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

2011 IHS Medical Providers' Best Practices and GPRA Measures Conference

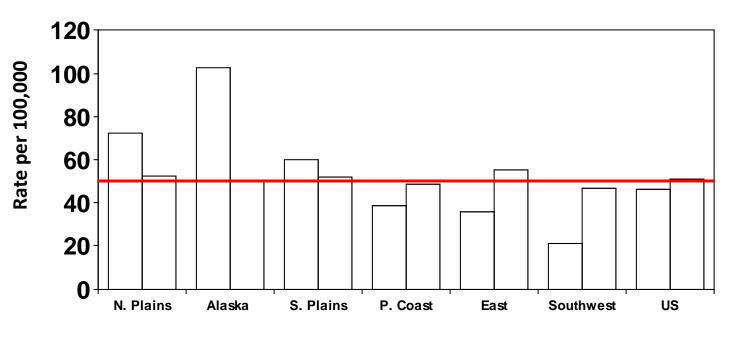
May 24th, 2011

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

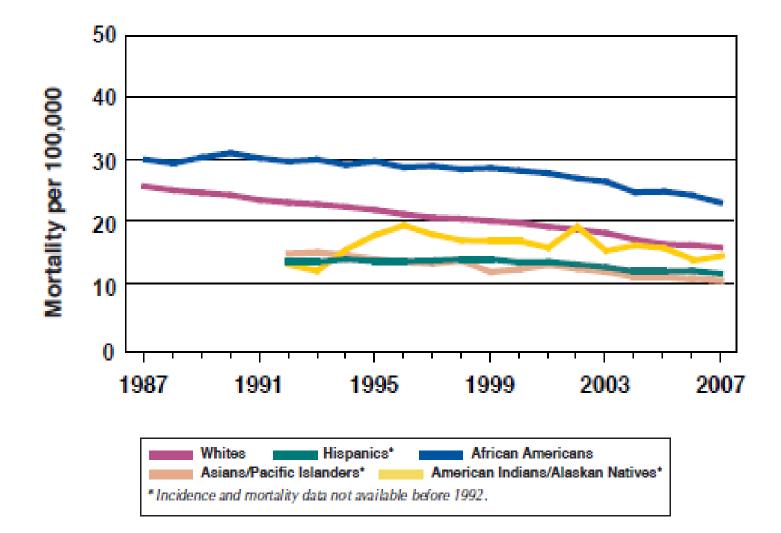
□ AI/AN □ NHW



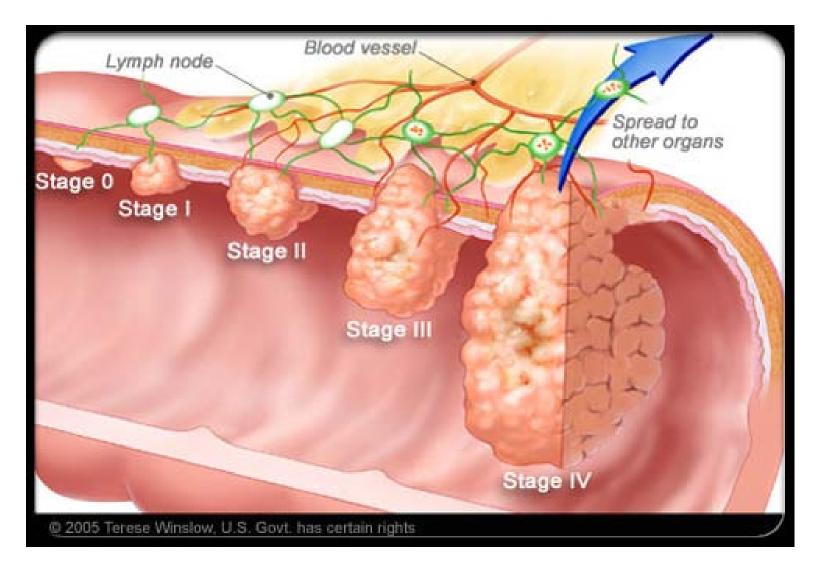
Region

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

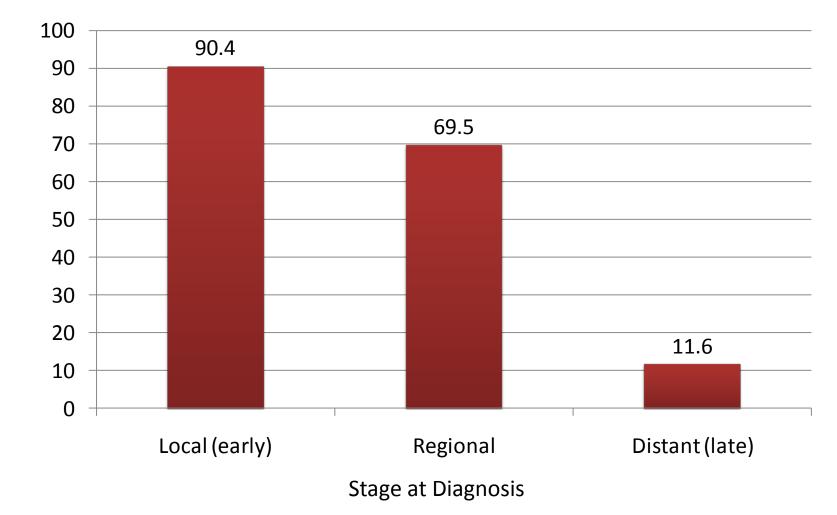
Colorectal Cancer Mortality in USA



Staging of Colorectal Cancer



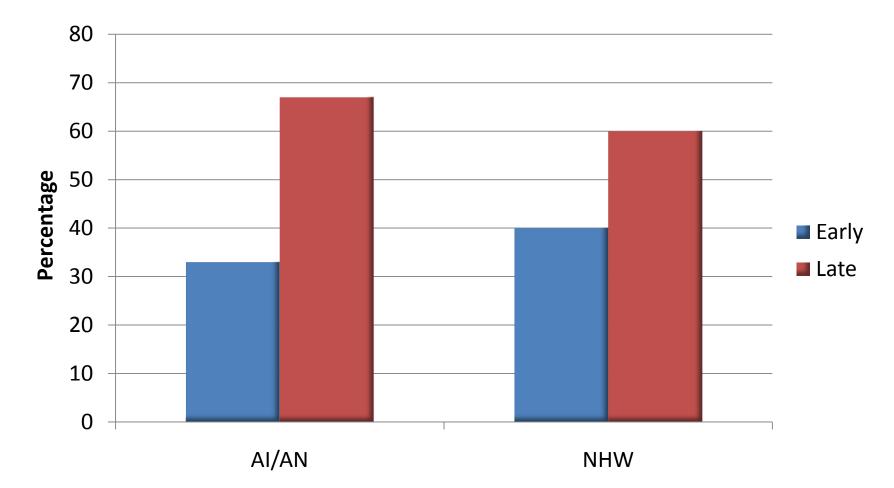
Five-year CRC-specific Survival by Stage at Diagnosis, All Races, 1999-2006



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

Survival Rate (%)

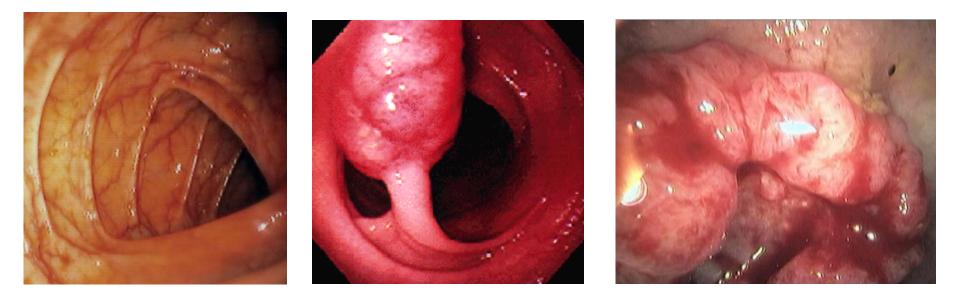
CRC Stage at Diagnosis* AI/AN and Non-Hispanic white, 1999-2003



*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.

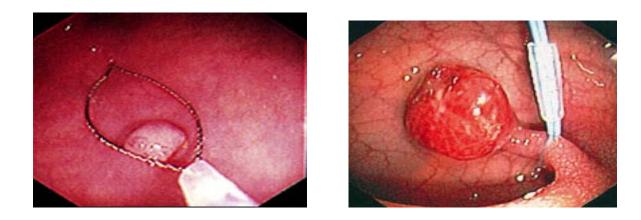
Colorectal Cancer



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

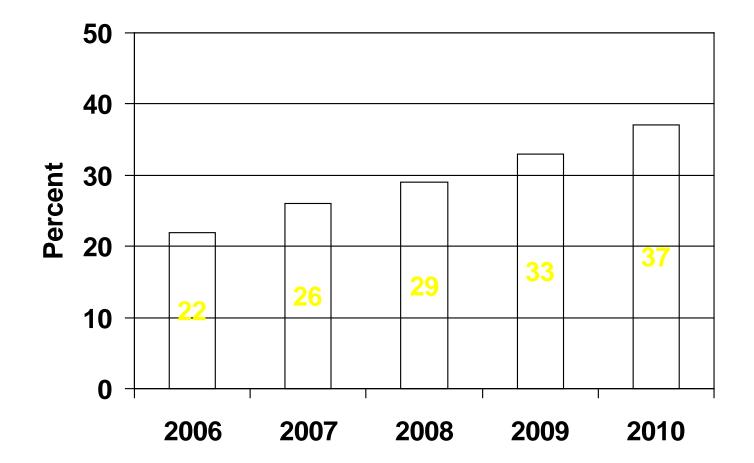
Early Detection



Prevention = polyp removal

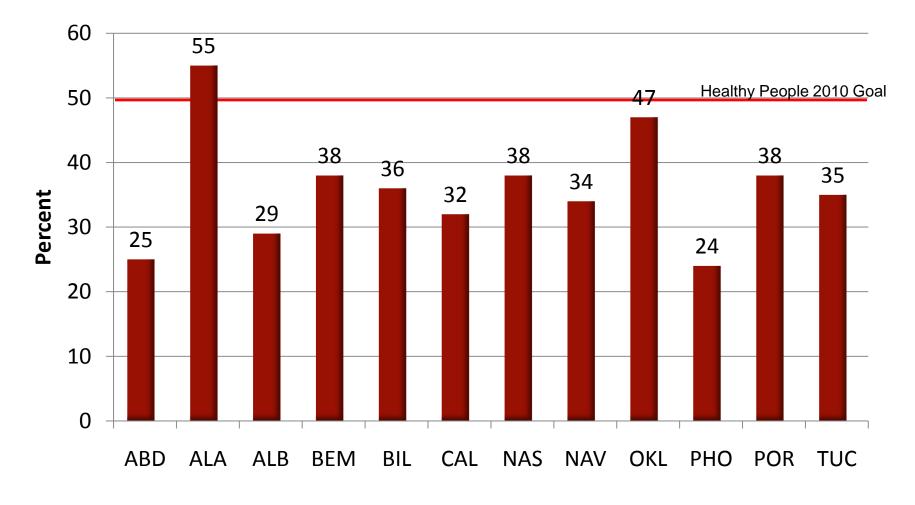
Decreased Incidence

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



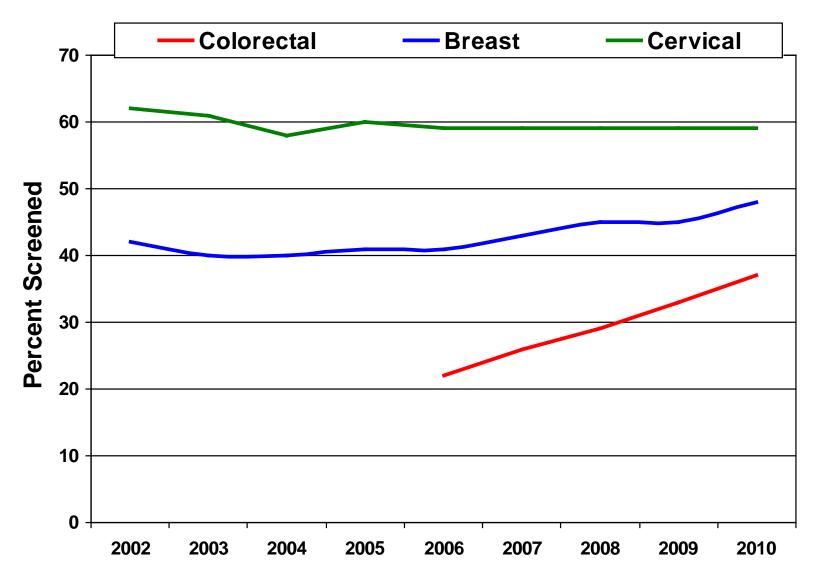
(Healthy People 2020 Goal is 70.5%)

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)

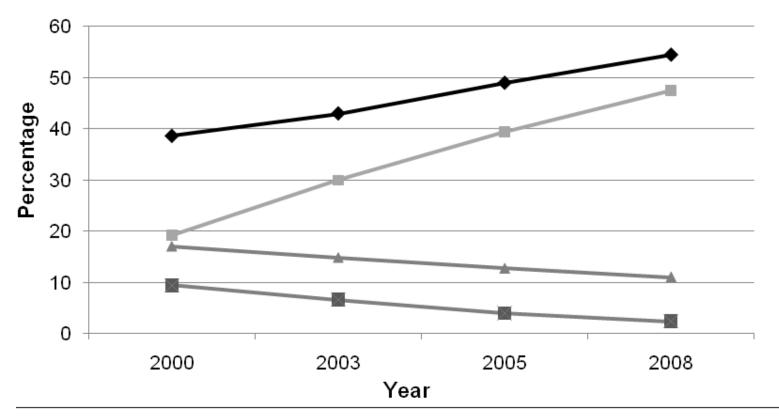
Colonoscopy

-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

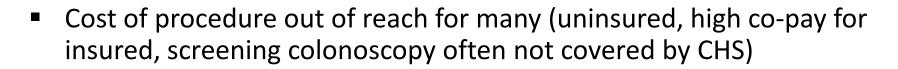


Any exam (FOBT in past year, sigmoidoscopy in past 5 years, or colonoscopy in past 10 years)

- ——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:

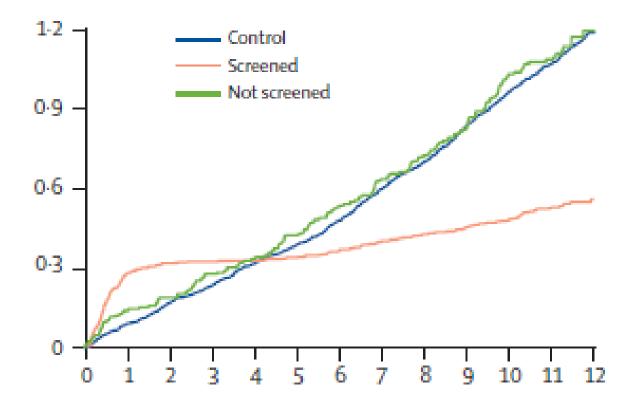
- Cumulative CRC incidence was reduced by:
 - 50% for distal cancers (rectum and sigmoid colon)
 - 33% for colorectal cancer overall
- CRC mortality was reduced by:

▶ 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)

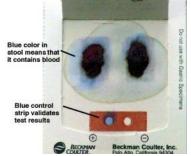
Guaiac-based FOBT

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

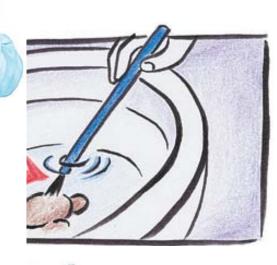
✓ Has been used in large, average-risk populations with result published in peer reviewed journals

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?

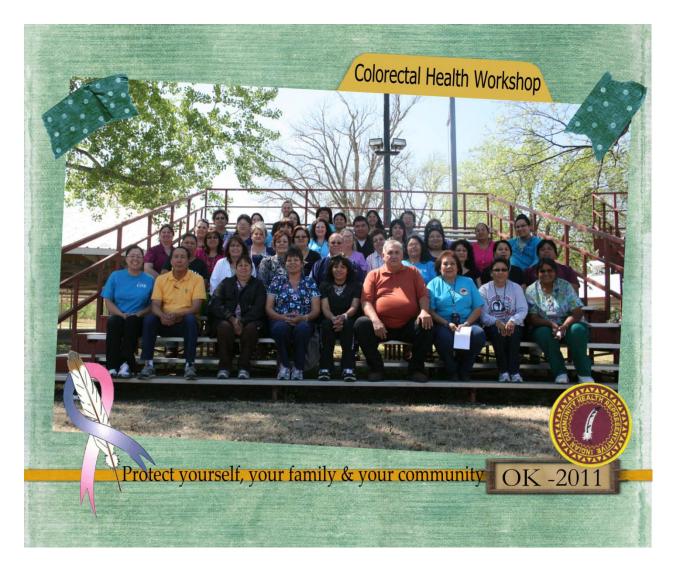
IHS Colorectal Cancer Screening Task Force Strategic Planning Areas of Focus

- 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!