NCI Community Cancer Centers Program

BIOSPECIMENS
SURVIVORSHIP

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Hartford Hospital

• 865 bed community and teaching hospital
• Busy cancer center with 3000 new cases annually (one of largest in state)
• Excellent pathology department
• Multidisciplinary cancer care
• Multifaceted cancer research effort

NCI Community Cancer Centers Program

• Named in 2007 as one of 16 sites in US, only one in New England (now one of 2)
• 2 of the 7 pillars-biospecimens and research
• Every patient has a unique tumor with its own characteristics
• Most cancer therapies are focused on rapidly dividing cells, not individual’s tumor characteristics
BIOSPECIMENS

- It will take many hospitals, cancer centers, MDs and their patients to participate in the translational research needed to produce personalized cancer therapy for a majority of our patients (tens of thousands)
- Community hospitals, therefore, must be involved!

Evidence supporting Biomarker Hypothesis

- Estrogen receptor – Tamoxifen (breast)
- HER2 - Trastuzumab (breast)
- BCR/ABL- Imatinib (CML, GIST)
- BRAF - PLX4032 (melanoma)
- EGFR mutations - Erlotinib (lung)
- Effective targeted therapies we use now!

In 2001, only one of three patients benefited from cancer drug treatment (Spear et al. (2001) Trends Molec. Med. 7, 201-203)

More effective
Less toxic
Less costly
Multiple pre-analytical variables can affect the molecular integrity of the biospecimen

**Variables (examples):**
- Antibiotics
- Other drugs
- Type of anesthetic
- Duration of anesthesia
- Arterial clamp time

**Variables (examples):**
- Time at room temperature
- Temperature of room
- Type of fixative
- Time in fixative
- Rate of freezing & storage temperature
- Size of aliquots

**Basic Requirements of Tissue Collection**
1. Identification of Patients
2. Informed Consent
3. Tissue Collection
4. Tissue Storage
5. Quality Control
6. Data Management
7. Tissue Shipment

*Each of these presents a unique challenge for a community cancer center*

**Total Cancer Care (TCC)**
- Moffitt Cancer Center’s approach to personalized cancer care
- A personalized cancer care longitudinal outcomes study
  - Single protocol and informed consent
  - Biorepository
  - Data warehouse
  - 19 hospital community cancer center consortium

Dr Timothy Yeatman, PI
Dr. William Dalton, Director
Clinical Trial Challenge

- Trial accrual too slow
- Patients do not want to leave home
- 80% of cancer care delivered locally
- Most novel trials performed in Academic Medical Centers
- Existing matching programs send patients to trial opportunities outside their communities

How can we streamline the trial accrual process through "gene based trial matching"?

Molecular Database to identify the right patients

Traditional Clinical Trials

- Broad Patient Population
- 10-12 Years

TurboTrials™

- Molecularly defined population
- ~Half the patients
- <Half the time
- >Response rates

3-5 Years
Total Cancer Care and HH

- Research to develop genetic and molecular “fingerprints” which might lead to targeted therapies in ways that are much quicker than normal
- Patients must be consented prior to surgery/biopsy
- Unique video consent process
- Grant funds 6 positions at HH
- Makes accessible unique treatment trials to patients (even prior ones!)
- All surgeons are collaborating in private practice environment

TCC-WHY DID WE CHOOSE TO PARTICPATE?

- Fulfills need to bring translational science to the community
- Meets NCCCP goal of biospecimen capability
- Obligation of large Cancer Center to contribute as large numbers needed
- Patients and clinicians greatly appreciate opportunity to participate
- Participate (and invest) in the modeling of the future of oncology care

Moffitt Total Cancer Care/Hartford Hospital

- Consented nearly 3000 patients
- Sent 2000 tissues and complete clinical correlative data to Tampa
- Breast, brain, lung, colorectal, kidney, ovary, pancreas
- Prostate-FFPE
- Quality “pass rate” over 90%
- One of highest accrual and quality in consortium!
THE CANCER GENOME ATLAS PROJECT

The purpose of the Cancer Genome Atlas Project is to create an “atlas” of the significant somatic mutations associated with most cancers.

THE CANCER GENOME ATLAS PROJECT

- The Human Genome was successfully mapped in 2003
- Building on this foundation, the TCGA is a collaborative project between the NIH and the National Human Genome Research Institute (NHGRI).
- Mapping of cancer mutations requires large numbers of cancer specimens to ensure statistical significance.
  - More than dozen institutions around the country are involved in tissue collection

Personalized Cancer Care

- Technology has evolved to permit human tumor assessments for individual genes and pathways
- Science suggests gene based trial matching, drug development, and clinical application is feasible if biomarker hypothesis is correct
- Challenges are largely operational
  - Assembling and analyzing huge data banks
  - Communicating with patients and physicians
  - Buy in from research establishment
  - Community hospitals must be involved
- Will likely change cancer medicine and substantially enhance results and decrease toxicity
Evolution

Somewhere, something went terribly wrong

SURVIVORSHIP

• Best practice sharing
• Treatment summary development and implementation
• Psychosocial distress and intervention
• Palliative care program enhancement
• Hospice referrals

NCCCP Palliative Care Work Group

• Develop a network to share resources and best practices to advance implementation of palliative care into community cancer programs

• Identify models of care, quality measures and evidence based tools to assess and manage symptoms and address psychosocial needs across the cancer continuum

• Promote community-based education and training in palliative care among the oncology care team
What is palliative care?

- The care of people with advanced disease states with an emphasis on:
  - Symptom control
  - Communication
  - Advanced care planning
  - Interdisciplinary care
  - Patient, family and caregivers
- Patient experience, not disease process is the focus
- Outpatients also

Palliative Care Matrix

- Support services across continuum
- Case finding
- Hospice services
- Barrier assessment
- Quality metrics
- Staff competencies, support
- Patient education
- Rehabilitation, spiritual care
Psychosocial care

- Assess for psychosocial distress
- Provide interventions as needed
- Patients and families
- Reassess
- Multi-tiered system of care
- Educated providers

Psychosocial Care Matrix

- Facilitates effective communication
- Identify specific patient needs
- Designs and implements plan
- Follow-up
- Education and quality metrics
### Treatment Summary and Survivorship Care Plan Workgroup

#### Goals
- Develop a collaborative network of NCCCP members interested in sharing best practice and resources utilized in implementation of treatment summaries and survivorship care plans
- Address the needs of underserved populations related to treatment summaries and survivorship care plans

### Best Practice Presentations

#### Models and processes within survivorship programs
- Physician
- Advanced practice nurse
- Nurse navigator

#### Templates / resources used to generate treatment summary and survivorship care plans
- ASCO templates
- Journey Forward
- Livestrong Survivorship Care Plan
- Electronic software

### Personalization Beyond Treatment: Survivorship Care

- Treatment summary and Care Plan
- Recommendations based on each patient’s individual treatment history
- Management of Side Effects & Late Effects
- Follow up guidelines and patient-specific schedules
Personalization Beyond Treatment: Survivorship Care

- Health Promotion
  - Exercise, nutrition, smoking cessation
- Prevention and Detection
  - High risk screenings, genetic counseling, screening for recurrence/second malignancies, follow-up care for primary malignancy

In 2008, the Helen & Harry Gray Cancer Center was one of eight programs across the U.S. chosen by the Lance Armstrong Foundation community-based grant program to develop a Survivorship Patient Navigation Program

LAF Grant Program Goals

Pilot Survivorship Program

- 3 year grant to develop a breast cancer survivorship program
- Nurse Practitioner hired to provide the survivorship care
APRN Survivorship Visit

- Breast Cancer Treatment Summary and Care Plan
- Healthy lifestyle
- Immediate health needs
- Follow up plan and guidelines
- Assistance with coordinating patient’s care among existing providers
- Appropriate referrals
- Support programs
- Signs of recurrence and late effects of treatments

Breast Cancer Treatment Summary and Care Plan

- Created using an electronic web-based survivorship record
  – Cogent's EQUICARE CS™
- Follows ASCO, NCCN guidelines

LIVESTRONG
LANCE ARMSTRONG FOUNDATION

Thank You