Response Measure Selection in Drug Studies

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In our previous meeting at Padua much progress was made on specifying scientifically acceptable procedures and analysis techniques for studying the effects of drugs on performance. Equal emphasis should be placed on the selection of the performance behaviors to be studied, since that issue is the prime factor in the validity of the study. By validity I refer to the relevance of the study to determining the effect of drugs on driving behavior.

Performance measure selection is the most difficult problem in designing drugs and driving studies. The difficulty stems from our limited understanding of the behavioral demands of driving. There is no behavioral taxonomy of the demands of driving.

How does one then proceed? It depends on one's goal. One possible objective is the empirical classification of a drug as potentially harmful. Another approach is to view the study of the effects of drugs on driving as a scientific endeavor at the intersection of engineering psychology and psychopharmacology where the aim is to develop a behavioral taxonomy to classify behaviorally active drugs so at some future point we would be more capable of predicting behavioral side effects of drugs, or designing drugs that avoid side effects.

Let us assume for the moment that one's only interest is making a regulatory decision with regard to the behavioral toxicology of the drug. If there were a representative sample available of the behaviors important for driving we might utilize those functions as the basis of a test for making our decision. This appears to be the underlying belief of those who espouse the use of simulators or automobile driving as measures to test the safety of drug.

The fundamental problem is the lack of knowledge of the important elements to be sampled from the world of driving that should be reproduced in the simulator situation. Simulator users emphasize their ability to convince the subject driver that he's undergoing the real experience, i.e., an emphasis on face validity. Unfortunately an afternoon at the cinema is not a good basis for assuming that one is in fact testing the important elements of driving. I have seen little evidence that
users of simulators or cars have defended or even identified the behaviors sampled in their task as representative.

In 1971 I performed 2 studies utilizing a film simulator constructed by a colleague at UCLA. Subjects sat in a completely functioning automobile mounted on a chassis dynamometer with the wheels actually rotating when the automobile engine was running. There were two film projectors, one facing a screen in front of the vehicle which filled a 160 degree forward visual field of the driver, and a rear projector facing a screen mounted at the back of the vehicle. Both projectors speeds were controlled by the speed of the car engine, which in turn was controlled by the driver. The steering wheel actually turned and controlled the angle of the front wheels, which in turn caused the projectors to rotate. The illusion created was so strong that if an experimenter opened the door during a run to speak to the subject they would react in fright.

The 2 studies examined the effect of slightly less than .10% BAC on performance in the simulator. The subjects responses permitted the derivation of 25 performance measures of car control and tracking. In the first of the 2 studies, none of the car control or tracking measures showed impairment at .10%. The study was then replicated with the inclusion of a simple subsidiary task which required the driver to respond appropriately to 2 colored lights presented at one of two positions near the rear view mirror with a frequency averaging one per minute during a 31 mile drive. With the additional information processing requirement of the subsidiary task, not only did the same .10% BAC produce impairment in the subsidiary task performance, but 12 of the 25 car control and tracking measures were significantly impaired.

Note that this demonstrates that face validity is no guarantee of scientific validity. Secondly, the addition of the subsidiary task to the simulator was based on theoretical and empirical grounds that suggested the importance of mental workload in determining the ability of drivers to perform adequately, and evidence from laboratory studies that alcohol impaired information processing.

I should mention parenthetically that before we performed the second study we ran several pilot studies to insure that the addition of the subsidiary task did in fact effect the workload of the driver by showing that the presence of the subsidiary task changed the car control measures, and that the car control requirement changed performance on the subsidiary task.

Another conclusion from this study is that if we hadn't run the original study without the subsidiary task our interpretations of the effects of alcohol on the response measures would have been quite different. We concluded the prime important effect was the effect on the workload capability and information processing of the driver, and that the specific car control and tracking measures impaired were secondary results. Without having the control study it would have
been difficult to have interpreted what the meanings of the deficits on the car control and tracking tasks were.

This again points to what I believe is a major failing in most simulator and on-the-road studies. Even if they do report significant positive findings it is unclear what behavioral functions are really being effected by the drug. Drugs don't effect wheel turning, they effect some behavioral function which may be exhibited in changes in wheel functioning.

Driving involves a complex set of drivers expectations, motivations and cognitive demands determined by the road, the car control task, the environment and the potential hazards in the particular environment. In simulators, as well as most closed course driving many of these factors are not there, or are attenuated. Those who conduct studies in simulators and cars, should describe and validate what behaviors they think they are investigating. Moreover, this should be accompanied by modesty in claiming they are measuring "real" driving.

To be a bit more positive, simulators have some advantages. The more recently designed simulators examine drug effects on tracking ability. However, rather than seeing a set of response measures which merely indicate whether or not tracking was impaired and to what degree, these studies should also attempt to utilize techniques, such as manual control theory, to elucidate what aspects of the subjects control processes are really being impaired.

Most simulator and on-the-road studies emphasize tracking and car control abilities. Yet in the literature on multidisciplinary accident investigation studies, car control characteristics represent the basis of only a small minority of accidents. The dominant problems are in the cognitive area; attention, perception, and judgment. Moreover, for the one drug that we do have good epidemiological knowledge about, namely alcohol, there is an even greater probability that the cause of the accident was likely attention/information processing/perception, and/or judgment.

Driving requires a wide range of skills determined by many behavioral functions. To assess the behavioral side effects of drugs requires sampling this wide range of behaviors.

While there are some basic limitations due to safety for car driving and technical limitations in simulators that prevent easy study of some behavioral variables, yet there is no intrinsic reason why most behavioral functions cannot be studied in these settings. That they have not is determined by emphasis of many of these studies on face validity and the measurement of car control variables rather than the underlying behavioral variables.
For these reasons I believe most of our understanding of the behavioral effects of drugs have come from simpler laboratory studies where it has been clearer what behaviors are being examined under the drug. A strategy of using a wide range of laboratory tasks to examine a drug appears at this time in history still the simplest, most valid and reliable means to examine a drug.

A final word on behavioral measures. The range of behavioral functions important for man-machine interaction is far from being completely specified. Psychology and human factors are in the midst of extensive research today to define and characterize the behavior factors in cognition and skills performance. Researchers in the psychopharmacology of driving and skills performance must be aware of the advances in those areas since that will be the prime source of the behavioral functions that we will wish to study. This is as important as remaining aware of advances in pharmacology.