Colorectal Cancer Screening: What are the best options for Indian Country?

2011 IHS Medical Providers' Best Practices and GPRA Measures Conference

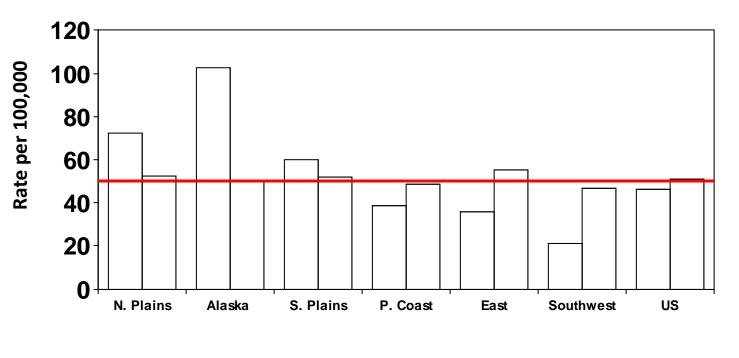
May 24<sup>th</sup>, 2011

#### **Presentation Outline**

- Epidemiology of CRC in US, by race/ethnicity
- Rationale for screening
- Screening rates among AI/AN
- Screening options
- Efforts to increase screening among AI/AN

# Colorectal cancer incidence rates, AI/AN and NHW, both sexes, 1999-2004

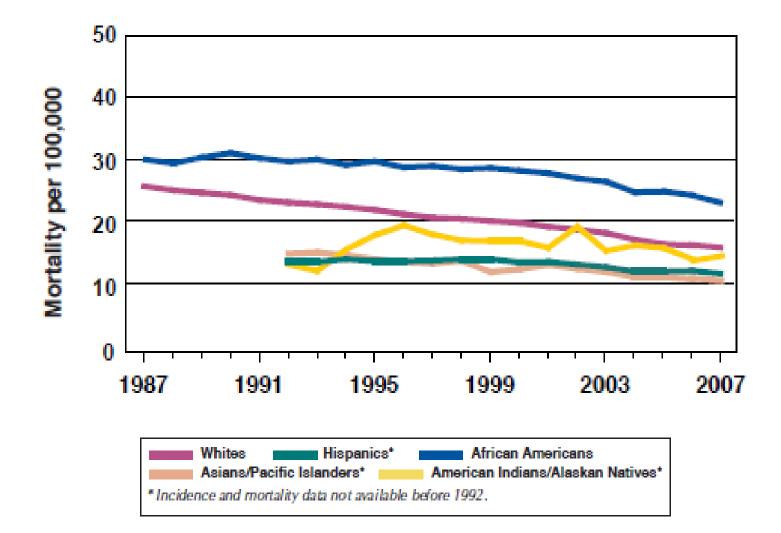
□ AI/AN □ NHW



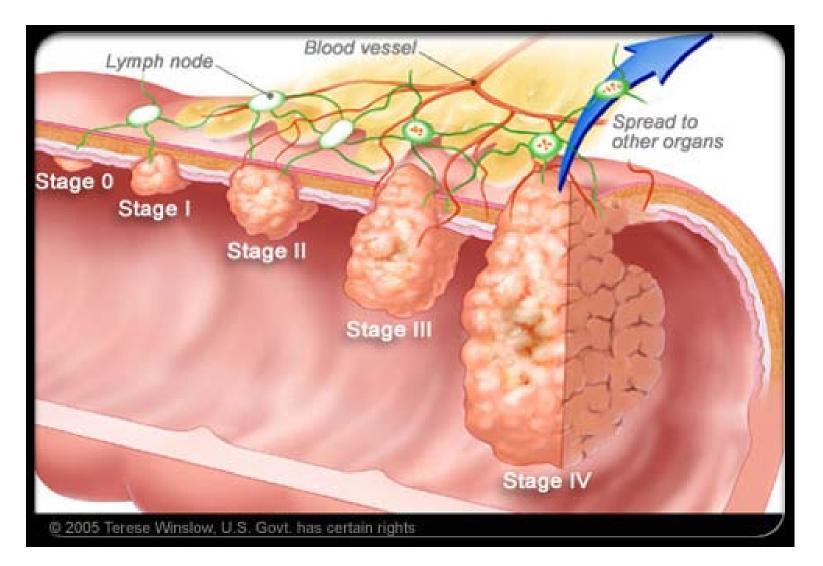
Region

Perdue D, et al. Cancer. Sep 1 2008;113(5 Suppl):1179-1190.

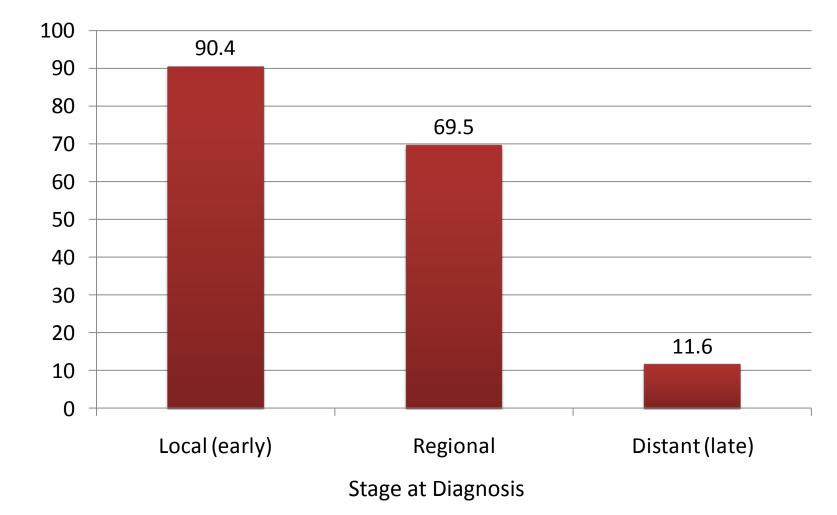
#### **Colorectal Cancer Mortality in USA**



### Staging of Colorectal Cancer



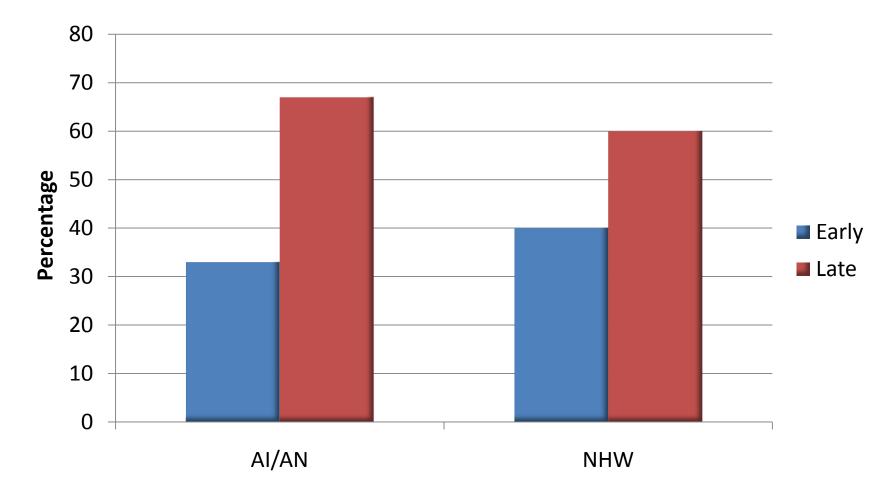
# Five-year CRC-specific Survival by Stage at Diagnosis, All Races, 1999-2006



Altekruse S et al. SEER Cancer Statistics Review, 1975-2007, National Cancer Institute. Bethesda, MD

Survival Rate (%)

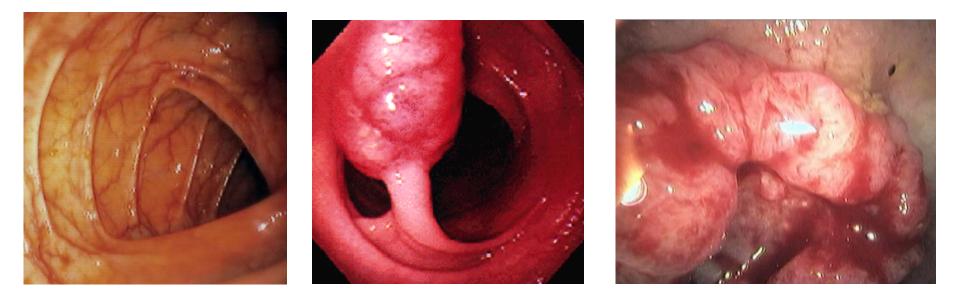
#### CRC Stage at Diagnosis\* AI/AN and Non-Hispanic white, 1999-2003



\*Early stage includes local disease; late stage includes regional and distant stage disease

Perdue D, et al. Cancer. Sep 1 2008;113(5 Suppl):1179-1190.

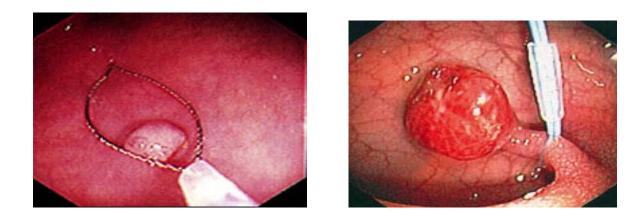
#### **Colorectal Cancer**



Normal Colon Polyp Colon Cancer

Adenoma-carcinoma sequence responsible for 95% of colorectal cancer

National Polyp Study suggested colonoscopy with polypectomy can decrease the lifetime risk of colon cancer by 76-90%



Winawer SJ et al., *N Engl J Med* 1993;329:1977-81.

#### CRC Screening = Early Detection & Prevention

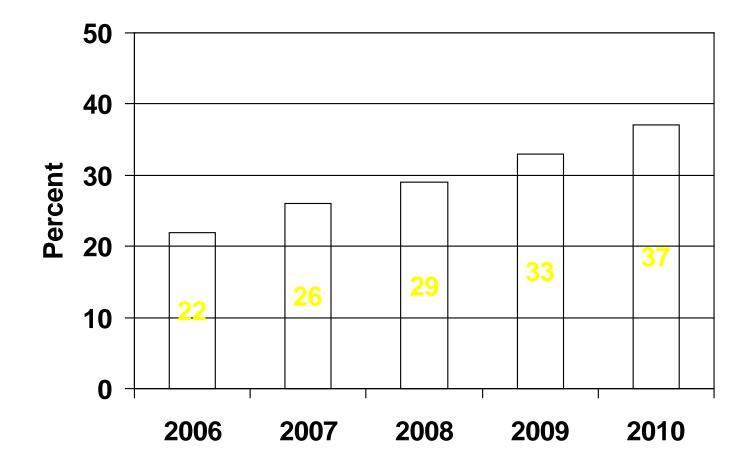
#### **Early Detection**



#### Prevention = polyp removal

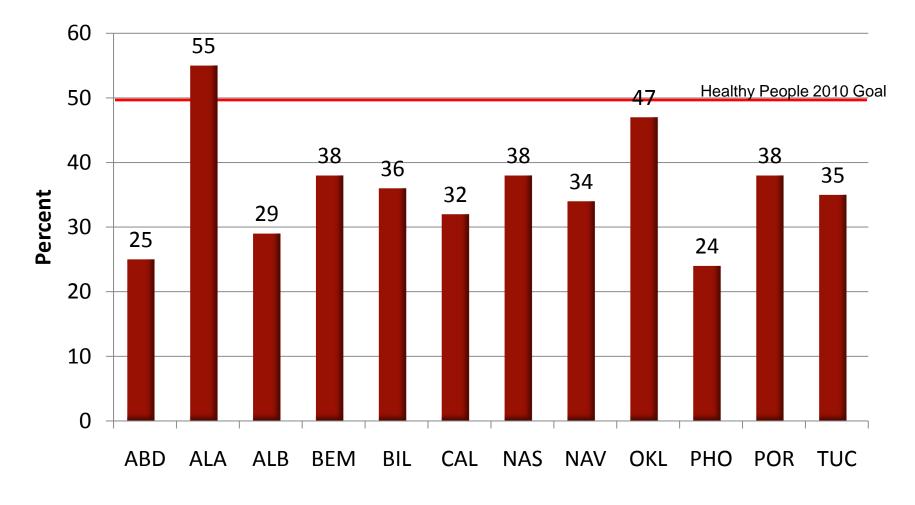
Decreased Incidence

# Colorectal cancer screening among IHS user population, ages 51-80 (GPRA Results)



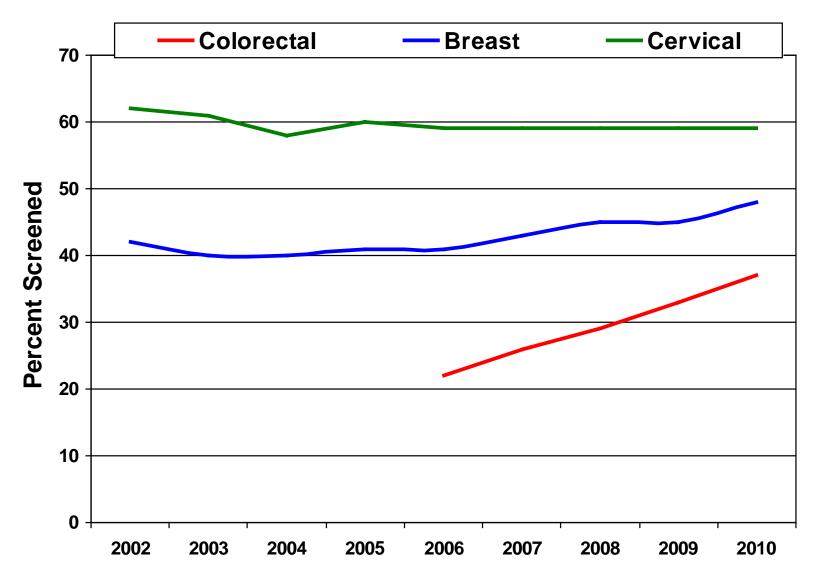
(Healthy People 2020 Goal is 70.5%)

#### Colorectal Cancer Screening: GPRA 2010 results, by IHS Area



(Healthy People 2020 Goal is 70.5%)

#### Cancer screening among IHS user population



Data source: GPRA 2010 CRS Results, GPRA Coordinators Conference November, 2010

## Who should be screened for CRC?

• USPSTF guidelines for average-risk persons:

– Ages 50-75 - Routine screening is recommended

Ages 76-85 - Routine screening not recommended

– Older than 85 - Screening not recommended

#### USPSTF screening test recommendations

 High sensitivity gFOBT\* and iFOBT\* —Every year



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-Every 5 yr (with FOBT every 3 yr)

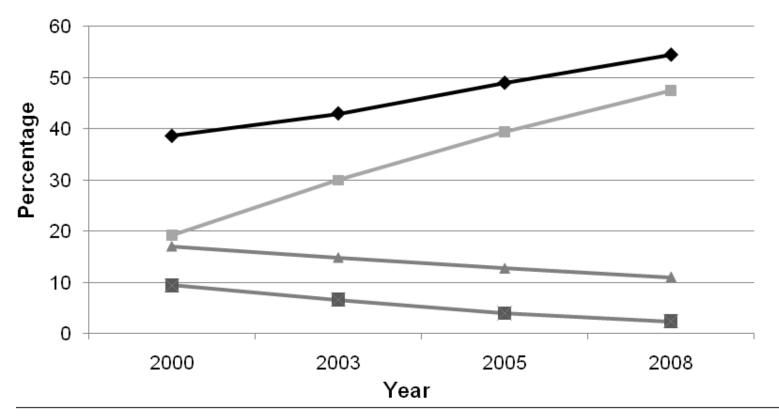
Colonoscopy

-Every 10 years

Flexible sigmoidoscopy\*

\* Positive findings require follow-up with colonoscopy

#### Colorectal cancer screening modality trends in adults ages 50-75, United States, 2000–2008

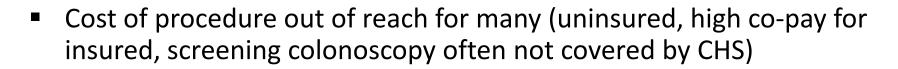


Any exam (FOBT in past year, sigmoidoscopy in past 5 years, or colonoscopy in past 10 years)

- ——Colonoscopy in past 10 years
- Home FOBT in past year
- Sigmoidoscopy in past 5 years

Is colonoscopy the best screening option for Indian Country?

Limited capacity



- Patient acceptance
  - Invasiveness of procedure
  - Inconvenience (bowel prep, person to transport)
  - Potential risks from procedure





#### **Don't forget about:**

## Flexible Sigmoidoscopy

Efficacy of a once-only flexible sigmoidoscopy (UK study)

After 11 years of follow-up, in people who had the screening:

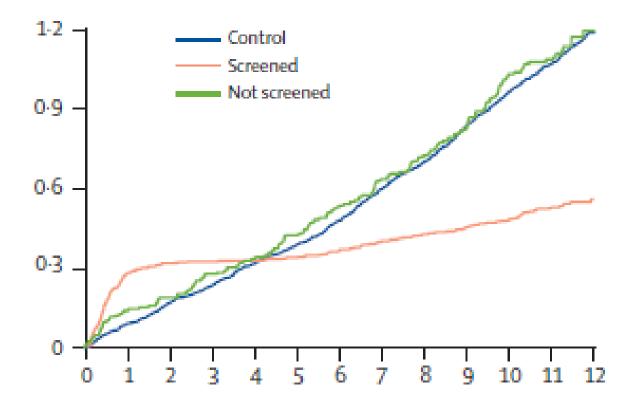
- Cumulative CRC incidence was reduced by:
  - 50% for distal cancers (rectum and sigmoid colon)
  - 33% for colorectal cancer overall
- CRC mortality was reduced by:

#### ▶ 43%

No signs of a waning of effect at longer follow-up times

Atkin et al. Lancet. 2010; 375: 1624-33

# UK flexible sigmoidoscopy study: Cumulative incidence distal cancer (%)



Time from randomization (years)

PLCO Cancer Screening trial: Results from baseline Flexible Sigmoidoscopy exams

- 83.5% accepted initial FS exam
- 23.4% of these had at least one polyp or mass
  - 74% received follow-up colonoscopy
- CRC or any adenoma detection per 1,000 screened subjects
  - ≻ 51-80 in women
  - ➤ 102-129 in men
- About 77% (130/169) of CRC cases associated with positive FS exam were early-stage at diagnosis

Weissfeld et al. J Natl Cancer Inst. Jul 6 2005;97(13):989-997.





Don't forget about:

#### Fecal Occult Blood Tests (FOBT)

## Cochrane Systematic Review of FOBT Randomized Controlled Trials

Table 2.	Number of CRC Deaths	, Mortality Incidence R	atio, and Mortality	Reduction for the Included Trials
		/ /	/	

	No. of CRC Deaths		Incidence Ratio		Mortality
Study	Screening Group	Control Group	Screening Group (py)	Control Group (py)	Reduction (%)
Funen	363/30,967	431/30,966	0.84/1,000	1.00/1,000	16
Goteborg	252/34,144	300/34,146	NR	NR	16
Minnesota (A)	121/15,570	177/15,394	0.67/1,000	1.00/1,000	33
Minnesota (B)	148/15,587	(as above)	0.79/1,000	(as above)	21
Nottingham	593/76,466	684/76,384	0.70/1,000	0.81/1,000	13

A = annual screening; B = biennial screening: NR = not reported; py = person years.

#### Types of FOBT

#### × Flushable Reagent tests (not recommended)

#### Guaiac-based FOBT (gFOBT)

Immunochemical FOBT (iFOBT)
Also called Fecal Immunochemical Test (FIT)

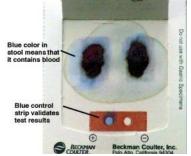
# **Guaiac-based FOBT**

- Most commonly used type of FOBT
- Detects the peroxidase-like activity of heme in hemoglobin
- Requires 2 samples from 3 consecutive bowel movements using at-home test
- Medicare reimbursement rate currently = \$4.75
- Test cost (\$2-3 US)



# **Guaiac-based FOBT: Issues**

Dietary and medication restrictions required
– False-positives (*H.pylori*, non-human blood)



- Patient acceptance influenced by method of specimen collection
- Accurate interpretation of results for gFOBT requires training and supervision
- Test is not amenable to automated development and interpretation
- Many providers still conducting in-office, single sample test following a digital rectal exam

## Guaiac-based FOBT examples

- Hemoccult (Smith Kline and French Laboratories) 1970
- Hemoccult II (SmithKline Diagnostics)
- Hemoccult SENSA (SmithKline Diagnostics) 1988
- Hemoccult II SENSA elite (Beckman Coulter Primary Care Diagnostics) 2003
- Seracult and Seracult Plus (Hardy Diagnostics)
- Coloscreen (Helena Laboratories)

w high-sensitivity (recommended for CRC screening)

#### Immunochemical Fecal Occult Blood Test (iFOBT)

- Uses antibodies to detect the globin portion of human hemoglobin
- Globin does not survive passage through the upper gastrointestinal tract; therefore, iFOBTs are specific for occult bleeding from the large intestine.
- Equal or better in sensitivity and specificity than gFOBT
- Medicare coverage began in January, 2004
- Current Medicare reimbursement rate = \$23.00
- Test cost (\$16-20)

#### FDA approved iFOBT

- Hemoccult<sup>®</sup> ICT (Beckman Coulter) 2005
- ✓ InSure™ (Enterix, Inc.) 2001
- ImmoCARE<sup>®</sup> (Care Products, Inc.)
- Instant-View<sup>®</sup> (Alpha Scientific Designs, Inc.) 2002
- iScreen (Instant Technologies)
- MonoHaem<sup>®</sup> (Chemicon International, Inc.)
- OC-FIT-CHEK<sup>®</sup> (Polymedco) 2005

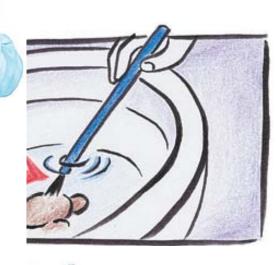
✓ Has been used in large, average-risk populations with result published in peer reviewed journals

## Example: Hemoccult ICT



- Stool sampling similar to gFOBT (stick and smear)
- •Three stools needed
- •No dietary restrictions!
- •No medication restrictions!

# Example: InSure





- No fecal handling
- Patient brushes surface of stool sample in the toilet with brush, then dabs on test card
- Laboratory services contracted with Quest Diagnostics
- Only <u>two samples</u> required

# Example: OC-Auto FIT-CHEK

- Completely closed sampling device
- Automated fecal occult blood analyzer
- Requires only <u>one</u> <u>sample</u> from a single stool specimen



# iFOBT advantages over gFOBT

- Greater sensitivity for CRC (requiring fewer samples)
- No dietary or medication restrictions
- Specific for human blood in large intestine
- Can be developed and interpreted by automation
- Specimen collection often allows for less stool handling
- Quantifiable so that sensitivity, specificity, and positivity rates can be adjusted for different screening populations

#### WHAT IS CURRENTLY BEING DONE TO IMPROVE CRC SCREENING IN INDIAN COUNTRY?

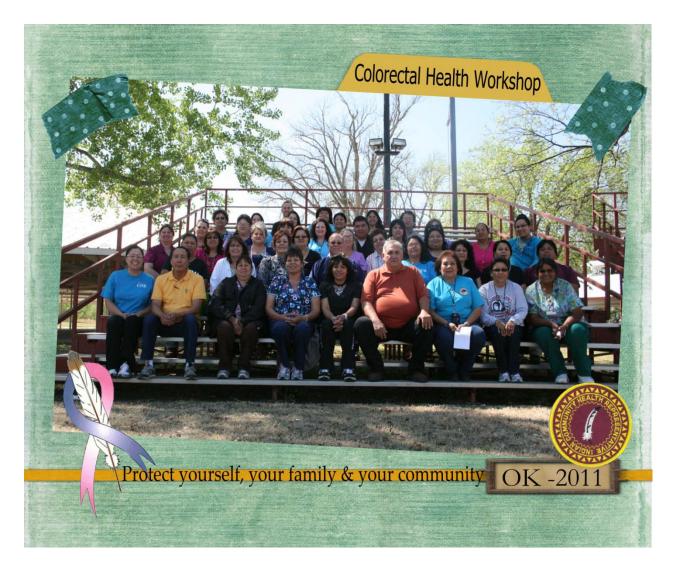
IHS Colorectal Cancer Screening Task Force Strategic Planning Areas of Focus

- 1. Healthcare professional education and practice
- 2. Public education and awareness
- 3. Health policy
- 4. Screening capacity

# 1. Healthcare professional education and practice

- Tribal Colorectal Health Education and Navigation Project (Albuquerque Area)
- Assessment of health facility ability to deliver CRC screening services (includes provider education component): American Indian Cancer Foundation (AICAF)
- Improving Patient Care (IPC) sites
- CRC focused CD-ROM (Alaska)
- CRC screening distance learning workshops (Alaska)

# Tribal Colorectal Health Education and Navigation Project, Regional workshop



#### 2. Public education and awareness

- Patient navigator for CRC screening (Alaska)
- CRC "Readers' Theatre" scripts (Alaska)
- First-degree relative database (Alaska)
- CHRs have developed AI-specific PSAs to raise CRC awareness

#### 3. Health policy

- Patient education codes added in 2011 (MH-CRC and WH-CRC) <u>http://www.ihs.gov/HealthEd/index.cfm?module=pepc</u>
- Report on tracking and reminder systems at I/T/U facilities (Alaska)
- CRC summits in IHS Areas with highest incidence and mortality (Aberdeen, Billings).
  - Next meeting: Portland Area, October 2011

- 4. Screening capacity
  - Itinerant endoscopy (Alaska)
  - Fecal immunochemical test (FIT) study (Alaska)
  - Survey endoscopic capacity of I/T/U facilities (AICAF)
  - Assess IHS, Tribal, and Urban (I/T/U) health facility ability to deliver CRC screening services (AICAF)

Continuing the CRC screening dialogue

- Subscribe to the IHS CRC listserv at: <u>http://www.ihs.gov/listserver/index.cfm?module=</u> <u>signUpForm&list\_id=138</u>
- Contact Donald Haverkamp (IHS Division of Epidemiology and Disease Prevention) at: <u>donald.haverkamp@ihs.gov</u>

# Thank you!