Use of Clinical Pathways in Oncology

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Clinical Pathways in Oncology

- Using clinical trial and other evidence-based data to guide rational therapeutic decisions
- Traditionally, oncologists did this “in their head” – pathways are formal structural elements to guide decisions.
- Grandfather = National Comprehensive Cancer Network (NCCN) guidelines. Most pathways are a derivative of this.
- Pathways can allow for coordination with appropriate clinical trials (prospective) and real-world prospective clinical trials.
- Pathways can improve quality of care and coordination within a health care system as well as decrease overutilization.
Examples of Oncology Clinical Pathways

- Initial diagnosis of localized/regional colon cancer
  - Baseline CEA
  - CT A/P, CXR **NO PET SCANS**
  - Endoscopic rectal ultrasound for rectal cancers
  - FOLFOX or 5FU/LV for node-positive patients * 6 months
- HER2+ node-positive breast cancer with curative intent
  - Taxotere/Carboplatin/Herceptin
  - Adriamycin/Cytoxan – Taxol/Herceptin
- Surveillance of breast cancer patients in remission
  - History, physical, breast exam
  - Breast imaging
  - NO tumor markers or imaging
- Diffuse large cell lymphoma
  - R-CHOP
    - Oral odansetron * 3 days
    - No cycle 1 growth factors if <60 years old
    - Baseline echocardiogram
    - Bone marrow biopsy, PET scan, LDH CBC CM

Clinical Pathways: Is There Anything New under the Sun?

- Derivative of NCCN guidelines
- Companies to create, implement, and sell pathways to payers or large groups have been developed, including:
  - Cardinal Health
  - Via Oncology (U of Pittsburgh)
  - eViti
  - McKesson/US Oncology
  - Internal/homegrown pathways
- NCCN guidelines are "all-inclusive" with many choices included.
- Clinical pathways narrow down choices.
- Within a health care group, choices can be narrowed down based on cost and perceived quality, local preferences.
Cultural and National Differences in Pathways

- Surveillance of Ovarian Cancer Patients in Remission
  - In US – PET scans, CA125
  - In Britain – history and physical?
  - CA125 surveillance results in a lead time bias with no documented improvement in overall survival (OS).
  - “Patient-driven” pathways generate tension in the provider-patient relationship.
  - Economics may drive patient choices in the future, e.g., shared payment, copays in “off-pathway” tests or drugs may limit choices.

- Early vs. late adoption of palliative care in noncurative setting

- Treatment of ovarian cancer patients:
  - In US, 5, 6, 7, or more lines of chemotherapy in platinum-refractory patients
  - In countries with scarce economic resources, only 2 or 3

Developing an Oncology Clinical Pathway: 5/12/2013

- Clinical example: Bisphosphonates in Multiple Myeloma Patients
- Bisphosphonates used to prevent bone fractures – NNT 6–15
- Guidelines (beta version):
  1. Zoledronic acid for 2 years q 3–4 weeks, then continue in patients with active myeloma
  2. Pamidronate for 2 years q 3–4 weeks, then continuance at physician’s discretion
  3. No mention of denosumab, which is not licensed in Europe
- These guidelines would only use generic medicines.
- They do not stratify usage by “virulence” of myeloma – will often go q 2 or q 3 months in patients who have responded early and dramatically.
Oncology Pathways Will FORCE the Value Proposition

- In a single-party health care system or an era of cost containment, clinical pathways will ultimately FORCE the value question in pharmacoeconomics.
- Cost-effectiveness analysis may become necessary, but not sufficient.
- As the US moves toward accountable care organizations (ACO), bundled payments, and at-risk models, the decision regarding the cost of cancer therapies will rise to the surface.
- e.g., total cost of care, including antiemetics and growth factors, will be under scrutiny as well as imaging, procedures, etc.

Oncology Clinical Pathways Raise Difficult Questions

- Branded vs. generic chemotherapy
- Varying parameters to minimize total cost of care while preserving outcomes
- Imputation of downstream costs in the equation
- e.g., appropriate use of growth factors (red cells, white cells) [currently $1 billion/year in US]
- Do “me two” or “me three” drugs command the price premium they have been charging?
- How important is progression-free survival (PFS) economically?
- Will PROs figure into the equation? How much price premium does increased quality of life command?
- e.g., avoiding alopecia