Preventing Cognitive Impairment & Dementia: Translating Epidemiological Findings into Public Health Action
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Director, Bryan ADRC

AGING & PUBLIC HEALTH

- Medical advances and improved access to quality health care, has led to longer life expectancy globally
- Increase in prevalence of age associated illnesses
- Population ages into risk
- Live longer with these chronic illnesses.
- Alzheimer’s disease and related disorders present major public health challenges.

EPIDEMIOLOGICAL STUDIES OF DEMENTIA

- Global evidence base expanded since earlier AD projections. The G8 Dementia Summit (2013) focused on the new evidence from China and Sub-Saharan African regions.
  - Included 73 new studies published in China and 7 new studies in Sub-Saharan Africa (previously one in Nigeria).
  - Revised projections of AD higher by ~16%.
  - 76 million affected globally in 2020; 135 million by 2050.
  - Population ageing is the main driver of projected increases.

DISCLOSURES

- Neuropsychology Lead for a global clinical trial to delay AD onset: the TOMMOROW study, supported via contracts through Takeda and Zinfandel Pharmaceutical Companies
- Consultant and/or contracts with technology and pharmaceutical companies: Muses Laboratories, Lumosity, NeuroCog Trials, Merck, Lilly, Johnson & Johnson/Janssen.

AGING & PUBLIC HEALTH

- Ten years ago, world wide estimates of AD projected that there were 24-26 million with dementia and that growth to 42.3 million by 2020 & 106 million by 2050
- Many countries expected to have most impact: growth of population in 60+ anticipated not well represented in early survey work
- Regions well covered
- Some studies
- Single studies

POPULATION GROWTH IN AGING SECTOR

(AGED 60+ YEARS)


Troubling....

How are these statistics relevant us and to the prevention of Alzheimer’s disease?
Currently ..... 

- 5.4 million people with Alzheimer’s
- 200 billion dollars in annual costs
- 6th leading cause of death
- >1.5 million unpaid caregivers

WITHOUT A CURE....

- 13.4 million + Americans affected by 2020
- 1.1 Trillion annually [Alz Assoc. 2013]

NATIONAL ALZHEIMER'S PROJECT ACT (NAPA)

- January 4, 2011 Enacted 
  - Passed unanimously by both houses of Congress
  - Signed into law by President Obama
  - Creates a national strategic plan to address & overcome the escalating crisis of Alzheimer’s disease
  - 2013 goal announced to develop treatments to slow progression and prevent onset of AD by 2025

NATIONAL ALZHEIMER'S PROJECT ACT (NAPA)

- Congress added $100 million in 2014 to the National Institute on Aging (NIA) portfolio for Alzheimer’s research
- Doubled the $100 million going to the so-called BRAIN initiative [Brain Research through Advancing Innovative Neurotechnologies] — important for new insights into treatment

WHERE WE ARE TODAY....

- Bad News
  - There is no treatment that will allow us to prevent the disease from occurring
  - There is no treatment to stop the disease once it has started

- Good News
  - Considerable progress in:
    - Scientific understanding of the biology of the disease
    - Advances in technology, allowing earlier diagnosis and treatment possibilities
    - Evidence based approaches for lowering risk and promoting healthy cognition
OBJECTIVES
Focus on prevention and delaying the onset of AD clinical symptoms
1. Illustrate unique contribution of epidemiology to our current understanding the impact of AD across human lifespan & highlighting opportunities for public health impact
2. Discuss prevention and treatment approaches underscored by epidemiological studies of dementia
3. Conclude by considering new treatment approaches designed to prevent disease and optimize cognitive health

MODIFYING PUBLIC HEALTH IMPACT OF ALZHEIMER’S DISEASE

* Cache County Study on Memory in Aging (CCMS; AG1380) illustrates the utility of population based approach for monitoring trends and identifying risk and protective factors for development of Alzheimer’s disease

EPIDEMIOLOGY OF DEMENTIA IN CACHE COUNTY, UTAH

- CCMS began in 1994 as a prospective epidemiological (population-based) study of adults over age 65
- Goals: examine genetic risk factors and environmental exposures in relation to cognitive disorders & AD in population of old-old (n > 5,000)

WHY CACHE COUNTY?

- Geographic location
  - Limited in and out migration
  - Median life expectancy exceeds national norms - longest lived population in US
    - men: 85.7 years (national: 74.8)
    - women: 88.1 years (national: 80.1)

WHY CACHE COUNTY?

- Little alcohol and tobacco use
  - 91% Latter Day Saints
- High educational achievement
  - 81% completed high school
- Close-knit community
  - Limited number of health care providers/pharmacies, facilitating verification of symptoms, medical history
- Exceptionally high response rates
  - 90%+ — important in reducing participation bias
  - Historic willingness to participate in research

UTAH STATE UNIVERSITY IN LOGAN UTAH

CAKE COUNTY- STAGED METHODS

- Stage 1: Screening
  Interviewed and conducting cognitive screening with everyone over age 65 who agreed to participate. Collected detailed health history and risk factor information regarding lifestyle, habits, environmental exposures

- Stage 2: Clinical Examination
  In home evaluation of all subjects with suspected cognitive impairments and all individuals over age 85. Also examined “designated controls” matched by age and gender and APOE genotype (2:1) to cases.

- Stage 3: Physician Evaluation
  Physician saw subject in the home, ordered and reviewed laboratory studies, assigned diagnosis with subsequent review by expert panel

- Stage 4: 18 month follow-up
  In all diagnosed as MCI and dementia follow up to affirm diagnosis
**CACHE COUNTY STUDY DESIGN**

>5,657 Eligible elderly in Cache Co, Utah

<table>
<thead>
<tr>
<th>Wave</th>
<th>Screened</th>
<th>DNA obtained (%)</th>
<th>DNA obtained in subjects over 85 years</th>
<th>Suspected cases of dementia</th>
<th>Inc dementia</th>
<th>Inc AD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wave 1</td>
<td>Screen=3,411</td>
<td>10780 person years</td>
<td>4932 DNA obtained (96.9%)</td>
<td>357 Prev dementia</td>
<td>246 Prev AD</td>
<td>357 Prev dementia</td>
</tr>
<tr>
<td>Wave 2</td>
<td>Screen=5,092</td>
<td>10780 person years</td>
<td>4932 DNA obtained (96.9%)</td>
<td>151 Inc dementia</td>
<td>154 Inc AD</td>
<td>151 Inc dementia</td>
</tr>
<tr>
<td>Wave 3</td>
<td>Screen=3,517</td>
<td>10780 person years</td>
<td>4932 DNA obtained (96.9%)</td>
<td>244 Inc dementia</td>
<td>177 Inc AD</td>
<td>125 Inc dementia</td>
</tr>
<tr>
<td>Wave 4*</td>
<td>Screen=4,483</td>
<td>10780 person years</td>
<td>4932 DNA obtained (96.9%)</td>
<td>122 Inc dementia</td>
<td>128 Inc AD</td>
<td>175 Inc dementia</td>
</tr>
</tbody>
</table>

*1,817 Deceased before Wave 4
573 Permanent Refusal
104 Moved

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**LESSON #1 CACHE COUNTY UTAH STUDY**

- Prevalence of dementia continues to increase in men and women over age 80
- There appears to be gender differences in risk, with women somewhat more vulnerable to AD, divergence occurring in later old age (after 80)
  - Gender differences in AD incidence not seen across all studies. Could be due to differences in diagnosis (AD vs DMT), small numbers of older ages [imprecision] or true cohort differences across countries [e.g., social, historical, cultural]

**CACHE COUNTY FINDINGS - PREVALENCE OF DEMENTIA AND AD**

**LESSON #2: DEMENTIA FREE SURVIVAL**

- AD is not the inevitable consequence of aging
  - A significant portion of the population (~30%) appear invulnerable even if they live to 90 years or older
    (Khachaturian et al, 2004 Arch Gen Psychiatry 2004;61:518-24)
  - Decline in incidence in older age is controversial and not seen across all studies
  - Despite the inconsistency across studies a substantial portion of the population (~20-30%) survive without dementia
- APOE gene is an important risk factor for AD
  - Inheritance of ε4 allele increases risk of AD
  - Even so, a substantial number of people with the gene may not develop the disease

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**Subjects - Baseline**

- 5092 Initially interviewed
- 4932 DNA obtained (96.9%)
- 700 DNA in subjects over 85 years
- 424 Suspected cases of dementia
- 322 actual dementia
- 220 with AD
- 671 Designated controls in sample

Response rates for clinical assessment 90%. Nonresponders older than responders with fewer years of schooling. Also had lower 3MS scores, higher age- and sex-adjusted mortality in year after assessment was requested. Response not related to APOE genotype or nursing home status.
LESSON #3
CACHE COUNTY STUDY

- Observed in CCMS population that risk for Alzheimer's disease not entirely accounted by genetic factors (Tschanz et al., 2013 International Rev Psychiatry)
- Lifestyle variables, untreated vascular health conditions, and a number of common exposures (e.g. medications) have relationship to AD risk and onset
- Effects are exerted over different timeframes in the adult lifespan

ALZHEIMER’S DISEASE IS MODIFIABLE
SMITH, YAFFE ET AL. [2014] / ALZHEIMER’S DIS 38, 699-703

- All genetic factors of AD known at present account for ~1/3 of the risk
- Non-genetic risks factors may include:
  - Societal-level: air, water quality, environmental stressors
  - Individual level: lifestyle behaviours - smoking, diet, social, cognitive, physical activity

Meta-analysis of Modifiable Risk Factors for AD
XU, TAN, WANG ET AL (2016) / J NEUROL, NEUROSURG, PSYCHIATRY 86:1299-1306

- 17,000 population based studies published from 1968 through July 2014
- In 323 investigations that met rigorous scientific standards, nine risk factors were identified as most reliably related to AD risk:
  - Obesity
  - Current smoking
  - Carotid artery narrowing
  - Type 2 diabetes
  - Low educational attainment
  - High levels of homocysteine
  - Depression
  - High blood pressure
  - Frailty

G8 CONSENSUS (2014)
ALZHEIMER’S DISEASE IS PREVENTABLE
SMITH ET AL (2014) G8 SUMMIT JOURNAL OF ALZHEIMER’S DISEASE 38 699–703
G8 DEMENTIA SUMMIT HELD ON 12 DECEMBER 2013; A CALL TO THE GOVERNMENTS OF THE G8 COUNTRIES TO MAKE PREVENTION OF DEMENTIA ONE OF THEIR MAJOR HEALTH AIMS

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NIH State of the Science: Preventing AD and Cognitive Decline 2010

EFFECTS OF REDUCING RISK
(NORTON, MATTHEWS, BARNES, YAFFE, BRAYNE [2014] LANCET NEUROLOGY 13:788-94)

- Relative risks from existing meta-analyses to estimate population attributable risk of AD worldwide for 7 factors & their combination
  - diabetes, HTN, obesity, physical inactivity, low ed, depression & smoking
- Examined combined effects of reducing risks by 10-20% on AD projections in 2050
  - Relative reductions of 10% per decade in prevalence of the 7 factors would reduce AD world prevalence by 8.3%, 20% reduction would result in 15.3% reduced AD prevalence by 2050.
LIFESTYLE - BEHAVIORAL INTERVENTIONS RANDOMIZED CONTROL TRIALS (RCT)

- Single domain interventions
  - Diet
  - Physical exercise
  - Cognitive engagement
- Older adults or middle aged adults at risk of AD
  - Mixed results
  - Largely negative in cognitively healthy
  - Short term gains seen in some instances of MCI
  - Longer term gains hinge on continued compliance

- Multi-domain interventions
  - FINGER: Finnish Geriatric Intervention Study to Prevent Cognitive Impairment & Disability
  - 2 year randomized study
  - Nutritional guidance, exercise, cognitive training & intensive monitoring of vascular risk factors

FINGER TRIAL RESULTS (NGANDU ET AL [2015] LANCET 385: 2255-2263)

- Multi-domain intervention over 24 months:
  - Nutrition:
    - individual (3h) & group (7-15) sessions with a nutritionist
  - Physical exercise:
    - exercise physiologist oversight
  - Cognitive training:
    - 10 group sessions with psychologist & individual sessions
  - Social activities:
    - built in with the cognitive training and other sessions
  - Management of metabolic & vascular risk factors:
    - meet with a study nurse at 3, 9, 18 months & with a physician (3,6,12)
  - Blood pressure, BMI & other markers with recommendations

FINGER TRIAL RESULTS (NGANDU ET AL [2015] LANCET 385: 2255-2263)

- Significant differences at 24 months on primary outcome (cognitive composite of 14 measures)
  - Mean change was 0.20 (intervention) and 0.16 (control).
  - Difference 0.042 (95%CI 0.002 to .042
  - Significant effect on secondary outcome of executive function & procession speed
  - No significant change on memory testing
  - Significant effects also on BMI, diet, and physical exercise
  - Good adherence at 2 years
  - Impact on dementia outcomes in subjects ≥ ≥7 and data pending
  - Results small but can have large effect on public health

CACHE COUNTY GRAY MATTERS STUDY (GMS)

- University of Ulster, Ireland & Utah State University
- Healthy lifestyle intervention targeting brain health for middle-aged individuals
  - evidence-based
  - mobile technology-supported, with daily interactions,
  - allow individuals to self-select behavioral domain(s) to target for improvement that will fit into their lives and in which they will realistically make behavioral changes

CACHE COUNTY GMS - OBJECTIVES

- Develop a health promotion intervention designed to encourage lifestyle changes targeted to improve vascular health in the short term and lower Alzheimer’s disease risk in the long term
- Educate on a wide range of behavioral domains but allow participants to customize intervention to personal needs
- Determine whether a focus on brain health and AD risk reduction with the assistance of engaging technology can result in both short-term and longer -term sustained healthy behavior changes
Determine magnitude (& directionality) of change over six months

**Primary outcomes**
1. intrinsic motivation for lifestyle change
2. evidence of health-related behavior changes in 6 domains
3. reduction in subjective memory complaints

**Secondary outcomes**
1. cognitive status (objective neuropsychological tests)
2. biomarkers related to vascular risk (inflammation, glucose regulation, lipid metabolism, body mass index, blood pressure)
3. psychosocial well-being (depression, perceived stress, sleep quality, social engagement)

**CACHE COUNTY - GMS**  
(USU & ULSTER UNIVERSITY - NORTON ET AL, 2015)

- Randomized 146 adults (45-64)
- 104 treatment
- 42 controls
- 6 mo intervention
- Customized, evidence-based health information & activity monitor
- Uses Smartphone app

**CACHE COUNTY - GMS**  
(USU & ULSTER UNIVERSITY - NORTON ET AL, 2015)

1) APP - Provides daily suggestion pair
   - Gives users a short snippet of text based on health literature about Alzheimer’s disease. It then suggests a lifestyle change that could improve vascular health and/or lower the likelihood of developing AD

2) APP facilitates user data entry to track lifestyle
   - Users answer 12 preset questions aimed to assess performance across 6 behavioral domains

3) APP provides real time performance feedback
   - Based on the users’ answers, they are provided with visual feedback in the form of a 5 star rating for each domain. They can also see a weekly summary of their efforts

**Results**

From the cohort in Cache County, Utah.

122k+ responses logged
- All 104 participants downloaded the app onto their Smartphone or tablet
- Exactly 122,719 behavioral logs were collected during the study.
Main Findings

- Treatment group (vs. control group) achieved significantly greater:
  - Increase in intrinsic motivation (p=0.003)
  - Decrease in concerns about memory (p=0.047)
  - Increase in social engagement (p=0.001)
  - Increase in HDL cholesterol (p=0.043)
- Within the treatment group, increase in vigorous physical activity was significantly correlated with decrease in:
  - Serum glucose (p=0.015)
  - Insulin (p=0.011)
  - LDL cholesterol (p=0.037)
  - CES-D depression (p=0.085)

FINDINGS
Plans for Behavioral Change at Study End

- no chgs; no plans (2.5%)
- no chgs; but now plan to (7.5%)
- want to continue; unsure (10%)
- def will continue (47.5%)
- will increase behavior (32.5%)

Lifestyle changes may have an impact in future risk....
But what about those who are now in the preclinical stages of AD and at imminent risk of clinical onset?

AD DRUGS IN DEVELOPMENT
CUMMINGS ET AL (2014) ALZHEIMER’S RESEARCH & THERAPY, 6:37-44

2002-2012 (n=413) Clinicaltrials.gov*
- 124 Phase 1 (healthy volunteers; safety)
- 206 Phase 2 (preliminary efficacy)
- 83 Phase 3 (full scale study in patients)
- 244 trials concluded
- 37% Symptomatic (cognition)
- 35% New compounds
- 18% Immunotherapies
- 10% Multiple mechanisms

*FDA Amendments Act of 2007 (FDAAA or U.S Public Law 110-85) requires registration of clinical trials

Success rate 0.4%; (99.6% failure) Despite promising compounds showing target engagement

ALZHEIMER’S DISEASE PREVENTION

Preclinical/ Latent Stage ("1st prevention")
Prodromal AD/ MCI ("2nd prevention")

Threshold
Symptomatic Stage (Treatment)

Age

Welsh-Bohmer, K.A. Neuropsychol Rev., 2008;18(1):70-8
ALZHEIMER’S DISEASE PREVENTION STUDIES

• Dominantly Inherited Alzheimer’s Network (DIAN).
• Alzheimer’s Prevention Initiative (API) examine compounds to prevent AD onset and cognitive decline in genetic forms of the disease (young age of onset).
• Alzheimer’s Disease Cooperative Study (ADCS-A4 Study) examines treatments in individuals who show increased brain amyloid on amyloid imaging studies.

TOMMORROW Study examines individuals at high and low genetic risk (algorithm: age, APOE, TOMM40).

TOMMORROW STUDY
DELAY OF MCI DUE TO AD ONSET (BUDAR, WELSH-BOHMER, BURNS ET AL., 2015)

• Started in June 2013 and has now over 59 sites in US, UK, Australia, Germany & Switzerland.
• 3494 cognitively healthy adults over age 65, enriched for risk of developing AD based on 2 genes (APOE, TOMM40).
• Testing a unique compound and mechanism.
• Uses a low dose of pioglitazone (compound commonly used to treat diabetes).
• At low dose, shown to have effects on mitochondria-cell energy metabolism.

AD DRUGS IN DEVELOPMENT
MULTIPLE TARGETS & COMBINATION APPROACHES


SUMMARY

1. Population based studies provide information not only regarding trends in disease burden but also the influence of various exposures and risk factors on disease expression.
   - Drive continuing inquiry into pathogenesis.
   - Suggest mechanisms of potential protective effects and.
   - Point to potential avenues for safe and effective treatment approaches and targets for drug development.

2. Studies in long-lived populations, such as that in Cache County, demonstrate that while genetics are important to risk, AD is not an inevitable consequence of human aging. Perhaps 20-30% of those surviving to late old age free of dementia.

3. Evidence across studies and global regions, consistently show that there is a modifiable component to Alzheimer’s disease risk associated with lifestyle factors and health habits.

4. Prevention strategies, aimed at controlling metabolic and vascular risk conditions, may play a role in staving off dementia in the absence of therapies that can “cure” the disease.

SUMMARY

1. Because the evidence is so strong of a modifiable component to AD risk, both the Institute of Medicine1 and the Alzheimer’s Association2 recommend that healthy habits that are “good for the heart” are “good for the brain.”
   - World Dementia Council3 encouraging all nations not only to invest in future research but to incorporate dementia risk reduction measures into public health policies and non-communicable disease strategies action plans.

CONCLUSIONS

2. The fields of nutritional sciences, gerontology, and behavioral health are positioned to play strong roles in improving both current and future public health as relates to AD risk. Through careful development of empirically tested approaches aimed at effecting & sustaining healthy lifestyle change, there is the potential to:

- Improve vascular health in the short-term
- Sustain cognitive health in the long-term
- And potentially delay onset of disorders such as AD

3. Successfully accomplishing this will require creative thinking & collaboration between multiple disciplines. And there are already ample examples where working together & leveraging technology, we can help support function in retirement:

- Brain fitness games, assistive devices, memory prostheses
- Smart homes
- Social robots
- Assistive technology
- Telemedicine
- Mobile phone monitoring

More details at www.gerontechnology.com

CONCLUSIONS

4. Unprecedented funding opportunities designed to motivate innovation:

- BRAIN initiative,
- Accelerating Medicines Partnerships (AMP) for AD
- Emerging challenges driven from the private sector, such as Alzheimer’s XPRIZES

http://www.weforum.org/agenda/2016/01/could-an-xprize-help-the-fight-against-alzheimers-

CONCLUSIONS

5. Envisioning a world with treatments for Alzheimer’s disease by the year 2025 is achievable. Effecting a global solution or solutions will require careful thoughtful leadership, which considers solutions that can be readily implemented in low- and middle-income populations where dementia will have its largest impact and where the resources to prevent and treat diseases, not just Alzheimer’s disease, are precious and scarce.

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