Establishment of an Academic-Community Hybrid Oncology System Focused on Value & Outcomes

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Allina Cancer Institute, Minneapolis, Sept 23, 2022



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Objectives

- ❑ Consider key challenges in healthcare today
- ❑ Define "value" in clinical medicine and why it is important
- ❑ Discuss how to develop a cancer system that addresses value and outcomes
- ❑ Describe system approach for controlling health care costs while maintaining the best outcomes

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Key Challenges

- ❑ We cannot afford current expectations for health care
- ❑ We cannot afford current systems of health care
- ❑ Expense of treatment vs. return on investment
- ❑ Disorganized systems of delivery
  - Unnecessarily competitive
  - Little rationalization of resource use
- ❑ Payment systems
  - Value versus cost versus price
  - Return on investment rarely defined
  - Doing everything
  - Hidden costs associated with the "under-served"

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Our Deficits of Structure & Function

- ❑ Operations in silos
- ❑ The medical/surgical ego
- ❑ Failure to provide adequate access with symmetrical quality
- ❑ Duplication and redundancy
- ❑ Failure to practice evidence-based medicine
- ❑ Philosophy of "new has to be better than old"
- ❑ Failure to differentiate between cost, price and value

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LET'S START WITH HEALTH CARE IN GENERAL IN THE U.S.A.

WHAT ARE THE KEY PROBLEMS

IN ONCOLOGY AS AN EXAMPLE?

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Health Care: The Government Shell Game

- ❑ The U.S. population has "expectations" for health care
  - Political promises
  - Advertising
  - Dr. Google
- ❑ Nobody is interested in health care unless illness involves them – patients, families, friends
- ❑ Governments cannot afford to provide the care that the population expects (and that it promises)
- ❑ NOBODY wants to pay for health care
- ❑ Lobbyists lobby
- ❑ Why did the Oregon experiment fail?????

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A Shared Responsibility for the Problem

- ❑ The population and health behavior – smoking, obesity, non-vaccinators, risky behavior
- ❑ Death is an un-American activity
- ❑ The medical profession – profits, fear of litigation, lobbying
- ❑ The pharmaceutical industry – profits, lobbying
- ❑ Politicians
- ❑ The legal profession – profits, lobbying, stirring the pot

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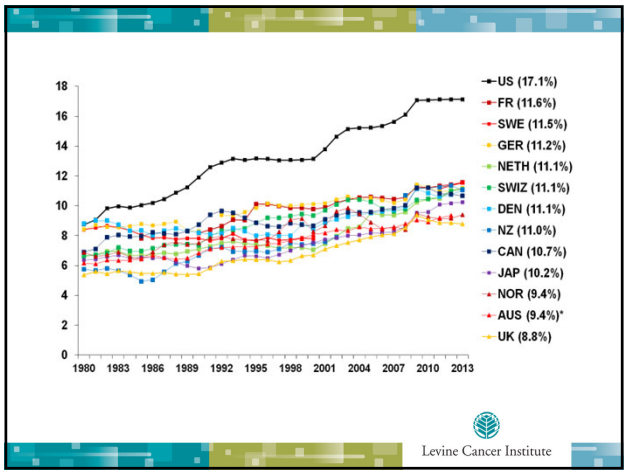

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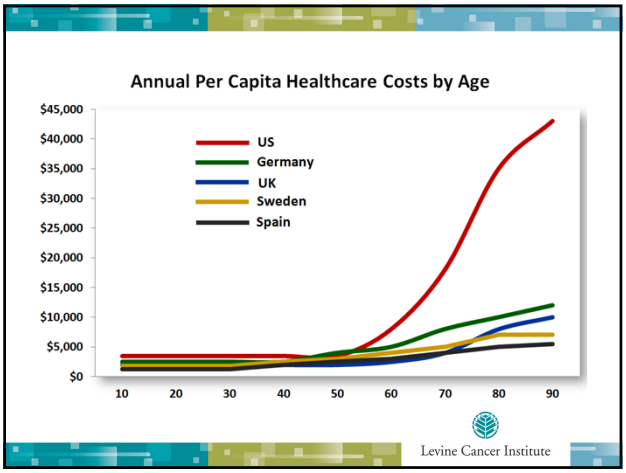

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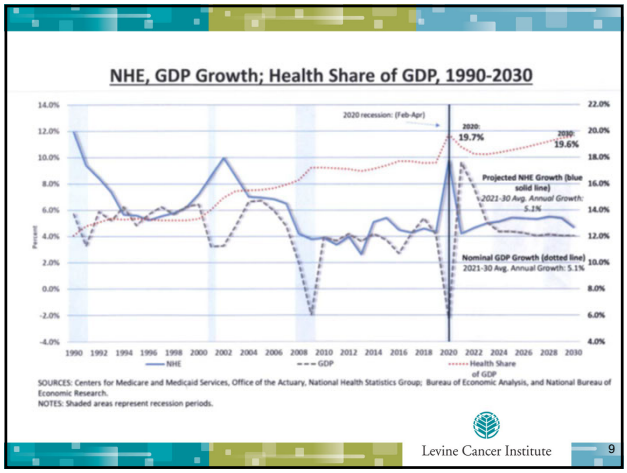

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Community Expectations

- ❑ The Press – cancer a "hot" topic
- ❑ "War on Cancer" generated false expectations, regularly revised as false expectations
- ❑ Driven by politicians
- ❑ Driven by experts with/ without skin in the game
  - Dartmouth
  - Ethicists
- ❑ Leapfrog, Press Ganey & clones – patient surveys
- ❑ Conflicts of interest in government evaluations
- ❑ Health Policy "experts"
- ❑ Influence of advocacy groups
  - Tension between science and opinion?
  - Influence of opinion leaders

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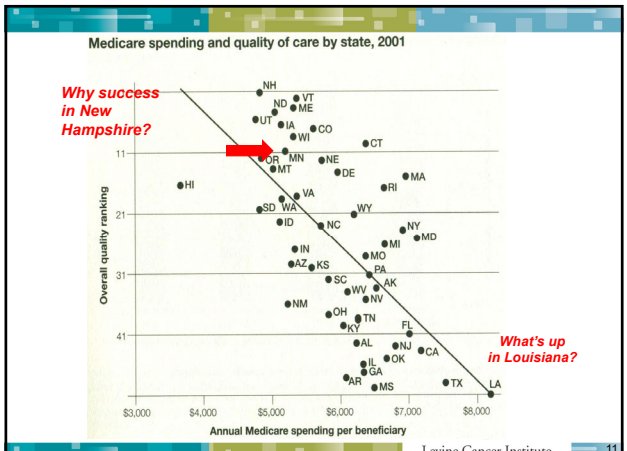

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What's The Story in NH and LA?

- **New Hampshire:**
  - Small area
  - Educated
  - Fewer indigent
  - High density academics
  - High density proximate hospitals
  - Dartmouth engineers of healthcare
  - Work conditions
  - Liberal state
- **Louisiana:**
  - Poverty
  - Large state
  - Poor access
  - Poor education
  - African American cultural issues
  - Targeting of advertisers
  - Work conditions
  - Conservative state

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Health Insurance Issues

- **Lack of transparency**
- **Profit margin (medical/hospital/CMS issue too)**
- **Changing rules and fine print**
- **Tricks to avoid payment**
- **Approaches that defy logic**

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Strategy for Health Plans

(Porter & Teisberg, 2006)

- **Provide health information and support to patients/physicians**
  - **Organize around medical conditions, not geography or administrative functions**
  - **Provide comprehensive disease management/prevention services for all members, healthy or unhealthy**
  - **Provide information and transparency regarding outcomes**
- **Restructure the health plan – provider relationship**
  - **Reward excellence/innovation**
- **Redefine the health plan – subscriber relationship**
  - **End cost-shifting practices**

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Bottom Line of a Sensible Approach

- **Access**
- **Partnership**
- **Involve key stake holders**
- **Functionally driven**
- **Comprehensive (including research that pays for itself)**
- **Transparent**
- **Reward excellence and value (and define both)**

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Measured Outcomes vs. Expectations

- **Changing Endpoints**
  - Survival
  - Quality of life
  - Cost
  - Patient satisfaction
  - Molecular targets
  - (Poorly connected to community expectations)
- **"Hype"**
- **Institutional advertorials**
- **Meetings & abstracts vs. published peer-reviewed data**
- **Real progress**
  - Peer reviewed publication
  - Survival statistics
  - Randomized trials
  - Be careful with "real world" data

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Proposed Strategic Approach to Cut Health Care Costs

- **Stay on top of the science**
- **Integrate clinical trials with rational design and careful costing**
- **Manage <u>across the system</u>**
  - Porter & Teisburg
  - Avoid skimming
- **Reduce unnecessary tests**
- **Blue ocean/Red ocean strategy**
- **Rational selection of treatment:**
  - Outcomes should drive this
  - Strong scientific rationale
  - Structured palliative care
- **Measure and present robust outcome data**
- **Listen to the lay evaluations, but structure them carefully**
- **Don't listen to everyone**

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An Important Added Dimension: The Value Proposition

- ❑ Value = outcomes / cost
- ❑ Cost vs. price
- ❑ Institute of Medicine: Elements of Quality Care Delivery
  - Safety/Effectiveness/Patient Centricity/Timeliness/Efficiency/Equity
- ❑ ASCO Value Task Force:
  - Clinical benefit (efficacy)
  - Toxicity (safety)
  - Cost (efficiency)

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My Strategy

- ❑ Physicians and bio-medical organizations reduce costs
- ❑ Address tort reform in a meaningful way – costs to system are VASTLY under-estimated
- ❑ Provide a safety net – especially for chronic disease and those who run out of health insurance
- ❑ Improve access – centrifugal approach, multi-site
- ❑ Re-educate the community about realistic expectations
- ❑ Require training for those who tinker with the system
- ❑ Reward excellence
- ❑ Transparency
- ❑ Refine costs of biomedical development

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Philosophy of Cancer Treatment

- ❑ Cure when possible
- ❑ Maximize length and quality of life
- ❑ Pioneering in science
  - Laboratory to clinic
  - Clinic to laboratory
- ❑ Care of the patient and family
- ❑ Rationalize costs when possible and ethically sound

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A Practical Example: Carolinas HealthCare System Cancer Care 2010

- ❑ Carolinas HealthCare System (2010) – no organized cancer care, patient out-migration, no BMT services
- ❑ 38 hospitals; NC, SC; > 50,000 staff; > 1500 physicians
- ❑ 12 million encounters/year
- ❑ Levine Cancer Institute – established 2011 to solve problems:
  - 6,500 new cases/year in 2011 – loss of complex cases from system
  - No organized approach to management standards or research
  - Small internally competitive teams
  - Generally high clinical quality

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A Practical Example: Levine Cancer Institute 2011 Game Plan

- ❑ Addressing costs and inconvenience of care
- ❑ Attracting new expertise to the region
- ❑ Integrate extant resources
- ❑ Bringing research to this area
- ❑ A new model of patient support
- ❑ Electronic standardization and evidence-based approaches
- ❑ Symmetrical care across the Carolinas – for everyone!
- ❑ Focus on the value proposition – cost, price, outcomes

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The NEW ENGLAND JOURNAL of MEDICINE

Perspective

DECEMBER 26, 2013

Implementing Obamacare in a Red State — Dispatch from North Carolina

Jonathan Oberlander, Ph.D., and Krista Perreira, Ph.D.

Serious problems have plagued the much-anticipated rollout of the health insurance exchanges created under the Affordable Care Act (ACA). Many Americans have been unable to sign up for insurance about states whose governments oppose Obamacare? How is health care reform faring in states that refuse to implement major ACA provisions? North Carolina is one such

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Our Vision – Changing the Course of Cancer Care

- ❑ Unified enterprise-wide network
- ❑ Spread across two states
- ❑ Patient-centered
- ❑ Research/training incorporated
- ❑ Clinically integrated
- ❑ Best-practice collaboration across the enterprise

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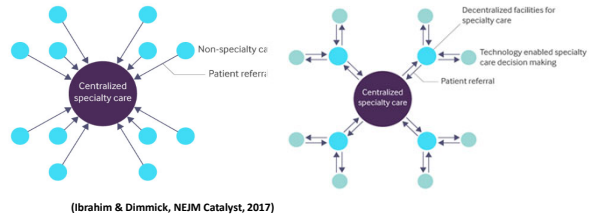
Current Model of Centralized Specialty Care | **Emerging Model of Decentralized Specialty Care**



(Ibrahim & Dimmick, NEJM Catalyst, 2017)

Decentralized specialty care enables access to high quality care and clinical trials that otherwise would not be available. ***New Cases 6,500/yr → 20,000/yr***

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ALIGNING ORGANIZATION TO GOALS

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Levine Cancer Institute Hospital Membership Criteria

- ❑ Central IRB – Advarra
- ❑ Local 0.1 FTE leader
- ❑ Staff participation in tumor boards/conferences
- ❑ E-treatment pathways
- ❑ Patient Navigation
- ❑ SOP's and quality
- ❑ All patients seen
- ❑ Clinical trials infrastructure
- ❑ Participation in survivorship programs
- ❑ Complementary/integrative cancer medicine program
- ❑ E-genetic counseling
- ❑ Disparities program

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Clinical Operations

- ❑ Tumor-Specific Teams
- ❑ Tumor-Specific Conferences: via Video/Live
- ❑ Standard Operating Procedures and E-pathways
- ❑ Electronic Connection
- ❑ Tele-medicine
- ❑ One standard of care - everywhere
- ❑ Multi-site decentralization

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CURRENT STATUS

- Organizational Structure – 4 Departments/Tumor Specific Divisions – clinical and research
- Major outreach and DEI programs
- Substantial commitment to Supportive Oncology
  - Survivorship
  - Palliative Cancer Medicine and Rapid Response Pain Team
  - Psycho-Oncology
  - Cancer Integrative Medicine
  - Cancer Rehabilitation Program
- Fellowship training programs:
  - Hem/Onc (12)
  - Breast Surgical Oncology (1)
  - Urologic Oncology (1)
  - Supportive Oncology (2-3)
  - Gynecologic Oncology (1)

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CURRENT STATUS – TRANSLATIONAL SCIENCE

- 25,000 square feet of lab space in LCI-2
- Cores
  - Molecular Core (Nury Steuerwald, PhD)
  - Immunobiology Core (David Foureau, PhD)
  - Cancer Pharmacology/Pharmacogenomics Core (Jai Patel, Pharm D)
  - Hematologic Oncology/Stem Cell Core (Larry Druhan, PhD)
  - Drug Discovery Core (Don Durden, MD)
- Cancer Biostatistics – 7 PhD/MSc staff
- Cancer Trials Office – 130 staff
- Biospecimen Repository
- Molecular Tumor Board and Research Support Services
- Processing Laboratory for BMT/CAR-T

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Clinical Trial Operations

- ❑ **Central Institutional Review Board**
- ❑ **Central data management and research nursing**
- ❑ **Relevant protocols**
- ❑ **Balanced budget**
  - Free agents when collaborate with some pharmaceutical teams
- ❑ **Electronic pathways**
  - Down-loading of paper work and consent sheets
  - Identify where research protocols exist/are needed

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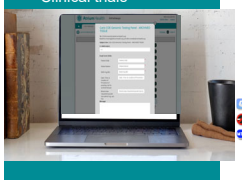
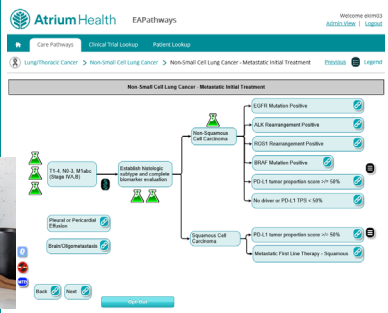
EA Pathways ensure access to

- Evidence based care pathways
- Tumor-specific teams
- Clinical trials





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Key Metrics: Accrual

Sponsor Type	2019	2020	Total
Interventional Treatment	489	427	916
Interventional Non-treatment	41	3,173	3,214
Non-interventional	2394	1,054	3,448
Total	2924	4,654	7,758

(20% are patients of color)

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Role of the Oncology Nurse Navigator

- ***Definition: oncology way-finding by experienced nurses***
- ***45 navigators***
- ***All tumor types***
  - ***Distance navigator***
  - ***Minority navigators***
- ***Developed software***
- ***Metrics***

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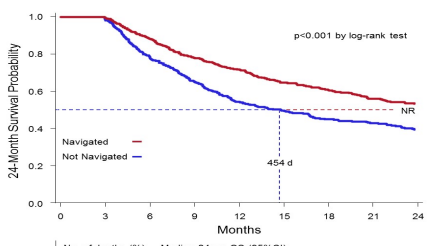
Impact of Nurse Navigation (Propensity Matched Study)



	No. of deaths (%)	Median 24 mo OS (95%CI)
Navigated	178 (46%)	NR (667-NR)
Not Navigated	230 (59%)	454 d (354-545)

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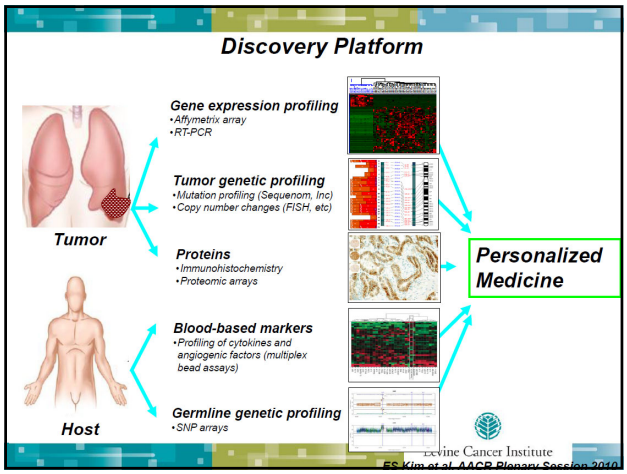

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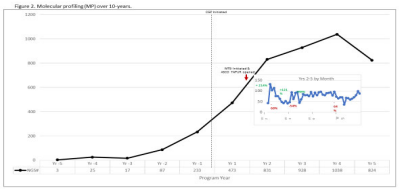
Molecular Profiling Pattern (Farhangfar et al, JCO-CCI, in press)



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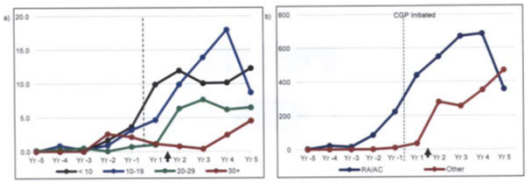
RESULTS:



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RESULTS:

- After CGP implementation, the number of physicians using MP and number of MP tests increased ≥10-fold.
- The proportion of Hispanic patients with MP was the same as that in the system (both 2%) with marginal differences observed in proportion of African Americans tested compared to the system population (16% vs 19%).
- Physicians followed MTB treatment recommendations in 74% of cases. Rapid clinical decline was the most common reason why physicians did not follow MTB recommendations.
- Clinical trial accrual was 15% (669/4459) for patients with MP alone; 28% (94/334) with both MP and MTB review. Clinical trial availability and patient out-of-pocket costs impacted MP use.

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Phase I Key Accomplishments

98 accruals in 2019	Heme Phase I accrual increased by 45.5% YoY (48 accruals) Solid Phase I accrual increased by 61.3% YoY (50 accruals)	Implementing designated CAR-T Team Enrolled over 100 CAR-T/BCMA patients
Enrolled 2 patients first in world	Opened additional Phase 1 Unit at LCI-Concord	Continued enrollment on Phase 1 Trials with required inpatient hospitalization during pandemic
Project Managers assigned to all Phase 1 Trials	Managing 71 Trials (Phase I/II-44, Phase 1b-27)	

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KEY DOMAINS OF CANCER TRIALS

- Phase I(FIRST IN MAN --- 90-100 entries per year)
- Phase II (e.g. TAPUR, ENZADA, Breast Cancer) – FREE DRUGS
- Cooperative Group Phase III
- High profile (new drug) pharmaceutical industry phase III (if we get named authorships/leadership)
- IIT's
- Pharmacogenomics
- Molecular prognostication – GI and GU cancers
- BMT/CAR-T/Lymphoma/Plasma Cell Disorders – major focus on minimal residual disease and immunologic modulation, new drug development

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Survivorship

- **Survivorship Program**
  - Identification via Tumor Registry and Physicians
  - Structured algorithms
  - Engagement of medical staff of system hospitals & practices
  - Engagement of key physicians for patients
  - Administrative system-wide structure – INCLUDES MEASUREMENT
  - Examples:
    - Long term survivor after radiotherapy for breast cancer
    - Long term survivor after chemotherapy for metastatic testis cancer
    - Psychological issues
    - Kids who are now adults

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Levine Oncology Program for Seniors

- **Identify defining issues and desirable outcomes**
  - **Who SHOULD be treated**
  - **Who SHOULD NOT be treated**
- **Geriatrician in place & support base in development**
- **Specific oncology & support personnel**
- **Novel approaches for older cohorts**
- **Focus on the WELL-ELDERLY**
- **Based at peripheral hospital centers**
- **Adaptive technology**
- **Age-adapted decisions regarding treatment = value**

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Potential Impact of Levine Cancer Institute

- **Care near home – less travel, accommodation, time**
- **Evidence-based standard approaches**
- **Optimal support – navigation, survivorship**
- **Focused cancer research and clinical trials**
- **Resources spread through the system – ALL patients**
- **Electronic support – tumor boards, video conferences, access, genetic counseling, second opinions, telemedicine (e.g. pain Rx)**
- **Costs addressed actively**

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Addressing Costs

- **Multi-site – less travel**
- **Evidence-based medicine**
- **Standardized approaches**
- **Oncology Pharmaceuticals Committee**
  - Cost effectiveness
  - Cost vs. price
  - IOM Choosing Wisely Principles
- **Active unit of Supportive/Palliative Medicine – on Pathways**
- **Clinical trials on the Pathways**
- **Financial Toxicity Tumor Board**

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Levine Cancer Institute Financial Toxicity Tumor Board

- **Raghavan et al, JCO-OP, June 2021 doi.org/10.1200/OP.21.00124**
- **Multi-disciplinary tumor board focused on financial toxicity**
- **$55 & $60 million in patient savings 2019 and 2020**

TABLE 2. Key Issues Addressed by the FTTB

Problem	Proportion of FTTB Cases (%)	Rate of FTTB Case Resolution (%)	Cases Affected by SOP or Policy Changes (%)
Uninsured or underinsured	29	43	43
Payer impediments	24	67	83
Coding or billing complexities	20	60	40
Precertification	4	100	100
Inadequate internal process[a]	20	80	100

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Cost Containment – Broader Efforts

Published Ahead of Print on April 3, 2012 as 10.1200/JCO.2012.42.8375
The latest version is at http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2012.42.8375

JOURNAL OF CLINICAL ONCOLOGY | ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Identifies Five Key Opportunities to Improve Care and Reduce Costs: The Top Five List for Oncology

Lowell E. Schnipper, Thomas J. Smith, Derek Raghavan, Douglas W. Blayney, Patricia A. Ganz, Therese Marie Mulvey, and Dana S. Wollins

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INSTITUTE OF MEDICINE – CHOOSING WISELY
ASCO Recommendations 2012

- ❑ Don't use cancer-directed therapy for solid tumor patients with low performance status (ECOG 3-4), no benefit from prior evidence-based interventions, not eligible for clinical trial, no strong evidence supporting value of further Rx
- ❑ Don't perform PET, CT and bone scans in staging of early prostate cancer at low risk for metastasis
- ❑ Don't perform PET, CT and bone scans in staging of early breast cancer at low risk for metastasis
- ❑ Don't check biomarkers or scans for asymptomatic patients treated for breast cancer with curative intent
- ❑ Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with less than 20% risk

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INSTITUTE OF MEDICINE – CHOOSING WISELY
ASCO Recommendations 2013

- ❑ If low/moderate risk of nausea/emesis, don't initially use expensive agents targeted vs. severe emesis
- ❑ Don't use combination chemotherapy for metastatic breast cancer unless rapid response needed to relieve symptoms
- ❑ Avoid PET or CT-PET scanning for routine follow up to monitor recurrence unless there is strong evidence that this will improve outcome
- ❑ No PSA screening for asymptomatic males with life expectancy less than 10 years
- ❑ Don't use targeted therapy intended for specific genetic aberration unless tumor cells show marker that predicts likely response

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Improvements

- ❑ QUALITY
  - via standardized, evidence based pathways
  - System-wide tumor conferences, education, pathway design
  - System approach to drug shortages
- ❑ IMPROVED COST
  - via pathways, trials, access, less travel
  - Integrated selection of palliative/supportive care
  - Trial selection linked to clinical practice section policy

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Next Generation

Cancer program teaches students to make a difference

Lessons teach children the value of healthy living

BY AUSTIN BAILEY

FOREST CITY — Sixth-graders at Chase Middle School have learned they can make a difference in cancer prevention after completion of the I CAN program.

The six-lesson program taught by Cancer Program Development Specialist Tiffany Crank of Levine Cancer Institute covered topics such as melanoma, stress, tobacco use, physical activity and eating healthy. The program is designed to help youth encourage their friends, families and communities to live healthier lives as a means of preventing cancer.

It began as a collaboration between the Levine Cancer Institute and the Girls Scouts Hornets' Nest council.

Crank has taught the program to students at Forrest Hunt and Cliffside Elementary schools as well as Crest and Shelby Middle schools prior to visiting Chase Middle.

Approximately 30 students in Sherry Matheny's health class at Chase participated in the program. Overall, Crank says the program has served over 1,000 students in Cleveland and Rutherford counties and the success of the program is measured by pre and post test scores for each lesson taught.

"For the programs completed in Cleveland and Rutherford counties, the average pre test score has been 87.4 percent and the average post test score has been 98 percent," said Crank.

SEE PROGRAM PAGE A6

Austin Bailey/Daily Courier

Students show off their certificates of completion along with Tiffany Crank, far left, and Sherry Matheny, far right.

DEATHS INSIDE

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Measurement

- ❑ Cost per case
- ❑ Survival
- ❑ Toxicity requiring admission
- ❑ Percentage of patients on cancer trials (& absolute numbers)
- ❑ Important innovations
- ❑ Published data, grants and contracts
- ❑ Patient-centric outcomes

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Disparities of Care: Consider the Problem → Create Solutions

Underserved Groups:

- African American
- Hispanic
- Rural
- Elderly
- Isolated
- Disabilities
- Immigrant

Indicators of Risk:

- Poverty
- Poor education
- Language & literacy barriers
- (Lack of insurance)
- Isolated geography
- Cultural
- Co-morbidities (Veterans)
- Health system issues

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COMMITMENT TO UNDER-SERVED:

- Program established 2011
- Key initiatives:
  - Education, outreach and fairs
  - Screening for cancer – breast, colo-rectal, skin, and prostate (in African Americans)
  - Fire fighter/first responder program – 3000+ educated, multiple screenings
  - "Lung Bus"
  - Food insecurity
  - Contact tracing during COVID
  - Pre-med Education – approx. 25 → medical school in past decade
  - High School Education
    - Minority "troubled youth" via Police Rehab Team
    - Broad range of HS students
- Fellowship Training – participation in match – small cadre of minorities to date

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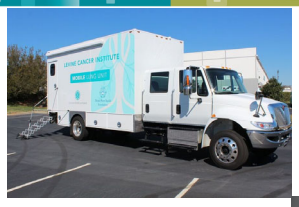
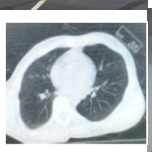


- *First in USA*
- *1500 heavy smokers*
- *26/38 localized cancers treated with curative intent*
- *Cardiac disease*
- *Follow-up scans*
- *S-E randomized trial*



- *Low dose CT scans*
- *High-risk subjects – 45 pack yr*
- *Nurse navigation*
- *Education of local docs*
- *Meticulous follow up*
- *Central radiology review*

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RESULTS:

CANCER DIAGNOSIS: 28 NSCL 1 SCLC 1 NET

•30 cases

- 7/213 African American (3.3%)
- 23/987 Caucasian (2.4%)
- 0 Hispanic/Latin-X/Native American

Other cancers: RCC (2) Pancreas (2) NPC (1)

(Carrizosa et al, Proc ASCO, 2021, abst 6540)

LOST TO FOLLOW-UP: 68 (5.7%)

ADDED 488 SCREENED → 9 CANCERS

23 early stage/39 lung cancers (ASCO 2022 update)

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Levine Cancer Institute – Atrium Health

2021 ASCO ANNUAL MEETING

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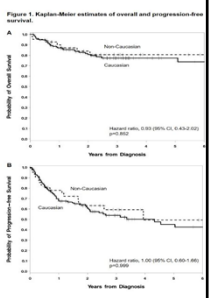
Minorities Do Not Have Worse Outcomes for Diffuse Large B Cell Lymphoma (DLBCL) If Optimally Managed

	Caucasian n= 155 (79%)	Non-Caucasian n=41 (21%)	P-value
Median age at diagnosis, years [range]	64 [19 to 90]	56 [26 to 85]	0.010
Male	74 (48%)	20 (49%)	>0.999
IE-IPI			
Very Good	7 (5%)	2 (5%)	0.824
Good	58 (37%)	18 (44%)	
Poor	69 (45%)	17 (41%)	
Missing	21 (14%)	4 (10%)	
Double hit	17 (11%)	3 (7%)	0.772
Insurance Type			
Government	104 (67%)	27 (66%)	0.012
Private	51 (33%)	11 (27%)	
Uninsured	0 (0%)	3 (7%)	
Frontline Treatment			
R-CHOP	103 (66%)	29 (70%)	0.574
R-EPOCH	18(12%)	6 (15%)	
Other	34 (22%)	6 (15%)	
Relapsed/Refractory to frontline therapy	63 (41%)	16 (39%)	>0.999
Median number of treatments received	2 (range 1-12)	2 (range 1-7)	0.582
Received Stem cell transplantation	17(11%)	8 (20%)	0.186
Enrolled on clinical trial	17 (11%)	5 (12%)	0.785



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SUMMARY

- ❑ Address problems of access, disparities of care, and quality
- ❑ Increasing regulation, oversight & documentation
- ❑ Decreasing reimbursement
- ❑ Government shell games
  - States vs Federal
  - Reduced reimbursement
  - Political conflicts of interest
- ❑ High community expectations
- ❑ Reducing funds for research
- ❑ Lay evaluations & advocates
- ❑ Impact of the press
- ❑ Increased sophistication of science
- ❑ Quality CAN be maintained with fiscal restraint

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