American Cancer Society | NATIONAL COLORECTAL CANCER ROUNDTABLE

Panel:
Current and Emerging Colorectal Cancer Test Technologies

2:25 PM – 3:15 PM

CELEBRATING 25 YEARS colorectal cancer alliance

NCCRT Annual Meeting

Current and Emerging Colorectal Cancer Test Technologies Panel

Michael Sapienza

Chief Executive Officer
Colorectal Cancer Alliance

Djenaba A. Joseph, MD, MPH
CAPT, U.S. Public Health Service

Chief, Program Services Branch
Division of Cancer Prevention and Control
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention

Richard Wender, MD

Professor and Chair Family Medicine and Community Health University of Pennsylvania

Agenda

- Provide Context for Today's Discussion
- Share a Practical Framework for Evaluating Colorectal Cancer Screening Options
- Discuss Integration of Screening Tests
- Q&A

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Context

Current Situation

- Screening modality innovation has accelerated
- Resulting in a complex and confusing landscape for both healthcare professionals and patients due to absence of robust discussion around the current and emerging tests
- Leading to difficulty in making informed decisions about screening options because of the lack of head-to-head clinical studies
- Highlighting barriers for adoption and equitable access to newly launched tests

CCA's Actions

- Synthesized comprehensive data on key CRC screening methods that are currently marketed along with those that are soon to be available
- Collaborated with Dr. Djenaba Joseph and Dr. Rich Wender to establish a framework that compares data on current and emerging screening tests
- Convened stakeholders at 2024 DDW to provide an opportunity where key stakeholders can discuss and evaluate various (expanded) data on current and emerging CRC detection tests

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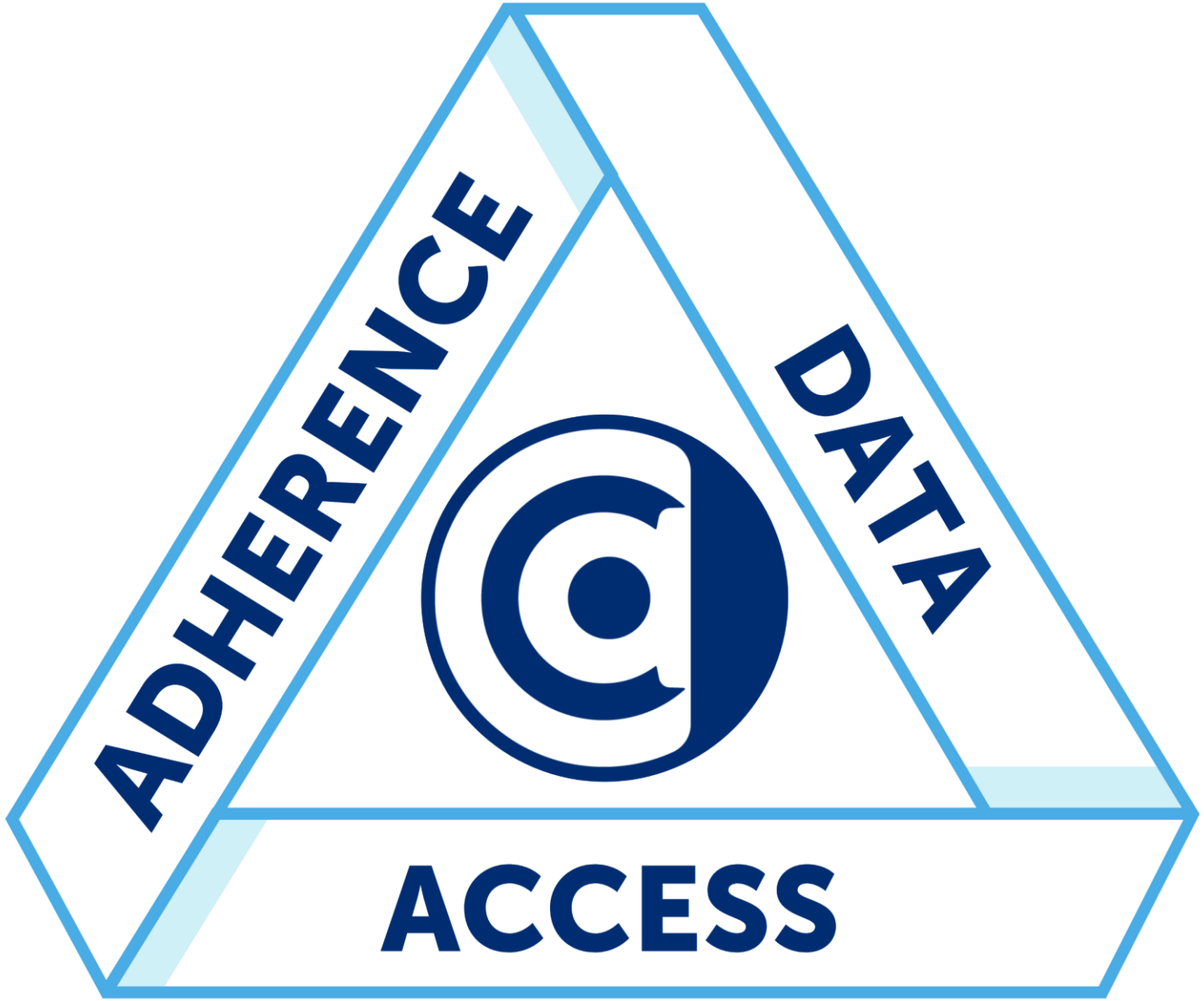

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Evaluating CRC Screening Options: A Practical Framework

Background assumptions

- Having a choice of tests is an asset that will increase screening rates.
- Every screening strategy relies on completion of colonoscopy to be effective.
- Every test has strengths and weaknesses.
- Consideration of cost is complicated.
  - Cost to whom?
  - Cost to individual vs. to the health care system as a whole.

Factors Influencing Choice of Test

- **Performance**
  - Sensitivity
  - Specificity
- **Test Characteristics**
  - Interval
  - Accessibility
  - Acceptability – patient, provider
  - Adherence – initial test, repeat testing, follow-up colonoscopy
- **Contextual Factors**
  - Stakeholder - Organization, provider, patient

Contextual Factors

- Stakeholder perspective
  - Patient
  - Provider
  - Healthcare systems
  - Organization
- Geography/climate
- Availability of primary care and specialty services
- Population specific (unhoused, migrant)

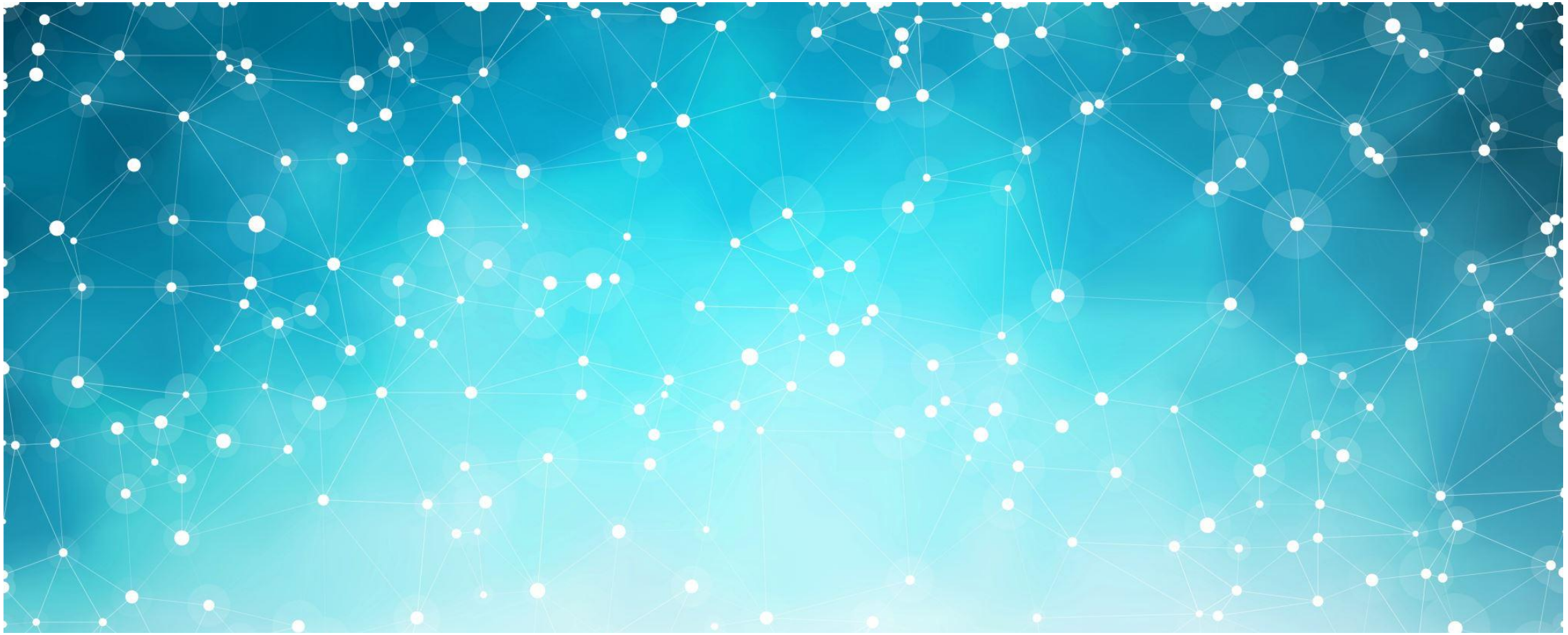
Acceptability - Patient

- All roads lead to colonoscopy
  - Prep and potential barriers to access.
- Stool tests
  - Sample vs whole stool. Clarity of instructions. Navigation available?
- Blood tests
  - Coverage and cost will be key to acceptability.
  - Transportation and time for testing will be barriers for some people.
- Patient preference

Acceptability – health care system & provider

- Provider perceptions of following characteristics:
  - Accuracy
  - Effectiveness
  - Availability
  - Acceptability to patients
  - Organizational burden, including test interval
  - Incentive to achieve high practice-wide screening rate

Overview of Tests



Sensitivity	Colonoscopy	FIT	Cologuard	Cologuard Plus	ColoSense	Shield	Freenome
Test Type	Visual (endoscopy)	Hemoglobin in stool	Mt-sDNA	Mt-sDNA	Mt-sRNA	Cell-free DNA blood test	Blood
CRC overall	95%	79%	92%	94%	94.%	83%	79.2%
Stage I	75-80%	75%	90%	87%	92%	65%(55% clinical)	57.1%
Stage II	85-90%	88%	100%	94%	92%	100%	100%
Stage III	85-90%	82%	90%	97%	100%	100%	82.4%
Stage IV	>95%	89%	75%	100%	No IV CRCs	100%	100%
APL/AA	90-95%	24% (APL)	42% (APL)	43% (APL)	43% (APL) 46% (AA)	13.2%	12.5% (AA)
High grade dysplasia	75-93%	-	69%	75%	65% (HGD or ≥10 adenomas)	_	29%
Sessile serrated	70-80%	5%	42%	46%	17% (hyperplastic and SS ≥10 mm combined)	_	_

APL = advanced precancerous lesion = Includes advanced adenomas (high-grade dysplasia or with ≥25% villous histologic features or measuring ≥1 cm in the greatest dimension) and sessile serrated polyps measuring 1 cm or more in diameter
AA = Advanced Adenoma

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Specificity	All	Negative Colonoscopy
Colonoscopy	90%	–
FIT	93%	–
Cologuard	87%	93%
Cologuard Plus	91%	93%
ColoSense	85.5%	87.9%
Shield	89.6% (advanced neoplasia)	–
Freenome	91.5% (non-advanced colorectal neoplasia)	–

References are included in the notes section.

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	Interval (years)	Adherence (%)
Colonoscopy	10	55-60%
FIT	1	35% (w/o intervention) 41.5% (w intervention) (real-world and study)
Cologuard	3 (1-3)	51% - 71% (real-world)
Cologuard Plus	3 (anticipated)	_
ColoSense	3 (anticipated)	80% (study)
Shield	1-3 (TBD)	96% (study)
Freenome	3	96% (study)

	Follow-up colonoscopy	Access	Cost
Colonoscopy	n/a	○ Medicare.gov	$2,750 (avg. cash price)
FIT	58% - 83%	Widely available/covered	$18 – $21
Cologuard	71.5% – 84.9% (real-world)	Widely available/covered	$508 (Medicare)
Cologuard Plus	_	Not currently available	_
ColoSense	80% 73% combined test and follow up (study)	Not currently available	Unknown
Shield	44% (study)	Not currently available	$895 (Cash)
Freenome	_	Not currently available	_

Thank You

Please find the presentation and references here: