Facilitating Development and Utilization of Genome-Based Diagnostic Technologies: A Workshop

November 15, 2011

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NCCS
NATIONAL COALITION FOR CANCER SURVIVORSHIP
The power of survivorship. The promise of quality care.

NCCS

- Founded in 1986.
- Mission: Advocate for Quality Cancer Care- Quality Chasm six aims.
- Survivor led: Bylaws require majority of BoD have personal diagnosis.
- Created concept and language of "cancer survivorship" as alternative to "patient" or "victim".

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About Me

- Long-term survivor (13+ years) metastatic melanoma.
- B-Raf (or other) unknown.
- Initial year's treatment -> surgery 1999.
- Surgery 2003, no tumor bank, but tried .
- N.E.D. now

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Patient Expectations

- Patients have rising expectations with regard to genomic and other tests.
- Better match to effective treatment.
- Less time lost on ineffective.
- Christopher Hitchens example.

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- Do not understand the complexity.
- Not just another blood test.
- Confusing claims about usefulness.

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NCCS positions

- Support FDA oversight.
- Cancer care planning.

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FDA Role

- NCCS would like a clear regulatory pathway for companion diagnostics and drugs- Comments Oct. 12, 2011.
- We assume that LDTs that will guide treatment decisions will be covered by Guidance, but this is not clearly stated.
- Uncertainty yields inefficiency.

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Support for patient understanding

- Cancer treatment planning becomes ever more complex.
- Patients need information and time to understand implications of choices offered.
- Comprehensive Cancer Care Improvement Act can help.

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CCCIA

- Would create a new Medicare service for cancer care planning.
- Provide more time with clinicians for patients to get their questions answered prior to decisions and when treatment changes.
- Rep. Lois Capps this and three prior Congresses.

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One patient's perspectives

- I want to reduce uncertainty.
- I want to manage my resources.
- I need to trust my entire care team.
- All are interdependent.
- Severe illnesses may be different from less threatening -> different rules?

Perceived value

- I believe there is value in genomic testing.
- It should help reduce uncertainty and narrow choices.
- If my cancer comes back, I would seek it and consider paying out of pocket.
- I already explored this in 2003.

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Can I rely on a test?

- Patients often seek second opinions.
- Even now there are issues of interpretation of pathology.
- Would I face repeat tests? Repeat costs?
- There seems to be a question of standards and standardization.

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- Reaction to FDA meeting in 2010- shocked by lack of standardization between labs.
- Sharon Terry- role for NIST.

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Care coordination a help?

- Who makes up my care team?
- Who advises me and how well do they understand the tests?
- This issue seems to involve more than just reimbursement and goes to physician roles.
- What models of coordinated care help?

Investigational interventions

- If an intervention is investigational, I need to know that. It will temper my expectations and may impact my choices.
- Investigational interventions should be used in a manner which generates evidence.

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- This was true for high dose chemotherapy with bone marrow rescue.
- Collection may not need to be RCT, but needs to be systematic.
- Setbacks such as at Duke are likely to undermine patient trust, harm the field and delay progress.

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One survivor's frustration

- Tired of conversations about how to bring best care models and goals to widespread use that always begin with the question "How can it be paid for?"
- Prefer dialogue that BEGINS with "What do patients and survivors want and need?" THEN: "How to align incentives to realize it?"

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