Does screening for CRC with FOBT reduce overall mortality? OTC FOBT kits – how to advise patients?

Presented by Dr Heather Murray GPEP1 Registrar on behalf of Dr Prakash Appanna, Dr Vinodha Naidoo, Dr Shadi Gadalla and Dr Heather Murray

(Don’t) bury your head in the sand and ignore it!

Bowel Cancer

kils more New Zealanders each year than breast cancer or prostate cancer.

The first sign of bowel cancer is usually invisible. Early detection through yearly screening is vital.

Ask your Pharmacist about Screening
Aims and Methods

**Aims**

1) Review evidence base for test
2) How to advise patients on OTC Screening Test Kits
3) Effect of FOBT screening on overall mortality

**Methods**

- Literature review
  - 'Summon' database
- Information from Enterix
  - producers of Insure FOB Test
- Visit & phone discussion
  - pharmacies selling kit
- Personal correspondence
  - labtests chemical pathologist
Why screen for CRC?

- High rates in NZ and rest of world, especially >50 years and males
- Earlier detection = better outcomes
- FOBT is the method with the most research available on population screening
- No screening programme in NZ yet – but pilot study due to start in WDHB soon

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FOBT performance

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity for adv NP (%)</th>
<th>Specificity (%)</th>
<th>PPV (%) (adv NP)</th>
<th>Positivity rate (%)</th>
<th>NNS (prevent 1 CRC-death over 10yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>gFOBT</td>
<td>54</td>
<td>80</td>
<td>29</td>
<td>4.28</td>
<td>1173</td>
</tr>
<tr>
<td>iFOBT</td>
<td>67</td>
<td>85</td>
<td>41</td>
<td>6.88</td>
<td>no trial data</td>
</tr>
</tbody>
</table>

- Immunochemical test shows better performance – but no test = 100% sensitive or specific
- Test available in pharmacies for $60 (InSure iFOBT), not through labtests
- Recommended for patients >50 years
- Concerns about the information presented to the public
Effect on mortality?

- FOBT screening can prevent 1 in 6 CRC deaths
- No trials demonstrate reduction in overall mortality
- Some suggest increased mortality – controversial
- Recommend further research into this
- Note no trial data for effect on mortality of iFOBT

<table>
<thead>
<tr>
<th>Relative reduction in CRC mortality (intention to screen)</th>
<th>Relative reduction (actually screened)</th>
<th>CRC mortality (OR)</th>
<th>All cause mortality (OR)</th>
<th>Non-CRC mortality (OR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>16%</td>
<td>25%</td>
<td>0.84</td>
<td>1.00</td>
<td>1.01</td>
</tr>
</tbody>
</table>
What about harms of screening?

- Colonoscopy complications - perforation, bleeding, surgery, death
- Pilot studies demonstrated low complication rates – under trial conditions in 'expert centres'
- False positives and anxiety
- Need to consider whether benefit outweighs potential risk – selected populations eg >50yrs

<table>
<thead>
<tr>
<th>Colonoscopy complication rate (trials &amp; pilot studies)(^{14})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perforation (%)</td>
</tr>
<tr>
<td>0.06-0.34</td>
</tr>
</tbody>
</table>

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How to advise patients?

- Ensure patients are fully informed – risks and benefits, interpretation of results
- Access to colonoscopy – will they qualify if positive?
- Bottomline = informed choice

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Key Messages

1) Direct to consumer screening is not the same as an organised national screening programme
   - why does the patient want the test?
2) Positive test does not necessarily = CRC or eligibility for public colonoscopy
   - false positives + negatives
   - Auckland regional colonoscopy guidelines do not include asymptomatic patients <50yrs with no risk factors or family history
3) No evidence of reduction in overall mortality, with potential increase
4) Proposed iFOBT for NZ screening has limited evidence to demonstrate effect on mortality

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References

4) Personal correspondence with Dr Jeffrey Barron, chemical pathologist at LabTests Auckland.

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References (contd)


10) BowelScreen Aotearoa health professional information


16) WHO criteria for screening,

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