UNIVERSITY OF
SOUTH CAROLINA

Cancer Prevention and Control Program Colloquium series, January 17, 2014

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Colorectal Cancer: A tale of WHY

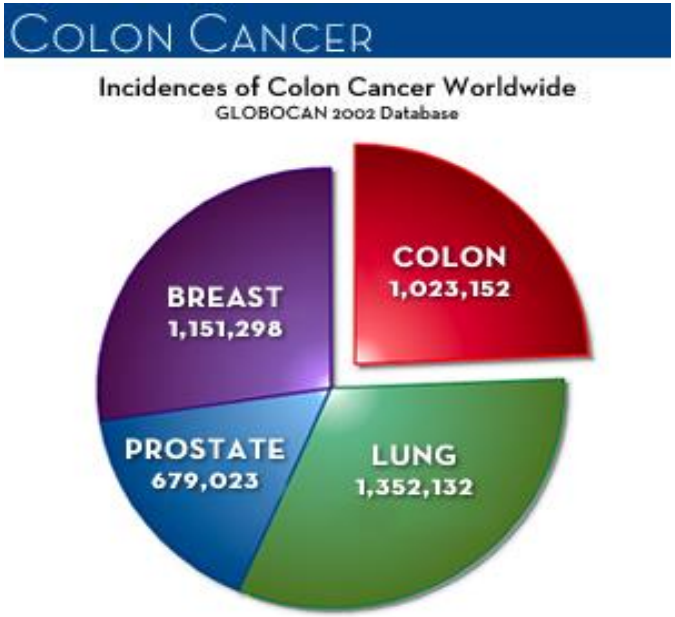
- “NO BEHIND SHOULD BE LEFT BEHIND “ (Steven Lloyd, 2006)

Summary of presentation

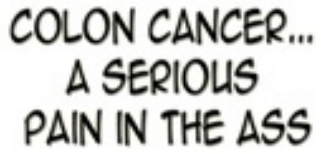
- CRC profile in the US population
- CRC prevention - cases and deaths
- Barriers to achieving prevention potential
- Our research areas
  - Screening efficacy potential
    - Performance quality using process indicators
    - Outcomes – CRC incidence and mortality
  - Screening capacity – Alternative workforce potential

Colorectal Cancer (CRC)

- 3rd most common cancer and 2nd leading cancer death
- 141,210 new cases and 49,380 deaths in 2011.
- 1 in 20 Americans will have CRC in lifetime
- Decline since 1995 due to increased screening



-GLOBOCAN 2002, American Cancer Society 2011



Cancer Statistics 2014

- 3rd most common cancer
- 3rd leading cancer death
- Est. 136,830 new cases and 50,310 deaths
- Lifetime interval CRC risk:
  - 5% in men
  - 4.6% in women

CRC incidence/mortality, 2014

Estimated New Cases*

Males				Females		
Prostate	233,000	27%		Breast	232,670	29%
Lung & bronchus	116,000	14%		Lung & bronchus	108,210	13%
Colorectum	71,830	8%		Colorectum	65,000	8%
Urinary bladder	56,390	7%		Uterine corpus	52,630	6%
Melanoma of the skin	43,890	5%		Thyroid	47,790	6%
Kidney & renal pelvis	39,140	5%		Non-Hodgkin lymphoma	32,530	4%
Non-Hodgkin lymphoma	38,270	4%		Melanoma of the skin	32,210	4%
Oral cavity & pharynx	30,220	4%		Kidney & renal pelvis	24,780	3%
Leukemia	30,100	4%		Pancreas	22,890	3%
Liver & intrahepatic bile duct	24,600	3%		Leukemia	22,280	3%
All Sites	**855,220**	**100%**		**All Sites**	**810,320**	**100%**

Estimated Deaths

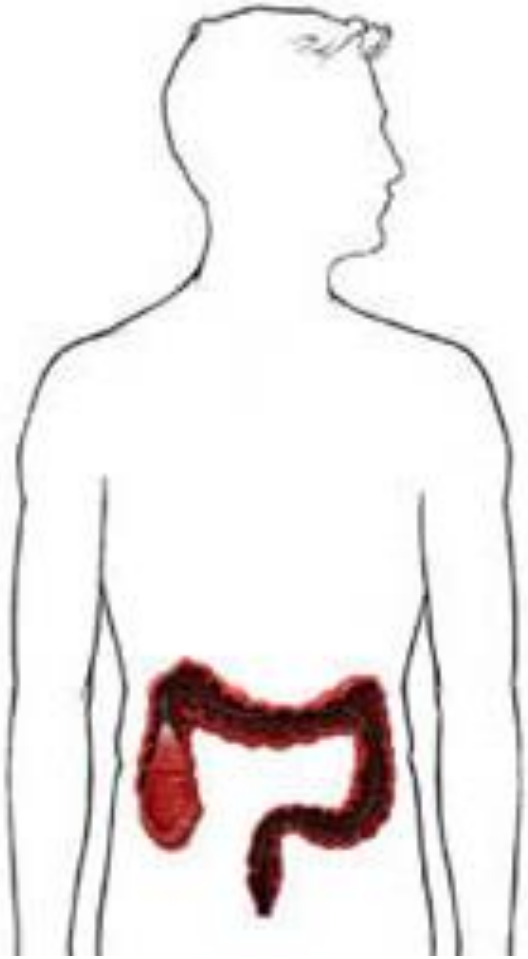
Males				Females		
Lung & bronchus	86,930	28%		Lung & bronchus	72,330	26%
Prostate	29,480	10%		Breast	40,000	15%
Colorectum	26,270	8%		Colorectum	24,040	9%
Pancreas	20,170	7%		Pancreas	19,420	7%
Liver & intrahepatic bile duct	15,870	5%		Ovary	14,270	5%
Leukemia	14,040	5%		Leukemia	10,050	4%
Esophagus	12,450	4%		Uterine corpus	8,590	3%
Urinary bladder	11,170	4%		Non-Hodgkin lymphoma	8,520	3%
Non-Hodgkin lymphoma	10,470	3%		Liver & intrahepatic bile duct	7,130	3%
Kidney & renal pelvis	8,900	3%		Brain & other nervous system	6,230	2%
All Sites	**310,010**	**100%**		**All Sites**	**275,710**	**100%**

Efficacy of screening

- Early detection (downstaging)
- Primary prevention

Why CRC screening is unique?

- CRC can be PREVENTED if precancerous polyps removed
- Screening NOT ONLY for frank CANCER, BUT ALSO polyps
- Screening prevalence in the US?



How colonoscopy, sigmoidoscopy, and FOBT work?

NHIS 2000, NHIS 2005, NHIS 2010

	Colonoscopy		Sigmoidscopy		Home FOBT	
	Male	Fem.	Male	Fem.	Male	Fem.
2000	15.5%	11.8%	9.2%	7.0%	17.4%	16.0%
2005	37%	29.7%	4%	2.4%	14.1%	9.8%
2010	54.4%	54.7%	1.6%	1.0%	8.9%	8.7%

Note: Colonoscopy in past 10 years, sigmoidoscopy in 5 years, or home FOBT previous year as part of a routine examination, NOT Follow-Up

Source: Chen X, White MC, Peipins LA, Seeff LC. Increase in Screening for Colorectal Cancer in Older Americans: Results from a National Survey. *Journal of the American Geriatrics Society.* 2008;56(8):1511-1516.
Shapiro JA, Klabunde CN, Thompson TD, et al. Patterns of colorectal cancer test use, including CT colonography, in the 2010 National Health Interview Survey. *Cancer Epidemiol Biomarkers Prev* 2012;21:895-904.

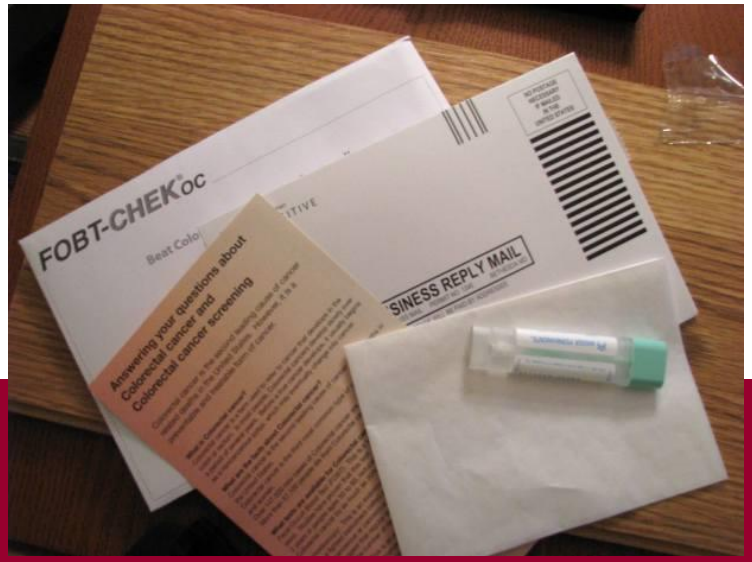
FOBT (fecal occult blood test)

- Low sensitivity, low specificity for adenomas (even under ideal research conditions)
- Reasonable sensitivity for cancer
- Adenomas bleed much less frequently
- High false positives and false negatives due to dietary and specimen collection logistics.

FOBT – Efficacy for CRC mortality prevention

Minnesota study (1976-1977 recruits), 18-year CRC mortality follow-up, 46,551 individuals - 3 groups

	18-year cumul. CRC mortality ratio
Control (no screening)	**1**
Annual FOBT	**0.67**
Biennial FOBT	**0.79**



-Mandel 1999

FIT (fecal immuno-chemical test)

- Subjects: 3 Northern Kaiser Permanente Medical Centers, April 1997 – October 1999. Sensitivity and specificity for ADVANCED NEOPLASMS in the LEFT colon only followed by colonoscopy within 2 years after the FOBT screening

	Sensitivity (%)		Specificity (%)	
	Cancer	Advanced neoplasm (L colon)	Cancer	Advanced neoplasm
FIT	**81.8**	**29.5**	**96.9**	**97.3%**
Sensi. GT	**64.3**	**41.3**	**90.1**	**90.6%**
FIT+ GT	**64.3**	**22.8**	**98.1**	**98.4%**

-Allison 2007

FIT vs. Detection of adenomas!

Test	Specificity per person, %	Sensitivity per lesion, %		
		Adenoma 6–9 mm	Adenoma ≥10 mm	CRC, all stages
gFOBT	98.9	1.3	6.5	18.2
FIT 200 ng hemoglobin per mL	98.7	2.0	10.6	46.0
FIT 150 ng hemoglobin per mL	98.3	2.3	12.2	47.0
FIT 100 ng hemoglobin per mL	97.8	4.0	13.0	51.0
FIT 75 ng hemoglobin per mL	97.0	4.1	15.2	56.0
FIT 50 ng hemoglobin per mL	95.8	8.4	16.7	61.0

Note: Sensitivity for adenoma ≤5 mm are 0 for all tests.

Source: Wilschut JA, Habbema JDF, van Leerdam ME, et al. Fecal Occult Blood Testing When Colonoscopy Capacity is Limited. *J Natl Cancer Inst* 2011;103:1–11

Sigmoidoscopy

- Norwegian population-based study (55-64 years), 7-year follow-up, Screening and control groups.

	Screening		Control	P-value
Cumulative Incidence	134.5/100,000		131.9/100,000	NS
Mortality (Hazard ratio)	CRC	0.41	1	P=0.011
	Rectosigmoid Cancer	0.24		P=0.016

-Hoff 2009

Early studies of Colonoscopy

- National Polyp Study - Prospective clinical trial
  - 76% CRC prevention rate following colonoscopic adenectomy (8,401 Person-Years of Observation (PYO) , 1,418 persons. -Winawer 1993
  - 53% reduction in CRC mortality (mean follow-up 15.8 yrs) -Zauber 2012
- Retrospective cohort study of negative initial colonoscopy cases
  - At a single academic medical center
  - NO subsequent CRC over a mean follow-up of 5.34 years -Imperiale 2008

Screening recommendations

- Colonoscopy screening superior to other screening strategies in reducing CRC incidence and mortality.

-Winawer 1993, Singh 2006

- Adenoma clearance reduces CRC incidence and therefore CRC mortality
- Currently the preferred screening method for average-risk patients

-Levin 2008, Baxter 2009, ACG 2012, Rex 2009

But….

- Colonoscopy has since lost credibility as a CRC reduction tool

Issue 1: Poor outcomes in Community-based series

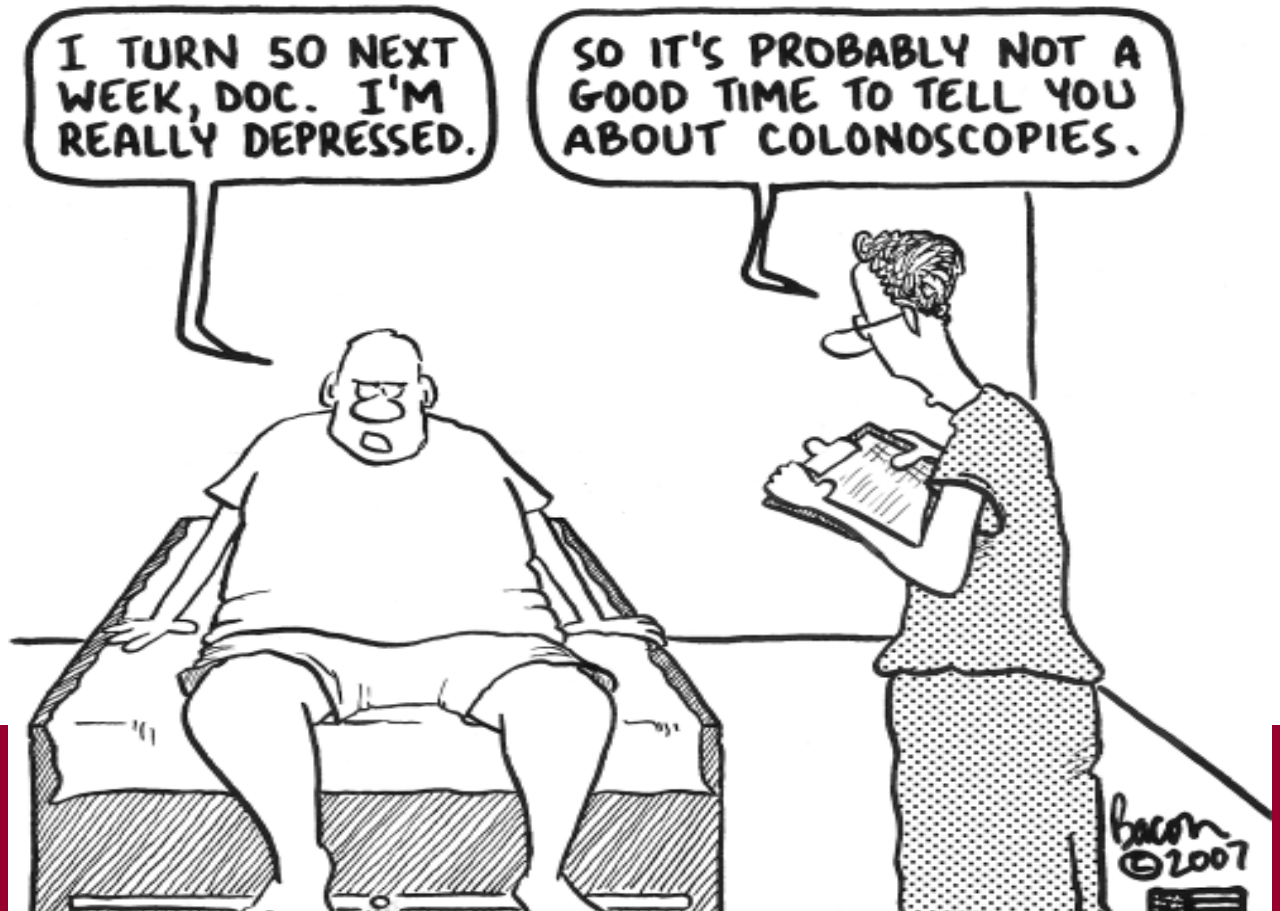
- Only 37% CRC incidence prevention in Canada (regardless of adenoma status at colonoscopy)

-Baxter 2005

Other community studies

- 35% protection following a negative initial colonoscopy and 26% protection among 2079 persons with at least one adenoma, followed up for a median period of 4.3 years.

-Singh 2006, Leung 2010



Latest community-based study

Nishihara et al 2013

- Longitudinal study using data pooled from the Nurses Health Study and Health Professionals Follow-up study
- 88,902 participants followed over 22 years
- CRC reduction by colonoscopy:
  - 43% among persons with adenomas at baseline
  - 56% among those without adenomas at baseline

Why colonoscopy does not work?

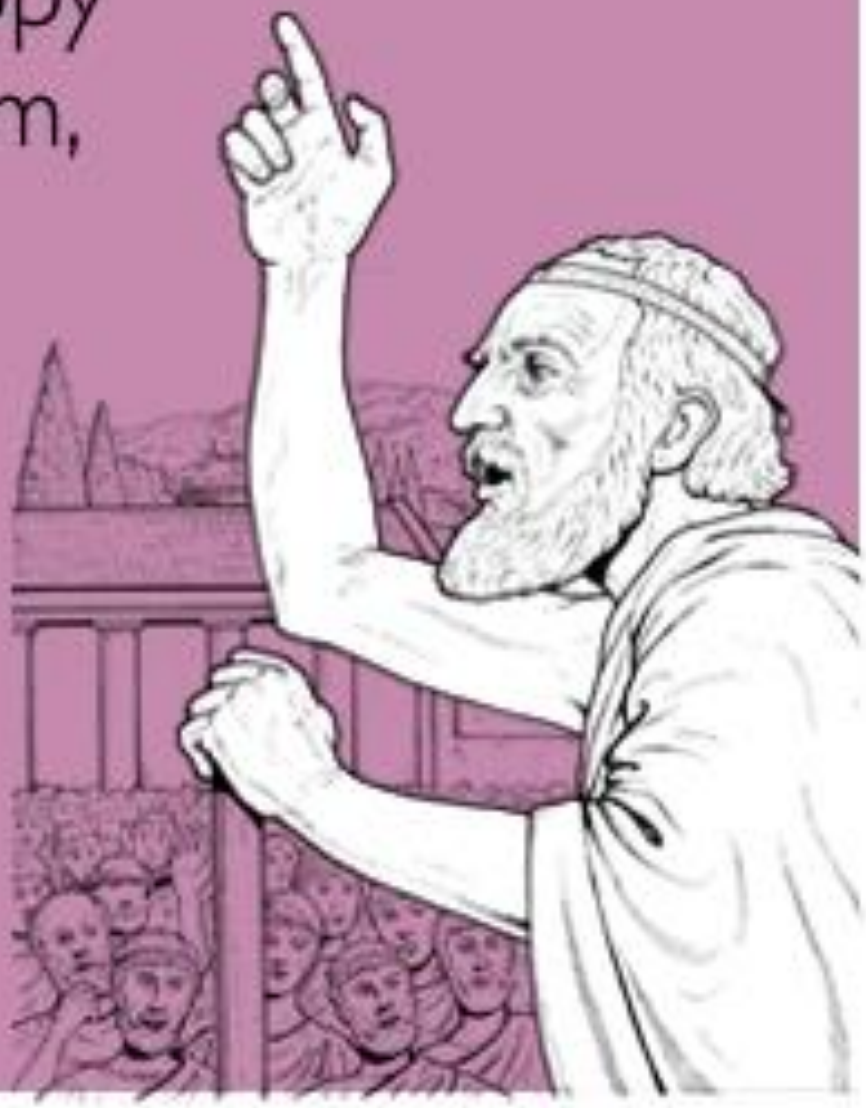
- Variable quality between providers

Procedure time	ADR	MNA	Advanced neoplasm rate	Cancer detection rate
<6 min	11.8%	0.17	0.03	0.002
≥ 6min	28.3%	0.61	0.07	0.006
P-value	<.0001	0.06	0.005	NS

-Barclay 2006

Tandem colonoscopies show adenoma miss rates of 22%, 26% for small adenomas <5 mm. -van Rijn 2006

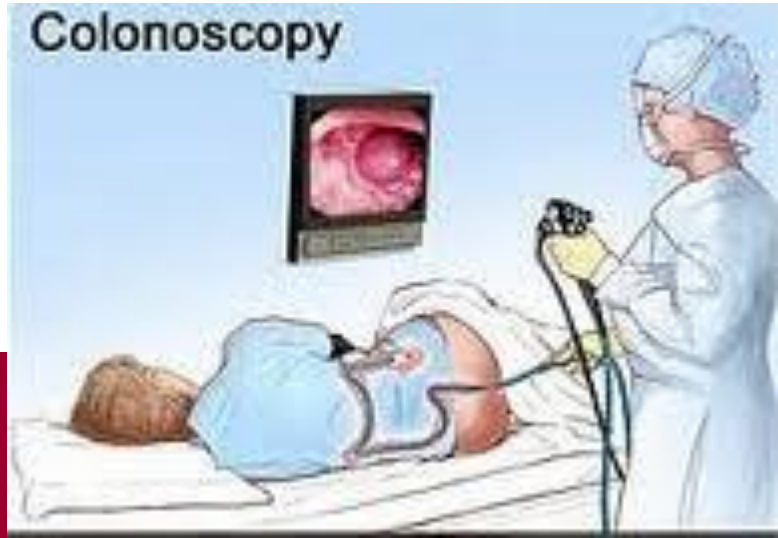
May your colonoscopy technician have a firm, but gentle hand.



Issue 2: Colonoscopy capacity

- But there is a huge capacity gap! (10 years to complete current backlog). Therefore, PCPs?!!
- Only 2% nationally by PCPs in 2002, and 5.7% in South Carolina in 2005. -Seeff 2006
- Colonoscopy capacity gap is critical because of steep declines in sigmoidoscopy and FOBT in recent years.

-Shapiro 2008, Phillips 2007



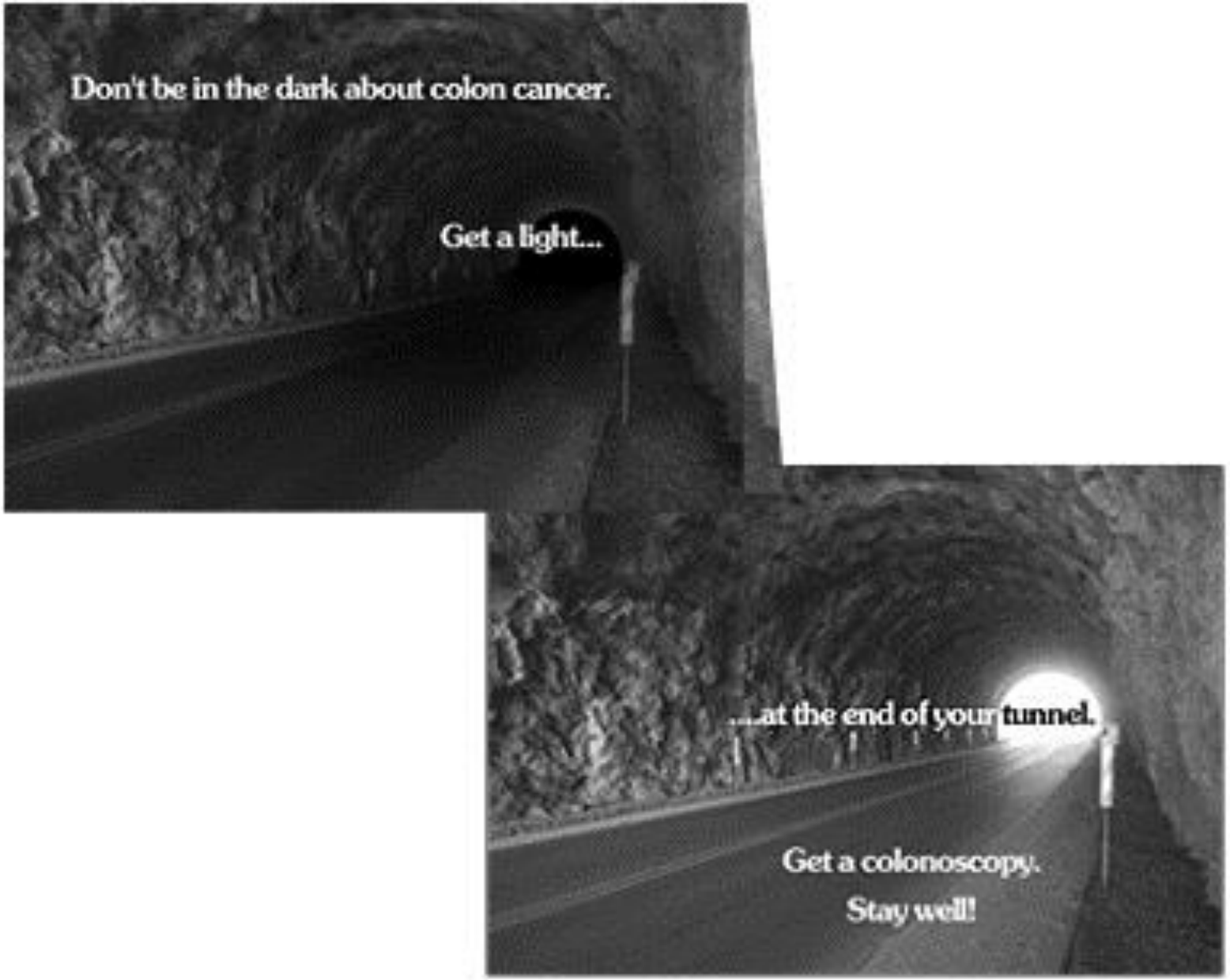
American Cancer Society®

For more information on the different ways you can be tested, call 1.800.227.2345 or visit www.cancer.org/NYNJ.

Colonoscopy quality norms

- Cecal intubation rates (>95%)
- Withdrawal time (≥ 6 minutes with no polyp)
- Adenoma detection rates (≥25% in men and ≥15% in women)
- Perforation rates (<0.1%).

ASGE/ACG Taskforce on Quality: Rex 2006


Don't be in the dark about colon cancer.
Get a light...
...at the end of your tunnel.
Get a colonoscopy.
Stay well!

Our research on colonoscopy effectiveness

A. Colonoscopy Performance quality under a polyp detection maximizing protocol (NCI funded pilot project – 2007-09)
B. Concurrent comparison of study center with other providers without this protocol (SCOPE SC DHEC study - completed)
C. Outcomes: Colorectal cancer incidence and mortality prevention (R-15 study)

Performance quality and indicators under a polyp detection maximizing protocol (NCI funded pilot project)

Methods

- Retrospective data, 10,958 consecutive colonoscopies performed by 51 PCPs on 9,815 patients, October 2002 to November 2007

- Center protocol – a)2-person technique (using a trained technician), b) polyp search and removal during both scope insertion and withdrawal, and c) onsite expert always available for rescue assistance (either navigational or therapeutic).

Training of PCPs

- Training with expert supervision up to 140 procedures

- Post-training, PCPs perform their cases at the SCMEC (with tech assistance) and an onsite expert available for backup assistance

Study objective

To examine the quality of colonoscopies performed by primary care physicians (PCPs) in a licensed ambulatory surgery center for colonoscopy

Conclusions

- PCPs' cecal intubation, adenoma detection, procedure time, all exceed the ASGE benchmarks.
- Mean withdrawal time of 8 minutes for no polyp
- Cecal intubation rate (98.1%)
- Adequate bowel preparation facilitates higher intubation rates. 91% had excellent to fair bowel preparation (national rate is 75% Harewood 2010)

Conclusions

- The study PCPs' high rates of adenoma detection in men (34.6%) women (25.4%), far exceed the ASGE benchmarks (men ≥ 25%; women ≥ 15%).
- Major adverse event rate of 0.06% (that included 2 perforations, both perforated diverticulae, unrelated to scope advancement or polyp removal; no death) is similar to the documented 0.067% perforation rate for specialist-performed screening colonoscopies.
- Under conditions of technical support and specialist backup, PCPs' quality and safety measures are comparable to those of well-performing gastroenterologists.

Concurrent comparison of study center with other providers without this protocol (SCOPE study)

Data source – SC SCOPE program

Funded colonoscopy screening for the indigent (<200%FPL and uninsured)

A unique natural experiment to compare polyp and adenoma detection rates between a center implementing a polyp detection maximizing protocol vs. usual practice by community-based gastroenterologists

SCOPE Objectives

a) Compare adenoma rates and characteristics between Site 3 (high-yield optimized protocol-SCMEC) with comparison sites
b) Assess cancer protection implications

SCOPE Findings

	Site 3	Site 1,2,4
No. Colonoscopies	325	336
Total adenomas found	252	86

SCOPE Conclusions

- Comparison sites detected fewer adenomas, “missing” adenomas being <9mm.
- “Excess” adenomas of Site 3 were histologically as advanced as comparison sites’ adenomas.
- Site 3 polyp detection rate is similar to documented autopsy studies, indicative of being the true population rate.
- Because ALL patients were of uniform SES, and similar race/gender among the 2 groups, Site 3 “excess” adenomas are likely a measure of missed adenomas by comparison sites.
- “Missed” small adenomas at comparison sites may have significantly reduced the cancer protection conferred.

Outcomes of SCMEC colonoscopies – colorectal cancer incidence and deaths (R-15 study)

Study objective

- Study the colorectal cancer incidence prevention impact of screening colonoscopies under a standardized, polyp yield-maximizing clinical protocol

Methods

- Retrospective cohort study of CRC incidence following screening colonoscopies.
- Probabilistic matching of the colonoscopy cohort (2001-2008) with the SC Cancer Registry (SCCCR) database from January 1, 1996 through December 31, 2009

Methods

- Generate expected number of CRC cases in the study cohort (apply SC population-wide age-, sex-, race-specific incidence rates (SCCCR 2010, SCAN), and the US (SEER-17), to the study cohort
- Population incidence rates reflect current screening rates in the SC population (i.e. comparison group is not screening-naïve)
- Standardized incidence ratio (SIR) - observed divided by expected number of cases.

Methods

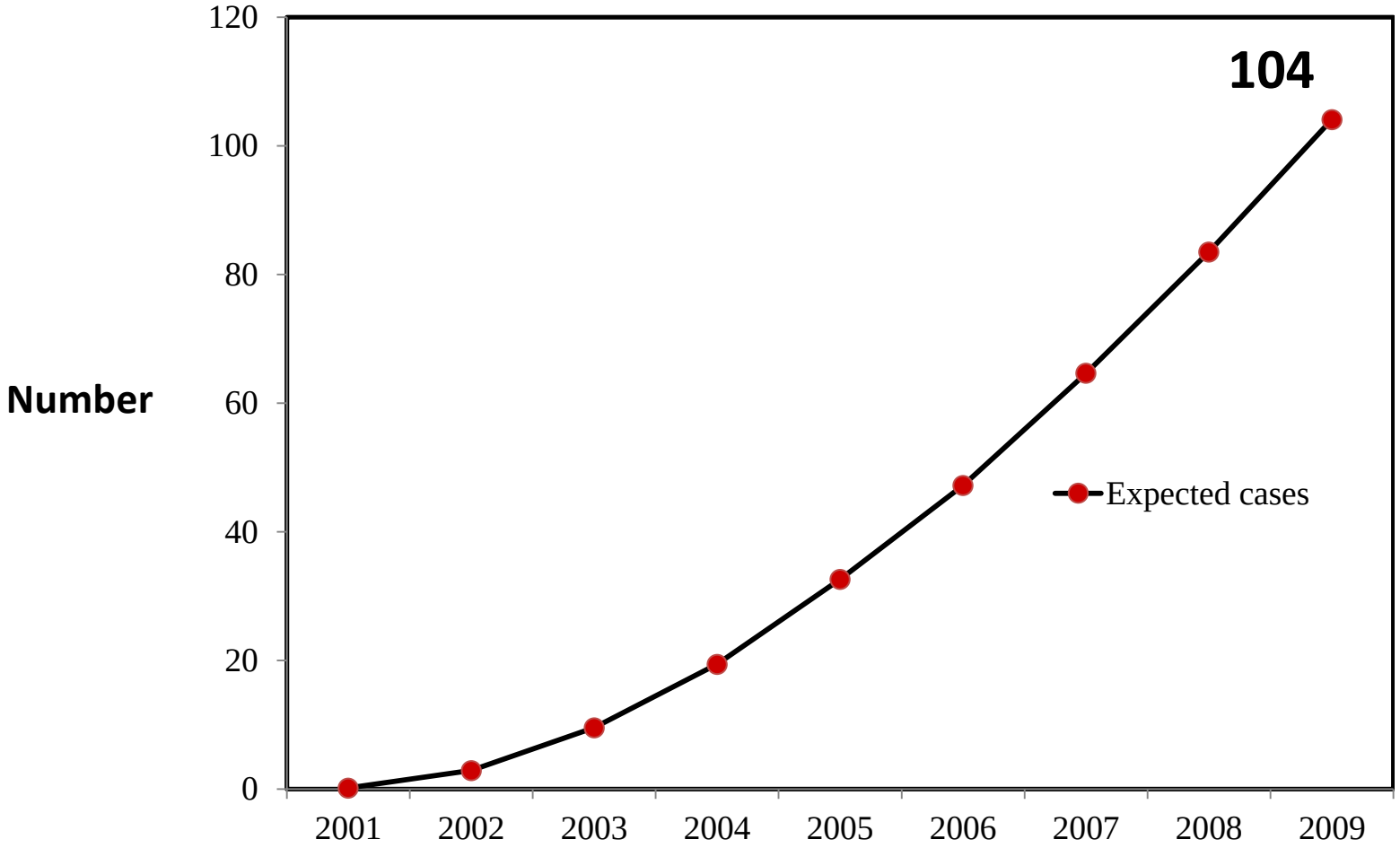
- Either CRC diagnosis or CRC death were defined as CRC incidence cases.
- Endpoints for censoring observation period:
  - Incident CRC (SCCR Registry match)
  - Death of individual (due to CRC or other cause), ascertained from the Vital Records Registry (measured as month/year of cancer diagnosis or death)

RESULTS

Cohort at Baseline (n=16,315)

- Mean age 57.7±10.3 years
- Female 53.3%
- African-American 49.4%
- Adenoma detection rate 31.4%
  - Male 36.6%, Female 27.4%
- Advanced adenoma rate 5.2%
- Mean follow-up 4.8 years

CRC Standardized Incidence Ratio



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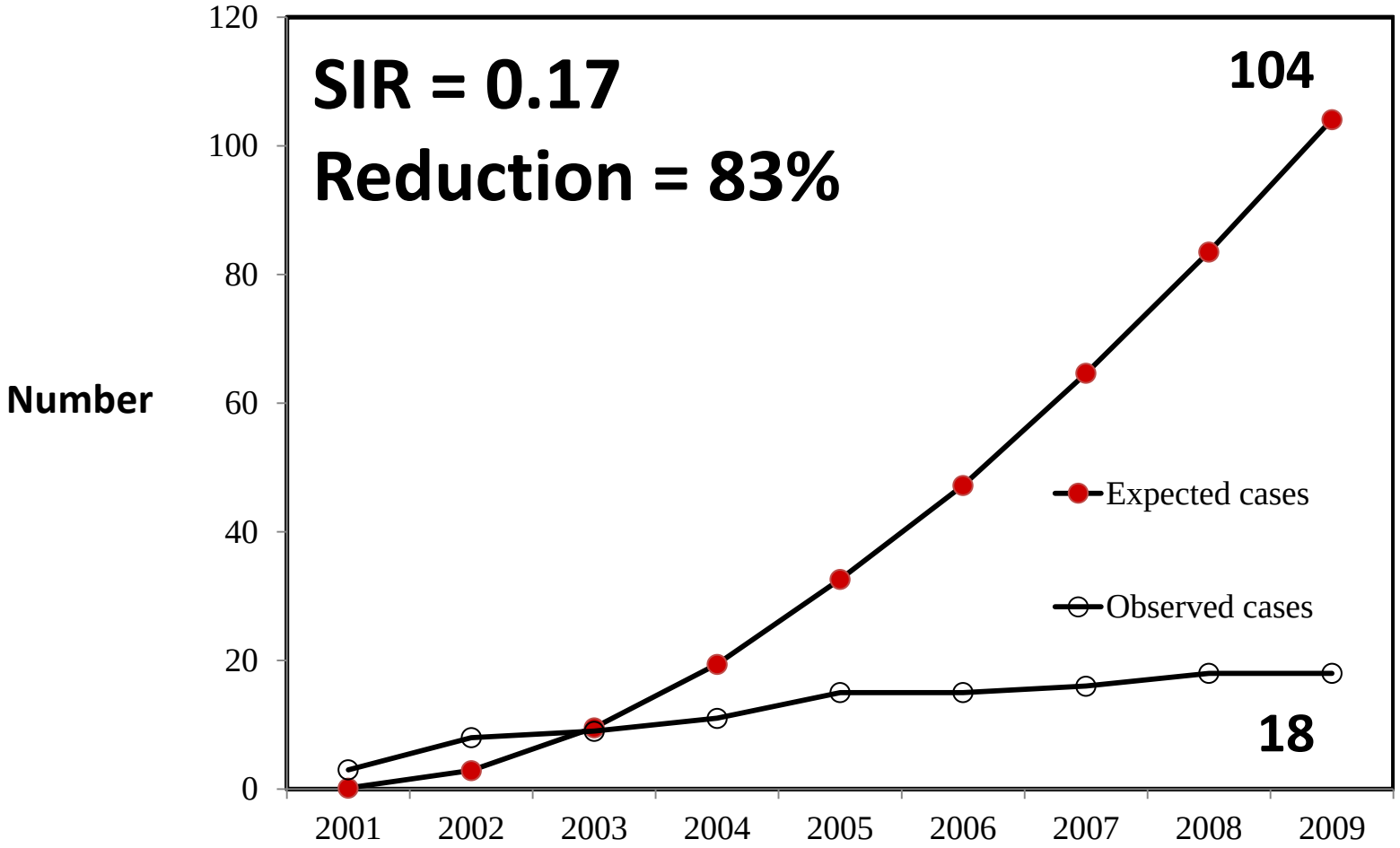
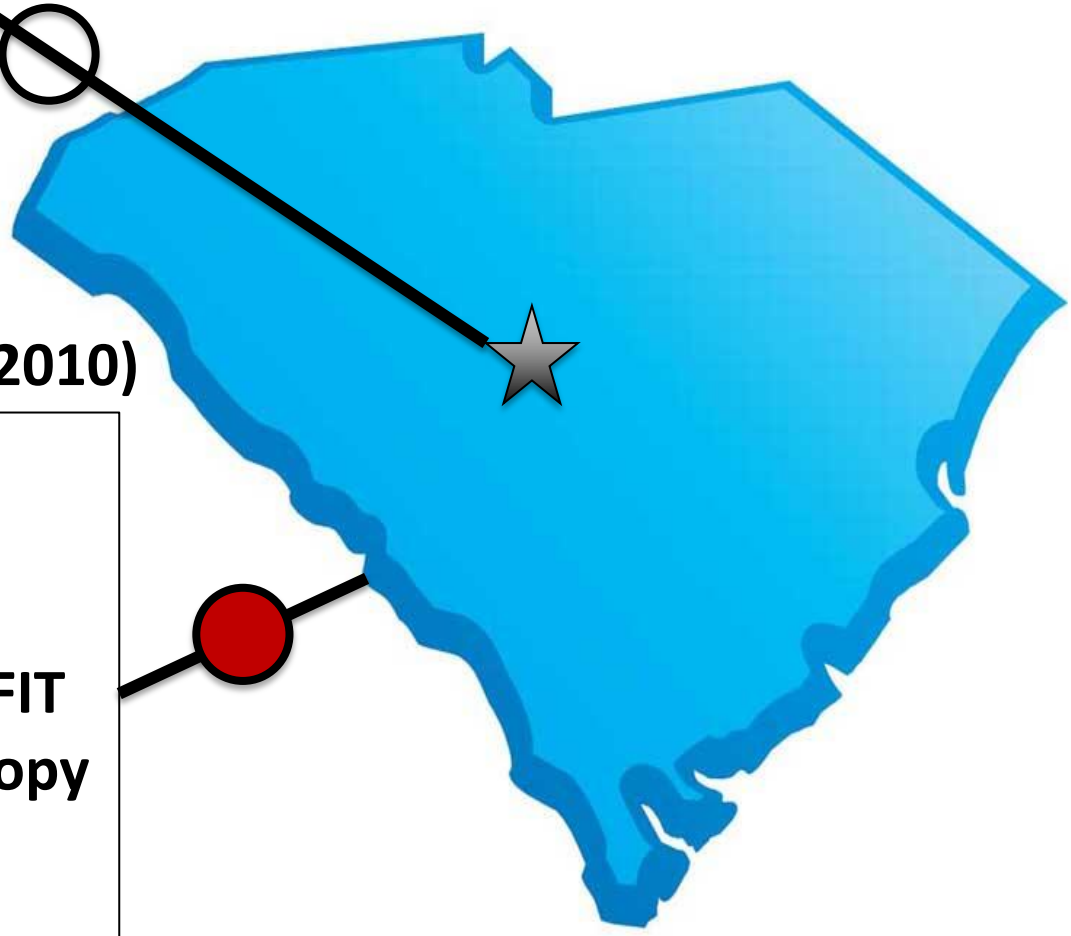


South Carolina

Observed 18 CRC cases
Per 16,000 patients
- **100% colonoscopy**

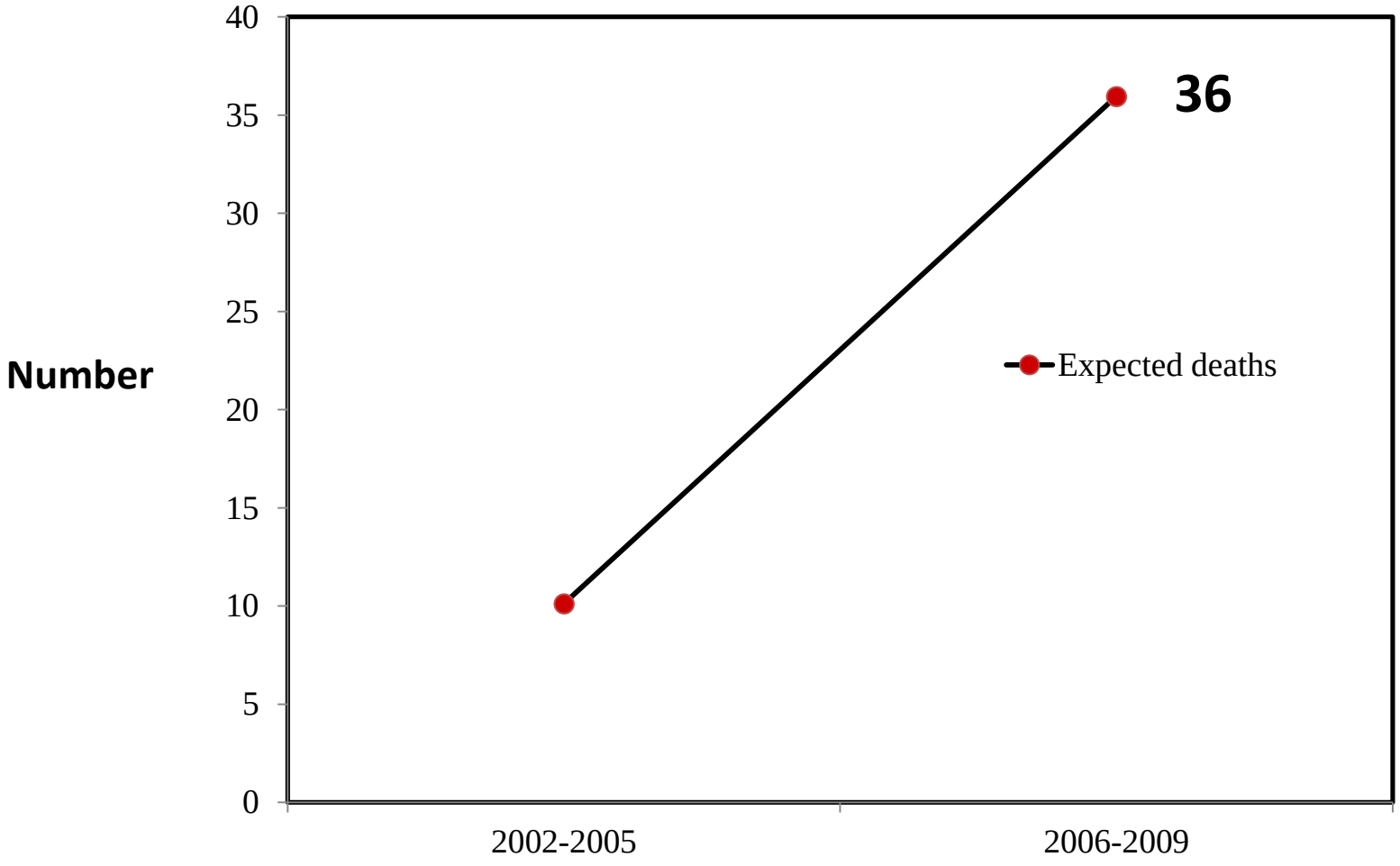
Columbia Group



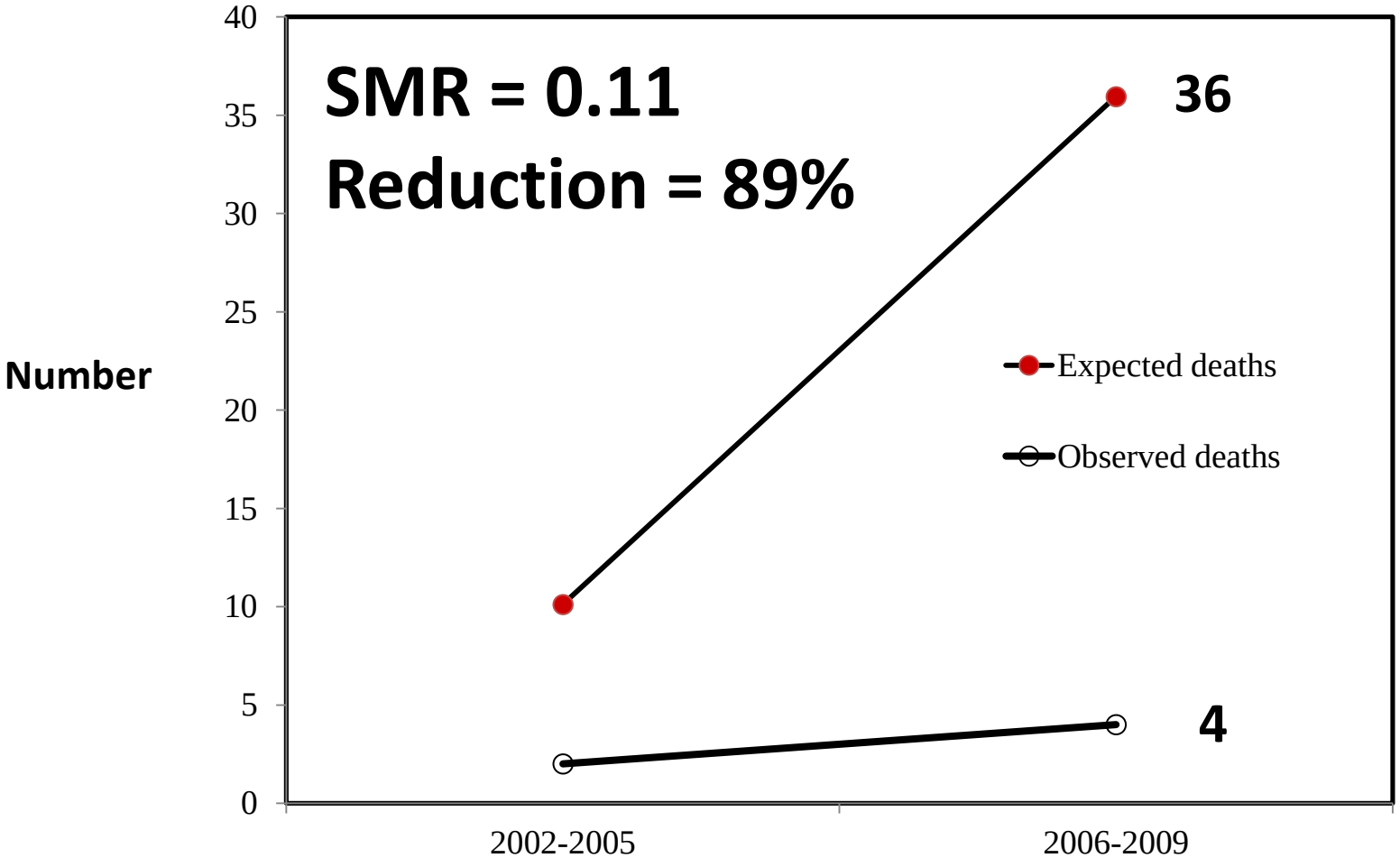
National rates (NHIS 2005&2010)

Expected 104 CRC cases
Per 16,000 patients
- **32% colonoscopy**
- **14% Occult fecal Hb and FIT**
- **1.2% Flexible sigmoidoscopy**
- **? Double contrast X-ray**
- **? CT Colonography**

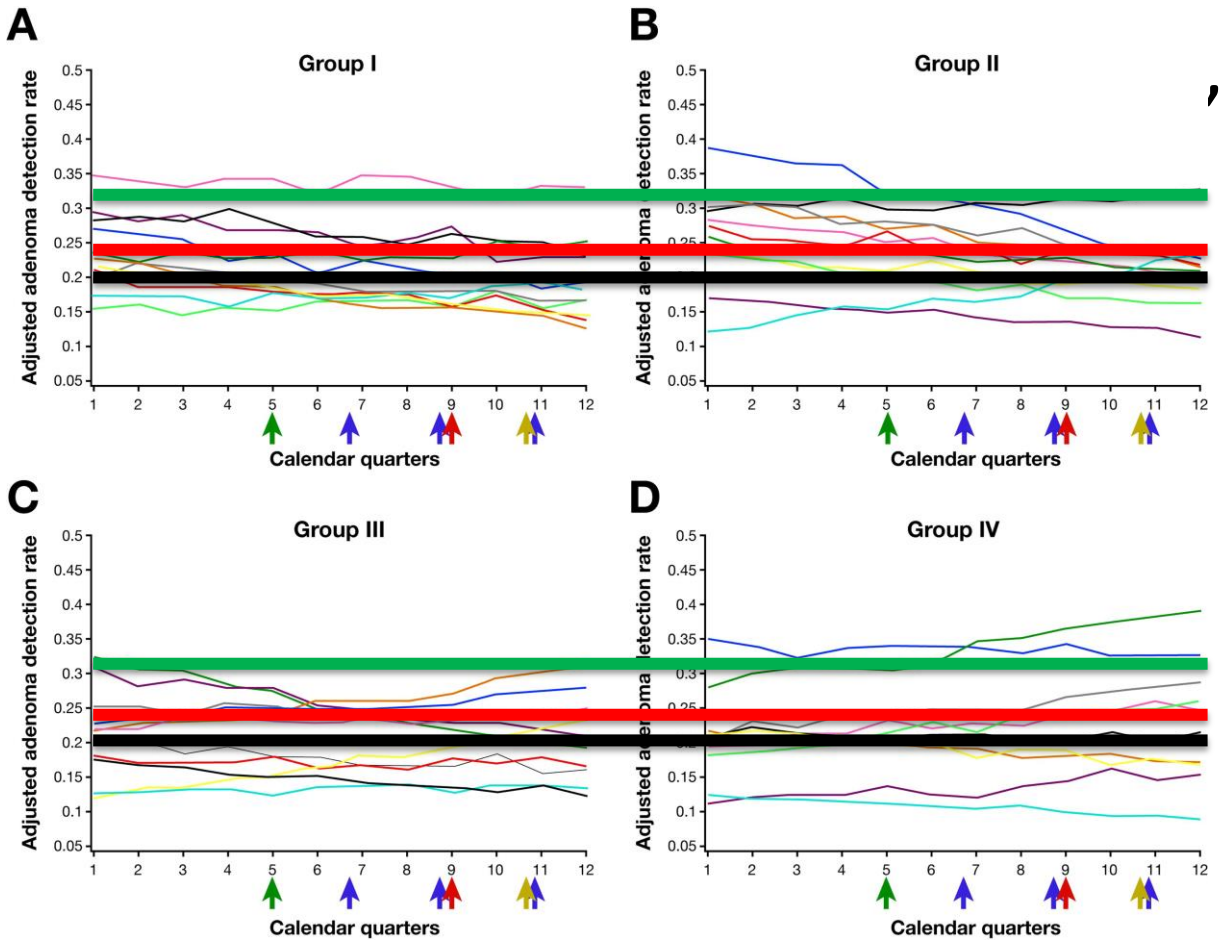
CRC Standardized Mortality Ratio



CRC Standardized Mortality Ratio



ADR and Endoscopist Performance by Procedure Volume



, P.A. (MNGI)

SC Endoscopists who followed protocol

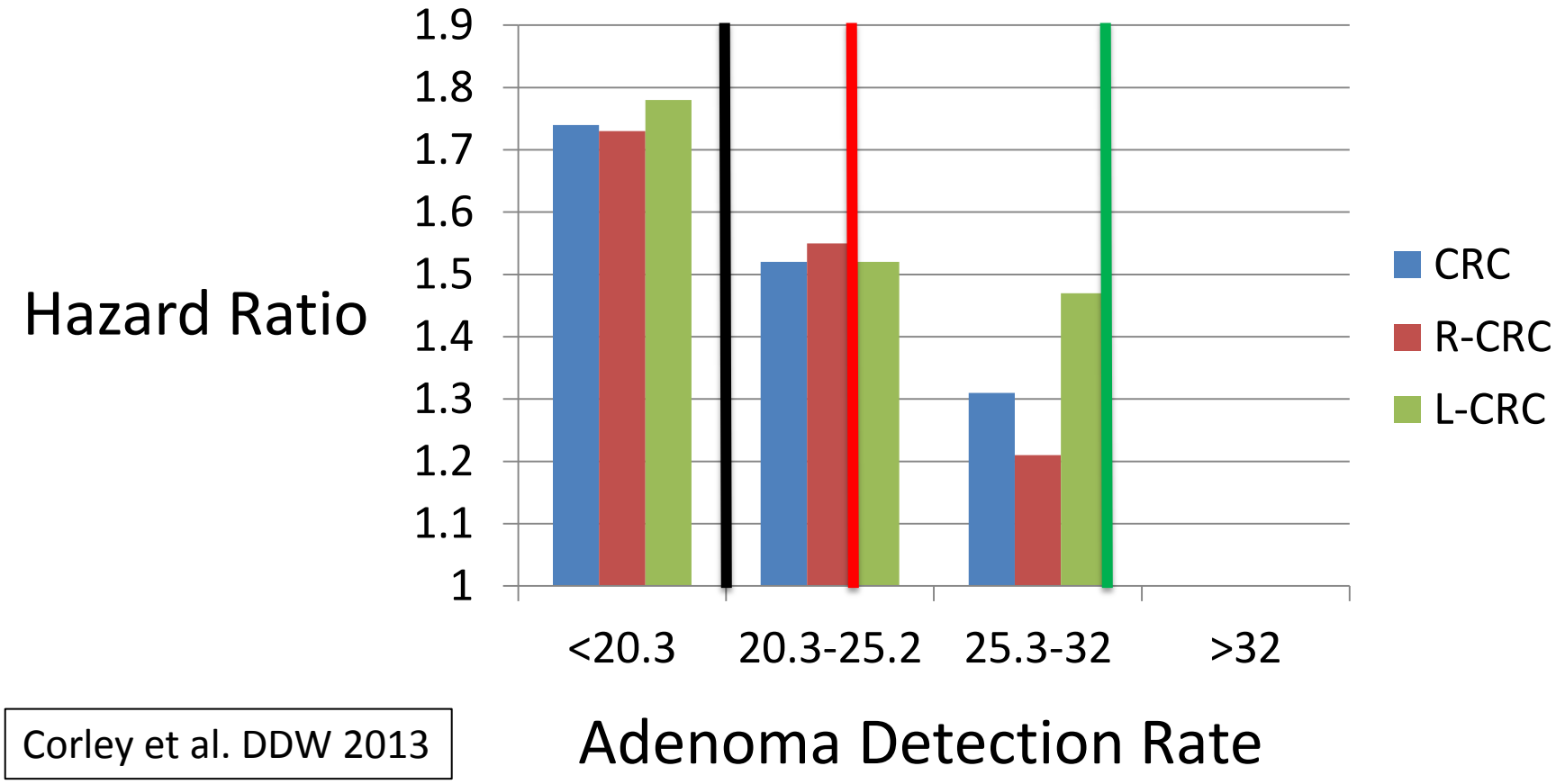
SC Endoscopists who did not follow protocol

ACG/ASGE guideline (20% ADR)

Shaukat et al. CGH 2009

ADR and Hazard Ratio for Interval CRC

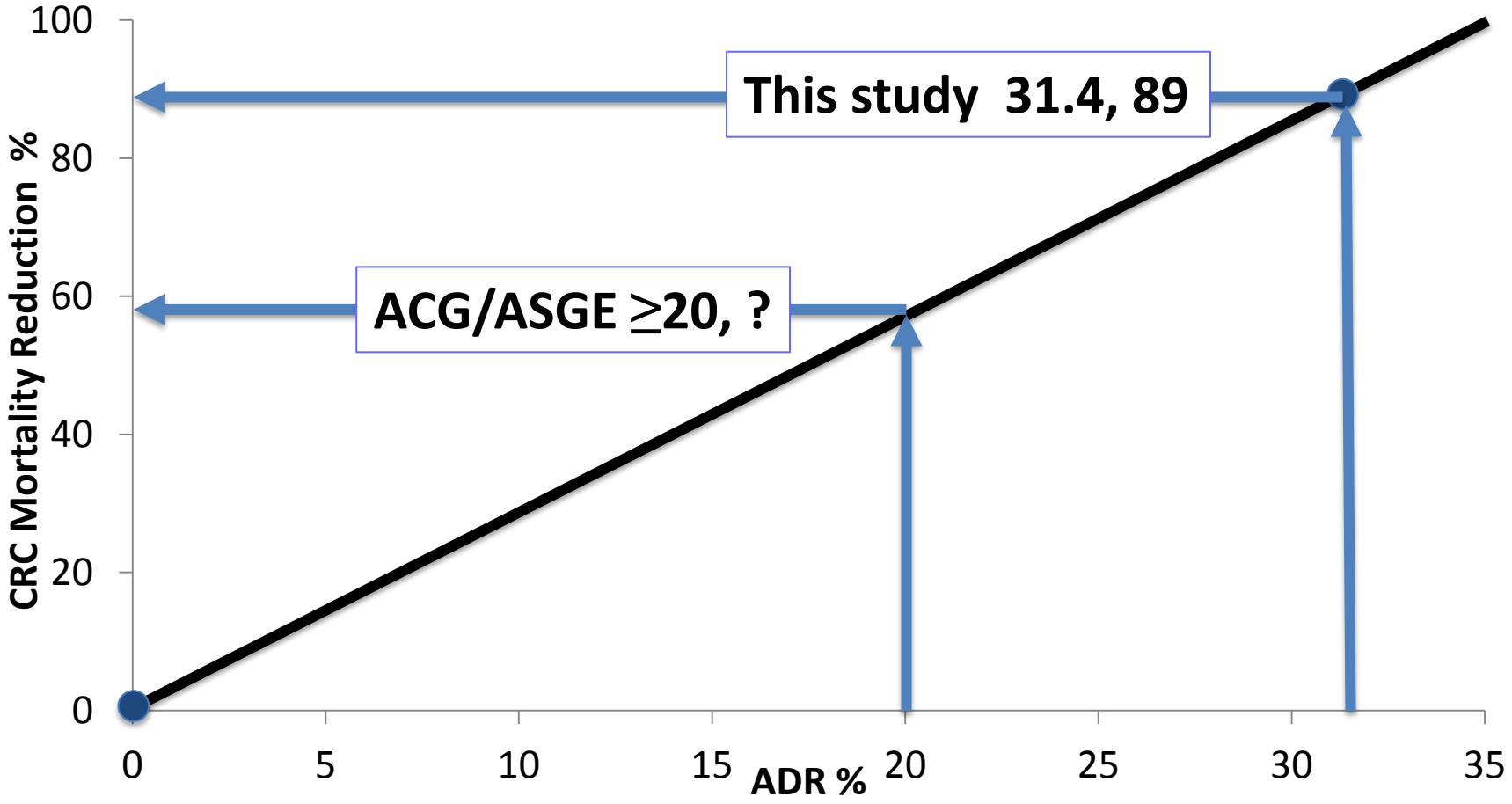
1998-2010 – Kaiser Permanente Northern California



Corley et al. DDW 2013

CRC Mortality Reduction vs. ADR

Corley et al: Linear Relation ADR and Interval CRC



Conclusions

- First ever to reproduce the National Polyp Study clinical trial results in community practice
- Reverses the recent world-wide skepticism about effectiveness of colonoscopy
- CRC is highly preventable among average risk individuals by well-performed colonoscopies
- Compared to population cancer rates. this series shows incidence reduction of 83% and mortality reduction of 89%

Summary of our research

- **Validates the following**:
- Full CRC protection for the population is achievable by:
  - Innovative clinical protocols focused on quality
  - Expanding endoscopy capacity using PCPs
- CRC protection potential is over 80% for incidence cases and nearly 90% for mortality

- “NO BEHIND SHOULD BE LEFT BEHIND “

Next steps and future research

- Studies of effectiveness of individual elements of SCMEC protocol
- Cancer downstaging and death reduction
- Evaluation of colonoscopy surface coverage – collaboration using software developed by a Mayo clinic gastroenterologist
- Scale up of the entire protocol – prospective study to evaluate time efficiency of specialist, optimum number of PCPs to be supported, cost of PCP vs specialist colonoscopies
- Setting up an integrated electronic medical record, research and administrative claims data system as part of scale up
- Studies of demand side – barriers and facilitators for colonoscopy screening – in collaboration with PCPs to be newly trained

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Q & A