Giving Tissue and Blood
Patient perspectives

Karl Schwartz
Patient advocate, Lymphoma

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Biospecimen to Biomarkers

- We urgently need practice-guiding biomarkers!
  - the trial-and-error approach to choosing therapy, for example, often leading to unproductive toxicity – to a narrowing range of choices

*If danger can be seen in terms of a **narrowing range of choices**, Billy Tyne's choices have just ratcheted down a notch."* ~ The Perfect Storm.

- **Patients want to contribute!**
  - The larger concern is the disease

But, is your study likely to add to the science - benefit future patients?

- Level of supporting evidence?
- Will you have enough biosample to do the analysis?
- Is the study size sufficient …. to have confidence in findings?
- Is the capture, storage , and analysis standardized?
  - Can the data be pooled to validate the findings?

Collaboration and standardized methods are needed to find answers that are likely to help patients.

Patients' Concerns

- Is it painful, dangerous, burdensome?
  - Travel expenses; time off from work?
  - Do other equally appropriate protocols require less of me?

** Curt, Chabner, 2008, The Oncologist*
One in Five Cancer Clinical Trials are Ever Published, most often from failure to accrue

- Privacy and Consent– best practice*
  - Is my privacy protected?
  - Other uses …

** NCI Best Practices for Biospecimen Resources*

… Uses of "my" biospecimen?

- Will you publish the status and uses of tissue, along with de-identified associated clinical data?
- "Ownership" versus stewardship
- Is my associated clinical information de-identified when shared?
- Are future uses limited to disease-specific study?
  - Based on merits of the science?
  - Cooperative group study – with standardized methods and informatics?
  - Sold to a company for commercial uses?

Perspective:

When we communicate with the public about the uses and the status of contributed biospecimen , we are encouraging also best practices and fostering public trust in clinical research.
*But doing this efficiently would require an informatics system, which is also a recommended part of best practices**

** NCI Best Practices for Biospecimen Resources*

Requiring Biospecimen Contribution

- To make sure the patient is appropriate for the study
  - Genuine uncertainty about the diagnosis?
  - Does the target of the drug exist in the tumor?
- To monitor for safety , especially for a new class of drug
  - Detect toxicity early
  - Monitor clearance, where it goes, etc.
- To see if new class of study drug is helping in sampled region
  - Effective in the marrow?
- When the finding is likely to help future patients –
  - To discover or validate biomarkers that can guide practice - reduce pain and suffering, and improve survival

Coercion?

When might requiring a high-risk or painful procedure to acquire biospecimen be considered coercion by the patient?

- When eligibility is already determined?
- When the analysis isn't tied to the primary study questions?
  - Particularly when there are high expectations about the efficacy of the study protocol – that harm will result if not accepted in the study.

Defined:
"The threat of further harm may lead to the cooperation or obedience of the person being coerced."

Optional Biospecimen Contribution?

- When the procedures are burdensome or worrisome –

  … and would add significantly to the challenge of accrual -- putting other important clinical questions in your study at risk.

- Ask patient representatives for guidance!

Summary

- Urgent need for validated biomarkers
  - To guide clinical practice and research
  - To improve efficacy and reduce unproductive toxicity
- But it's not easy to do right: often requires large studies using standardized methods - collaboration
- Required tissue contribution
  - When is it Coercion?
  - Feasibility – consider burden, risks, and patient perceptions –the impact on accrual. Are there competing protocols that ask less of the patients?
- Communication about uses?
  - Would build public trust and foster best practice
  - Burdensome – if done without an informatics system to automate publication to website

? Do we inform the participants when findings are practice-changing?

Sincere thanks for the work you do on behalf of patients – all of us!