Challenge of a Clean Slate – Designing Rational Cancer Care & Research for a Health System

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PRESIDENTIAL POLITICS

HEALTH CARE

WORDS IN COMMON

INTEGRITY
SECURITY
RELIABILITY
BIG DATA

INTEGRATION
COST MANAGEMENT
FIDELITY

HONESTY
TRACK RECORD

LEADERSHIP EDUCATION CONFERENCE
Objectives

• After this presentation, participants should be able to:
  – Understand elements of creating a new system for cancer research and management
  – Integrate key factors in the value proposition into the implementation of cancer care programs
  – Know how clinical pathways are integral to the creation of a symmetrical health care system
  – Improve accrual to important cancer trials

Environmental Assessment 2010

• Large population of patients with cancer
  – insufficient organization
  – poor access to first-class care and research – particularly for geographically distant patients
  – variable quality of care
• Impact of Affordable Care Act
• North Carolina not participating in federal support program
• Increasing numbers of indigent/self-pay/Medicaid/Medicare
• Carolinas Health Care System – safety net
• Increasing costs of care – especially in cancer field
• Greatest cost increment in the elderly
• Problems with access to care and translational research
• Increasing complexity of science and treatment in oncology
• Efflux of patients for routine and complex care
Our Vision – 2010 Playbook: Changing the Course of Cancer Care

- Unified enterprise-wide network
- Spread across two states
- Patient-centered
- Emphasis on VALUE
- Clinically integrated + research
- Best-practice collaboration across the enterprise
- Cost considerations

ALIGNING ORGANIZATION TO GOALS

How do we Align Organization to Strategic / Goals?
Structure for Enterprise Engagement & Collaboration

2x/Year
Enterprise Summits
Education, Networking/Team Building

Quarterly
Enterprise Cancer Strategy Council
Coordination of Enterprise Cancer Initiatives
Launch by May 2011

Monthly
Charlotte Regional Cancer Strategy Council
Western Regional Cancer Strategy Council
Lowcountry Regional Cancer Strategy Council
Upstate Regional Cancer Strategy Council

Market Development, Regional Tumor Site Planning & Development

Levine Cancer Institute – Charter Membership

- AnMed
- Blue Ridge Healthcare
- Cleveland Regional
- CMC
- CMC-Lincoln
- CMC-Mercy
- CMC-NorthEast
- CMC-Pineville
- CMC-Union
- CMC-University
- Roper-St. Francis
- Stanly Regional
LCO Participation Agreement - Elements

- General requirements
  - 0.1 FTE for local cancer program
  - Commission on Cancer, etc.
- Accreditation
- Quality of Care
- Patient Navigation
- Multidisciplinary Conferences and Tumor Site Teams
- Information Technology
- Data Monitoring and Sharing
- Clinical Research
  - Single IRB – Chesapeake
  - Active support
- Marketing & Branding
- Healthcare Disparities and Community Outreach

RECRUITMENT
Leadership

- Ed Kim MD FACP (MDAH)
- Ed Copelan MD FACP (CC)
- Belinda Avalos MD (OSU)
- Declan Walsh MD FACP FRCP (CC/TC)
- Antoinette Tan MD FACP (Rutgers/RWJ)
- Jimmy Hwang MD (GU)
- Stuart Burri MD
- Roshan Prabhu MD (Emory)
- Steve Rigg MD (EVU)
- Jubilee Brown MD (MDAH)
- Ram Ganapathi PhD (CC)
- Carol Farhangfar PhD (MDAH)
- Jim Symanowski PhD (NCCC)
- Jon Gerber MD (Hopkins)
- Saad Usmani MD FACP (Arkansas)
- Nilanhan Ghosh MD (Hopkins)
- Pete Voorhees MD (UNC Chapel Hill)
- Steve Park MD PhD (UNC Chapel Hill)
- Maryann Knovich MD (Wake Forest)
- Ify Osunkwo MD (Emory)
Initial LCI Strategic Growth Initiatives

- Bone Marrow Transplantation
  - Increased target 20 → 50 (>200 done, FACT accredited at 2 yr)
  - Staff increments
- Clinical Pathways
- Growth of HemOnc Program:
  - Lymphoma program
    - New recruits in place – Hopkins, MDAH, Cleveland Clinic
    - Outreach to physicians
    - New referrals have begun
  - Myeloma program with rapid increase in patients & trials
    - New recruits from Arkansas, NCI, UNC and MD Anderson Cancer Institute
    - Outreach visits to referring doc’s in progress → new referrals
- Expansion of Phase I-II Trials
  - Studies active
  - New unit at Charleston SC
  - New unit at Concord NC opening
- Survivorship Initiatives
  - Cancer Rehabilitation
  - Survivorship & Navigation
  - Cancer Supportive/Palliative Medicine
  - Patient and family support
- LCI Expansion Project
  - Business plan established
  - Targets established
  - New sites – 22 rural & suburban

LCI New Patient Clinic Visits

Increase of 63% from 2010 - 2014

Total > 16,000

• Primary Enterprise locations
Expansion Throughout Health System

- **Data from:**
  - Tumor Registry
  - Billing Information
  - Referrals and participation in cancer trials

- **Physical site expansion projects:**
  - LCI Union Hospital, Monroe NC
  - LCI Northeast Hospital, Concord NC
  - LCI Pineville Hospital, Pineville NC
  - LCI Cleveland Regional, Shelby NC
  - LCI St. Lukes Hospital, Tryon NC
  - LCI University Hospital, North Charlotte NC
  - LCI Lincoln, Lincolnton NC
  - LCI Columbus Regional Med Center, Whiteville NC
  - LCI Stanly Regional Med Center, Albemarle NC
  - AnMed Hospital, Anderson, SC
  - Roper-St Francis-Bon Secours, Charleston, SC
  - LCI Rock Hill, SC
Meticulous Fiscal Planning

- Business plan at the base of each initiative
- Value shift → *value-driven volume algorithm*
- Strong fiscal administrative leadership
- Bone marrow transplant unit – contracting via LCI
- Careful due-diligence on new geographic sites
- Extensive disparities program – offset by 340B pricing
- Pharmacy/pharmacology Committee for drugs
- Increased control of research finance
- Essential services that don’t pay – even tighter control

NEXT GEN. STRATEGIC INITIATIVES

- Further expansion of hematologic oncology
  - New divisions
  - Expansion of trials
  - Funded research
- Further expansion of solid tumor oncology/investigational therapeutics
  - Investigator initiated trials – major emphasis, with rapid completion
  - Significant Return on Investment for CHS
  - EA Pathways – definable management, cost, and outcomes
  - Participation in ASCO TAPUR study – 75% of registered cases to date, half from peripheral centers!
- Value driven approach via pathways
  - Quality
  - Contracting
- New domains
  - Endocrine oncology
  - New collaboration – Carolinas Ear Eye Nose Throat (CEENTA) – via PSA’s
  - Department of Medical Support & Survivorship Services
  - Dermatologic Oncology
Phase I (first-in-man) Clinical Trials

- Variety of different trials needed with different drug pathways involved
- Broad molecular marker reflex testing may assist in directing patients to particular clinical trials
  - Funds set aside to assess tissue biomarkers in all phase I patients
  - Pharmacogenomic collection
- Staff: Phase I research team, PharmD, PA
- Commenced July 2013 – 3 sites – Charlotte, Charleston, Concord
- Trials now under way
- Center of Excellence – molecular diagnosis with Caris

Molecular Prognostication (using genes to predict outcome)

- CHS labs – Steuerwald (molecular), Foreau (immunol)
- Caris Centers of Excellence
  - LCI
  - Georgetown University/Lombardi Cancer Center
  - Wayne State/Karmanos Cancer Institute
  - U Tenn./West Clinic
  - Fox Chase Comprehensive Cancer Center
  - New sites being added
  - >80,000 specimens with molecular characterization
  - LCI consulting provides their biostatistical support
- Relationship with UNC Charlotte Genomic Biostats
**OVERALL SURVIVAL**

- **Gene expression profiling**
  - Affymetric array
  - RT-PCR
- **Tumor genetic profiling**
  - Mutation profiling (Sequenom, Inc)
  - Copy number changes (FISH, etc)
- **Proteins**
  - Immunohistochemistry
  - Proteomic arrays
- **Blood-based markers**
  - Profiling of cytokines and angiogenic factors (multiplex bead assays)
- **Germline genetic profiling**
  - SNP arrays

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Carolina HealthCare System
Cancer Pathways and Trials

- EAPathways
- Levine Cancer Institute
- Secure, Web-based
- Customize to any health system
Role of the Oncology Patient Navigator

45 navigators
All tumor types
Distance navigator
Developed software
Metrics

Presentations at national meetings
5th Navigator Academy
Median survival incr. 1 yr

LCI Survivorship & Supportive Care

Medical/Clinical
Examples:
Survivorship Care Plans
Acute Nutritional Interventions
Lymphedema Program
Survivorship Clinics
Incontinence/Impotence Program
Fertility Preservation/Assistance
Rehabilitation Programs
Long Term Survivorship Research

Psychosocial
Examples:
Social Work
Counseling
Support Groups
Psychoeducational Classes
Psychiatry Consultation
Pastoral Care
Financial Counseling

Wellness
Examples:
Exercise Program
Nutrition
Lifestyle Counseling
Tobacco Cessation
Substance Program (AA/NA)
Weight Management

Integrative Oncology
Examples:
Integrative MD Consults
Integrative therapies
Class/Groups/Workshops
Integrative trained Staff
Integrative Research
LCI/Planetree Project – System Wide

Executive Readiness Sessions
Staff Information Sessions
Organizational Assessment
Kick off Celebration/Facilitator Training
Staff and Physician Retreats
Steering Committee

LCI Accreditations

• Commission on Cancer (CoC) – outstanding award/Gold commendation; max. of 7/7 commendations
• ASCO Quality Oncology Practice Initiative (QOPI)
• National Accreditation Program for Breast Centers (NAPBC®)
• External Advisory Board
• Foundation for Accreditation of Cellular Therapy (FACT)
• Survivorship Training and Rehabilitation Program (STAR)
• American College of Radiology
• Magnet (Carolinas Medical Center)
• We have not sought NCI designation – advice of EAB
Levine Cancer Institute has partnered with System Pathologists to develop an Inter-Facility Quality Assurance Program. This program when fully implemented will ensure Carolinas HealthCare System is functioning optimally as a coordinated system for the cancer patients we serve.

LCI - Pathology Project Phases

Administrative/Support Processes Established

Case Selection Criteria Established

Pilot Currently In Process

Program Feedback LCI Summit-Dec 2015

Implement System wide 2016
Value Proposition

- EA Pathways
- Integrated Pharmacy and Therapeutics Committee
- Importance of Supportive/Palliative Medicine
- Measurement of real outcomes, not just p values
- ASCO Choosing Wisely Campaign
- ASCO/ESMO attribution of value
- Avoidance of ineffective therapies
- We did NOT initiate proton beam therapy at this time

LCI Clinical Research

- Accruals and number of clinical trials increased as well as complexity of studies
  - >300 Clinical Trials open at end of 2014
  - ~40% of studies pending are Phase I (9) or Investigator-initiated (12)

- Trial financial performance
  Example:
  - Ipilimumab trials
    - Meticulous, REAL budgets
    - Time allocation
  - Attracted patients from 31 NC/SC counties and 6 states
LCI Physician Presentations

- “Phase II study of daratumumab (DARA) monotherapy in patients with ≥ 3 lines of prior therapy or double refractory multiple myeloma (MM): 54767414MMY2002” (Dr. Saad Usmani, ASCO 2015)

- “Identification Of Tight Junction Protein (TJP)-1 As a Modulator and Biomarker Of Proteasome Inhibitor Sensitivity In Multiple Myeloma” (Dr. Saad Usmani, ASH 2013)

- “Five Gene Probes Carry Most Of The Discriminatory Power Of The 70-Gene Risk Model In Multiple Myeloma” (Dr. Saad Usmani, ASH 2013)

- “Correlation of acute myeloid leukemia (AML) stem cell phenotype with cytogenetic/molecular features and prognosis.” (Dr. Jon Gerber, ASCO 2015)

- “Nivolumab (anti-PD-1; BMS-936558, ONO-4538) in combination with sunitinib or pazopanib in patients (pts) with metastatic renal cell carcinoma (mRCC)” (Dr. Asim Amin, ASCO 2014)

LCI Research - Publications

- ~1200 publications/abstracts since 2010
- JAMA publication, 2016 – S. Burri/A. Asher
  - Radiation approaches for brain mets
- NEJM publication, 2015 – D. Haggstrom
  - AZD9291 in EGFR Inhibitor-Resistant NSCLC

- Submission to national meetings increasing annually
LCI Research Grants (2013 – present)

PI: Saad, Usmani, MD
- Amount: $929,180.00
- Sponsor: National Institutes of Health (NIH)
- Title: PET Scan for Prognostication in Newly Diagnosed High Risk Multiple Myeloma

PI: Saad, Usmani, MD and David Foureau PhD
- Amount: $87,850
- Sponsor: International Myeloma Foundation
- Title: Minimal Residual Disease (MRD) Measurement by Flow Cytometry for Newly Diagnosed Multiple Myeloma

PI: LCI, Disparities
- Amount: $75,000 (Hearst Foundation), $25,000 Carolinas HealthCare Foundation
- Sponsor: Hearst Foundation and Carolinas HealthCare Foundation
- Title: Think PINK Stanly County - A Rural Breast Cancer Outreach Program

PI: Manisha, Bhutani, MD
- Amount: $50,000 (2 years)
- Sponsor: Conquer Cancer Foundation of ASCO
- Title: Evaluating and targeting mechanisms of resistance with extended dosing of lenalidomide in multiple myeloma (MM)

PI: Jai Patel, PharmD
- Amount: $20,000 (18 months)
- Sponsor: ASHP Research and Education Foundation
- Title: Impact of a Pharmacist-driven Personalized Medicine Approach Using Pharmacogenomics and Therapeutic Drug Monitoring to Optimize Voriconazole Prophylaxis

PI: LCI, Disparities
- Amount: $5,000
- Sponsor: Genentech Foundation
- Title: Fight Colon Cancer Union County

PI: Ify Osunkwo, MD and Daniel McMahon, MD
- Amount: $150,000 per year ($450,000)
- Sponsor: N.C. Department of Health and Human Services
- Title: SCD Treatment Demonstration Grant

PI's: Derek Raghavan MD PhD and Ed Kim MD
- Amount: $500,000 over two years
- Sponsor: Caris Life Sciences
- Title: Structured studies in molecular prognostication and prediction

Grant Funding to Date: $2,117,030
Innovation

- Stem cell biology of leukemia – Gerber assay system
- New drugs/diagnostic work for multiple myeloma – Usmani
- New drugs for melanoma – Amin
- Cancer pathways – electronic – Kim
- Patient reporting APP – Raghavan/Kim/Accenture
- Navigation software – Green (Stanly Regional)
- New drugs for lung cancer – Haggstrom, Mileham, Kim et al
- New approaches to brain cancer – Sumrall, Burri, Asher
- Multisite approach to cancer care – Raghavan et al
- New approaches to surgery – Salo, Iannitti, Hill, Riggs

Accolades

- Becker’s Top 100 List – hospital cancer centers
- “The Cancer Letter” – two features
- Patient Satisfaction Surveys
- Best Doctors Surveys
- Other Health Systems – e.g. National Cancer Institute
- Sanjay Gupta MD
- “Sixty Minutes”
Future LCI Strategic Growth Initiatives

- Senior Oncology Program
  - Recruitment of ancillary team
  - Focused at Carolina Lakes, Mercy, Stanly
  - Pathways in design phase
- Expansion Thoracic Oncology volumes – contingent on recruitment (in progress)
- Expansion Urologic Oncology volumes – contingent on recruitment (in progress)
- Expansion Colorectal cancer volumes – recent recruitment to Dept. of Surgery
- Established sites – all expanding
- New sites
  - St. Lukes
  - Western expansion
  - Northern expansion
- Endocrine oncology
  - Endocrine cancers
  - Complications of treatment
- Head & neck cancer:
  - Joint recruitment with CEENTA
- LCI Consulting
  - Biostatistics
  - Clinical trials
  - How to build cancer centers
Summary

- 2010 Strategy Playbook → rapid trajectory of growth
- Improved quality with embedded translational research
- Substantial innovation and research → benefits patients
- Tight and robust fiscal management
  - > 60% increase in net margin in 4 years
  - Business plan attached to all ventures, focus on value
- Rapid clinical and research expansion at all sites
- Focus on value proposition
- Research trajectory with business model & funding
- LCI consulting businesses
- Telemedicine
- Social aspects of medical care still heavily emphasized
- Fellowship training program – populates the environs

The Future Looks Bright!
(always be cautious in prediction)