

WEO
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Experience with OC-SENSOR in Australia Positivity and Temperature Effects

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Expert Working Group: FIT for Screening

Factors that may influence FIT positivity rate

Variable	Effect
Age	✓ (most studies) ↑ Age ↑ positivity rate
Gender	✓ Males more likely to have positive FIT
Socioeconomic status	✓ ↓ socioeconomic status ↑ positivity rate
Presence of rectal bleeding	✓ overt rectal bleeding ↑ positivity
Location of neoplasia	✓ (most studies) distal neoplasia more likely to have positive FIT
Previous FIT screening	? ↓ positivity rate or no change
Sample return time	? ↑ time, ↓ positivity rate or no change
Temperature	? ↑ temperature, ↓ positivity rate

Australia average maximum daily temperature can be > 40°C (104°F) in summer

Netherlands (south west):
summer = 8.0%
winter = 9.7%²

Florence: 17% lower probability
in summer of FIT positivity¹

Netherlands (central): no effect⁴

Veneto:
summer = 4.53%
winter = 4.97%³

The National Bowel Cancer
Screening Program avoids
sending FIT kits in summer,
but there has been no formal
investigation

1- Grazzini et al, Gut (2010) 59: 1511-5.
2- van Roon et al Am J Gastroenterol (2012) 107: 99-107.
3- Zorzi et al Gut (2012) 61: 162.
4- van Rossum et al Gut (2011) 60: 1303-4.

Aim of the study

- To investigate the effect of temperature on FIT (OC Sensor) positivity rate, while taking into account the demographic factors that could also be influencing test outcome.
- This was assessed:
 - *In vitro*
 - Within a screening research program setting

Screening for colorectal cancer

- Since August 2008, screening has been undertaken with the Eiken OC Sensor immunochemical faecal occult blood test (using what is now referred to as the *old buffer*)
- Patients are mailed the screening test to their home address
- Two different faecal samples are collected and sent to lab via postage paid envelope
- Reminder letters are sent to non-participants after 6wk
- Samples are analysed for haemoglobin concentration
 - >100ng/mL (20µg/g stool) in either sample is considered positive (triggers colonoscopy)

Effect of sample storage temperature and duration on FIT positivity

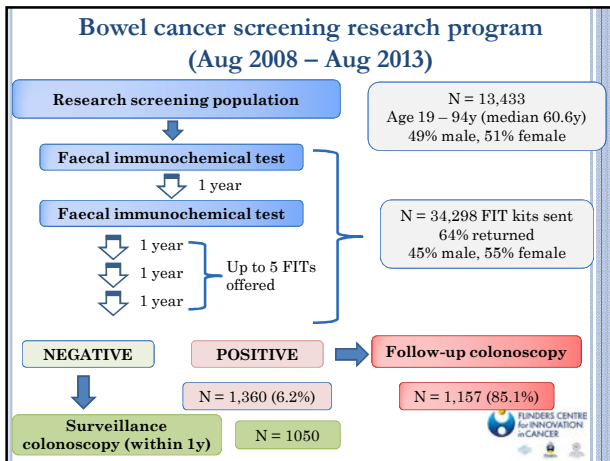
Samples from screening programs were analysed and those with [Hb] ≥50ng/mL were stored:

- Refrigerator
- Freezer
- Room temperature

for 1 – 14 days and then re-analysed

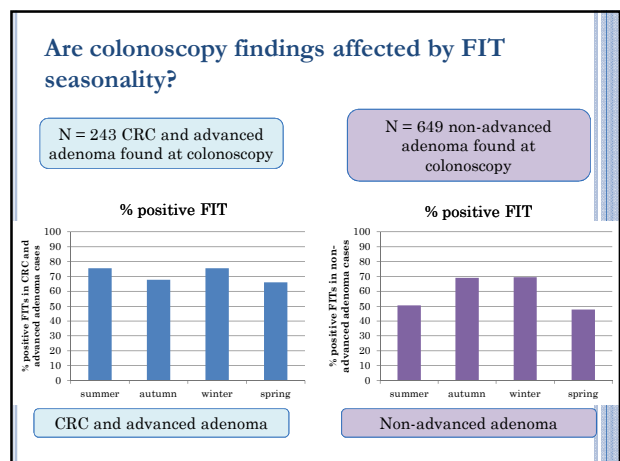
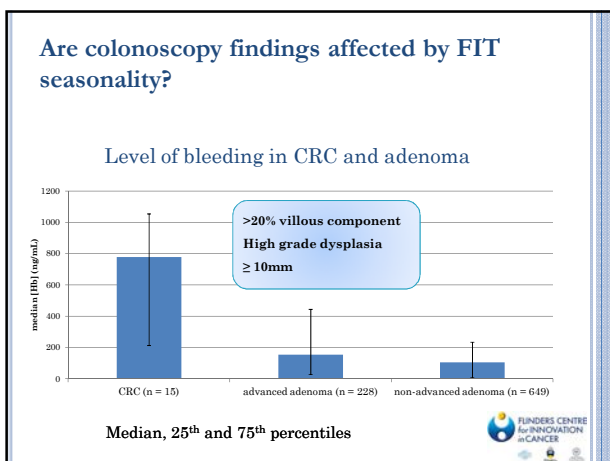
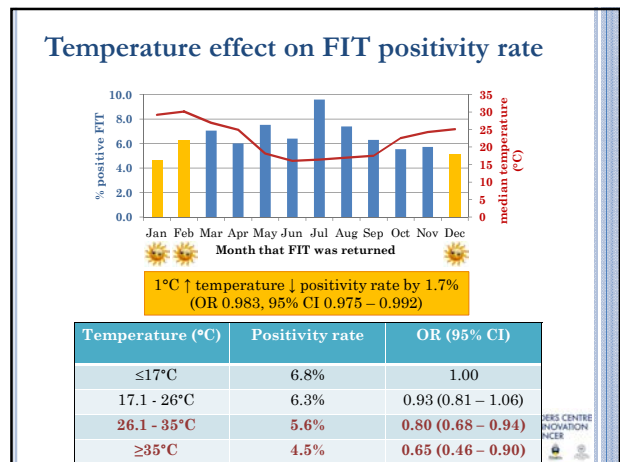
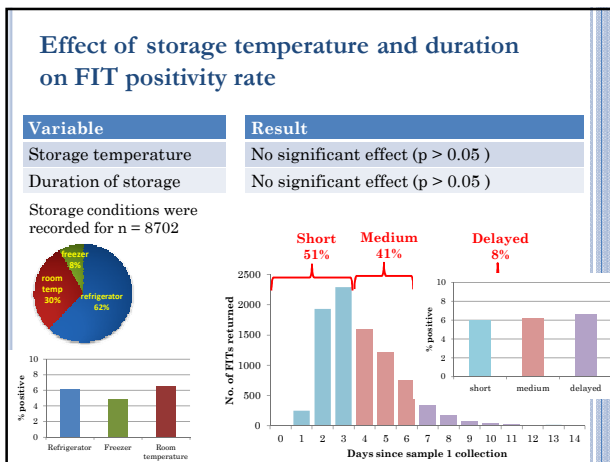
- [Hb] levels expressed as % of original level n ≥ 5 per time point

Storage in the freezer and at room temperature decrease [Hb]



Factors that influence FIT positivity rate

Risk Factor	% positive	OR for positivity (95% CI)
Gender		
Female	5.0%	1.00
Male	7.6%	✓ 1.51 (1.35 – 1.68)
Age (years)		
<50	4.2%	1.00
50 – 59	4.7%	1.15 (0.89 – 1.48)
60 – 69	6.5%	✓ 1.60 (1.25 – 2.03)
≥70	9.0%	✓ 2.21 (1.72 – 2.85)
Socioeconomic status		
1 (most disadvantaged)	7.8%	1.00
2	7.1%	0.90 (0.75 – 1.08)
3	6.4%	✓ 0.81 (0.67 – 0.99)
4	5.4%	✓ 0.70 (0.58 – 0.85)
5 (least disadvantaged)	5.0%	✓ 0.64 (0.53 – 0.77)
Previous FIT		
No screening	7.1%	1.00
Previous screening	5.5%	✓ 0.73 (0.65 – 0.81)



Summary and Conclusions

Variable	Effect
Age	✓ (↑ Age ↑ positivity rate)
Gender	✓ (Males ↑ positivity rate)
Socioeconomic status	✓ (↓ socioeconomic status ↑ positivity rate)
Previous FIT screening	✓ (Previous screening ↓ positivity rate)
Sample return time	✗ No effect
Sample storage	✗ No effect
Temperature	✓ (↑ temperature ↓ positivity rate)

- Despite temperature related degradation of haemoglobin, CRC and advanced adenoma are unlikely to be missed
- To optimise accuracy of FIT in a screening program, testing should be avoided in high temperatures (unless buffer can stabilise Hb)
- Independent testing should be performed with other FITs

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