Psychological impact of providing women with personalized ten-year breast cancer risk estimates

David P French, Jake Southworth, Anthony Howell, Michelle Harvie, Paula Stavrinou, Donna Watterson, D Gareth Evans & Louise Gorman.
University of Manchester & Manchester University NHS Foundation Trust
Why risk stratified screening?

**Benefits**
(fewer deaths, lower stage at detection, chemotherapy avoided, mastectomy avoided)

**Harms**
(false positive test results, overdiagnosis, radiation-induced cancers, opportunity costs, anxiety)
Now possible to estimate breast cancer risk

- Self-reported information (family history of cancer, age, age at menarche, age at first full term pregnancy, HRT use, BMI, etc)
- Breast density (assessed from mammograms)
- Genetic factors (BRCA1 and BRCA2 gene mutations, + currently 200 known genetic variants that can increase the risk of breast cancer: Single Nucleotide Polymorphisms [SNPs])
- Predicting Risk of Cancer At Screening (PROCAS)
Invitation to screening
~70% attend

Invitation to fill in a risk factor form
~47% enter

Mammography + informed consent
~94% want to know risk

Risk estimation
Tyrer-Cuzick + Density (+SNPs)

Consultation to discuss prevention options

High-risk (3.2%)

Moderate risk (10.3%)
Average risk (59.3%)
Below average risk (27.2%)
What is the psychological impact of receiving breast cancer risk estimates?

- To assess the psychological impact of receiving breast cancer risk estimates, based on: (a) the Tyrer–Cuzick (T-C) algorithm including breast density or (b) T-C including breast density plus SNPs, versus (c) comparison women awaiting results.

- Need to communicate risk to women in PROCAS between 2-5 years after risk estimated.
Present study

- PPI input suggested verbal labels more helpful than precise numerical estimates (10 years)
  - High risk (8% and over)
  - Moderate risk (5-7.9%)
  - Average risk (2-4.9%)
  - Below average risk (up to 1.9%)

- Letters sent out – some also received questionnaires
Design/Sample/Analysis

• Natural experiment
  – Test group (TC, TC+SNPs, control)
  – Result group (moderate, average, below average)
• 2066 questionnaires sent/ 765 returned (37%)
• At least 200 sent to each group (59<n<110 returned)
• Analysis (ANCOVA – control for confounders)
  – (1) TC v TC+SNPs
  – (2) Intervention (TC and TC+SNPs v controls)
Results: Comparative risk perception
Results: State anxiety (STAI short form)
Results: Cancer worry (Lerman)
Results: Satisfaction with information
Understanding and intentions to change behaviour

• Understanding generally good: “which of the following best describes what your test result means”

• No consistent effects on intentions to change 6 behaviours
So what do we know now?

- No evidence of major harms (anxiety or cancer worry)
- Good satisfaction with information
- Understanding generally good
- Not a barrier to examining feasibility of implementing in routine screening.
- PROCAS2 study

Thank you

david.french@manchester.ac.uk
Communicating test results:
Developing materials

- Developed leaflet
- PPI input
- Drafted text
- “Think aloud” interviews + open-ended interviews
- Iterative revisions
Results: not well matched groups

<table>
<thead>
<tr>
<th></th>
<th>TC+SNPs (n=271)</th>
<th>TC only (n=197)</th>
<th>Controls (n=297)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>62.9 (6.9)</td>
<td>54.3 (4.2)</td>
<td>52.4 (2.9)</td>
</tr>
<tr>
<td>First mammography</td>
<td>30.3%</td>
<td>81.2%</td>
<td>93.9%</td>
</tr>
<tr>
<td>BMI</td>
<td>27.4 (5.6)</td>
<td>27.0 (4.8)</td>
<td>26.1 (4.6)</td>
</tr>
<tr>
<td>IMD</td>
<td>5.3 (2.7)</td>
<td>5.8 (3.0)</td>
<td>6.3 (2.9)</td>
</tr>
<tr>
<td>Area</td>
<td>Trafford (36%)</td>
<td>Trafford (26%)</td>
<td>Trafford (19%)</td>
</tr>
<tr>
<td></td>
<td>Withington (33%)</td>
<td>Withington (9%)</td>
<td>Withington (4%)</td>
</tr>
<tr>
<td></td>
<td>Manchester (11%)</td>
<td>Manchester (8%)</td>
<td>Manchester (7%)</td>
</tr>
<tr>
<td></td>
<td>Oldham (11%)</td>
<td>Oldham (18%)</td>
<td>Oldham (14%)</td>
</tr>
<tr>
<td></td>
<td>Salford (9%)</td>
<td>Salford (12%)</td>
<td>Salford (10%)</td>
</tr>
<tr>
<td></td>
<td>Trafford (27%)</td>
<td>Trafford (27%)</td>
<td>Trafford (27%)</td>
</tr>
<tr>
<td></td>
<td>Tameside (0%)</td>
<td>Tameside (0%)</td>
<td>Tameside (0%)</td>
</tr>
<tr>
<td></td>
<td>Trafford (46%)</td>
<td>Trafford (46%)</td>
<td>Trafford (46%)</td>
</tr>
<tr>
<td></td>
<td>Withington (9%)</td>
<td>Withington (9%)</td>
<td>Withington (9%)</td>
</tr>
<tr>
<td></td>
<td>Manchester (8%)</td>
<td>Manchester (8%)</td>
<td>Manchester (8%)</td>
</tr>
<tr>
<td></td>
<td>Oldham (18%)</td>
<td>Oldham (18%)</td>
<td>Oldham (18%)</td>
</tr>
<tr>
<td></td>
<td>Salford (12%)</td>
<td>Salford (12%)</td>
<td>Salford (12%)</td>
</tr>
<tr>
<td></td>
<td>Trafford (27%)</td>
<td>Trafford (27%)</td>
<td>Trafford (27%)</td>
</tr>
<tr>
<td></td>
<td>Tameside (0%)</td>
<td>Tameside (0%)</td>
<td>Tameside (0%)</td>
</tr>
<tr>
<td></td>
<td>Trafford (46%)</td>
<td>Trafford (46%)</td>
<td>Trafford (46%)</td>
</tr>
<tr>
<td>Days from test to result</td>
<td>1132 (77)</td>
<td>992 (81)</td>
<td>939 (67)</td>
</tr>
</tbody>
</table>
Where next? PROCAS-2 study

• Feasibility of automated risk estimation as routine part of NHS Breast Screening Programme
• Developing care pathways and refining materials, with input of low SES and BME women, and other key stakeholders
• Automating risk estimation (online)
• Establish major benefits and harms
• Including likely cost effectiveness
• Implementation meetings