ACS NCCRT Presents:

Blue Star Conversations

Leveraging the EHR for Cancer Prevention: A Look at How Yale New Haven Health System is Systematizing Risk Assessment and Risk Stratification to Identify Candidates for Genetic Testing

May 29, 2024
12:00–1:00pm ET

American Cancer Society

NATIONAL COLORECTAL CANCER ROUNDTABLE

Virtual Housekeeping

1. Please note the presentation is being recorded, but not the discussion groups.
2. Remember to mute yourself during the presentation
3. Plan to come on camera during the breakout sessions.
4. Let's get to know each other– put your name, what state you're from and which organization you represent in the chat. Add your organization after your name in Zoom by clicking the three dots to the top right of your video tile to help with breakouts.
5. Don't forget to complete our evaluation at the end of today's call!

Objectives for Today's Blue Star Conversations

- Introduce and engage with the ACS NCCRT Family History & Early Age Onset CRC Strategic Priority Team and other attendees through our interactive format
- Learn how Yale New Haven Health System is using the EHR to systematically identify and invite at risk patients to participate in genetic testing for Lynch Syndrome.
- In small and large groups, discuss potential opportunities and challenges to implementing a program like this.
- Share top takeaways.

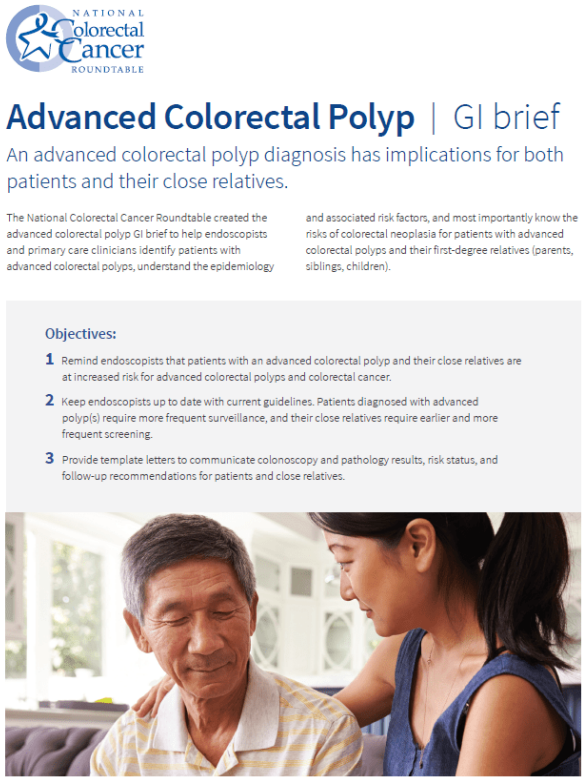
ACS NCCRT Family History & EAO-CRC Strategic Priority Team Chairs

Heather Hampel, MS, CGCC
Professor, Department of Medical Oncology & Therapeutics Research
Associate Director, Division of Clinical Cancer Genomics
City of Hope

Paul Schroy, MD, MPH
Emeritus Professor of Medicine
Boston University School of Medicine

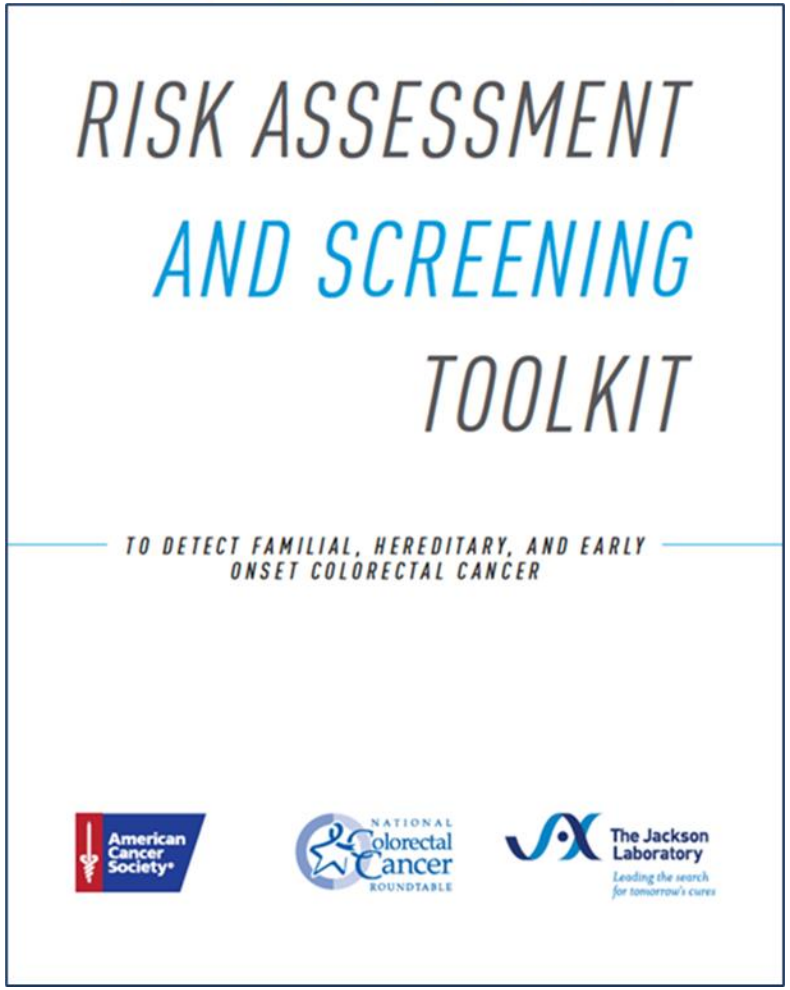
Family History & EAO-CRC Strategic Priority Team Overview

***Team Charge**: to identify key issues and areas of need around familial colorectal cancer and early onset colorectal cancer for the purpose of identifying opportunities for the NCCRT to be a catalyst for change.*



The ACS NCCRT Risk Assessment and Screening Toolkit

- Aims to improve the ability of primary care clinicians to systematically collect, document, and act on a family history of CRC and adenomas polyps.
- Educates clinicians on the need for timely diagnostic testing for young adults who present with symptoms of CRC.
- Features:
  - Quick Start Guide
  - Sample Risk Assessment Screening Algorithm



Today's Presenter:

Xavier Llor, MD, PhD
Professor of Medicine
Director, GI and Pancreatic Cancer Prevention Program, Digestive Diseases
Yale School of Medicine

LEVERAGING THE ELECTRONIC HEALTH RECORD FOR CANCER PREVENTION

Xavier Llor, MD, PhD

Professor of Medicine

Yale University

Yale SCHOOL OF MEDICINE

DISCLOSURE INFORMATION

No conflicts to disclose

No financial relationships with a commercial interest

HEREDITARY CANCER IN THE GENERAL POPULATION

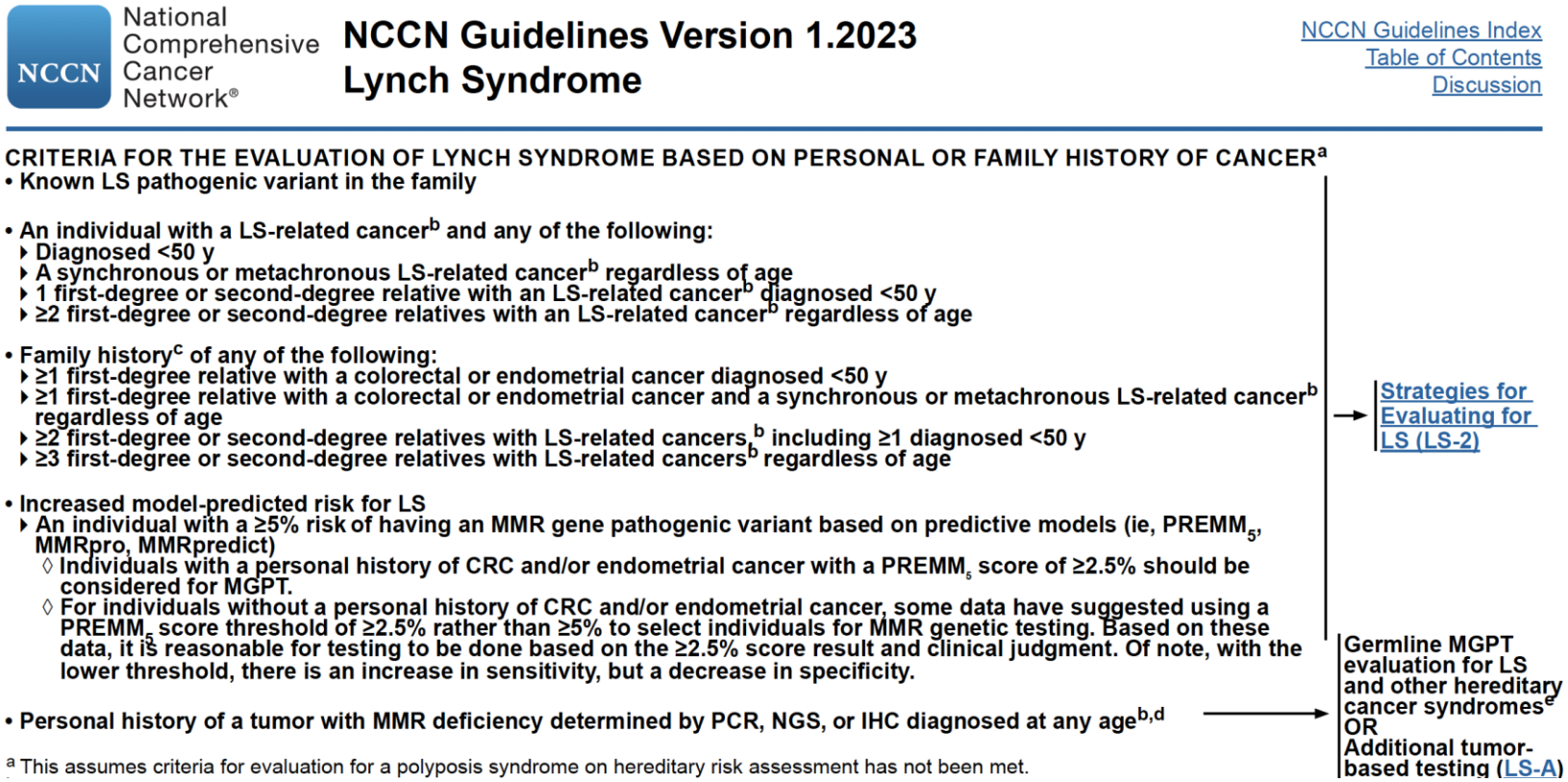
- > 3% of cancers are due to known pathogenic variants in cancer-predisposing genes[1]

- 0.6% of individuals (2M Americans) have a *BRCA1/2* mutation causing **Hereditary Breast and Ovarian Cancer syndrome-HBOC**)[2]: high risk of breast, ovarian, melanoma, prostate, pancreas

- 0.36% individuals (1M Americans) have an MMR (*MLH1*, *MSH2*, *MSH6*, *PMS2*, *EPCAM*) gene mutation causing **Lynch syndrome**[3]: colorectal, small bowel, gastric, biliary, pancreas, endometrial, ovarian, urothelial, brain, skin, adrenocortical

[1]Rahman N. Nature 2014 Vol. 505 Issue 7483 Pages 302-8
[2]Maxell KN *et al.* JCO. 34, No 34 (December 1), 2016: pp 4183-4185
[3]Win AK. *et al.* Cancer Epidemiol Biomarkers Prev. 2017 March ; 26(3): 404–412

GENETIC TESTING CRITERIA TO EVALUATE FOR LYNCH SYNDROME



National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2023
Lynch Syndrome

NCCN Guidelines Index
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Discussion

CRITERIA FOR THE EVALUATION OF LYNCH SYNDROME BASED ON PERSONAL OR FAMILY HISTORY OF CANCER[a]

- Known LS pathogenic variant in the family

- An individual with a LS-related cancer[b] and any of the following:
  - Diagnosed <50 y
  - A synchronous or metachronous LS-related cancer[b] regardless of age
  - 1 first-degree or second-degree relative with an LS-related cancer[b] diagnosed <50 y
  - ≥2 first-degree or second-degree relatives with an LS-related cancer[b] regardless of age

- Family history[c] of any of the following:
  - ≥1 first-degree relative with a colorectal or endometrial cancer diagnosed <50 y
  - ≥1 first-degree relative with a colorectal or endometrial cancer and a synchronous or metachronous LS-related cancer[b] regardless of age
  - ≥2 first-degree or second-degree relatives with LS-related cancers[b] including ≥1 diagnosed <50 y
  - ≥3 first-degree or second-degree relatives with LS-related cancers[b] regardless of age

- Increased model-predicted risk for LS
  - An individual with a ≥5% risk of having an MMR gene pathogenic variant based on predictive models (ie, $PREMM_5$, MMRpro, MMRpredict)
    - ◊ Individuals with a personal history of CRC and/or endometrial cancer with a $PREMM_5$ score of ≥2.5% should be considered for MGPT.
    - ◊ For individuals without a personal history of CRC and/or endometrial cancer, some data have suggested using a $PREMM_5$ score threshold of ≥2.5% rather than ≥5% to select individuals for MMR genetic testing. Based on these data, it is reasonable for testing to be done based on the ≥2.5% score result and clinical judgment. Of note, with the lower threshold, there is an increase in sensitivity, but a decrease in specificity.

- Personal history of a tumor with MMR deficiency determined by PCR, NGS, or IHC diagnosed at any age[b,d]

→ Strategies for Evaluating for LS (LS-2)

→ Germline MGPT evaluation for LS and other hereditary cancer syndromes[e]
OR
Additional tumor-based testing (LS-A)

[a] This assumes criteria for evaluation for a polyposis syndrome on hereditary risk assessment has not been met.

Criteria based on:

-Personal history of cancer/ family history of cancer

-Evidence of MMR deficiency in tumors

GENETIC TESTING CRITERIA: TUMOR TESTING

- Recommended universal tumor testing for MMR deficiency (MSI and/or IHC) at the time of cancer diagnosis of **all colorectal and endometrial cancers** (+ *BRAF* V600E mutation/ *MLH1* methylation analysis)

- Recommended considering tumor testing for MMR deficiency (MSI and/or IHC) for **all LS-related cancers**: **all GI adenocarcinomas**, bladder/urothelial, adrenocortical, brain (glioblastoma, astrocytoma), sebaceous neoplasms

IDENTIFYING INDIVIDUALS FOR LYNCH SYNDROME TESTING BASED ON MMR TUMOR TESTING

- Implementation <50% of CRC in North America[1]
- Even when implemented, only 29.5% of individuals with MMR-deficient tumors underwent genetic testing[2]

- [1] *Jain A, Shafer L, et al. Dig Dis Sci 2019;64:3489–501.* Survey practicing gastroenterologists through the CAG and the ACG
- [1] *Mittal C, et al. Dig Dis Sci 2020;65:3305–15.* Two large Veterans Affairs medical centers
- [1] *Shaikh T, et al. JAMA Oncol 2018;4:e173580.* National Cancer Database
- [1,2] *Muller C et al. Clin Gastroenterol Hepatol 2018;16:1911–8.* Four large academic centers

	Patients (1/2012-5/2015) with MMR deficient CRC: n=29
CG referral among requiring evaluation	8/29 (27.59%)
Seen by CG among referred	8/29 (27.59%)
LS diagnosis	2/8 (25.0%)

Singh, V. *et al*. J Med Genet. 2022 Sep 17

IDENTIFYING INDIVIDUALS FOR LYNCH SYNDROME TESTING BASED ON PERSONAL AND FAMILY HISTORY OF CANCER

Published in final edited form as:
Gastroenterology. 2020 March ; 158(4): 1159–1161. doi:10.1053/j.gastro.2019.11.297.

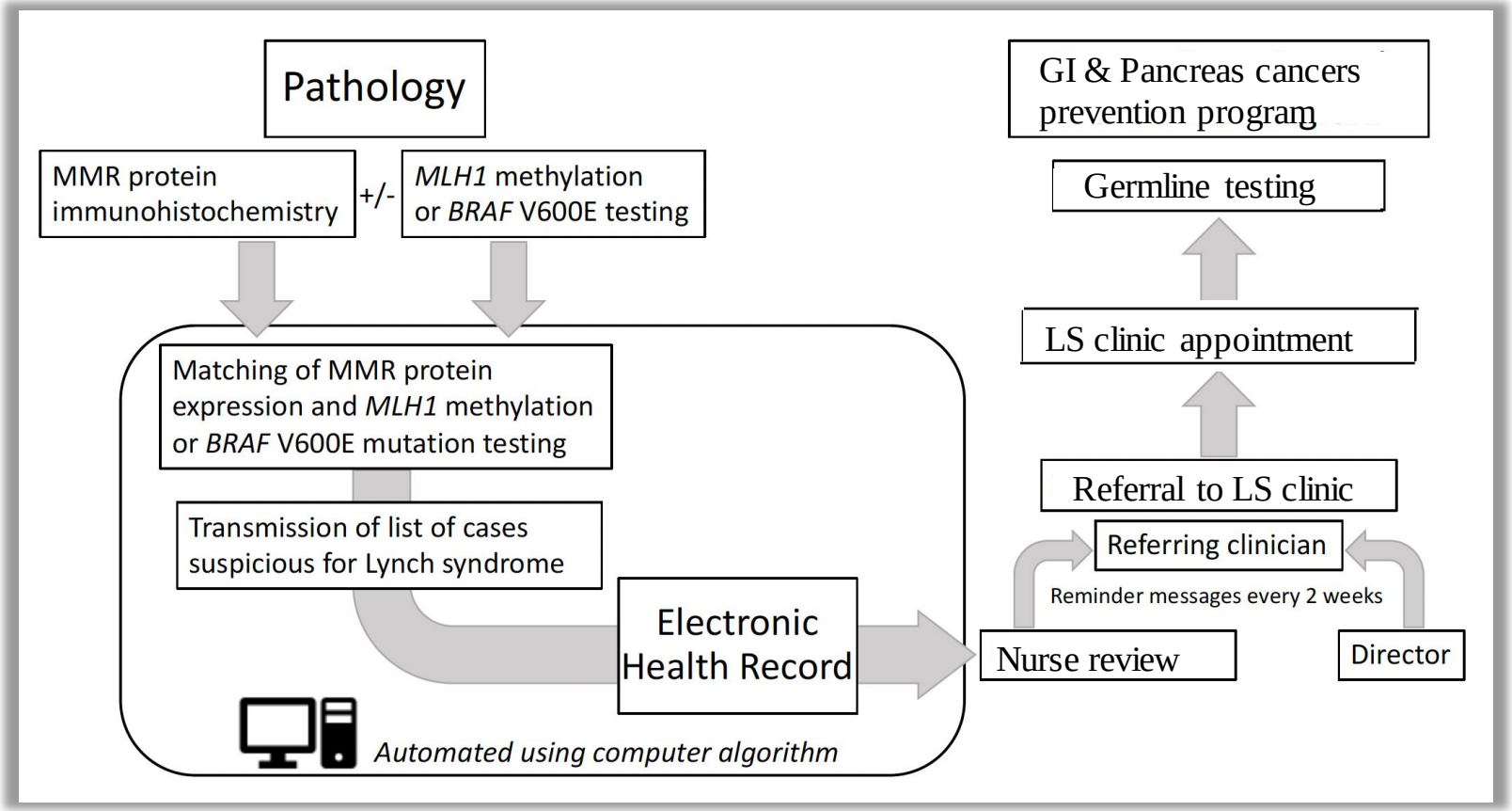
Low Rates of Genetic Counseling and Testing in Individuals at Risk for Lynch Syndrome reported in the National Health Interview Survey

Nolan Faust, M.D.[1,*], **Charles Muller, M.D.**[2,*], **Joshua Prenner, B.A.**[3], **Sang Mee Lee, Ph.D.**[4], **Sonia S. Kupfer, M.D.**[2]

- US National Health Interview Survey (NHIS): Only **8.4%** of patients who qualified for genetic testing to rule out Lynch syndrome were recommended testing and **6.7%** were finally tested

Lack of awareness of guidelines by clinicians, largely due to their complexity, prevents them from identifying eligible individuals (M. K. Frey, *et al*. Gynecol Oncol 2023 Vol. 173 Pages 22-30)

CLEAR LS INTERVENTION: CLOSED LOOP ENHANCED ASSESSMENT AND REFERRAL FOR LYNCH SYNDROME



- Automated search of tumors:
  - -MMR deficient: abnormal IHC
  - -Mutated at *BRAF V600 E*
  - -*MLH1* promoter methylation
- Patients with MMR tumor with wild type *BRAF* V600 E or unmethylated *MLH1* selected for automated message to LS clinic
- LS clinic reach out to surgeon for reminder of referral 2 weeks after Dx. Two attempts and third personal message by clinic director

Partnership with Yale Pathology/Lynch syndrome clinic GI & Pancreas Cancers Prevention Program (GIPCPP)

Singh, V. *et al.* J Med Genet. 2022 Sep 17. PMID: 36115663

CLEAR LS INTERVENTION: RESULTS

	Intervention cohort, N=76 (%)			Adjusted *p* value
	Referral prior to reach out (%)	Referral after reach out (%)	Total (%)	
CG referral among eligible	38/76 (50.00)	32/76 (42.10)	70/76 (92.11)	*<0.0001*
Seen by LS clinic among referred	32/38 (84.2)	20/32 (62.5)	52/70 (74.29)	*<0.0001*
LS diagnosis	9/32 (28.12)	4/20 (20.00)	13/52 (25.0)	*1.0000*

- The intervention resulted in:
  - -Referral rate of 92.11% (baseline 50%)
  - -Seen and tested among referred: 74.29%
  - -Increased LS diagnosis by 50%

Singh, V. *et al*. J Med Genet. 2022 Sep 17

CLEAR LS INTERVENTION: IMPACT ON DISPARITIES

Appropriate referral to Cancer Genetics placed				
Race/Ethnicity*	Number of patients (%)	Original cohort (%)	Intervention cohort (%)	Adjusted P-value
NHW	57/100 (57)	6/24 (25)	51/76 (67.1)	<0.001
Other	21/29 (72.4)	2/5 (40)	19/24 (79.2)	0.193
Adjusted P-value			0.376	
Patients seen by Cancer Genetics among the ones referred				
Race/Ethnicity*	Number of patients (%)	Original cohort (%)	Intervention cohort (%)	Adjusted P-value
NHW	46/75 (61.3)	6/24 (25.0)	40/51 (78.4)	<0.001
Other	13/24 (54.2)	2/5 (40)	11/19 (57.9)	0.629
Adjusted P-value			0.193	

*NHW: 79.1%Other: 11.8% African American; 6.7% Hispanics; 2.2% Asians

Referral and genetic testing uptake:

- No significant differences in referral rates
- No significant differences in evaluation and testing

CLEAR LS INTERVENTION: IMPACT ON DISPARITIES

Race/ Ethnicity	LS Dx original cohort (%)	LS Dx post-Intervention (%)
Total	**2 (0.56)**	**17 (1.43)**
NHW	1 (0.35)	11 (1.18)
African Am.	0	3 (2.07)
Hispanics	1 (4.35)	2 (2.47)
Asians	0	1 (5.88)
Other	0	0

- Lynch syndrome diagnosis almost 3x higher with intervention
- The significant increase in Lynch Syndrome diagnosis was seen in all different racial/ethnic groups

CLEAR LS

- Summary:
  - Deficient implementation of tumor testing for MMR deficiency
  - When implemented, many patients are still not being referred for testing
  - Need to develop mechanisms to improve genetic testing uptake
  - Systematic approaches often have a disproportionally positive effect on underserved populations: can tackle unconscious bias

HOW DO WE IDENTIFY INDIVIDUALS SUSPICIOUS FOR LYNCH SYNDROME?

- Criteria based on personal history of cancer:
  - Known LS pathogenic variant in the family
  - An individual with a Lynch syndrome-related cancer[#] and any of the following:
    - Diagnosed <50 y
    - A synchronous or metachronous LS-related cancer[#] regardless of age
    - 1 first-degree or second-degree relative with an LS-related cancer[#] diagnosed <50 y
    - ≥2 first-degree or second-degree relatives with an LS-related cancer[#] regardless of age*

*Same side of the family

[#]LS-related cancers include colorectal, endometrial, gastric, ovarian, pancreas, urothelial, brain (usually glioblastoma), biliary tract, and small intestine, as well as sebaceous adenomas, sebaceous carcinomas, and keratoacanthomas

NCCN guidelines v.1, 2024

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NCCN guidelines v.1, 2024

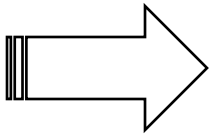
CHALLENGES FOR LYNCH SYNDROME DIAGNOSIS

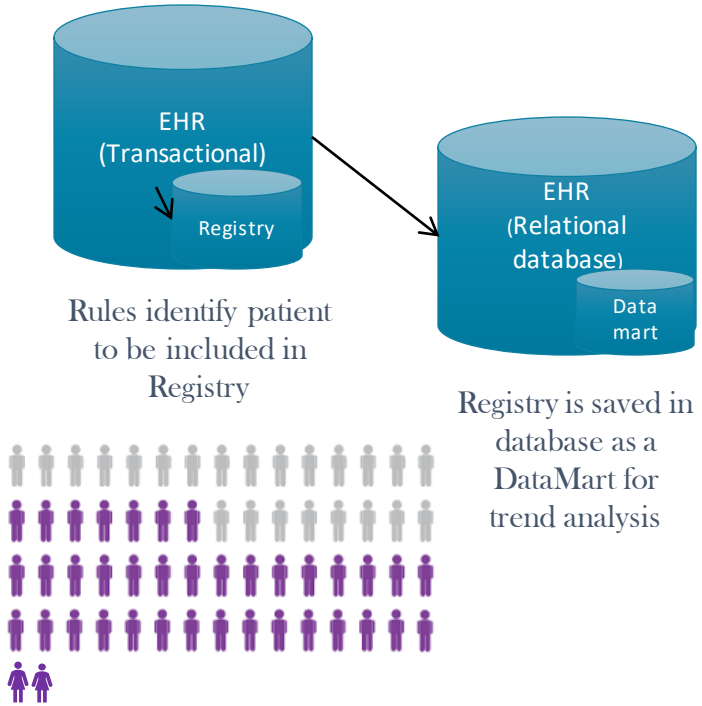
- Challenges to increase genetic testing to rule out Lynch syndrome:
    - Complexity of the guidelines
    - Lack of awareness of guidelines for testing
    - Lack of awareness of Lynch syndrome
    - Capacity to test: need to use new models that can handle larger volumes

CAN WE IDENTIFY MANY MORE AT-RISK PATIENTS?

- Can we use already available information in the EMR to help identify candidates for genetic testing?

Manual, clinician-based identification of at-risk individuals





ARCAGEN-ID (At-Risk Cancer Genetic Syndrome Identification)

- Strategy:
  - YNHH wellness registry: active patients in the YNHH system defined as having had a face-to-face visit in any of Yale's inpatient, ambulatory, or affiliate locations using the single instance of Yale's Epic® EHR within the past 3 years.
  - Testing criteria:
    - NCCN: Lynch syndrome, High penetrance breast CA, Ovarian CA, Pancreas CA
    - ACMG: Pheochromocytoma, adrenocortical carcinoma, medullary thyroid cancer, ocular melanoma, paraganglioma, sarcoma, renal cell carcinoma
  - Structured data from the EHR:
    - Personal history and family history of specific cancers, histology types, and age at diagnosis

ARCAGEN-ID (At-Risk Cancer Genetic Syndrome Identification)

- Strategy:
  - External data: registry enabled to capture external data received from standard interoperability exchange of information (Care Everywhere, Epic® HER)
  - Logic build: 218 rules serially evaluate each aspect of an individual NCCN/ACMG criteria, which together roll up into a logic statement of "at risk" for the types of syndromes of interest
  - Outreach: exclusion of individuals with a cancer syndrome diagnosis and individuals seen by cancer genetics/Lynch syndrome-polyposis clinic or pending appointments with these programs

ARCAGEN-ID (At-Risk Cancer Genetic Syndrome Identification)

- Strategy limitations:
  - Pathology information: Inability to capture molecular/IHC testing of tumors as this information is not included in a discrete field and pathology reporting system is different from EPIC. Eg: triple (-) breast cancer.

  - Family history of cancer: limited diagnosis options from EPIC's discrete field menu. Eg:

    Not available:

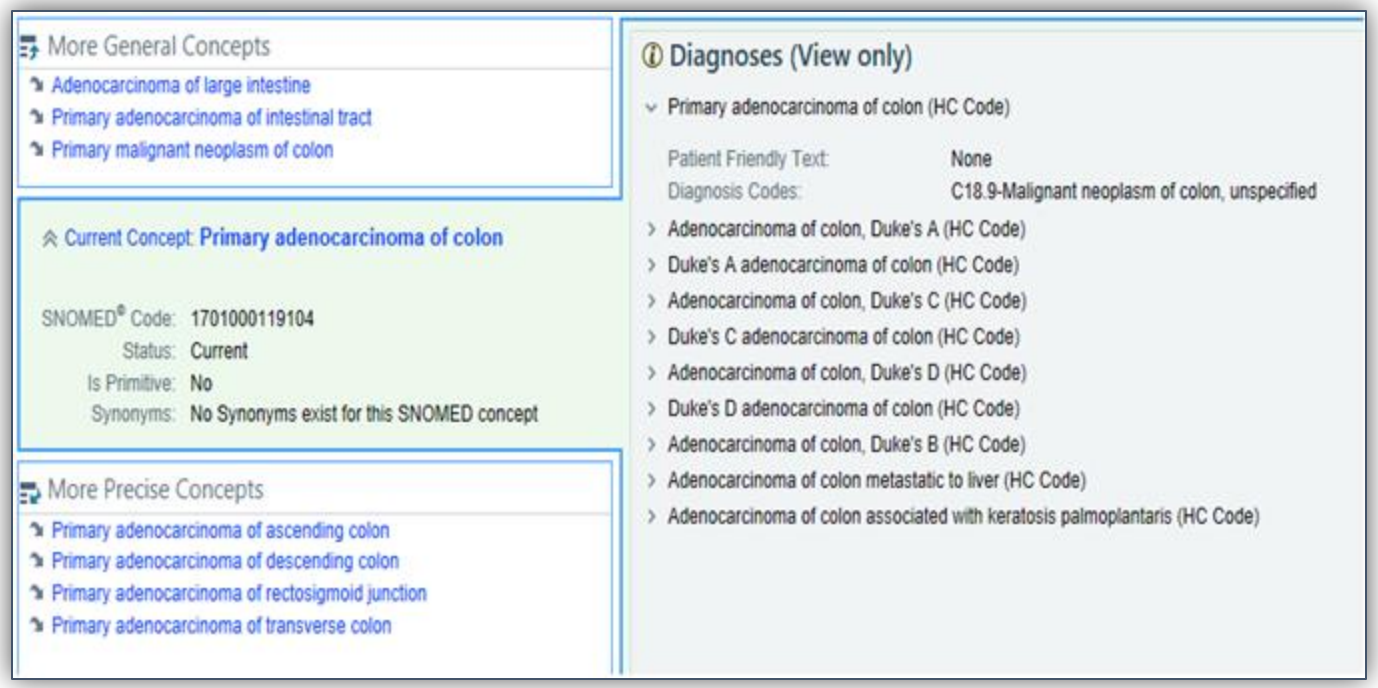
Small bowel/intestinal cancer		Urothelial/urether cancer
Biliary tract		Keratoacantoma
Glioblastoma		Sebaceous adenoma

    Available:

Colon	Stomach	Ovarian
Endometrial	Pancreas	Bladder and renal

ARCAGEN-ID: IDENTIFYING DIAGNOSIS

Which individual diagnoses do we want?



SNOMED: a systematically organized computer-processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting

Which SNOMED Concept Hierarchies do we use?

ARCAGEN-ID (AT-RISK CANCER GENETIC SYNDROME IDENTIFICATION)

Logic statements dissect each criteria into a series of rules that evaluate a patient's personal or family history as true or false, calculate age at onset of personal history or family history as relevant to each NCCN/ACMG criteria, and categorize family relationships into degree of relationship by generation

Detailed Lynch Syndrome Inclusion Logic

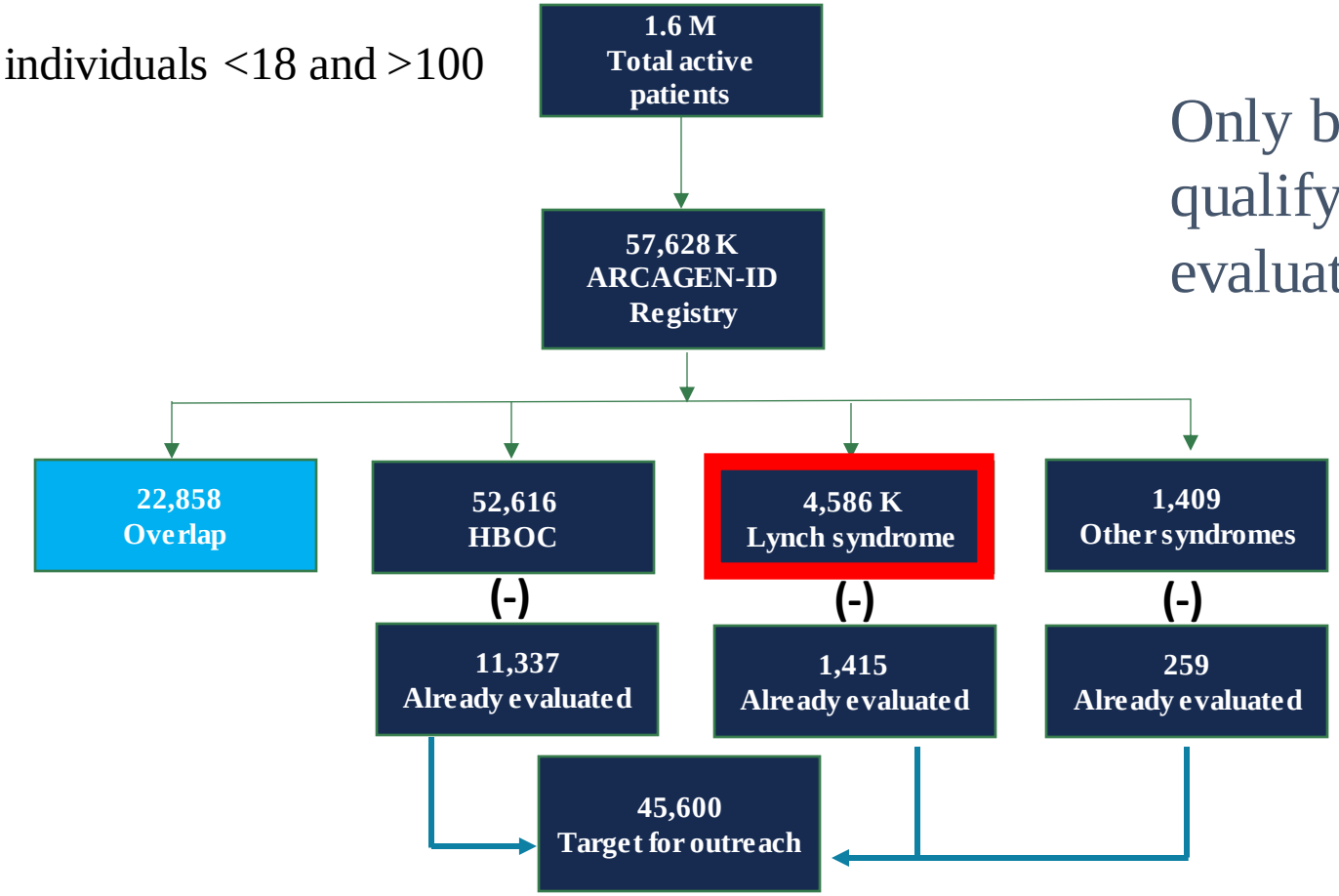
- Encounter diagnoses & date of entry
- Problem & date of entry
- Family history & age of onset

(1 or 2) or (3) or (4 and 5) or (6 and 7) or ((4 or 6) and (8 or 10 or 14)) or (8 and 9) or (10 and 11) or ((8 or 10) and (4 or 6 or 14)) or (12 or 13)

1. Does the patient have Lynch Syndrome Diagnosis in their problem list?
2. Does the patient have Lynch Syndrome Diagnosis in their encounter diagnoses?
3. Does the patient have any 1st degree family history of colorectal or endometrial cancer diagnosed before the age of 50?
4. Does the patient have Colorectal Cancer Diagnosis in their Problem List?
5. Was the CRC problem added before the patient was 50 yo?
6. Does the patient have Colorectal Cancer Diagnosis in their Encounter Diagnoses?
7. Was the CRC encounter diagnosis added before the patient was 50 yo?
8. Does the patient have Endometrial Cancer in their Problem List?
9. Was the EC problem added before the patient was 50 yo?
10. Does the patient have Endometrial Cancer in their Encounter Diagnoses?
11. Was the EC encounter diagnosis added before the patient was 50 yo?
12. Does the patient have Small Bowel Cancer in their Problem List?
13. Does the patient have Small Bowel Cancer in their Encounter Diagnoses?
14. Does the patient have any of the following adenocarcinomas in their Problem List or Encounter Diagnoses?
    - Gastric, ovarian, pancreatic, urothelial, glioblastoma, biliary tract, cholangiocarcinoma, sebaceous neoplasms

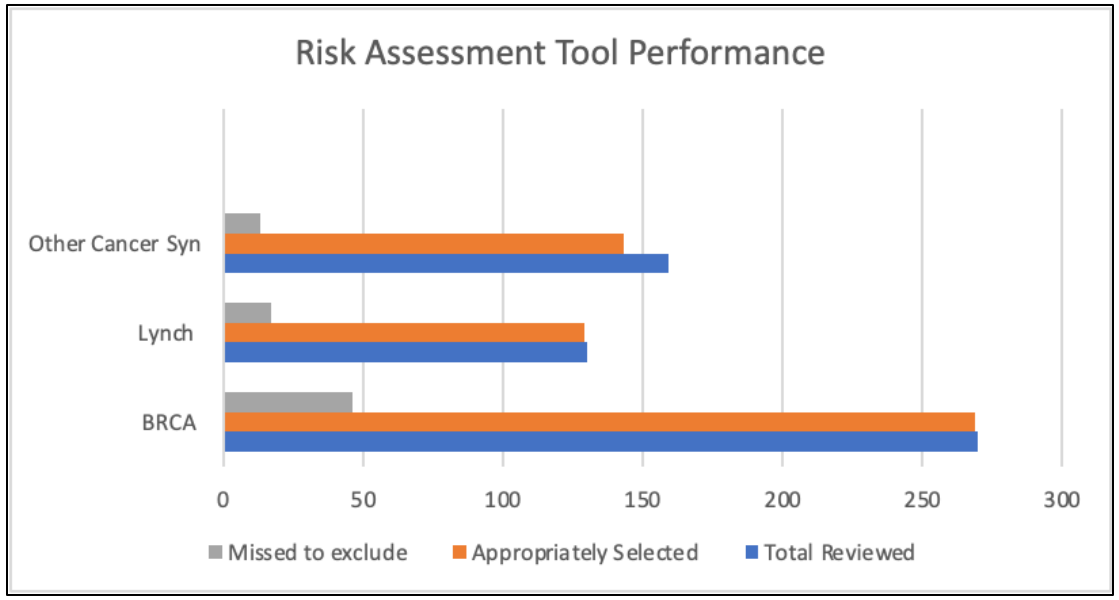
ARCAGEN-ID (AT-RISK CANCER GENETIC SYNDROME IDENTIFICATION)

Excluded individuals <18 and >100



Only between 18% and 30% of qualifying individuals had been evaluated

ARCAGEN-ID PERFORMANCE



- 559 MRs reviewed. Correctly included: 541/559 (96.2%)

270 HBOC:	96.6%
130 LS:	99.2%
159 Other:	89.9%*

- Already tested and missed: 76/532 (14.2%)

Almost exclusively due to existence of genetic testing result as scanned results or embedded as free text in provider's notes, and not selected as a discrete field in diagnosis and/or problem list

*Suspected pheochromocytoma that were coded with visit diagnosis of pheochromocytoma but was ruled out by negative laboratory work up

ARCAGEN-ID *VS* WELLNESS REGISTRY

Characteristic	Wellness Registry N = 1,299,709[1]	Registry Pt. N = 57,628[1]	p-value[2]
Age	49.84 (19.53)	54.19 (16.72)	<0.001
Gender			<0.001
Female	709,319 (55%)	47,123 (82%)	
Male	590,390 (45%)	10,505 (18%)	
Ethnicity			<0.001
Hispanic	205,308 (16%)	6,163 (11%)	
Non-Hispanic	1,094,401 (84%)	51,465 (89%)	
Race			<0.001
White	849,028 (65%)	44,777 (78%)	
African American	147,058 (11%)	5,424 (9.4%)	
Other	303,623 (23%)	7,427 (13%)	
Payer			<0.001
Commercial	645,237 (50%)	33,221 (58%)	
Medicaid	193,290 (15%)	5,669 (9.8%)	
Medicare	283,855 (22%)	14,755 (26%)	
Other	177,327 (14%)	3,983 (6.9%)	

[1]Comparison of Patient Characteristics between patients with and without familial cancer syndrome risk

[2]Wilcoxon rank sum test; Pearson's Chi-squared test

ARCAGEN-ID: DISPROPORTIONATE EFFECTS ON CANDIDATE IDENTIFICATION

Characteristic	Newly Identified, N = 45,646[1]	Previously Identified, N = 11,982[1]	p-value[2]
Age	53.96 (17.24)	55.09 (14.51)	<0.001
Gender			<0.001
Female	36,487.00 (79.93%)	10,636.00 (88.77%)	
Male	9,159.00 (20.07%)	1,346.00 (11.23%)	
Ethnicity			<0.001
Hispanic	5,014.00 (10.98%)	1,149.00 (9.59%)	
Non-Hispanic	40,632.00 (89.02%)	10,833.00 (90.41%)	
Race			<0.001
White	35,243.00 (77.21%)	9,534.00 (79.57%)	
African American	4,516.00 (9.89%)	908.00 (7.58%)	
Other	5,887.00 (12.90%)	1,540.00 (12.85%)	
Payer			<0.001
Commercial	25,975.00 (56.91%)	7,246.00 (60.47%)	
Medicaid	4,662.00 (10.21%)	1,007.00 (8.40%)	
Medicare	11,825.00 (25.91%)	2,930.00 (24.45%)	
Other	3,184.00 (6.98%)	799.00 (6.67%)	

ARCAGEN-ID: ENRICHING IDENTIFICATION AMONG NON-CANCER PATIENTS

Inclusion	Newly Identified, N = 45,646[1]	Previously Identified, N = 11,982[1]	<0.001
Both Personal and Family History Present	5,417 (11.87%)	4,685 (39.10%)	
Only Family History Present	36,830 (80.69%)	5,994 (50.03%)	
Only Personal History Present	3,329 (7.29%)	1,070 (8.93%)	
[1]Comparison of Patient Characteristics based on previously identified status			
[2]Wilcoxon rank sum test; Pearson's Chi-squared test			

ARCAGEN-ID

- Summary:
  - Most individuals who qualify for genetic testing to rule out Lynch syndrome and other cancer syndromes are not being identified
  - Leveraging information already in the EHR can help identify a high number of candidates with a disproportionally positive effect among minorities
  - Robust systems should be put in place to test the large number of newly identified individuals
  - Need to develop strategies to improve cascade testing (testing family members who might share the familial mutation) once a patient has been diagnosed

THE YALE TEAM

Health Informatics/IT

Thomas Rafter
Jing Liu
Quiana Brown
Nitu Kashyap

Cancer Genetics/Lynch syndrome clinic

Karina Brierly
Claire Healy
Vinit Singh

Pathology

Peter Gershkovich
Joanna Gibson
John Sinard

Genetics

Rosa M Xicola

American Cancer Society | NATIONAL COLORECTAL CANCER ROUNDTABLE

Questions?

Small Group Discussion

- You will be placed at random into a breakout room with a moderator who has been prepped for today's session.
- We encourage you all to come on camera.
- Each breakout group will have roughly 20 minutes to review the topic and discussion questions.
- Please choose someone to take notes and share back with larger group.

Discussion Questions

1. What are some potential benefits and limitations of a systematic approach to risk assessment and risk stratification like this?

2. If you work in a health system, how could your organization implement a program like this? If you do not work in a health system, how could your organization support implementation in health systems that you partner with?

Report Back & Discussion

1. What are some potential benefits and limitations of a systematic approach to risk assessment and risk stratification like this?

2. If you work in a health system, how could your organization implement a program like this? If you do not work in a health system, how could your organization support implementation in health systems that you partner with?

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Thank You

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Blue Star Conversation Evaluation – May 29, 2024