
UNC Lineberger Cancer Network
ADVANCED PRACTICE PROVIDER
Live Webinar
Jonathan Sorah, MD
Cancers of Unknown Primary and the UNC Undiagnosed Cancer Clinic
March 5
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11:55
Start Time
12:00
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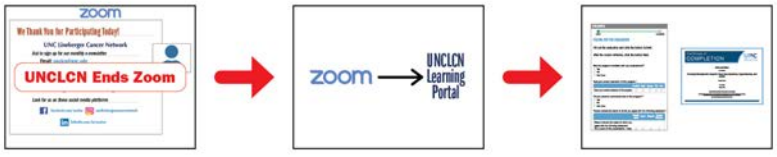


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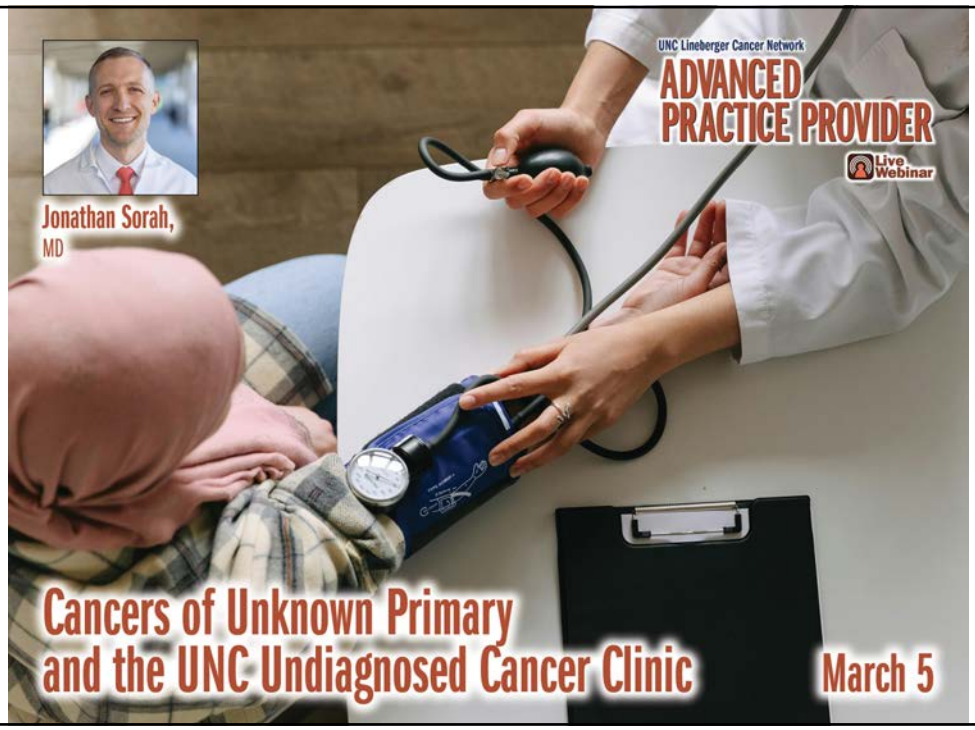


7

7

## Our Presenter

**Jonathan Sorah,** MD

Jonathan Sorah, MD, is a Medical Oncologist with the UNC Lineberger Comprehensive Cancer Center where he specializes in the care of patients with GI malignancies and advanced melanoma.

He did his undergraduate at Virginia Tech, medical school at Virginia Commonwealth University, before doing his residency and fellowship in Medical Oncology here at UNC.

Within the Department of Medicine, he serves as the service leader for the inpatient oncology and medical oncology consult teams and has helped create the Undiagnosed Cancer Clinic to aid in expedited work-up and treatment of presumed malignancies.

His professional interests are in medical education, goals of care, and inpatient medical oncology. In his free time, he enjoys spending time with his wife and two rambunctious young sons, running, and hiking

8

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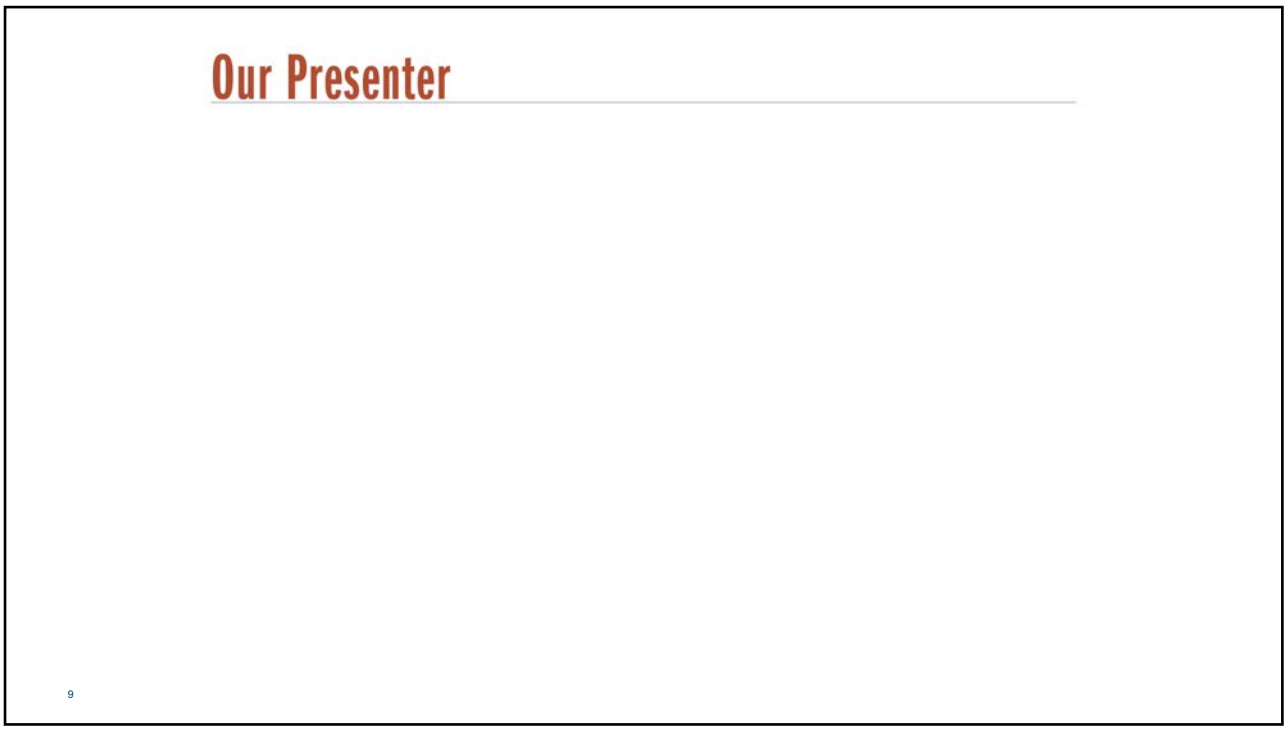
Our Presenter
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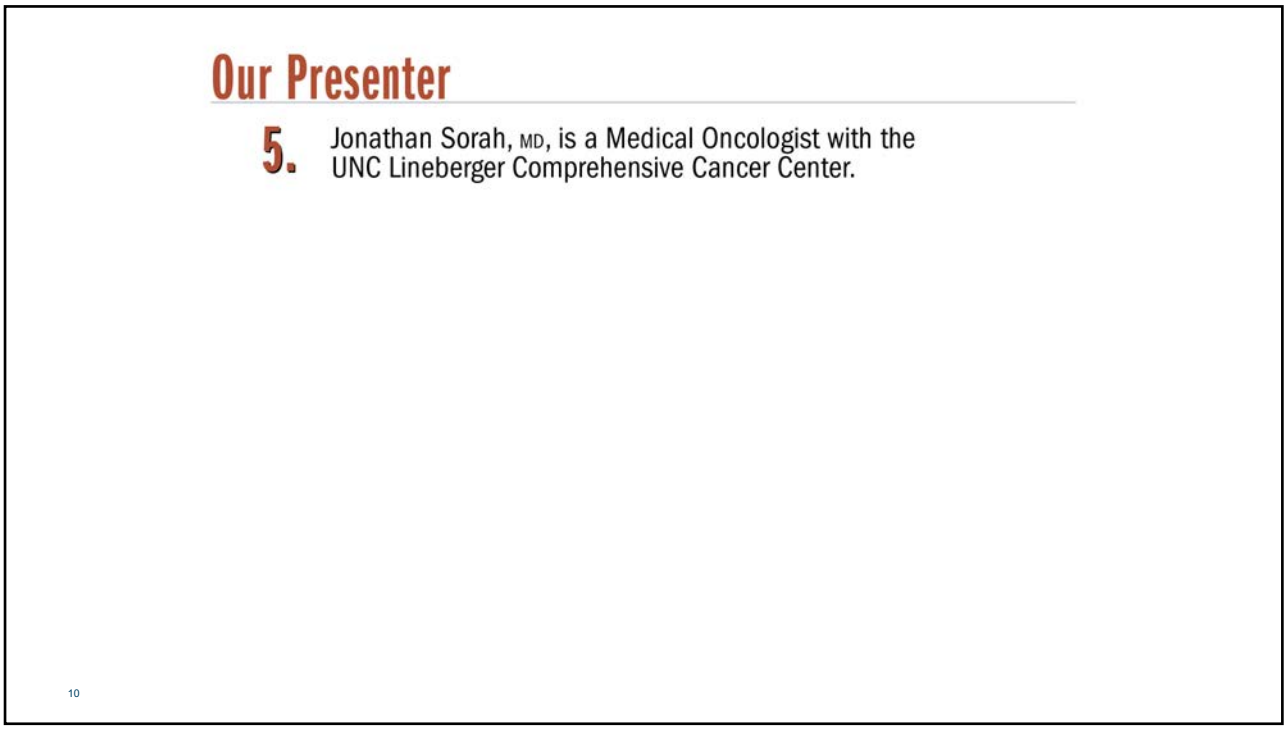
Our Presenter
5. Jonathan Sorah, MD, is a Medical Oncologist with the UNC Lineberger Comprehensive Cancer Center.
10

10

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11

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12

12

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13

13

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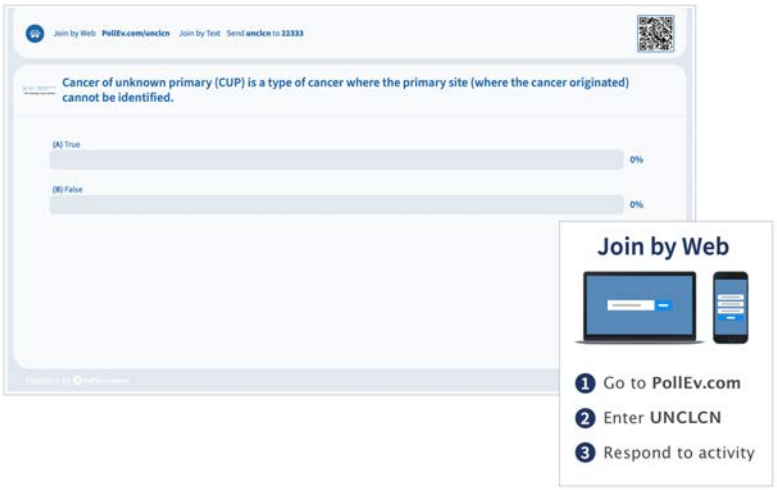
1. He helped to create the Undiagnosed Cancer Clinic to aid in expedited work-up and treatment of presumed malignancies.

14

14

## Sample Poll Everywhere Question

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***Disclosures***

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**1.0 Contact Hours Provided**

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**Criteria for Activity Completion:** Criteria for successful completion to claim CE Certificate requires attendance at the NCPD activity, and submission of an evaluation within 30 days.

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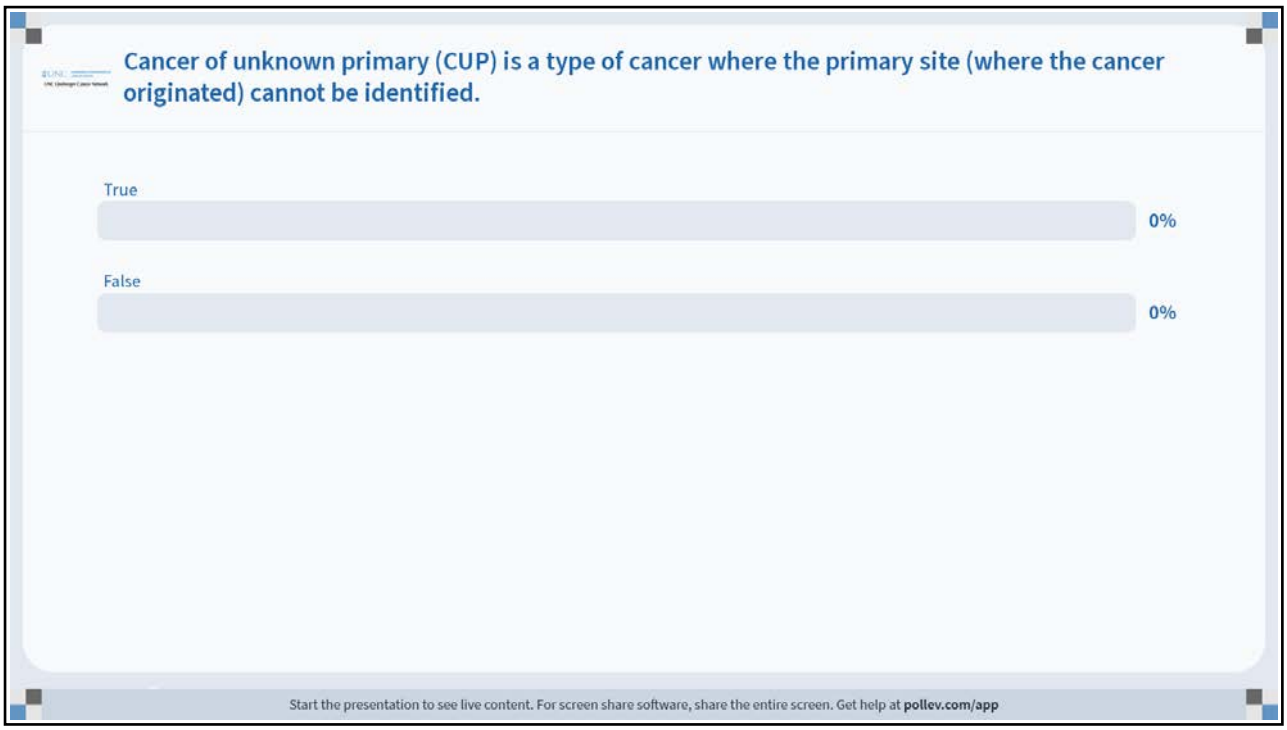
16

16




17

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UNC CANCER CARE

# Cancers of Unknown Primary
# UNC Undiagnosed Cancer Clinic

Jonathan Sorah, MD
Division of Oncology, GI Section
UNC School of Medicine
March 5, 2025
jonathan_sorah@med.unc.edu

18

## Objectives

1. **Describe the work-up of a cancer of unknown primary**
2. **Describe the treatment of a cancer of unknown primary**
3. **Define and use the UNC Undiagnosed Cancer Clinic (UCC)**



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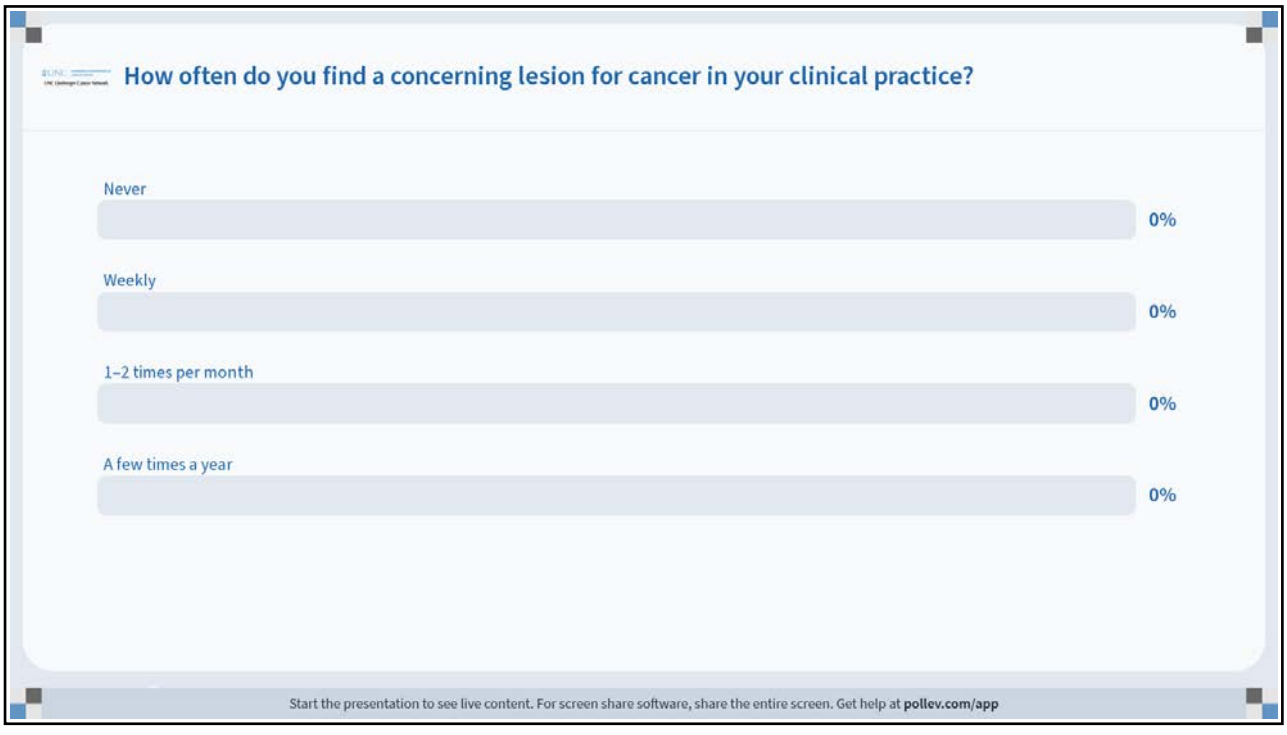
19

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## Cancer of Unknown Primary - CUP

- CUP is fairly common – up to 2% of all invasive cancers
- Most common presenting symptom is pain
- Work-Up:
  - H&P with focus on appropriate cancer screening
  - CBC, CMP, often UA, +/- PSA
  - Imaging (see next slide), consider mammogram
  - Evaluate based on this work-up….



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## Imaging in Cancer of Unknown Primary – to PET or not to PET

| CT | PET |
|---|---|
| Cheaper and easier to schedule | More expensive and takes longer |
| Quicker | Can take much longer, more logistics |
| Still a good preliminary test and can follow-up with PET | Can be slightly more sensitive, can be better to find primary |
| CT scans pick up most masses | Some Cancers do not have much FDG avidity:<br>- Neuroendocrine tumors<br>- Mucinous tumors<br>- Some lung cancers (bronchioalveolar)<br>- Some sarcomas<br>- Low grade lymphomas<br>- Renal cell carcinoma<br>- Among others |
| Contrast allergy, CKD | Does not need iodinated contrast |
| Does not evaluate metabolic activity | Evaluates metabolic activity – can help with biopsy and tumor grading |



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## Further work-up

Bone mets in male: PSA
Bone mets in female: mammogram, breast MRI
Peritoneal disease in female: GYN exam
Microcytic anemia, FOBT+: colonoscopy, EGD
Protein Gap, Hypercalcemia: SPEP + immunofixation, SFLC
Young male with retroperitoneal LNs: HCG, LDH, AFP
Cervical LAD: head and neck exam

All roads lead to…….BIOPSY of something



## Biopsy Principles:

- Metastatic site > primary site
- Try to avoid bone biopsies if possible – slightly more work to make sure you can run moleculars (cannot decalcify bone)
- Less invasive is better
- Excisional LN Biopsy, diagnostic lap -> surgical oncology (sometimes GYN Onc)
- LN Core biopsy -> radiology
- Bone Biopsy -> usually MSK radiology

## What do we find?

Adenocarcinoma: ~70%

Squamous Cell Carcinoma: ~5%

Poorly Differentiated Histology or Non-Carcinoma: 20-25%

- 80% end up being carcinoma

- Non-Carcinomas: heme malignancy, melanoma, sarcoma, germ cell tumor

Neuroendocrine Tumors: ~1%



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## Types of Undifferentiated Neoplasms

| Neoplasm | Cytokeratin | EMA | LCA | S-100 | Desmin/ vimentin* | OCT 4/ HCG/ AFP/ PLAP* | Chromogranin/ synaptophysin |
|---|---|---|---|---|---|---|---|
| Carcinoma | + | + | - | S | - | S | S |
| Melanoma | -, R | - | - | + | + | - | - |
| Sarcoma | - | S | - | - | + | - | - |
| Lymphoma | - | -, R | + | - | - | - | - |
| Neuroendocrine carcinoma | + | + | - | - | - | - | + |
| Germ cell tumor | -, R | - | - | - | - | + | - |



UTD: Adenocarcinoma of unknown primary site

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## IHC Testing - Adenocarcinoma

- 2/3 of cases are pancreaticobiliary, renal, lung
- 20-30% of the time no primary is easily found

| | CK7 | CK20 | CDX2 | TTF-1 | P40 | Cg/Synaptophysin | Hep Par 1 | PAX 8 | GATA 3 | WT-1 | Thyroglobulin |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Colorectal | - | + | + | - | - | - | - | - | - | - | - |
| Upper GI | + | - | S | - | - | - | S | - | - | - | - |
| Pancreas | + | S | + | - | - | - | - | S | - | - | |
| Lung Adeno | + | - | - | + | - | - | - | - | - | - | - |
| Lung SCC | S | - | - | - | + | - | - | - | - | - | - |
| Neuroendocrine Carcinoma | S | S | S | - | - | + | - | S | - | - | - |
| Renal | + | - | - | - | - | - | - | + | - | - | - |
| HCC | - | - | - | - | - | - | + | - | - | - | - |
| Thyroid | + | - | - | + | - | - | - | - | - | - | + |
| Breast | + | - | - | - | - | - | - | - | + | - | - |
| Ovarian | + | - | - | - | - | - | - | + | - | + | - |



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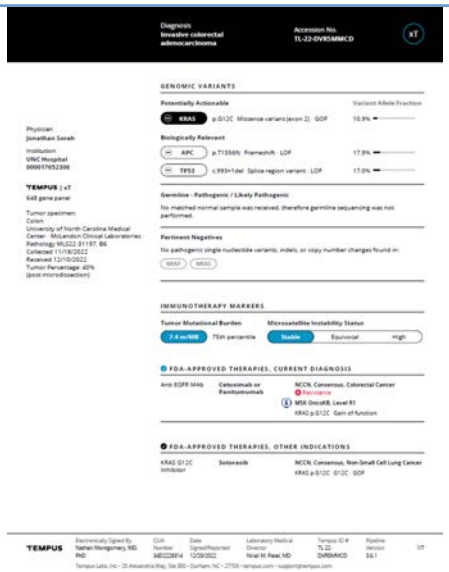
## What if it is still not clear? – Further testing to hopefully help

**1. Next Generation Sequencing/Comprehensive Profiling**

- Tempus xT or xF
- Guardant 360 (liquid biopsy)
- NeoGenomics
- Caris
- Foundation Medicine
- Many more….



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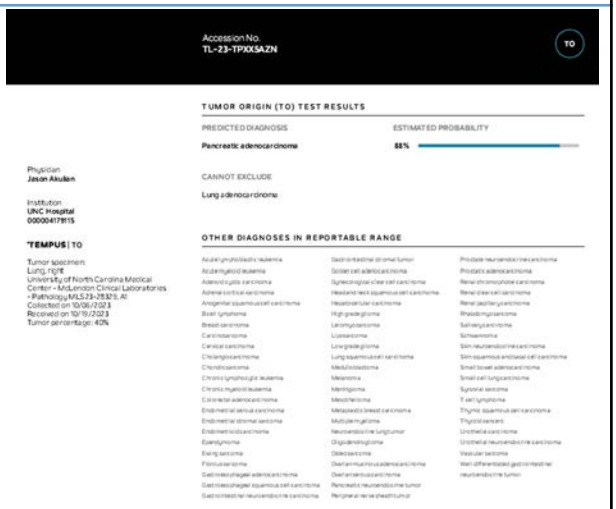
## What if it is still not clear? – Further testing to hopefully help

**2. Tumor Origin Testing ("molecular cancer classifier assays")**

- uses RNA expression results to predict most likely primary cancer type among 68 cancer types (Tempus TO, Cancer ID, etc)
- Several small studies showing improved OS with MCCA based therapy rather than empiric therapy

**3. Tumor Markers (rarely)**

- Often multiple are elevated and not helpful for diagnosis but can use to track treatment response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TO

TUMOR ORIGIN (TO) TEST RESULTS

PREDICTED DIAGNOSIS

ESTIMATED PROBABILITY

Pancreatic adenocarcinoma

88%

CANNOT EXCLUDE

Lung adenocarcinoma

OTHER DIAGNOSES IN REPORTABLE RANGE

Physician
Jason Akulian

Institution
UNC Hospital
00000417815

TEMPUS | TO

Tumor specimen:
Lung, right
University of North Carolina Medical Center – MyLemon Clinical Laboratories
- Pathology MLS23-25323, A1
Collected on 10/06/2023
Received on 10/10/2023
Tumor percentage: 40%



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## Treatment of Cancer of Unknown Primary

**1. Surgery if oligometastatic or symptomatic**

**2. Radiation or Locoregional Therapy**

**3. Systemic Therapy**



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## Systemic Therapy for CUP (no actionable mutations)

**Cancer with Predicted Treatment Sensitivity:**

- renal cell carcinoma
- colorectal cancer
- NSCLC
- melanoma
- breast cancer
- ovarian cancer
- bladder cancer

**Treat with site specific therapy**

**Cancer with Predicted Treatment Resistance:**

- pancreas cancer
- bile duct cancers
- primary liver cancer
- gastroesophageal cancer

**Treat with empiric chemotherapy:**

**carboplatin + paclitaxel**

**gemcitabine + cisplatin/carboplatin**

**gemcitabine + irinotecan**



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## Systemic Therapy for CUP (targetable mutation found)

MSI-H = tumor agnostic indication for pembrolizumab

Tumor Mutation Burden >10 = pembrolizumab

BRAF V600E, NTREK, HRR, etc = consider targeted therapy alone or in combination with chemotherapy



Maio M et al, Pembrolizumab in microsatellite instability high or mismatch repair deficient cancers: updated analysis from the phase II KEYNOTE-158 Study. Anals of Oncology 2022; 33:9; 929-938

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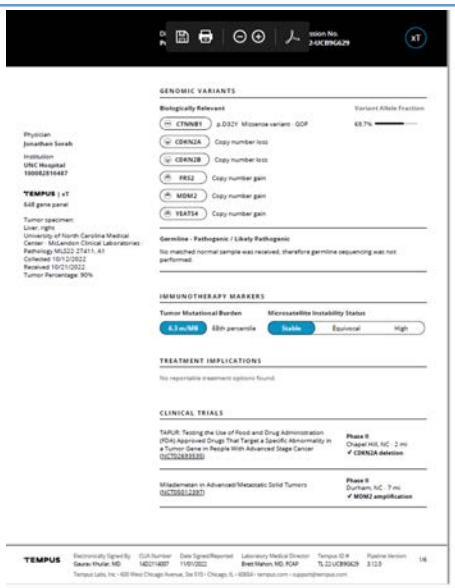
## Case 1

- 53 yom presented with abdominal pain found to have a large hepatic mass 14.5cm with obstructive jaundice.
- Liver biopsy showed poorly differentiated carcinoma
  - Hep Par 1, CK7, CDX2 positive
  - Pancytokeratin Positive
  - CK20, PAX8, TTF-1, p40, GATA3, S100 chromogranin, synaptophysin negative
- AFP 22,236 CA 19-9 <2 CEA 1.1
- S/p hepaticogastrostomy then cystogastrostomy with improvement in bilirubin

**Tumor IHC profile suspicious for biliary tract, HCC, or mixed biliary tract/HCC**



## Molecular Profiling and TO testing – does this change your treatment?



GENOMIC VARIANTS

Biologically Relevant

CTNNB1 p.D32Y Missense variant · GOF

CDKN2A Copy number loss

CDKN2B Copy number loss

FRS2 Copy number gain

MDM2 Copy number gain

YEATS4 Copy number gain

Germline - Pathogenic / Likely Pathogenic

IMMUNOTHERAPY MARKERS

Tumor Mutational Burden

Microsatellite Instability Status

TREATMENT IMPLICATIONS

CLINICAL TRIALS

TAPUR: Testing the Use of Food and Drug Administration (FDA) Approved Drugs That Target a Specific Abnormality in a Tumor Gene in People With Advanced Stage Cancer

Phase II Chapel Hill, NC · 2 mi ✓ CDKN2A deletion

Phase II Durham, NC · 7 mi ✓ MDM2 amplification

TEMPUS

TUMOR ORIGIN (TO) TEST RESULTS

PREDICTED DIAGNOSIS

ESTIMATED PROBABILITY

LOWER PROBABILITY DIAGNOSTIC PREDICTIONS

CANNOT EXCLUDE

PATHOLOGIST REPORT NOTES

OTHER DIAGNOSES IN REPORTABLE RANGE

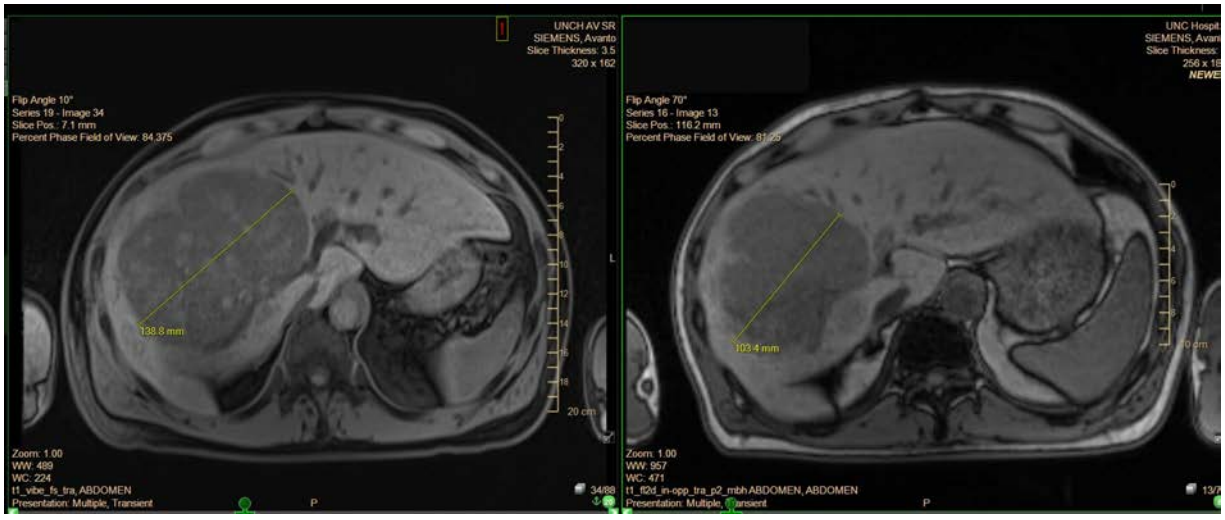
TEMPUS



IPREHENSIVE



## Gemcitabine + Cisplatin + Durvalumab (per Topaz-1)




Sept 2022 AFP 26922

Dec 2022 AFP 4486



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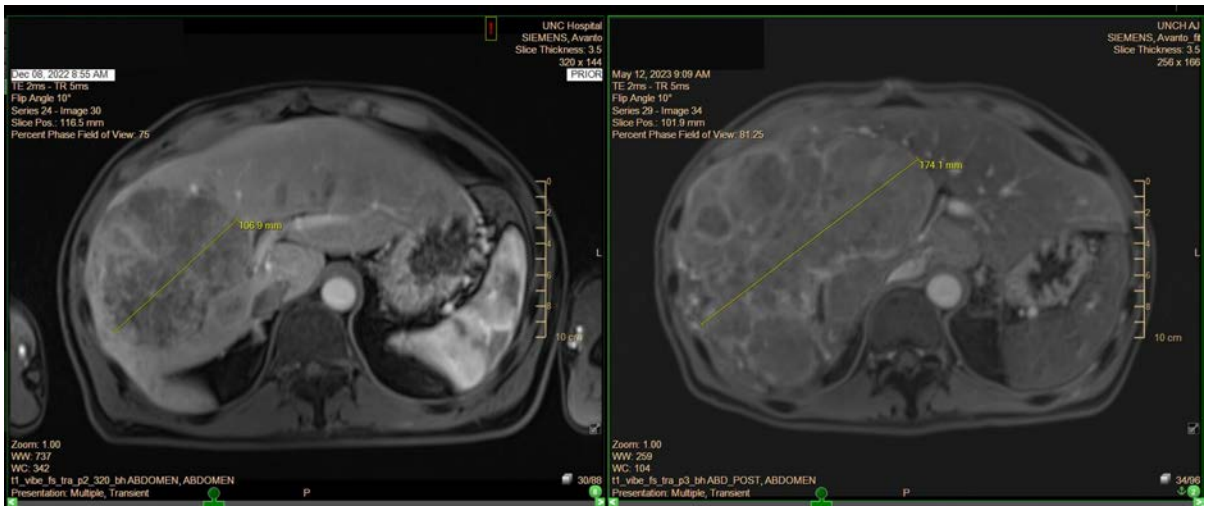
## It worked well, until it didn't…..



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## Case 2

46 yom with chest pain found to have a pulmonary embolus and a 6cm liver mass with several satellites.

Follow-up MRI showed multifocal hepatic lesions and some lesions along the hepatic dome and caudate lobe. No other evidence of disease.

Liver biopsy showed high grade carcinoma with neuroendocrine features positive for CDX2, CK20, synaptophysin. Patchy p40 positive. Negative for HepPar1, GATA3, TTF-1, PAX8.



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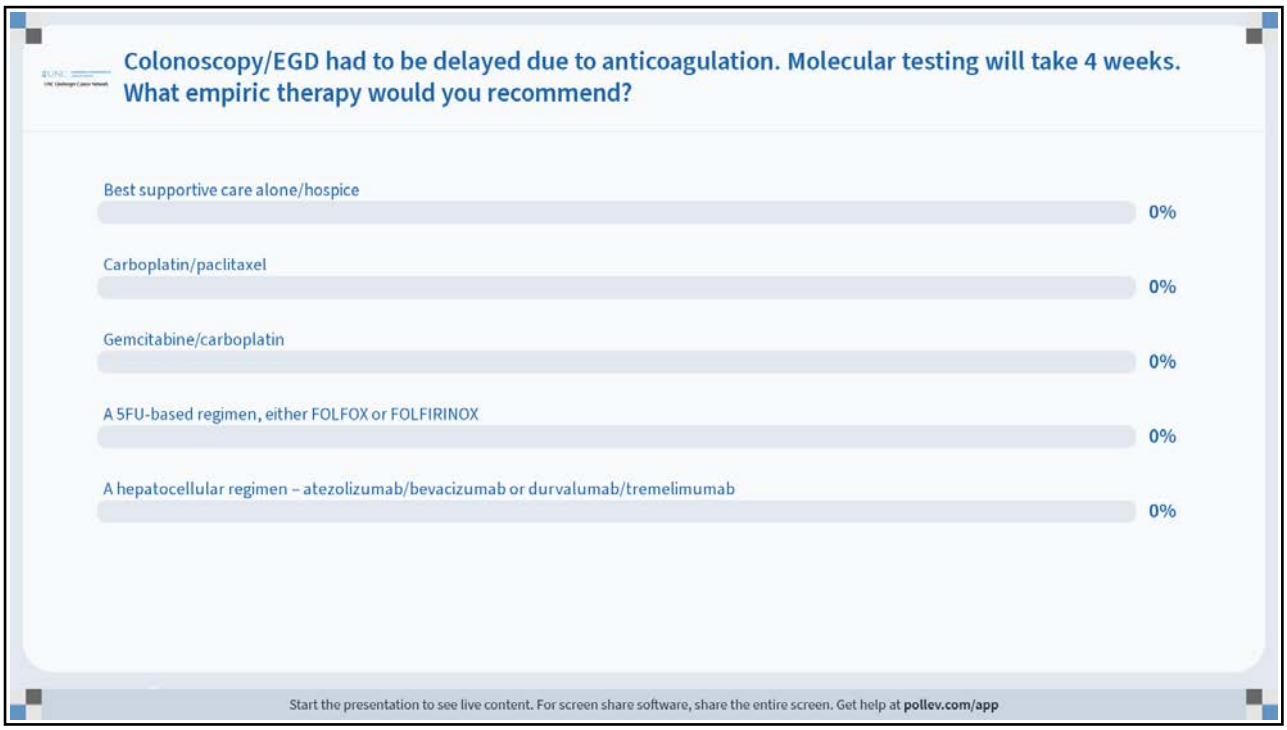
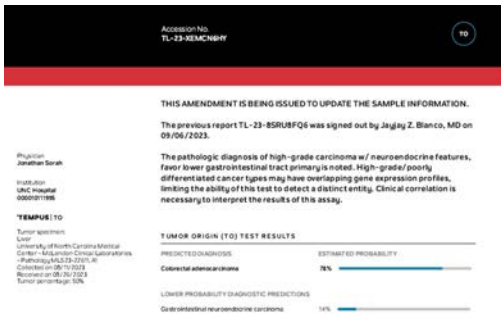



39

## Colonoscopy had to be delayed due to having just started apixaban.

- **Given CDX2 and CK20 positive, suspected colorectal primary so treated with FOLFOX→mFOLFIRINOX**
- **4 weeks later: Tempus xT showed RB1, TP53, APC, PPP2R1A, no BRAF/KRAS/NRAS, MSS**

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40

## Colonoscopy Report

Estimated Blood Loss:
Estimated blood loss was minimal.
Impression: - Malignant tumor in the cecum. Biopsied.
- One 15 mm polyp in the mid ascending colon, removed with a hot snare. Resected and retrieved.
- Two 3 to 4 mm polyps in the descending colon, removed with a cold snare. Resected and retrieved.
- Two 8 to 10 mm polyps in the descending colon, removed with a hot snare. Resected and retrieved.
- One 8 mm polyp in the rectum, removed with a hot snare. Resected and retrieved.
- Internal hemorrhoids.

Diagnosis
A: Cecum mass, biopsy
– Invasive moderately differentiated adenocarcinoma, multiple fragments; see comment

B: Right colon polyp, biopsy
– Tubular adenoma with focus with at least high-grade dysplasia; final diagnosis pending additional levels

C: Descending colon polyps, biopsy
– Tubular adenoma with no evidence of high-grade dysplasia, multiple fragments

D: Rectum polyp, biopsy
– Tubular adenoma with no evidence of high-grade dysplasia and negative ink base margin of resection

This electronic signature is attestation that the pathologist personally reviewed the submitted material(s) and the final diagnosis reflects that evaluation.



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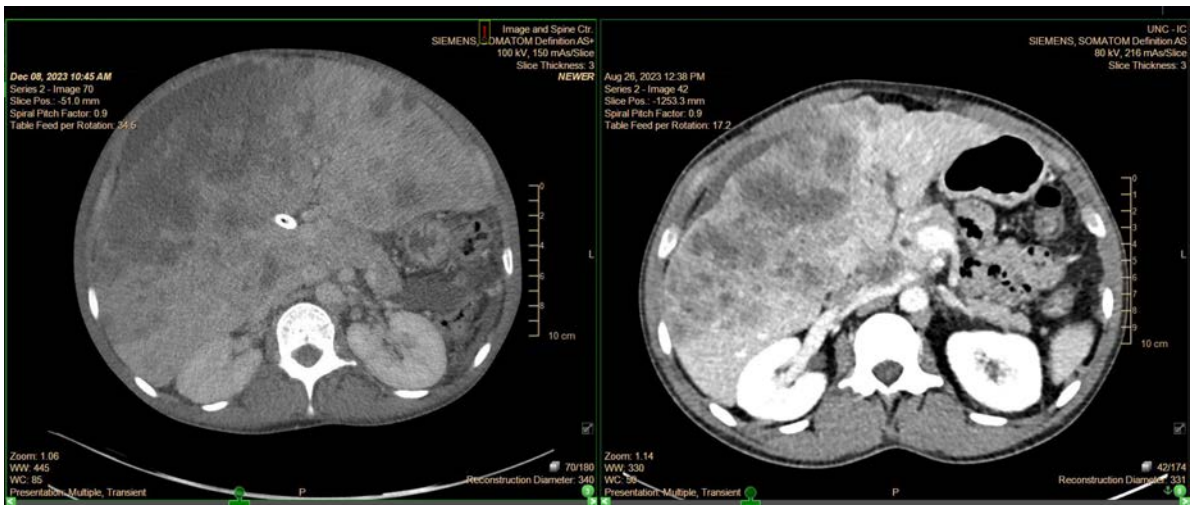
41

## Scans



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42

# UNC Undiagnosed Cancer Clinic (UCC)



## Background

***Gap in Care: Access for Undiagnosed Cancers***

- Disease-specific clinic models of academic programs often require diagnosis for scheduling resulting in delayed consultation
- Average wait time: about 17 days over 4-month period (n=14)
- Delayed entry into cancer center and its resources
- Patients go to ED/get admitted for “expedited work-up” when they otherwise do not warrant admission
- Patients discharging from ED without a diagnosis fall through the cracks

***Remove barriers to rapid oncology consultation***

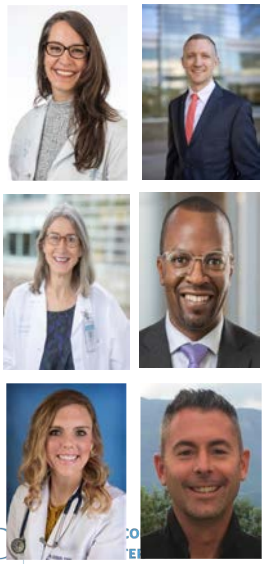
- Goal: decrease wait time for initial oncology consultation

## Background

***Established Undiagnosed Cancer Clinic (UCC)***
***(est. Sept 2022)***

- Staff: MDs (3), APPs (1), Nurse Navigator (1), Intake Coordinator (1)
- Referral process and EPIC order
- Slots every day on provider templates

- Oncology-led diagnostic work-up
- Symptom management
- Disease education
- Goals of care discussions
- Early navigation for barrier mitigation
- Transition to subspecialist at final diagnosis



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## Undiagnosed Cancer Clinic
## Division of Oncology

UNC HEALTH CARE SYSTEM

UCC Flyer

The UCC Program offers streamlined, specialty care to work up a concern for cancer diagnosis (without a clear primary) while offering symptom management and patient-centered goals of care with transition to appropriate care teams at final diagnosis.

- **Concern for solid tumor cancer, diagnosis and work up pending**
- **Work up in process, biopsy ordered/scheduled, results pending**
- **Who should be referred?**
  - Imaging results concerning for cancer
  - Liver lesions
  - Bone lesions
  - Enlarged lymph nodes concerning for cancer
  - Pathology concerning for cancer with unclear primary

How to Refer: (add to your preference list)
**Ambulatory Referral to Hematology/Oncology**
**Dept: UNC ONC MULTID 2nd FLR CANCER HOSP**
In comments add: **Undiagnosed Cancer Clinic**

Contact for questions (EPIC in-basket) : Tammy Triglianos, NP or Jonathan Sorah, MD

UNC HEALTH CARE

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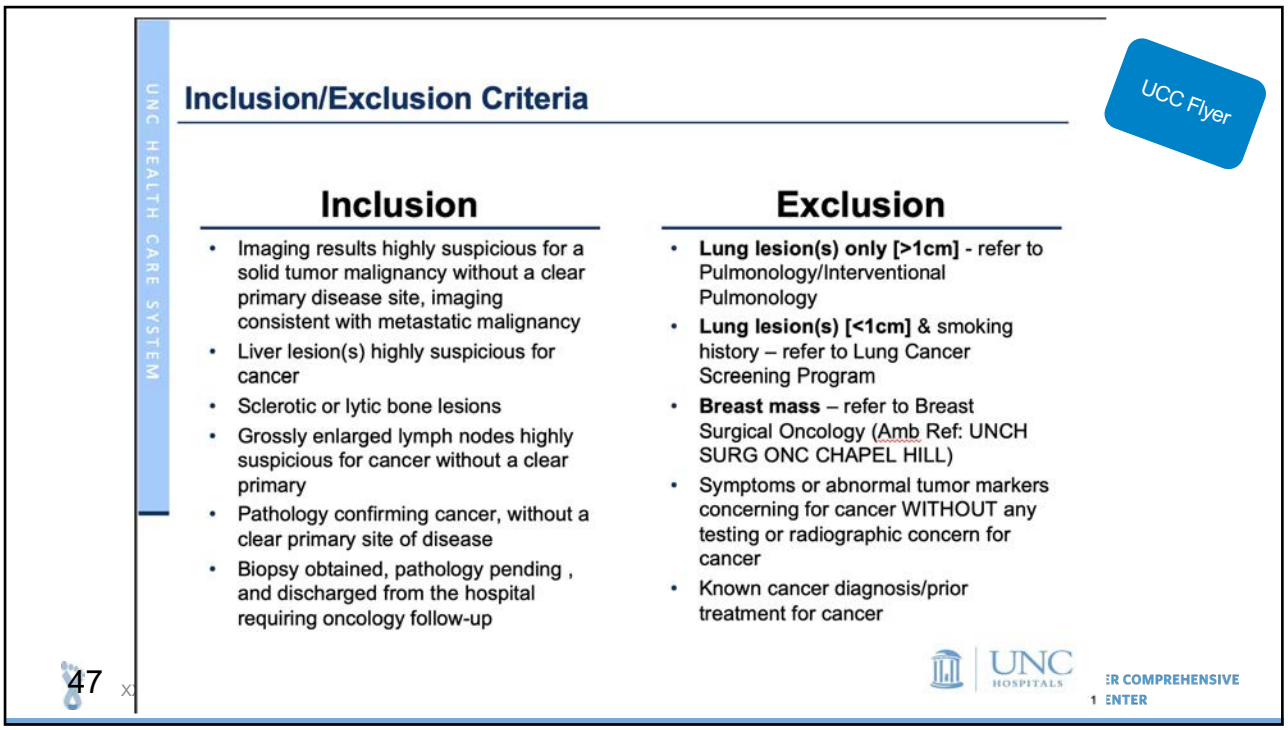
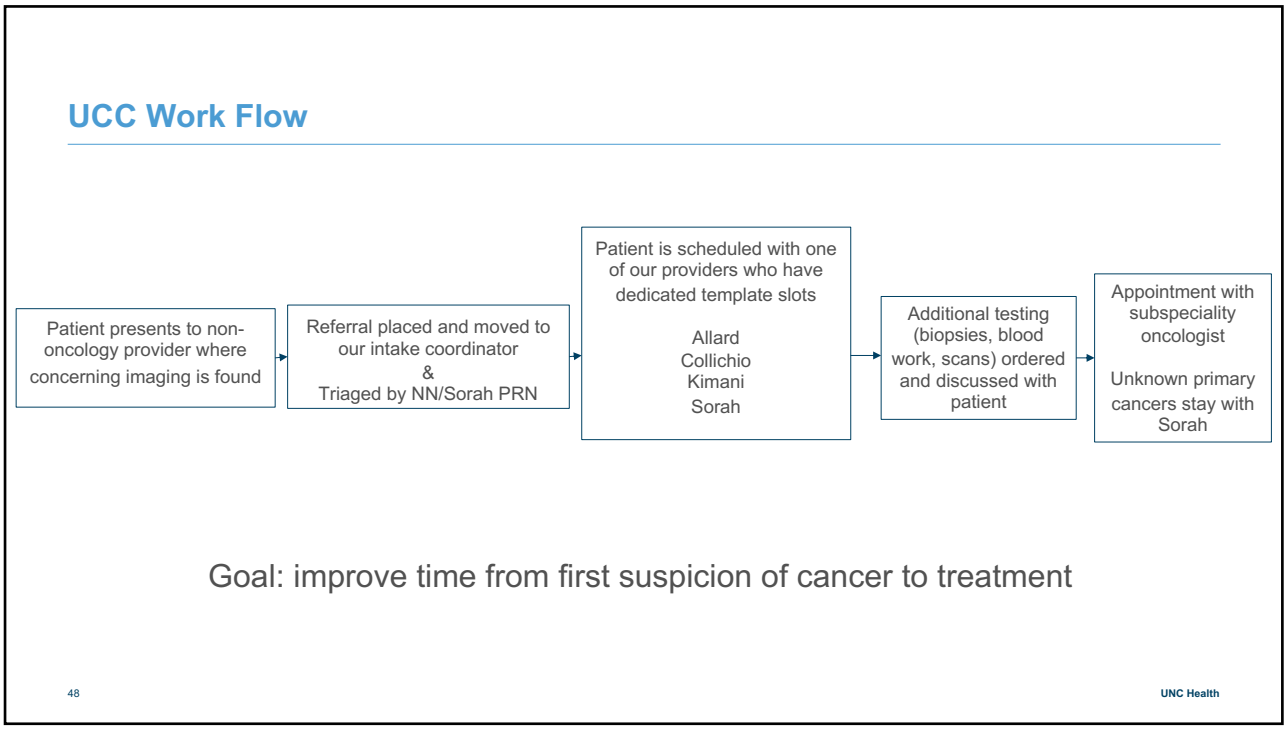
46

46


UNC HEALTH CARE SYSTEM
Inclusion/Exclusion Criteria
UCC Flyer
Inclusion
Imaging results highly suspicious for a solid tumor malignancy without a clear primary disease site, imaging consistent with metastatic malignancy
Liver lesion(s) highly suspicious for cancer
Sclerotic or lytic bone lesions
Grossly enlarged lymph nodes highly suspicious for cancer without a clear primary
Pathology confirming cancer, without a clear primary site of disease
Biopsy obtained, pathology pending , and discharged from the hospital requiring oncology follow-up
Exclusion
Lung lesion(s) only [>1cm] - refer to Pulmonology/Interventional Pulmonology
Lung lesion(s) [<1cm] & smoking history – refer to Lung Cancer Screening Program
Breast mass – refer to Breast Surgical Oncology (Amb Ref: UNCH SURG ONC CHAPEL HILL)
Symptoms or abnormal tumor markers concerning for cancer WITHOUT any testing or radiographic concern for cancer
Known cancer diagnosis/prior treatment for cancer
47
UNC HOSPITALS

47


UCC Work Flow
Patient presents to non-oncology provider where concerning imaging is found
Referral placed and moved to our intake coordinator & Triaged by NN/Sorah PRN
Patient is scheduled with one of our providers who have dedicated template slots
Allard
Collichio
Kimani
Sorah
Additional testing (biopsies, blood work, scans) ordered and discussed with patient
Appointment with subspeciality oncologist
Unknown primary cancers stay with Sorah
Goal: improve time from first suspicion of cancer to treatment
48
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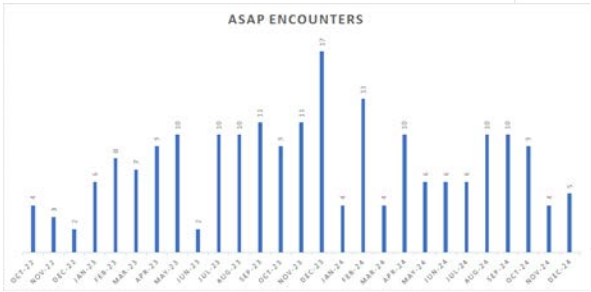
48

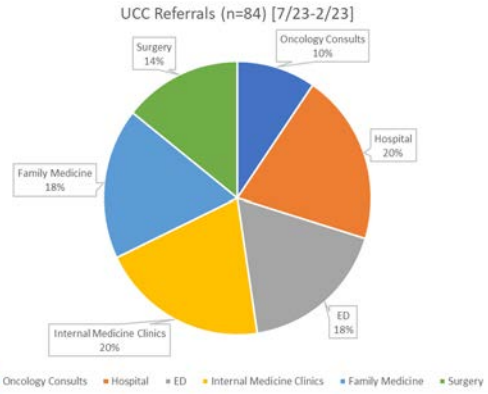
## Referrals and Statistics

Referral Turnaround Time: 2.5 days

Schedule to Service: 5.8 days

Average Time from Visit to Biopsy: 7.4 days (n=45)




49

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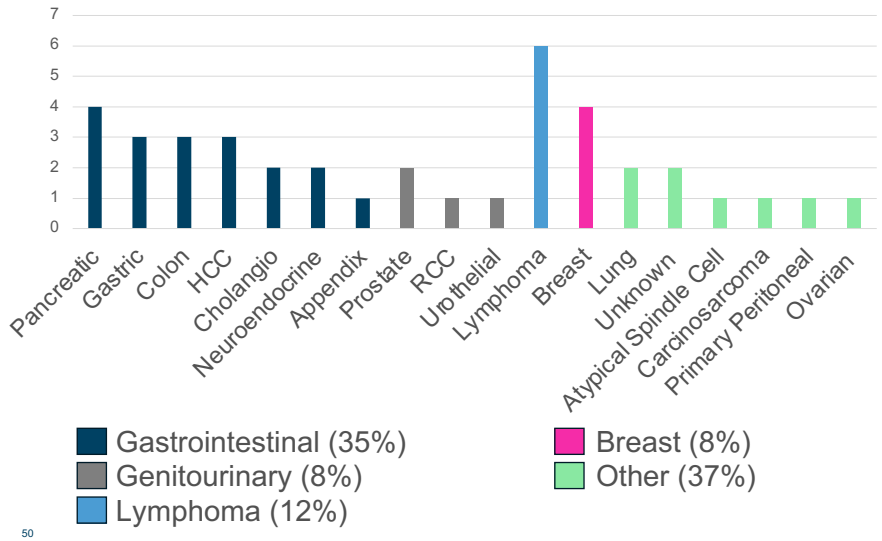
49

## Final Cancer Diagnosis (Initial Prelim Data N=52)




- 79% of solid tumor had metastatic disease
- 15% no cancer diagnosis
- 8% diagnosed referred directly to hospice

Gastrointestinal (35%)
Genitourinary (8%)
Lymphoma (12%)
Breast (8%)
Other (37%)

50

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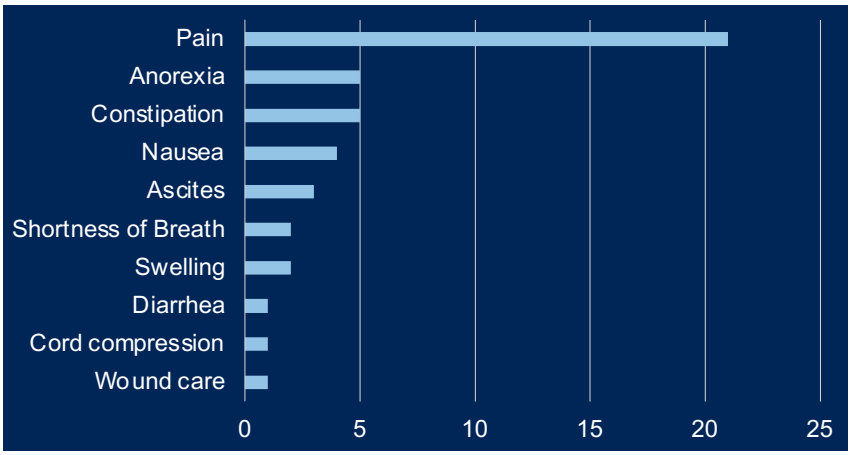
50

## Symptoms Managed (Initial Prelim Data N=52)




58% ≥1 ED visit prior to UCC

8% ≥1 ED visit between UCC visit and established care with primary team



## Current Challenges and Solutions for the UCC

**Appropriate referrals and triage of referrals:**

- Intake coordinator (Demetrice Bullock) training how to triage requests effectively
- Nurse Navigator (Adam Bunch) helps to ensure our referrals are triaged correctly
- MD (Sorah) makes final decision on unclear cases
- We have met with IM, Family Medicine, and ED leadership to advertise

**Data Dashboard:**

- In process: treatment ticker to determine time from visit to start of treatment

**Quick referrals to cancer subspecialists and other consultants**

- Partnerships developing with palliative care, VIR, and radiation oncology
- Priority scheduling with oncology sub-specialists once we have seen patients

## Ongoing Challenges for the UCC

**Rapid Access vs Rapid Work-up**
- Are we getting patients worked up/fully staged faster?
- Are we actually getting patients started on treatment faster?
- Do we create an unnecessary extra step for some patients?

**Work-Up Logistics not in our control**
- Delayed outpatient scheduling for biopsies and staging studies
- Delayed start of treatment due to infusion limitations, prior authorization, etc
- Social Determinants of Health: patient barriers to care

**Consider cost-effective analysis**
- Are we saving the patient and hospital money?



## Future Directions and Goals

**Cut down on schedule to service time, ideally less than 3 business days**
- Increase access to our UCC providers

**Improve time from first suspicion of cancer to begin cancer-directed therapy**
- Requires ongoing collaboration with oncology colleagues, radiology, IR, etc

**Improve inpatient to outpatient transitions**
- Early touch points with UCC nurse navigator
- Early communication between inpatient providers and UCC team

**Cancer Screening Research Network (NCI)**
- Multi-cancer early detection tests clinical trial


Thank you!!
Any questions?

55


Questions/Comments?
Nobody has responded yet.
Hang tight! Responses are coming in.
Start the presentation to see live content. For screen share software, share the entire screen. Get help at pollev.com/app

56

## Thank You . . .

University Cancer Research Fund

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**UNC Lineberger Cancer Network**

**The Telehealth Team**

**Tim Poe** – Director

**Veneranda Obure** – Technology Support Specialist

**Andrew Dodgson,** DPT – Continuing Education Specialist

**Jon Powell,** PhD – Continuing Education Specialist

**Patrick Muscarella** – Technology Support Technician

**Oliver Marth** – Technology Support Technician

**Barbara Walsh,** DNP, MPH, MSN, RN – Nurse Planner

The song ***Back Rhodes*** written and performed by **Don Poe**

57

57

## Upcoming Live Webinars

learn.unclcn.org


PATIENT-CENTERED CARE Live Webinar

***March 12***
Second Wednesday
***12:00 PM***

Cancer Prevention: How Do We Make a Difference?
**Melissa Gilkey,** PhD


PATIENT-CENTERED CARE Live Webinar

***April 2***
First Wednesday
***12:00 PM***

Genetic Testing for Cancer Patient Family Members: Recommendations
**Kate Foreman,** MS, CGC


RESEARCH TO PRACTICE Live Webinar

***April 16***
Third Wednesday
***12:00 PM***

Management of Older Adults with AML: Are We Finally Seeing Light at the End of the Tunnel?
**Joshua Zeidner,** MD

58

58

## Self-Paced, Online Courses

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RESEARCH TO PRACTICE — Self-Paced, Online Course

Antibody-Drug Conjugates in Oncology: From Bench to Bedside
**Kevin Chen,** PharmD, MS, BCOP, CPP


PATIENT-CENTERED CARE — Self-Paced, Online Course

Workplace Safety: Creating a Culture of Care and Respect
**Paul Perryman,** MSN, MS, RN, NE-BC
**Catherine Capp,** MSN, RN, NE-BC


ADVANCED PRACTICE PROVIDER — Self-Paced, Online Course

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**Brianne Buchanan,** PA-C

59

59

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60

60