Clinical Oncology Research and Cancer Care Delivery Research (CCDR) in an Integrated Health Care Delivery System:

The Kaiser Permanente Northern California (KPNC) Experience

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“Emerging” Integrated Health Care Systems: KP NC Version

- Non Profit KP Health Plan/KP Hospitals and
- The Permanente Medical Group (TPMG)
- 2 distinct corporations with exclusive contracting re: TPMG receives prepaid $ for MD services including shared health care delivery planning.
Unique Features of KP NCAL: Size and Integration

- 3.5 million members 90 x 90 miles. 35% of market, 1% of the US cancer burden
- 8000 NCal TPMG MDs (100 Med oncs, 25 Rad oncs, 20 Gyn oncs)
- 20 KP Hospitals/Med Centers, 40+ clinics, Pharmacy. KP/TPMG exclusively
- 99% of Cancer care within system (not BMT)
**Diverse Patient Population:**

**KPNC/KP NCORP**

3.5 M KPNC and 8.1 M KPNCORP members reflect the socioeconomic profile of the West Coast.

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<th>KPNC</th>
<th>KP</th>
<th>KPNC NCORP</th>
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<tr>
<td><strong>Accrual</strong></td>
<td>65.7%</td>
<td>60 %</td>
<td>59 %</td>
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<tr>
<td><strong>Caucasian</strong></td>
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<td><strong>Hispanic</strong></td>
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<td><strong>Non Caucasian</strong></td>
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<td>41</td>
<td>34.3</td>
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<td><strong>&gt;65yo</strong></td>
<td>13</td>
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# Large Cancer Burden

**KPNC KPNCORP**

- **Annual Analytic**
  - **Cancers**
    - Breast 3700  8146
    - Colo-Rectal 1485  3353
    - Lung 1590  3303
    - Prostate 2497  5416
    - Total Cancers 19,007  43,358
Continuity of Cancer Care KPNC

• 99% of the continuum of Cancer care within system (not BMT)
  – Primary Care, Cancer Screening, Imaging, Pathology, Oncology, Hospice
  – Cancer Surgery: all except organ transplantation
  – Centers of Excellence: RadOnc, SRS XRT (2), BrachyXRT, NeuroSurgery(2), HepatoBiliary, Head&Neck, Soft-tissue/Bone Ca,
  – Regional Oncology Clinical Trials Program: SWOG, NRG. NCORP application pending KPNC grantee
Dr. Morris Collen, a founding leader of Kaiser Permanente from the early 1940’s, championed medical research and was a pioneer in medical information technology.

Morrie Collen, born 11-12-13 celebrates His 100 birthday with a lecture on medical informatics.
KPNC EMR/Data Repositories

- **EMR**
  - Standard EMR *(EPIC)* Clarity 2007
  - **BEACON**: ChemoRx Delivery System 2009
    - (KP National Build)
      - Standard Care Regimen:
      - Regimen, Indication, Intent, Delivery (dose, dates, sites, MD, Clinical Trial Arm Builds)
    - **Non Epic data bases**: Pathology, Pharmacy, Laboratory, Imaging, Visits, Demographics, Diagnoses

- **Virtual Data Warehouse VDW**:
  - Common data elements at each KP NCORP member site: Allows single research program to “Extract, Transform, Load” into SAS format.
  - >3.0 Billion data observations in KPNC alone

- **Tumor Registry (SEER)**, Multiple Ca Cohorts, Genetics, High Risk Groups
KP Oncology Treatment Trials

KPNC Past Experience

• SWOG, NSABP, RTOG, GOG, (NRG) CTSU individual members
• 365 NCI Enrollments, 425 credits/2013
• KPNC, KPHI, KPCOL
• NCI Prevention Grant
• Cancer Control
• 25 years of experience

KP NCORP Application

• 600 SWOG, NRG NCI enrollments 2015 in NCTN
• KPNC, KPSC, KPCOL, KPNW, KPHI,
• Prevention, Cancer Control
• CCDR
NCI Definition of Cancer Care Delivery Research (CCDR)

- How social factors, financing systems, organizational structures/processes, health technologies, and healthcare provider and individual behaviors affect:
  - Cancer outcomes
  - Access to and quality of care
  - Cancer care costs
  - Health and well-being of cancer patients and survivors
Samples of Current Oncology Cancer Care Delivery Research in KPNC

- Choices: Evaluation of Clinical Trial Recruitment, Enrollment, Barriers, and a Patient Centered Intervention
- Rx Decisions and PRO in Low Risk Prostate Cancer
- Pathways: Breast Ca Survivors
- Lifestyles and Molecular Factors of Bone Health in Breast Cancer Survivors
- Body Composition, Weight, and Colorectal CA Survival
- Molecular Subtypes, Lifestyle, and Breast Cancer Outcomes
- Epidemiology/Natural History of Zoster in Cancer patients
- Predictors of Poor Outcomes after Resection of NSCL Cancer
- Long Term Trends in Breast Cancer Subtypes and Disparities
- Effects of antioxidant use during adjuvant chemorx of Breast Cancer
- Incidence and Determinants of Trastuzumab Induced Cardiotoxicity in Population based Breast Cancer Patients
Clinical Trial vs Standard Care

Cost of Care

• 135 patients enrolled in diverse menu of NCI phase II, III clinical trials matched for age CA site, stage with non clinical trial patients

• Costs modeled on assigned value of clinical care delivered (imaging, drugs, labs, visits, hospitalization, all encounters)

• No difference in costs outside of BMT trials

Choices: Evaluation of Clinical Trial Recruitment, Enrollment, Barriers, and a Patient Centered Intervention

• Carol Somkin PhD, PI, R01
• Survey of all oncologists re: attitudes + demographics, trial experience, accrual hx.
• Electronically real time ID eligible patients for specific treatment trials
• Cluster randomize to a pre Oncology appt direct patient education interaction phone/brochure or standard care
• Record barriers and drop out from Dx to enrollment
CHOICES: continued

• Patient survey pre+post or no educational intervention re: knowledge + attitudes
• Enrollment correlated with socio-demographic variables and oncologists trial participation prior hx
• Conclusions:
  – **Patient’s attitudes** can be enhanced re: the positive value of clinical trial participation
  – The major determinant of enrollment to a clinical trial is **providing MD** trial enrollment history and certain attitudes
SWOG-1204: A Sero-Epidemiologic Survey and Cost-Effectiveness Study of Screening for HIV, HBV, HCV in Newly Dx Ca Patients

- Current SWOG activity: “run in phase with limited centers-7”.
- SWOG plan to extend to group-wide study to test all new Cancer patients at selected sites (planned) N=3061, 91% white, 1.6% asian, 11% hispanic).
- Measure prevalence, socio-demographic, clinical, behavioral correlates, treatments, adverse events, outcomes, cost effectiveness of screening.
Hepatotoxicity with Chemotherapy in Patients + for Hepatitis B Virus. KPNC

- Retrospective review of chemoRX (2000-2010) records (VDW)
- 44,590 pts received 74,630 chemorx courses. 289 patients found to be hepatitis BsAg positive at some time in KPNC. (0.64%)
- Hepatotoxicity (NCI CTC grade 3 and 4) in 16 - 21% (nonlymphoma and hepatoma) hepatitis B + pts treated without antiviral prophylaxis
- Hepatotoxicity: in 62 – 69% of Hepatitis B+ Lymphoma Pts
- Hepatotoxicity: in 6% of untested for hepatitis B
- 7 pts identified who died from fulminant reactivation hepatitis B+, 6 had lymphoma, 1 had NSCLC. None had antiviral prophylaxis.
- (Data on hepatitis C were collected but not yet analyzed)

HepB, HepC Testing and Chemorx
KP Learning System?

- KP national consensus to initiate prechemorx HepB/ HepC screening in all KP: 12/2013.
- Jan through March 2014 – Orders to test for hepatitis BsAg and hepatitis C Ab became default BEACON chemorx order sets for first starts.
- 8,334 new unique chemorx starts a year in KPNC, 19,000 in KP NCORP sites (>1500 a month).
- 3000 Pts tested by spring SWOG mtg and 15,000 by end of 2014, 38,000 end of 2015
Challenges of Conducting Oncology Research in Delivery System Like KPNC

- Primary mission is high quality high value health care delivery, not research
  - Highly competitive market place
  - High cost of living area
  - Not a philanthropy recipient or taxpayer supported
  - Research encouraged but a secondary mission
  - Clinical trial enrollment is not a performance metric

- Therefore, time challenges for oncology clinicians concerning clinical trial participation and research design

- Career Research Track exists in Division of Research: Epidemiology, Public Health, and Health Services but not in direct patient contact clinical research
Some Personal Oncology Research Priorities

- Measuring Rx outcomes in average non CT pts, NOT the healthiest quartile of the youngest quartile
- Developing strong evidence for Rx choices including diagnostics, surveillance, refractory disease care
- Evaluation of patient/provider/delivery system information and communication exchange
- Tailoring oncology care to patient values and reported outcomes
- Evaluating Care Delivery systems relative to outcomes and costs adjusting for patient factors