Clinical Trials of Prevention in the Elderly
the ASPREE/STAREE Studies

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On behalf of Dr Richard Grimm & ASPREE investigators
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- R Woods
Declining mortality in middle aged Australians

Curtis & Gambhir 2014 (unpublished)
Table 2a. The number of deaths in men by age 70 from major causes

<table>
<thead>
<tr>
<th>Age specific death rates applied to cohort</th>
<th>No. of deaths in men by age 70 from major causes ±</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All circulatory diseases</td>
</tr>
<tr>
<td>1960</td>
<td>29250</td>
</tr>
<tr>
<td>1970</td>
<td>30036</td>
</tr>
<tr>
<td>1980</td>
<td>21398</td>
</tr>
<tr>
<td>1990</td>
<td>13701</td>
</tr>
<tr>
<td>2000</td>
<td>7388</td>
</tr>
<tr>
<td>2010</td>
<td>4633</td>
</tr>
</tbody>
</table>

Although many policy-makers realize that the world’s population is ageing, the pace of this change and its social, economic and health-care consequences have not been adequately recognized.  (Vaupal Nature 2010)
116 years of aspirin

CH₃ CO₂ C₆H₄ CO₂ H

Aspirin in the New Yorker 1956
ASPREE: Basics

ASPirin in Reducing Events in the Elderly

- 19,000 patients (2,500 US; 16,500 Australia)
- 2300 general practitioners
- Aged: 70 plus, healthy at entry,
- Low-dose Aspirin (100mg EC) vs placebo
- Follow-up: average 5 years in first instance
- Recruitment: complete 2014

- Bi-annual cognitive assessments [3MS, HVLT-R, COWAT, SMDT]
- Outcome: disability-free survival assessed annually
Study Progress (AUS & US at 7th Nov 2014)
ASPREE as a high-quality cohort study of the elderly

- Large sample-size
- ‘Normal’ at baseline
- Low-drop-out rate
- Annual face-face review (objective measures)
- Access to clinical records (adjudicated endpoints)
- Routine cognitive assessment [3MS, COWAT, SDMT, COLOUR TRAILS*, STROOP*]
  - If trigger then ADAS-COG, IADL, Imaging, bloods
- Rapid end-point development

High quality discovery science needs high quality epidemiology
ASPREE enhancements

- Baseline blood/urine/genetics: CSIRO
- 3–year bloods/urine: US NCI
- Regional trial centres: Victorian Cancer Agency
- Biorepository: Monash
- Mobile laboratories: charities, NHMRC
- Questionnaires: charities
- Imaging: Monash bio-imaging/NHMRC
- Vision (& retina), hearing, sleep: NHMRC, Monash
How ASPREE will assist dementia research

• Efficacy of aspirin/statins

• Identifying genetic predictors

• Establishing role of inflammation

• Efficacy of reducing cardiovascular risk factors (STAREE)

• Improving prediction (better targeting of preventive strategies)

• Earlier diagnosis (earlier the diagnosis the more effective the treatment)

• Social impact of dementia

• Miscellaneous
  – Role of sleep apnoea
  – Significance of cerebral microbleeds
  – Role of hearing loss, vision loss
  – Role of retinal vascular imaging
  – Infrastructure for future trials

Introducing PET-MRI in late 2015
Low dose aspirin and cancer

Rothwell et al  Lancet 2010

IMPERATIVE FOR CONTINUED FOLLOW_UP to 10+ YEARS
Challenges

• Minimising drop-outs
• Handling media
• Collecting documentation
• Auditing
• Data requests
• Bureaucracy/committees

“Working with ASPREE”
ASPREE mark II

Stone NJ, et al.
2013 ACC/AHA Blood Cholesterol Guideline

2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Preventive Cardiology, Association of Black Cardiologists, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease

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