Brisbane Electoral Roll Naevus Study ("Core Study")

Adele Green
on behalf of CRE Naevi ‘Core Study’ Team
Background & Aims

• Dearth of current knowledge about prevalence, incidence of naevi in adults and their natural history

Aims

• Primary
  - to improve our understanding of the epidemiology and natural history of melanocytic naevi

• Secondary
  - identify methods and motivation of participants for skin self-examinations, with and without teledermoscopy
  - detect genotype variants associated with naevus phenotypes
  - examine use of microbiopsy for genetic analysis and its correlation with histopathological outcomes
Methods

• Design:
  - 3-year prospective, population-based cohort study of adults living in the greater Brisbane area, ascertained from the electoral roll

• Participants
  - Source sample: 4500 electors in 5 age groups (20-69 yrs) + 500 records for men 50-69 yrs (oversampled)
  - anticipate 20% participation, 30% eligibility
  - inclusion criteria:
    - ability to provide informed consent
    - skin types I-IV
    - at least one naevus
    - willingness to attend for frequent skin exams and follow-up visits
  - goal of 200
Recruitment Flow Chart

Initial Letter mailed - Invitation to participate, ‘Consent to be contacted’ form ‘Information to participants’

Completed ‘Consent to be contacted’ form returned

Member of study team calls participant – study, participation criteria & involvement explained

Participant expresses interest to participate

May call research team with questions

PICF mailed out, appointment made

Baseline appointment: PICF explained to ensure sound understanding – if OK, consent form signed

Participant does not wish to participate – No further action required
<table>
<thead>
<tr>
<th>Summary of visit procedures</th>
<th>Baseline Visit</th>
<th>6-Monthly Follow-up Visits</th>
<th>Naevi Excision Visit</th>
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</thead>
<tbody>
<tr>
<td>Informed Consent</td>
<td>Y</td>
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<tr>
<td>Sun Behaviour Questionnaire</td>
<td>Y</td>
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<td>Clinical Examination Form</td>
<td>Y</td>
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<td>Full Body Photography &amp; Dermoscopy</td>
<td>Y</td>
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<td>Naevi counts and classification</td>
<td>Y</td>
<td>Y</td>
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<tr>
<td>Identifying changing naevi</td>
<td></td>
<td>Y</td>
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<tr>
<td>Skin Self-Examination Instructions</td>
<td>Y</td>
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<tr>
<td>Skin Self-Examination Review</td>
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<tr>
<td>Clinical Examination Follow-up Form</td>
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<td>Saliva Sample</td>
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<td>Microbiopsy</td>
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<td>Y</td>
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<tr>
<td>Naevi Excision</td>
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<tr>
<td>Exit Interview</td>
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<td>Y (last visit)</td>
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Data processing & analysis

- Q’aire, Skin exam, Naevus data stored securely
- Databases and data dictionaries developed
- All data entered/checked; naevus data processed
- Frequency distributions & univariate analyses

Statistical analyses of epidemiological data
- Cross-sectional: prevalence of naevi & assoc’d factors
- Longitudinal: change in prevalence over time by age, sex

- Skin self-examination trial (MJ)
- Micro-biopsy vs routine histopathological classification (TP)
Core study outcomes:

• Better understanding of normal behaviour of naevi over time & at different ages, including “natural regression”

• ....Improved prevention and detection of melanoma