

The Evolving Impact of Health Care Reform on Academic Clinical Oncology Practice and Clinical Research: Metaphysical Observations

Robert Dreicer, M.D., M.S., FACP, FASCO
Head, Medical Oncology Section
Associate Director for Clinical Research and Deputy Director, University of Virginia Cancer Center
Professor of Medicine and Urology
University of Virginia School of Medicine

Disclosures

- 28 years as an academic GU oncology clinical investigator at 3 academic centers, 2 NCI Comprehensive Cancer Centers 1 NCI Clinical Center all with different models of care
- 11 years as Assoc Div Director/Dept Chair
- 18 yrs as Chair of the ECOG bladder subcommittee
- Co-chair NCI GU Steering committee
- Member ABIM Medical Oncology test writing committee

A brief history of external forces on academic clinical practice

- Impact of Medicare/Medicaid (I will spare you)
- 1970's to mid 1990's
 - Era of increasing NIH \$
 - Academic Dept of Medicine and the R01
- Late 1990's-
- The era of the shrinking NIH budget begins
 - Clinical revenue increasingly needed
 - Impact on physician scientists, clinical educators, clinical investigators

A brief history of external forces on academic clinical practice and research

- 2000's
 - Change in drug development, i.e. this stuff appears to work
 - Crisis time for the cooperative groups
 - Cancer and neurologic disorders replacing cardiology and inpt surgery as drivers for the engine
 - Academic oncology subspecialization
 - Inpatient oncology as focus replaced by outpatient management as focus of both clinical and research activity and reimbursement

The Evolving Impact of Health Care Reform on Academic Clinical Oncology Practice and Clinical Research: Metaphysical Observations

- Academic clinical practice
 - oncology subspecialization
 - Multidisciplinary care
 - Integrating community oncology practices
- Transition to Payment for “episodes of care”
 - Care paths
 - Yours and theirs
- Clinical research
 - NCTN and The Cooperative Groups
 - Academic “credit” for investigator initiated and “routine pharma sponsored trials

Oncology Subspecialization: The Good, The Bad, The Ugly

- 1973 first ABIM specialty exam for medical oncology
- Starting in the mid-1980's at a number of NCI Cancer Centers with strong programs in disease sites
 - Characterized by having leading academic surgical colleagues who were interested in clinical/translational research
- 2016: Essentially no disease states in which "it doesn't matter how much you know"

Oncology Subspecialization: **The Good, The Bad, The Ugly**

- In 2014 at most “large” academic medical centers subspecialization is the norm
 - Smaller centers, struggle to cover the disease spectrum with “experts” more on this later
- In large community-based oncology groups, this is increasingly common
- Although there is no prospective “data”, hard to believe that care is not improved given the complexity of disease management issues
- Integration of multidisciplinary care: now the norm
 - Impact on clinical/translational research (PSA failure/neoadjuvant chemotherapy for bladder cancer)

Oncology Subspecialization: **The Good, The Bad, The Ugly**

- Enables multidisciplinary care
 - Disease expertise by medical oncology provides surgical colleagues with the needed “gravitas” to engage in effective and meaningful disease management decisions
 - Centers love the concept, patients love the concept (and even more if it actually works)
- **Effective, functional, multidisciplinary care IRRESPECTIVE of the MODEL OF REIMBURSEMENT enables a smoother transition to development and implementation of care paths and movement to reimbursement for episodes of care**

Oncology Subspecialization: The Good, **The Bad**, The Ugly

- Fragmented (at times)
 - Fellow education ?
- An additional complexity as one attempts to overlay the need for subspecialty care into the mixture of, clinical educators, clinical investigators, basic investigators
- Meeting the needs of surgical colleagues
 - The more you do, the more they want

Oncology Subspecialization: The Good, The Bad, **The Ugly**

- Your head and neck doc left to take another job
 - Who is going to see these patients?
 - The recruit with this skill set, is in GREAT DEMAND, its going to cost you \$\$\$
- MOC (no eggs please)
 - You are a thyroid cancer doc, how much do you need to know about hairy cell leukemia?

Oncology Subspecialization: The Future

- Academic general medical oncology
 - Opportunity for clinical educators
 - Fellowship directors
 - Quality/outcomes
 - Physician communication experts
 - Admixture of palliative medicine/oncology
- Are RVU's the only thing that's important?
 - Finding the right balance of investigators/educators etc.

Clinical Care Paths: Yours and Theirs

- Background
 - Back in the day: extensive use of growth factors (all kinds) in nearly every patient, every patient with bone mets gets bone targeted therapy
 - Q 21 day therapy, patients get weekly or mid cycle cbc
 - Metastatic urothelial cancer, second and third line rx (without data), including agents such as

Clinical Care Paths: Yours and Theirs

- Goals
 - Decrease management heterogeneity as an initial step
 - Produce a product
- A visit in 2014 from a major national health care carrier
 - Therapy guide pathway
 - Level 1 evidence driven, follow the path get a monthly “supplement”, don’t follow the path, you get paid (for now)
 - Currently iteration without supplement guidance re imaging/diagnostics

Clinical Care Paths: Yours and Theirs: **IMPLICATIONS**

- However you define it, payment for episodes of care in oncology is coming and fast
 - Changes during the transition period i.e. “when do we turn the switch on”
- This has the potential for major implications for drug, imaging and biomarker development (peripheral to our current discussion)
- Whether you follow or lead will have implications
- Current iteration doesn't include imaging/diagnostics (depending upon how things evolve may not need to)

Clinical Care Paths: Yours and Theirs: **IMPLICATIONS**

- Depending upon your model i.e. how much control does the Dept/Division/Cancer Center director have
- Herding academic cats or even more challenging admixtures of academicians/"employed non-academic clinicians"
- Presence/integration/utility of EMR
 - Implementation/real time tracking of outcomes
 - Ability to determine real costs and thus negotiate from a stronger position

Clinical Care Paths: Yours and Theirs: IMPLICATIONS

- Imagine a day when chemotherapy revenue is rolled into payments for episodes of care
- What if you work in a shop that all the chemotherapy revenue is collected by others, or entirely credited to you, or some admixture
- Do oncologists suddenly become seen as Endocrinologists? Or now gate keepers of a potentially very expensive (or potentially lucrative) part of the business

Therapeutic Intent

- Curative
- Improve survival
- Delay time to disease progression
- Palliation (not prophylactic palliation)
- Investigational
- Because you have cancer and I can treat you with something and its easier than having “the talk”

Intersection of Oncology Subspecialization/Multi-Disciplinary Care and Care Paths

- Episodes of care
 - If you have interdisciplinary care ability to slide into this reimbursement process smoother as care has been provided in this manner
 - Aids in implementation of level 1 evidence perioperative therapy
 - Improves follow-up i.e. removes heterogeneity
 - Improves if needed integration into “allied” practices

Academic Clinical Investigation

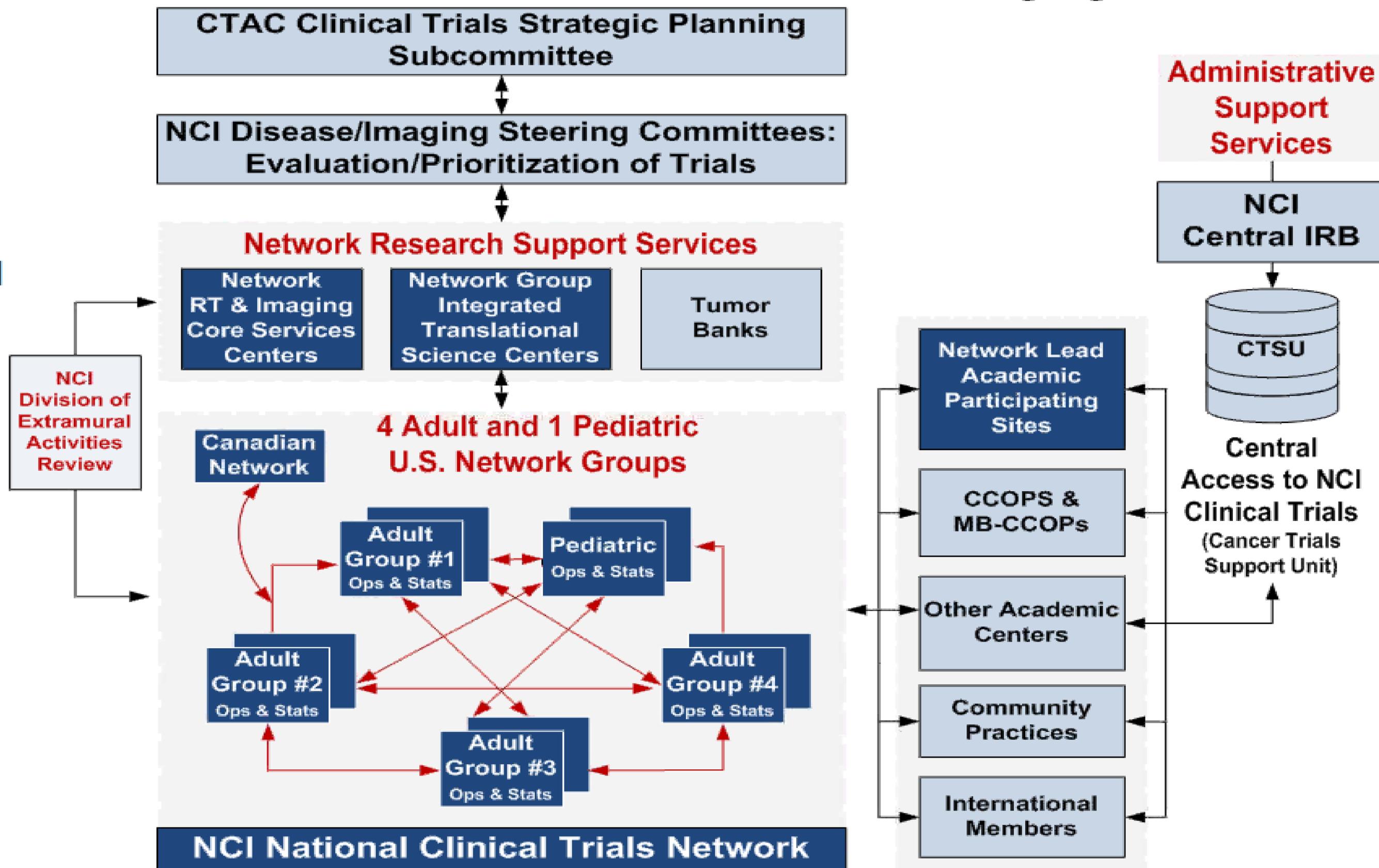
- Historically in many institutions, costs/budgeting for clinical research was “empiric”
- Many shops had no real idea of what came in versus costs
 - Centers made an “investment” given the import of the process to the mission
- Today many centers operate with tighter controls, using more experienced folks to budget/negotiate clinical trial costs
 - More careful planning re: RN/data time
 - Many centers still do a poor job in understanding the full value of dollars from non- NIH sponsored clinical research

NCTN and the “New and Improved” Cooperative Groups

- Historically the cooperative group system enabled young clinical investigators to develop skills, reputations in a setting of a mostly volunteer process
 - Drugs were scarce, this was the path forward for clinical investigators
 - Per patient reimbursement was inadequate, but institutions “filled” the gap, Quid pro quo
- Fast forward to today, a very different reality
 - Pharma rules re: drug availability
 - NCI funding is melting away
 - Per patient funding is when adjusted for inflation is so low that support for these trials are now in serious jeopardy
 - Many smaller centers avoid opening trials, especially phase II trials in “less common cancers”
 - NCTN and Group reorganization decreases “loyalty”

Introducing A New Organizational Structure for a NCI National Clinical Trials Network for Cancer Treatment & Advanced Imaging Trials

Dark blue boxes signify NCI DEA reviewed, grant-funded components under the NCTN Program



NCTN and the “New and Improved” Cooperative Groups

- Annual accrual at max 26-28,000
 - Recent years in the 20,000 range
 - Current goals in the 17-18,000 range
- U10/:LAPS
- ORIEN and other new networks
- How and where are young investigators now to get experience and exposure

Health Care Reform: Implications on Clinical Research

- Implications for drug development
- Implications for imaging/diagnostic development
- Imaging
 - Sodium Fluoride PET/C 111 Choline PET
- Genomics

Metaphysical Observations

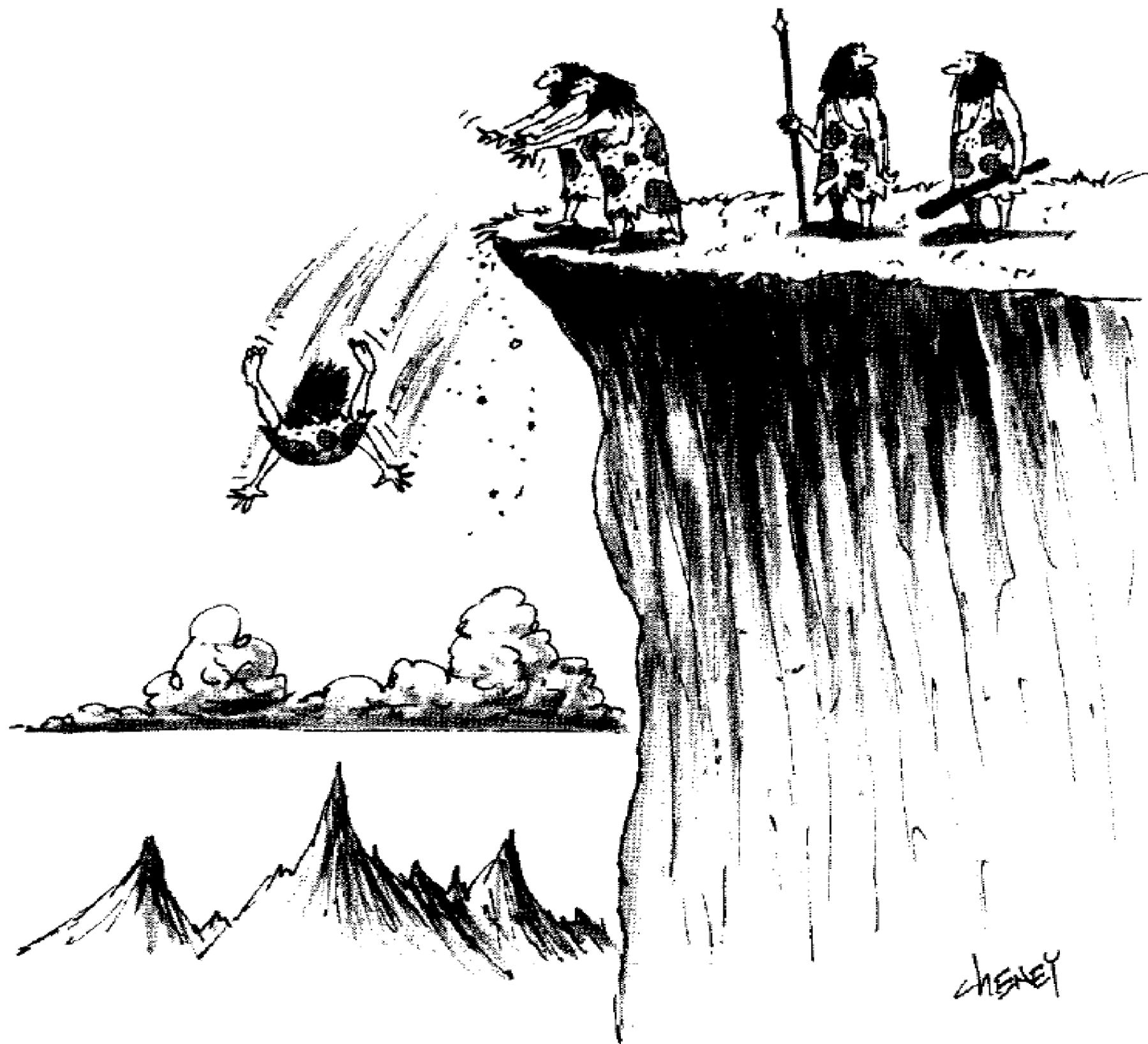
- Oncology subspecialization is here to stay, we have gotten much smarter about most neoplasms, the era of the oncology generalist is ending
- Academic medical centers are better positioned for this as the model has been in place and the ability to allow docs disease specialization is built in to the system
- Flexibility is required i.e. academic clinical educators in general oncology

Metaphysical Observations

- Clinical investigation is rapidly evolving the old paradigm of learning in the coop groups while not dead, you can see it from here
- Developing intellectual relationships with pharma to drive integration and development from early to late is critical to allow mentoring of young clinical and translational investigators
- Disease based philanthropy may provide additional competitive sources of funding

Metaphysical Observations

- Care paths are here to stay, better to be out front than behind
- Integration of imaging/diagnostics coming (and this is not necessarily a bad thing)
- Depending upon the model, herding the docs more or less challenging but its going to happen those who do it best, will reap early benefit



“It’s the only treatment option he has under his current health plan.”