

Minutes of the Meeting of the Blue Ribbon Panel (BRP)
for Evaluation of Advanced Airbags

August 10-11, 2005

Chairperson, Dr. Susan Ferguson, called the meeting to order at 2:00 P. M. on August 10, 2005 in the City Club of Washington at Franklin Square in Washington, D.C. All panel members and observers were present with the exception of members, Mr. Timothy Hoyt (Note: Mr. Hoyt was present for the continuance of the meeting on the 11th), Dr. Jeffrey Augenstein and Dr. Maria Segui-Gomez (Note: Dr. Segui-Gomez participated by teleconference on August 11th as a respondent to the Request for Proposal issued by the BRP). NHTSA had several staff from the National Center for Statistics and Analysis (Mr. John Kindelberger and Mr. Santokh Singh) sit in, in addition to regular BRP observers Dr. Joseph Carra and Mr. Chip Chidester, to help with specific questions about the NASS and FARS data files.

Dr. Ferguson noted that three proposals had been received in response to the Request for Proposal for Analysis of Crash/Injury Databases re: Frontal Crash Protection in Airbag Equipped Vehicles. The three respondents were: National Study Center (NSC) for Trauma and Emergency Medical Systems at University of Maryland, The Pacific Institute for Research and Evaluation (PIRE), and the Department of Health Policy and Management of the John Hopkins Bloomberg School of Public Health.

There was some discussion of the relative merits of the individual proposals that ultimately led to a decision to prepare a set of general questions to be asked of all the respondents. The proposers were to be interviewed individually on the following day. In addition, several questions, which applied to particular proposals, were developed and assigned to panel members. It was decided that the general questions would be asked by Chairman Ferguson. The general questions were as follows:

1. Looking at the historical context of the research that has been conducted to date, what is unique in your proposal with regard to methodology, approach, and selection of variables that would give the BRP more confidence in your research findings?
2. What are the challenges in using NASS/CDS data and how do you propose to overcome these challenges?
3. Which among these challenges do you consider the most critical when addressing the three questions posed in the RFP?
4. When including ΔV as a variable of interest, how do you plan to treat the issue of missing values?
5. What are the issues involved with analyzing weighted and un-weighted data in NASS/CDS?
6. Discuss your choice of databases; how did you decide which datasets to use?

The meeting was adjourned at 5:00 P.M. and then reconvened at 8:30 A.M. on August 11, 2005.

The first interview was conducted with Dr. Maria Segui-Gomez of the University of Navarra by teleconference. In response to question no.1, Dr. Segui-Gomez said that she proposed to use injury preventive measures that have been rarely applied. One particular method that Dr. Segui-Gomez mentioned was propensity scores wherein mathematical modeling that creates a distribution is used. Second, she said that model year would be used as the primary independent variable and a “safety variable” would be developed in an effort to detangle airbag safety from other changes in the vehicle. Third, they would try to keep a broader injury prevention view over time by trying to check improvement over time using a policy perspective. Fourth, they would use a marriage of biomechanical engineers and statisticians to help choose systems to study and to help understand the results.

Dr. Ferguson asked for an expansion of the explanation of the “safety variable.” Dr. Segui-Gomez said that 5 to 8 variables in NASS that measure attributes that relate to vehicle safety would be combined into a single safety index variable. Some of the variables mentioned included head restraint type, antilock brakes and seat belt tensioners.

In response to question no.2, Dr. Segui-Gomez responded that if NASS is truly representative of the Nation then it should replicate FARS in terms of fatalities; however, very few of the fatalities are captured in NASS. Dr. Segui-Gomez noted that fatalities have been fairly well analyzed already. With regard to children, when it comes to breakdown of the data we will run into sample size limitations.

Dr. Larry Schneider asked why the oldest data was limited to 1994 NASS. Dr. Segui-Gomez responded that age can be a confounder and that NHTSA analysis in 2005 showed that the fatality risk from airbag peaked in 1994-96 and therefore the analysis would be cleaner if limited to no older than 1994. Dr. Segui-Gomez said that enough data would still be available without going back further.

In response to question no.3, Dr. Segui-Gomez said that developing a safety index that was comfortable to everyone would be a challenge. Also, determining at the end of the statistical analysis how the results relate to airbag system design changes would be a challenge.

In response to question no.4, Dr. Segui-Gomez said that in order for ΔV to be a confounder it must have an effect on injury outcome and on the effect of the airbag. They will use ΔV in some analyses, such as the when deployed analyses, but not others.

In response to question no.5, Dr. Segui-Gomez said that from a logistical point of view use of weighted vs. un-weighted data is not a problem. Conceptually, however it is a different issue. If talking about the Nation you need to use weighted data. The weights are not perfect. The variables that determine the weights may also be confounders in the analysis so you may in effect be double counting if you adjust for these variables. Dr. Constantine Frangakis, Professor of Biostatistics, will be very helpful in understanding the inevitable differences in results when comparing the use of weighted vs. un-weighted data.

Dr. Ferguson asked about the choice of outcome measures when addressing Aims 1-5 in their proposal. Dr. Segui-Gomez responded that injury severity by AIS level could check whether

there is an MAIS; also by particular body region. ISS or NISS could be incorporated and propose to use Functional Capacity Index (FCI) to assess long-term effects. In the end results could be expressed in dollars, considering both direct and indirect costs. Dr. Segui-Gomez indicated that they plan to use a wide range of outcomes covering injury, fatality, long range and costly.

Dr. Durbin noted that the approach is model year by model year and asked what the baseline was. Dr. Segui-Gomez said the baseline is MY 94-96 when the injury rate from airbags was highest.

Dr. Durbin asked for an explanation of the concept of propensity scores. Dr. Segui-Gomez responded that it is one of the means to counter factual statistics. Mathematical modeling can create a probability distribution. For example you could develop a probability distribution that Mister X is driving different model year vehicles in any particular crash. She said the latest paper by Dr. Ellen McKenzie includes propensity analysis in analyzing outcomes of people transported to trauma centers vs. hospitals.

The second interview was conducted on-site with Dr. Elisa Braver and Mr. Timothy Kerns from the NSC at the University of Maryland. In response to question no.1, Dr. Braver said that the proposed analyses will give us a chance to look at new airbag designs with more answers to tradeoffs between reducing risk of airbag induced injury vs. protection for unbelted males in the more severe crashes.

She said that the analysis using head-on collisions in FARS is unique as is the analysis using FARS data in the numerator with GES data in the denominator. The platform based analysis is unique in its ability to help control for biases. Use of multiple denominators will let us get better answers about efficacy of the technology.

Dr. Schneider asked: “in head-on analysis using FARS, how do you control for variables such as type of impact?” Dr. Braver responded that you match vehicle type and size within type.

In response to question no.2, Dr. Braver said they have proposed to use FARS in addition to NASS because of the limited number of fatalities in NASS. In NASS to deal with missing data you need to look at the results and make an informed interpretation. Dr. Braver noted that in the report “Who Wants Airbags”, authors M.C. Meyer and T. Finney did not question the results.

Dr. Durbin asked what experience they had with missing data in NASS. Dr. Braver responded that you have to be very thoughtful about comparing weighted vs. un-weighted data and try to understand if it makes sense.

Dr. Schneider asked for further commentary on the Meyer/Finney report. Dr. Braver said that they threw out half the data (those without known ΔV and some other variables) but then used many variables to break out the analysis.

In response to question no.3, Dr. Braver said that the strength of the NASS is the injury data by body region. Dr. Ferguson followed up with: How will you treat missing ΔV values? Dr. Braver

said that some have imputed ΔV but didn't know whether it was reasonable to use multiple imputations.

Dr. Durbin asked if they have used imputation in the past. Mr. Timothy Kerns responded that they had used imputation to calculate belt use. In the new SAS there is an algorithm for imputation. Dr. Braver added that she thought imputation is questionable when the missing data is a large percentage, e.g. something like 75%.

Dr. Ferguson asked about the rationale for using both FARS and NASS data. Dr. Braver responded that it provides a more complete picture. Different methods have strengths and limitations. By using multiple analyses you get a better approximation of the truth.

Dr. Schneider asked about how they would separate out the behavioral effects (such as moving children to the rear seat) from the effects due to airbag system changes. Dr. Braver said that the denominator from GES accounts for some of the changes. However, it is conceivable that advanced airbag designs are confounded with results and may not be totally separable.

Dr. Ferguson asked for an elaboration of the statistical regression analysis techniques to be used. Dr. Braver said that they think that negative binomial regressions may have some advantages. One theory is that you put all possible variables into the model, but there needs to be more thought given to whether to include all possible, as there needs to be a relationship. If you put too many variables into the model you get collinearity.

Dr. Durbin asks if strata analysis or multivariate regression analysis is the proposed primary analysis technique. Dr. Braver responded that you need to explore both and understand what the data is telling you.

Dr. Ferguson asked if they plan to control for vehicle age. Dr. Braver responded that many discussions and results in past studies of vehicle age are all over the place, some showing increased crash experience in newer vehicles and other studies showing the opposite. It is important to control carefully for calendar year. They will explore vehicle age by calendar year.

Dr. Ferguson asked about the rationale for waiting for 2005 NASS data. Dr. Braver said that it is essential to wait for the 2005 NASS data if you are interested in studying Certified Advanced Compliant (CAC) airbag systems. 2005 data will probably double the number of CAC vehicle crashes.

Dr. Schneider asked about the effects of waiting for 2005 data on the timing and cost of the study. Dr. Braver said that it will effect both time and cost but that she thinks it is important to analyze the CAC vehicles.

Dr. Durbin asked what years of NASS data will be used. Dr. Braver said that 2000 to 2005 NASS data will be used. Dr. Ferguson asked why not earlier data. Dr. Braver said they are trying to do model year specific analysis but there may be some advantage to using earlier NASS data and that she may need to revisit that issue.

Dr. Digges asked what outcome we can expect. Dr. Braver responded that initial results have been encouraging with regard to the performance of the newer airbag systems but there are some indications that certain areas have adverse effects, e.g. her FARS analysis showed that newer pickup trucks had fatality odds ratios 35% higher with the newer airbags. We want to see if injury patterns have changed by body region, with AIS \geq 2 being of most interest. Are there certain injuries that are occurring more often? You need to look at overall injury as well as injury distribution by body region and severity.

Dr. Schneider asked about the overall level of effort. Dr. Braver responded that they will use a team approach at the University and that not all participants are listed in the proposal. Different people will be used as needed.

Mr. Tom Carr asked if the University policy on academic freedom prohibits comments in the final report by the sponsor. Dr. Braver and Mr. Timothy Kerns both responded that they have seen final reports that contained comments and disclaimers that had been inserted by the sponsor and that they were not aware of any prohibitions on the part of the University to that effect.

Mr. Danius Dalmotas asked about the advantage of the head-on analysis approach. Dr. Braver said that the technique sheds light on whether there are differences in performance of the airbag systems, since presumably this technique controls for differences in drivers and other confounders. Mr. Dalmotas asked what measures would be used for the net effect. Dr. Braver responded: death, severe head injury and chest injury.

Dr. Durbin commented that death and head injury are good numerators, and asked what the good denominators are. Dr. Braver said that GES is a good denominator because it gives a good idea of given a crash what is the outcome. She went on to say that each denominator may shed additional light on the answer.

The third interview was conducted on site with representatives of PIRE. PIRE was represented by: Dr. George Bahouth, Dr. Ted Miller and Dr. Edward Zaloshnja. In response to question no.1, Dr. Bahouth said that the approach uses logistic regression; the unique aspect is to predict cost, which is a continuous outcome variable. The use of a continuous scale will add power to the regressions and more likely lead to findings of statistical significance. Dr. Miller added that the unique aspect is the marriage of biomechanics, economics and statistics.

Dr. Durbin asked how they will interpret cost differences. Dr. Miller offered that cost is something the average person can relate to. He would compare the differential costs to the cost of overall crashes.

Dr. Schneider asked: Are you saying that costs only analysis can analyze by body region? Dr. Miller responded that it goes to the power of the analyses. Mean injury costs by body region are expected to provide true differences in injury prevalence and severity even at the body region level.

Dr. Digges asked if the costs have been peer reviewed. Dr. Miller responded that the costs were developed for NHTSA and have been used in their regulatory analyses for many years. The

Office of Information and Regulatory Analysis at OMB has praised NHTSA regulatory analyses as the best in government. Dr. Digges asked how the costs were developed. Dr. Miller said that the medical costs come from hospital discharge records and the work loss costs come from MEPS and BLS data. Quality Adjusted Life Years are the standard measure used in cost-effectiveness analyses of health interventions.

Dr. Schneider asked about the correspondence between cost and likelihood of injury. Dr. Miller said that if you are not injured the cost is zero. They have not done a regression between cost and the likelihood of injury. Dr. Zaloshnja added that the regression does not give answers about marginal differences.

Dr. Digges asked why we should have confidence in functional loss compared to Functional Capacity Index (FCI). Dr. Miller noted that some of the details of FCI are still being worked on but that NHTSA will soon be using FCI in future regulatory analyses.

Dr. Ferguson asked question no.2. Dr. Bahouth responded that the mechanisms of injury are often not easily identifiable. He suggested that it may require the help of the BRP. It also may be difficult to determine the influence of such things as seat belt pre-tensioners and load limiters. He suggested that other databases, such as the NCAP program, may provide better indicators. NHTSA's "Buying a Safer Car" brochure may have better data as well.

Dr. Ferguson asked question no.3. Dr. Bahouth responded that the small number of cases is a problem when you look at the performance of the airbag.

Dr. Ferguson asked how they would account for missing data when using ΔV . Dr. Bahouth responded that they would use CDC extent of damage to predict ΔV . He said that they have done some work in this area but couldn't give the specifics at this time.

Dr. Ferguson asked question no.5. Dr. Miller responded that they would peel back the analysis starting from the fully weighted data. Dr. Bahouth said that they would have to use earlier years of NASS data in order to do some of this since the later NASS data files did not contain the PSU level weights. There was some discussion among the NHTSA people present and the consensus was that the later NASS files did not contain the PSU level weights due to concerns over being able to identify individual crashes from the data.

Dr. Schneider asked how they deal with the cost of fatalities which often do not have much in the way of medical costs. Dr. Miller said fatalities are costed in the same way as injuries. He conceded that there were often low medical costs, but the primary driver of the high cost of fatalities was the lost wages.

Dr. Digges asked to what extent they would use the FARS database. Dr. Miller responded that they would do some logistic regressions using FARS data but that it would not be as rich an analysis as with the NASS data.

Dr. Ferguson asked what years of NASS data would be used. Dr. Bahouth responded that he had not thought about what years would be used. Dr. Miller said that they would seek input from the BRP on this issue, seeking to learn the pros and cons of using the later data.

Dr. Durbin asked about the level of effort on the standard logistical regressions versus the cost based regressions. Dr. Miller responded that 60% of the effort is getting the data ready to run and that making multiple runs of statistical analyses is not that much more expensive. Writing it all up is what takes more time as well.

At this point the interviews with the proposers was complete and the BRP went into Executive Session to discuss the merits of the individual proposals, the individuals involved and the feedback received during the face to face interviews. After detailed discussions it was decided that the proposal from the NSC offered the best prognosis for a successful conclusion. It was also judged that Dr. Elisa Braver, the Principal Investigator of the effort, was a strong candidate with strong credentials. There was discussion of the desirability of extending the contract term beyond 12 months to analyze 2005 NASS data as proposed by NSC. It was decided to ask NSC to restructure the proposal to a 12 month timeframe leaving off the analysis of the 2005 data and to submit a separate cost proposal to subsequently analyze the 2005 data. This would allow more time for the BRP in concert with the proposer to make a better informed decision on the extent that CAC vehicles could be analyzed with and without the 2005 NASS data.

The BRP was also impressed with the cost analysis proposed by PIRE, believing that it had greater potential for producing statistically significant findings as the data were broken down further. It was decided that Chairman Ferguson should contact both parties to see if a joint proposal could be worked out. It was decided to further stipulate that the NSC would be the Principal Contractor and that there would be only one set of statistical models. PIRE would be tasked only with helping NSC set up the models to run with cost as the outcome variable. It was also decided for the moment to not endeavor to hold the revised proposals to the currently allocated budget amount. If the total cost was to exceed the budgeted amount we would seek further funding. Failing that we would possibly have to restructure the proposals.

Dr. Ferguson entertained a motion for adjournment. It was so moved and the meeting was adjourned at 2:30 P.M.