

# **IBSN Biennial Meeting**

## **COMPARING YIELD AND COST OF FOBT AND FS IN AN AVERAGE RISK POPULATION: RESULTS AFTER 2 SCREENING ROUNDS**

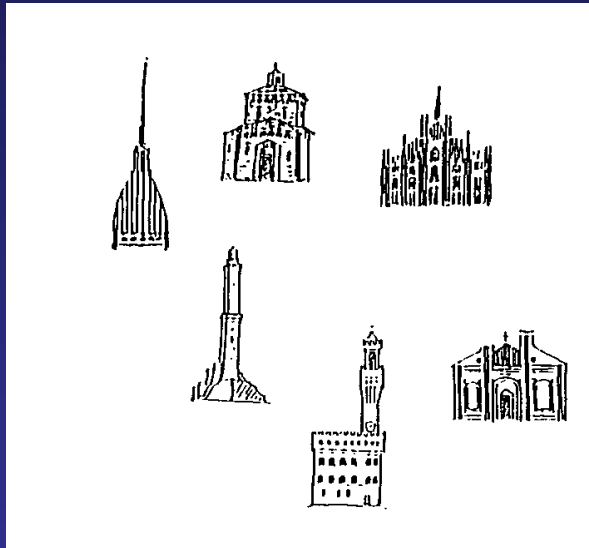
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**Center for Cancer Prevention (CPO Piemonte) and  
S. Giovanni Battista Hospital. Torino (Italy)**

**Ottawa May 10-12, 2006**

# SCORE2

Studio multicentrico italiano per la valutazione  
di diverse strategie di  
screening dei tumori del colon-retto



**CPO Piemonte**

**Fondo Edo Tempia – ASL 12 Biella**

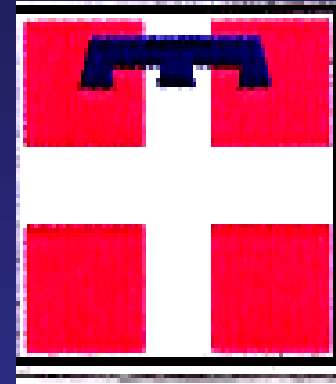
**ASL Città di Milano**

**CSPO Firenze**

**ASL 13 Rimini**

**Associazione Italiana per la Ricerca sul Cancro**

Progetto dimostrativo di  
screening dei tumori del colon-retto



**Regione Piemonte - Assessorato alla Sanita'**

**CPO Piemonte**

**ASL 1-4**

**AO S. Giovanni Battista-Molinette,**

**Ospedale Mauriziano "Umberto I" - IRCC**

**Medici di Medicina Generale**

**Associazione Italiana per la Ricerca sul Cancro**

# AIMS (1)

- a) a) To estimate compliance and coverage adopting different screening strategies
- b) To compare Detection Rate of different tests (first test, subsequent tests and follow-up) **and to estimate screening impact on CRC incidence and mortality**
- c) To estimate costs of different strategies
- d) **To define quality indicators of the screening programme**

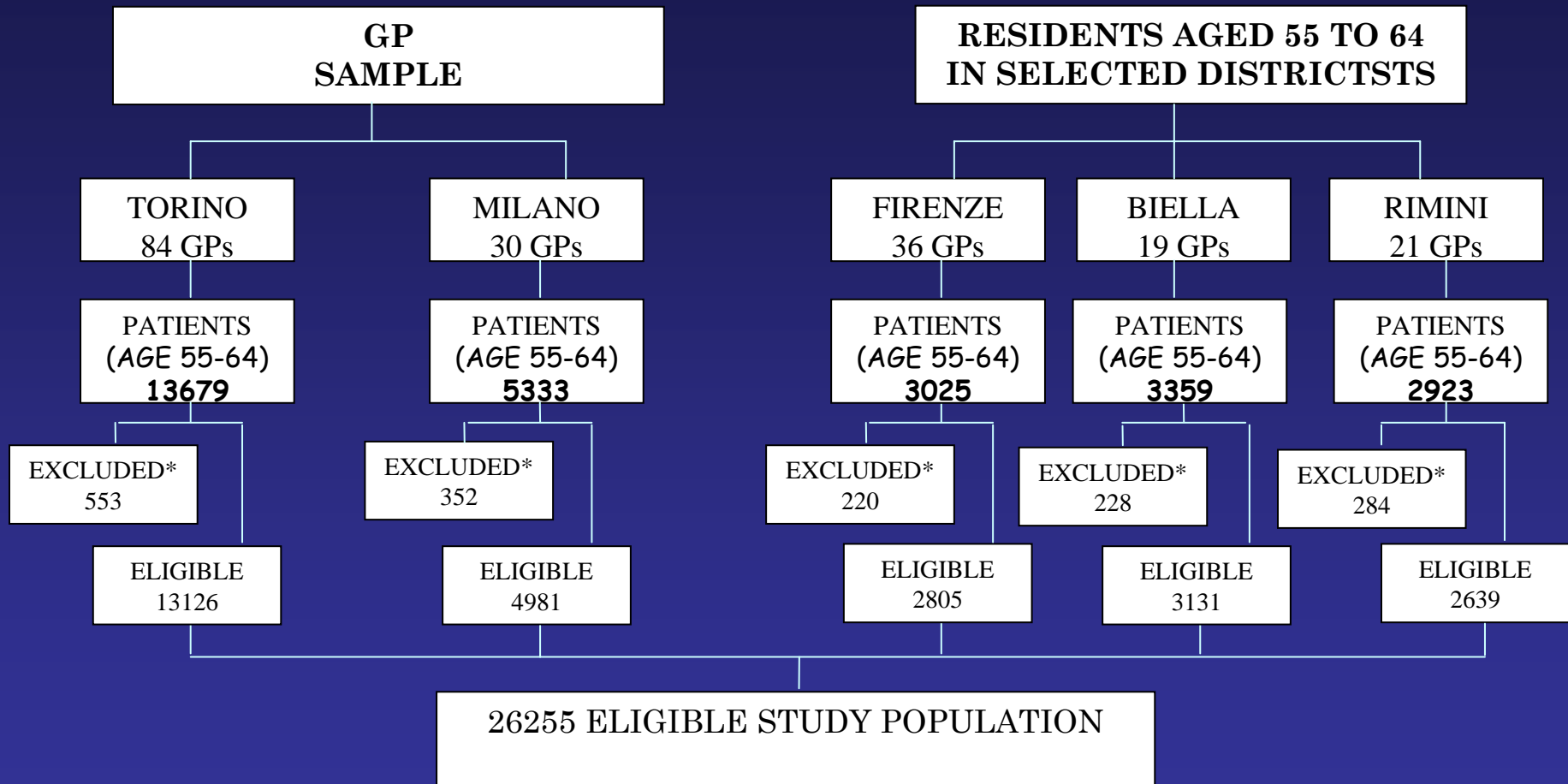
# POPULATION

- **Males and females  
aged 55 to 64 years of age**

## EXCLUSION CRITERIA

- ✓ **Previous CRC, polyps, IBD**
- ✓ **Endoscopy within previous 2 years**
- ✓ **2 first degree relatives with CRC**
- ✓ **Severe disease**
- ✓ **Severe psychiatric symptoms**

# Source sampling by study center - Fig. 1



# SCREENING TEST - FOBT

- ***IMMUNOLOGICAL TEST*** (*Immunodia-HempSp- Fujirebio. Inc Tokio,Japan*)
- ***AUTOMATED READING IN A CENTRAL LABORATORY***

# SCREENING PROCEDURE - FS

- SCREENING TEST

*Flexible sigmoidoscopy :*

Scope advanced beyond the sigmoid-descending colon junction (complete test). Polyps < 10 mm removed during FS cold-snare technique recommended for polyps < 6 mm

- BOWEL PREPARATION:

Single enema (133 ml sodium-phosphate) self-administered 2 hours before the test.

# REFERRAL FOR COLONOSCOPY

- 1 distal polyp  $\geq 10$  mm
- $\geq 3$  adenomas  $< 10$  mm
- 1 high risk (severe dysplasia or cancer, villous histology) adenoma  $< 10$  mm



# INTERVENTIONS

- **BIENNIAL FOBT**
- **"ONCE-ONLY" SIGMOIDOSCOPY**
- **PATIENTS' CHOICE**
- **SIGMOIDOSCOPY + BIENNIAL FOBT  
(PATIENTS WITH NEGATIVE FS)**

**Participation rate by sex, age, and screening arm  
(undelivered invitations are excluded from the denominator) (2)**

	<b>TOTAL</b>	
	<b>55-59 yrs</b>	
<b>SCREENING ARM</b>	<b>invited</b>	<b>attended (%)</b>
<b>FOBT by mail</b>	<b>2266</b>	<b>682 (30.1)</b>
<b>FOBT by GP or screening facility</b>	<b>5893</b>	<b>1654 (28.1)</b>
<b>Once-only sigmoidoscopy</b>	<b>3650</b>	<b>1026 (28.1)</b>
<b>Sigmoidoscopy + biennial FOBT</b>	<b>10867</b>	<b>3049 (28.1)</b>
<b>Patient's choice</b>	<b>3579</b>	
<b>FOBT</b>		<b>522 (14.6)</b>
<b>Sigmoidoscopy</b>		<b>448 (12.5)</b>
<b>Total</b>		<b>970 (27.1)</b>
<b>TOTAL</b>	<b>26255</b>	<b>7381 (28.1)</b>

## Odds ratio for advanced adenomas in FOBT and sigmoidoscopy arms by age and sex and among all patients examined, excluding those in the patient's choice arm, by age, sex, and screening test (2)

	<b>n</b>	<b>OR* (95% CI)</b>
<b>ALL PATIENTS EXAMINED (excluding those in patient's choice arm)</b>		
<b>FOBT arms</b>	<b>2336</b>	<b>1.00 (referent)</b>
<b>Sigmoidoscopy arms</b>	<b>4025</b>	<b>3.58 (2.49-5.14)</b>
<b>55-59 yrs</b>	<b>2578</b>	<b>1.00 (referent)</b>
<b>66-64 yrs</b>	<b>3783</b>	<b>1.32 (1.01-1.72)</b>
<b>Women</b>	<b>3316</b>	<b>1.00 (referent)</b>
<b>Men</b>	<b>3045</b>	<b>1.61 (1.24-2.090)</b>

\* Multivariable ORs adjusted for screening center and for all the other variables in the table

*The study has been  
enlarged.....*

**N = 42801**

# INTERVENTIONS

- **BIENNIAL FOBT (17,730)**
- **“ONCE-ONLY” SIGMOIDOSCOPY (5,057)**
- **(PATIENTS’ CHOICE) stopped**
- **SIGMOIDOSCOPY + BIENNIAL FOBT  
(PATIENTS WITH NEGATIVE FS) (20,414)**

# FOBT – compliance

17730	invited
4599 (25.9%)	Attenders (1 <sup>st</sup> screening round)
5837 (32.9%)	Attenders (at least 1 invitation over 2 screening rounds)

# FS once only - compliance

	5057	Invited
	1405(28%)	Attendees

# FS + FOBT - compliance

<b>20414</b>	<b>Invited</b>
<b>5689(27.9)</b>	<b>Attenders - FS</b>
<b>5192</b>	<b>Invited after 2 years – FOBT</b>
<b>3220(62%)</b>	<b>Attenders - FOBT</b>



# FOBT – Detection Rates

		CCR		AAD
<b>1 test: 1<sup>st</sup> or 2<sup>nd</sup> round</b>				
<b>N. TESTS</b>	<b>5837</b>	<b>17</b>	<b>71</b>	
<b>POSITIVE</b>	<b>215 (3.7%)</b>	<b>0.29%</b>	<b>1.21%</b>	
<b>PPV</b>	<b>40.9%</b>			
<b>2<sup>nd</sup> test (1<sup>st</sup> neg.)</b>				
<b>TESTS</b>	<b>3368</b>	<b>3</b>	<b>29</b>	
<b>POSITIVE</b>	<b>112 (3.3%)</b>	<b>0.09%</b>	<b>0.86%</b>	
<b>PPV</b>	<b>28.6%</b>			
<b>at least 1 test (over 2 rounds)</b>				
<b>PATIENTS</b>	<b>5837</b>	<b>20</b>	<b>100</b>	
<b>POSITIVE</b>	<b>327 (5.6%)</b>	<b>0.34%</b>	<b>1.71%</b>	
<b>PPV</b>	<b>36.7%</b>			

# FOBT – Detection Rates

		CCR		AAD	
1 <sup>st</sup> test		DISTAL	PROXIMAL	DISTAL	PROXIMAL
<b>N. TESTS</b>	4599	11	5	48	9
<b>POSITIVE</b>	164 (3.6%)	0.24%	0.11%	1.04%	0.20%
<b>PPV</b>	44.5%				
<b>2<sup>nd</sup> test (1<sup>st</sup> neg.)</b>					
<b>TESTS</b>	3368	2	1	22	7
<b>POSITIVE</b>	112 (3.3%)	0.06%	0.03%	0.65%	0.21%
<b>PPV</b>	28.6%				
<b>1<sup>st</sup> test (2<sup>nd</sup> round)</b>					
<b>TESTS</b>	1238	0	1	10	4
<b>POSITIVE</b>	51 (4.1%)	0.0%	0.1%	0.8%	0.3%
<b>PPV</b>	29.4%				
<b>at least 1 test (over 2 rounds)</b>					
<b>PATIENTS</b>	5837	13	7	80	20
<b>POSITIVE</b>	327 (5.6%)	0.22%	0.12%	1.37%	0.34%
<b>PPV</b>	36.7%				

# FS + FOBT - Detection Rates

		CCR		AAD	
1 <sup>st</sup> test		DISTAL	PROXIMAL	DISTAL	PROXIMAL
<b>FS TESTS</b>	5585	21	2	265	7
		0.38%	0.04%	4.74%	0.13%
<b>subsequent tests</b>					
<b>FOBT TESTS</b>	3220	1	4	7	10
<b>POSITIVE</b>	114	0.03%	0.12%	0.22%	0.31%
<b>total</b>		22	6	272	17
		0.39%	0.11%	4.87%	0.3%

# *FS once-only - Detection Rate*

		CCR		AAD	
		DIST	PROX	DIST	PROX
<b>FS TESTS</b>	<b>1381</b>	<b>5</b>	<b>0</b>	<b>78</b>	<b>1</b>
<b>DR %</b>		<b>0.36%</b>	<b>0.00%</b>	<b>5.65%</b>	<b>0.07%</b>

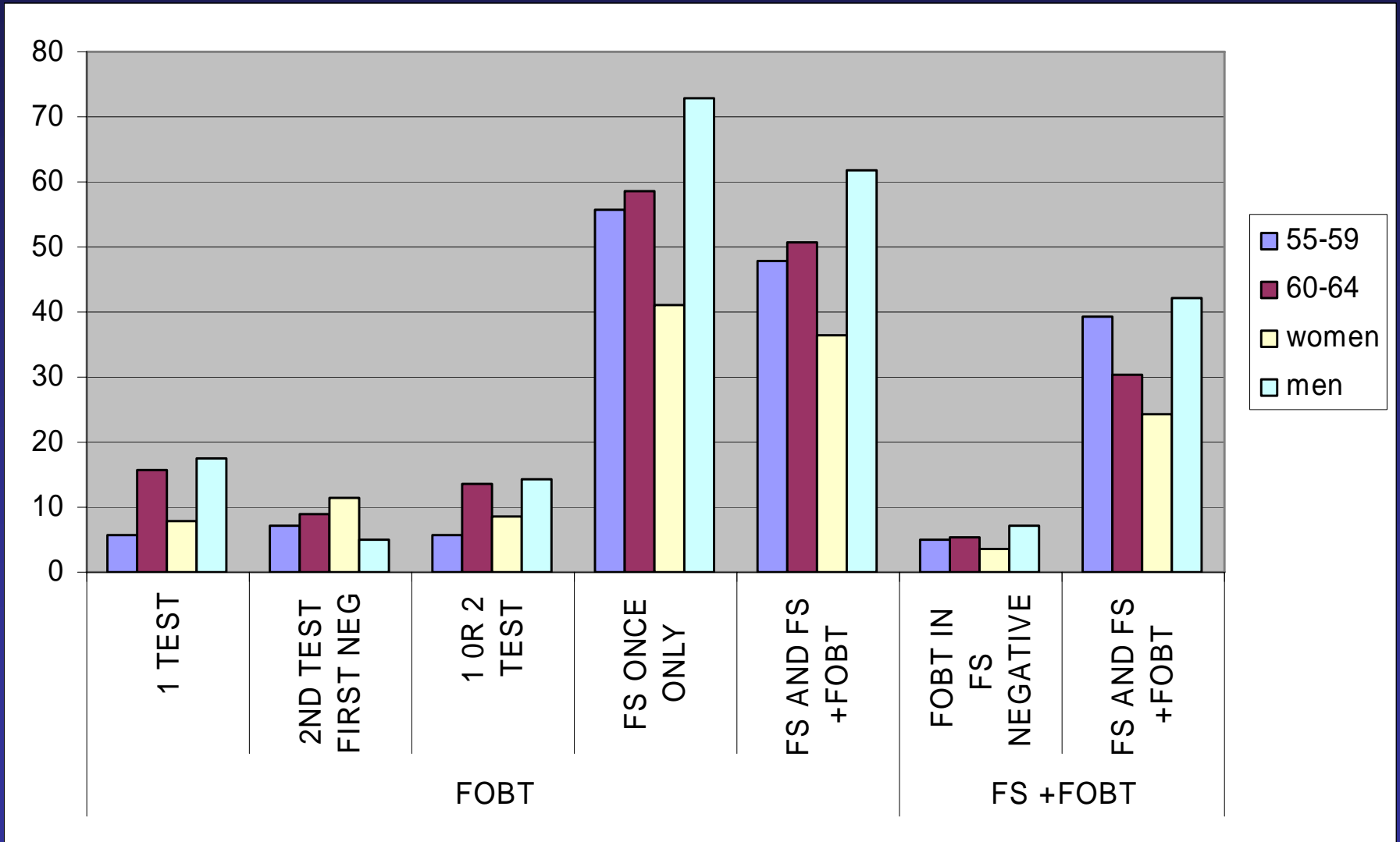
# Detection rate by screening arm

PATIENTS		n CRC %	n AAD %	Total %
FOBT, 2 rounds invit	5837	20 0.34	100 1.71	120 2.06
FS + FOBT	5585	28 0.50	289 5.17	317 5.67
FS	1385	5 0.36	79 5.70	84 6.07

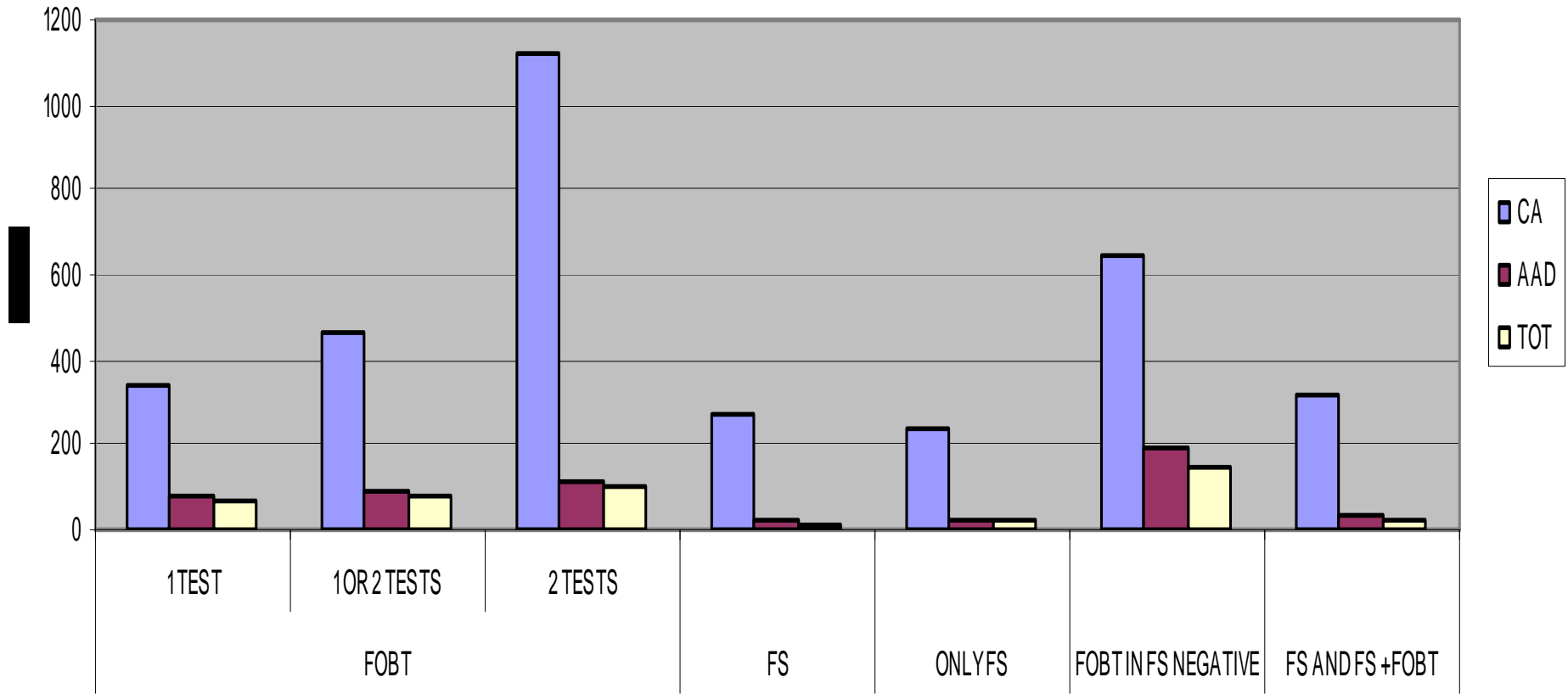
# Detection rate by intention to treat

	Invited	n CRC %	n AAD %	Total %
FOBT,2 rounds invit	17330	20 0.12	100 0.58	120 0.70
FS + FOBT	20414	28 0.14	289 1.42	317 1.56
FS	5057	5 0.1	79 1.56	84 1.66

# ADVANCED ADENOMAS DETECTION RATES PER 1000 BY AGE AND GENDER

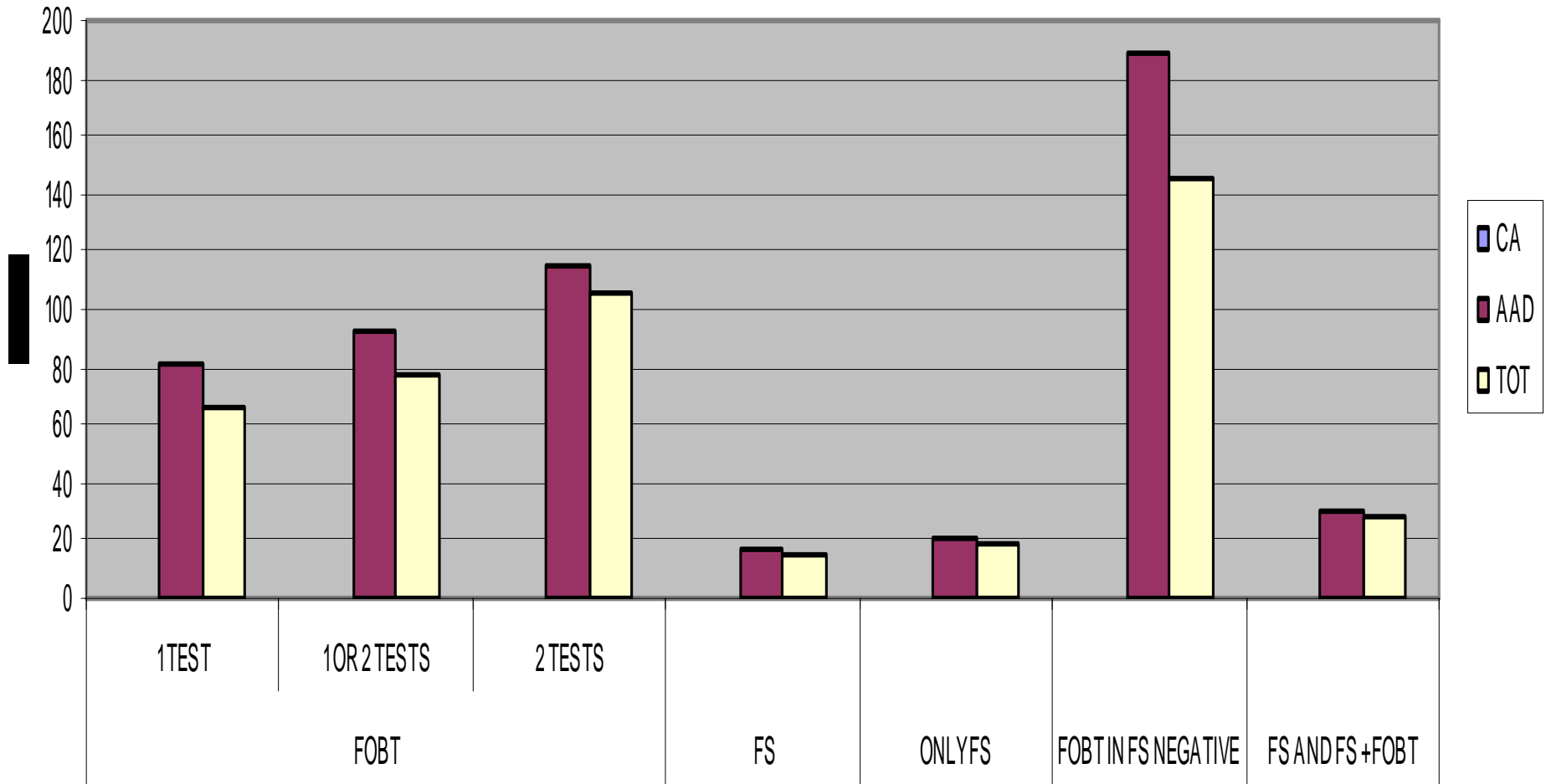


# NNS per detected lesion





# NNS per detected lesion

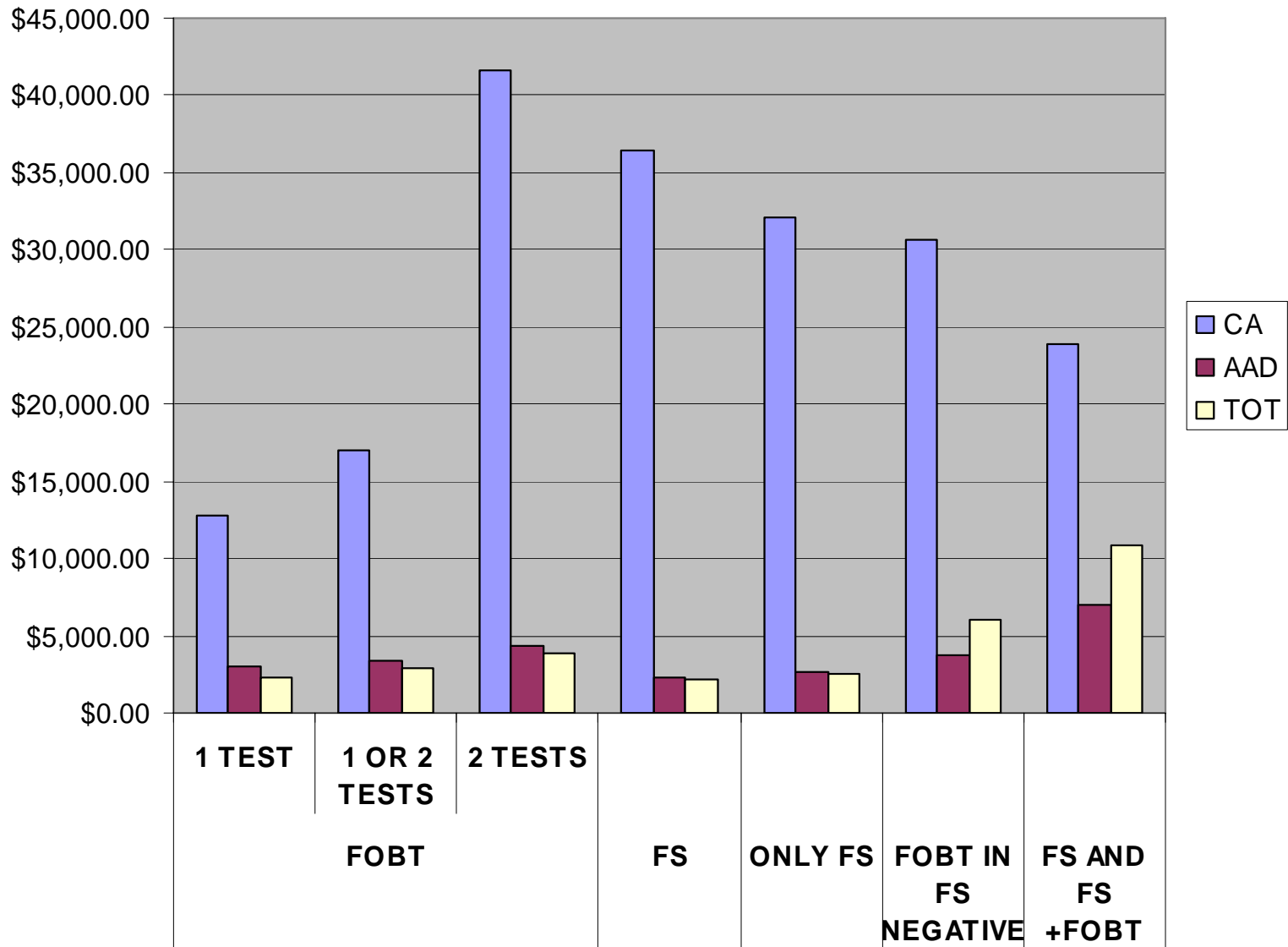


# COST

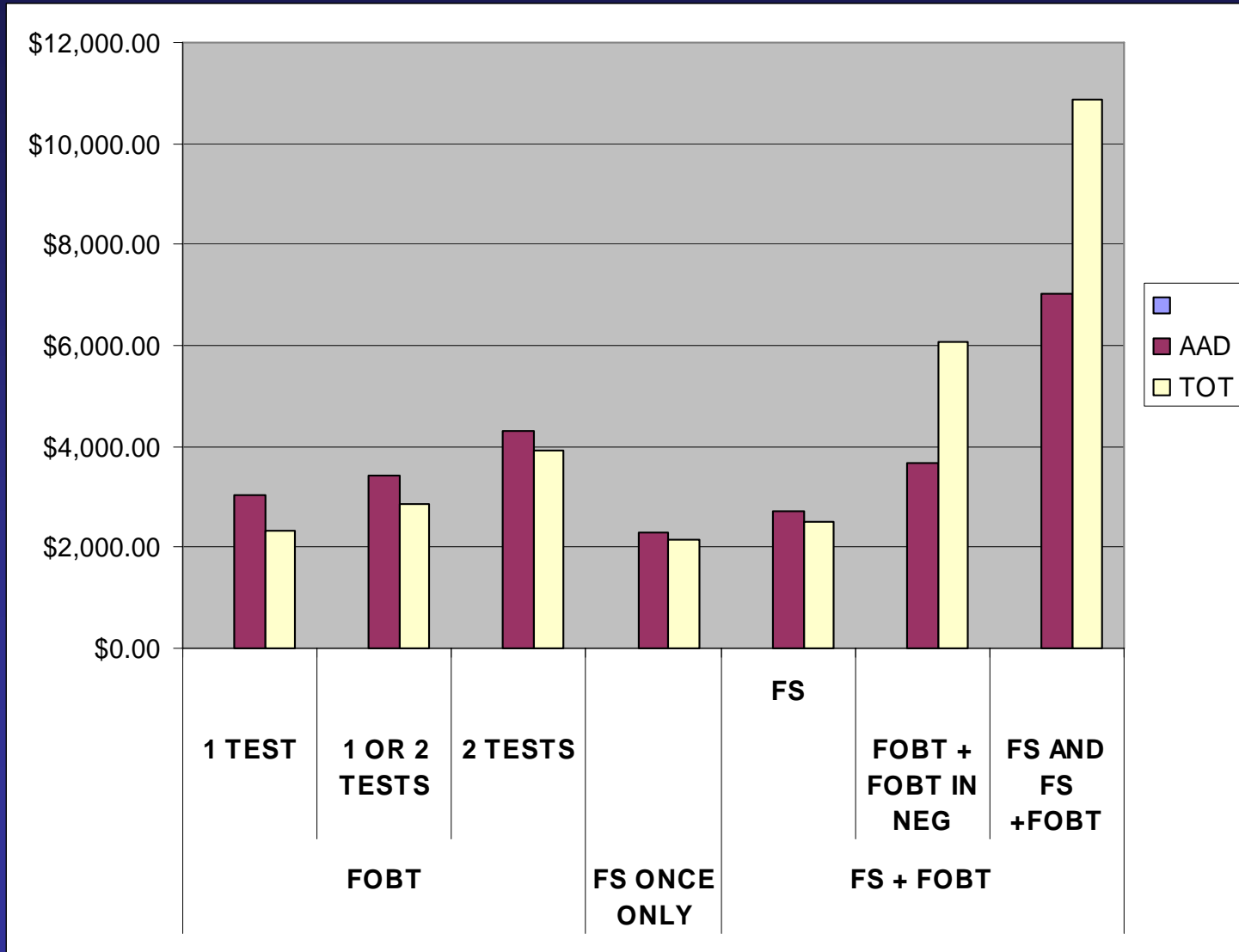
- FS: 132 \$
- FOBT: 37\$

The cost includes the assessment (referral to colonoscopy, histology ...) and the organization

# Cost per Detected Lesion



# Cost per Detected Lesion



# *Conclusions 1*

**After 2 FOBT screening rounds, the cumulative yield of advanced adenomas was about one third for FOBT compared to FS, while CRC yield was similar.**

**The participation to FOBT (in the screening programs recently started in the study areas attendance is above 40%) might influence the estimates of the relative difference in neoplasia yield.**

# ***Conclusions 2***

**\*At the prevalent round:**

- **the cost per detected CRC is lower for FOB Test than for FS**
- **the cost per detected AAD is higher for FOB Test than for FS**

**\* after 2 FOB Tests, the cost per detected lesion is higher both for CRC and for AAD compared to FS**

**\* The detection rate of AAD is the same at 55-59 years and at 60-64 years both in men and in women, supporting the observation of a plateau of prevalence of AAD around 60 years**

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