

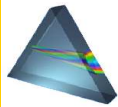
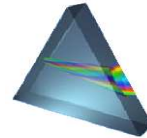
Five Things You Should Know About Medication and Alzheimer's Disease

Care4U Family Conference The Alzheimer Society of Manitoba October 29th, 2016



UNIVERSITY
OF MANITOBA

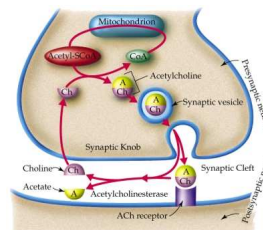
Kyle MacNair and Shawn Bugden
College of Pharmacy, Rady Faculty of
Health Science
University of Manitoba

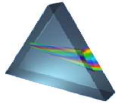


Five Things You Should Know – About Medication and Alzheimer's Disease

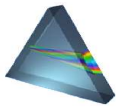
OUTLINE

- Thing #1: Ignore Headlines
- Thing #2: Beware of Anecdotes
- Thing #3: Don't Make Things Worse
- Thing #4: Use the Right Drug at the Right Time
- Thing #5: Less Medication Is OK



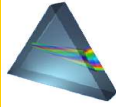


Five Things You Should Know – About Medication and Alzheimer’s Disease



Ignore Headlines





Ignore Headlines

Benzodiazepines Linked to Increased Alzheimer's Risk

Deborah Brauser

September 09, 2014

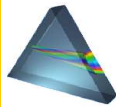
EDITORS' RECOMMENDATIONS

5p DAILY EXPRESS
KINGDOM'S SENIORS
HER TOUCHING
STORY MAKES
AMERICA CRY
WIN A FORD TRIBUTE MOTORHOME WORTH OVER £35,500
**STATINS HALT
ALZHEIMER'S**
40p a day pill
used by millions
tackles cruel
brain disease
DAYS AFTER RECORD HIGH TEMPERATURES
SNOW CHAOS SWEEPS BRITAIN

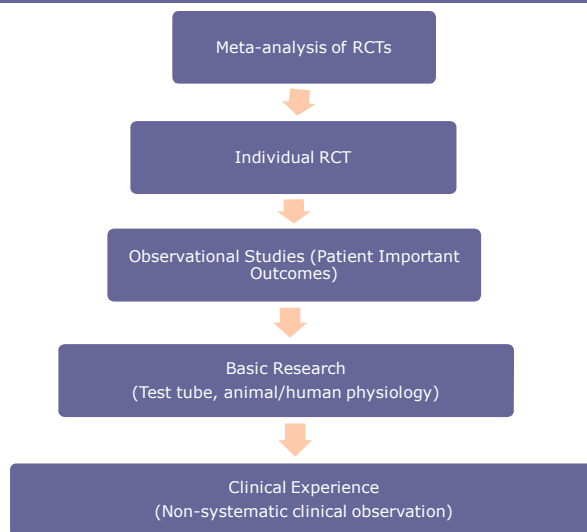
Use of benzodiazepines to treat insomnia or anxiety may increase the risk for Alzheimer's disease (AD), new research suggests.

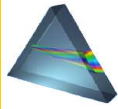
Daily Mail
Women who refuse
to let their husbands
see them naked
**ALZHEIMER'S
REVOLUTION**
Breakthrough
drug could stop
dementia from
ever developing
125,000 ops
face axe in
doctors' five
day strikes

The Daily Telegraph
Transfer
deadline day
Brexit deal
will limit
migration,
May pledges
Drug could be
breakthrough
for Alzheimer's

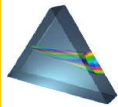
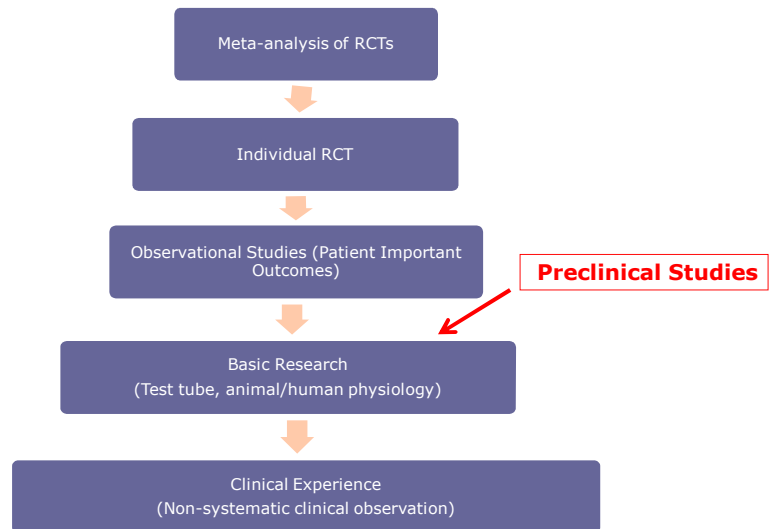


Hierarchy of Evidence





Hierarchy of Evidence



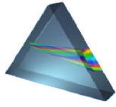
Ignore Headlines



≠



TEST TUBE Does NOT Equal **PEOPLE**



Ignore Headlines



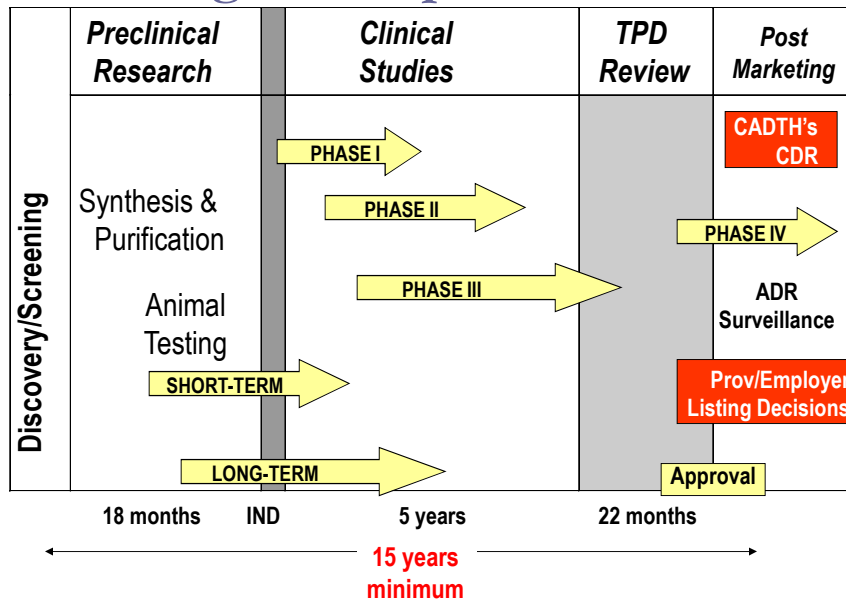
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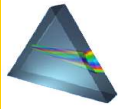


RAT

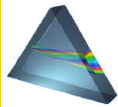
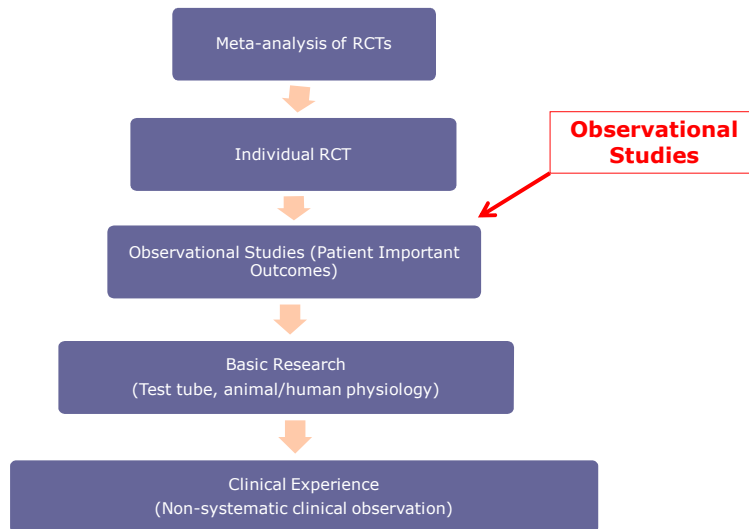
Does NOT Equal **PEOPLE**

New Drug Development

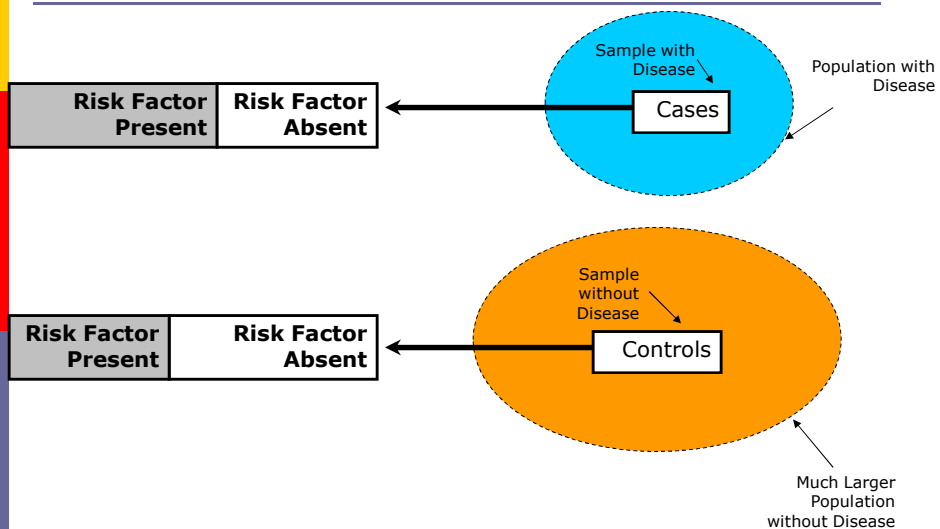


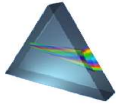


Hierarchy of Evidence

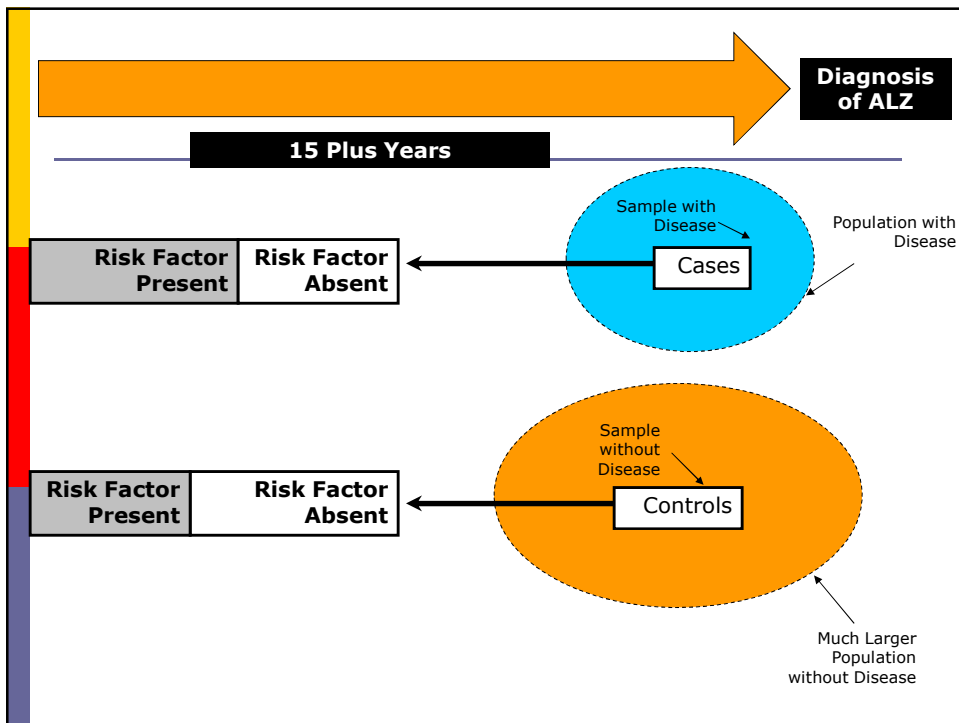
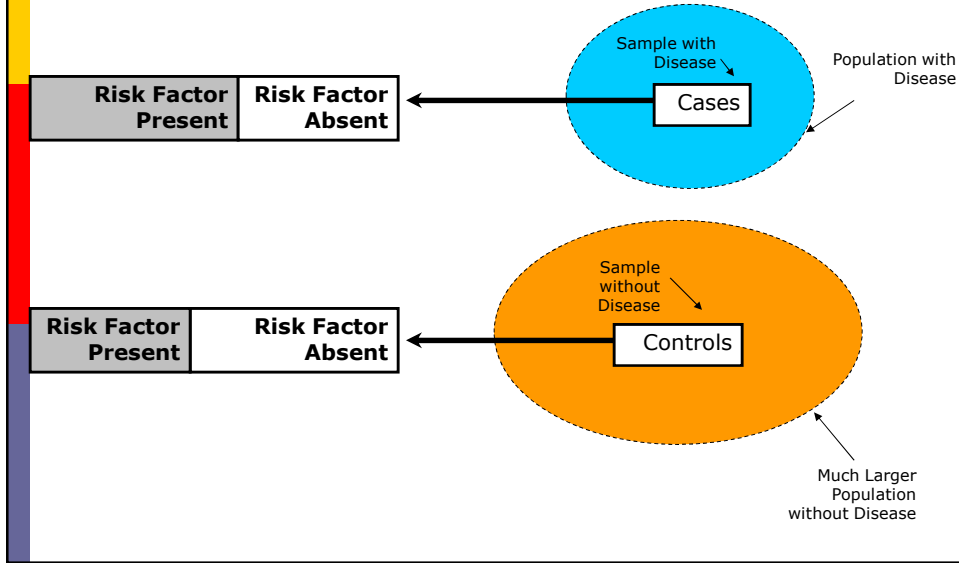


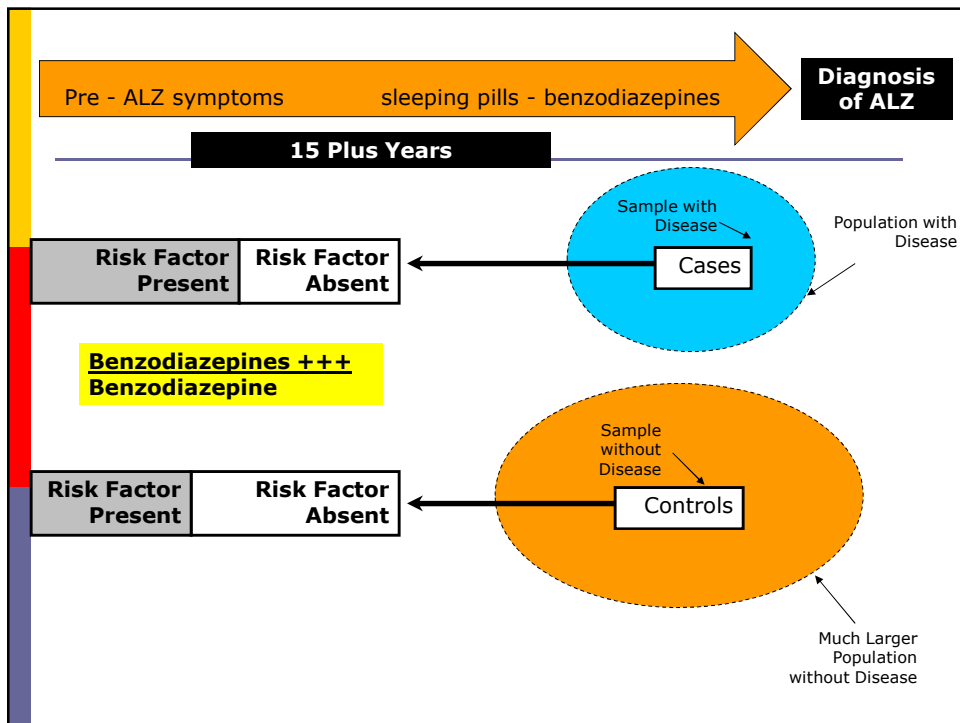
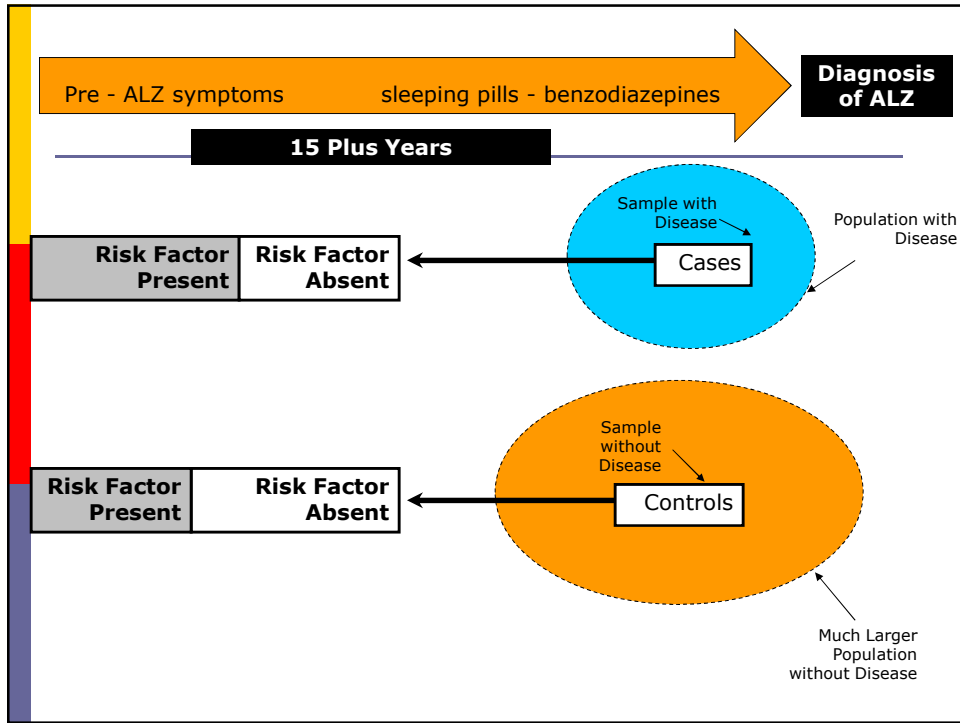
Case - Control Studies

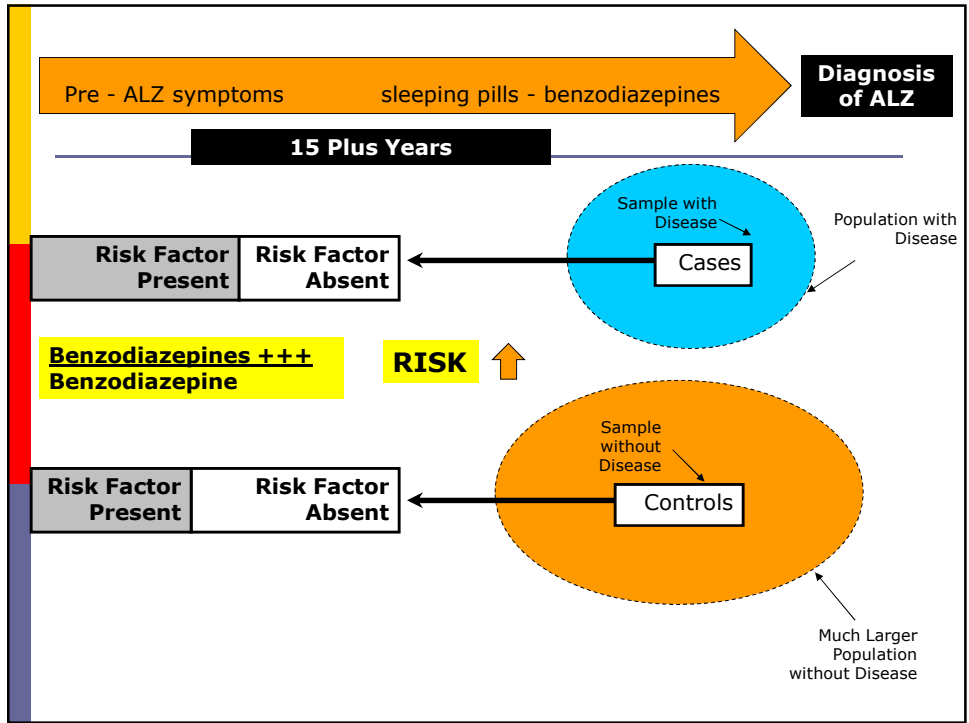


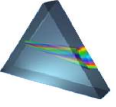


Protopathic Bias










Ignore Headlines

Benzodiazepines Linked to Increased Alzheimer's Risk

Deborah Brauser
September 09, 2014

EDITORS' RECOMMENDATIONS



Benzodiazepine Use Linked to Dementia Risk

Alzheimer's Disease News & Perspectives


Geriatrics News & Perspectives

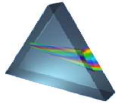
RELATED DRUGS & DISEASES

Use of benzodiazepines to treat insomnia or anxiety may increase the risk for Alzheimer's disease (AD), new research suggests.

A case-control study of nearly 9000 older individuals showed that risk for AD was increased by 43% to 51% in those who had "ever used" benzodiazepines in the previous 5 years.

The association was even stronger in participants who had been prescribed benzodiazepines for 6 months or longer





Ignore Headlines

~~Benzodiazepines Linked to Increased Alzheimer's Risk~~

~~Deborah Braucher
September 09, 2014~~

~~EDITORS' RECOMMENDATIONS~~



~~Benzodiazepine Use
Linked to Dementia Risk~~

~~Alzheimer's Disease News &
Perspectives~~

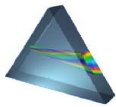
~~Geriatrics News & Perspectives~~

~~RELATED DRUGS & DISEASES~~

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~~The association was even stronger in participants who had been prescribed benzodiazepines for 6 months or longer.~~



Ignore Headlines

~~Benzodiazepines Linked to Increased Alzheimer's Risk~~

~~Deborah Braucher
September 09, 2014~~

~~EDITORS' RECOMMENDATIONS~~



~~Benzodiazepine Use
Linked to Dementia Risk~~

~~Alzheimer's Disease News &
Perspectives~~

~~Geriatrics News & Perspectives~~

~~RELATED DRUGS & DISEASES~~

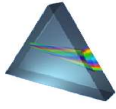
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~~A case-control study of nearly 9000 older individuals showed that risk for AD was increased by 43% to 51% in those who had "ever used" benzodiazepines in the previous 5 years.~~

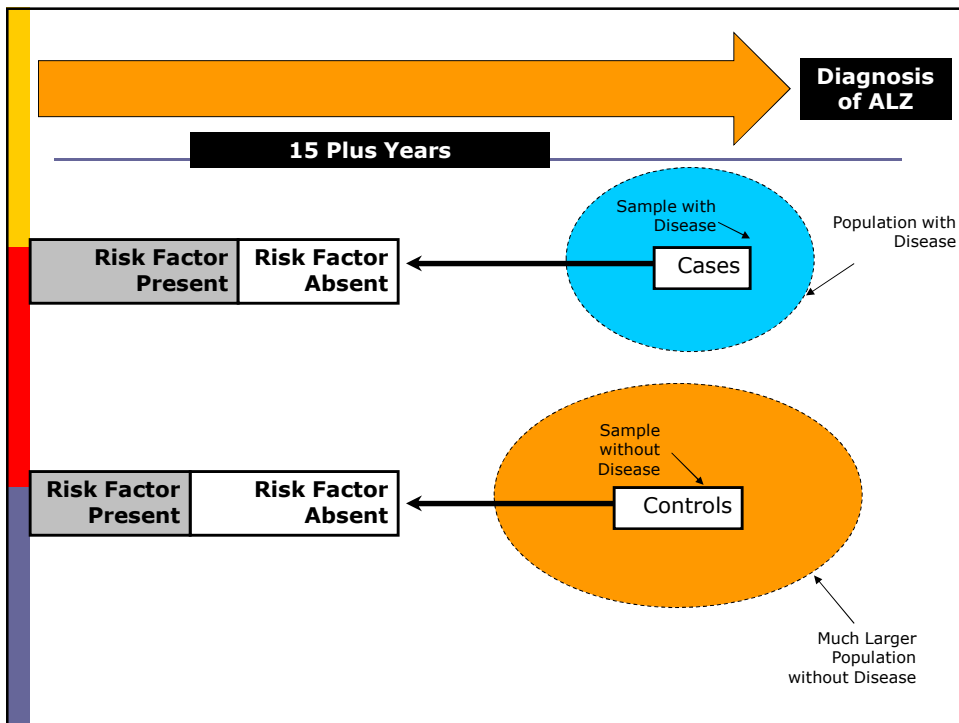
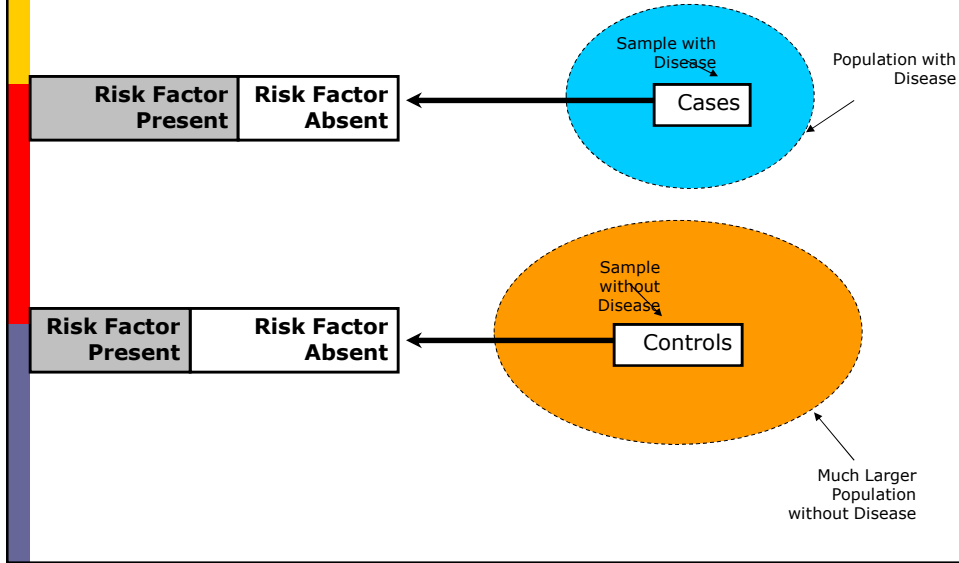
~~The association was even stronger in participants who had been prescribed benzodiazepines for 6 months or longer.~~

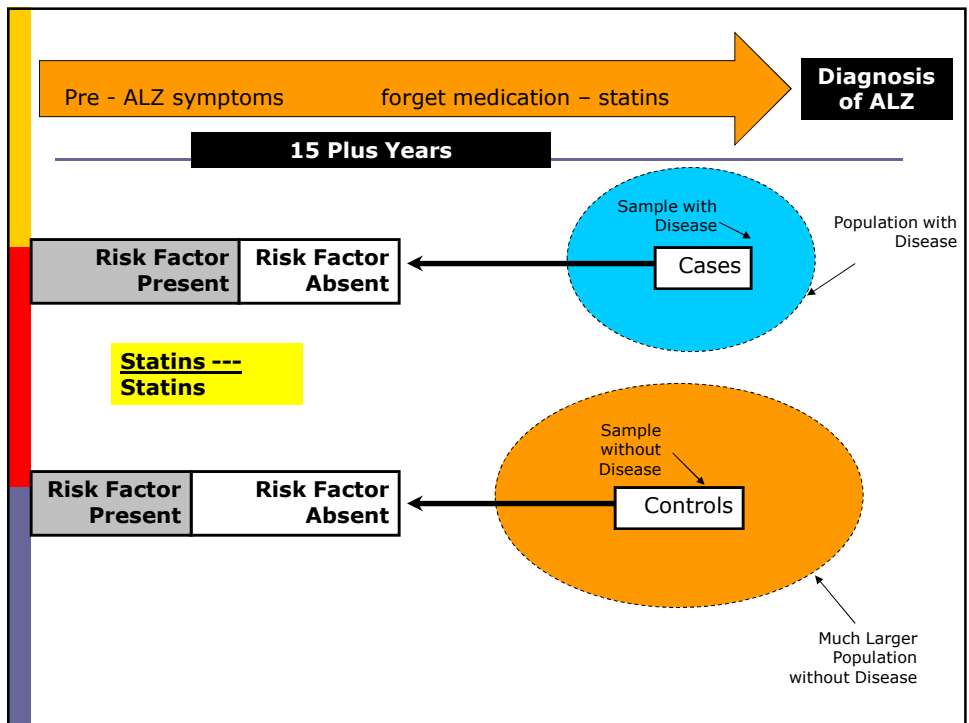
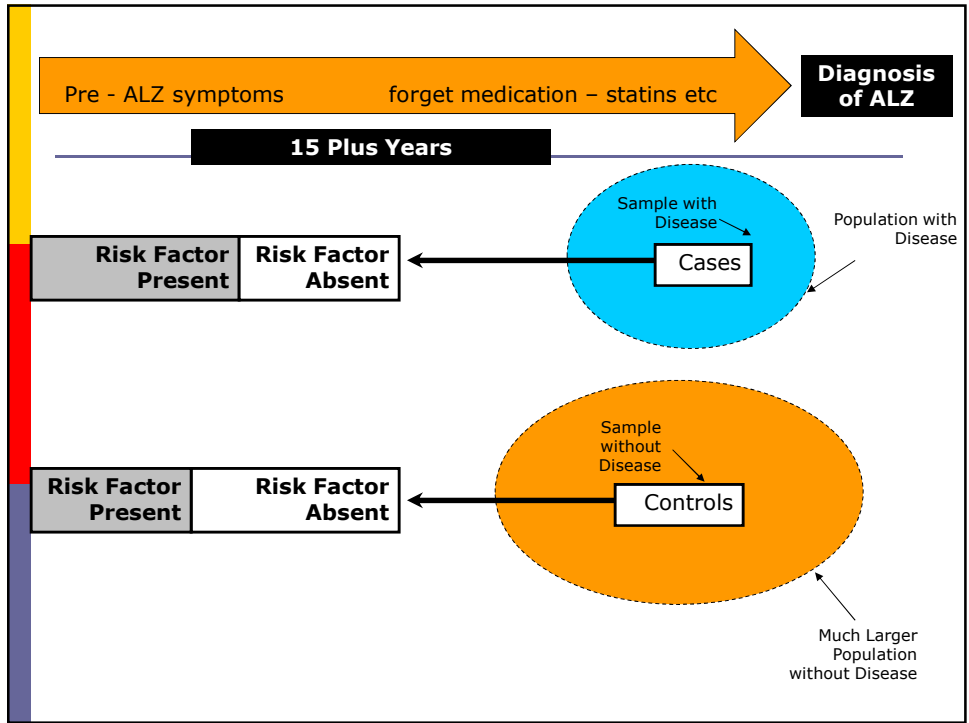


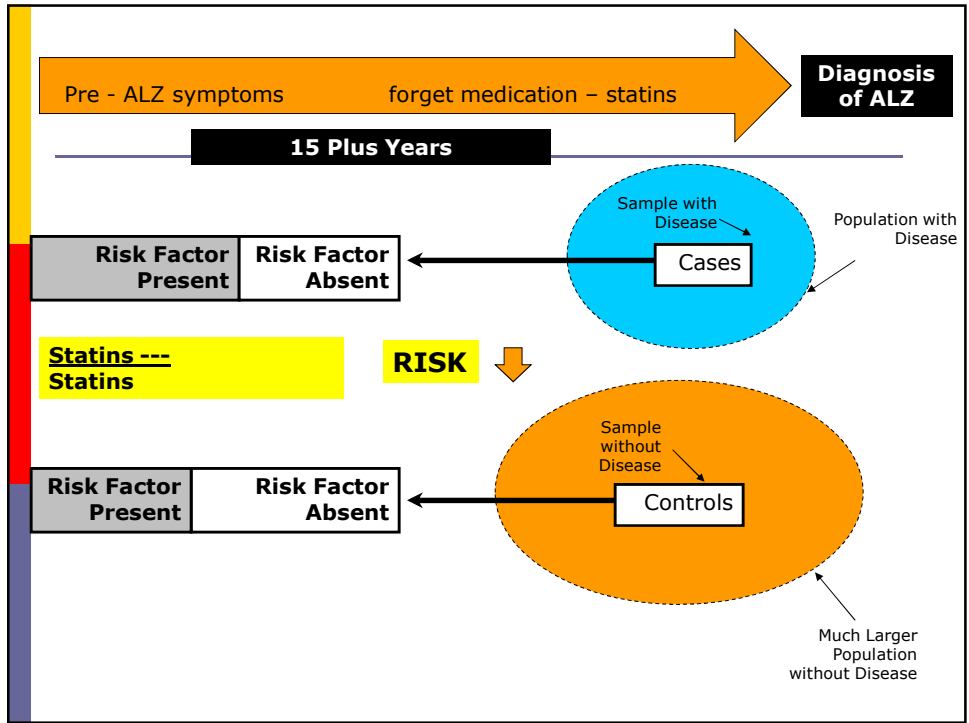
- Unlikely that Benzodiazepines increase risk of Alzheimer's Disease
- **However,** Benzodiazepines do affect thinking and cognition – best avoided



Reverse Protopathic Bias







Ignore Headlines

5p DAILY EXPRESS

KATHRINE: SENATOR HER TOUCHING STORY MAKES AMERICA CRY

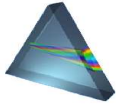
Scandal of our benefits paid to migrants' children who have never set foot in the UK

WIN A FORD TRIBUTE MOTORHOME WORTH OVER £35,500

STATINS HALT ALZHEIMER'S

40p a day pill used by millions tackles cruel brain disease

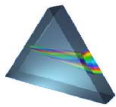
DAYS AFTER RECORD HIGH TEMPERATURES SNOW CHAOS SWEEPS BRITAIN (WE DID BRILL YOU)



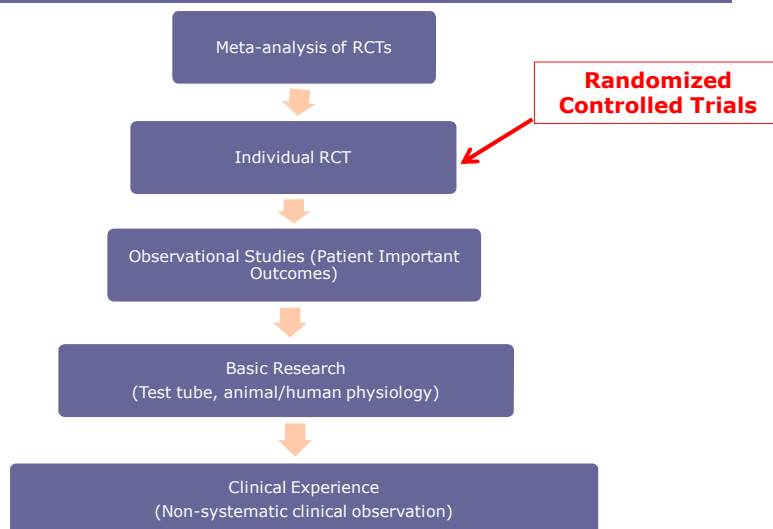
Ignore Headlines

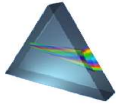


- No compelling evidence that statins have a role in prevention or treatment of Alzheimer's disease
- Excellent evidence for cardiac conditions
- Time to Benefit
- Quality of Life

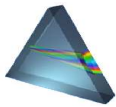


Hierarchy of Evidence





Ignore Headlines



Ignore Headlines

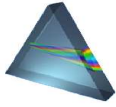
ARTICLE

doi:10.1038/nature19323

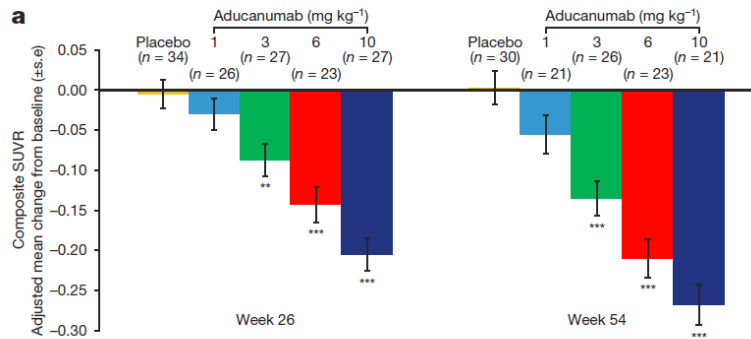
The antibody aducanumab reduces A β plaques in Alzheimer's disease

Jeff Sevigny^{1*}, Ping Chiao^{1*}, Thierry Bussière^{1*}, Paul H. Weinreb^{1*}, Leslie Williams¹, Marcel Maier², Robert Dunstan¹, Stephen Salloway³, Tianle Chen¹, Yan Ling¹, John O'Gorman¹, Fang Qian¹, Mahin Arastu¹, Mingwei Li¹, Sowmya Chollate¹, Melanie S. Brennan¹, Omar Quintero-Monzon¹, Robert H. Scannevin¹, H. Moore Arnold¹, Thomas Engber¹, Kenneth Rhodes¹, James Ferrero¹, Yaming Hang¹, Alvydas Mikuskis¹, Jan Grimm², Christoph Hock^{3,4}, Roger M. Nitsch^{5,6*} & Alfred Sandrock¹

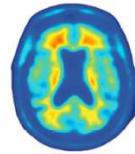
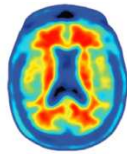
50 | NATURE | VOL 537 | 1 SEPTEMBER 2016



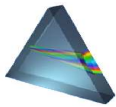
Behind the Headlines



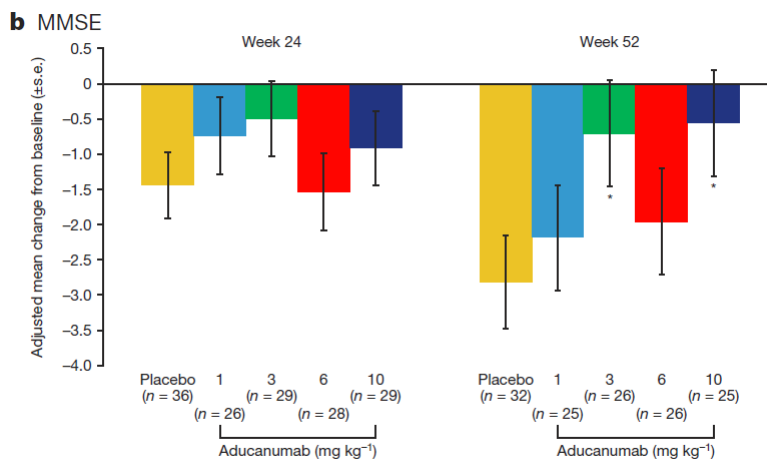
Dose-response $P < 0.001$ at weeks 26 and 54 based on a linear contrast test



6 mg kg⁻¹

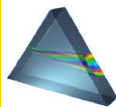
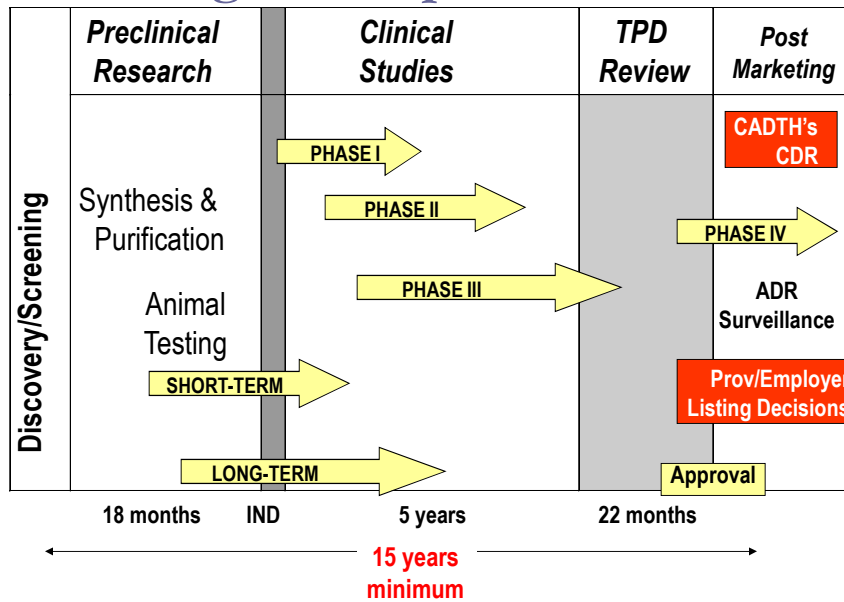


Behind the Headlines



Dose-response $P < 0.05$ at week 52 based on a linear contrast test

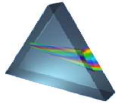
New Drug Development



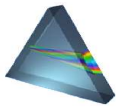
Ignore Headlines



- Phase II trial
 - 165 patients
 - 1-year
- Phase III trial planned
 - 2700 patients
 - 20 countries
 - Won't report until at least 2020

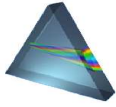


Five Things You Should Know –
About Medication and Alzheimer's Disease

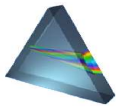


Beware of the Anecdote





Beware of the Anecdote



Beware of the Anecdote

- Acute example
- Alzheimer's progressive but good days/periods and bad days/periods

Natural Course of Disease

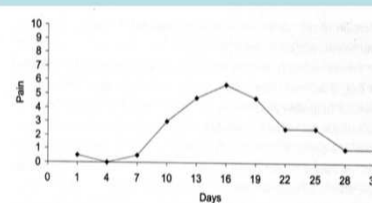
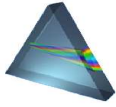


Figure 3.1. Hypothetical Natural History of Sarah's Arthritis Pain



Beware of the Anecdote

Start Natural Product Here

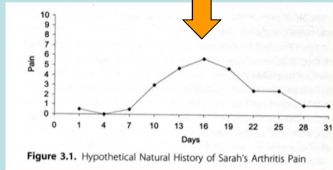


Figure 3.1. Hypothetical Natural History of Sarah's Arthritis Pain

Starting in the Middle

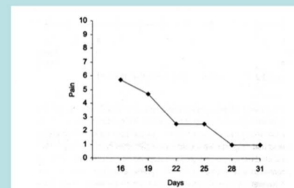
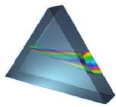


Figure 3.3. Natural History Masquerading as a CAM Analgesic Effect



Beware of the Anecdote

- Placebo effect of 30-40% response

Placebo Plus Decreasing Pain

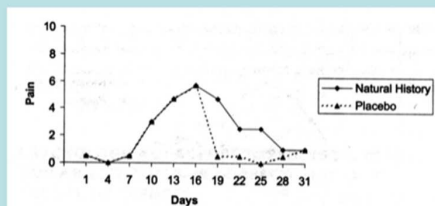
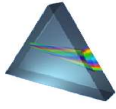
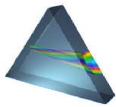
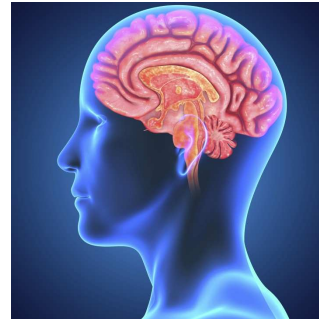


Figure 3.4. The Placebo Effect Added to a Natural History Effect



Ginkgo biloba



Ginkgo biloba

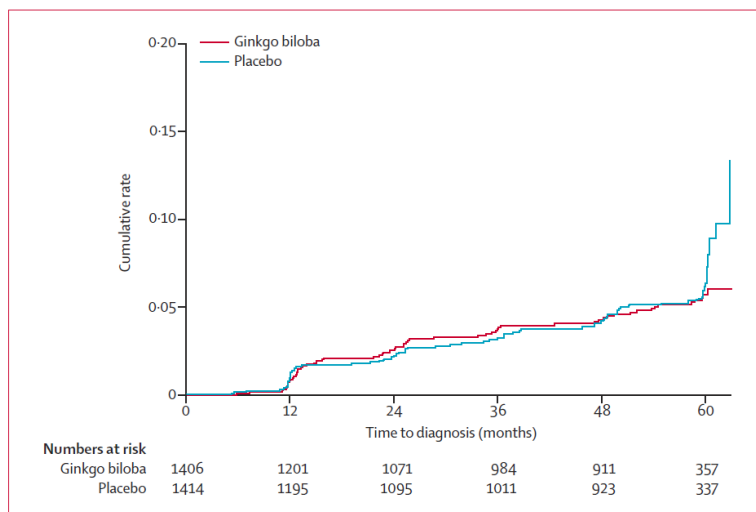
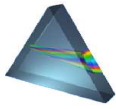


Figure 2: Cumulative incidence of Alzheimer's disease

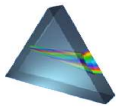
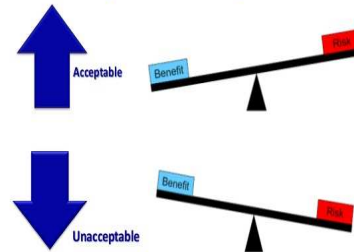
Vellas B et al. Lancet Neurology 2012;11:851.



Ginkgo biloba

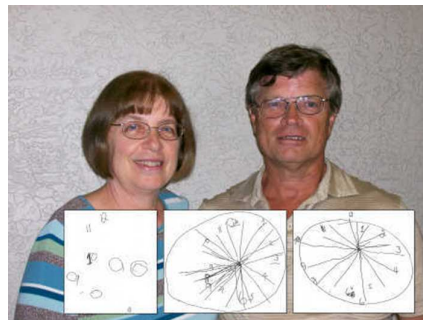
- Benefit?
- Risks
 - Allergies
 - Bleeding risks

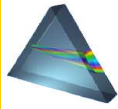
Risk/Benefit Balance of medications



Coconut Oil

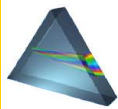
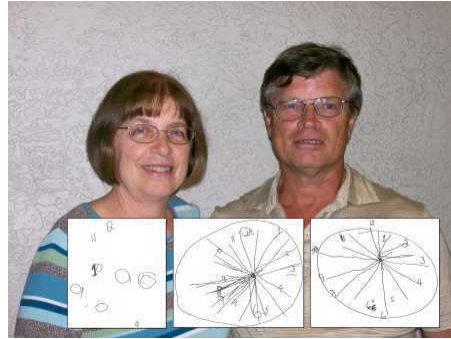
- Pharmacology is a story not evidence
- Pharmacology is low level evidence
- Anecdote is not evidence
- Risks?
- Benefits?





Coconut Oil

- University of South Florida Trial
- 65 patients
- \$250,000 grant from private foundation
- Economics of Trials
- Study started in 2013
- Results expected in a ~~year~~ ... 2018



Other Agents

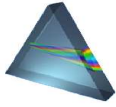
- Metal protein attenuating compounds (chelation – ex clioquinol)
 - no evidence beneficial and questionable safety
- Statins for prevention
 - no good evidence that they reduce the risk
- Vitamin E
 - no convincing evidence of benefit
- Estrogen supplements
 - no evidence of benefit, may be harmful
- ASA, and NSAIDS for treatment
 - no evidence of benefit, may be harmful

Scott HD et al. Cochrane Database of Systematic Reviews 2001

Jaturapatporn D et al. Cochrane Database of Systematic Reviews 2012

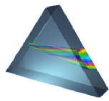
Farina N et al. Cochrane Database of Systematic Reviews 2012

Sampson EL et al. Cochrane Database of Systematic Reviews 2012



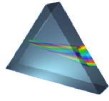
Five Things You Should Know – About Medication and Alzheimer’s Disease

THING
3



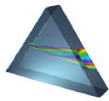
Don't Make Things Worse





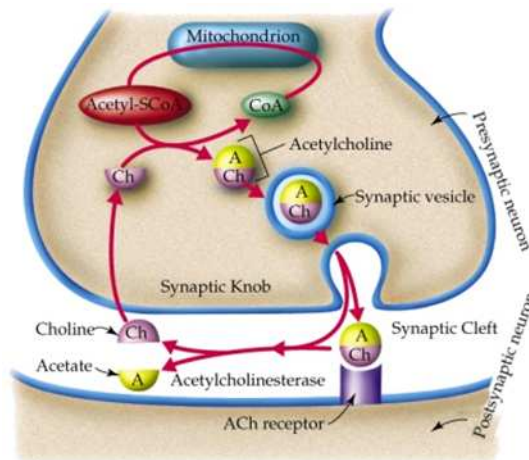
Don't Make Things Worse

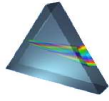
- Don't undo the effects of one medication with another



Alzheimer's Medications Mechanism

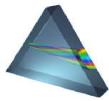
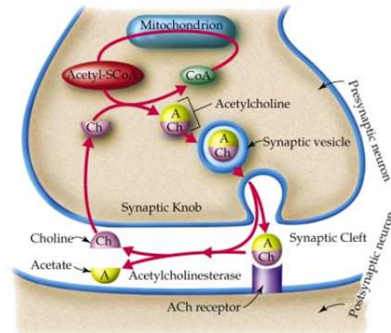
- Cholinesterase Inhibitors
 - Aricept
 - Reminyl
 - Exelon





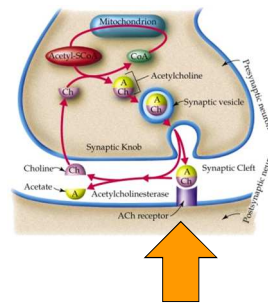
Alzheimer's Medications Mechanism

- Acetylcholine is an important neurotransmitter
- Diminished in Alzheimer's Disease
- Acetylcholinesterase breaks down Acetylcholine
- Aricept® like drugs inhibit acetylcholinesterase and **increase Acetylcholine**



Alzheimer's Medications Mechanism

- Anticholinergic drugs block the effects of Acetylcholine
- Known to impair thinking /cognition
- **BLOCK** the very receptor we are trying to stimulate with increase acetylcholine



**Anticholinergic
Drugs BLOCK
Acetylcholine
Receptor**

Reference List of Drugs with Anticholinergic Effects

Aricept (donepezil) and Exelon (rivastigmine) are reversible inhibitors of the enzyme acetylcholinesterase. Because of their mechanism of action, anticholinergic medications can interfere with the activity of Aricept and Exelon. The following is a list of drugs with anticholinergic effects with emphasis on those with moderate to high activity. This list has been reviewed by DQAC and SFC and will be used for assessing Aricept and Exelon requests. Coverage cannot be approved if a patient is using a drug on this list concurrently with Aricept or Exelon.

Antidepressants with moderate to high anticholinergic effects

- amitriptyline (Elavil)
- clomipramine (Anafranil)
- doxepin (Sinequan)
- imipramine (Tofranil)
- nortriptyline (Aventyl)
- protriptyline (Triptil)
- trimipramine (Surmontil)

Antiparkinsonian

- benztropine mesylate (Cogentin)
- biperiden HCl (Akineton)*
- ethopropazine (Parsitan)
- orphenadrine (Disipal)
- procyclidine (Kemadrin)
- trihexyphenidyl (Novo-Hexidyl, Apo-Trihex)

Antiemetics/Antivertigo with moderate to high anticholinergic effects

- dimenhydrinate (Gravol)
- meclizine (Antivert)
- promethazine (Phenergan)*
- scopolamine (Transderm V)

Antipsychotics with moderate to high anticholinergic effects

- chlorpromazine (Largactil)
- clozapine (Clozaril)
- flupenthixol (Fluanxol)
- loxapine (Loxapac)
- mesoridazine (Serentil)
- methotrimeprazine (Nozinan)
- olanzapine (Zyprexa)
- pericyazine (Neuleptil)
- pimozide (Orap)
- thiothoprazine (Majeptil)*
- thioridazine (Mellari)
- zuclopenthixol (Clopixol)

Antispasmodics

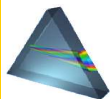
- dicyclomine (Formulex, Bentylol)
- flavoxate (Urispas)
- glycopyrrolate (Robinul)
- hyoscine butylbromide (Buscopan)
- hyoscyamine/atropine/hyoscine/phenobarbital (Donnatal)
- oxybutynin (Ditropan)
- pinaverium bromide (Dicetel)*
- propantheline bromide (Pro-Banthine, Propanthel)
- tolterodine l-tartrate (Detrol)

Antihistamines/Antipruritics with moderate to high anticholinergic effects

- chlorpheniramine (Chlor-Triplon)*
- cyproheptadine (Periactin)*
- diphenhydramine (Benadryl)*
- trimeprazine (Panectyl)

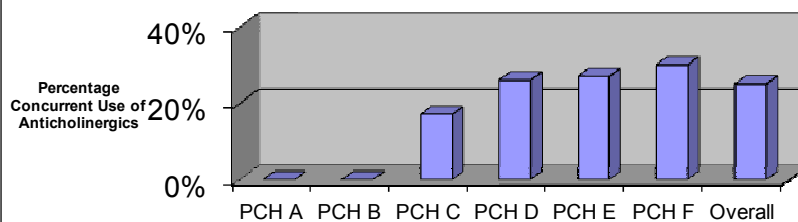
Miscellaneous

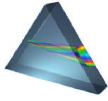
- cyclobenzaprine (Flexeril) - moderate
- diphenoxylate/atropine (Lomotil) – moderate
- disopyramide (Norpace) – moderate



Evaluation of Practice

Concurrent Anticholinergic Use with Acetylcholinesterase Inhibitors

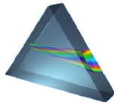




Please complete all sections to allow this request to be processed.

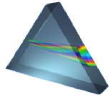
1. Drug requested (check one): Aricept or Exelon or Reminyl
2. This patient is (check one):
 - not currently taking the requested medication (new patient)
 - currently taking the requested medication (existing patient) or renewal
 - switching from one cholinesterase inhibitor to another
3. Diagnosed with probable Alzheimer disease as per DSM-IV criteria. Yes No
4. Recent+ MMSE score* _____ date _____
5. FAQ score* _____ date _____
6. Drugs with anticholinergic activity++ are to be discontinued at least 14 days before the MMSE and FAQ are administered and are not to be used concurrently with Aricept, Exelon or Reminyl.
List all medications the patient is currently taking or attach a list.
 this patient is not taking other medications

_____	_____
_____	_____
_____	_____
_____	_____

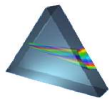


Five Things You Should Know – About Medication and Alzheimer’s Disease





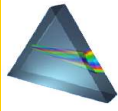
Use the Right Drug at the Right Time



Use the Right Drug at the Right Time

- Work with your Doctor and pharmacists to make wise choices about the use of medications





Safety

 MSNBC.com

New anti-psychotic drugs may double heart risk

Study: Meds for schizophrenia, bipolar disorder up chance of cardiac death

The Associated Press

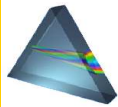
updated 4:03 p.m. CT, Wed., Jan. 14, 2009

NEW YORK - Newer anti-psychotic drugs are no safer than older ones for the risk of suddenly dying from a heart problem, says a study that finds they roughly double that hazard.

Dementia death risk doubles on some antipsychotics

[CBC News](#) Posted: Feb 24, 2012 4:25 PM ET Last Updated: Feb 24, 2012 4:51 PM ET

An analysis of tens of thousands of people in nursing homes in the U.S. suggests that residents who take certain antipsychotic drugs for dementia are at about double the risk of dying compared to residents not taking those specific medications.



Hierarchy of Evidence

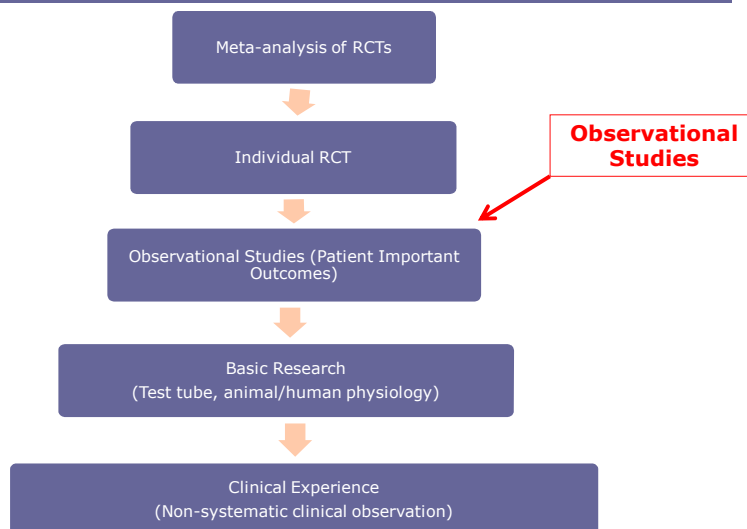
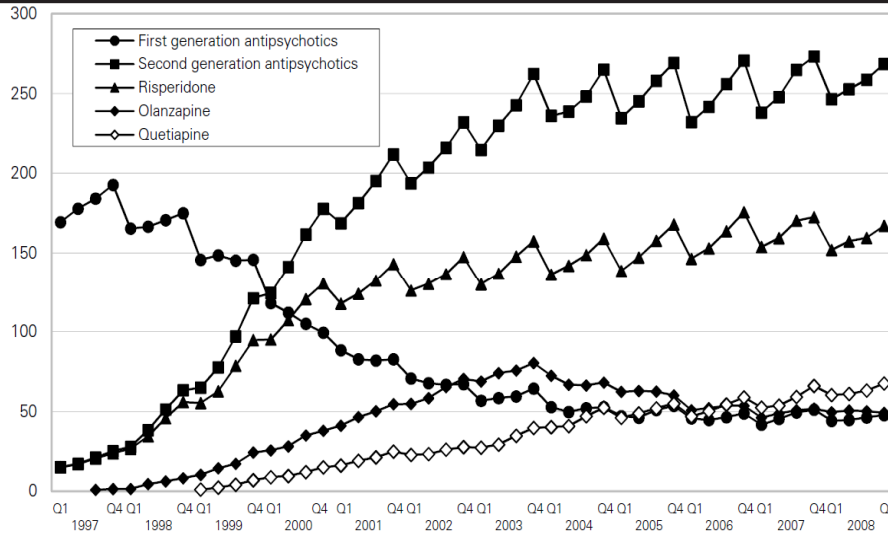


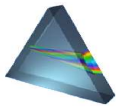
Figure 2.11: Antipsychotics, PCH Residents Quarterly Prevalence
 Crude user rates per 1,000 residents in personal care homes aged 65+, Q1 1997-Q4 2008



'Q1' indicates rates for the 1st quarter (April to June)
 'Q4' indicates rates for the 4th quarter (January to March)
 'Q2' and 'Q3' data points are displayed, but not labeled

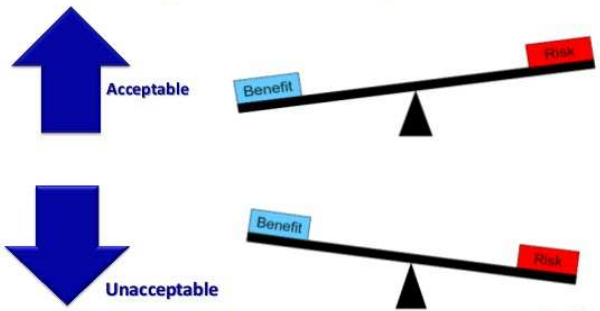
Health Canada warning Risperidone 2002Q3
 Health Canada warning Olanzapine 2003Q4
 Health Canada warning all SGA 2005Q2

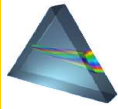
Source: Manitoba Centre for Health Policy, 2010



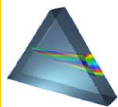
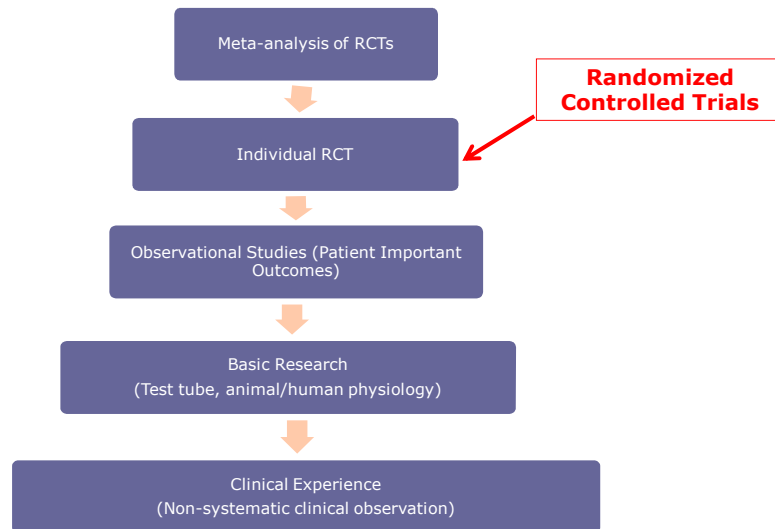
Anti-psychotic Medications Balancing the Risks

Risk/Benefit Balance of medications





Hierarchy of Evidence



Cochrane Review: Efficacy-Quetiapine

- CMAI Total Aggressiveness
 - Cohen-Mansfield Agitation Inventory
 - 29 types of agitated behaviour – pacing, verbal aggression ...
 - 7 point scale for frequency (1 = never, 7 = several times per hour)
 - Total aggression cluster score

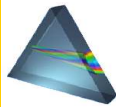
Ballard, C. et al. 2006. Cochrane Database of Systematic Reviews CD003476.

Cohen-Mansfield Agitation Inventory

A seven point rating scale for assessing the frequency with which people show certain behaviours.
Rate each descriptor from 1-7. The scale takes 10-15mins to complete.

- 1 = never
- 2 = less than once per week
- 3 = 1-2 per week
- 4 = several times per week
- 5 = 1-2 per day
- 6 = several times per day
- 7 = several times per hour

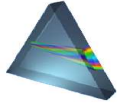
	1	2	3	4	5	6	7
1. Pace, aimless wandering							
2. Inappropriate dress or disrobing							
3. Spitting (include at meals)							
4. Cursing or verbal aggression							
5. Constant unwarranted request for attention or help							
6. Repetitive sentence or questions							
7. Hitting (include self)							
8. Kicking							
9. Grabbing onto people							
10. Pushing							
11. Throwing things							



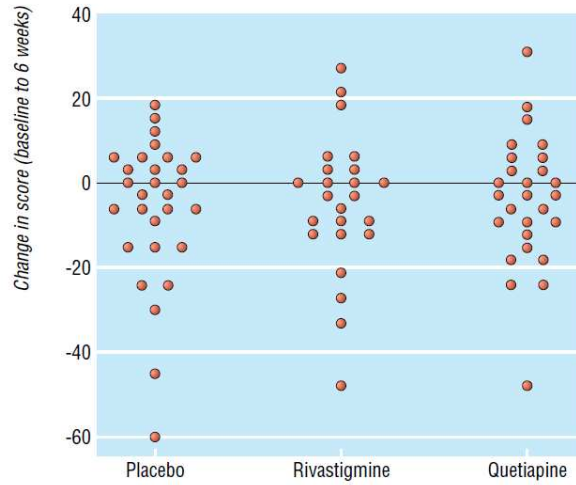
Cochrane Review: Efficacy - Quetiapine

Quetiapine vs placebo
-1.17 95% CI (-2.02 to -0.32)

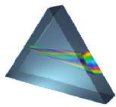
Ballard, C. et al. 2006. Cochrane Database of Systematic Reviews CD003476.



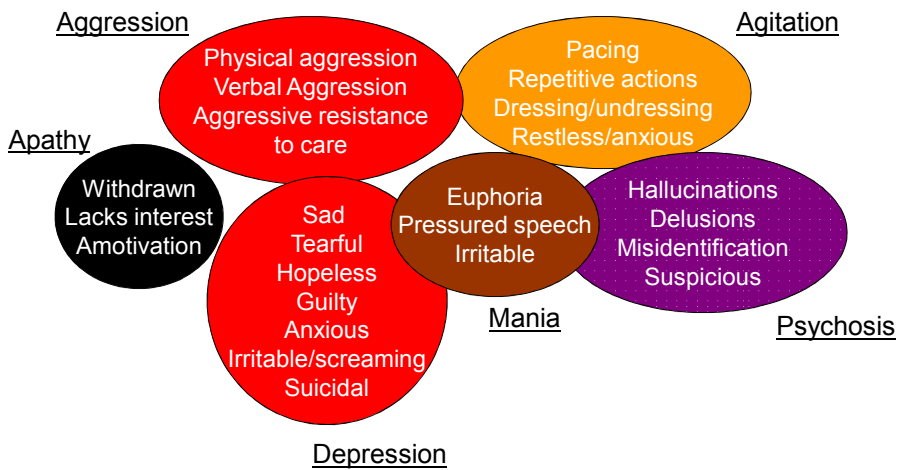
Cohen-Mansfield Agitation Inventory



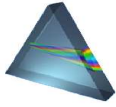
Ballard, C. et al. BMJ;2005;330:874



Behavioral & Psychological Symptoms of Dementia (BPSD)



McShane, R. International Psychogeriatrics. 12 -S1:147-153.



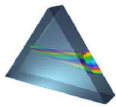
BPSD

Table 1. Common BPSD Symptoms

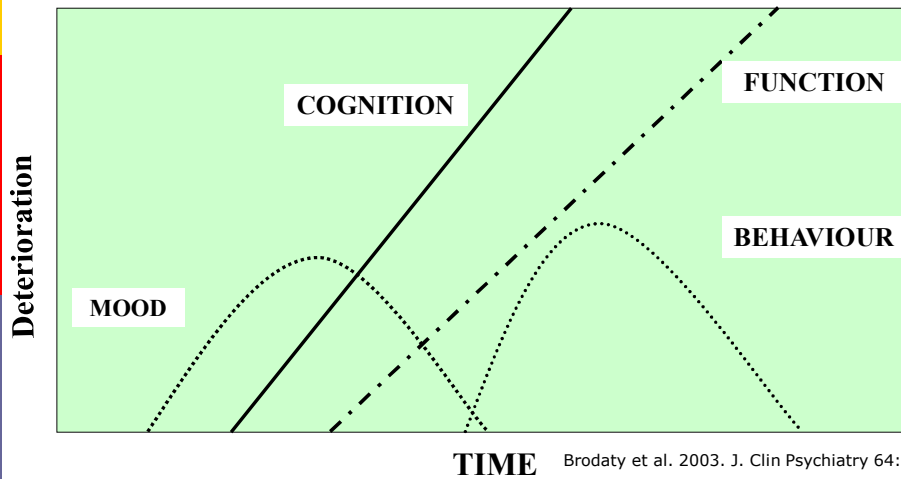
agitation*	vocalizations
apathy	hoarding
aggression* (verbal/physical)	nocturnal restlessness
calling out, screaming	emotional lability
hostility	paranoid behaviours
sexual dis-inhibition	psychosis* (hallucinations/delusions)
resistive	intrusiveness
wandering	repetitive behaviours

* symptoms with some evidence of benefit for antipsychotics

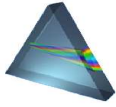
Adapted from RxFiles – October 2011



When?



Brodsky et al. 2003. J. Clin Psychiatry 64:36.
<http://www.ucc.ie/en/>

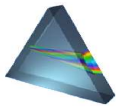


Trigger Factors

Table 2. Common Triggering Factors in BPSD

Psychosocial	
Distress	Feeling Abandoned
Fear of Danger	Loss of Autonomy
Misinterpretation	Paranoia
Environmental	
"Bad Company"	Excessive demands
Boredom	Change or Lack of Routine
Confusing Surroundings	Loneliness
Noise	Inadequate Lighting
Medical	
B12/Folic Acid Deficiency	Infection (UTI/Pneumonia)
Hunger/Thirst	Nocturia
Hypercalcemia	Pain
Hypo-thyroidism	Constipation
Medications (Drug Induced Delirium)	
Anticholinergics	Digoxin
Benzodiazepines	Opioids.....

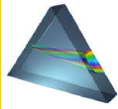
Adapted from RxFiles – Octobre 2011



Nonpharmacological Interventions

- Unmet Needs Interventions
 - Anticipate unmet need
 - E.g. Pain, lack of socialization
- Learning and Behavioral Interventions
 - Undesirable behaviors inadvertently reinforced
- Reduced Stressful Environments
 - Mismatch between environment and ability to cope
 - E.g. Agitated by too much noise
 - E.g. Round wards to deal with wandering

Ayalon, L. et al. 2006. Arch Intern Med 166:2182.



Balanced Decisions

- Avoid if possible but not always possible
- When needed – assess for tolerability and efficacy in 3 to 7 days
- Reassess for taper and/or discontinuation every 3 months

RxFiles 2011



Canadian Foundation for
**Healthcare
Improvement**

**Reducing Antipsychotic Medication
Use in Long Term Care Collaborative**

15 teams > **181** team members
across **7 provinces** and **1 territory**





416

LTC residents participated



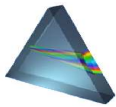
54%

of residents had their
antipsychotic medication
reduced or discontinued

36%
discontinued

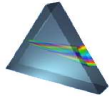


18%
lowered dosage

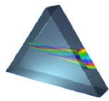


Five Things You Should Know –
About Medication and Alzheimer’s Disease

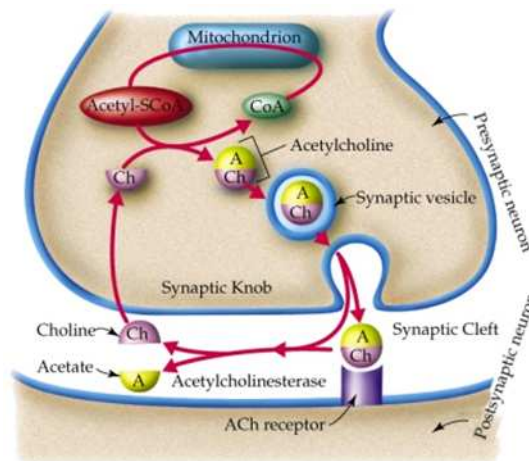


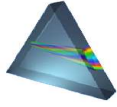


Less Medication is OK

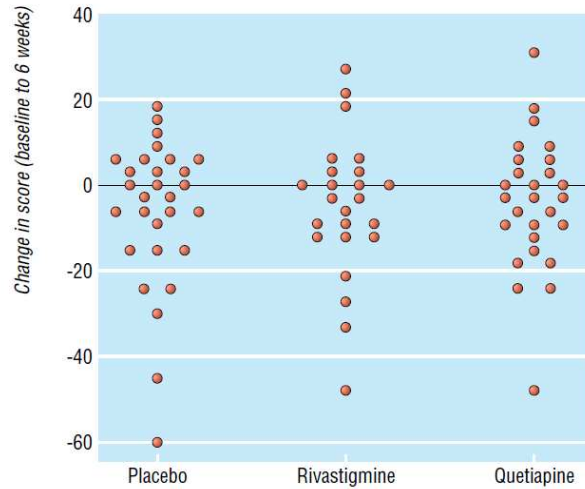


Alzheimer's Medications Mechanism

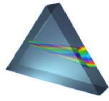




Cohen-Mansfield Agitation Inventory



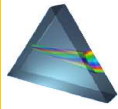
Ballard, C. et al. BMJ;2005;330:874



Cholinesterase Inhibitors Common Side Effects

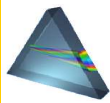
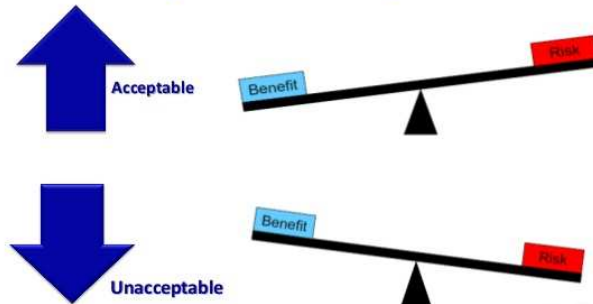
Donepezil	Nausea 11% Diarrhea 10% Headache 10 % Insomnia 9% Pain 9%
Galantamine	Nausea 17% Dizziness 10% Headache 8% Injury 8% Vomiting 7%
Rivastigmine (oral)	Nausea 37% Vomiting 23% Dizziness 19% Diarrhea 16% Headache 15%

Hogan DB et al. CMAJ 2008;179:1019.



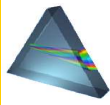
Balancing the Risks and Benefits

Risk/Benefit Balance of medications



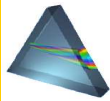
Research: Problem with Dropouts

- Drop rates > 20%
- 1-year drop rates in trials (26.9 – 48.1%)



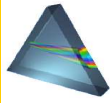
Life: Problem with Dropouts

- Drop rates even higher in community
- 65% of patients taking suboptimal doses
- Adherence to therapy low
- Average duration therapy 4-5 months



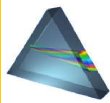
Shared Decision Making





Deliberate Continuation or Discontinuation

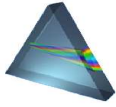
- In conjunction with your caregiver
 - Adequate trial duration at reasonable dose
 - Assess personal benefit and risk
 - Impact on targeted symptoms
 - Appropriate review and taper or discontinue



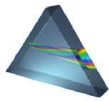
Consensus Guidelines - Discontinuation

- Family or patient decides to stop based on benefit/risk
- Non-adherence
- Cognitive/functional decline is greater than prior to treatment
- Intolerable side effects
- Dementia progresses to point where no further clinically meaningful benefit is possible

Hogan DB et al. CMAJ 2008;179:1019.
Gauthier S et al. Can J Neurol Sci 2012;38:S1
Gauthier S et al. Can Geriatrics J 2012;15:120



Five Things You Should Know – About Medication and Alzheimer’s Disease



BONUS TIP

Your Pharmacist Can Help

- You are not alone
- Your pharmacist should be able to help you through the medication maze
- Help solve any drug related problems with your doctor
- Use ONE pharmacy for all your medications
- If your pharmacist is not helpful – get a new one!





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Shawn Bugden: shawn.bugden@umanitoba.ca