Effective Legislation Producing Realized Health Services

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Abstract

Public Law 104-166, more commonly known as the Traumatic Brain Injury Act of 1996 serves as a critical first step from a legislative perspective, in assuring that brain injuries are fully understood and treated in both an acute clinical environment and in the public health arena. And, through this discussion and research it will foster the discussion needed to understand its underlying causes, its overlying costs, and what can be done to prevent such tragic occurrences that affect the lives of so many Americans.

This discussion analyzes the mechanisms and processes that were essential in the making of Public Law 104-166 through the legislative process. As with any law or rule, it is fundamental to understand whom it affects, and what it addresses, as well as the significance of the problem it attempts to influence.

TRAUMATIC BRAIN INJURY (TBI)

The incidence of traumatic brain injury in the United States consists of about one million people who are treated and released from hospital emergency centers, 230,000 people who are hospitalized and survive, and 50,000 people who die.[1] The incidence rate of TBI (combined hospitalization and mortality rate) is 95 per 100,000 population, where 22% of those who suffer a TBI eventually die from their injury.[1] Risk of TBI is highest among adolescents, young adults, and people older than 75 years of age.[1] Leading causes of TBI include motor vehicle accidents, violence, and falls, though this varies by age where falls account as the leading cause in people 65 years of age or over, and transportation leads for people aged 5 to 64 years.[1] Every year 80,000 Americans survive a TBI and are released from the hospital with a TBI-related disability, at last estimate there are 5.3 million Americans living with a TBI disability.[1] TBI related injuries may result in impairment of: (1) cognitive abilities such as concentration, memory, judgement, and mood; (2) movement abilities including strength, coordination, and balance; (3) sensations such as tactile and special senses such as vision.[1]

There is limited available in terms of total monetary cost analysis of TBI in addition to the immeasurable cost borne by those suffering from TBI and the friends and family who must provide daily support. A 1985 study showed the total cost as $37.8 billion by combining direct annual expenditures of $4.5 billion and indirect annual costs of $33.3 billion.[1]

The National Center for Injury Prevention and Control (NCIPC) provides the following guidelines in its dealing with TBI as a public health problem[1]:

- Ongoing surveillance to follow trends in the incidence, risk factors, causes, and outcomes of these injuries through its Guidelines for the Surveillance of Central Nervous System Injury, a publication that sets forth standards and recommendations to improve coordination of central nervous system injury surveillance.
- The development of effective, science-based strategies to prevent the occurrence of these injuries.
- The development of more effective strategies to improve the outcomes of these injuries and minimize disability among those injured.

In the NCIPC's 1999 report to the United States Congress it defined TBI as:

an occurrence of injury to the head that is documented in a medical record, with one or more of the following conditions attributed to head injury: observed or self-reported decreased

level of consciousness, amnesia, skull fracture, objective neurological or neuropsychological abnormality, or diagnosed intracranial lesion; or as an occurrence of death resulting from trauma, with head injury listed on the death certificate, autopsy report, or medical examiner's report in the sequence of conditions that resulted in death.[2]

THE LEGISLATIVE PROCESS

The legislative process is a complex multi-step and multi-tiered system of creating law. There are generally four methods in which Congress can initiate legislation: bills, joint resolutions, concurrent resolutions, and simple resolutions.[3]

Bills are the common form that most legislation is initiated with. Bills originating in the House of Representatives are designated by the letters “H.R.” and are followed by an identifying number that remains with it through the legislative process. Bills originating in the Senate begin with an “S.” and are also followed by an identifying number. Bills are presented to the President when they are approved in identical form by both the House of Representatives and Senate.

Joint resolutions have little practical difference from a bill and can begin in either the House of Representatives or in the Senate.[3] Joint resolutions originating in the House of Representatives are indicated by “H.J.Res.” followed by its identifying number, and those originating in the Senate are indicated by “S.J.Res.” followed by its identifying number.

Concurrent resolutions deal with the operations of both the House of Representatives and Senate.[3] Concurrent resolutions originating in the House of Representatives are indicated by “H.Con.Res.” followed by its identifying number, and in the Senate by “S.Con.Res.” followed by its identifying number. On approval by both chambers of the Congress, a concurrent resolution is then signed by the Clerk of the House and the Secretary of the Senate, it does not require Presidential action.[3] If a matter deals with only one chamber of Congress, then it is referred to as a simple resolution, and are designated by “H.Res.” and “S.Res” followed by their identifying number in the House of Representatives and the Senate, respectively.

After a bill is introduced by a member of Congress, and provided it meets various requirements such as signature of the sponsor, as well as signatures of any co-sponsors (it is not necessary for a bill to have co-sponsors), the bill is assigned its legislative number and referred to the appropriate committee.[3] The committee phase of legislation is one of the most critical stages of the legislative process. It is an opportunity for open discussion on the matter. The first step by a committee is to hold a public hearing, where a committee can engage in discussion with witnesses representing various viewpoints on the bill.[3] The committee will announce the date, place, and subject of any hearing it holds on pending legislation.[3] Upon the completion of hearings, a bill is then considered in a session referred to as a “mark-up.”[3] The committee examines the evidence, viewpoints, and other information it has gathered and can then offer amendments to the bill, with the whole committee then voting whether to accept or reject these changes.[3] These mark-up sessions may happen at the subcommittee or full committee level, or both. At the conclusion of a committee session on a particular bill, one of three things may happen: the bill can be reported as-is, reported with amendments, or tabled, which would mean that no further action would be taken on the bill.[3] A fourth possibility is a “clean bill,” these are usually reported when there are extensive amendments to a proposed bill where it would be better presented in a new format, these bills would receive a new identifying number.[3] A Committee Report is drawn up if the committee decides to report the bill, this report would explain the purpose of the bill along with reasons as to its approval.

The next step is floor consideration of a bill. This can be a simple or complex operation that is dictated by what “rules” of debate are adopted for the consideration of a specific bill.[3] Debate time is usually divided between proponents and opponents, and amendments may also be debated on and voted upon.[3] After the debate stage has concluded, the bill goes for final passage, unless some opposition is able to vote to “recommit” where a bill is returned to the committee for further modification.[3] Both the House of Representatives and the Senate follow special and distinct rules in parliamentary procedure for floor consideration of a bill. It is suffice to say, that the general explanation above is satisfactory in understanding the general process for floor consideration.

After a measure is passed in either chamber of Congress, it is sent to the other chamber for consideration. A bill must pass both chambers in the exact same form before it can be presented to the President for signature into law.[3] If the Senate changes any aspect of the legislation, it is returned to the House for concurrence, or a conference committee may be drawn up consisting of both members of the House and Senate to work out the differences in committee.[3]

The final step is a vote for final passage. In the House of Representatives this may be done by recorded electronic vote where individual votes are registered or by a voice vote and no record of individual responses is made.[3]

The Senate does not use electronic voting mechanisms, and votes are Yea/Nay votes by voice and are registered in the record.[3] After a measure has been passed, it is considered "enrolled" and is then sent to the President who can sign it into law, veto it, let it become law without his signature, or at the end of a session, pocket-veto it.[3]

The summary of the legislative process is presented to provide context for better understanding how and why certain matters are enacted into law and others become lost in the abyss of theoretical policy. It is important to recognize that the above schema of the legislative process does not take into consideration the full political scope and mechanism under which legislators must work under to effectively carry a piece of legislation from introduction to enactment into law. Nevertheless, with a contextual framework, it provides for a better opportunity to parse legislation affecting public health concerns in a manner that can make legislative efforts on the part of health care professionals more effective.

H.R.248

GENERAL OVERVIEW OF LEGISLATIVE PROCESS FOR H.R.248

On January 4, 1995, U.S. Representative James Greenwood (R, PA-8), introduced a bill to amend the Public Health Service Act to provide for the conduct of expanded studies and the establishment of innovative programs with respect to traumatic brain injury, and for other purposes.[4] This bill was assigned legislative tracking number H.R.248 and subsequently referred to the House Committee on Commerce on the day of introduction.[4] On February 6, 1995 the House Committee on Commerce referred H.R.248 to the Subcommittee on Health and Environment.[4]

Concurrently on January 4, 1995, U.S. Senator Orrin Hatch (R, Utah), introduced similar legislation in the Senate. This bill was assigned legislative tracking number S. 96 and subsequently referred to the Senate Committee on Labor and Human Resources on the day of introduction.[5] The bill gained the co-sponsorship of Senator Edward Kennedy (D, Massachusetts), Senator Paul Simon (D, Illinois), and Senator Charles Grassley (R, Iowa).[5]

On June 6, 1996, the Subcommittee on Health and Environment met in an open markup session and approved H.R.248 for Full Committee consideration with amendments by a voice vote.[6] From the time of introduction to the Subcommittee markup session the bill had gained thirty-three co-sponsors; 20 Democrats, 12 Republicans, and 1 Independent.[4] On June 13, 1996 the Full Committee met in open markup session and ordered H.R.248 reported to the House, as amended, by a voice vote.[6] The amendment made in committee was by Mr. Greenwood providing specified dollar amounts for the authorization of appropriations.[6] Through June 13, 1996 the bill picked up an additional two co-sponsors; one Democrat and one Republican.[4] On June 27, 1996 H.R.248 was reported to the House with amendment by the House Committee on Commerce.[4] On July 9, 1996 H.R. 248 passed the House by voice vote.[4,7]

The Senate eventually took up the House bill, and members from both chambers of Congress worked together in finalizing the legislation.[8]

On July 10, 1996, H.R. 248 was received in the Senate and passed by unanimous consent.[4,9] The legislation was presented to President Bill Clinton (Democrat) on July 17, 1996 and was subsequently signed on July 29, 1996 thereby becoming Public Law 104-166.[4]

DISCUSSION OF REPORT ON H.R.248 FROM THE HOUSE COMMITTEE ON COMMERCE

The House Committee on Commerce issued a 15-part report to the full House, and it is relevant to discuss the findings of the Committee as indicated in the report along with the analysis of the legislation.

The amendment is effected through three avenues, which are then unified by a Consensus Conference. The first part of the amendment provides for the Centers for Disease Control and Prevention to establish projects to prevent and reduce the incidence of traumatic brain injury.[6] These projects may include research, strategies, and public information and education program on prevention. This section also defines the term "traumatic brain injury." Prior to this there had been no standard and clear definition, which made it difficult to normalize research data with consistency.

The second part authorizes the National Institutes of Health (NIH) to award grants to conduct basic and applied research on developing new methods for more effective diagnosis, therapies, and continuum of care.[6] Research may include developing new methods to improve diagnosis, measuring severity of injury, post-injury monitoring, and assessment

methods.[6] Also promoted through the NIH would be the development, modification, and evaluation of therapies to retard, prevent, or reverse brain damage after injury as well as improving the continuity of care from initial treatment of trauma to long-term rehabilitation.[6] One of the other major objectives of the second part is to foster the development of programs that improve the participation of academic medical centers.

The third part instructs the Health Resources and Services Administration to make grants to States to carry out demonstration programs to improve access to services regarding traumatic brain injury.[6] These programs have been authorized $5 million for each fiscal year from 1997 through 1999.[6] The grants require that participating States must establish and maintain an advisory board to coordinate and manage a state's various initiatives. The grant also requires a matching clause, requiring States to provide no less than $1 cash for every $2 of Federal funds provided.[6] Reports consisting of findings, results, and outcomes of a state's initiatives must be submitted to the Secretary of Health and Human Services no later than 2 years after enactment.

The Secretary of Health and Human Services is requested to carry out a Consensus Conference where the three directives are fully studied in relationship to each other and in context of the issue of TBI as a whole. $3 million per year for 1997 through 1999 has been authorized for this purpose.

The Congressional Budget office estimated the cost of H.R. 248 to the Federal Government for fiscal years 1997 through 1999 to total $24.5 million.[6] The table below shows the appropriations for H.R. 248 by Section or program objective.[6]

Figure 1

(By fiscal years, in million of dollars)

	1997	1998	1999	2000	2001	2002
Section 3 - Grants to States (Health Resources and Services Administration):						
Budget authority	5.0	5.0	5.0	_	_	_
Outlays	1.0	3.5	5.0	3.3	1.5	-
Section 4, Part (a)(1)(A) - Study (Centers for Disease Control and Prevention):						
Budget authority	3.0	3.0	3.0	-	-	-
Outlays	1.1	2.2	2.8	1.9	1.0	-
Section 4, Parts (a)(1)(B) and (a)(1)(C) - Study (National Institutes of Health) and Part (b) - Consensus Conference (National Institutes of Health):						
Budget authority	0.5	-	-	-	-	-
Outlays	0.2	0.3	-	-	-	-
Total:						
Budget authority	8.5	8.0	8.0	-	-	-
Outlays	3.0	6.0	7.8	5.2	2.5	-

IMPETUS OF LEGISLATIVE ACTION

Legislation, such as H.R. 248, that enjoys bipartisan and bicameral support finds itself on a fast track to enactment. Nevertheless, any legislation must endure fair and thorough examination. An examination of the motivation to introduce and commitment to pass H.R. 248 heralds many lessons to be learned about the legislative process and how those in health care can be more effective in presenting important health issues to government.

Earlier in Congressman Greenwood's legislative career, when serving as a member of the Pennsylvania State Legislature, a constituent suffering from TBI presented their personal account of a flawed trauma system.[10] State Representative Greenwood took on the issue of unorganized trauma services in Pennsylvania and was able to successfully win passage of legislation that allowed for better organization of state-wide trauma services including TBI and creating avenues under which there could be standardization and improved handling of care at different stages.[10]

As a member of the United States House of Representatives, Congressman Greenwood felt that more needed to be done at the national level to ensure that states were given the resources to effectively manage programs dealing with TBI.[10] In addition, Congressman Greenwood recognized the need for a national plan to prevent, treat, and understand TBI, which would be a well-correlated part of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) programs on injury prevention and research respectively.[10]

This was manifested as H.R. 248 or the Traumatic Brain Injury Act of 1996. The legislation's focus on designing a standardized system and improving already established protocols in dealing with TBI in place of excessive funding of broadly-defined public health needs was an important factor in the success the bill enjoyed. Congressman Frank Pallone (D, New Jersey) when speaking on the House floor in support of H.R. 248 presented his position in a manner much similar to the effect desired by the bill itself.

Traumatic brain injury is the primary cause of death and disability among young people in the United States. By anyone's definition, these injuries have reached epidemic proportions, affecting nearly 2 million Americans each year, with severe and devastating consequences. Five hundred thousand are injured so severely that they must be hospitalized; 90,000 suffer irreversible loss of function; 50,000 people, many in the prime of their lives, die as a result of an injury or blow to the head from a fall, a violent crime, or a motor vehicle or sports accident. The cost to care

for people with brain injuries is astronomical, over $98 billion a year. But this is not an epidemic that we have read about in novels or seen in movies. It is a silent epidemic, quietly claiming its young victims without the sort of public alarm that would accompany any infectious disease outbreak of this magnitude.[7]

There are three key elements to the Greenwood legislation both in its content and its approach that are highlighted in Representative Pallone's statements. The first is establishing it as a public health concern. It is imperative to establish by numeration that the clinical condition has significant impact on a large enough portion of the population whether it be direct or indirect. Second, the cost of the disease must be demonstrated in terms of monetary as well as valuable years of life lost. Finally, it has to be demonstrated that current measures do not meet the needs of the community to adequately deal with the problem and that there is not enough being done to prevent the injury, illness, or disease. These three key elements play a crucial role in not only allowing the legislation to pass freely through Congress, but also in its implementation and analysis by the CDC and NIH and practical use by state governments and agencies.

TRAUMATIC BRAIN INJURY STATE DEMONSTRATION GRANT PROGRAM

With any legislation that becomes a law, it is vital to understand and correlate the policy and practice ramifications. H.R. 248 and subsequently PL 104-166 are multi-faceted and call on various branches of federal government as well as state agencies. Much of the federal aspects of the law relate to basic science research and organizational responsibility to examine the issue, bring about standardization, and report to Congress any substantial findings. Outside of basic science research funding, the only other appropriations that have immediate impact on the issue of TBI relate to resources made available to States. The manifestation of which is the Traumatic Brain Injury State Demonstration Grant Program referenced under program number 93.234 in the Catalog of Federal Domestic Assistance.[11]

This program was federally managed by the Health Resources and Services Administration (HRSA) in the Department of Health and Human Services, and designed to provide 1-year project grants to States for demonstration projects to improve access to health and other TBI-related services for people of all ages.[11] The grants were made available in two categories, State planning grants and State implementation grants.[11] Planning grants were designed to support the development of core components to providing TBI services whereas the implementation grants provide funding for States that had the core components in place.[11] Applications were only accepted from State governments and implementation grant applications only from the single State agency designated as the lead for TBI services.[11]

The selection process consisted of review by a committee of experts and persons with TBI or their family members, and notification of grant approval or denial was usually made within 2-3 months after receipt of application.[11] As stipulated in the original legislation, States were required to provide formula-based matching funds in an amount no less than $1 for every $2 provided by Federal funds through this grant.[11] There were expected requirements of program service reports, financial reports, and other special reports as deemed by the HRSA as well as long-term record keeping.[11]

Twelve projects from fiscal year 1998 were continued into 1999 with an additional 12 new projects, and it was estimated that a total of 38 projects would be funded in 2000 and 2001.[11] Some examples of funded projects include: New York State Traumatic Brain Injury (TBI) Program for Culturally Competent TBI Services in NY City, Arizona KIDS with TBI, Oregon TBI Link Improving Access to Services for Individuals with TBI, and Alabama an Interactive Community Based Model for Children with TBI.[11]

Programs such as these are critical to providing services to people suffering from TBI, not simply because of their existence, but more so because of the organizational requirements of such project grants. Independently run organizations, while providing important services, have a much more difficult time being efficiently networked to provide a level of continuous and time-appropriate care. Excellent care provisions can sometimes be grossly ineffective when they are not organized, and can lead to a cascade of events in the personal lives of TBI sufferers, as highlighted by the following example[2]:

In 1988, Dr. J.M.Z.—a 44 year-old marriage and family counselor—was struck by a powerboat while kayaking and knocked unconscious for a short time. In the hospital emergency department he was briefly examined, told that he had suffered a “concussion,” and sent home an hour later without other treatment. Despite symptoms including headache, fatigue, and memory loss, he returned to his counseling practice. His clients noticed his memory and

concentration problems and he had to close his practice in six months.

His health insurance company raised his premium rates until he could no longer afford coverage. His wife divorced him. His applications for Social Security disability income were denied over two years, and for six months he had to live in a van. Finally, he received some Social Security benefits. Years later, he learned about and enrolled in a new college program designed for people with brain injury. He developed ways of partially compensating for his continuing memory and concentration difficulties and re-opened a part-time counseling practice that provides minimal income. Appropriate follow-up from a State TBI registry might have led him to helpful programs earlier.

The need for continued and increased funding of State managed TBI programs by the Federal government is a crucial vehicle by which to prevent, treat, educate, and most importantly provide relevant and time-appropriate services to those who may need it.

EFFECTIVE LEGISLATION PRODUCING REALIZED HEALTH SERVICES

This discussion provides only a cursory understanding of the legislative process as it relates to health care services in the United States. The ability to condense the process into a few pages, is a testament to the hard working members of Congress and their tireless staff along with the commitment of caring by health care professionals and the dedication to important causes by everyday people. The problems facing health care delivery are not simple ones, and their solutions rarely are, but with directed and focused efforts on specific problems and specific solutions great progress can be made in effectively creating legislation that produces realized health services.

Personal accounts of where current systems fail, a conveyance of this to legislators both in local, state, and national government, and a persistence to compromise and work within rational limitations can produce solutions that can be acted upon quickly, resulting in little bureaucracy, and providing ultimate success. Yet, it is fundamental to the process that realized health services are not a realized final goal, but a means to build upon, and promote other important issues in and out of health care and social services.

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