regression: ☐ Odds Ratio: ☐ Specify, if others:

Logistic (LOGIT) Regression: ☐ Chi-square: ☐ t-test: ☐

36) In your opinion, are the reported findings clinically meaningful?:

37) Was there a serious flaw in the logic of the experimental design or in the analysis of the data?:

Yes: ☐ No: ☐ Cannot Say: ☐

If yes, please describe:

Question #1: Does the Application of Early, Interdisciplinary Rehabilitation Improve Outcomes for Persons With Traumatic Brain Injury?

Paper ID: 0

1.) Was interdisciplinary rehabilitation applied during the acute care hospital stay?

Yes: ☑ No: ☐

2.) What disciplines were included in the primary intervention?

OT: ☐ Speech: ☐ Other: ☐

PT: ☐ Cognitive: ☐ Specify, if other:

3.) What other treatments/procedures were offered outside the primary intervention?:

Briefly describe intervention 1:

Briefly describe intervention 2:

Briefly describe control 1:

Briefly describe control 2:

4.) Was intervention fixed or goal oriented?

Intervention 1: Fixed: ☐ Goal Oriented: ☐

Intervention 2: Fixed: ☐ Goal Oriented: ☐

5.) Application of Intervention:

Intervention 1: ☐ Duration (hrs/day): Frequency (applications/day):

Intervention 2: ☐ Duration (hrs/day): Frequency (applications/day):

Control 1: ☐ Duration (hrs/day): Frequency (applications/day):

Control 2: ☐ Duration (hrs/day): Frequency (applications/day):

6.) Number of days intervention was applied:

Intervention 1: Intervention 2: Control 1: Control 2:

7.) What short term complications were assessed as an outcome?

None: ☐ Skin Disorder: ☐ Lung Disorder: ☐ Specify, if other:

Duration of followup (# of Days):

8.) What measures of functional status at discharge from acute care were assessed as an outcome?

None: ☐ GOS: ☐ Rancho: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

9.) What measures of long-term impairment were assessed as an outcome?

None: ☐ Halstead-Reitan (HRNTB): ☐ WAIS: ☐ PAI: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

10.) What measures of long-term disability were assessed as an outcome?

None: ☐ FIM: ☐ FAM: ☐ KATZ: ☐ PAI: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

11.) Were any other measures of outcome assessed?

None: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

12.) Were results provided separately by:

Age: ☐ Gender: ☐ Race: ☐ Specify, if other: [ ]

Question #2: Does the Intensity of In-Patient Rehabilitation Affect Outcomes for Persons With Traumatic Brain Injury?

Paper ID: 0

1.) Was intensive, interdisciplinary rehabilitation applied during the in-patient rehabilitation stay?

Yes: ☑ No: ☐

2.) What disciplines were included in the intervention?

OT: ☐ Speech: ☐ Other: ☐

PT: ☐ Cognitive: ☐ Specify, if other:

3.) Intervention Descriptions:

Briefly describe intervention 1:

Briefly describe intervention 2:

Briefly describe control 1:

Briefly describe control 2:

4.) Were other treatments, in addition to intensive, interdisciplinary rehab, applied to any groups?

Yes: ☐ No: ☐ Not reported: ☐ If yes, please describe:

5.) Days in in-patient rehabilitation:

Intervention 1:	☐	Range:		Mean:		Standard Deviation:		Median:	
Intervention 2:	☐	Range:		Mean:		Standard Deviation:		Median:	
Control 1:	☐	Range:		Mean:		Standard Deviation:		Median:	
Control 2:	☐	Range:		Mean:		Standard Deviation:		Median:	

6.) What measures of functional status at discharge from in-patient rehab were assessed as an outcome?

GOS: ☐ Rancho: ☐ FIM: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

7.) What measures of long-term impairment were assessed as an outcome?

None: ☐ Halstead-Reitan (HRNTB): ☐ WAIS: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

8.) What measures of long-term disability were assessed as an outcome?

None: ☐ FIM: ☐ FAM: ☐ KATZ: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

9.) What measures of independence, relationships, family life, and/or satisfaction were assessed as an outcome?

None: ☐ QOLI: ☐ GAF: ☐ NRS: ☐ Specify, if other:

Duration of followup (# of Days):

10.) Were any other measures of outcome assessed?

None: ☐ Specify, if other:

Duration of followup (# of Days):

11.) Were results provided separately by:

Age: ☐ Gender: ☐ Race: ☐ Specify, if other:

Question #3: Does the Application of Compensatory Cognitive Rehabilitation Enhance Outcomes for Persons Who Sustain Traumatic Brain Injury?

Paper ID: 0

1.) What compensatory strategies were used?

Memory Book: ☐ Auditory Cues: ☐ Specify, if other:

Computer Aid: ☐ Video Play-back: ☐

Visual Cues: ☐ Card Cues: ☐

2.) Intervention Descriptions:

Briefly describe intervention 1:

Briefly describe intervention 2:

Briefly describe control 1:

Briefly describe control 2:

3.) Days of training for compensatory aid:

Intervention 1 ☐	Range:	Mean:	Standard Deviation:	Median:
Intervention 2 ☐	Range:	Mean:	Standard Deviation:	Median:
Control 1 ☐	Range:	Mean:	Standard Deviation:	Median:
Control 2 ☐	Range:	Mean:	Standard Deviation:	Median:

4.) Was a neuro-psych evaluation done before intervention?

Yes: ☐ No: ☐ Not Recorded: ☐ If yes, please describe:

5.) Were other treatments, in addition to compensatory cognitive rehab, applied to any groups?

Yes: ☐ No: ☐ Not Recorded: ☐ If yes, please describe:

6.) Were ADL's assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

7.) Were "return to work or school" assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

8.) Were "maintenance of work or school" assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

9.) What measures of long-term impairment were assessed as an outcome?

None: ☐ Halstead-Reitan (HRNTB): ☐ WAIS: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

10.) What measures of long-term disability were assessed as an outcome?

None: ☐ FIM: ☐ FAM: ☐ KATZ: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

11.) What measures of independence, relationships, family life, and/or satisfaction were assessed as an outcome?

None: ☐ QOLI: ☐ GAF: ☐ NRS: ☐ Specify, if other:

Duration of followup (# of Days):

12.) Were any other measures of outcome assessed?

None: ☐ Specify, if other:

Duration of followup (# of Days):

13.) Were results provided separately by:

Age: ☐ Gender: ☐ Race: ☐ Specify, if other:

Question #4: Does the Application of Supported Employment Enhance Outcomes for Persons With Traumatic Brain Injury?

Paper ID: 0

1.) Was the supported employment program:

Permanent: ☑ Transitional: ☐ Unspecified: ☐

2.) Intervention Descriptions:

Briefly describe intervention 1:

Briefly describe intervention 2:

Briefly describe control 1:

Briefly describe control 2:

3.) If transitional, what was the number of days coaching was applied?

Intervention 1: ☐	Range:		Mean:		Standard Deviation:		Median:	
Intervention 2: ☐	Range:		Mean:		Standard Deviation:		Median:	
Control 1: ☐	Range:		Mean:		Standard Deviation:		Median:	
Control 2: ☐	Range:		Mean:		Standard Deviation:		Median:	

4.) Were other treatments, in addition to supplemental employment, applied to any groups?

Yes: ☐ No: ☐ Not Recorded: ☐ If yes, please describe:

5.) Was a social support measure completed before intervention?

Yes: ☐ No: ☐ If yes, what measures:

6.) Were "maintenance of work or school" assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

7.) Was job success assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

8.) Was the level of income measured:

Pre-injury Yes: ☐ No: ☐

Post-injury Yes: ☐ No: ☐

9.) What measures of independence, relationships, family life, and/or satisfaction were assessed as an outcome?

None: ☐ QOLI: ☐ GAF: ☐ NRS: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

10.) Were any other measures of outcome assessed?

None: ☐ Specify, if other: [ ]

Duration of followup (# of Days): [ ]

11.) Were results provided separately by:

Age: ☐ Gender: ☐ Race: ☐ Specify, if other: [ ]

Question #5: Does the Provision of Long-Term Care Coordination Enhance the General Functional Status of Persons With Traumatic Brain Injury? What is the Cost-Effectiveness of the Provision of this Intervention?

Paper ID: 0

1.) Was long-term care provided by:

Professional: ☑ Family Member/Friend: ☐

2.) For the sample in this study, what treatment modalities were involved?:

Acute Care Hospital: ☐ Long-term Care Facility: ☐

In-Patient Rehabilitation Hospital: ☐ Supported Employment: ☐

Out-Patient Rehabilitation: ☐

3.) What disciplines were included in the course of rehabilitation?

Cognitive: ☐ OT: ☐ Specify, if other:

Psy/Counseling: ☐ PT: ☐

Employment Training: ☐ Speech: ☐

4.) Were "return to work or school" assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

5.) Were "maintenance of work or school" assessed as an outcome?

Yes: ☐ No: ☐

Duration of followup (# of Days):

6.) What measures of long-term impairment were assessed as an outcome?

None: ☐ Halstead-Reitan (HRNTB): ☐ WAIS: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

7.) What measures of long-term disability were assessed as an outcome?

None: ☐ FIM: ☐ FAM: ☐ KATZ: ☐ PAI: ☐ Specify, if other:

Duration of followup (# of Days):

8.) What measures of independence, relationships, family life, and/or satisfaction were assessed as an outcome?

None: ☐ QOLI: ☐ GAF: ☐ NRS: ☐ Specify, if other:

Duration of followup (# of Days):

9.) Were any other measures of outcome assessed?

None: ☐ Specify, if other:

Duration of followup (# of Days):

10.) Were results provided separately by:

Age: ☐ Gender: ☐ Race: ☐ Specify, if other:

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Questions 1 and 2

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Special Attachment

Toward an Integrated Approach to Quantitative Research on the Rehabilitation of Patients with TBI: a Call for Consensus Formation of a Universal, Uniform Data Set

Proceedings of the Subcommittee on TBI Rehabilitation at the Fourth Annual Aspen Neurobehavioral Conference
Aspen, Colorado
5-9 April, 1998

To optimize evidentiary review of the five TBI rehabilitation projects chosen for this investigation, the document was presented for peer review at the level of drafting of evidentiary tables as part of the Aspen Neurobehavioral Conference.

The Aspen Neurobehavioral Conference is held yearly in Aspen, CO to address timely and pressing issues and developing evidence-based consensus statements on neurobehavioral issues. This conference, now in its fourth year, originated through the generosity of Judy Neisser of Chicago, IL, in response to a neurotrauma experience in her family. The Aspen conference began and continues under the direction of Dr. Christopher Filley and Dr. James Kelly. At past conferences, issues such as the minimally conscious state, guidelines for end-of-life decisionmaking, the Guidelines for the Management Of Severe Head Injury, and prognostic indicators in severe TBI have been addressed. The conference is attended by professionals with diverse backgrounds and interests in brain and brain-behavioral issues, so it provided an exceptional venue for peer review of the present effort.

This review was accomplished at the fourth Aspen Neurobehavioral Conference, held in Aspen, CO from April 6-9, 1998. The conference was attended by 52 participants (list appended). The entire group gathered daily to review the process, provide input and, at the conclusion of the conference, to assess the results of the committee's work (*vide infra*) and to further guide its development and dissemination. This input was extremely valuable and has been incorporated into the evidence report.

A committee was formed from the participants to perform a detailed analysis of the status of our evidentiary review. The members of this committee were selected for their interests in the topics, their professional background, and in some cases, their previous involvement with this particular review as members of the National Panel (Dr. James Kelly, Ms. Bryna Helfer). The background of this committee varied widely, ranging from survivors of TBI through TBI rehabilitation program directors, therapists of various disciplines, activists in political processes related to TBI, as well as acute care providers. The specific members of the committee were:

- Duane Alexander MD; Director, NICHD
- Terri Antoinette; Director of Nursing, Greenery Rehabilitation Center
- Nancy Carney PhD; Oregon Health Sciences University
- Randall M Chesnut MD; Director of Neurotrauma and Neurosurgical Critical Care, Oregon Health Sciences University
- Michael Diringer MD; Department of Neurology, Washington University
- Flora Hammond MD; Charlotte Institute of Rehabilitation
- Daniel F. Hanley MD; Director, Neuro-Critical Care, Johns Hopkins Medical Center
- Bryna Helfer; TBI Technical Association Center
- Douglas I. Katz MD; Clinical Director, Traumatic Head Injury Program, Braintree Hospital
- James P. Kelly MD; Director, Brain Injury Program, Rehabilitation Institute of Chicago
- Brent Masel MD; President and Medical Director, Transitional Learning Community
- Paula Sundance MD; Paradigm Health Corporation
- Michael A. Williams MD; Assistant Professor, Department of Neurology, Johns Hopkins Hospital

In addition to the above members, Dr. Ross Zafonte, Rehabilitation Institute of Michigan, and Candy Gustafson spent significant time with the committee. They provided much valuable input and many valuable suggestions.

This committee met daily during the conference. The goals of this process were: 1) to review the literature and 2) to facilitate its interpretation. The literature review was intended to critically evaluate articles selected by the OHSU group as the primary contribution toward the five questions. In addition, contributions from non-selected articles were reviewed. A third purpose was to ensure that we had not missed major literature pieces that might serve as primary or contributing documents. Since this process is fundamental to the work in general, most of the results of this aspect of the committee's efforts have been incorporated into the evidence report.

The committee's second focus was interpreting selected literature in light of the state of the art of TBI rehabilitation. The purpose here was to interpret those articles most powerfully contributing to each of the five selected questions in terms of how they should influence the practice of TBI rehabilitation as well as future research. Due to the manifest lack of Class I and Class II studies, the major effort became development of processes that would focus future research on the most relevant questions, as well as ensure the quality of that research. The express purpose of work at the Aspen Neurobehavioral Conference became to develop rehabilitation and research recommendations to improve recovery and long-term outcomes of individuals with acquired brain injury using TBI as an example. We targeted injury description, rehabilitation methodologies, and clinical outcome studies in this effort. The results of this work are contained herein.

Two major themes arose from these discussions: 1) continuity of care and 2) comparability of studies. The theme of continuity of care addresses both the ability to track patient recovery and the influences of TBI rehabilitation over time as well as the issue of optimal timing of various therapeutic interventions. Since TBI recovery and the influence of rehabilitation is characteristically an evolving process that continues for the life of the patient, it is critical to evaluate the role of rehabilitation and its timing. The TBI population as a whole is studied at various, often overlapping, times after injury. In essence, “one study’s outcome measures can be another study’s input variables.” Such a concept mandates accurate and thorough time-dependent classification of patient and process-related input characteristics as well as clear descriptions of independent and dependent variables.

The timing issue is highly relevant to the presently highly controversial issue of the appropriate timing of therapeutic interventions. The impact of various treatment modalities will not only strongly interact with the natural recovery process, but the efficacy of these manipulations may be directly related to their timing. This is relevant to optimizing the efficiency of various therapies and the allocation of resources.

The theme of comparability of studies relates directly to the previous theme in that it mandates a common language to be shared across all disciplines and along the time continuum of the recovery from TBI. A major drawback in reliable comparison of even the few most relevant articles for the evidence report is their lack of comparability. In general, there has been little or no consensus on the validity of various descriptors and endpoints or their common definitions. There has been a tendency for studies to use unique, individual tools and combinations of them without attention to common data elements. The focus of this theme was, therefore, to suggest the formation of a uniform data language that could be used as a common infrastructure in future studies to ensure their comparability.

The committee focused on three specific areas. The first was the classification of intracranial and extracranial injuries as potentially confounding input variables. The second was the issue of description of the rehabilitation processes that are commonly applied as independent variables. The third was the measurement of outcome.

Recommendations for Classification of Intracranial and Extracranial Injuries for Outcome Research on Rehabilitation Efficacy

The needs and goals of an injury classification system include:

- identifying comparable patient groups and specific subgroups
- providing uniform standards and measures and a minimal data set to describe injury type, severity, and significant interacting variables
- accounting for multiple interacting injury and non-injury factors
- recognizing that different variables and classification systems may be necessary depending on time post-injury and outcome of interest (e.g. GCS or Traumatic Coma Bank CT classification may not be as useful in the post-acute period as during the acute period when mortality is a major outcome of interest)

These needs and goals mandate some degree of consensus on a basic set of data points and their definitions that should be shared across research efforts. It would be expected that such a basic data set would be supplemented in many if not all investigations by measures or items that are unique to that effort. The presence of a uniform infrastructure, however, would ensure proper interpretation of these new variables in light of a common ground and also facilitate replication of such research at other institutions.

The numerous difficulties and challenges inherent in meeting such goals include:

- limited direct pathophysiologic measures of some injury types (e.g., diffuse primary and secondary injuries such as diffuse axonal injury, or hypoxic-ischemic insults)
- concomitant occurrence of multiple injury types and severities (focal/diffuse, primary/secondary) and lack of understanding of their interactions
- common occurrence of comorbidities including premorbid conditions and concurrent extracranial injuries
- variable correlation of anatomic details of injury type and severity with clinical and functional status (e.g., clinical-anatomic correlations of focal injuries, neurologic syndromes, functional disabilities, recovery history, and outcome)
- lack of standardized definitions and reliability values of some measures (e.g., duration of unconsciousness, duration of post-traumatic amnesia, anatomic classification of focal lesions)

Such difficulties give rise to at least two major concerns. First, many of the above listed entities are incompletely understood. Secondly, many of these items also lack strict definitions. It is to be expected that, as our understanding progresses, the definitions will evolve or change. Nevertheless, to optimize the present state of research it is necessary to agree on an initial list of relevant data points and ad hoc definitions for those items. Because these items and their definitions are presently in a state of flux and will probably remain so for some time, formulating a well-defined minimal data set will necessarily involve consensus formation.

It is proposed that such a basic and common injury classification system should:

- account for varying injury types, severities, and comorbidities
- recognize that different injury types and subtypes may require specific severity variables
- allow for a total injury profile that may include multiple injury types, severities, and comorbidities (e.g., must facilitate statistical manipulation while avoiding mutually exclusive categories)
- allow some variation, depending upon time since injury, research questions, and outcomes of interest
- lend itself easily to multivariate analysis since the predictive value of some variables may vary with time and with injury outcome measures of interest and they may fall out of outcome models as the patient evolves

- account for individual, non-injury variables including demographics, age, psychological/psychiatric status, education, work and school history, social and family network, habits, and substance abuse
- account for intervention variables prior to and during the study;
- account for late developments (e.g., seizures, heterotopic ossification, hydrocephalus, chronic subdural hematomas, social/psychological dysfunction, etc.)

The development of an injury classification system that can be applied at the earliest point of patient contact and continue throughout the patient's course will necessarily initially be heavily weighted toward acute-care variables. Since one of the goals of such a system is to promote continuity, however, it will have to include capture of elements that appear later in time. Obviously, the formulation of such a system is an onerous task, but it is imperative for successful TBI rehabilitation research. As an example of such a program, the following elements are outlined:

- brain injury profile should include subtypes categorized according to dimensions such as focal/diffuse, primary/secondary, comorbidities, and late complications
- it should also define criteria for diagnoses of injury subtypes and establish severity measures for each subtype with specific definitions

The attached table presents an example of what an early iteration of such a scheme might look like.

Injury category/ diagnostic criteria	Proposed severity measures
diffuse axonal injury (and accompanying pathophysiologic processes) according to clinical and supporting imaging criteria	GCS duration of unconsciousness duration of PTA cerebral atrophy on neuroimaging other indices such as functional measures (e.g. FIM)
focal parenchymal and extracerebral pathology based on imaging criteria	lesion characteristics - size/depth, number, laterality, mass effect (e.g. TCDB class. + new system for localization) GCS duration of unconsciousness duration of PTA other indices such as functional measures (e.g. FIM)
Secondary diffuse & focal pathology: based on specific risk factors (e.g. sustained hypotension, hypoxia, intracranial hypertension, intensity of acute care, ? Other) and imaging criteria (e.g. Herniation shifts, infarctions)	Gradation of risk factors, probability of occurrence based on risk factors, measures of acute intensity, ? others
late complications: imaging, slowing of clinical recovery, changing neurologic status, ? other	imaging clinical measures physiologic measures lab data others to be determined
comorbidities-premorbid and concurrent: history, clinical, appropriate dx evaluations	AIS Apache others
individual associated non-injury variables	Age SF 36 Family Assessment Measure others
measures of interventions	type expertise duration frequency carryover strategies treatment intensity

Recommendations for Classification of Severity of TBI for Outcome Research on Rehabilitation Efficacy

The three major descriptions of severity of neurologic injury to date have been the Glasgow Coma Scale (GCS) score, the duration of post traumatic amnesia, and the duration of coma (duration of unconsciousness). The GCS score is well-defined, and when used properly, is a very valuable tool for describing the depth of coma at a given time. The difficulties involved in its proper use have been well-described (Marion & Carlier, 1994). However, the GCS score provides only a snapshot of the patient's function and provides no index of its duration or rate of recovery.

Length of coma (LOC) is an attempt to quantify injury by the length of time it takes to recover consciousness. Its utility has been confounded by a lack of a uniform definition and the difficulty of describing the point at which a patient reaches consciousness. Recent work in the area of minimally conscious state has been forced to deal with this effort directly and has described the existence of a nebulous period between coma and full consciousness where a patient may be described as unconscious but not in coma. The existence of such a period obfuscates the definition of length of coma and, therefore, its usefulness. The idea of substituting length of unconsciousness (LOU) for LOC has significant potential utility but is not helpful with literature that has already been published using LOC as a measure.

Probably the most useful index of the degree of brain injury that contains an element of recovery is post-traumatic amnesia (PTA). Again, this measure's validity directly reflects the use of a clear, widely accepted definition. In general, this has been codified as the time at which a patient reaches a 75 percent performance on the Galveston Orientation and Amnesia Test (GOAT). Because of the clarity and general acceptance of such a definition and the widespread availability of its measurement tool, PTA is probably the most reliable recovery-linked index of severity of brain injury in use today. It should be included as a potentially confounding injury descriptor in any current TBI rehabilitation study.

As with any effort that deals with neurologic recovery, there are a number of confounding issues in the definition of either LOU (LOC) or PTA. For instance, if the definition of LOU is the point from injury through the patient's ability to follow commands, the presence of a deficit such as a receptive aphasia seriously confounds the determination of this endpoint. Such issues must be considered when using these descriptors to describe general TBI populations.

Using GOS measured at 6 and 12 months after injury as the index of recovery, the predictive value of the GCS, PTA, and LOC have been prospectively compared (Katz & Alexander, 1994). The study cohort was a consecutive sample of 243 patients with TBI admitted to a rehabilitation unit. In this study, PTA was clearly associated with the greatest predictive value at 6 and 12 months ($R2 = 0.45$, $P < .0001$; $R2 = 0.48$, $P < .0001$). Of interest, it appeared that the predictive value of PTA was greater in patients with diffuse injury patterns and worse in patients with primarily focal injuries. Although these predictive values are undoubtedly dependent upon the design of the study, the ease of using a standardized measurement tool and the inclusion of rate of recovery within its scope suggest that PTA should probably be added to the GCS score as a routine descriptor of TBI severity.

Many descriptors of injury are specific to the intensive care unit environment and have established utility in determining outcome. Examples of these include indices of cerebral perfusion (such as the arterial venous oxygen difference as measured between systemic arterial and jugular venous blood), the cerebral perfusion pressure (mean arterial pressure minus intracranial pressure), and ICP (Gopinath et al., 1994; Marmarou et al., 1991a; Rosner, Rosner & Johnson, 1995). In addition, secondary insults such as hypotension are also highly determinant of recovery during the acute phase (Chesnut et al., 1993a; Chesnut et al., 1993b). However, the interventions applied within the critical care setting also appear to be determinant of outcome (Chesnut, 1998; Cruz, 1998; Rosner et al., 1995) In addition, because such therapies often include sedation or neuromuscular blockade, they may confound measurement of neurologic recovery. For this reason, the therapeutic intensity level (TIL) is commonly now added to acute TBI description databases in addition to descriptors of LOC, etc (Marmarou et al., 1991b). The TIL is an attempt to describe how much treatment was required to achieve a patient's given LOC/state of recovery. Specifying the TIL assists in recognizing the difference between two patients whose physiologic indices are similar but who require vastly different degrees of therapeutic intervention in order to maintain those indices. An example of a TIL rating scale is given below.

Therapeutic Intensity Level

Treatment	Score
Sedation/Neuromuscular Blockade	1
Ventricular Drainage	1
Mannitol (1 g/kg/hr)	2
Mannitol (>1 g/kg/hr)	4
Pressors/Inotropes for CPP Management	2
Hyperventilation (PaCO2 30-35 mm Hg)	4
Vigorous Hyperventilation (PaCO2 <30 mm Hg)	6
Barbiturate/Propofol Coma	15
Hypothermia	15
Surgical Decompression	15

Maximum score is 15. Without barbiturate/propofol coma, hypothermia, or surgical decompression, the score is the sum of the other components.

Comorbidities need also to be indexed when describing patients, particularly during the early stages. The most common method of doing this has been to use the Abbreviated Injury Scale (AIS) with or without its integration into the Injury Severity Scale (ISS) (Committee, 1985).

A major unresolved issue in the description of injuries is salient codification of the anatomy of injury. With the advent of scanning methods such as Computerized Tomography (CT), Magnetic Resonance Imaging (MRI), and other modalities, our ability to describe the anatomy of injury has increased. Unfortunately, outside of general descriptors, we have achieved little success in correlating specific injuries with outcome or the efficacy of rehabilitation efforts. General descriptions such as that from the Traumatic Coma Data Bank (Marshall et al., 1991) have become very useful in predicting recovery based primarily on correlating CT imaging with intracranial pressure or mass effect. Unfortunately, descriptors of injury location have yet to be shown to be useful in predicting recovery in TBI populations despite their importance in determining specific neurologic deficits. The relationship between recovery and issues such as bilateral or unilateral pathology, acute versus delayed lesions, and location of lesions within specific lobes of the brain remain unproven and unclear. Although some attempts have been made to include descriptors of the anatomy of injury into lists of confounding descriptive variables, such efforts have been seriously hampered by the lack of a uniform system of describing such anatomy using a commonly accepted set of definitions. The development of such a uniform nomenclature represents a critical first step in addressing the important issue of anatomy of injury (Mills, Cassidy & Katz, 1997).

As a patient progresses along a continuum of recovery, the importance of many of these acute indicators will wane. Optimally, this would be represented by formally demonstrating their non-contributory status by including them in regression analysis of confounding variables and showing them to not be predictive in a given setting. Notably, as some of these variables become less important over time, they will necessarily be replaced by other variables. As an example, although GCS is a very strong predictor of outcome during the acute care period, its importance tends to be supplanted by measures such as duration of PTA as patients progress over time.

Consequently, new descriptive variables will necessarily be added over time. Many such variables which will be viewed as patient descriptors in later studies will have served as outcome variables at earlier points. Examples of such measures will be the Disability of Rating Scale (DRS), the Glasgow Outcome Scale (GOS), the Rancho Los Amigos (RLA) Scale, and the Functional Index Measure (FIM). Such indices are characteristically first being measured at the close of acute trauma care management.   Thereafter, they should be entered into the list of patient descriptors as confounding variables in subsequent analyses.

Another area of descriptive variables that needs to be considered as a confounder arises from the pre-morbid period. Items such as pre-injury employment or school attendance, level of education, family or social support structure, history of substance abuse, and psychosocial factors such as measured in the CIQ must be entered into consideration throughout the entire course of patient recovery. Unfortunately, there exists no uniformly accepted sets of tools or definitions for these purposes. This represents a critically under-addressed issue in TBI rehabilitation.

Recommendations for Description of Rehabilitation for Outcome Research on Rehabilitation Efficacy

The description of rehabilitation services is a critical yet under-addressed area of TBI rehabilitation research. The critical aspect here, as with any scientific study, is that comprehensive and widely accepted nomenclature must be formulated and used such as that all investigations are comparable and replicable. Any published study needs to be described sufficiently so that it can be reliably replicated in another setting. Such a description needs to be applied not only to the independent variable, which may be a novel therapy or other intervention, but to the entire rehabilitation program that represents the setting in which it was applied. Too often, rehabilitation is described as a gestalt, and qualitative and quantitative differences between programs are ignored. It is only through the accepted use of a common nomenclature to describe rehabilitation programs in reasonable detail that we will be able to determine what interventions are effective in improving outcomes and identify those that are not.

Examples of points that need to be addressed in describing rehabilitation programs include:

- frequency of individual therapeutic interventions
- duration of individual therapeutic interventions
- content of individual therapeutic interventions
- training and level of therapists' experience
- intensity of therapy (including but not limited to hours of application)
- treatment settings
- interaction styles
- milieu of therapies (e.g., dedicated TBI rehabilitation unit, skilled nursing facility, etc.)
- milieu of time spent outside of specific therapeutic interventions
- degree of program supervision and by whom

In addition, a number of methods of intervention that are less specific and/or more recently developed need to be described. These may be programmatic or interdisciplinary and, therefore, be more difficult to describe in discrete terms. These include social, psychological, physiological, or pharmacological interventions. Their focus may be compensatory, augmentative, or restorative, and they may be accomplished as individual and/or group interactions. In general, most inpatient rehabilitation efforts include several such interventions but, characteristically, their distributions and intensities of applications vary widely between programs as well as between patients. Unless they are well-described, however, the entire spectrum of therapeutic interventions that confound any rehabilitation efficacy study will remain unclear and, therefore, uncontrolled.

Optimally, the testing of an intervention should be accomplished in a controlled setting wherein all interventions are well-described and uniformly applied to the experimental and control groups. In a large number of instances, given the absence of uniform patient populations for a study, such homogenization of rehabilitation will be neither appropriate nor ethical. It is for this reason that a well-defined and accepted nomenclature for describing rehabilitation programs is necessary so that those interventions that vary between patients can be controlled statistically.

Recommendations for Description of Outcomes for Outcome Research Rehabilitation Efficacy

The measurement of outcome is a vitally important yet grossly unsettled issue in the area of traumatic brain injury. The absence of a uniform set of definitions and a commonly accepted descriptive approach is highly disruptive to both the execution and comparison of individual investigations. One area where the issue of outcome measurement has been extensively addressed is in studies on the efficacy of acute, post-traumatic intervention in improving outcome. This is perhaps the easiest point on the TBI spectrum to study because it is a finite point of patient injury (i.e., time of trauma) and presents a set of patient descriptor variables that are relatively easily quantified (physiologic indices). In addition, much research has been driven by well-funded efforts of pharmacological companies directed toward developing drugs that may assist in promoting recovery. Nevertheless, even in this well-defined area, outcome description remains unsettled. For instance, until rather recently, most studies described outcome in term of the GOS, which is an extremely limited and very poorly descriptive measure of recovery even at a fairly acute stage. Only recently has there been a concerted effort to use more sensitive and widely-relevant outcome measures for recovery.

One of the main issues confounding outcome measurement in the setting of traumatic brain injury is that recovery is a lifelong process. In addition, it is highly evolutionary in that its focus changes over time from primarily physiologic to physical to psychosocial, etc. Such an evolutionary nature necessitates parallel alterations in outcome measures. Because this evolution progressively and non-exclusively involves numerous interactions with various caregivers, support systems, social institutions, and payor groups, the focus of outcome measures may be different even when applied to a given patient at a definite point in recovery. This variability in areas of interest and disciplines along and across the continuum of recovery has been highly instrumental in preventing the development of a useful, uniform nomenclature in this area.

An example of this situation is illustrated by the World Health Organization's definitions of impairment, disability, and handicap:

Term	WHO Definition
Impairment	Abnormality in physical or mental function
Disability	Limitation in performance because of an impairment
Handicap	Loss of social role function because of disability

It is obvious from these definitions that their relevance will vary along the course of recovery as well as at a given stage of recovery across different disciplines and situations. For instance, a deficit measured as an impairment during the acute stages will manifest as a handicap farther along recovery.

An exemplary but incomplete list of outcome variables (and some candidate measurement scales) that need to be addressed in a uniform outcome nomenclature includes:

Variables	Outcome Measures
Function	RLA, GOS, DRS, FIM,
Cognition	PASAT, WMS, Wisconsin Card Sorting Test
Psychosocial Adjustment	Katz Adjustment Scale, Neurobehavioral Rating Scale, Portland Adaptability Inventory, Global Assessment of Functioning, Psychosocial Rating Scale
Awareness of deficit	Patient Competency Rating Scale, WAIS IQ, BNI Screen for Higher Cerebral Functions
Quality of Life	SF36
Autonomy	SF36
Social Integration	SF36
Community Integration	CIQ, Life Skills Profile
Patient/Family Satisfaction	Subjective/Objective Burden Questionnaire, Family Burden Interview Schedule, Quality of Life Interview

Since many of these outcome measures can be repeated over time and will serve as progress monitors for patient recovery as well as important patient descriptive data for research studies, items from the various outcome measures should be added into the overall outcome profile of a patient as early as possible in that patient's course. In parallel, items should be eliminated from serial measurements only when they have plateaued or are definitely no longer relevant.

Summary Recommendations

The entire OHSU EPC project started out to find answers to specific questions. The results of this concerted and exhaustive effort to review the literature in five tightly defined areas has been less successful in finding definite answers than in defining problems in the research literature. There are certainly definite issues within each question that have arisen from the literature and these are described in those sections devoted to each individual point. A major, if not the major, result of this effort, however, has been to delineate specific, recurrent problems that seem to span the literature and appear to generally coalesce into the overriding issue of the lack of a unifying nomenclature and data set.

The major problem with meaningful interpretation of the present literature arises from a dearth of a common and well-accepted basic data set within disciplines and lack of communications between disciplines. The comparability of investigations dealing with similar questions would be universally improved if they shared a fundamental set of definitions and basic variables addressing patient description, rehabilitation interventions, and outcomes. If these definitions and data elements could be shared over the continuum of recovery, the critical question of the optimal timing of various therapeutic modalities could be adequately addressed.

TBI rehabilitation desperately needs to come to consensus on a well-defined, minimal universal data set if the above issues are to be properly addressed. The construction of this data set should be pragmatic in nature. As discussed previously, there are presently no optimal methods for fully describing patient injury characteristics, rehabilitation procedures, or outcome. Due to the immediate need for a common language, however, a utilitarian approach is required wherein less than perfect elements are assembled into a minimum uniform data set compiled by consensus opinion and included in future research efforts by agreement between investigators. These efforts need to be focused on the three areas outlined previously: classification of injury and non-injury variables, description of rehabilitation services, and outcomes measurement. Within each of these areas, a well-defined minimal uniform data set needs to be assembled with the goals of its being adequately descriptive to facilitate well-controlled and replicable research, broad enough to adequately describe the necessary elements in a field while allowing integration of the new or unique elements, and concise enough to be manageable or not overburden smaller research efforts. Collection of those elements of such a minimal uniform data set that are relevant to an individual study would then be expected by journal editors, grant reviewers, and funding agencies to be included in the experimental design of such an investigation.

Such a process must avoid duplicating previous efforts. Definitions developed by groups such as the Committee for the Accreditation of Rehabilitation Facilities (CARF), the Centers for Disease Control (CDC), the National Institute for Disabilities Rehabilitation and Research (NIDRR—i.e., TBI model systems investigations), and ongoing HRSA work groups, should be used whenever possible. Existing outcome measures should also be used whenever possible and supplemented rather than replaced in investigations choosing to use other measurement scales.

In forming such a data set, it is important to borrow from present efforts rather than attempt to replace them. The elements of the Uniform Data Set for Medical Rehabilitation (UDSMR), a minimalistic and proprietary rehabilitation data set, plus the NIDRR TBI model systems data set, a highly complex and therefore rather exclusive effort, should be investigated and the minimal uniform data set be design to be complementary to these efforts.

The development of such a minimal uniform data set must include all groups doing data set assembly directed at all stages of recovery in the effort. It is the lack of such communication that presently hampers analysis of the literature. For example, outcomes of importance will vary with discipline. To an emergency room physician, a good outcome is that the patient leaves the emergency department alive and resuscitated. To the neurologic or neurosurgical intensivist, a good outcome is having the patient leave the intensive care unit in stable physiologic condition. To the inpatient physiatrist, a good outcome involves learning independence in activities of daily living and psychosocial skills to allow durable existence outside the inpatient setting. To an employment support specialist, a good outcome is achieving long-term employment. From a patient or family viewpoint, however, a good outcome may be the development of active social interactions or interpersonal relationships. Optimally, each one of these issues would be addressed and defined in a uniform outcome description nomenclature that is meaningful as well as research descriptive power across disciplines. Such a wide scale, cooperative venture would ensure the continuity of data along the process of recovery and also optimize the development of a data set useful to the widest variety of investigators.

The potential benefits of such a data set would be enormous. The acute care practitioner would be able to understand how their interventions were reflected in long-term outcome. Investigations into the efficacy of various employment strategies would be able to easily describe those patients to whom job coaching skills were being delivered using commonly understood terms. It would be possible to study the effect of various therapeutic modalities on patients who had been lost to the system for a period of time if outcome variables collected at the point at which they were lost were meaningful to investigators or rehabilitation specialists at the point when such patients reentered the system.

The optimal outcome of the present evidence-based study, reflected in the work of the Fourth Aspen Neurobehavioral Conference, would be the establishment of grant-supported consensus conferences directly focused on developing minimal uniform data sets and descriptive nomenclature dealing with the three specific areas of 1) characterization of patients and injury, 2) description of rehabilitation services, and 3) measurement of outcomes. The acceptance of the work of such consensus conferences would serve to greatly improve the value of investigations initiated at this fairly early stage in quantitative rehabilitation research. The use of such a well defined, minimum uniform data set by journal authors, grant reviewers, and funding agencies would optimize the use of funding dollars and the value of the derived information.

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