

Australian NBCSP; the drop in positivity in 2009

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The kits and the problem

- In **2006** the NBCSP began using an FIT kit that used Rabbit Serum Albumin (RSA) - known as the HemTube FOBT. **Positivity rate 6.6%.**
- In **December 2008**, an upgrade to the analyser required a new kit—"New HemTube FOBT".
- NBCSP was suspended in May 2009** after a **drop in the positivity (to 3.5%).**
- Investigations revealed the New HemTube FOBT using BSA to preserve blood in collected samples was not as stable at high temperatures as the previous RSA preservative.

Kit revised

- An updated kit was developed using and called New HemTube (B) (TGA registered).
- The NBCSP restarted in November 2009 using the New HemTube (B) FOBT kit.

Remedial action

Changes were made to the handling and processing of the New HemTube (B) FOBT kits:

- the declaration of 'hot zones'— postcodes that were not sent kits where the average maximum temp > 30.5°C
- the provision of enhanced collection and storage instructions to participants
- Reduction of the valid laboratory analysis time frame for returned kits to within 14 days of the first sample being taken (down from 1 month)
- As a result, positivity returned to 7.7%

Positivity

Table 6.6. Differences in FOBT positivity between kits, by age and sex, Phase 2

	HemTube		New HemTube		New HemTube (B)									
	%	95% CI	%	95% CI	Previous negative		Previous inconclusive		Previous no return		First invitation	New HemTube (B) total		
					%	95% CI	%	95% CI	%	95% CI		%	95% CI	
Males														
50 years	6.4	6.1-6.7	3.2	2.9-3.4	4.9	4.6-5.2	7.0	3.5-10.5	7.6	7.0-8.1	7.4	7.2-7.6	7.0	6.6-7.1
55 years	7.6	7.2-8.0	3.6	3.4-3.9	5.7	5.3-6.0	8.3	4.5-12.0	8.5	7.9-9.2	8.5	8.3-8.7	8.1	7.9-8.3
65 years	9.8	9.3-10.3	5.2	4.9-5.5	7.6	7.2-8.0	13.0	8.9-17.0	11.5	10.7-12.4	11.9	11.6-12.1	11.1	10.9-11.3
Total	7.5	7.3-7.7	3.0	3.8-4.1	6.0	5.8-6.2	8.7	7.5-12.0	8.0	8.5-9.3	9.2	9.1-9.3	8.7	8.5-8.8
Females														
50 years	5.1	4.9-5.3	2.8	2.6-3.0	4.5	4.2-4.8	6.2	3.3-9.2	5.7	5.3-6.2	6.3	6.1-6.4	5.9	5.6-6.0
55 years	5.4	5.1-5.7	2.9	2.7-3.2	4.6	4.3-4.9	8.5	4.9-12.0	6.0	5.5-6.6	7.0	6.8-7.2	6.5	6.4-6.7
65 years	7.5	7.1-8.0	4.0	3.8-4.3	6.4	6.0-6.7	11.0	7.7-14.4	8.6	7.9-9.4	8.8	8.6-9.0	8.4	8.2-8.5
Total	5.7	5.5-5.9	3.2	3.1-3.3	5.1	4.9-5.2	8.9	6.9-10.8	6.5	6.2-6.8	7.3	7.2-7.4	6.9	6.8-6.9
Persons														
50 years	5.7	5.5-5.9	3.0	2.8-3.1	4.7	4.5-4.9	6.6	4.3-8.9	6.6	6.2-7.0	6.8	6.7-6.9	6.4	6.3-6.5
55 years	6.4	6.1-6.7	3.2	3.1-3.4	5.0	4.8-5.3	8.4	5.8-11.0	7.2	6.9-7.6	7.7	7.5-7.8	7.2	7.1-7.4
65 years	8.6	8.3-9.0	4.6	4.4-4.8	6.9	6.7-7.2	11.9	9.3-14.5	10.1	9.5-10.7	10.3	10.1-10.4	9.7	9.6-9.8
Total	6.5	6.4-6.6	3.5	3.4-3.6	5.5	5.3-5.6	9.3	7.8-10.7	7.6	7.4-7.9	8.2	8.1-8.3	7.7	7.6-7.8

PPV

Table 6.9. Differences in colonoscopic diagnosis outcomes between kits, Phase 2

Kit type		Colonoscopy outcome					Outcome not specified	All Colonoscopy Report forms
		Suspected cancer	Polyp(s) > 10mm	Polyp(s) ≤ 10mm	Other diagnoses	No abnormality		
HemTube	Number	192	737	2,056	1,375	1,319	7	5,687
	Per cent	3.4	13.0	36.2	24.2	23.2	0.1 ¹	
New HemTube	Number	171	424	991	749	591	n.p.	2,928
	Per cent	5.8	14.5	33.8	25.6	20.2	n.p.	
New HemTube(B)	Previous Number	94	347	1,541	7,000	817	3	3,808
	Previous Per cent	2.5	8.1	40.5	25.4	21.5	0.1 ¹	
New HemTube(B)	Previous Number	0	0	41	23	15	0	85
	Previous Per cent	n.p.	n.p.	n.p.	n.p.	n.p.	n.p.	
New HemTube(B)	Previous Number	55	294	840	530	437	n.p.	2,160
	Previous Per cent	2.5	13.0	39.2	24.5	20.2	n.p.	
First Invite	Number	659	2,785	6,692	5,182	4,254	17	21,590
	Per cent	3.1	12.0	40.3	24.0	19.7	0.1 ¹	
New kit total	Number	806	3,433	11,123	6,743	5,523	21	27,651
	Per cent	2.9	12.4	40.2	24.4	20.0	0.1	
Total	Number	1,171	4,984	14,170	8,868	7,433	30	36,296
	Per cent	3.2	12.7	39.1	24.5	20.5	0.1	

(n) Based on numerator = 20 or denominator = 300. Interpret with caution.

Notes

- HemTube kit used July 2008-December 2008. New HemTube kit used December 2008-May 2009. New HemTube (B) kit used October 2009 onwards.
- Only colonoscopies with a Colonoscopy Report form (36,261) could be included in this analysis; colonoscopies identified from Histopathology Report forms or Medicare claims only were not included.

Source: National Bowel Cancer Screening Program Register as at 21 July 2011.