The Outcomes Project: A Pediatric Proposal

By Bruce Kaufman, MD

Introduction

Several years ago, the AANS and CNS formed a joint Outcomes Initiative project to encourage outcomes studies in neurosurgery. The initial motivation for this project resulted from the perception that forces outside of neurosurgery (payors, the government, credentialing agencies) would be collecting information on our practices that likely would be inaccurate and yet might be used to our detriment.

There are other important reasons to pursue a neurosurgical outcomes project. Managing variation in practice is often the first step in improving practice both clinically and financially. Outcomes assessments are one tool that can help to define that variation. In the course of an outcomes project, accurate data on a neurosurgeon’s practice would have been developed, and could be used by the neurosurgeon to counter any claims brought by third parties. The anonymous pooling of all practice data in the project can be used by individual neurosurgeons to rapidly identify significant differences in their practices and allow adjustments in practice to be applied.

The Outcomes Committee of the AANS and CNS has representatives from each of the joint sections. The committee is charged with providing the mechanisms that neurosurgeons can use to create and use an outcomes study. The committee asked each Section to consider sponsoring and developing an outcomes project.

Pediatric Section Topic

A number of outcomes topics are of particular interest to neurosurgeons who care for children. These include dysraphism, minor head injury, tumors of childhood and hydrocephalus. Outcomes work in the area of dysraphism and childhood tumors would have limited applicability to general neurosurgery and are complex enough to preclude easy analysis. Minor head injuries would be difficult to assess in a meaningful way, since the majority of these injuries may not ever see a neurosurgeon.

However, the evaluation and treatment of hydrocephalus and shunting in particular affects most neurosurgeons. It is performed with enough frequency and has enough variation that even a small improvement in one aspect would lead to a significant change in the overall pattern of care, even in an individual’s practice. Given the frequency of shunting in their practices, the members of the Pediatric Section might be considered leaders in the care of hydrocephalus and shunting procedures. It is appropriate that an outcomes study on shunting be developed under the auspices of the Pediatric Section.

The success of any outcomes project is dependent on the ease with which the members can perform the study. The “reporting instrument” (simply the format of data collection) must be designed in conjunction with a neurosurgeon knowledgeable in the topic. It must not be complex or burdensome to collect the information. There must be some flexibility, allowing the individual to customize the collected information. The “mechanism” of data collection and storage must be simple to use. Data retrieval and analysis also must be simple.

The Outcomes Committee has worked with an outside company, Outcome Sciences, Inc., to formulate an easy-to-use method of data collection, storage and analysis. Their POINT system is based on computers maintained in Boston and accessed over the Internet. If the Pediatric Section sponsored a shunt study, the specifics of that study would be under the control of the Pediatric Section.

Method

Any neurosurgeon who is member of the AANS or CNS could sign up to participate in this (or any online) outcome study. Each neurosurgeon would be responsible for the collection and submission of their own data; arrangements continued on page 6
Pediatric Section Highlights at the AANS Annual Meeting in Toronto

Monday, April 23

**Breakfast Seminars 7:30-9:30 AM**

115 Advances in the Management of Pediatric Brain Tumors
Moderator: J. Gordon McComb
Panelists: Robin P. Humphreys, Ian F. Pollack, Derek A. Bruce

116 Pediatric Epilepsy
Moderator: Frederick A. Boop
Panelists: Tae Sung Park, John A. Lancon, Andre Olivier, David W. Pincus, Diane L. Krate, Michael Lee Levy

**Scientific Session II 2:45-5:15 PM**

718 Pediatric Ependymoma
Robert A. Sanford, Renatta J. Osterdock, Thomas Merchant
Discussant: James T. Rutka

726 The Surgical Resection of Non-cerebellar Juvenile Pilocytic Astrocytomas
Jeffrey S. Weinberg, Z. L. Milas, R. Sawaya, F. F. Lang
Discussant: Timothy B. Mapstone

Tuesday, April 24

**Breakfast Seminars 7-9 AM**

215 Pediatric Head Injury
Moderator: Ann-Christine Duhaime
Panelists: Thomas G. Luerssen, Lorenzo F. Munoz, John P. Laurent

217 Neurosurgical Management of Spasticity
Moderator: David W. Pincus
Panelists: Tae Sung Park, Richard Deren Penn

Wednesday, April 25

**Breakfast Seminars 7:30-9:30 AM**

317 Contemporary Management of Synostosis
Moderator: David F. Jimenez
Panelists: Dominique Renier, John A. Jane, Robin M. Bowman, J. Gordon McComb

**Scientific Session VIII 9:45-11:15 AM**

772 Risk Factors for Intracranial Hemorrhage in Full-Term Infants and their Impact on Physical and Cognitive Long-Term Prognosis
Balraj S. Jhawar, Adrianna Ranger, Rolando F. Del Maestro
Discussant: R. Michael Scott

**AANS/CNS Section on Pediatric Neurological Surgery 2:45-5:30 PM**

Donald D. Matson Memorial Lecture 2:45-3:15 PM
Donald H. Reigel, to be introduced by John P. Laurent

The Distinguished Service Award 3:15-3:30 PM
John Shillito, to be presented by Michael R. Scott

Kenneth Shulman Award 3:30-3:45 PM
The Executive Committee of the AANS/CNS Joint Section on Pediatric Neurological Surgery met on December 6, 2000, at Coronado, California. A motion was made to eliminate the current post of Secretary-Treasurer and create two separate new posts of Secretary and Treasurer and to change the term of office from three years to two.

The reason for the proposed change is that the financial dealings of the Joint Section have become increasingly complex and could be better managed by a single person serving as Treasurer than by a combined Secretary-Treasurer. This motion was passed at the business meeting on December 7, 2000.

The creation of such a new office necessitates changing the Rules and Regulations of the Joint Section. The proposed changes are presented for your perusal. These changes will be voted on at the next business meeting of the Section, which will take place at the AANS Annual Meeting in April 2001 in Toronto.

Alan R. Cohen, MD, is Chair, Rules and Regulations Committee, AANS/CNS Section on Pediatric Neurological Surgery.

Proposed Changes to Bylaws

The following are the proposed changes to the bylaws of the AANS/CNS Section on Pediatric Neurological Surgery. Proposed changes are in italic.

CURRENT BYLAWS

Article IV
Officers

Section 1. Officers
The officers of the Joint Section shall be the Chairman and the Secretary-Treasurer.

Section 2. Terms of Officers
a) The Chairman shall serve a term of two years.
b) The Secretary-Treasurer shall serve a term of three years.

c) Secretary-Treasurer. It shall be the duty of the Secretary-Treasurer to keep a true and accurate record of the proceedings of the Section, preserve all books, papers and articles that belong to the Joint Section, and to provide the central office of the AANS and CNS with current membership information. The Secretary-Treasurer shall conduct all correspondence of the Joint Section. The Secretary-Treasurer shall send notice of all meeting to each member at the appropriate time and notify all members of committee appointments. The Secretary-Treasurer shall act as Secretary of the Executive Council. An accurate record of all monies collected as dues or assessments from members will be kept. Funds will be dispersed for the ordinary expenses of the Section as well as other expenses when ordered by the Executive Council. An accurate record of all expenses will be kept by the Secretary-Treasurer.

PROPOSED CHANGES

Article IV
Officers

Section 1. Officers
The officers of the Joint Section shall be the Chairman, Secretary and Treasurer.

Section 2. Terms of Officers
a) The Chairman shall serve a term of two years.
b) The Secretary shall serve a term of two years, elected in such a manner that the term is staggered and does not begin the same year as the Chairman.
c) The Treasurer shall serve a term of two years, elected in such a manner that the term is staggered and does not begin the same year as the Chairman.

c) Treasurer. It shall be the duty of the Treasurer to keep the accounts of the Section and to collect all monies due the Section. The Treasurer and the Chairman shall be authorized to expend such funds as are necessary in payment of the expenses of the Section, and to keep accurate records of all transactions.
December 7, 2000, San Diego, Calif.

Call to Order
Chairman John P. Laurent, MD, called the meeting to order at 5:45 p.m.

Approval of the Minutes
The minutes of the previous business meeting on December 3, 1999, were passed out to members in attendance for their review. There were no corrections and the minutes were approved by acclamation.

Financial Report
Rick Abbott, MD, reviewed the financial status of the Joint Section. Projected assets of the Section as of September 2000 have decreased $17,148 due to a projected decrease in registration fees to the winter meeting. The financial report was approved.

Committee Reports
Membership Committee
The report from the Membership Committee was given by Ann Marie Flannery, MD. She proposed that the following applicants be accepted into membership: Darryl Warder, Galveston, Texas; Mark Iantosca, Hartford, Conn.; Peter Sun, Oakland, Calif.; Dale Swift, Dallas, Texas; Nalin Gupta, San Francisco, Calif.; Michon Morita, Honolulu, Hawaii; Jose Bermudez, West Monroe, La.; Gerald Tuite, St. Petersburg, Fla.; and Howard Silberstein, Rochester, N.Y. It was moved, seconded and passed to recommend to our membership at the upcoming business meeting that all candidates be admitted for membership. It was moved and seconded that these members be accepted at their designated status. This was approved by acclamation.

Rules and Regulations Committee
Chairman Alan R. Cohen reported on changes made to the bylaws as had been outlined in a previous Short Cuts. It was moved and seconded that the changes be made to the bylaws as outlined by Dr. Cohen. This was approved by acclamation.

Nominating Committee
Marion Walker, MD, reported on the Nominating Committee’s proposed slate of officers. Thomas G. Luerssen, MD, was proposed for the chairmanship and Fredrick Boop, MD, and Andrew Parent, MD, for members at-large for the Nominating Committee. They will take office at the spring 2001 meeting of the Section.

Election of Officers
Drs. Luerssen, Boop and Parent were nominated and seconded. Dr. Laurent requested any nominations from the floor. There were none. Nominations were closed. Voting was by show of hands. All nominated officers were elected by acclamation.

Ad Hoc Committee Reports
The Distinguished Service Award
No report.

Traveling Fellowship
Chairman R. Michael Scott, MD, reported for this committee. The committee had received three applications for traveling fellowships. Traveling fellowships for the year 2000 were awarded to Ketan Bulsara, MD, a PGY5 at Duke who will spend four weeks with Arnold Menezes, MD, in Iowa City studying pediatric spine procedures, and Ian Hegger, MD, who will spend two weeks with Michael Scott, MD, at Boston Children’s Hospital.

There were three applicants for the International Traveling Fellowship. Fajardo Rivera, MD, of Honduras will be awarded the fellowship to spend four weeks in Denver with Kenneth Winston, MD.

American Academy of Pediatrics
Joseph H. Piatt III, MD, reported as liaison to the AAP. He again described the provisional nature of the new Section on Neurosurgery in the American Academy of Pediatrics. Things seem to be on track for the neurosurgical section to be granted full status during this next year. Plans for collaborative presentations that fulfill the educational and scientific contributions to the Academy are in place for the fall 2001 meeting of the AAP. The neurosurgical section will participate with the orthopedic section to provide a program on the management of spasticity for the AAP membership. The neurosurgical section also will participate with the critical care section to provide a program on head injury.

New Business
Dr. Abbott brought before the membership a proposal to amend the bylaws to split the current office of secretary-treasurer into two separate offices. The increasing complexity of the office and the greater need for close scrutiny of the budget given the desire of members to minimize registration costs at our meetings were cited as reasons for doing so. After discussion it was moved and seconded to approve setting in process the amendment. The motion was then passed by acclamation. Dr. Cohen will set about to amend the bylaws so that the change can be disseminated in Short Cuts and the measure voted upon at the Toronto meeting.

Dr. Laurent reported that the Section had been requested to provide three topics to Neurosurgical Focus in the coming year. It was proposed that these topics be Chiari 1 Malformations, Myelomeningocele and Child Abuse. It was moved and seconded that Jerry Oaks, MD, be given the task of assembling the Chiari 1 Malformation text. The motion was then passed by acclamation. Dr. Cohen will set about to amend the bylaws so that the change can be disseminated in Short Cuts and the measure voted upon at the Toronto meeting.

Dr. Lorenz reported that the Section had been requested to provide three topics to Neurosurgical Focus in the coming year. It was proposed that these topics be Chiari 1 Malformations, Myelomeningocele and Child Abuse. It was moved and seconded that Jerry Oaks, MD, be given the task of assembling the Chiari 1 Malformation text. The motion was then passed by acclamation. Dr. Oaks then asked for members to submit text to him for review.

Dr. Laurent then announced that the 2005 winter meeting will be held in Birmingham, Ala.

Adjournment
No further business was brought from the floor. The meeting was adjourned at 6:15 p.m.
A paper titled “Death Following Delayed Failure of Third Ventriculostomy: A Report of 3 Cases” by Drs. Walter J. Hader, Jim Drake, Doug Cochrane, John Kestle and Owen Sparrow was presented at the recent annual meeting of the Section on Pediatric Neurological Surgery. The paper described how three patients died as a result of increased intracranial pressure following delayed failure of a third ventriculostomy.

In the first case, a 13-year-old girl who underwent a successful third ventriculostomy three years previously deteriorated rapidly over six hours and was found dead at home. The second case involved a 4-year-old boy, two years post-op from a successful third ventriculostomy. He was taken to the emergency room with symptoms of increased intracranial pressure (ICP). In the absence of a shunt, his symptoms were discounted and while he was under observation in the hospital he deteriorated rapidly and died. In the third case, a 10-year-old boy who had undergone third ventriculostomy six months earlier developed raised ICP and had emergency insertion of a VP shunt. However, he remained vegetative and died of complications.

While these three cases are a rare outcome of third ventriculostomy, they are noteworthy and troubling. They point to the need for patients, families and medical professionals to understand that while third ventriculostomy is more and more becoming a viable treatment option for hydrocephalus in many patients, just like a shunt. However, he remained vegetative and died of complications.

Discussion following the presentation of this paper stressed the need for neurosurgeons to keep a watchful eye on their third ventriculostomy patients, just as they do with their shunted patients. Additionally, it is important that patients and families understand and be alert to possible symptoms of recurring hydrocephalus that may signal the failure of third ventriculostomy.

The Hydrocephalus Association is pleased to announce that with the support of NMT Neurosciences, Inc., maker of the Orbis-Sigma Valve, we are in the process of developing a wallet-size identification card for people who have undergone a third ventriculostomy. The card will state that medical attention by a neurosurgeon is required if symptoms of uncontrolled hydrocephalus (headache, lethargy, mental dullness, nausea, vomiting, papilledema, etc.) are present. The card will include the patient’s name, and the name and telephone number of a neurosurgeon. We plan to have these cards ready for distribution by March 2001. At that time they will be available free to our members and at a small cost in bulk to neurosurgeons who perform third ventriculostomy for distribution to their patients.

Story courtesy of the Hydrocephalus Association in San Francisco, California.

Hydrocephalus Conference to be in Chicago

Hydrocephalus 2002—the 7th National Conference for Families and Professionals will be held in Chicago from May 25-28, 2002, Memorial Day weekend.

The conference, sponsored by the Hydrocephalus Association in San Francisco, will be held at the Sheraton Chicago Hotel & Towers, located in downtown Chicago within walking distance of Lake Michigan, Navy Pier, the Magnificent Mile, the Art Institute and the Loop business district.

Two of the nation’s finest, most experienced neurosurgeons will serve as medical directors for the 2002 conference: David G. McLone, MD, PhD, Head of Pediatric Neurosurgery, The Children’s Hospital, Chicago, and Marion L. (Jack) Walker, MD, Head of Pediatric Neurosurgery, Primary Children’s Medical Center, Salt Lake City. The combined talents and many years of hydrocephalus experience of these two compassionate physicians ensure a thoughtful program that will address the complexities of hydrocephalus in all age groups from pre-natal diagnosis through adult onset normal pressure hydrocephalus.

As always, the conference will combine general sessions on the latest diagnostic and treatment protocols with smaller workshops on specific topics and interactive sessions for individuals with hydrocephalus, parents, spouses and family members.

International Resident Fellowship Offered

The Pediatric Section has established an international traveling fellowship for neurosurgical residents who are in training in programs outside the United States and Canada. The fellowship is intended to cover the traveling and living expenses for up to a three-month period for residents observing the activities of an established pediatric neurosurgical service in the United States or Canada.

The fellowship is for any activity that broadens the resident’s exposure to pediatric neurosurgery. It can include observation at a clinical or research center or any other relevant activity that the committee finds acceptable.

One fellowship per year will be awarded on the basis of the recommendation of a committee of the Pediatric Section. The maximum fellowship stipend is $5,000.

The application should include: 1) a statement of the purpose of the proposed fellowship and estimated expenses for the period of the fellowship, 2) a letter of recommendation from the applicant’s current neurosurgical program director, 3) a letter of acceptance from the institution where the applicant will seek the fellowship confirming the description of the fellow’s activities during the period of the award, and 4) a current Curriculum Vitae of the applicant.

The deadline for application submission is November 15, 2001.

The completed application should be sent to R. Michael Scott, MD, Department of Neurosurgery, The Children’s Hospital, 300 Longwood Avenue, Bader 319, Boston, Massachusetts 02115. Or it can be e-mailed to scottr@a1.tch.harvard.edu.
would be made for group practices to submit data. All data is stripped of identifying information before submission to the database, protecting the neurosurgeon and the patients.

The group formulating the outcomes study would define the basic set of data to be collected. In the POINT system, there can be a small set of required data fields, used for the basic reports. There can also be more specific data elements available for capture and thus for later analysis. The proposed study would also have a few user defined data elements. There are several ways to submit data: by transcription of forms onto the Internet, by direct Internet access and by the use of a Palm device data collection program that is under development.

The data submitted by a neurosurgeon can at any time be analyzed by that neurosurgeon. The Web site will have pre-defined reports, which in the case of shunting would include an infection rate or complication rate. It may be possible to generate (offline) a shunt survival curve (Kaplan-Meier style).

The neurosurgeon can also download all of his/her submitted data in a “raw” format (Excel table) for personal analysis offline. The neurosurgeon could look for factors associated with a particular outcome.

Group Data
The ability to compare one’s practice with the overall group of neurosurgeons submitting data is one particularly useful function of an outcomes database. However, this is limited by the quality of data that each individual submits. Remember it’s “garbage in—garbage out.” The verification of data submitted is one of the constraints on a functioning outcomes database.

Data validation can be accomplished by a number of methods. Most clinical studies require the inspection of records or a random sampling of charts to verify or establish the accuracy of data collected. These are very labor intensive and quite costly, both in terms of time and money.

A simple method that the Outcomes Committee can use involves “case number matching.” When enrolling for the study, each database participant agrees to allow the committee to contact the hospitals at which the participant practices to verify the number of eligible cases performed. If the number of cases performed is not consistent with the number of cases submitted to the database, then the participant’s data cannot be considered representative of that person’s practice and would not be used in any group analysis. Failure to submit all or nearly all eligible patients makes any analysis worthless, even for the individual.

Cost of the Study
The costs of establishing and running an outcomes study are relatively marginal. The cost for the initial database definition and set-up, including the formation of several routine pre-defined reports, is likely to be less than $5,000. The creation of additional defined reports would cost about $1,000 per report. The ongoing costs of the database management are included in the costs for running all outcomes projects and are financed through the Outcomes Committee budget.

The Outcomes Committee currently has the sponsoring Section cover the startup costs.

Note that any person or group can develop their own outcomes study and use the database techniques of the Outcomes Committee and Outcomes Sciences, Inc. They are only required to arrange for the costs of setting up the database. The Pediatric Section could elect to pursue a new or an additional project. The mechanism for establishing a project is in place.

Issues to Consider
A number of issues have been raised regarding an outcomes project, some of which have not been resolved to the satisfaction of the Pediatric Section Executive Committee. These issues include:

- Institutional Review Board involvement
  A number of individuals have questioned whether IRB approval would be necessary for participation in an outcomes project. The collection of patient data is often a trigger for IRB review. The Outcomes Committee believes that IRB approval is not necessary. The data is being collected under the auspices of quality assessment and improvement, and that is not usually controlled by an IRB. In addition, there is no identifying data on individual patients that is not already known to the treating physician.

- Access to the aggregate data
  Individual practitioners have access to their own data and to pre-defined summaries of the aggregate data (used for the reports). A formal process adopted by the Outcomes Committee covers whether the raw aggregate data can or should be made available to others. Analysis of the aggregate data has the potential for identifying trends and topics for further, more scientifically rigorous evaluation.

  Requests for access to the aggregate data might reasonably come from one of the submitters of data in search of additional information on a cause of an observed variation. It might come from a neurosurgeon not directly involved in the study or from one of the supporting neurosurgical organizations (AANS, CNS, Pediatric Section committee or the Outcomes Committee). There could be a request for data from a governmental, industry (device or insurance), or legal (trial lawyer) entity.

  The Outcomes Committee believes that the aggregate data belongs to the sponsoring organization. For example, data from the shunt study done under the sponsorship of the Pediatric Section would be under the control of the Pediatric Section leadership. Data would be accessible only to members of the AANS or CNS and only after approval of the sponsoring group or the Outcomes Committee. In no case would the data be made available to a commercial, governmental or private entity.

- Unauthorized access to an individual’s data (“discoverability”)
  There is a constant fear of any collected data being “discovered” in a medical malpractice or civil trial. The Outcomes Committee believes that this data is collected under the
have no oversight or input into the data collection or the use of outcomes study. In that event, the Section would allow direct oversight of the use of collection tool and reports and funding the cost of that development.

If the Section pays for or sponsors any part of the outcomes project on shunting, the topic is of particular interest to surgeons. It has the potential for helping a large number of patients.

It is my recommendation that the Pediatric Section sponsor an outcomes project on shunting. The topic is of particular interest to surgeons. It has the potential for helping a large number of patients.

If the Section should decide not to participate in or sponsor this particular outcomes study, the possibility exists that the same or a similar study may be developed by another group (even the Outcomes Committee itself). In that event, the Section would have no oversight or input into the data collection or the use of any data collected. The Section should not participate unless assured that there will be no direct connection between studies and commercial entities.

Recommendation

It is my recommendation that the Pediatric Section sponsor an outcomes project on shunting. The topic is of particular interest to the Section members and potentially of great interest to all neurosurgeons. It has the potential for helping a large number of patients.

Section sponsorship would include development of the data collection tool and reports and funding the cost of that development. Section sponsorship would then allow direct oversight of the use of the data according to the Outcomes Committee protocol.

If the Section should decide not to participate in or sponsor this particular outcomes study, the possibility exists that the same or a similar study may be developed by another group (even the Outcomes Committee itself). In that event, the Section would have no oversight or input into the data collection or the use of any data collected. The Section should not participate unless assured that there will be no direct connection between studies and commercial entities.

Bruce Kaufman, MD, is Chairman, Outcomes Committee.

Resident Traveling Fellowship Available

The Pediatric Section has established a traveling fellowship for residents in neurosurgical training. The fellowship is intended to cover the traveling and living expenses for up to one month for residents who want to pursue additional experience in pediatric neurosurgery during their residency years.

The one-month fellowship can be spent in any activity that broadens the resident's exposure to pediatric neurosurgery. It might include observation at a clinical or research center or any other relevant activity.

Two fellowships per year will be awarded on the basis of an evaluation by a Section committee. The maximum fellowship stipend is $2,500.

The application should include: 1) a statement regarding the purpose of the proposed fellowship and estimated expenses, 2) written permission to apply for the fellowship from the applicant's program director, and 3) a letter of acceptance from the institution where the applicant will seek the fellowship.

The deadline for application submission is October 15, 2001. The completed application should be sent to R. Michael Scott, MD, Department of Neurosurgery, The Children's Hospital, 300 Longwood Avenue, Bader 319, Boston, Massachusetts 02115. Or it can be e-mailed to scottr@1.tch.harvard.edu.
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<tr>
<th>Event</th>
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<tr>
<td>American Association of Neurological Surgeons Annual Meeting</td>
<td>April 21-26, 2001</td>
<td>Toronto, Ontario, Canada</td>
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<tr>
<td>Third International Hydrocephalus Workshop</td>
<td>May 17-20, 2001</td>
<td>Kos, Greece</td>
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<td>International Society for Pediatric Neurosurgery Annual Meeting</td>
<td>June 29-July 3, 2001</td>
<td>Aalborg, Denmark</td>
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<td>AANS/CNS Joint Section on Pediatric Neurosurgery Annual Meeting</td>
<td>Nov. 28-Dec. 1, 2001</td>
<td>New York, N.Y.</td>
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<td>World Congress of Neurosurgery</td>
<td>Sept. 15-21, 2001</td>
<td>Sydney, New South Wales, Australia</td>
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