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

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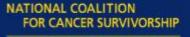


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NCCS

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.



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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The power of survivorship. The promise of quality care.

FOR CANCER SURVIVORSHIP

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.



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



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.

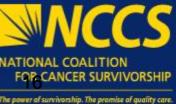


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 This was true for high dose chemotherapy with bone marrow rescue.

 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.



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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