## **Injury Epidemiology: Fourth Edition**

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## Chapter 14. Evaluation of Post-injury Treatment and Rehabilitation

Research questions regarding the treatment of injuries and rehabilitation range from the profound issue of who survives trauma to the more mundane estimates of costs and payment. Only a small minority of physicians and other professionals delivering care to traumatized patients conduct research, but because of their familiarity with the treatment and rehabilitation scene, these persons are usually in a better position to ask good research questions than epidemiologists (Findley, 1989) but epidemiologists can collaborate with them to design and implement research projects.

Mortality from trauma usually occurs in the first hour, mainly from massive nervous system or heart and blood vessel damage. Many of the injuries to those who do not survive the first hour are not treatable, but there is substantial evidence that the timing and quality of emergency response and treatment can increase survival (Trunkey, 1983). The longer-term survival of those who survive is shorter for patients with traumatic brain and spinal cord injuries (Brooks, et al., 2013; Frankel et al., 1998).

More and better research in the delivery of emergency services and on specific treatment and rehabilitation regimens can lead to increased survival and a better quality of life for those impaired by injury when the knowledge is used. Although research on the efficacy of modes of treatment and rehabilitation has accelerated (Maier and Rhodes, 2001), many practices are based on impressions from experience rather than quantitative evidence (Basmajian and Banerjee, 1996).

Issues include placement of emergency responders to minimize response time, amount and type of treatment at the scene, the safety of transportation modes (ambulances, helicopters, fixed-wing aircraft), triage to designated trauma centers, designation of trauma centers, referral to rehabilitation, and efficacy of specific treatments in acute care and rehabilitation (Committee on Trauma Research, 1985). The injury epidemiologist who becomes knowledgeable in these issues can assist in study design, validation of measurements of injury severity, and statistical analysis to other health and organizational researchers involved in their investigation. **EMERGENCY RESPONSE.** The effect on survival of delay in treatment of injuries has been inferred from the extent of delay and survival in war (Table 14-1). Bypassing field treatment and transport to M.A.S.H. units in Korea and the transport directly to surgical units for definitive treatment in Viet Nam are thought to be the major factors in reduced mortality (Trunkey, 1983), although controls for type and extent of wounds and improved surgical technique and technology might raise or lower the estimates somewhat. Delay in surgery for other forms of serious injury, such as hip fractures in the elderly increases the risk of death as well (Whinney, 2005). Early surgery is also associated with improved function of persons with spinal cord compression (Fehlings, et al., 2012).

War	Delay in Hours	Percent Mortality
World War I	12–18	8.5
World War II	6–12	5.8
Korea	2-4	2.4
Viet Nam	1.1	1.7

Table 14-1. Delay Between Injury and Surgery and Percent Mortality of the Injured in Wars

Source: Trunkey (1983).

In the U.S., civilian emergency response systems have evolved from ambulance services, about half operated by morticians (who had an obvious conflict of interest), to a variety of systems based in hospitals, fire or police departments, volunteer services, and for-profit organizations (Boyd, 1983). The study of the effect of response times is complicated by the fact that response times are longer in remote rural areas where the injuries are also more severe and the quality of care upon arrival at a hospital is more often inferior. Controlling for types of motor vehicle crashes that would affect survival among rural counties in Texas, the extent of access to emergency response systems reduced the ratio of mortality to disabling injuries, but the cost-effectiveness of improving systems in remote areas was guestioned (Brodsky and Hakkert, 1983). The lack of adequate emergency services in rural areas is often in those that can least afford them (Martin, et al., 1990). Leading international authorities on trauma care argue that improved initial response to injury should concentrate on response time by responders with a few basic skills to alter immediate life-threatening conditions which would reduce death substantially in parts of the world where a delay and lack of skills is common (Sasser, et al., 2006).

Some U.S. data are available on emergency response times to fatal motor vehicle crashes in the Fatality Analysis Reporting System, although the lack of complete reporting is a problem. For fatal crashes in urban areas during 2004, the emergency service arrived at the scene an average of 6.5 minutes after being called, but the data are questionable because 50 percent of cases had no time reported. For fatal rural crashes, arrival occurred at an average of 11.3 minutes after the call but times

were unreported for 40 percent. The reporting did not improve in the ensuing decade. Given the limits of the data, there is some evidence that emergency response times were reduced in time (Cruz and Farenchak, 2020).

In an area with a regionalized trauma system in which patients with severe trauma are supposed to be taken to a special treatment center, the probability of survival was not directly related to time at the scene or transport time. Time at the scene averaged 16.7 minutes for survivors and 15.2 minutes for non-survivors. Transport time was an average of 13.0 minutes for survivors and 11.9 minutes for non-survivors (Shackford, et al., 1989). While there does not appear to be a difference in an area with the range of response times studied, that does not mean that response time would not have an effect in areas where it is longer. In urban areas where response times to 911 calls average less than 8 minutes, survival is improved by less than a percentage point by shorter response times (Blanchard, et al., 2012). This raises the issue of the point at which the cost of additional ambulances and crews is justified and how the evidence is affected by mutual aid agreements among communities (Wilde, 2013). Some research indicates that "scoop and run" by the police when ambulances have not arrived reduces the risk of death (Jacoby, et al., 2020). A prospective multicenter study of mortality in areas with different protocols for "scoop and run" vs. treatment at the scene in Canada found that treatment at the scene by EMTs could not be justified in areas with Level 1 trauma centers (Liberman, et al., 2003).

**TREATMENT AT THE SCENE**. Emergency responders and the public generally should learn how to clear breathing passages, stop obvious hemorrhage, stabilize the spine, and perform cardiopulmonary resuscitation in the absence of pulse or breathing (Jacobs and Bennett, 1983). Many questions remain about the advisability of the kinds of treatment that should be delivered at the scene of injury versus the delay involved before transport to more definitive treatment. The main controversies revolve around various practices at the scene, such as intravenous infusion of fluids, the use of pneumatic anti-shock garments, endotracheal intubations, and esophageal obturator airways (Lewis, 1983). A review of the literature suggests that there is little or no difference in outcomes from a variety of airway management techniques (Carney et al., 2021)

Many techniques used by paramedics in the Viet Nam War were adopted in civilian emergency systems, particularly early on in those manned by military veteran paramedics returned to civilian life. Some have become routine and in a few cases, at least, the law mandates availability. For example, the pneumatic antishock garment was required equipment on ambulances in one-third of the states by the early 1980s despite a lack of evidence of its efficacy (Lewis, 1983).

A study of the use or non-use of the pneumatic anti-shock garment, assigned for use in the recommended circumstance on alternating days, indicated that an average of 4 minutes was added to time at the scene on the days that the garment was used. Survival was 69 percent on days when the garment was used and 75 percent on days it was not used. Although the assignment was not random, as claimed, it is doubtful that day-to-day differences biased the results. The authors concluded that the use of the garment had no net positive effect on survival and possibly a negative effect (Mattox, et al., 1989).

That study does not quite lay the issue to rest because survival was higher when the garment was used (38 percent versus 29 percent when not used) among those with systolic blood pressures less than 50, although the difference was not statistically significant due to the small number of patients with those blood pressures. The remaining issue is whether more selective use of the garment on a sample and control group of sufficient size would indicate statistically significant benefit for selected patients.

Such controlled trials are unusual in the evaluation of pre-hospital emergency systems. The use of intravenous fluids before arrival at the hospital -- studied retrospectively - indicates no advantage to trauma patients in several important subcategories of severity and clinical status. Patients taken to six hospitals in San Diego County for 2.5 years were studied (Kaweski, et al., 1990). The use of fluids appeared to be random relative to the severity of the diagnosis and clinical status -- some 56 percent received pre-hospital fluids. Time to the hospital was also similar in most severity groups, the exception being a 5-minute longer time among those who received fluids in the group with Injury Severity Scores 25-50 and systolic blood pressure greater than 90. Survival was similar in those treated with and without fluids in subgroups with various combinations of injury. A review of the literature found that evidence regarding the infusion of fluids remains inconclusive (Kwan, et al, 2014). A randomized control study found no difference in trauma outcome between patients given plasma in the experimental group and a saline solution in the control group before arrival at the hospital (Moore et al., 2018).

Another type of study involves a retrospective review of procedures and outcomes by a committee of emergency room physicians, trauma surgeons, and neurosurgeons. For example, one such study concluded that advanced life support (the care delivered by the best-trained paramedics including intravenous fluids, endotracheal intubations, and pneumatic shock garments) "appears to be beneficial in the treatment of multi-system trauma in a rural state" (Reines, et al., 1988). This is even though advanced life support took an average of 5 minutes more at the scene and a 10-physician review committee judged the treatment, as not in compliance with recommended practice in 74 percent of cases for endotracheal intubations and 54 percent of cases for pneumatic garments. In the cases where the techniques were applied, the review committee judged advanced life support as "helpful or essential in 85 percent of cases" and harmful in less than 2 percent.

An ecological study found a correlation between levels of training of emergency response personnel and fatality rates per population among counties in North Carolina. Counties with advanced or paramedic training had lower fatality rates after adjusting statistically for numerous other differences among the counties. Since all of the urban counties had advanced training, however, it was not possible to completely disaggregate the possible effects of other factors (Messick, et al, 1992). Treatment of traumatic brain injury at the scene was not significantly related to mortality and morbidity in a retrospective study in Sweden (Falk, et al., 2014).

There is a conflict between the results of the clinical trial and prospective studies and the results of the post-injury review study. Since the methodological power of randomized field trials and prospective studies generally is far superior to ecological studies and retrospective judgment, the use of such studies must be employed to evaluate more definitively the efficacy of particular procedures. Of course, if the procedures are substantially unused even when there is a policy regarding their use, or policy guidelines are not followed, the issue is largely moot.

Better designed evaluation of the effectiveness of treatment of opioid overdoses with an antidote by family as well as police or EMS personnel is needed (Straus, et al. 2013). One summary of the literature found no randomized controlled trials but did note that several studies found that people could be made knowledgeable of the antidotes and use them (Clark, et al., 2014). More recent trials of drugs to reduce relapse have shown some effects (Lee, et al., 2018). The reversal of opioid effects improved as dosages of naloxone increased but an even greater increase in dosage may be required to counter the effects of fentanyl (Mahonski et al., 2019). Antidotes for CO and cyanide poison can be administered at scenes of fires (Huzar, et al., 2013).

The efficacy of modes of transportation for injured patients is also a matter of controversy. Many hospitals have purchased helicopters ostensibly to reduce travel times, although the use in transplant programs, as well as the publicity and prestige of having one, also no doubt contributed to the decision to purchase one. While the use of helicopters to transport trauma patients from remote locations is seldom questioned, research has raised doubts about its net benefit in urban areas.

For example, based on a comparison of patients suffering from blunt trauma with survivable Injury Severity Scores and Glasgow Coma Scores, no advantage of helicopter transport in patient outcomes was indicated within a metropolitan area (Schiller, et al., 1988). Other studies suggest increased survival in helicopter transfers (Schwartz, et al., 1989). A complete assessment of the efficacy of the available forms of transportation would require an assessment of the costs of helicopter systems as well as injury to patients and emergency personnel in crashes during transport by whatever mode. Newspaper anecdotes of commercial helicopter ambulance cases included a charge of \$47,000 for an 80-mile trip (New York Times, 5/6/2015). Since helicopters cannot fly in certain weather conditions or where there is insufficient landing space, land-based ambulance systems cannot be eliminated when a helicopter is purchased. Criteria have been suggested for the choice of modes of transportation that need to be researched (Black, et al., 2004). A recent analysis of costs claims that helicopters would have to increase survival rates by 15 percent to justify their costs (Delgado, et al. 2013). A study in Germany

found a substantially increased survival rate of helicopter-transported trauma patients when injury severity and other factors were controlled statistically (Weinlich et al., 2019).

Assessment of the effect of changing any one system component is complex because of the inter-correlation of various factors. Attempts to assess survival, length of hospital stay, and costs as a function of mode of transport and direct transport to a trauma center, versus an interim stop at another hospital, must control at least for age and injury severity. The numbers of cases in certain combinations of the factors become thin even when beginning with a large sample size. Given these limitations, the available data suggest that arrivals at a trauma center from inter-hospital transfers have a longer length of stay and greater costs than those brought directly to the trauma center (Schwartz, et al., 1989). Among spinal cord patients, the increased time in hospital is a result of the increased need for acute care; time in rehabilitation is not significantly different (Oakes, et al., 1990). This could be partly because only the more severe cases or cases with complications are transferred, but those who are not transferred are known to be at greater risk in many community hospitals.

**TRAUMA CENTERS.** Once the injured person is en route to a hospital, the hospital of choice is at issue. While time to the hospital may be a factor in outcome in some cases, if the medical care received on arrival is inadequate or misdirected, the probability of survival can be reduced. There is little doubt that the treatment received in hospitals makes a difference in the chance of survival (e.g., Baker, et al., 1971). Adjusted for the severity of the trauma and other factors, the survival rate of those treated in Level I trauma centers is about 25 percent better than at other hospitals (Mackenzie, et al., 2006). When Great Britain reorganized its trauma response system to bypass local hospitals and transport patients directly to trauma centers, survival rates improved by about 19 percent, corrected for other changes in risk factors (Moran, et al., 2018).

Some patients appear to be dead on arrival (DOA) at the hospital but the question of what criteria to use for attempting resuscitation remains under investigation. Based on a literature review and discussion, one trauma team defined DOA as follows:

-- All blunt trauma and penetrating trauma of the abdomen, head, neck or groin: pre-hospital CPR (cardiopulmonary resuscitation) >5 minutes, age >12 years, no pulse on arrival

-- Penetrating trauma of the chest: pre-hospital CPR >15 minutes, age >12 years, no pulse on arrival

-- Child with any of the above that has in-hospital CPR >15 minutes (open or closed) without a pulse (Pasquale, et al., 1996).

None of the 86 patients that met the DOA criteria survived despite continued resuscitative efforts on 70 at a cost of more than \$4000 each. Three of the 20 patients

that did not meet the criteria survived. Children were excluded from the analysis because of the small number.

The authors of the study noted that there are potential cost savings from the application of DOA criteria. They also noted that the use of the criteria in their institution was "erratic". Two issues are raised by this research. First, the sample is relatively small. A multi-center study is needed to specify factors predictive of survival probability. Second, if criteria are established, will they be followed? The definition of DOA can bias survival statistics. If any treatment is applied, the death is not classified as DOA but as a hospital death (Haren, et al., 2012).

The movement to designate certain hospitals as trauma centers and to transport severely injured patients to such centers evolved from the understanding that the necessary experience and training to treat severe trauma, as well as efficient use of technology, could only occur in facilities that treat large numbers of cases. While this has been accomplished in many areas, the extent of compliance with a designation in a given area varies. For example, Illinois was among the first states to have regionalized trauma centers. Yet Chicago, where the fire department managed the emergency medical system, did not join the state system, and the old practice of transporting a patient to the nearest hospital continued. A study of the patients' destinations relative to their trauma scores indicated no correlation between serious injury and the probability of being taken to a trauma center (Cadigan, 1985).

One question for research in any given area is the extent to which the guidelines for the transportation of patients to designated trauma centers are being followed. One surgeon has hypothesized that persons taken to community hospitals who have insurance (assessed by "wallet biopsy") are more likely to be retained there while the rest are sent to trauma centers (Gann, 1989). In a Canadian study, persons who fell, women, and persons over 65 years of age were less likely to be transported to a trauma center (Doumouras, et al., 2012).

The survival rate of seriously injured patients among hospitals is inversely correlated to the volume of patients seen. In one study, for example, the survival rate was 30 percent higher in hospitals that treated more than 110 such patients per year than in those that treated 75 or fewer (Smith, et al., 1990). Detailed data on severity scores were not available for more refined adjustment of the estimate and more research incorporating such data is needed. When adjusted for injury severity within a hospital, patients treated by a trauma team were more likely to survive than those treated by others (Petrie, et al., 1996). In another study, adjusted for several risk factors, patients taken to another hospital before transfer to a Level I trauma center were 2.7 times more likely to die than those taken directly to the trauma center (Garwe, et al., 2011)

Traditionally, two methods have been used in the assessment of the adequacy of treatment -- called the autopsy method and the clinical method (West and Cales, 1983). The autopsy method involves an examination of autopsy records for certain types of cases -- eliminating pre-hospital deaths, dead on arrivals, and central

nervous system cases for which treatment is ineffective. Deaths to persons less than 50 years old, those that occurred less than six hours after arrival, those in which laparotomy or thoracotomy was not done, and deaths from hemorrhage are examined in particular detail and preventability assessed.

The "autopsy method" has identified substantial proportions of preventable deaths among the defined subsets of all deaths, a process that helped justify the designation of trauma centers and substantial reductions in deaths judged preventable in those subsets (West, et al., 1983). The method is not adequate to assess the overall effect of trauma center designation, however. If the designation were to result in deaths due to longer transport times, and more deaths in emergency-vehicle crashes due to longer travel distances, for example, those would have to be subtracted from the net lives preserved rather than eliminated from the analysis before counting.

The "clinical method" includes an audit of the pre-hospital as well as hospital records, identification of fatalities thought to be survivable, and determination of the phase of response or treatment that failed. The use of the method is dependent on the quality of the records of paramedics, hospitals, and coroners as well as the lack of bias in those who audit the cases. Use of the method in Orange County, California, before and after the implementation of a comprehensive trauma system, indicated a reduction in preventable deaths from 34 percent to 15 percent even though the average age and Injury Severity Scores of the patients audited increased during the study period (West and Cales, 1983).

The use of committees to review records of deaths to judge the numbers that were preventable by treatment has been brought into serious question by reliability studies. When separate panels reviewed the same cases, the agreement was poor (MacKenzie, et al., 1992; Wilson, et al., 1992). A statistical technique called reliability adjustment greatly reduces the mortality ratios when comparing trauma centers (Hashmi, et al., 2013)

Various factors have been identified to improve outcomes for patients suffering trauma and other maladies. Increasing physicians' openness to staff concerns about possible mistakes based on "safety-culture scores" and transparency of patient records and videos of procedures have been found to improve patient care (Makary, 2012).

The designation of trauma centers can concentrate a cost burden on the designated hospitals that threatens their ability to continue the service. In an attempt to control rising medical care costs, insurance companies and governments use average costs in diagnosis-related groups (DRGs) to determine the amounts hospitals will receive for given diagnoses (Waller, et al., 1989). Trauma center closures due to costs in California resulted in an estimated increase of 21 percent in mortality due to increased travel times (Hsia, et al., 2014). There is substantial evidence that diagnosis-related groups (DRGs) are inadequate for determining the costs of trauma treatment and certainly should not be used for quality assurance. Since only one DRG category is assigned per patient, multiple

injuries are not adequately reflected as they are in more detailed classification systems (Chapter 4). Comparison of DRG classifications of trauma patients and other classifications of criteria for injury management indicate that DRGs are relatively poor predictors of the cost of treatment (Young, et al., 1990).

The overall impact on hospital financial status of the costs of treatment of severely injured patients compared to the amounts specified for reimbursement in DRG systems has produced conflicting results depending on the case mix examined. While some studies find that the less severe injuries are reimbursed at more than cost, offsetting insufficient reimbursement of the more severe injuries (Waller, et al., 1989), other hospitals have substantial net shortfalls. In the trauma center for southern New Jersey, the average cost per case in 1985 was \$7137 and the average reimbursement was \$3574, resulting in the hospital losing a total of almost \$1.9 million in revenues. The research indicates that the Injury Severity Score could be used to predict costs to some extent (Schwab, 1988).

More research from other trauma centers would perhaps lead to an adjustment of DRGs based on case-mix criteria. For example, a DRG category was added for certain burn injuries, but the categories in use remain inadequate. The categories in use do not distinguish substantial variations in the costs of burn treatment (Chakerian, et al., 1990). Four Multiple Significant Trauma DRGs were added in 1991 to account for trauma to more than one body site. Nevertheless, a study of 49 consecutive patients that met the criteria for the new DRGs during 5 months found that 38 percent of the cost of care was not covered by the DRGs, a shortfall of US\$ 492,057 or about \$10,000 per patient in 1990 dollars (Jacobs and Jacobs, 1992).

The finances of 70 trauma centers in 12 metropolitan areas with populations exceeding 1 million indicate that public hospitals were more likely to have "financial stress" from trauma care than private hospitals. Any cuts in Medicaid, Medicare, or other programs that subsidize trauma centers would put many in jeopardy of survival (Bazzoli, et al, 1996). Surveys of trauma centers that closed found that uncompensated services, high operating costs, and inadequate reimbursement from medical assistance programs were primary factors in the closings (Dailey, et al., 1992, Committee on the Consequences of Uninsurance, 2003). A question ripe for research is whether the increase in the number of insured patients under the Affordable Care Act increased the survival rate of trauma centers.

Attempts to control costs by "managed care" may be affecting prevention as well. Suicidal patients whose care was refused or attenuated by managed care personnel who did not see the patient have allegedly resulted in suicide completions (60 Minutes, 1997). About 75 percent of persons who committed suicide contacted their medical care providers before the incident (Luoma, et al., 2002). Research is needed on the extent of the problem.

CLINICAL STUDIES OF TRAUMA AND SPECIFIC TREATMENT. Injury in America laid out a series of questions for research in the understanding and treatment of trauma (Committee on Trauma Research, 1985). Examples are: What happens to cells in shock and what can be done to prevent or reduce cellular dysfunction? How do metabolic systems respond to trauma and can interventions reduce harmful reactions or optimize reactions favorable to recovery? How does the immune system react and what can be done to control infection by augmenting the immune system or use of antibiotics? What factors contribute to healing or failure to heal and can healing be enhanced therapeutically? What can be done to minimize nervous system damage and is nerve regeneration possible?

Answers to these and other questions depend on the continued revision of models of anatomic systems at the cellular, organ, and whole system levels based on animal and human studies. When a reasonable point of intervention is identified, a controlled clinical trial of a hypothesized effective intervention is warranted. Textbooks are available on experimental designs and statistical power issues in clinical trials and all of the issues cannot be repeated here (Fleiss, 1986; Stein, 1989).

In the simplest form of a controlled clinical trial, a change in procedure, medication, or whatever is introduced in the treatment of a randomly selected experimental group while a randomly selected control group with the same medical condition receives the old accepted treatment or a placebo if there is no extant treatment. If the effects of subsets of clinical conditions are in question, the experimental and control groups can be assigned within each group of patients with a given condition.

To avoid bias in measurement where possible, those treating the patient or obtaining measurements pre- and post-treatment should not know if the patient is in the experimental or control group. This is rather easily done in the case of drug therapy, but not in surgery or other hands-on treatment. At the least, the surgeons or others who administer obvious treatments should not be the persons to obtain measurements of outcomes used in the evaluation. Under certain circumstances, a crossover design can be used in which patients in an experimental group for a period are in the control group in a succeeding period and vice versa. For example, the effects of manual and mechanized ventilator support on blood gasses were studied using such a design (Hurst, et al., 1989).

The timing of treatment must also be considered in clinical trials. For example, based on animal studies, methylprednisolone was hypothesized to improve the motor and sensory function of patients with acute spinal cord injury. In a controlled clinical trial, significant improvement was found among patients given the drug within 8 hours after injury, but not if delayed beyond 8 hours (Bracken, et al., 1990). Although the treatment is not a cure, spinal-cord patients treated within 8 hours were found better able to care for themselves and otherwise lead more independent lives. Further experiments using pharmacological and other approaches to improve the functioning of spinal cord patients are underway (Kahn, et al., 2020)

Non-experimental epidemiologic methods can be used to generate hypotheses regarding certain clinical issues. For example, the efficacy of surgical exploration of penetrating injuries of the spine has been questioned based on retrospective analysis of cases. The percentage whose nervous system function improved, remained the same, or deteriorated was similar with or without surgery. The proportion with complications such as infection and cerebrospinal fluid leakage, however, was significantly higher among those with surgery than those without - 22 percent versus 7 percent (Simpson, et al., 1989).

Some clinical studies would benefit from the appropriate use of multivariate analysis. For example, in a study of patients with vascular injuries in the abdomen, infection was related to low initial systolic blood pressure, the number of blood transfusions, multiple injuries, and cross-clamped aorta during surgery (Wilson, et al., 1989). A multivariate analysis, such as logistic regression, was not done, however, and might better isolate the potential contribution of each controlling for the others. A controlled clinical trial of the use of blood transfusions and surgical techniques could be guided by the results.

Simple improvements in diagnostic tools may greatly improve clinical decisions. For example, assessment of the neurological status and possible effects of alcohol in unconscious patients is important. Epidemiologists and physicians working together showed that a device to measure the concentration of alcohol in passive nasal exhalation of comatose patients is almost perfectly correlated to blood alcohol concentration (Gerberich, et al., 1989).

Because of the long-term effects of traumatic brain injury (TBI), the effects of treatment regimens and the effectiveness of rehabilitation are particularly important. A review of randomized control trials of the treatment and rehabilitation of TBI patients indicates little or no effect of pharmaceuticals but other treatments and rehabilitation had beneficial effects (Lu, et al., 2012).

**LONG-TERM CARE AND REHABILITATION**. Many people who survive traumatic injuries have lost abilities because of brain and spinal damage, lost digits or limbs, lost sensory function, and distortion of tissue from a burn or other scars. These patients, and additional others, are affected psychologically, socially, and economically. There is substantial anecdotal evidence of fears of being injured again, of family breakup and disruption, of discrimination, and economic deprivation (Kaufman, 1989). The quantification of these effects and factors that contribute to reduced dependency and productive and personally satisfying lives is a challenge to epidemiologists as well as other scientists. A study of traumatic brain injury and matched controls in Denmark found an increased risk of job loss and divorce in the patient group (Norup et al., 2020).

Injury in America identified numerous research issues in rehabilitation (Committee on Trauma Research, 1985). A panel on disability expanded these (Pope and Tarlov, 1991). Examples are: What are the most effective methods of rehabilitation to restore activity and at the same time conserve the energies of the

disabled? What are effective procedures and counseling in acute care that lead to a reduction of scar contraction, muscular atrophy, and skeletal deformity as well as referral to rehabilitation and preparation of the patient for fit and use of prosthetic and cosmetic aids? What is the relative effectiveness of methods to control spasticity, optimize ventilation, improve cognitive function, and the like? What changes in the environments of persons with various handicaps would reduce their dependency or increase their productivity and satisfaction? How many persons are not receiving services that would benefit them, their families, or the community? What are the aspects of the medical care and rehabilitation systems, personal and family beliefs, or social situations of those in need of services that are barriers to the use of services or benefit from them?

Studies of the post-hospitalization outcomes of injury are limited by a lack of representative samples, small sample sizes, and other methodological problems. Studies are usually confined to the patients discharged from one or more hospitals serving an urban area or region. To the extent that there is the selectivity of hospitals by type of injury or severity, these studies may result in over- or underestimation of the extent of a given identified problem, limitations usually recognized by the researchers.

Although not representative of the injured population, follow-up studies of discharged patients are useful in the development of criteria to identify patients while in a hospital that will have problems and needs thereafter. In a study of discharged patients from two trauma centers, 80 percent had problems with posthospital self-care and an additional 12 percent who could care for themselves had problems with mobility or other physical activities. One year post-discharge, 23 percent continued to have problems with self-care and an additional 4 percent had continued mobility or other physical problems. Only 57 percent of those who had worked before the injury had returned to full-time employment one-year post-discharge. Even among those with minor to moderately severe injuries of the extremities (AIS 1-3), half to two-thirds who had been employed before their injuries had not returned to work after one year. Those with lower pre-injury incomes were less likely to be working, controlling statistically for functional impairment (MacKenzie, et al., 1988).

In another study, children up to age 18 in a children's hospital were followed for six months if they had one or more severe injuries (AIS = 4-5) or two or more moderate to severe injuries (AIS = 2-5). Of the 62 percent on whom follow-up data were obtained, about half had not returned to normal activities after six months. The authors stated that the results supported the need for more rehabilitative services, but they did not document the number and types of rehabilitation used for the children (Wesson, et al., 1989). Without relating outcomes to the type and degree of rehabilitation received, it is not possible to say that more such services would have made a difference.

Most of the longer-term studies of patient outcomes are of small samples of patients during a few years post-injury. For example, in a follow-up study of 101

brain-injured patients 5 to 10.4 years post-injury, 63 were located (of which 8 were deceased including several undocumented mentions of suicide). Disability at follow-up was lower among those who had entered rehabilitation earlier, but the study did not include persons with brain injuries that were not referred to or did not use rehabilitation facilities. Among patients able to respond to the survey themselves, "significant others" (spouse, another relative, or friend) rated the patients as more impaired than the patients rated themselves. Among the major problems identified at follow-up were a lack of social relationships (45 percent), unemployment (17 percent), physical problems, dependency, and lack of motivation (21 percent). Needs for education, support groups, and supervision were stated but not quantified (Rappaport, et al., 1989).

An interesting difference in findings from retrospective and cross-sectional studies when compared to a prospective study occurred in the attempt to find risk factors for post-injury use of acute-care facilities by patients with spinal injuries. Although such factors as level of lesion, years disabled, and cigarette use were significantly correlated to the hospitalization in retrospective and cross-sectional studies, a prospective study found no such correlations. Hospitalization proved unpredictable prospectively, but outpatient facility use was correlated to age, years of disability, formal education, and dissatisfaction with medical care. Those in managed care programs for independent living were less likely to use outpatient care, suggesting that the programs may reduce the cost of medical care (Meyers, et al., 1989).

When the psychosocial factors are assessed before hip fractures in the elderly, they are less predictive of institutionalization than in ex post facto assessments (Marottoli, et al., 1994). Post-injury assessments are likely influenced by the injury experience.

In a study of 756 people with traumatic brain injury, the most important predictor of involvement in rehabilitation was not physical or demographic factors, but the specialization of the treating physicians (Wrigley, et al., 1994). If a Physical Medicine and Rehabilitation specialist was involved in referral decisions, the patient was more likely to receive rehabilitation, controlling for injury severity and demographic factors. Research is needed on the extent to which medical teams without this speciality are aware of the opportunities and benefits of rehabilitation.

**IMPROVING OUTCOMES.** Models of rehabilitation have been developed which include not only the effects of drugs and physical therapy but also social support and transitional living centers. Effectiveness research is needed at each stage of rehabilitation (Wood and Eames, 1989). To determine the effects of treatment and rehabilitation on outcomes, there must be some consensus on expected outcomes from particular interventions. For some types of injury, e.g. traumatic brain injury, a consensus on the priority of outcomes has not been attained. Clients, therapists, and third-party payers have different expectations (Garner and Finlayson, 1996). The effects on families are somewhat dependent on the pre-injury status of family roles (e.g., Rivara, et al., 1996).

There may be substantial selection bias in the choice of therapies. Results of studies of the use of catheters for bladder emptying of spinal cord patients are in substantial conflict as to extent of complications (Smith, et al, 1996). Individual economic situations that affect the availability of skilled caretakers and living conditions would have a substantial effect on the use and maintenance of catheters and infection opportunities. Such factors would also affect the affordability, and likely systematic use, of prophylactic antibiotics for urinary tract infections.

One promising approach to the mobility of spinal injured patients is the use of electrical stimulation found efficacious in one review of clinical reports (Luo et al., 2020) Most studies find improvements in patient physiology and mobility but the attrition rate is high. The complexity of the current technology and the effort required from the patient relative to the noticeable improvement often is discouraging to the patients (Smith, et al, 1996; Dietz and Harkema, 2004). Studies using small samples need to be replicated before assuming that they are valid (e.g., Carty, et al., 2012). Some drugs improve the mobility of people with incomplete spinal injury (Domingo, et al., 2012). Stem cell therapy has shown promise to improve outcomes (Silvestro, et al., 2020). Research is needed on the degree of improvement needed to motivate patients to continue therapy fails to meet expectations.

The practice of physical therapy has evolved as the mix of problems presented to rehabilitation facilities has changed and the models of the functioning of the central nervous system and musculoskeletal systems have been improved by theory and research. Increased survival of persons with central-nervous-system damage presents a major challenge to physical therapists (Gordon, 1987; Pinkston, 1989). Technology for potentially improving aspects of impairment must be studied relative to traditional methods of hands-on movement and exercise. The relative effectiveness of available and new methods can be discerned in controlled clinical trials.

For example, one study compared the consequences of three types of therapy among patients with incomplete cervical spinal cord injuries -- physical exercises supervised by a therapist (PET), electrical stimulation (NMS), and biofeedback (EMG). The patients were randomly assigned to four groups and the sequence of the different therapies was varied among three groups -- EMG-PET, EMG-NMS, and NMS-PET -- while the fourth group received only PET. Persons unaware of the group assignment did baseline and subsequent measurement of outcomes. Although improvements in function were found among all four groups, there were no differences among the groups that suggested any advantage of one therapy over the others (Klose, et al., 1990).

The evaluation of therapy and rehabilitation for impairment from trauma is substantially dependent on the reliability, validity, and prognostic predictability of measures of impairment. Epidemiologists can contribute to the development of quantified scales of such outcomes as sensation, motor ability, and balance. One such study, for example, indicated the importance of early identification of discrepancies in sensation and motor ability as diagnostic tools for patients with spinal injury (Bracken, et al., 1977-78).

The Glasgow Coma Scale is useful in acute care decisions but is not strongly correlated to long-term functioning (Zafonte, et al., 1996). A battery of quantitative tests of sway among brain-injured patients is sensitive enough to distinguish even minimal balance problems (Lehmann, et al., 1990). Accelerometers that can be worn by the patient to monitor physical activity have been studied for reliability and validity (Kochersberger, et al., 1996). Performance in an obstacle course is not adequately correlated to other balance and functional measures (maximum  $R^2 = .29$ ) to be used as a screening measurement (Means, et al., 1996).

In addition to their use in diagnosis and rehabilitation, reliable and valid measurements could be important in the prevention of repeated trauma. For example, falls are a problem among hospitalized and institutionalized patients. In a rehabilitation hospital, 12.5 percent of patients fell in a year, mainly from wheelchairs (Vlahov, et al., 1990). The fracture rates of men in Veteran's Administration nursing homes were 5 to 11 times those in the age-matched general population (Rudman and Rudman, 1989). The VA has developed a "falls toolkit" for use in its and other hospitals (Stalhandsk and Landesman, 2004). The newsletter announcing it says that there will be a follow-up to see if and how it is used. I found no such study but there is a study of falls in VA hospitals reporting a small decrease between 2011-2017 (Young-yu et al., 2020). The possible effect of the "falls toolkit" should be studied using an experimental-control design.

Potentially even more serious injuries can occur to people whose impairments are not severe enough to prevent driving, but severe enough to increase the probability of a crash. One study followed 22 brain-injured patients for five years after a physician, a neuropsychologist and a driving specialist judged them fit to drive. Measurement of driving records and fitness was based on telephone interviews with the patients and "matched" control group of close friends and spouses of the patients. A neuro-psychologic test battery was administered to those that claimed to have driving problems. The authors concluded that the screening was adequate to identify those "fit to drive" (Katz, et al., 1990). Unfortunately, the study is wholly inadequate to reach that conclusion. The sample size is too small to obtain any statistical power in a study of driving risk. There were significantly more women than men in the control group. Self-report of crashes, violations and other problems in driving is not an acceptable methodology without independent validation from driving records.

**LENGTH OF STAY AND COSTS**. The pressure from the managed care systems to reduce hospital stays may result in earlier or more frequent referrals to rehabilitation facilities, which may in turn be pressured to release the patient to

home or nursing home care. In a study that included patients whose impairment originated from both trauma and other conditions, length of stay was moderately correlated to an index of impairment of specific abilities (such as eating, toileting, bathing, and mobility), referral source, and year of admission. Type of medical insurance, gender, race, other medical conditions, and "psychologic capacity" were not predictive of length of stay. Age was said to have a complex interaction with the other predictive factors and was not included in the prediction model (Stineman and Williams, 1990). The authors were appropriately cautious about generalizing the results to other facilities without similar research in those facilities. Matched for gender and injury severity, older patients require longer, more costly periods of rehabilitation to achieve the same degree of functioning (Cifu, et al., 1996).

Despite the wide variation in patient needs and resultant length of stays, the DRG system has only one category for rehabilitation based on an overall average cost, but an exemption is allowed which minimized the effects for hospitals that obtained exemptions. The system was used by the Veterans Administration (VA) to place its hospitals in competition for a set budget. A study from one VA hospital looked at the length of stay, readmissions, and referrals to nursing homes or home health care before and after the system was adopted. While the length of stay decreased by an average of three days, the discharges to nursing homes increased and those to home health care decreased significantly. The net effect may be increased costs, but costs were not assessed (Evans, et al., 1990).

A study of the effect of prospective payment on the treatment of hip fractures among the elderly (Palmer, et al., 1989) resulted in a lively debate regarding the relative efficacy and costs of rehabilitation in hospitals and skilled nursing care facilities (Lipson and Minassian, 1990). Comparison among facilities and the extent of referral to facilities may be influenced by home situations as well as medical conditions and costs (Palmer, et al., 1990).

The effect of DRGs on who is treated where and who pays has been described as "squeezing the balloon". "Prospective payment systems hold the line on inpatient use and revenues, but outpatient services and spending rise dramatically" (Brown, 1988).

Certain programs have traditionally claimed to be cost-beneficial, that is, they return more in economic benefits to society than their costs. Vocational rehabilitation, for example, has a specific economic goal -- to return the patient to gainful employment. If that employment returns more in taxes to the government than the cost of rehabilitating the person, then the investment paid off, at least from the government's viewpoint, irrespective of the issues of intangible costs and benefits (more on this in Chapter 15). One review of the evidence on vocational rehabilitation for traumatic brain injury found no effect (Lannin, et al., 2013). A controlled trial found that people with traumatic brain injury in the rehabilitation group were more often employed after three months but not so after 12 months when most of the injured in both groups had returned to work (Fure et al., 2021).

Comparisons have been done of earnings before and after rehabilitation, but with insufficient follow-up to confirm that immediate post-rehabilitation earnings were sustained (Berkowitz, 1988). The decline in returns to investment as increased numbers of severely disabled persons are included in the program could sway the balance of costs and benefits to the negative. Costs exceed benefits among those with certain sensory disabilities in certain age groups, for example (Gibbs, 1988). Those who live by cost-benefit could also die by cost-benefit.

## **References - Chapter 14**

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