Opinions of Expert Panel

Parkinson's Disease and Commercial Motor Vehicle Driver Safety

Medical Expert Panel Members

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Outline

- Driving
- Parkinson’s Disease
- Multiple Sclerosis
- Findings
- Opinions

Questions

1) Are individuals with PD at an increased risk for a crash?
2) What factors associated with PD are predictive of an increased crash risk?
3) What are the criteria that define when an individual with PD should stop driving?
4) How frequently should individuals with PD be assessed in order to monitor whether they remain safe to drive?
5) What is the impact of pharmacotherapy for PD on driver safety?
6) Are individuals with MS at an increased risk for a crash?
7) What factors associated with MS are predictive of an increased crash risk?
8) What are the criteria that define when an individual with MS should stop driving?
9) How frequently should individuals with MS be assessed in order to monitor whether they remain safe to drive?
10) What is the impact of pharmacotherapy for MS on driver safety?

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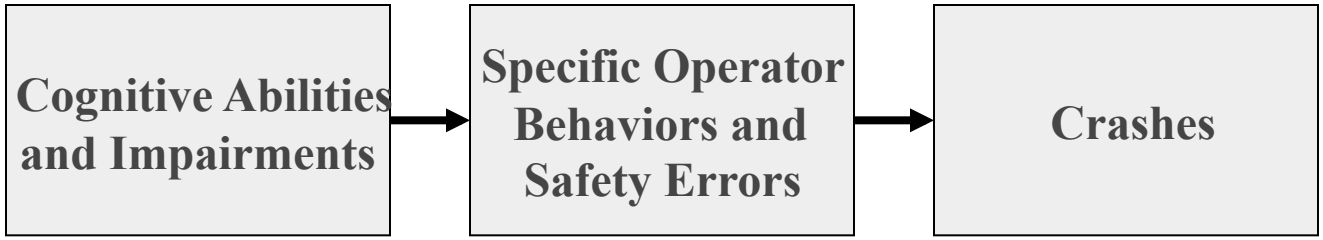
1) What are the criteria that define when an individual with Parkinson's disease (PD) should stop driving a CMV?
2) What is the impact of pharmacotherapy for PD on driver safety?
3) Are individuals with multiple sclerosis (MS) at an increased risk for a motor vehicle crash?
4) What factors associated with MS are predictive of an increased crash risk?
5) How frequently should individuals with MS be assessed in order to monitor whether they remain safe to drive?
6) What is the impact of pharmacotherapy for MS on driver safety?

Considerations

- The Medical Expert Panel (MEP) is charged with exploring the issues surrounding the impact of PD and MS using available evidence as justification.
- Recommendations from the MEP must be implementable.
- Noting that PD or MS impact cognitive and psychomotor function is not useful unless:
  - one intends to argue that all individuals with the condition should be disqualified from driving a CMV

    or
  - one puts forth a strategy for determining what types and measurable levels of reduced function provide a threshold for disqualification.

Chain of Causality in Vehicle Crashes



- Serious crashes are relatively rare events (Popper's "black swans") and difficult to predict.*
- The causal pathway often involves a concatenation of factors.
- Countermeasures can operate before, during or after adverse events occur, at levels of operator capacity, equipment, system design and policy (Haddon).

*follow a Poisson distribution) like horse-kicks deaths over 20 years in the Prussian cavalry (von Bortkiewicz L, 1898: *Das Gesetz der Kleinen Zahlen*. Leipzig: Teubner).

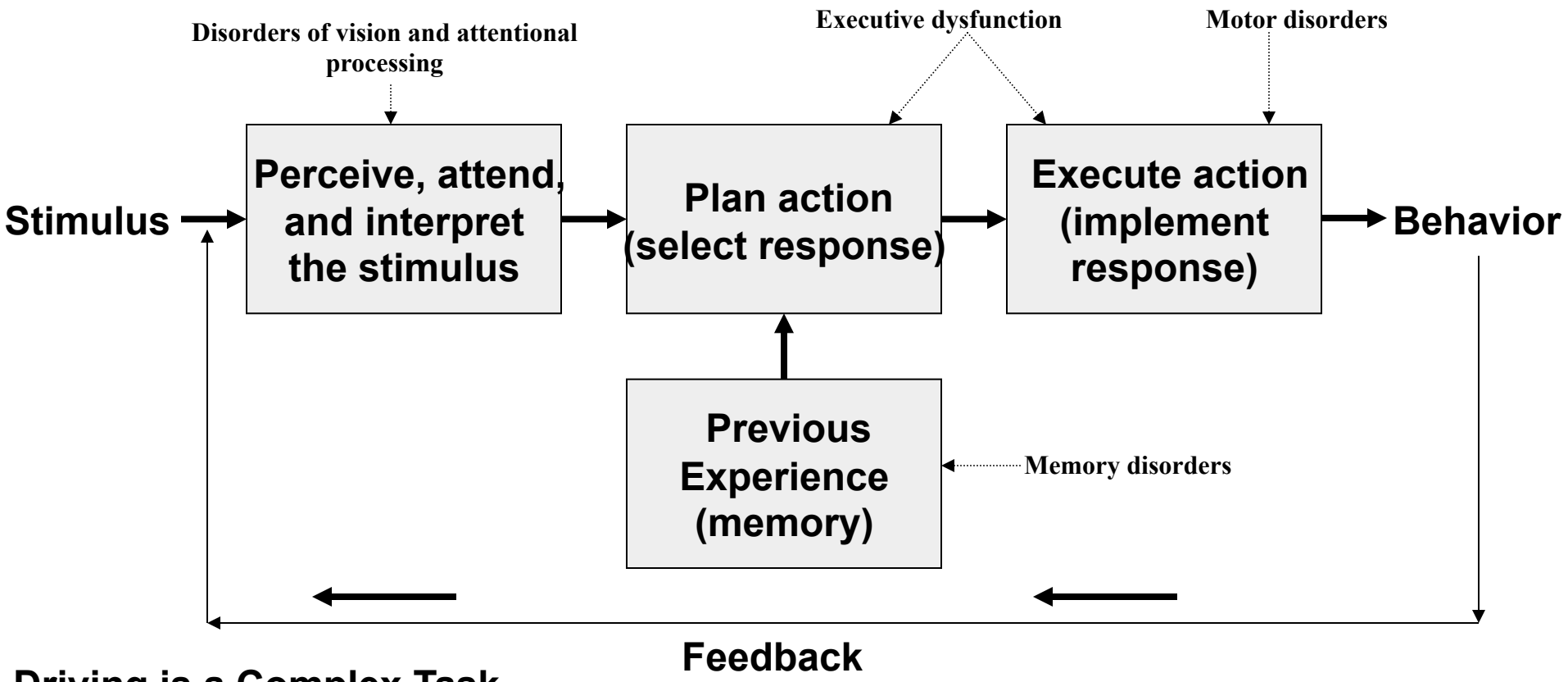
Haddon Matrix

	Human	Vehicle/Equipment	Physical Environment	Social/Economic
Pre-Crash	Poor vision or reaction time, alcohol, speeding, risk taking	Failed brakes, missing lights, lack of warning systems	Narrow shoulders, ill-timed signals	Cultural norms permitting speeding, red light running, DUI
Crash	Failure to wear seat belt	Malfunctioning seat belts, poorly engineered air bags	Poorly designed guardrails	Lack of vehicle design regulation
Post-Crash	High susceptibility, alcohol	Poorly designed fuel tanks	Poor emergency communication systems	Lack of support for EMS and trauma systems

A tool for focusing injury prevention efforts. Could be applied to dog bites, school or workplace violence, burns, and motor vehicle crashes (Haddon , 1970).

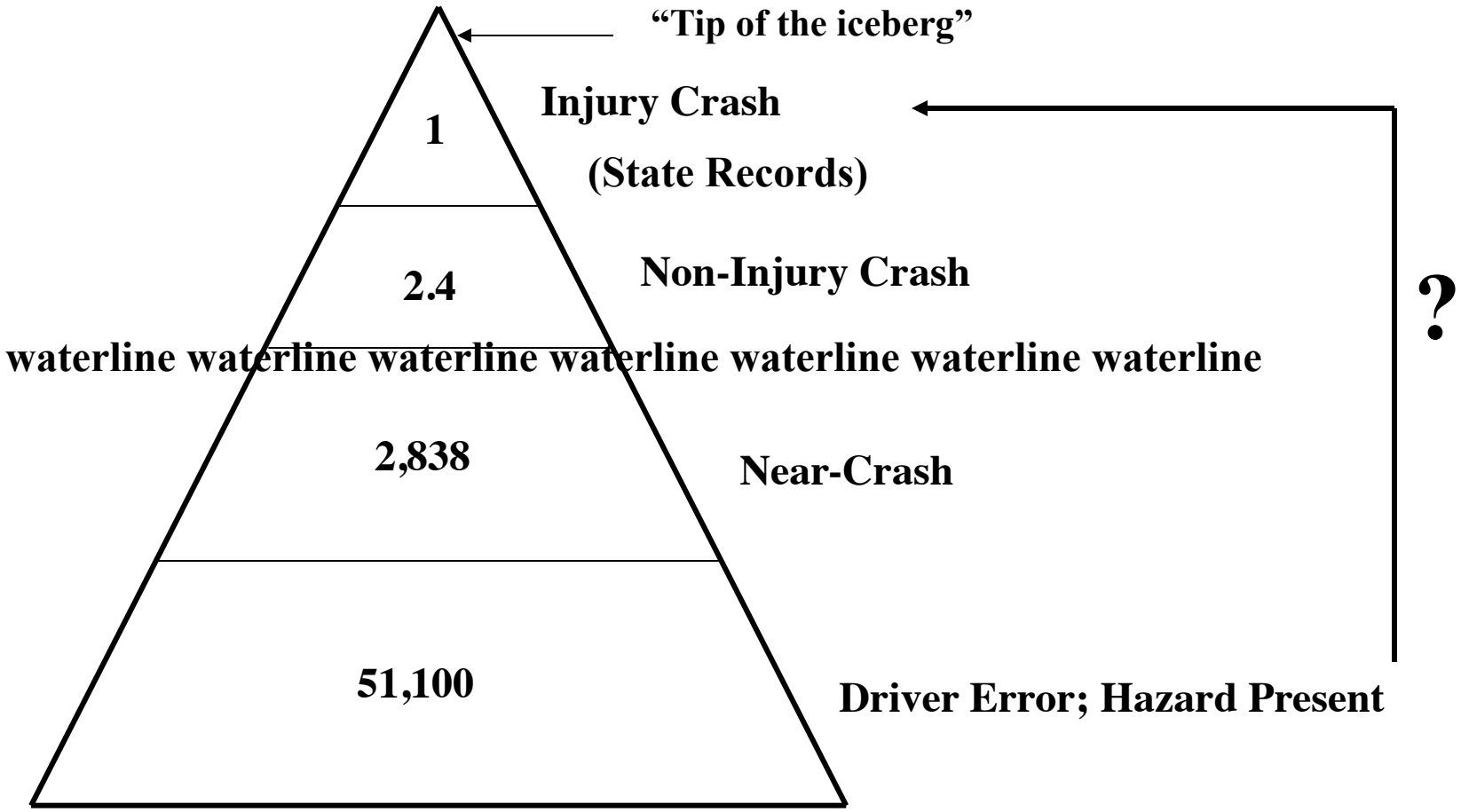
Columns represent causal agents in the crash.
Rows represent time phases: pre-, during and post crash event.

Information-Processing Model for Understanding Human Error



Driving is a Complex Task

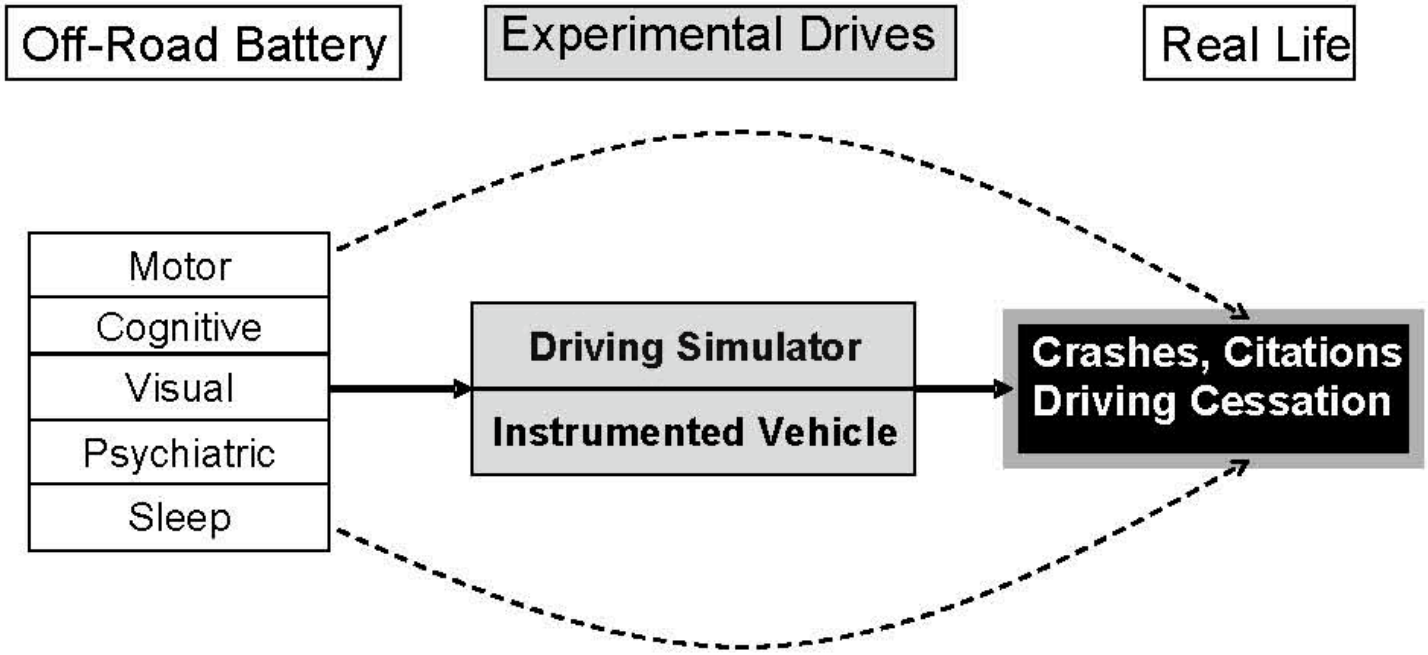
- Monitor multiple objects and events, despite being unsure where hazards may lie.
- Code inputs from central and peripheral vision and the other senses
- Allocate attention among environmental targets and distracters.
- Remember rules of driving, the route, and positions of nearby objects
- Carry out effective decision making and execution, acting on feedback.



Heinrich's Triangle

Theoretical relationship between high-severity, low-frequency events (injury crashes) and high-frequency, low-severity events are shown. Mock counts are included.

Broad Approach



- Analyze individual operators' perception, cognition (attention, memory, executive and motor functions) and emotions.
- Assess performance in simulations and instrumented vehicles
- Determine links between off-road (e.g. cognitive) data, experimental drives, and real-life outcomes (errors, crashes).
- *Develop countermeasures.*

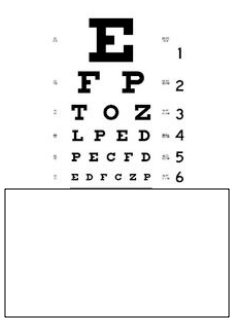
Driving Research Approaches

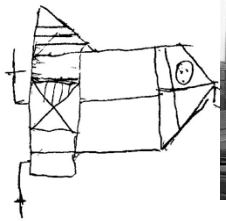
Fidelity

Cognitive Tests | **Driving Simulation** | **Naturalistic Driving**

Health and Driving Habits Assessment

Cognitive Assessment





Driving Assessment using PC simulation

Driving Assessment in Simulator

Driving Assessment in Laboratory Instrumented Vehicle

Driving in Personal Vehicle with DriveCam

Department of Transportation Driving Record

Experimental Control

Sources of Evidence: Cognitive Tests, Driving Simulators, Road Test, Test Tracks, Instrumented Vehicles, DOT Record of Crashes and Citations

Neuropsychological Tests

- Tests of vision and cognition
- Standardized
- Easy to use
- Widely available

Cognitive Assessment

- **All drivers have standardized neuropsychological tests assessing a range of cognitive functions**

(1) Controlled Oral Word Association (COWA)

(2) Rey-Osterreith Complex Figure Test (CFT)- Copy

(3) CFT- Recall

(4) Rey Auditory Verbal Learning Test (AVLT)- Recall

(5) Benton Visual Retention Test (VRT)

(6) Block Design (BLOCK)

(7) Judgment of Line Orientation (JLO)

(8) Trail Making Test (TMT)

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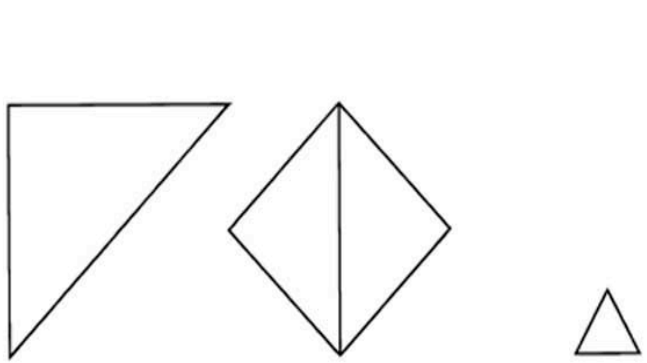
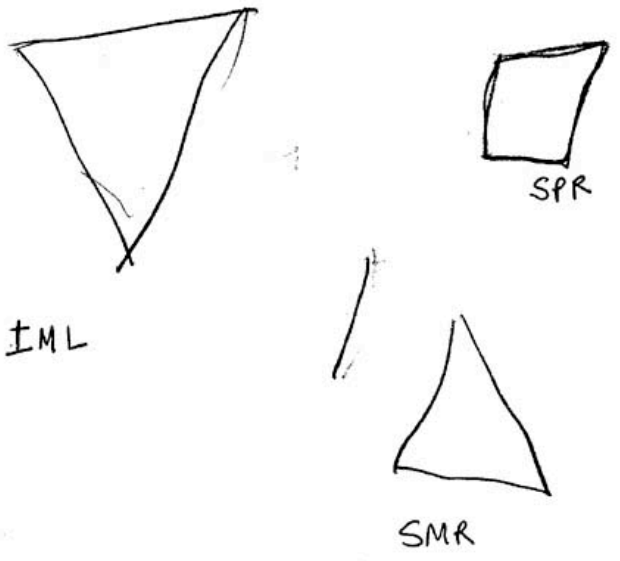
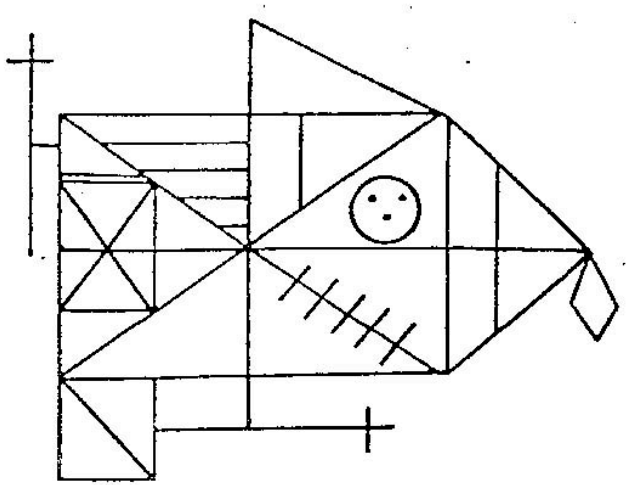
(9) "COGSTAT" overall composite score

Benton Visual Retention Test (VRT)

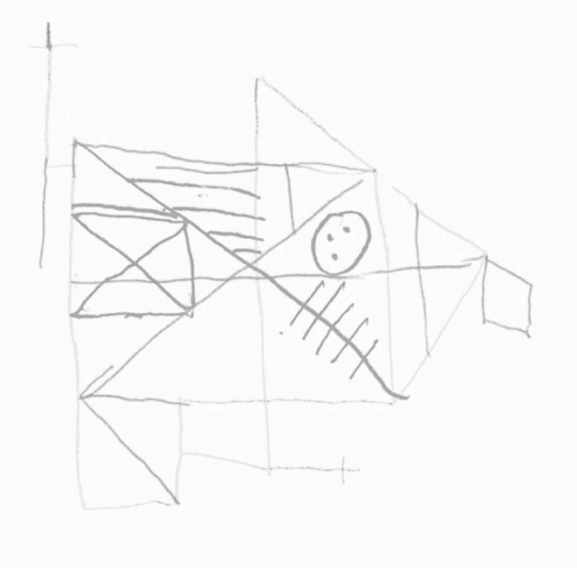




CFT



Rey figure



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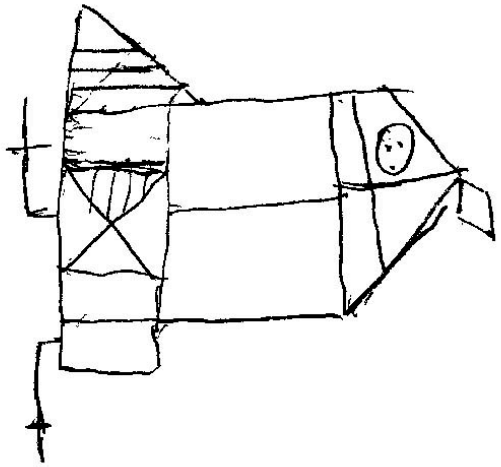
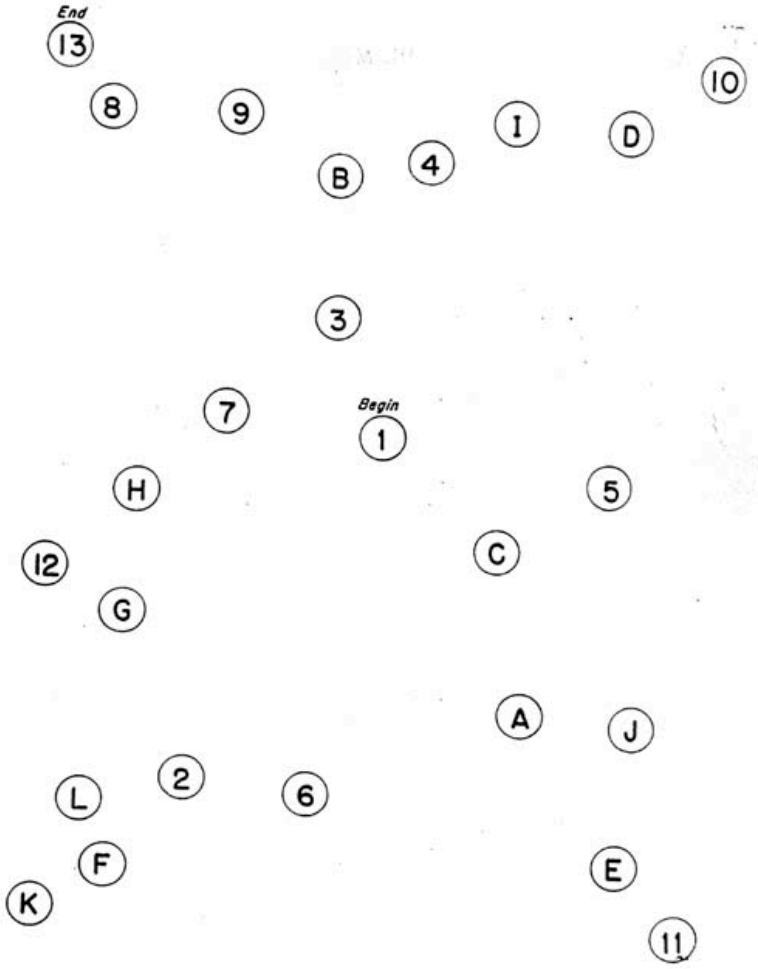


30’ recall

Trail Making Test, Part B



Cognitive tests predict real world performance

The New York Times

February 24, 2009

VITAL SIGNS

Safety: When to Ground Alzheimer's Drivers?

By ERIC NAGOURNEY

Sooner or later, people who have Alzheimer's disease will have to give up the keys to the car. But figuring out when poses a problem for doctors and families, because the loss of driving privileges also means less freedom and mobility.

Now a new study reports that a series of cognitive tests may help doctors determine which early Alzheimer's patients are likely to pose a danger behind the wheel.

The researchers, led by Jeffrey Dawson of the University of Iowa, said the findings could prove valuable as an aging population results in more drivers with dementia on the road.

NYT 022409

Predicting Driver Safety in Parkinson's Disease

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Road safety in drivers with Parkinson disease

E. Y. Uc, M. Rizzo, A. M. Johnson, E. Dastrup, S. W. Anderson and J. D. Dawson

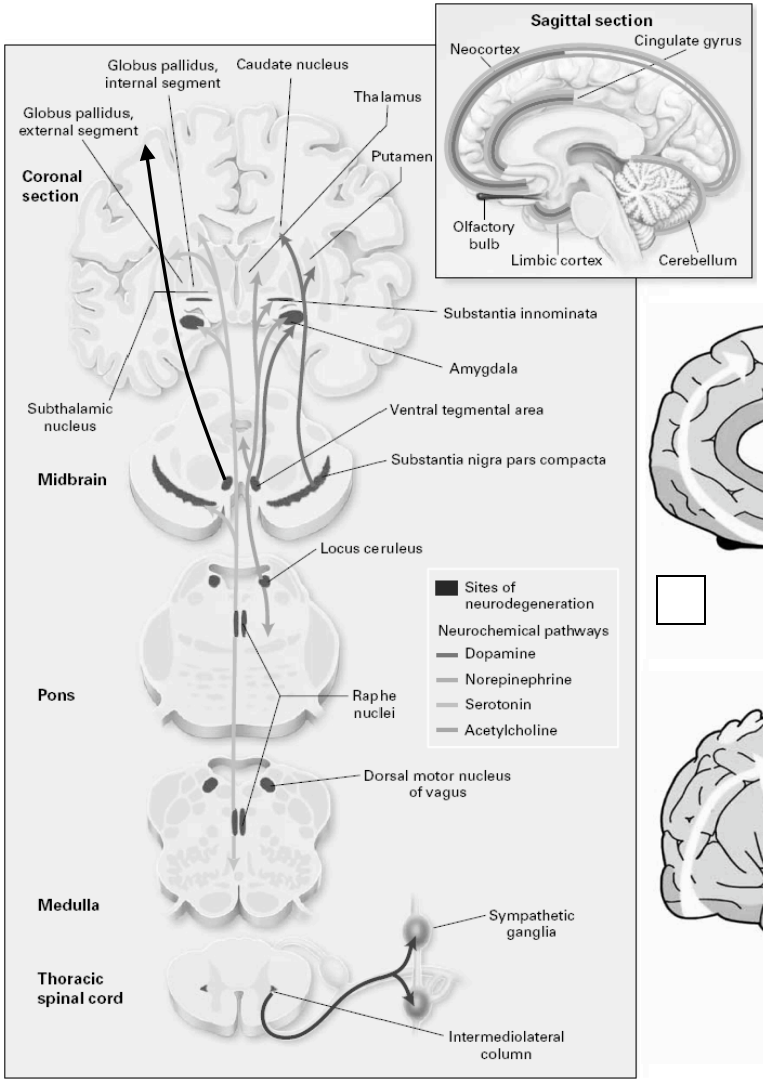
Neurology 2009;73;2112-2119
DOI: 10.1212/WNL.0b013e3181c67b77

What is PD

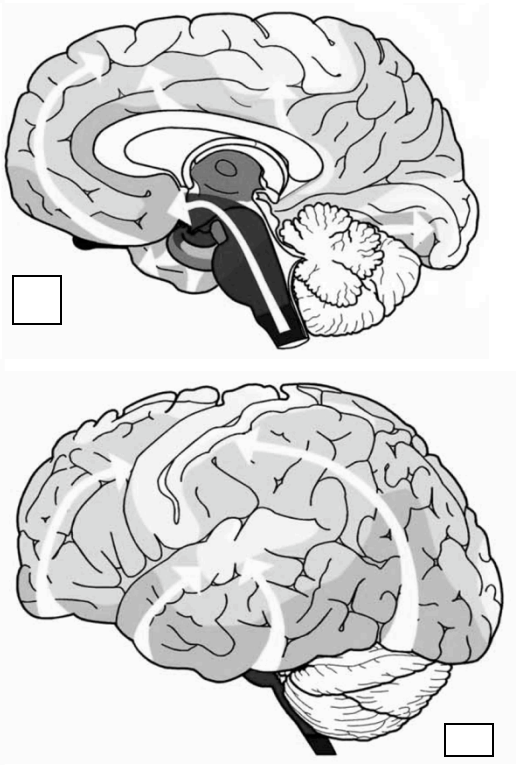
- PD is a neurological disorder that is chronic, progressive, neurodegenerative, and associated with a loss of dopaminergic nigrostriatal neurons.
- Symptoms include tremors of the hands, arms, legs or jaw; a distinctive gait; muscle stiffness of the limbs and trunk; unusual slowness of movement (bradykinesia); stooped posture and postural instability; falling or jerking uncontrollably; impaired balance and coordination; rigidity; and dementia.
- All of these symptoms have the potential to adversely affect driving ability.

Hoehn-Yahr Scale
1. Stage One
1. Signs and symptoms on one side only 2. Symptoms mild 3. Symptoms inconvenient but not disabling 4. Usually presents with tremor of one limb
5. Friends have noticed changes in posture, locomotion and facial expression
2. Stage Two
1. Symptoms are bilateral 2. Minimal disability 3. Posture and gait affected
3. Stage Three
1. Significant slowing of body movements 2. Early impairment of equilibrium on walking or standing 3. Generalized dysfunction that is moderately severe
4. Stage Four
1. Severe symptoms 2. Can still walk to a limited extent 3. Rigidity and bradykinesia 4. No longer able to live alone 5. Tremor may be less than earlier stages
5. Stage Five
1. Cachectic stage 2. Invalidism complete 3. Cannot stand or walk 4. Requires constant nursing care

Possible Mechanisms of Driver Impairment in PD



Lang & Lozano, NEJM 1998



Braak et al., Neurobiol Aging 2003

- **Motor**
  - –Bradykinesia, rigidity
  - –Tremor
  - –Postural instability/gait disorder
  - –Fluctuations, dyskinesia
- **Cognitive ***
  - –Executive dysfunction
  - –Decreased attention
  - –Decreased visuospatial abilities
  - –Memory disturbances
  - –Dementia prevalence ~40%
- **Visual ***
  - –Decreased contrast sensitivity
- **Sleep**
  - –Excessive daytime sleepiness
  - –"Sleep attacks"
- **Psychiatric**
  - –Depression
  - –Anxiety

*** Important!**

N.B. Medications for movement may worsen cognition and sleepiness.

Drowsy Operators

Indirect Outcomes	Significant Predictors
Falling asleep while driving	Epworth Sleepiness Scale Inappropriate Sleep Composite Score
Driving fitness	Disease duration Contrast sensitivity Cognitive function Motor function
Driving suitability	Disease stage Car test score Reaction time to brake
On-road testing performance	Visual processing speed and attention Non-verbal memory Familiarity Ability to switch attention between competing tasks Levodopa dosage Age Perception
Simulator testing performance	H&Y stage Trail Making Test- subtest A and B Symbol Digit Modalities Test Judgment of Line Orientation Test Brixton Test Weschler Adult Intelligence Scale-III of visual attention measurement Block Design Age Mini Mental Status Exam

Predictors of indirect outcomes of crash risk in PD

MEP Opinion in PD

- A diagnosis of PD precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.
- A diagnosis of PD should not exclude all individuals; CMV certification may be possible in some instances.
- A person with PD may be considered for CMV certification if he or she meets a set of criteria based upon an evaluation by appropriate qualified specialists.
- This qualified specialist (e.g., neurologist, movement disorders specialist, neuropsychologist, as appropriate) should assess for symptoms which may adversely affect driving ability.

Criteria for certification to drive a CMV in PD

- Shows mild symptoms only, as indicated by a HY stage 1 or less and a high score (90% or higher*) on the Schwab and England Activities of Daily Living Scale.
  - *HY1 - Signs and symptoms on one side only, symptoms mild, symptoms inconvenient but not disabling, usually presents with tremor of one limb
  - **90% – Completely independent. Able to do all chores with some degree of slowness, difficulty and impairment. Might take twice as long. Beginning to be aware of difficulty.
- Tolerates medications well, without cognitive, motor, or other side effects that might affect driving.
- Shows no significant fluctuations in motor response or “on-off” effects (i.e., sudden fluctuations in disability involving rapid and abrupt alterations between periods of good mobility and periods of hypokinesia, tremor, and dyskinesia).

Criteria for certification to drive a CMV in PD

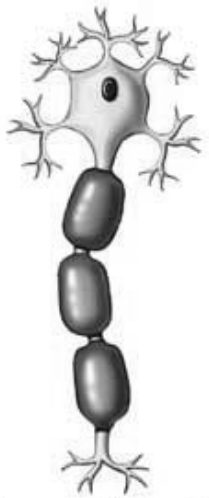
- Demonstrates satisfactory functioning on a battery of tests assessing key cognitive functions important for safely driving a motor vehicle (e.g., processing speed, attention, perception, memory, executive functions, emotion).
  - Satisfactory functioning should be defined as performing within or above the normal range using test norms that adjust for relevant factors, such as age and education.
- Shows no evidence of a mood disorder or satisfactory control of an existing mood disorder (see psychiatric disorders MEP report).
- Provides written documentation of the specialist's report at the time of the CMV medical evaluation.
  - The medical examiner form should be updated by adding a place to indicate that the applicant has been referred to a specialist who has documented the individual's condition relevant to safely operating a motor vehicle.

Criteria for certification to drive a CMV in PD

- An individual with PD who meets the criteria for certification should be **reevaluated on a semi-annual basis** by a neurologist or other qualified specialist, and obtain an annual neuropsychological evaluation.
- The choice of a qualified specialist should be based on the judgment of the medical examiner in the context of the complexity of the examinee's case.
- This choice depends on factors of illness severity, symptoms, duration, stability over time, and interventions such as medications required for management.
- It also depends on the available resources, with general preference given to more highly trained and experienced consultants.

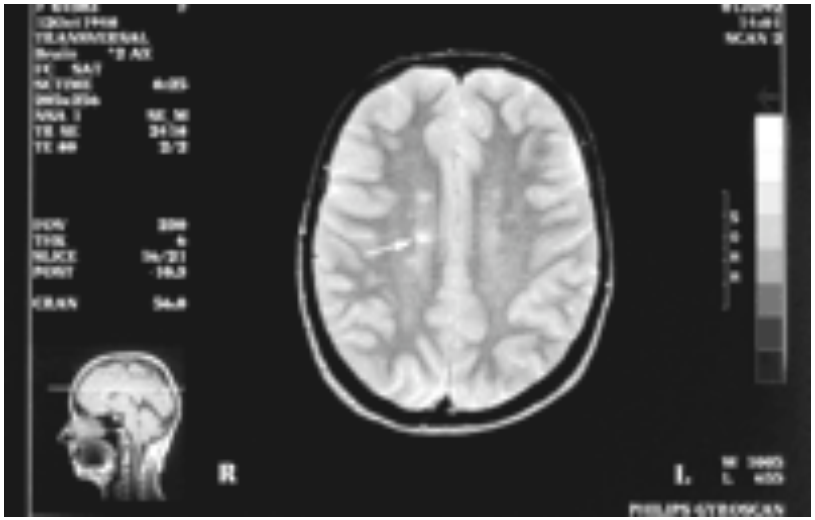
What is MS

- Multiple sclerosis is an autoimmune condition that affects the brain and spinal cord.
- Symptoms vary, because location and severity of each attack can differ. Episodes can last for days, weeks, or months. These episodes alternate with periods of remission.
- Fever, hot baths, sun exposure, and stress can trigger symptoms or attacks.
- It is common for the disease to return (relapse). However, the disease may continue to get worse without periods of remission.
- Symptoms and depend affected areas and can affect coordination, strength, vision and other senses, bowel and bladder control, cognition, and mood.



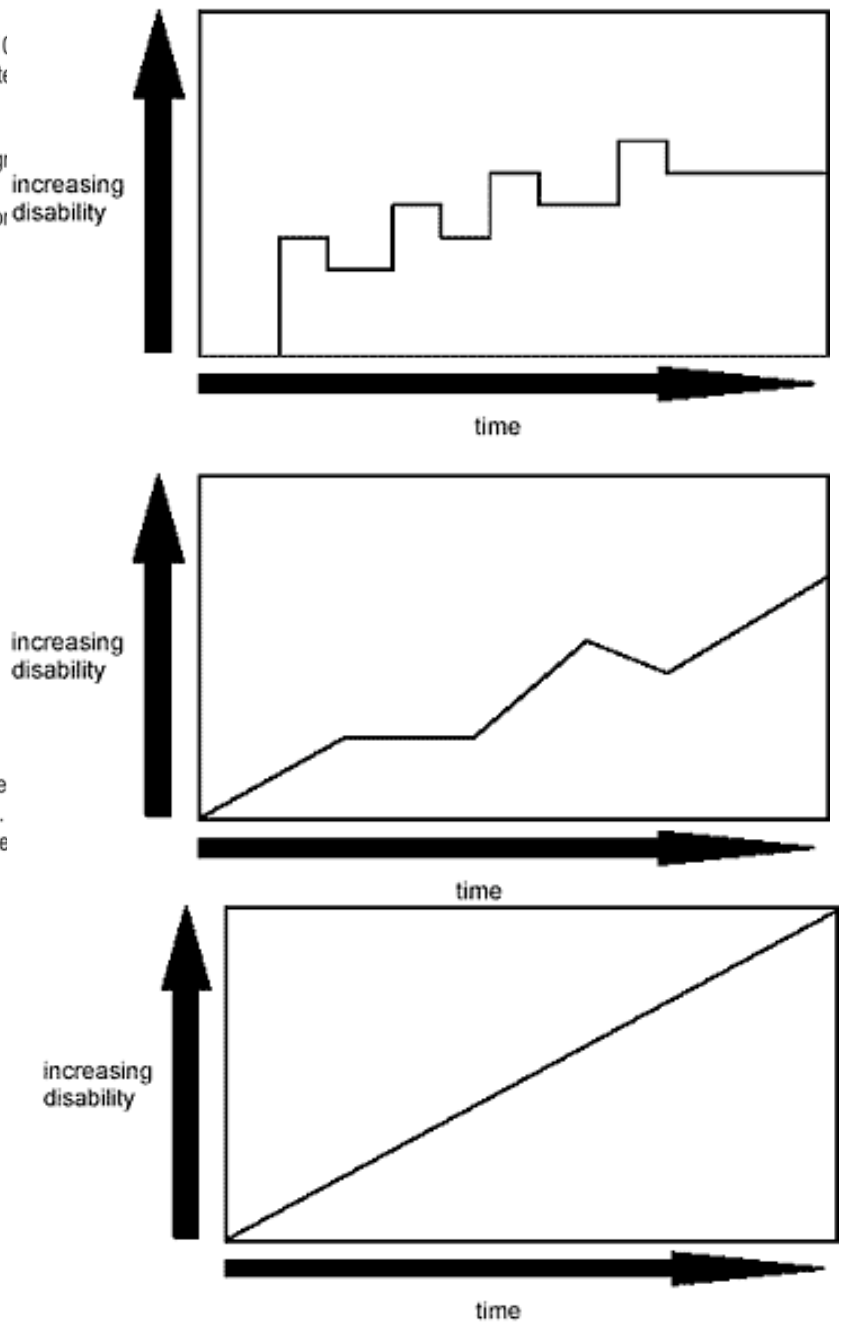
Neuron with myelin sheath

Neuron with damaged myelin sheath



Types of Multiple Sclerosis

Type	Prevalence	Characteristics
Benign MS	25% of MS patients and 15% of relapse remitting patients	Mild course with minimal disability. May not have symptoms for at least 1(years. Symptoms are mild to moderat and do not get worse or cause permanent disability. There is no method of determining who has benig MS. So, many people diagnosed with MS may be taking medication they do yet need and suffering from unnecessary anxiety. Drugs are useful but are not always necessary.
Relapse Remitting MS (RRMS)	**85% of MS patients**	Patient has episodic relapses and remissions that might be partial or complete. First attack is called a clinically isolated syndrome. Symptoms suddenly reappear every few years, last for a few weeks or months, and then go back into remission. Symptoms sometimes worsen with each occurrence. Drugs are useful.
Primary Progressive MS (PPMS)	10-15% of MS patients	Slowly progressive pattern without relapses and remissions. Symptoms gradually worsen after symptoms first appear. Drugs not useful.
Secondary Progressive MS (SPMS)	50% of RRMS in 10 yrs & 90% of RRMS in 25 yrs.	Secondary progressive MS is a phase of progression with or without attacks. After time, even years, without relapse and remissions, patients may later relapse. Symptoms suddenly begin to progressively worsen. Drugs are not useful.
Progressive Relapsing MS	5% of PPMS patients	Least common form of MS. After time without relapses, patients relapse. Symptoms gradually worsen after symptoms first appear. One or more relapses may also occur. Drugs are not useful.



Opinion: MS and CMV Driver Certification

- A diagnosis of MS precludes an individual from obtaining unconditional certification to drive a CMV for purposes of interstate commerce.
- A diagnosis of MS, however, should not exclude all individuals with the disorder from driving a CMV; certification may be possible in some instances.
- An individual with a diagnosis of MS may be considered for certification to drive a CMV if that individual meets a set of criteria (to follow).
  - based upon an evaluation by a qualified specialist(s) (e.g., neurologist, MS specialist, neuropsychologist, ophthalmologist, occupational therapist, as appropriate depending upon the signs and symptoms of the individual being evaluated).

Criteria for CMV Driver Certification in MS

- Shows no signs of recent relapse or chronic progression.
- Tolerates medications well, without cognitive, motor, or other side effects that might affect driving.
- Has satisfactory vision including acuity, fields, and ocular alignment (see vision MEP report).
- Demonstrates satisfactory cognitive functioning based upon a standardized neuropsychological test battery assessing key domains important for safely driving a motor vehicle (e.g., processing speed, executive functioning, attention, perception, memory and emotion).
- Satisfactory functioning should be defined as performing within or above the normal range using test norms that adjust for relevant factors, such as age and education.

Criteria for CMV Driver Certification in MS

- Shows no evidence of a mood disorder or satisfactory control of an existing mood disorder (see psychiatric disorders MEP report).
- Shows satisfactory motor function and mobility (see musculoskeletal MEP report).
- Has no history of excessive fatigability or periodic fluctuations of motor performance, as in relation to heat, physical and emotional stress, and infections.
- Provides written documentation of the specialist's report at the time of his or her medical examination.
  - The medical examiner form should be updated by adding a place to indicate that the applicant has been referred to a specialist who has assessed the individual's condition relevant to safely operating a motor vehicle

Criteria for CMV Driver Certification in MS

- An individual with MS who meets the criteria for certification above, should be reevaluated on a semi-annual basis by a neurologist or other qualified specialist, and obtain an annual neuropsychological evaluation.
- The choice of a qualified specialist should be based on the judgment of the medical examiner in the context of the complexity of the examinee's case.
- This choice depends on factors of illness severity, symptoms, duration, stability over time, and interventions such as medications required for management.
- It also depends on the available resources, with general preference given to more highly trained and experienced consultants.

Opinion 3: Fitness to Drive Framework

- The MEP believes that FMCSA should adopt a general framework for determining fitness to drive a CMV that relies upon a "functional" evaluation of multiple domains (cognitive, motor, perceptual, psychiatric) that are important for safe driving.
- Such a framework could be applied across many diseases/conditions, including ones that have rarely been studied with respect to CMV driving.
  - (Of note, this framework is compatible with MRB considerations regarding approach to drivers with multiple conditions).
- The framework would serve as a functional "screen" comprising elements of cognitive, psychomotor, and psychiatric function. It would screen for primary effects of illness (e.g., cognitive dysfunction), effects of medications (e.g., sedation), and illness-medication interactions. Examples include:
  - Cognitive: processing speed, attention, perception, memory, executive functions, and emotion
  - Psychomotor: heel-to-toe walking, rapid alternating movement, and measures of perseveration for psychomotor function
  - Psychiatric: Patient Health Questionnaire (PHQ) or PHQ-2 for depression, among others

Opinion 3: Fitness to Drive Framework

- The screen would be administered by the medical examiner, based on the obtained medical and psychological history, and used as an additional guide for referral.
- Two key elements of this approach are validity of each element of screening and practicality.
  - The screen would need to comprise validated testing measures and not be easily defeatable by examinees.
  - The evaluation would need to be easily teachable to medical examiners (e.g., through the National Registry process) and relatively quickly and effectively administered during the certification examination.
- We suggest revisiting evidence reports on other conditions (e.g., stroke, diabetes, TBI, etc.) and pooling these data to examine the predictive value of various factors (e.g., cognitive, motor, medication, etc.) in determining ability to drive safely and crash risk.

- Questions?