ATTACKING MEDICAL STUDIES AND STATISTICAL ASSOCIATIONS

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Attacking Medical Studies & Statistical Associations

Presented By John Jerry Glas

Why do we pause when a hostile expert smiles, and takes great joy in telling us that a study recently proved an association? It is not that we fear studies, or news of a statistical association. Most lawyers are comfortable explaining the difference between proving an association and proving causation. Perhaps we pause for the same reason that a parent pauses after smelling a dirty diaper. It is that moment after we realize there is work to be done, and before we start doing it. There is only fear among the uninitiated.

Every lawyer needs a strategy for attacking the validity of studies, especially in our post-*Daubert* world. More judges are willing to allow expert testimony when the expert can cite a published study, and more journals are willing to publish studies involving more confounding variables than participants. It has become our duty to protect our clients and jurors from experts who surf the internet in search of obscure cohort studies.

Every lawyer needs to understand the basic questions that can be used to attack medical and behavioral studies, and the experts who string-cite them. The following list of one hundred (100) questions has been designed to dissect a prospective longitudinal study, but the questions either apply, or can be modified to apply, to other study designs. Following the actual list, there is a discussion of each question. That discussion sometimes includes, for demonstrative purposes, an excerpt from a study which plotted cognitive changes after childhood traumatic brain injury. Good luck and good hunting.

100 QUESTIONS TO ANSWER
WHEN AN EXPERT RELIES ON A MEDICAL STUDY

Design Of The Study

1. What Was The Design Of The Study?
2. Was The Study Retrospective Or Prospective?
3. What Was The Research Question?
4. Why Was It Important To Answer That Research Question?
5. What Was Already Known?
6. What Answer Did The Researcher Expect?
7. How Did The Study Add To Existing Knowledge?
8. Was The Research Question Modified?
9. What Was The Study Protocol?
10. Who Funded & Who Conducted The Study?
11. Has The Study Been Replicated?

Variables & Validity

12. What Is The "Independent Variable"?
13. What Is The "Dependent Variable"?
14. What Is Internal Validity?
15. Why Does Internal Validity Depend On The Ability To Eliminate Chance, Bias, & Confounding?
16. What Is A Confounding Variable?
17. Why Do Researchers Try To Eliminate Confounding Variables?
18. What Are All Of The Confounding Variables In The Present Study?

Relevance Of The Study

19. Would The Plaintiff Have Qualified For The Study?
20. What Were The Inclusion Criteria?
21. What Were The Exclusion Criteria?
22. What Confounding Variables Were Eliminated By The Exclusion & Inclusion Criteria?
23. What Inclusion & Exclusion Criteria Have Been Used By *Other* Researchers In Similar Studies?
24. What Inclusion & Exclusion Criteria Have Been Used By The *Same* Researchers In Previous Or Subsequent Studies?
25. Does Proper Statistical Research Require The Elimination Of All Confounding Variables?
26. Does This Study Eliminate All Confounding Variables?

Definition Of Terms

27. How Does The Author Define Each Critical Term That Appears In The Conclusion Or Abstract?
28. How Do Other Studies Define Each Critical Term?

100 QUESTIONS TO ANSWER
WHEN AN EXPERT RELIES ON A MEDICAL STUDY

Study Members

29. How Does The Size Of A Study Population Affect Internal Validity?
30. How Many "Similar" Study Members Does The Expert Require Before Relying On A Study?
31. What Was The Study Population?
32. How Were The Study Members Selected?
33. What Were The Demographic Statistics Of The Study Members?

Classification Of Study Members

34. Were Study Members Classified
35. Why & When Were Study Members Classified?
36. Were Study Members Classified Using Subjective Criteria?
37. Was More Than One Criteria Used To Classify Study Members?
38. Was The Confounding Variable Equally Represented In Each Group?

Classification Of Plaintiff

39. Does The Expert Admit That Any Classification Of The Plaintiff Is Subjective?
40. Why Did The Expert Include Plaintiff In That Classification?
41. When Did Expert Include Plaintiff In That Classification?

Differences Within Classification

42. How Is Plaintiff Similar To Study Members In That Classification
43. How Is Plaintiff Different From Study Members In That Classification?
44. What Did The Article Reveal About Each Study Member?
45. What Do You Know About The Plaintiff That You Do Not Know About Each Study Member?
46. What Additional Information Would The Expert Like To Know About Each Study Member?
47. Why Would The Expert Want To Know That Information About Each Study Member?
48. Is The Presence Or Absence Of An (Unknown) Characteristic Among Study Members A Confounding Variable?

Bias & Effect Of Classification

49. How Would The Expert's Opinion Been Different If The Expert Had Subjectively Classified Plaintiff Differently?
50. Did Expert's Subjective Classification Benefit The Attorney Who Retained The Expert?
51. Was The Expert Aware That The Subjective Classification Would Benefit The Attorney Who Retained Her Or Him?

100 QUESTIONS TO ANSWER
WHEN AN EXPERT RELIES ON A MEDICAL STUDY

Control Group

52. What Is A Control Group?
53. Have Similar Studies Used Control Groups?
54. Why Did Similar Studies Use A Control Group?
55. How Did The Control Group Perform In Those Similar Studies?
56. Did This Study Use A Control Group?
57. How Was The Control Group Selected?
58. How Did The Study Eliminate Natural, Biological & Environmental Confounding Variables?

Measures

59. How Was Initial Participation In The Study Encouraged?
60. What Was The Method Of Assessing The Dependent Variable?
61. Why Did They Select That Method Of Assessment?
62. Is That Method Of Assessment Scientifically Reliable?
63. What Is An Alternative Method Of Assessment?
64. What Was The Period Of Assessment?
65. What Was The Frequency Of Assessment?

Retention Rate

66. What Was The Retention Rate In The Study?
67. Why Is The Retention Rate Important?
68. How Did Attrition Affect The Cohort & The Control Group?
69. How Did Attrition Effect Plaintiff's Classification?
70. How Was Subsequent Participation (Retention) Encouraged?

National Statistics

71. What Percentage Of Study Members Developed The Condition Or Experienced The Outcome Studied?
72. How Many Americans Would Have Qualified For The Study?
73. Is The Percentage Of Study Members Consistent With National Statistics?
74. How Does The Percentage Observed Among Study Members Differ From National Statistics?

100 QUESTIONS TO ANSWER
WHEN AN EXPERT RELIES ON A MEDICAL STUDY

Expert Methodology

75. How Does The Expert Explain Any Difference Between The Study Member Percentage & The National Percentage?
76. Was The Plaintiff A Member Of The Study?
77. Is The Expert Predicting That The Plaintiff Will Experience The Same Outcome As Study Members?
78. According To The Study, What Is The Likelihood That Plaintiff Will Experience The Outcome (Dependent Variable)?
79. According To The Expert, What Is The Likelihood That Plaintiff Will Experience The Outcome (Dependent Variable)?
80. Is The Expert's Prediction Based On Only This Study?
81. What Was The Expert's Methodology For Making That Prediction?
82. Did The Expert Consider Any Conflicting Findings, Factors, Or Studies?
83. What Weight Did The Expert Assign To Conflicting Predictors Or Studies?
84. Did The Expert Previously Publish This Opinion?
85. Did The Expert Develop The Opinion For This Litigation?
86. Where Did The Expert Find The Study?
87. How Did The Expert Find The Study?
88. How Long Did The Expert Spend Researching?
89. How Much Did The Expert Bill For Researching?

Bias In Expert's Research & Report

90. Did The Expert Read Only The Abstract?
91. Why Did The Expert Cite Medical Studies In His Or Her Report?
92. Did The Expert Find Or Read Any Conflicting Studies?
93. Why Did The Expert Omit Conflicting Studies From Report?
94. What Did The Study Report About Study Members Who Were In Plaintiff's Classification?
95. How Does The Expert Explain Any Reported Conflicting Data Or Conclusions About Plaintiff's Classification?
96. Why Did The Expert Fail To Report The Conflicting Data Or Conclusions About Plaintiff's Classification?

Tests Of Significance

97. Why Do Researchers Use Tests Of Significance?
98. What Tests Of Significance Did This Study Use?
99. What Significant Predictors Of Outcome Did The Study Identify?
100. What Statistical Association Did The Study Suggest?

Design Of The Study

1. What Was The Design Of The Study?

A cohort study involves the observation of a group of persons (a "cohort") who were born at approximately the same time, or who share a common characteristic over a defined period of time. This is also called a "longitudinal study" because it involves the gathering of data about the cohort over an extended period of time.

A cross-sectional study gathers data about different study members at different periods of time. It produces a "snapshot" of a particular population at a particular point in time.

Example: The design of the study we will be using as an example is a *longitudinal* study. That design is indicated in the Abstract which appears at the beginning of the study.


comes.
Design. Prospective longitudinal study.

2. Was The Study Retrospective Or Prospective?

Retrospective studies look back. They often focus on individuals (study members) who have reached a defined end point or state. Retrospective studies require researchers to base their conclusion on the available information about those study members, including interviews, documents, reports, and diagnostic images.

Prospective studies look forward. These studies take a selected group of people (study members), and follow these people, and their health problems, for a period of time.

Example: The design of the study we are using as an example is a *prospective* longitudinal study. That also appears in the Abstract at the beginning of the study.

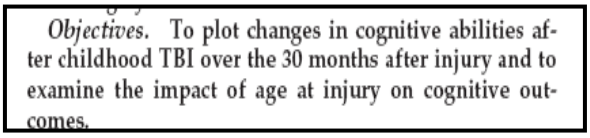

comes.
Design. Prospective longitudinal study.

3. What Was The Research Question?

Most studies are designed to answer a specific research question, and that question may be identified as an "Objective" in the Abstract. Treat the published "Objective" like a code which has to be deciphered. First, you should determine what the researchers actually (physically) did with the study members. Then, you should re-frame the research question as an attempt to determine whether a statistical association existed between the

occurrence of the Independent Variable and occurrence of the Dependent Variable.

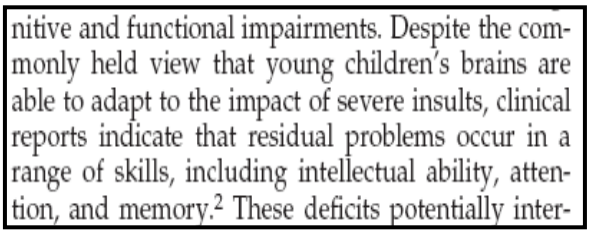
Example: First, instead of admitting that they "gave IQ tests," these researchers "plotted changes in cognitive abilities." Second, the objective assumes that age has an impact on outcome. We want to re-frame the objective as a research question: Is there an association between a child's age (when they experience a Traumatic Brain Injury) and their cognitive outcome?


Objectives. To plot changes in cognitive abilities after childhood TBI over the 30 months after injury and to examine the impact of age at injury on cognitive outcomes.

4. Why Was It Important To Answer That Research Question?

Go fish. If the expert did not author the study, then he/she may support his/her reliance on a particular study by criticizing competing studies (which will allow you to call the researchers who performed those studies and read from the expert's deposition). If the expert authored the study, then you need to know what caused them to design the study.

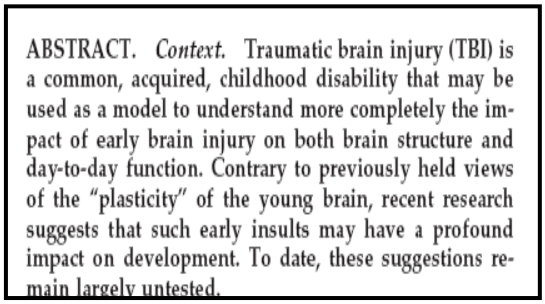
Example: The researchers revealed that the research question needed to be answered because of the difference they perceived between the "commonly held view" and "clinical reports." The question becomes: What clinical reports persuaded the researchers to conduct this study?


nitive and functional impairments. Despite the commonly held view that young children's brains are able to adapt to the impact of severe insults, clinical reports indicate that residual problems occur in a range of skills, including intellectual ability, attention, and memory.[2] These deficits potentially inter-

5. What Was Already Known?

A review of the literature should indicate what was known about the research question before the study. Many studies will reference the existing literature. You should look at the Abstract, and then look at the Introduction to the medical study.

Example: Researchers sometimes make their study sound more important by indicating that their conclusions are "contrary to previously held views." Statements like this are red flags, marking where studies attempt to disprove prior studies and accepted beliefs within the scientific community. Find the name of each

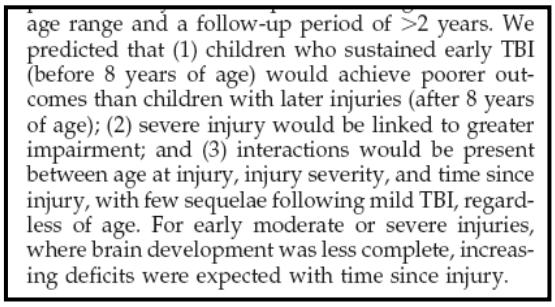

ABSTRACT. *Context.* Traumatic brain injury (TBI) is a common, acquired, childhood disability that may be used as a model to understand more completely the impact of early brain injury on both brain structure and day-to-day function. Contrary to previously held views of the "plasticity" of the young brain, recent research suggests that such early insults may have a profound impact on development. To date, these suggestions remain largely untested.

study that contributed to the "previously held views," and the name of every authority who endorsed that view.

6. What Answer Did The Researcher Expect?

A researcher either did, or did not, have expectations before designing a study. Find out what result the researcher expected, and whether they will admit having a pre-existing belief or theory.

Example: Some researchers will admit that they made predictions. If a researcher "predicted" the outcome of the study, then: (1) they formed an opinion before the study; and (2) they hoped that the study would prove their opinion correct. This is called "Bias."



age range and a follow-up period of >2 years. We predicted that (1) children who sustained early TBI (before 8 years of age) would achieve poorer outcomes than children with later injuries (after 8 years of age); (2) severe injury would be linked to greater impairment; and (3) interactions would be present between age at injury, injury severity, and time since injury, with few sequelae following mild TBI, regardless of age. For early moderate or severe injuries, where brain development was less complete, increasing deficits were expected with time since injury.

7. How Did The Study Add To Existing Knowledge?

The author of the study will usually tell you in the study how the study added to existing knowledge. You should also check the Abstract, especially if it was written by a panel or publisher who wants to encourage people to purchase the article.

Search for subsequent articles which cite the medical study. In time, the scientific community often pigeon-holes a study as standing for, or supporting, a very specific conclusion. Has this study become a part of a string-citation for a specific principle? What other studies are included in the string-cite?

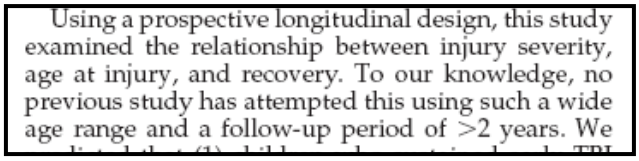
Search for subsequent articles which cite the researchers who conducted the study. It may tell you something if subsequent studies commonly cite other studies by these researchers, but do not cite this study. You may want to speak with (or retain as a consultant) each subsequent author who explores the same subject, but does not cite the study.

8. Was The Research Question Modified?

Researchers can change or modify their research question based on what they discover. Find out *why*, *when*, and *how* the research question was modified.

9. What Was The Study Protocol?

The author of the study will often distinguish their study from other studies in terms of protocol. Review these statements, which often reveal something about the existing medical literature.


Using a prospective longitudinal design, this study examined the relationship between injury severity, age at injury, and recovery. To our knowledge, no previous study has attempted this using such a wide age range and a follow-up period of >2 years. We

Example: In this study, the authors point out that there are no prior studies involving the same age range with a follow-up period of more than 2 years.

10. Who Funded & Who Conducted The Study?

Find out who paid for the study, and who conducted the study. One article indicated that private corporations funded approximately 1 out of every 3 original manuscripts published in the largest 2 general medicine journals in the United States; and that academic faculties receive approximately $1.5 billion annually in research money from private industry

11. Has The Study Been Replicated?

Unless a study has been replicated, researchers do not know whether there were any problems (design flaws) which resulted in misleading findings. Throughout history, there have been examples of results based on a single study which could not be replicated (i.e., cold fusion).

In a prospective longitudinal study, a study could be repeated with a new cohort. Force the Expert/Author to admit that the study could be replicated, and that it has not been replicated.

Variables & Validity

12. What Is The "Independent Variable"?

Most research questions identify independent and dependent variables.

In any interventional study, the variables that a researcher manipulates are called "independent variables." For example, if a researcher is studying how massage affects scar tissue formation, then the intervention (the massage) would be the independent variable.

In social epidemiology, independent variables are the characteristics hypothesized to explain the phenomena of health and disease. For

example, researchers can study the association between depression (independent variable) and alcohol abuse (dependent variable).

Example: In a prospective longitudinal study of the association between age at injury and cognitive recovery, age is the independent variable or "predictor."

13. What Is The "Dependent Variable"?

The variables that are measured by a researcher to determine if an independent variable had an intended effect are called "dependent variables." If a researcher is studying how massage affects scar tissue formation, then scar tissue formation is the dependent variable. In social epidemiology, the dependent variable is the social condition or outcome that the researcher is trying to understand. For example, researchers can study the association between homelessness (independent variable/predictor) and becoming a victim of violent crime (dependent variable/outcome).

Example: In a prospective longitudinal study of the association between age at injury and cognitive recovery, cognitive "outcome" is the dependent variable.

14. What Is Internal Validity?

Internal validity is the extent to which we can assume that changes in the dependent variable are caused by the independent variable, and not by a confounding variable.

15. Why Does Internal Validity Depend On The Ability To Eliminate Chance, Bias, & Confounding?

"Sufficient evidence of an association" means that the study showed an association between the Independent and the Dependent variable, and chance, bias, and confounding were ruled out. This results in Internal Validity.

16. What Is A Confounding Variable?

A confounding variable is an extrinsic factor that is associated with the dependent variable and is a cause of the outcome, or dependent variable. A confounding variable is so called because it operates as a confounder of the association between the independent and the dependent variable. Simply put, a confounding variable provides an alternative explanation for the results of an experiment.

17. Why Do Researchers Try To Eliminate Confounding Variables?

A well-designed study involves no confounds; and, therefore, has high internal validity. In a poorly-designed study, it is not possible to rule out a confounding variable as the *cause* of the dependent variable.

18. What Are All Of The Confounding Variables In The Present Study?

If you are questioning an expert who is relying on a study, force the Expert: (1) to identify every confounding variable; (2) to explain how each confounding variable could have caused the dependent variable; and (3) to explain the necessity for eliminating each confounding variable, which will require them to address the internal validity of the study. Try asking: "Ideally, what confounding variables would have been eliminated in the present study."

Relevance Of The Study

19. Would The Plaintiff Have Qualified For The Study?

This question requires the witness to know the Inclusion Criteria, and the Exclusion Criteria. It can be a very simple question if the only Inclusion Criteria are purely objective, like age or blood type. It can be a very complicated question if the Inclusion Criteria are more subjective.

20. What Were The Inclusion Criteria?

Inclusion criteria are usually broader than exclusion criteria, and are a good place to start. Each inclusion criteria narrows the potential pool of study members.

Example: This study was cited by a pediatric neurologist in a case involving a child of Mexican immigrants, whose primary language was Spanish, and whose parents did not speak English. If counsel had not looked at the Inclusion Criteria, then counsel would never have known that the child failed to meet *two* of the Inclusion Criteria: (1) English as a first language; and (2)

Methods

Participants

One hundred and seventeen children participated in the study. Eighty-four children with a diagnosis of closed head injury were recruited from consecutive admissions to the neurosurgical ward of the Royal Children's Hospital, Melbourne, between 1993 and 1997. Inclusion criteria were: (i) age at injury 2.0–7.0 years; (ii) documented evidence of TBI, including a period of altered consciousness; (iii) medical records sufficiently detailed to determine injury severity; (iv) able to complete evaluations; (v) completed acute, 12 and 30 month evaluations; (vi) English as a first language; and (v) parents competent with English. Exclusion criteria were: (i) TBI as a result of abuse; (ii) penetrating injury; (iii) history of previous TBI; and (iv) evidence of pre-existing neurological, psychiatric or developmental disorder.

parents competent with English.

21. What Were The Exclusion Criteria?

Exclusion criteria are usually "red flags," marking Confounding Variables previously identified by the authors of the study, or recognized by the scientific community.

Note: For every Inclusion criteria there is usually a corollary (unwritten) Exclusion Criteria. For example, an Inclusion Criteria of "age at injury 2.0-7.0 years," could also be stated as two exclusion criteria: (1) "age at injury younger than 2.0;" and (2) "age at injury older than 7.0.

22. What Confounding Variables Were Eliminated By The Exclusion & Inclusion Criteria?

The initial question is *why* did the authors of the study select each of the Inclusion & Exclusion Criteria. In this regard, the Inclusion & Exclusion Criteria will always include the independent variable. Any attempt to determine whether there is an association between TBI and loss of memory will require study members who sustained TBI.

However, when a researcher establishes *additional* Inclusion & Exclusion Criteria, that researcher usually believes the *additional* Criteria will eliminate a confounding variable. On those occasions, counsel needs to determine why that researcher believed the confounding variable could provide an alternative explanation for the results of the study.

Example: The study included the Inclusion Criteria that the parents of study members be "competent in English." What does that mean? How did they determine competency? What was the threshold for competency? What similar Criteria did the researchers consider? Why didn't researchers add an Inclusion Criteria that "English is primarily spoken in the home?" How does that Inclusion Criteria eliminate culture and language as a confounding variable?

> 1997. Inclusion criteria were: (i) age at injury 2.0–7.0 years; (ii) documented evidence of TBI, including a period of altered consciousness; (iii) medical records sufficiently detailed to determine injury severity; (iv) able to complete evaluations; (v) completed acute, 12 and 30 month evaluations; (vi) English as a first language; and (v) parents competent with English. Exclusion criteria were:

23. What Inclusion & Exclusion Criteria Have Been Used By *Other* Researchers In Similar Studies?

Inclusion & Exclusion Criteria narrow the pool of study members, and studies are often judged by the number of participants. Do not assume

that the authors of the study selected the correct Criteria. Counsel needs to know if the author has intentionally or unintentionally failed to identify and eliminate a confounding variable.

24. What Inclusion & Exclusion Criteria Have Been Used By The *Same* Researchers In Previous Or Subsequent Studies?

Counsel needs to know what Inclusion & Exclusion Criteria have been used by the same authors in their other studies. If the same authors used an additional Exclusion Criteria in prior studies, you need to know why they dropped it. If the same authors added an Exclusion Criteria in subsequent studies, one needs to know what criticism or data caused them to recognize the need to address the confounding variable which that Exclusion Criteria was designed to eliminate.

Example: Interestingly, the same researchers who authored the excerpted study authored a similar study which did not include the Inclusion Criteria "parents competent with English" or "English speaking."

25. Does Proper Statistical Research Require The Elimination Of All Confounding Variables?

Most Experts will agree that the validity of a study is a direct function of the degree to which confounding variables are controlled. Get the Expert to admit that it is impossible to eliminate all confounding variables. Get them to identify which confounding variables cannot be eliminated, and how many confounding variables they require to be eliminated before the Expert will rely on a study. *See Dennis Mitchell*, 1999 WL 33923713 ("Dr. Rothstein criticized Dr. Phelan's research techniques. Proper statistical research requires removing all variables or confounding variables from the equation to. . . To do otherwise would result in the researcher drawing false & incorrect conclusions.").

26. Does This Study Eliminate All Confounding Variables?

If the Expert admits that the study did not remove all confounding variables, then find out which confounding variables *could have caused* the dependent variable (i.e., provide an alternative explanation).

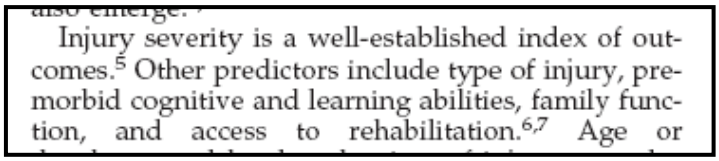
Definition Of Terms

27. How Does The Author Define Each Critical Term That Appears In The Conclusion Or Abstract?

Do not assume you know what a researcher means when they use a specific term anywhere in the study, especially in their review of the

existing medical literature, in their conclusions, or in the Abstract. Look for the definition of each critical term within the study itself.

Example: The authors of the excerpted study did not define the critical term "injury severity," but their use of the term suggested that it meant something other than the type of brain injury sustained by the study member.



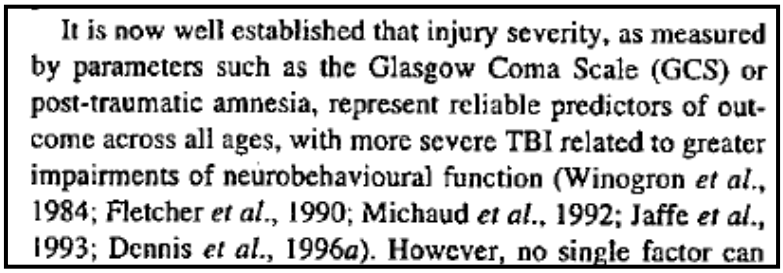
also emerge.

Injury severity is a well-established index of outcomes.[5] Other predictors include type of injury, premorbid cognitive and learning abilities, family function, and access to rehabilitation.[6,7] Age or

28. How Do Other Studies Define Each Critical Term?

Whether or not the author provides a definition for each critical term appearing in their study, check the cited studies to make certain that the authors did not change the definition.

Example: The authors of the excerpted study did not define "injury severity" in the study, but they defined it in a prior study (excerpted here) as a patient's Glasgow Coma Scale Score. Unfortunately, the plaintiff's Expert did not read the prior study, and assumed that the authors meant the (subjective) extent of neurological deficits and visible injury on diagnostic images.



It is now well established that injury severity, as measured by parameters such as the Glasgow Coma Scale (GCS) or post-traumatic amnesia, represent reliable predictors of outcome across all ages, with more severe TBI related to greater impairments of neurobehavioural function (Winogron *et al.*, 1984; Fletcher *et al.*, 1990; Michaud *et al.*, 1992; Jaffe *et al.*, 1993; Dennis *et al.*, 1996*a*). However, no single factor can

Study Members

29. How Does The Size Of A Study Population Affect Internal Validity?

The internal validity of a statistical association is often judged by the number of participants in the study. The smaller the study population, the greater the chance that the study's findings are due to chance.

30. How Many "Similar" Study Members Does The Expert Require Before Relying On A Study?

Ask the Expert if he or she requires a study to have a 1,000 study members who were "similar to the plaintiff." Work your way down to whatever study population the Expert is willing to rely on, then ask the Expert to define what he or she means by "similar to the plaintiff." If the

study classifies study members by demographic or injury characteristics, the Expert may adopt the criteria for the Plaintiff's classification.

31. What Is The Study Population?

Determine the number of study members who actually participated in the study, even though a large percentage of the study members may not have been "similar to the plaintiff" or in Plaintiff's classification.

32. How Were The Study Members Selected?

A study can be based on a random sample or a sample taken from a specific town or hospital. This information may not be apparent from the Inclusion and Exclusion Criteria.

33. What Were The Demographic Statistics Of The Study Members?

Studies which do not eliminate demographic variables as Confounding Variables often assess the Socio-Economic Status (SES) of each study member. In theory, by assessing the SES of each study member, the researchers develop the ability to classify study members based on SES, and to later determine whether there is a difference in outcome among members of different SES classifications.

Example: Researchers used the Scale of Occupational Prestige to rate parental occupations, and used the Family Function Questionnaire to rate intimacy, conflict and parenting style. Consequently, the SES classification of each study member, and the validity of all conclusions regarding SES, were based on the reliability of the Scale & the Questionnaire.

> *Injury and Demographic Variables*
>
> Children's medical and developmental histories, parental education and occupation, and family configuration were documented. During hospitalization, GCS scores, length of coma, neurologic abnormalities, and surgical interventions were recorded. Environmental factors (socioeconomic status [SES] and family function) were also assessed, given the previously reported relevance of such variables to recovery after TBI. SES was coded with the Scale of Occupational Prestige reported by Daniel,[24] which rates parental occupations on a 7-point scale, with high scores representing low SES. Family factors were measured (at all time points) with the Family Function Questionnaire,[25] which includes 3 scales, ie, intimacy, conflict, and parenting style.

Classification Of Study Members

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34. Were Study Members Classified?

Researchers may divide study members who satisfy the Inclusion & Exclusion Criteria by "classifying" the members of the study. For example, study members who satisfy the Inclusion Criteria that study members be less than 4 years old at the time of injury, may be *further* divided or

"classified" based on age (infant, young adult, adult), or injury severity (mild, moderate, severe).

NOTE: Do not remind an expert who is relying on a study (that he did not author) of the criteria used to classify study members *until after* you have asked him why he included plaintiff in a certain classification (*See* questions in section entitled "Classification Of Plaintiff," *below*). There is a chance the expert never determined the criteria used by the study.

35. Why & When Were Study Members Classified?

When a researcher classifies study members *before* a prospective longitudinal study, the classifications often reveal the researcher's belief or prediction that study members in the same classification will have similar outcomes, and members of different classifications will have different outcomes. Find out the basis for that belief.

Example: Researchers divided study members into groups based on their Glasgow Coma Scale Score and their ages. Researchers selected three ages, and explained their selection by noting that it was "made on the basis of theoretical grounds and recent research…" Counsel needed to learn everything about those theoretical grounds and recent research.

> Children were divided into groups on the basis of age at injury and injury severity, as follows: young TBI (n = 53), 3 year 0 months to 7 years 11 months at injury; old TBI (n = 69), 8 years 0 months to 12 years 11 months at injury. The age categorization was made on the basis of theoretical grounds and recent research supporting substantial changes in cerebral and cognitive development in infancy and before 8 years of age, with more gradual development from 8 to 12 years.[17,20,21]

36. Were Study Members Classified Using Subjective Criteria?

Medical studies can divide study members by objective criteria, including age, height, weight, school grade, date of injury, etc. Many medical studies, however, will distinguish study members based subjective criteria.

37. Was More Than One Criteria Used To Classify Study Members?

When a classification involves more than one criterion, the plaintiff may satisfy one criteria and not the other(s). In these instances, the expert must subjectively decide in which classification to place the plaintiff.

38. Was The Confounding Variable Equally Represented In Each Group?

A study should not classify study members by one confounding variable (i.e., injury characteristic), if that classification results in another confounding variable (i.e., demographic characteristic) being unequally

represented in each group. If groups are not fair and balanced, then they may not be capable of comparison.

Classification Of Plaintiff

39. Does The Expert Admit That Any Classification Of The Plaintiff Is Subjective?

When an expert relies on a study which involves a subjective classification of study members (especially by injury characteristics), make certain that the expert admits that the classification was subjective, and explains why the classification was subjective.

40. Why Did The Expert Include Plaintiff In That Classification?

When an expert relies on a study which involves a subjective classification of study members (especially by injury characteristics), find out why he included the plaintiff in a certain classification. You may be surprised by the reasons that you are given, especially if the expert only read the Abstract.

41. When Did Expert Include Plaintiff In That Classification?

It is possible that the Expert classified the plaintiff before receiving the data required by the medical study for that subjective classification. Compare the date that the expert issued a written report (either stating or assuming the classification), or provided opposing counsel with a "preliminary opinion," with the date that he received the required data.

Example: What if an expert was retained shortly before a deadline, and quickly issued a report citing the study in support of his conclusion that the plaintiff would have a bad cognitive outcome because he experienced moderate TBI, *even though* the expert had not yet received the documents and reports needed to classify the plaintiff (i.e., GCS score, neurological deficits at presentation, and objective evidence of injury)?

Differences Within Classification

42. How Is Plaintiff Similar To Study Members In That Classification?

A plaintiff who would have qualified for the study will always have all of the Inclusion and Exclusion Criteria in common with the other members of the study in a certain classification. If the classification is based on objective criteria (i.e., gender), then you already know how plaintiff is similar to study members in that classification. However, if the classification is based on more than one criterion, or on subjective criteria, identify every

characteristic other than the Inclusion & Exclusion Criteria that the plaintiff has in common with members of a certain classification within the study.

43. How Is Plaintiff Different From Study Members In That Classification?

This is the real question. If the classification is based on a single, objective criteria (i.e., gender), the plaintiff may not be different from other members of the classification. However, if the classification is based on more than one criterion, or on subjective criteria, determine every possible characteristic about the plaintiff (including injury and medical characteristics) which distinguishes plaintiff from members of a certain classification within the study.

Example: The table (below) tells us the average GCS score for infants in each classification (Mild, Moderate & Severe TBI); and it tells us how many infants in each classification spent more than an hour in a coma. The table indicates that thirteen (13) of the infants who experienced "Moderate" TBI, and all eight (8) of the infants with "Severe" TBI, spent more than an hour in a coma. If the plaintiff had a GCS score of 10.2, but never spent a second in a coma, should the plaintiff be classified in the "Moderate" category?

TABLE 2. Injury and Medical Characteristics of the Sample According to Age at Injury

	Infant TBI		
	Mild	Moderate	Severe
Coma characteristics			
GCS score (24 h), mean (95% CI)	13.0 (10.8–15.0)	11.4 (10.2–12.6)	9.0 (7.3–10.7)
Coma of >1 h, no. (%)		13 (86.7)	8 (100.0)
Abnormal CT/MRI findings, no. (%)		11 (73.3)	5 (62.5)
Fractures (nonlinear)		9 (33.3)	2 (15.4)

Limited Data About Study Members

44. What Did The Article Reveal About Each Study Member?

Most medical studies will have finite information about each study member. Find out if the study members were interviewed, or if they just completed a form or application.

45. What Do You Know About The Plaintiff That You Do Not Know About Each Study Member?

An Expert will always know more about the plaintiff than the study members. An Expert often has access to the plaintiff's diagnostic images, to the plaintiff's medical records, and treating physician reports. An Expert often also has the depositions of eyewitnesses, family members, doctors, caretakers, and to the plaintiff. You need to know what the Expert knows

about the plaintiff's injury and recovery that the Expert does not know about each study member.

46. What Additional Information Would The Expert Like To Know About Each Study Member?

Experts understand the limitations of a medical study, and are often willing to discuss what additional information they would like to know about each study member. This information may include diagnostic images, performance on certain tests, and physical examinations. Do not limit yourself to those images obtained or tests actually administered. Ask the Expert to forget what the treating physicians and caretakers did, and tell you what he wishes they had done. This can be incredibly revealing.

47. Why Would The Expert Want To Know That Information About Each Study Member?

Once an Expert has testified that he or she would like additional information, make the expert explain why.

48. Is The Presence Or Absence Of An (Unknown) Characteristic Among Study Members A Confounding Variable?

If an Expert *would like to know* more about the study members, then the information they would like to know can sometimes provide an alternative explanation for the statistical association. The information can reveal a confounding variable which the authors of the study either did not consider, or did not address with their Inclusion Criteria, Exclusion Criteria, or Classifications.

Bias & Effect Of Subjective Classifications

49. How Would The Expert's Opinion Been Different If The Expert Had Subjectively Classified Plaintiff Differently?

An Expert will never admit bias, but an Expert may admit that, *if he* had classified the plaintiff differently (i.e., Mild TBI vs. Moderate TBI), then the medical study would not have supported the principles or conclusions he reached (and for which he cited the study).

50. Did Expert's Subjective Classification Benefit The Attorney Who Retained The Expert?

It is difficult to get Experts to admit that they hunted for medical studies that *specifically* supported a claim made by the attorney who was paying

the bills. However, you may be able to get the Expert to admit that his classification benefited his employer.

51. Was The Expert Aware That The Subjective Classification Would Benefit The Attorney Who Retained Her Or Him?

Do not forget to establish that the Expert, at the moment he made the subjective decision to include the plaintiff in one classification instead of the other, knew that his decision would benefit the Attorney who retained her or him.

Control Group

52. What Is A Control Group?

A control group is a comparison group. The members of a control group are people who would otherwise qualify for the study (i.e., satisfy every Inclusion and Exclusion Criteria), except they do not have the condition, illness, or trauma (the Independent Variable) being studied.

The purpose of a control group is to show what would normally happen, and to compare it with what happens when you change the independent variable. In theory, this comparison is an indicator of whether the Independent Variable is really responsible for the Dependent Variable.

Example: In a prospective longitudinal study of the association between age and traumatic brain injury among children, a control group would include children who satisfy all of the Inclusion and Exclusion Criteria, except they have never sustained traumatic brain injury.

53. Have Similar Studies Used Control Groups?

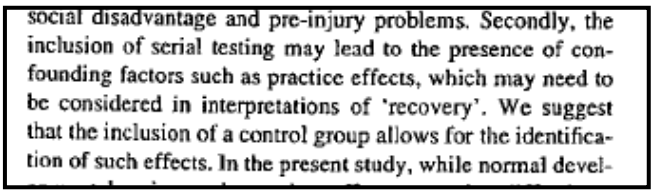
It is important to establish that other studies, with similar objectives, employed a control group. Correctly or incorrectly, judges and jurors will often consider a study which employs a control group as being "more reliable" or "more valid" than a study which does not.

Example: The authors of the excerpted 2005 study did a prior study in 2004 in which the authors used a control group.

54. Why Did Similar Studies Use A Control Group?

Researchers who select and use a control group often explain the basis for their decision. That explanation usually identifies a confounding variable, and explains why the researchers believed that the control group would eliminate that confounding variable.

Example: In the 2004 study, the researchers admitted that serial testing could lead to confounding variables, and explained that the inclusion of a control group allowed for the identification of "such effects."


social disadvantage and pre-injury problems. Secondly, the inclusion of serial testing may lead to the presence of confounding factors such as practice effects, which may need to be considered in interpretations of 'recovery'. We suggest that the inclusion of a control group allows for the identification of such effects. In the present study, while normal devel-

55. How Did The Control Group Perform In Those Similar Studies?

If similar studies have used a control group, determine how the control group performed in those studies. It may tell you why the present study decided not to use a control group.

Example: In the 2004 study, the children who sustained "Moderate TBI" actually scored *better* on all but one language test administered 30 month after the injury. On this language test, their scores were within the standard deviation. This may explain why researchers decided not to use a control group for their 2005 study.

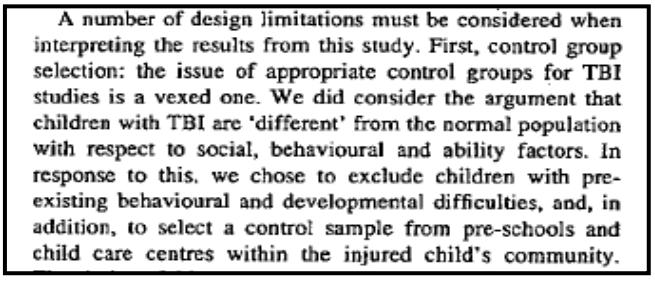
56. Did This Study Use A Control Group?

The study will compare the control group and the study population. Find out what, if anything, the Expert recalls about the control group.

57. How Was The Control Group Selected?

It is important to know as much as possible about the control group. If the study reveals that there is a difference between the study population and the control group, counsel needs to know if there are any confounding variables specific to the control group.

Example: In the 2004 study, the authors admitted that there is an "issue of appropriate control groups for TBI studies," and tried to address the confounding variable by selecting the control sample from the injured child's community.


A number of design limitations must be considered when interpreting the results from this study. First, control group selection: the issue of appropriate control groups for TBI studies is a vexed one. We did consider the argument that children with TBI are 'different' from the normal population with respect to social, behavioural and ability factors. In response to this, we chose to exclude children with pre-existing behavioural and developmental difficulties, and, in addition, to select a control sample from pre-schools and child care centres within the injured child's community.

58. How Did The Study Eliminate Natural, Biological & Environmental Confounding Variables?

Different study members are born with different natural abilities, and are raised in different environments. In studies that do not employ a control group, some researchers try to eliminate confounding variables by assessing pre-morbid ability and function.

Example: Researchers recognize that different children are born with different cognitive abilities. In order to address this confounding variable, they tried to determine the "Preinjury Abilities" of each child, and they based that determination on a questionnaire which they provided to the parents of each child. Is a parent's memory of how an infant functioned before an injury a reliable indicator of how that child functioned, or that child's cognitive ability?

> *Preinjury Abilities*
>
> The VABS[23] was completed by parents on the basis of children's preinjury functioning. Four measures were derived, ie, communication, daily living skills, socialization, and total adaptive behavior score (mean: 100; SD: 15).

Measures

59. How Was Initial Participation In The Study Encouraged?

A study can provide monetary and other incentives, which are more effective with certain members of the study. It can have a direct effect on the demographic characteristics of the study population.

60. What Was The Method Of Assessing The Dependent Variable?

The reliability of a study depends on the reliability of the method of assessing the dependent variable. The test or method used to assess the dependent variable is often called a "measure," and there is a difference in reliability between using objective testing as a measure, and using subjective interviews or questionnaires.

Example: In the study, researchers assessed outcome or cognitive ability (dependent variable) by administering the Bayley Scales of Infant Development. As such, the reliability of the study depends on the reliability of that measure.

> For children in the infant TBI group, the Bayley Scales of Infant Development[28] were administered. A Mental Developmental Index (MDI) was derived from this measure, reflecting global intellectual ability. The MDI has psychometric properties similar to those of the Wechsler scales, as described above (mean: 100; SD: 15).

61. Why Did They Select That Method Of Assessment?

If the Expert authored the study, then this is usually a very interesting question. If the Expert did not author the study, then the question can sometimes: (1) establish the Expert does not know the reason why a method of assessment was selected; and (2) encourage the Expert to reveal everything the Expert knows about the method of assessment.

Example: In the study, researchers explained that they selected the Bayley Scales Of Infant Development because the Bayley Scales were similar to the testing administered to the young and old TBI groups.

> For children in the infant TBI group, the Bayley Scales of Infant Development[28] were administered. A Mental Developmental Index (MDI) was derived from this measure, reflecting global intellectual ability. The MDI has psychometric properties similar to those of the Wechsler scales, as described above (mean: 100; SD: 15).

62. Is That Method Of Assessment Scientifically Reliable?

If the reliability of the study depends on the reliability of the method used to assess the dependent variable, then researching the strengths and weaknesses of that method is often an excellent investment of time and money.

63. What Is An Alternative Method Of Assessment?

Different researchers favor different methods of assessment. Find out what "other" tests or methods are being used by researchers, and locate one of those researchers to find out why they prefer the "other" method.

64. What Was The Period Of Assessment?

Find out the first year of contact with (i.e., testing, interviewing, or assessing) study members, and the most recent contact with study members.

65. What Was The Frequency Of Assessment?

Find out how many times during that period of assessment the study members were
e measured (i.e., tested, interviewed, assessed).

Retention Rate

66. What Was The Retention Rate?

Prospective longitudinal studies can require long-term contact with large cohorts. A major focus of these studies is the retention of those large cohorts, especially when contacts are years apart. The retention rate is typically measured at each contact (interview, measure, assessment). The numerator of the retention rate is the number of people who were measured during that contact, and the denominator is the number of people who originally participated in the study.

67. Why Is The Retention Rate Important?

Biased attrition can lead to an incorrect estimate of the relationship between variables, and the association between Independent and Dependent Variables. For example, in evaluation studies of substance abuse treatment programs, when sizable numbers of participants were not retained for follow-up, the evaluations overestimated treatment effects or demonstrated sample selectivity.

68. How Did Attrition Affect The Cohort & The Control Group?

Compare the characteristics (i.e., demographic and injury characteristics) of the retained cohort with those of the original cohort, and compare the characteristics of the retained control group with the original control group.

69. How Did Attrition Effect Plaintiff's Classification?

A study can have a high retention rate, and still lose a majority of the members in Plaintiff's classification. Always determine how many members of Plaintiff's classification were actually measured (i.e, tested or assessed).

70. How Was Subsequent Participation (Retention) Encouraged?

A study can provide incentives that are more effective with certain members, and can cause biased attrition. Find out what techniques the researchers used to retain resistant subjects.

National Statistics

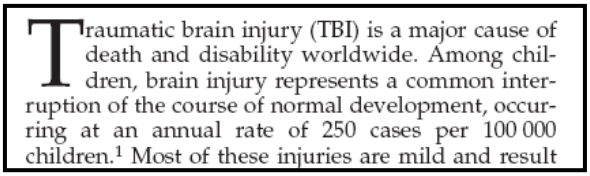
71. What Percentage Of Study Members Developed The Condition Or Experienced The Outcome Studied?

Determine the percentage of the study members who actually developed the condition, or experienced the outcome. Then, determine the percentage of study members who were *similar* to the plaintiff (demographic characteristics, injury characteristics, etc.), and who actually developed the condition, or experienced the outcome.

72. How Many Americans Would Have Qualified For The Study?

Determine how many Americans would have qualified for the study. Some studies will provide you with an estimate while trying to define the scope of the problem, or the need for the study. If the study does not contain an estimate, then counsel will have to research the answer. An excellent resource for statistics is the website for the U.S. Census Bureau (www.census.gov) which contains a statistical abstract supplement which distinguishes population based on certain criteria, including age, gender, race, and State.

Example: The study involved study members who experienced traumatic brain injury during childhood. The study itself stated that there are 250 cases annually of TBI per 100,000 children.



Traumatic brain injury (TBI) is a major cause of death and disability worldwide. Among children, brain injury represents a common interruption of the course of normal development, occurring at an annual rate of 250 cases per 100 000 children.[1] Most of these injuries are mild and result

73. Is The Percentage Of Study Members Consistent With National Statistics?

In theory, the percentage of study members who developed the condition or experienced the outcome studied should be the same as the percentage of Americans (who would have qualified for the study) who have developed the condition or experienced the outcome studied.

Example: The authors of the study indicated that traumatic brain injury among children occurs "at an annual rate of 250 cases per 100,000 children." If there were 20 million children under the age of 5 in 2005, then there should have been 50,000 children should have experienced traumatic brain injury. Hypothetically, if 5% of children who participated in the study were unable to care for themselves as adults, and the study was an accurate predictor of outcome, then 5% of the 50,000 children (or 2,500 children) who experienced TBI in 2005 will be unable to care for themselves as adults. Is this the case?

74. How Does The Percentage Observed Among Study Members Differ From National Statistics?

Experts will rarely know what the national statistics are. In a deposition, it is usually sufficient to get them to admit that they have not considered checking national statistics to determine whether their percentage of study members is consistent with the national percentage.

75. How Does The Expert Explain Any Difference Between The Study Member Percentage & The National Percentage?

As a matter of strategy, you have to decide whether to present the Expert with the difference between the percentage of study members and the national percentage, or wait until trial and do it during your cross-examination of the Expert (or during your direct examination of your own Expert).

Expert's Methodology

76. Was The Plaintiff A Member Of The Study?

This question reminds the Expert (and later the fact-finder) that the Plaintiff is not represented in any chart or graph or finding in the study. It draws a line between the Plaintiff and the study members.

77. Is The Expert Predicting That The Plaintiff Will Experience The Same Outcome As Study Members?

If the study did not involve the plaintiff, then the Expert is predicting that the Plaintiff will experience the same outcome as the members of the study because of a statistical association among members of the study.

78. According To The Study, What Is The Likelihood That Plaintiff Will Experience The Outcome (Dependent Variable)?

This is the fish or cut-bait question. If the study establishes an association between the independent variable and the dependent variable, then the Expert should be able to answer this question. If the study does not, then the Expert will have to admit that the study does not establish a percentage for Plaintiff's Classification.

79. According To The Expert, What Is The Likelihood That Plaintiff Will Experience The Outcome (Dependent Variable)?

In many cases, the Expert will conclude that it is "more likely than not" that the Plaintiff will experience the outcome, but will admit that there is no exact number or range of statistical probability.

Example: The neuropsychologist who relied upon the excerpted study testified during his deposition that it was more likely than not the Plaintiff would experience the outcome. When pressed, the neuropsychologist stated that the likelihood the Plaintiff would experience the predicted outcome was "50% to 100%." The neuropsychologist later admitted that he made up that number range.

80. Is The Expert's Prediction Based On Only This Study?

Experts often rely on more than one medical study in support of their conclusion. When this occurs, the Expert usually reaches a conclusion, or makes a prediction, which is beyond the scope of either study. Ask the Expert if his or her prediction is based *only* on the study members in the present study, or *only* on the association established by the present study.

81. What Was The Expert's Methodology For Making That Prediction?

Many Experts just read the medical studies, and then they give an opinion. That is called "*ipse dixit*." Some will say that there was no methodology because the study obviously applies to the Plaintiff. Ask the Expert what they *physically* did before making their prediction

82. Did The Expert Consider Any Conflicting Findings, Factors, Or Studies?

Experts will often admit that they "considered" conflicting findings and studies. If an Expert "considered" conflicting findings, factors, or studies, which could be applied to members of Plaintiff's classification, then the Expert has to explain: (1) how they reconciled those findings, factors, and studies; or (2) how they factored those conflicting findings and studies into their prediction, and get them to describe their specific methodology.

83. What Weight Did The Expert Assign To Conflicting Predictors Or Studies?

Most experts do not identify, let alone assign a specific weight, to each predictor (independent variables) of outcome. Most experts will admit that there is "no mathematical formula." When pressed, many experts will admit that they "just gave more weight" to a specific factor, or a specific medical study. Make the expert explain what weight he or she gave to each predictor of outcome. Make the expert explain his decision to use one study, and ignore another.

Example: The neuropsychologist who relied upon the excerpted study predicted a bad outcome based on the plaintiff's age and location of injury. The expert admitted that GCS scores were also predictors of outcome, and that plaintiff's GCS score predicted a good outcome. He testified that he "considered" the plaintiff's GCS score, but it did not change his prediction. When asked what weight he assigned to the GCS score, the expert admitted that there is no mathematical formula, but he assigned "equal weight" to all three factors.

84. Did The Expert Previously Publish This Opinion?

There is no difference between a prediction and an opinion. If the Expert has read medical studies, and discovered an association which allows him or her to predict the occurrence of a certain outcome (dependent variable), then counsel has a right to know if he has published that opinion. Identify all of the Expert's opinions which are based on the medical study. Find out if the Expert has published an article which included those opinions, or an article which cited the medical studies relied upon.

85. Did The Expert Develop The Opinion For This Litigation?

There is a difference between remembering and fishing. Some experts get the call from an attorney, and are already familiar with the relevant studies because they previously treated a patient, written an article, or researched the issue. Other experts get the call from an attorney and start looking for an answer. Find out when the Expert performed the literature review or research during which she or he found and read the study.

86. Where Did The Expert Find The Study?

Did The Expert obtain the article from the internet? Find out the website, and go there. There may be links to similar articles which the Expert did not cite or read which reach different conclusions.

87. How Did The Expert Find The Study?

Did The Plaintiff send the Expert the Study? Did the Expert do a word search on Google or some other search engine? If so, find out what search was run, and what articles were identified by that search.

88. How Long Did The Expert Spend Researching?

Whether the Expert already knew the answer or not, you want to know how long the Expert spent researching the issue.

89. How Much Did The Expert Bill For Researching?

Experts will often testify that they spent "days" researching an answer to a question, and then their bill indicates that they charged the attorney for "3 hours" of research. Get a copy of their bill.

90. Did The Expert Read Only The Abstract?

You will be surprised how often an Expert reads an Abstract, and either quotes directly from the Abstract, or includes the study in a string-citation.

Bias In Expert's Research & Report

91. Why Did The Expert Cite Medical Studies In Their Report?

If the Expert is asked why he cited each medical study, the Expert will probably answer by reading the sentence which cited each study. However, if counsel asks the more general question of why the Expert routinely includes citations in his or her report, counsel can get some interesting responses. The answer may lay a foundation for asking why the Expert did not cite conflicting medical studies. The answer may also uncover any professional feelings the Expert has about his having to cite medical studies to support his or her opinion.

92. Did The Expert Find Or Read Any Conflicting Studies?

Many medical studies begin by reviewing the existing medical literature, and calling attention to any differences in opinion within the scientific community, or to differences in prior study results. Did the Expert take the time to read all of the conflicting medical studies cited in the present study? Did the Expert read the studies cited in those conflicting studies?

93. Why Did The Expert Omit Conflicting Studies From Report?

If conflicting medical studies exist, then the jury is entitled to know why the Expert omitted them from his or her report. The answer to this question can establish the Expert's bias, and destroy the Expert's credibility.

94. What Did The Study Report About Study Members Who Were In Plaintiff's Classification?

Experts have a tendency to cherry-pick. Find out all of the data, measures, comparisons and conclusions reported by the cited study regarding Plaintiff's classification (i.e., about "Moderate TBI").

95. How Does The Expert Explain Any Reported Conflicting Data Or Conclusions About Plaintiff's Classification?

It is easier to quote a medical study, than to defend it. When a medical study reports conflicting data about the Plaintiff's Classification, make the Expert explain how that could happen, and its effect on the study.

96. Why Did The Expert Fail To Report The Conflicting Data Or Conclusions About Plaintiff's Classification?

Jurors do not like intentional omissions. If the Expert intentionally omitted conflicting conclusions, or even differences between Plaintiff and other members of Plaintiff's Classification, then this question can establish Bias, and destroy the Expert's credibility.

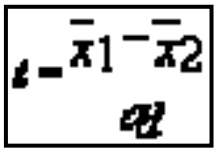
Tests Of Significance

97. Why Do Researchers Use Tests Of Significance?

A "Test of Significance" is a statistical test used to calculate the significance of observed differences between the mean of two samples. The null hypothesis holds that there is no significant difference between the means of two samples; and, therefore, the results of the study could be random. Tests of Significance allow researchers to prove that there is a significant difference between the means of two samples, and to reject the null hypothesis.

98. What Tests Of Significance Did This Study Use?

There are different Tests of Significance. The T-Test Of Significance determines whether the t-value exceeds the calculated tabulated value.



The Chi-Square Test of Significance determines the square of the difference of the observed ("o") and expected ("e") amounts, and then divides that number by the expected ("e") amount. If the Chi-Square value is greater than the critical value, then researchers can reject the null hypothesis.

$$\text{Chi-Square Value} = \sum \frac{(o_n - e)^2}{e}$$

99. What Significant Predictors Of Outcome Did The Study Identify?

Is the "t-value" far from 0? The T-Test of Significance produces a t-value. If the t-value is far from 0 (either + or -), then the researcher can reject the null hypothesis.

Is the *p*-value less than .05? The Chi-Square Test of Significance produces a p-value. The p-value is the probability of obtaining a result at least as extreme as a given data point, *assuming* the data point was the result of chance alone. If the p-value is less than the significance level (usually .05), then researchers can reject the null hypothesis

Example: In the 2004 study, researchers rejected the null hypothesis based on the t-value and p-value, and concluded that the Glasgow Coma Scale score for the study members 24 hours after the injury was a significant predictor of injury.

Table 5 *Significant predictors of outcome at 30 months post-injury*

Predictor variables	FSIQ	VIQ	PIQ
GCS 24 h			
β	0.36	0.29	0.37
t value	3.52	2.80	3.44
P	0.001	0.006	<0.001

100. What Statistical Association Did The Study Suggest?

The mere existence of a statistical association between the occurrence of the independent and dependent variable does not prove that the independent variable caused the dependent variable.

Medical and behavioral studies seek to measure degrees of probability, not causality. Uncertainty is never completely abolished in any form of behavioral or medical science statistical manipulation. Therefore, conclusions must be defined in terms of 'suggestions' or 'associations' rather than causes. This is not due to some inaccuracy or vagueness of the technique or conclusion, but rather is intrinsic to the properties of statistics. *Adams v. Cooper Industries*, 2007 WL 1075647 (E.D. Ky 4/4/07).

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Mr. Glas is a partner in the firm, and a member of the Civil Litigation Department. A significant portion of his practice involves Product Defect, Transportation, Negligent Security, Premises Liability, Intentional Torts, Toxic Exposure, and General Aviation cases throughout Louisiana.

Mr. Glas focuses on handling brain trauma claims, and has tried to verdict four brain trauma cases in the last four years. He has lectured on the testimony of neuroposychologists and neurosurgeons at legal education seminars, and serves as the moderator for Lorman Educational Services' annual one-day *Fundamentals Of Brain Trauma Cases* Seminar in New Orleans.

He has handled several cases for the oil and gas industry, including defending against claims involving plant exposure, scaffolding accidents, equipment failure, premises defect, slip & fall, and work-related auto accidents.

Mr. Glas has also defended manufacturers and owners of equipment against claims that their machinery is unreasonably dangerous by design under the Louisiana Products Liability Act. He has defended the design of 900-Series streetcars, mobile containeramps, and bucket trucks.

Mr. Glas has defended numerous commercial airlines, handling claims arising out of boarding accidents, claims governed by the Warsaw Convention, and claims brought under the Louisiana Products Liability Act.

Mr. Glas has defended law enforcement personnel in Parishes throughout Louisiana, as well as the leading manufacturer of electronic control devices, against claims filed by criminals and prisoners.

Mr. Glas has defended companies and employees against claims filed by co-workers who alleged that their workplace accident was the result of intentional tort and that their claims fell under the intentional tort exclusion to the Louisiana Workers Compensation Act.

Before joining the firm in 1999, Mr. Glas served as an assistant district attorney for the Parish of Orleans.