

# A web based method for individualizing outcome measurement in clinical practice and clinical trials

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# Disclosures - in last 5 years

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# Outline

Individualized outcome measures:

- the rationale for their use.
- an example from hip fracture
- an example from dementia.
- consideration in relation to biomarkers
- summary

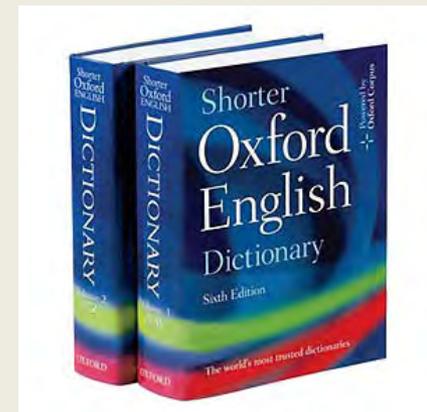
# What does it mean to individualize?

To characterize by distinctive, individual qualities.

To point out, specify, particularize.

To personalize; to make more obviously related, identifiable as belonging to a particular individual.

(not everyone's considerations are the same)



# Overview of the argument (1)

- Older adults and anyone with dementia commonly have health problems with high dimensionality.
- Typical statistical dimensionality reduction methods commonly are too crude for clinical use, as they result in irrelevant or arbitrary standards.
- *Individualized measures* offer an alternative for clinical care and when used in conjunction with standardized measures, allow for formative evaluation of health care programs.

# Overview of the argument (2)

- Individualized outcome measures are rooted in clinical thinking and allow for clinical meaningfulness to be evaluated.
- The *criteria* by which clinical meaningfulness should be evaluated should themselves be: relevant, non-arbitrary, quantifiable and replicable.
- No single measure meets all criteria; judgment, aggregating many sources of information, will be needed.

(We must get over “gold standard” thinking.)

# An example from hip fracture rehabilitation

- An 87 year old woman is transferred from the orthopaedic ward to the geriatric restorative care unit on her third post-operative day.
- She requires the maximal assistance of two people to transfer to a bedside chair, can pivot but not walk, is able to feed herself if the tray is set up, but otherwise cannot do any personal care.
- She is discharged home after 9 days; the mean length of stay on restorative care is 11 days.
- ***Is she a success?***

	Mobility	Function	Future care
Much better than expected (+2)			
Somewhat better than expected (+1)			
Goal (0)			
Somewhat worse than expected (-1)			
Much worse than expected (-2)			

	Mobility	Function	Future care
Much better than expected (+2)			
Somewhat better than expected (+1)			
Goal (0)			
Somewhat worse than expected (-1)			
<b>Much worse than expected (-2)</b>	<b>Cannot walk. 2-person max assist for transfer</b>	<b>Can feed self with set up.</b>	<b>In hospital</b>

	Mobility	Function	Future care
Much better than expected (+2)			
Somewhat better than expected (+1)			
<b>Goal (0)</b>	<b>Walks with walker 30 m in 7 days</b>	<b>Help in house-work, bathing by 7 days</b>	<b>Discharge to flat in 7 days with help</b>
Somewhat worse than expected (-1)			
Much worse than expected (-2)	Cannot walk. 2-person max assist for transfer	Can feed self with set up.	In hospital

	Mobility	Function	Future care
Much better than expected (+2)	<b>Independ't with walker &gt; 50 m in &lt; 7 days</b>	<b>Independent inside her flat in &lt; 7 days</b>	<b>Discharge in &lt;7 days, needs no assistance</b>
Somewhat better than expected (+1)	<b>Independ't with walker 30 m in &lt;6 days</b>		<b>Discharge in &lt;6 days with assistance</b>
Goal (0)	Walks with walker 30 m in 7 days	Help in house-work, bathing; 7 days.	Discharge to flat in 7 day with assistance
Somewhat worse than expected (-1)	<b>Requires stand-by assistance; or goal takes &gt;9 d</b>	<b>Needs help with</b>	<b>Discharge in 9-12 days</b>
Much worse than expected (+2)	Cannot walk. 2-person max assist for transfer	Can feed self with set up.	In hospital

	Mobility	Function	Future care
Much better than expected (+2)	Walks with walker > 50 m in < 7 days	Independent inside her apartment in < 7 days	Discharge in <7 days without need for assistance
Somewhat better than expected (+1)	Walks with walker 30 m in <6 days		Discharge in <6 days with assistance
Goal (0)	Walks with walker 30 m in 7 days	Help in house-work, bathing; 7 days.	Discharge to apt in 7 day with assistance
Somewhat worse than expected	Requires stand-by assistance; or goal takes >9 days	Needs help with	Discharge in 9-12 days
Much worse than expected	Cannot walk. 2-person max assist for transfer	Can feed self with set up.	In hospital

	Mobility	Function	Future care
Much better than expected (+2)			
Somewhat better than expected (+1)			
Goal (0)	Able to climb 2 flights stairs with help, 14 days	Help in housework, cooking, bathing; 10 days.	Discharge to apt in 14 day with assistance
Somewhat worse than expected			
Much worse than expected			

	Delirium	Medications	Breathing
Much better than expected (+2)			
Somewhat better than expected (+1)			
Goal (0)	Not calling out at night; accepts need for care.	On 12 medications; no anti-psychotics	No PND; can climb stairs with only one stop to rest
Somewhat worse than expected			
Much worse than expected			

# GAS Scoring

$$50 + \{[10\sum(w_i x_i)] / [0.7\sum w_i^2 + 0.3(\sum w_i)^2]^{1/2}\}$$

$w_i$  = weight applied to the  $i^{\text{th}}$  goal

$x_i$  = degree to which goal is achieved  
(+2,+1,0,-1,-2)

50= goals achieved

<50=goals not met

>50=goals exceeded

# What is the rationale for using individualized outcome measures?

- **Validity** (content; dimensionality, dynamics)
- **Generalizability** (*cf.* educational bias in cognition, gender/ cultural bias in function)
- **Clinical meaningfulness** (meeting patient preferences)
- **Knowledge translation** (knowing what to look for)
- **Responsiveness, & seeing what you did not know to look for**



# Criteria for clinical meaningfulness in neurological drug trials.

- Statistically significant differences
- Replicable differences, within and across trials
- Big enough differences to be at least clinically detectable
- Dose response
- Biologically plausible
- Important to individuals (this is a sly dig against “biomarkers”)

# Sample Goal

(one of five for this patient)

Step 1 – identify a goal area

Step 2 – define the problem

in plain language

	operate new TV (function) wt: 4
Much better than baseline (+2)	
Somewhat better than baseline (+1)	
Baseline (0)	Watches news and sports programs daily. Turned old TV on/off and changed channels using manual knobs but now can't operate remote for new TV. Knows when the news and other programs are on but unable to turn TV on or change channel with remote. Watches TV if it's already on but usually doesn't try to change the channel. Sometimes tries to use remote but finds all the buttons too confusing. Pulls plug out of the wall to turn TV off.
Somewhat worse than baseline (-1)	
Much worse than baseline (-2)	
<ul style="list-style-type: none"><li>Attainment level achieved at final visit</li></ul>	

# Sample Goal

(one of five for this patient)

Step 3 – identify potentially better and worse outcomes

Step 4 – rate the goals relative to each other (only for patient/carer goals)

Step 5 – at follow-up, scale attainment (current status) as compared to the baseline status

	operate new TV (function) wt: 4
Much better than baseline (+2)	Learns and remembers which buttons on the remote to use to turn the TV on/off and change the channel.
Somewhat better than baseline (+1)	Learns and remembers location of the manual button to turn TV on/off. Uses button instead of unplugging TV.
Baseline (0)	Watches news and sports programs daily. Turned old TV on/off and changed channels using manual knobs but now can't operate remote for new TV. Knows when the news and other programs are on but unable to turn TV on or change channel with remote. Watches TV if it's already on but usually doesn't try to change the channel. Sometimes tries to use remote but finds all the buttons too confusing. Pulls plug out of the wall to turn TV off.
Somewhat worse than baseline (-1)	No longer tries to use remote – just asks others to help turn TV on/off or change channel.
Much worse than baseline (-2)	Stops watching TV at all because trying to operate it is too much of a bother.
<ul style="list-style-type: none"> <li>Attainment level achieved at final visit</li> </ul>	

# GAS Scoring

$$50 + \{[10\sum(w_i x_i)] / [0.7\sum w_i^2 + 0.3(\sum w_i)^2]^{1/2}\}$$

*w<sub>i</sub> = weight applied to the i<sup>th</sup> goal*

*x<sub>i</sub> = degree to which goal is achieved*

*(+2,+1,0,-1,-2)*

50=no change (maintenance)

<50=decline in 1 or more goals

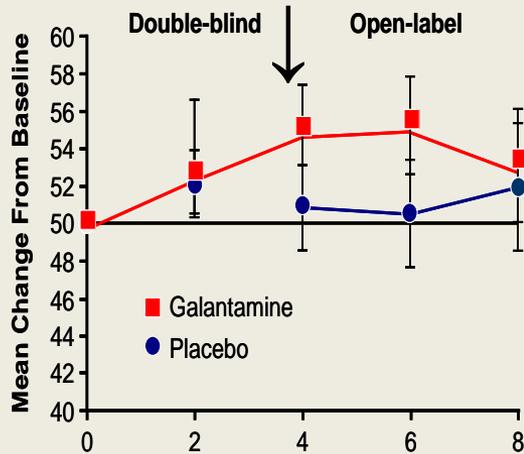
>50=improvement in 1 or more goals

Rockwood, et al., *CMAJ* 2006;174:1099-1105.

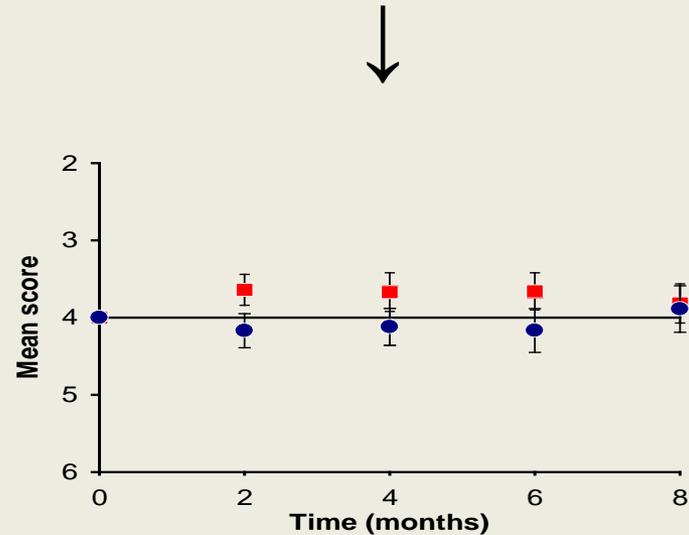
T. J. Kiresuk, A. Smith, & J. E. Cardillo (Eds.), *Goal Attainment Scoring:*

*Application, Theory, and Measurement.* Hillsdale, NJ: Lawrence Erlbaum (1994).

# GAS by the treating physician compared with the CIBIC+ by a blinded clinical rater in the VISTA trial



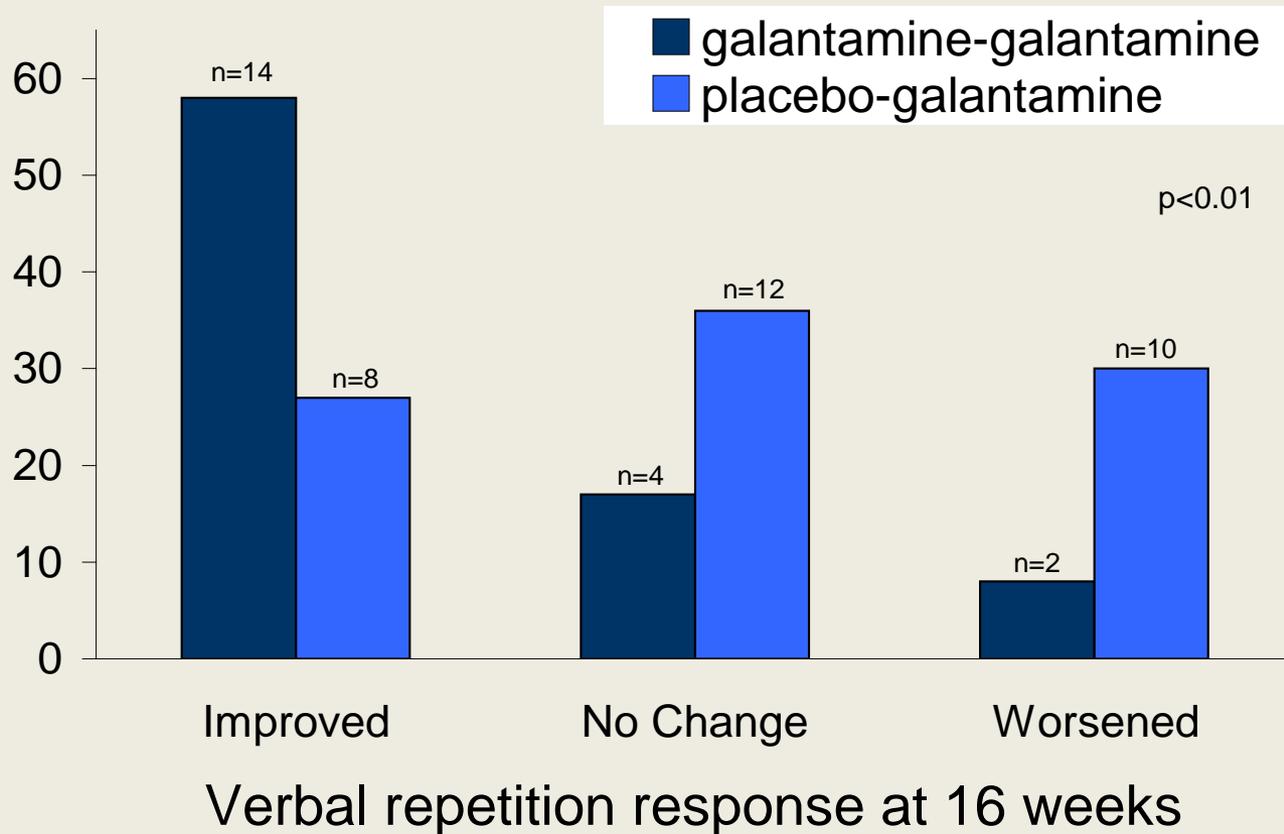
CIBIC +



Effect size (SRM, end of DBP) = 0.48

Effect size (SRM, end of DBP) = 0.52

# Impact of galantamine on repetitive questioning: end of double-blind phase



# Why individualize? Systematic review clinical significance in dementia RCTs

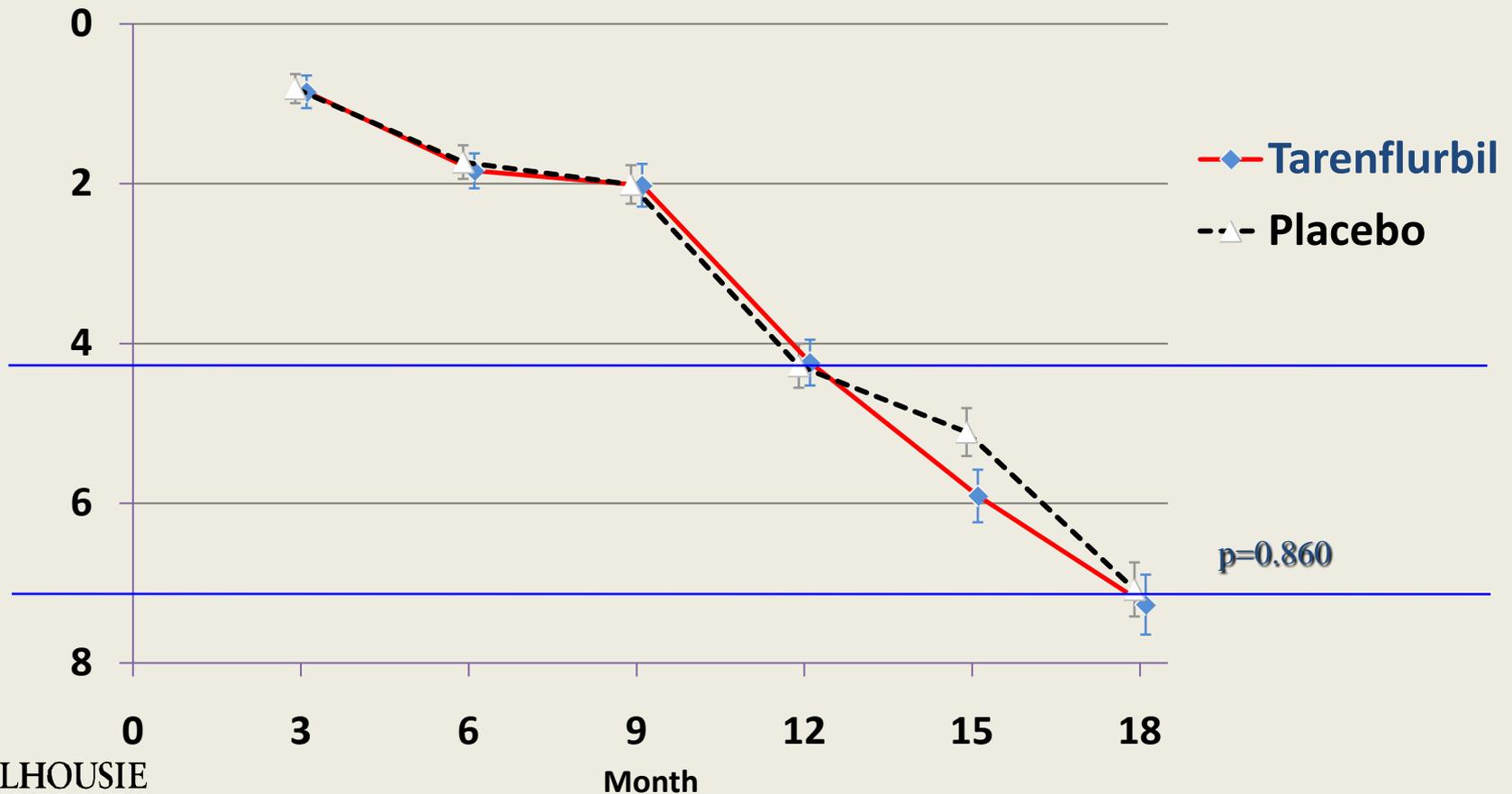
- Of 57 dementia drug RCTs, only 46% discussed clinical significance.
- Most used a **4-point change** in the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) and changes on global scales.
- Only one trial studied patient perspectives on thresholds for clinical significance.

Molnar *et al.*, *J Am Geriatr Soc.* 2009;57:536-46.

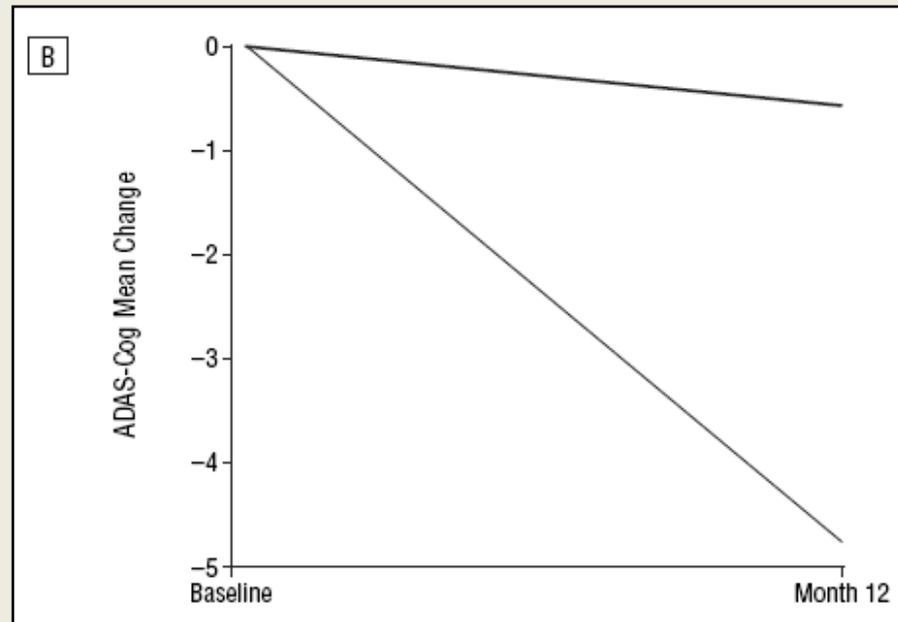
# Tarenflurbil trial: Change in the ADAS-cog over 18 months.

Change from Baseline  
ADAS-cog  
(Mean±SE)

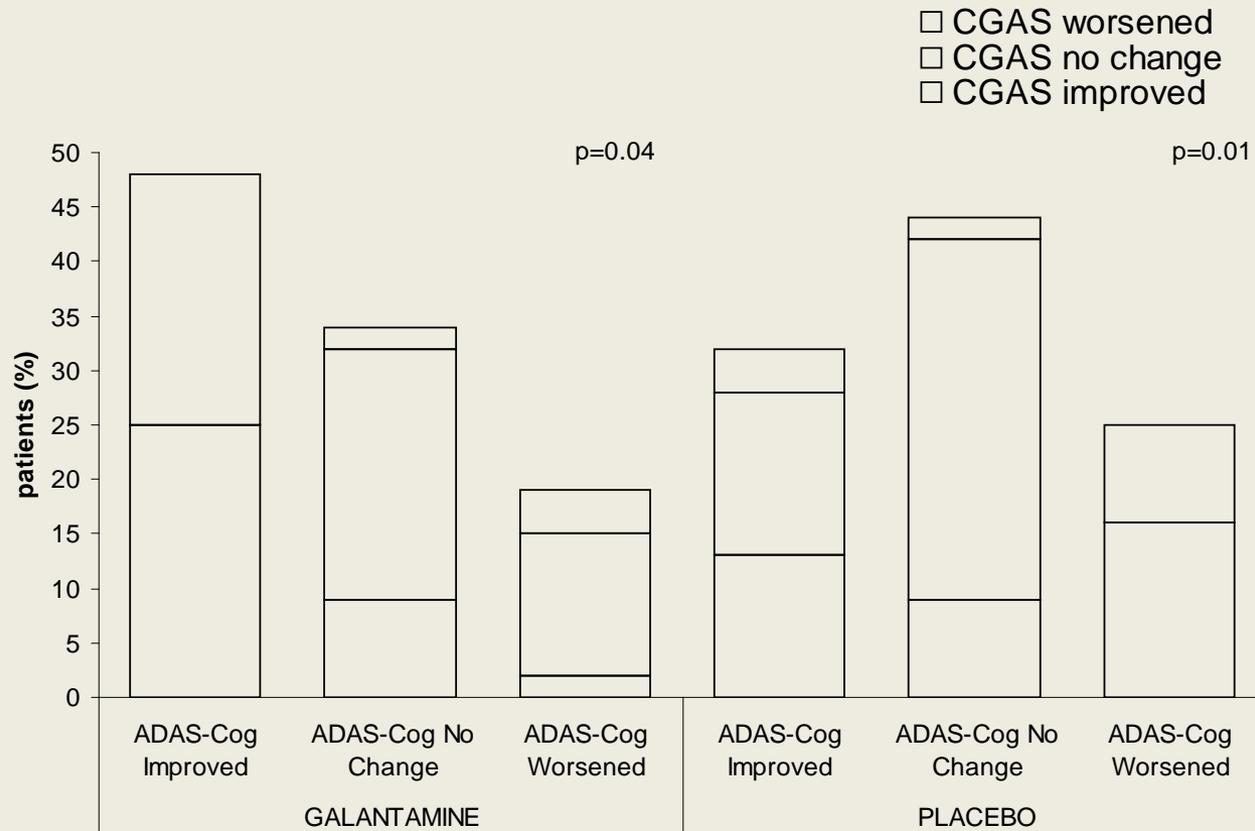
ITT population



Decline in ASAS-Cog in relation to staging.  
Top line: MMSE 21-26. Bottom line: MMSE 15-20



# Figure 2b. Individual responses on clinician-GAS by ADAS-Cog outcome at 16 weeks



# The dementia disconnect

- Clinical trials track a lot of information about memory, language, visuospatial function and calculation.
- Patients/ families care about initiative, planning, irritability social conduct, and verbal repetition as typically the most important symptoms



# Online tracking: [www.DementiaGuide.com](http://www.DementiaGuide.com)

The screenshot shows the DementiaGuide website homepage. At the top, the logo reads "DementiaGuide" with the tagline "HELPING PEOPLE AFFECTED BY DEMENTIA". A navigation bar includes links for HOME, LEARN, TRACK, JOIN, BOOKMARK THIS SITE, PRINT, HELP, and TEXT SIZE. The main content area features a large image of a man with glasses and a hand on his chin, with the text "Tell your doctor, and your family, exactly what's going on." and a "LEARN MORE" button. Below this are three columns: "Learn" (about Alzheimer's), "Track" (symptom tracking tools), and "Join" (free trial membership). A "login" section is on the right, and a "From our Subscribers" quote is at the bottom right. The footer contains contact information, copyright notices, and a trustmark logo.

**DementiaGuide**  
HELPING PEOPLE AFFECTED BY DEMENTIA

HOME | LEARN | TRACK | JOIN | BOOKMARK THIS SITE | PRINT | HELP | TEXT SIZE Aa Ab

**Tell your doctor, and your family, exactly what's going on.**

**LEARN MORE**

**Learn**  
Learn about Alzheimer's disease and dementia - its symptoms and effects. Discover strategies to help you manage day-to-day situations. Know what to expect, and how to improve your loved one's quality of life...and yours.  
[Learn More...](#)

**Track**  
DementiaGuide's tools can help you understand and track symptoms as they occur over time. Share the 'picture' with other family members, friends and Doctors who need to be aware of changes.  
[Learn More...](#)

**Join**  
Signup for our free trial membership. Get connected to a whole new world of information about dementia. Start tracking symptoms to create a better picture of the road ahead.  
[Learn More...](#)

**login**  
login   
password   
[create account](#)

DementiaGuide! We're here to help. When someone you care for is experiencing symptoms, or has received a diagnosis of Alzheimer's disease or another dementia, it raises questions for everyone involved.

DementiaGuide provides helpful information and tools created by people who understand what it's like caring for someone who has Alzheimer's disease.  
[Learn More...](#)

**From our Subscribers...**

"...well layed out, easy to navigate, and offers excellent information for those learning about dementia"

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FOR CREDIT 04/2007  
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[www.dementiaguide.com](http://www.dementiaguide.com) website:

**SymptomGuide™:** web enabled interactive tool to identify/track symptoms of dementia and create individualized profiles

**Applications:** carers and health care providers to help inform the diagnosis, communication, care planning and disease management

**Proprietary Technology**

# Symptom Library

[Physical Changes](#)  
[Thinking & Judgment](#)  
[Memory & Language](#)  
[Everyday Activities](#)  
[Behaviour](#)  
[Personality Changes](#)  
[Leisure Activities](#)

## Symptom Library

If you or someone you care about shows symptoms of dementia, it can be a confusing and scary time. It's a time when you need as much information and support as possible.

The SymptomGuide™ Symptom Library is a comprehensive source of information about the symptoms associated with dementia. By understanding the symptoms, you will gain a deeper sense of awareness about dementia and its affects. Knowing what you're dealing with and what you can expect in the future can lead to greater confidence and peace of mind.

In order to assist with your research, we have organized symptoms in the following groups:

<a href="#">Description</a>	<a href="#">Stage</a>	<a href="#">What's Happening in the Brain?</a>	<a href="#">Management Strategies</a>	<a href="#">Doctor's Diary</a>
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To start, please select one of the options on the left.

## Symptom Library

[Description](#)

[Stage](#)

[What's Happening  
in the Brain?](#)

[Management  
Strategies](#)

[Doctor's  
Diary](#)

### **Dressing** | [Description](#)

Difficulty with dressing is typical in moderate dementia, especially when the person you care for has not been given treatment yet. They may need to be reminded to change clothes or dress appropriately. Often they will require assistance, as they may have difficulty with buttons, zippers or shoelaces. They may resist assistance due to the lack of privacy and loss of independence, or because of feelings of vulnerability without their clothes on. Dressing requires the support of complex web of [neurological](#) skills that the progress of Alzheimer's diseases will, over time, disrupt. For example, to dress themselves, people must understand that time has passed. They must be able to look for and find their clothing. The person you care for may not realize that their physical appearance may be inappropriate due to [memory](#) loss or confusion of time and place.

Physical Changes  
Thinking & Judgment  
Memory & Language  
Everyday Activities

- Bathing
- Dressing
- Driving
- Eating (problems with)
- Financial Management (problems with)
- Household Chores
- Incontinence
- Meal Preparation/Cooking
- Operating Gadgets/Appliances
- Personal Care/Hygiene

## Symptom Library

Description

Stage

What's Happening  
in the Brain?

Management  
Strategies

Doctor's  
Diary

### Dressing | Stage

Difficulty with dressing is usually seen with moderate dementia. It starts with requiring prompting to change clothes. As it progresses, people need more and more hands-on help.

[Previous Symptom](#)

[Next Symptom](#)

# Symptom Library

Description

Stage

What's Happening  
in the Brain?

Management  
Strategies

Doctor's  
Diary

## Dressing | What's Happening in the Brain

To get dressed requires a series of complex functions. You need to be aware of your situation, and that it will change, requiring you to put on clothes. You need to have the judgment to choose the correct clothes, and the initiative to want to put the clothes on. You also need to be able to make the right sequence of movements, including the fine motor movements involved in buttoning and zipping.

A part from the judgment, awareness and initiative features, all parts of [executive function](#), the recognition and coordination of movement is known as [praxis](#), and its loss is called [apraxia](#). [Apraxia](#) is common in [Alzheimer's disease](#), and reflects the disruption of the [brain chemicals](#) that make up motor sequences. The inability to get dressed is one form of [apraxia](#).

Remember that dementia exists when [cognitive impairment](#) (e.g. problems with thinking, [memory](#), judgment) is severe enough to interfere with function. Function can relate to complex activities, such as driving or complex hobbies, which are impaired first, but also to more basic activities, such as personal care, that become impaired later.

The capacity for function does not exist in one part of the brain, but rather requires the integration of several brain activities. Functions like dressing are basic and over learned, so that by the time they become affected, many brain areas are involved. Still, we have some hints based on patterns. For example, the fact that a person can still get dressed when prompted to do so suggests that the problem in that case is one of initiation, which is characteristically a [frontal lobe](#) function. Later, as the disease is more widespread, the inability to carry out a motor function because the thinking parts of the brain are affected is known as [apraxia](#). Characteristically, the brain's [parietal lobes](#) are also involved then.

## Symptom Library

Description	Stage	What's Happening in the Brain?	Management Strategies	Doctor's Diary
-------------	-------	--------------------------------	-----------------------	----------------

### Dressing | Doctor's Diary

Descriptions of changes in personal care items such as dressing must take into account an individual's life-long standard. Changes in personal care therefore can provide important insights into staging. In mild dementia, there are usually no changes, although sometimes, with attention to detail being impaired, subtle problems can be observed - stains persist, for example, or combinations do not match. With moderate dementia, people need prompting to get dressed; typically, even if it is all put on properly, they will wear the same clothes over and over. Another sign of problems with dressing in moderate dementia is when they choose clothes that are unsuited to the weather. With severe dementia, they need progressive assistance, and will make errors such as putting underwear on outside of their outer clothes, or getting their head stuck in the sleeve of a pullover.

Dr. Barry Reisberg of New York University pioneered descriptions of the staging of dementia based on decline in functional capacity. His excellent short description of functional decline in dementia (the Functional Assessment Staging Tool) notes that requiring prompting to change clothes is a hallmark of moderate dementia. My colleagues and I have been impressed by the uncanny characteristicness of this change.

## Profile

### 's Personal Profile

#### Current Personal Profile

The following information is associated with 's Personal Profile created on January 21, 2010.

##### Personal Information

**Date of Birth:** February 5, 1928

**Sex:** Male

**Race:** White

**Ethnicity:** [no data entered]

**Marital Status:** Married

**Education Level:** High school completion

**Employment Status:** Retired

##### Living Arrangements Information

Which of the following best describes 's current living arrangements?

With me (if you are caregiver)

Have there been any changes in these living arrangements in the past 5 years?

No

Approximately how often do you see on a weekly basis?

Everyday (we live in same household)

During a typical visit, how much time do you spend with ?

7 or more hours

# Personal Profile

## Living Arrangements

## Health & Medication Information

**How long ago did you first notice that was experiencing cognitive problems? (e.g. memory troubles, repeating things, etc.)**

1 year or more

**Has been diagnosed with dementia?**

Yes

**Which type of Dementia?**

Alzheimer's disease

**When did receive this diagnosis?**

September, 2008

**Is currently being treated with prescription medication for dementia?**

Yes

**Please indicate which medication therapy is currently taking to treat dementia:**

Aricept (donepezil) Dosage: 5 mg tablet, once per day

**When did start using this drug therapy?**

January, 2009

**Is currently taking any other prescription or non-prescription medications? If so, please indicate which:**

[no data entered]

**Does also have problems with any of the following?**

[no data entered]

# Health and Medication Information

## SymptomGuide™ Creating 's Symptom Profile

This section allows you to record and track the progress of symptoms. You will be prompted to categorize and rank the symptoms at each step. If you have any technical difficulties while completing this section, please contact us.

- 1 Describe Symptoms
- 2 Rank Symptoms
- 3 Save Profile

### Choose Symptoms to add to 's Profile

To start, please select a Category from the column on the left. By selecting a Category, you will see a range of associated symptoms in the middle column. When you select one of the symptoms, a description will appear to the right. If this description fits the symptom you are trying to record, click on Select this Symptom and Continue. Or, alternately, add a symptom in the space marked 'Other', and then click Select this Symptom and Continue.

#### Category

- Everyday Activities
- Memory & Language
- Thinking & Judgment
- Behaviour
- Leisure Activities
- Personality Changes
- Physical Changes

#### Symptoms

Judgment  
Comprehension/ Understanding  
Attention/Concentration (lack of)  
Following Instructions  
Decision Making (problems with)  
Insensitivity  
Inappropriate Language and Beh:  
Unsafe Actions

Other:

#### Definition

Inability to remain focused or alert.

Select & Continue

# Choosing Symptoms to Track

## 1 Describe Symptoms

## 2 Rank Symptoms

## 3 Save Profile

## Interest/Initiative (lack of): Personality Changes

People with this symptom (Interest/Initiative (lack of)) may exhibit: Shows a lack of interest in activities/events. Is apathetic, listless

## Descriptors

From the descriptors below, please select those that best describe , and that would be important for you to track over the course of the treatment.

- shows less interest in daily tasks or activities (e.g. cooking, bathing, watching TV)
- requires prompting to start most tasks or activities (e.g. take a bath, water the flowers)
- is reluctant to participate in previously enjoyed activities (e.g. going for a walk, going out for dinner)
- initiates tasks or activities but does not complete them
- does not care about hygiene or personal appearance
- shows little interest in the lives of others
- shows little interest in current events
- is uninterested in events that are going on around them
- avoids making decisions
- complains of being bored; says there is nothing for them to do
- seems "vacant" or stares into space
- is less motivated as the day progresses

Other:

Other:

Other:

[Go Back & Edit](#)
[Select & Continue](#)

# Descriptors for tracking symptoms

## SymptomGuide™

### Create 's Symptom Profile

1 Describe Symptoms

2 Rank Symptoms

3 Save Profile

#### Interest/Initiative (lack of): Personality Changes

People with this symptom (Interest/Initiative (lack of)) may exhibit: Shows a lack of interest in activities/events. Is apathetic, listless

#### Descriptors:

- shows less interest in daily tasks or activities (e.g. cooking, bathing, watching TV)
- is reluctant to participate in previously enjoyed activities (e.g. going for a walk, going out for dinner)
- is uninterested in events that are going on around them
- avoids making decisions
- seems "vacant" or stares into space

#### Frequency

Overall, problems with this symptom occur  times per .

hour  
day  
week  
month

week

Go Back & Edit

Select & Continue

Frequency  
of  
symptoms  
being  
tracked

## Profile

### Creating 's Symptom Profile

1 Describe Symptoms

2 Rank Symptoms

3 Save Profile

#### Ranking Symptoms

Please rank the symptoms you have chosen in order of most important (at top) to least important (at bottom). You can drag and drop the symptoms to place them in proper order.

##### Most Important

Driving (Everyday Activities)

Interest/Initiative (lack of) (Personality Changes)

Attention/Concentration (lack of) (Thinking & Judgment)

Memory of Recent Events (Memory & Language)

##### Least Important

Go Back

Select & Continue

# Ranking Symptoms

[Home](#) > [Profile](#)

## Profile

### Current Symptom Profile Summary Report

The following symptoms were tracked on Jan 18, 2010 0:00:00.

#### **Driving (Everyday Activities)**

No Change

Occurs 2 time(s) a day

#### **Interest/Initiative (lack of) (Personality Changes)**

This symptom has not been tracked yet.

Occurs 4 time(s) a week

#### **Attention/Concentration (lack of) (Thinking & Judgment)**

Somewhat Better

Occurs 2 time(s) a day

#### **Memory of Recent Events (Memory & Language)**

Much Worse

Occurs 1 time(s) a day

[top](#)

# Symptom Report

#### Symptom Profile Symptom Reports

- [Summary Score Report](#)
- [Summary Report](#)
- [Summary Detailed Report](#)
- [Summary Over Time Report](#)

#### Personal Profile Surveys

**Symptom Profile**  
**Symptom Reports**

- Summary Score Report
- Summary Report
- Summary Detailed Report
- Summary Over Time Report

**Personal Profile**  
**Surveys**

## Profile

### Current Symptom Profile Detailed Report

The following symptoms were tracked on Jan 18, 2010 0:00:00.

#### Driving (Everyday Activities)

No Change

Occurs 2 time(s) a day

##### Descriptors:

- has difficulty maintaining attention and concentration when driving
- forgets familiar routes when driving
- fails to recognize traffic signs (e.g. stop signs)
- forgets where they parked the car
- forget where they were going or gets lost when driving

#### Interest/Initiative (lack of) (Personality Changes)

This symptom has not been tracked yet.

Occurs 4 time(s) a week

##### Descriptors:

- shows less interest in daily tasks or activities (e.g. cooking, bathing, watching TV)
- is reluctant to participate in previously enjoyed activities (e.g. going for a walk, going out for dinner)
- is uninterested in events that are going on around them
- avoids making decisions
- seems "vacant" or stares into space

#### Attention/Concentration (lack of) (Thinking & Judgment)

Somewhat Better

Occurs 2 time(s) a day

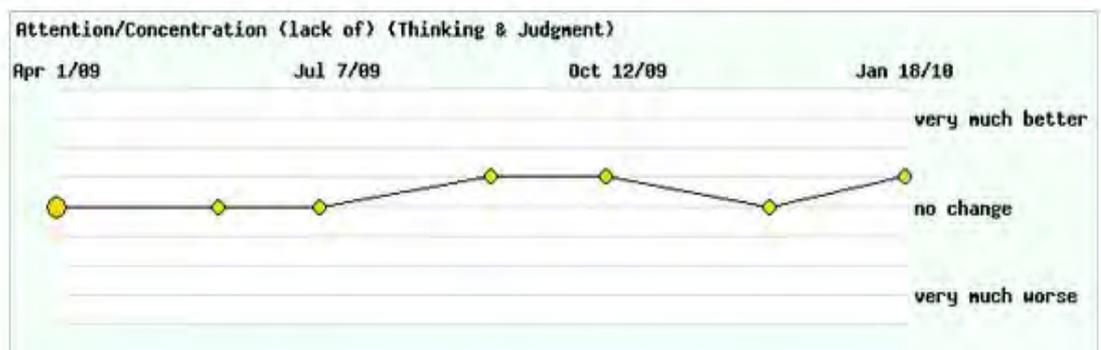
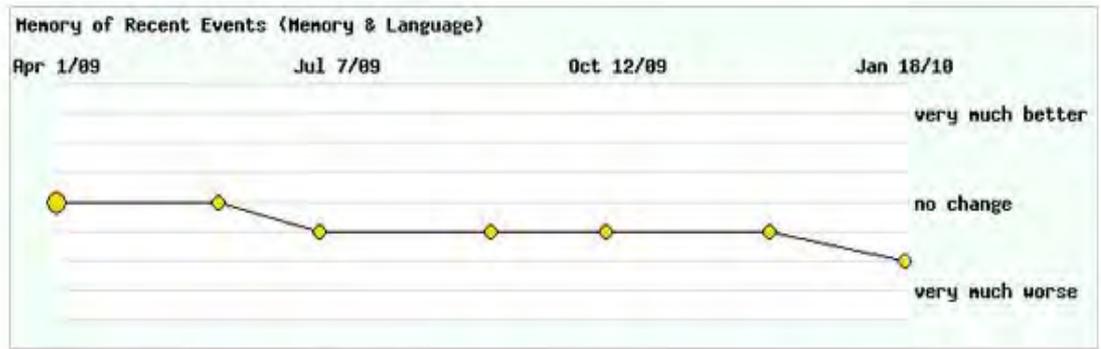
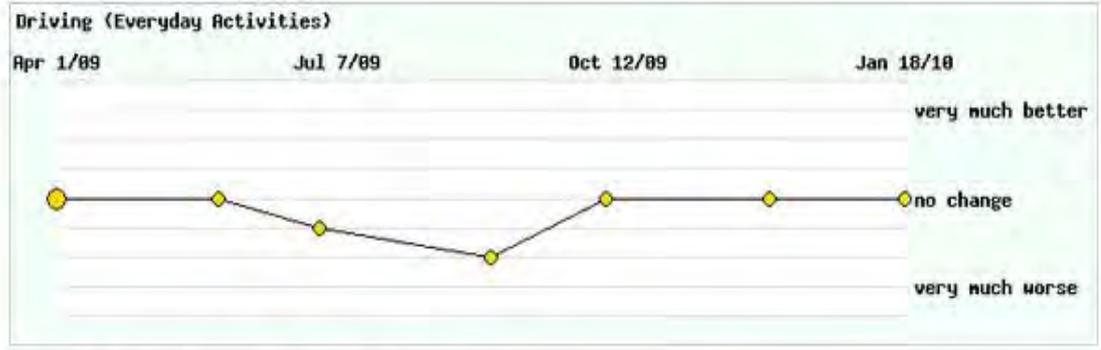
##### Descriptors:

- is easily distracted

# Detailed Symptom Report

Profile

Symptom Profile Graphs



# Symptom Profile Graphs

# Responsiveness of the SymptomGuide™

- Cohen's d of CLOX-1 = 0.25; SymptomGuide™ = 0.25
- Interpretation: 1.3 point improvement, vs. “a 54% reduction in symptoms in responders”. Most improvement was seen in a reduction in anxiety, irritability and improvement in initiation of hobbies & social activities.

# Objections to individualization

- Not everyone has the same goals, so how can we tell if active treatment and placebo groups set the same goals?
- Isn't it too susceptible to "gaming"? What if people just set goals that are too easy to achieve?
- Isn't it too subjective compared with the ADAS-Cog, or with MRI measures?
- Doesn't it take too much time?
- What if just a few items drive the treatment effect?
- Is it reliable?
- How feasible is it to introduce a new measure that takes a different approach?

**NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS**

**REQUEST FOR 1<sup>st</sup> CHOLINESTERASE INHIBITOR**  
**(FOR INITIAL 90 DAYS COVERAGE)**

Please provide the following to support your request for insured coverage of the first cholinesterase inhibitor for an initial period of 90 days.

PATIENT INFORMATION			
PATIENT'S SURNAME	PATIENT'S GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH
PATIENT'S ADDRESS			

DIAGNOSTIC INFORMATION
The patient has a confirmed memory problem and: MMSE score: _____ FAST score: _____  The cause of the patient's dementia is (check as appropriate): <input type="checkbox"/> probable Alzheimer's Disease <input type="checkbox"/> possible Alzheimer's Disease with vascular component <input type="checkbox"/> possible Alzheimer's Disease with Lewy bodies <input type="checkbox"/> possible Alzheimer's Disease with other (specify): _____

TARGET SYMPTOMS ESTABLISHED
List the 3 target symptoms established: 1. _____ _____ 2. _____ _____ 3. _____ _____

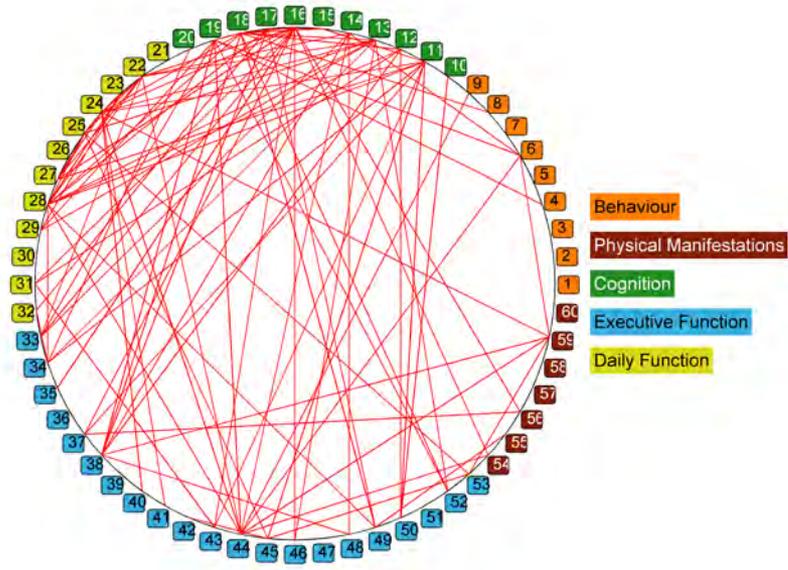
CHOLINESTERASE INHIBITOR
Has this patient been on this cholinesterase inhibitor before? <input type="checkbox"/> YES since _____ <input type="checkbox"/> NO
Cholinesterase inhibitor requested and starting dosage: <input type="checkbox"/> Donepezil (Aricept®) – Dosage: _____ mg _____ times daily <input type="checkbox"/> Galantamine (Reminyl®) – Dosage: _____ mg _____ times daily <input type="checkbox"/> Rivastigmine (Exelon®) – Dosage: _____ mg _____ times daily
Check for tolerance within <u>2 weeks</u> of starting the above cholinesterase inhibitor.

PHYSICIAN'S NAME & ADDRESS:   CPSNS #: _____	_____ PHYSICIAN'S SIGNATURE _____ DATE
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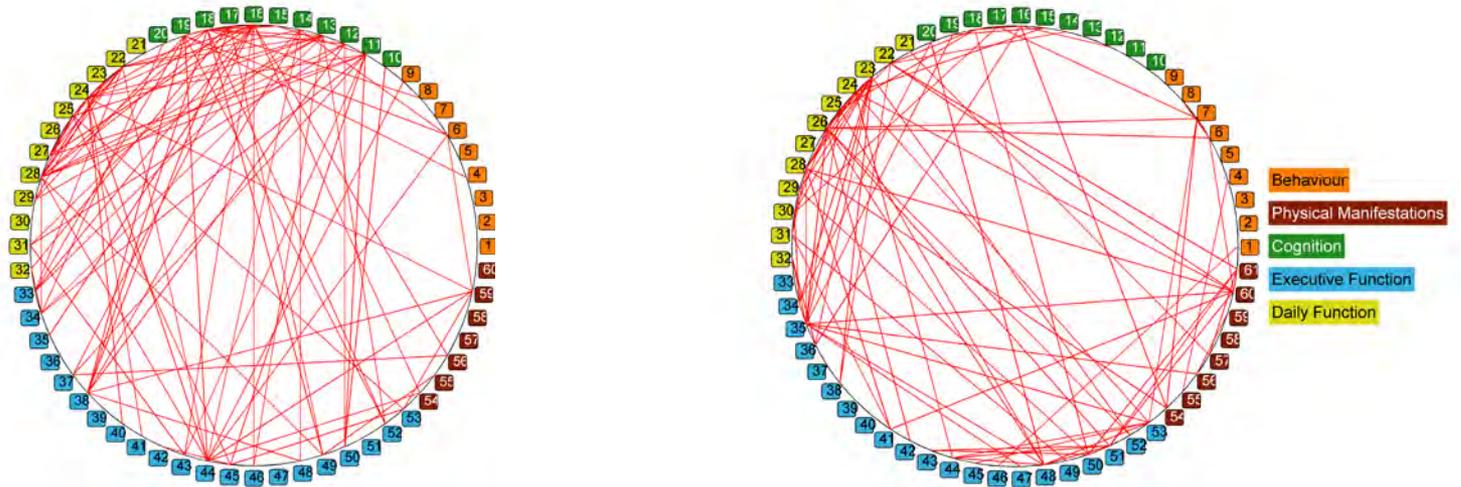
If you need assistance, please contact the Pharmacare Office at (902) 496-7001 or 1-800-305-5026.



# Connectivity graph of relationships between symptoms



# Connectivity graphs in dementia: treated mild vs. untreated moderate



# Synthesis

- Tracking patient goals lessens arbitrariness in care.
- Evaluation of dementia treatment effects need to be individualized in practice.
- Individualization can also happen in trials, where its enhances evaluation of clinical meaningfulness and effectively complements standardized measures



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