Interests, Attitudes, and Participation in Clinical Trials Among Lymphoma Patients (with online access)

SUMMARY

A purpose of our study was to identify patient attitudes about clinical trials and factors that may predict trial interest and participation in order to inform future study design and improve the clinical trial referral system.

LIMITATIONS

This is a non-random sample, restricted to online users; subscribers to web-based support forums were the main participants.

Average age was 54 years, much younger than the mean for NHL, which is approximately 64 years at diagnosis. Only 6% of survey participants had Hodgkin's lymphoma (average age, 28 years).

We cannot tell from this survey if the factors associated with interest and participation in clinical trials are related to clinical necessity (higher-risk disease) or that (online / younger) patients are more proactive, or are more likely to be eligible for studies.

We are considering applying an improved version of our survey instrument to a random sample, pending feedback on this report.

FINDINGS

Participation (27%) in clinical trials is much higher than expected among this population. Commonly, 3-5% participation rates are cited among the general population with cancers.

Having Second Opinions, Second Evaluations of Pathology, and Consulting Outside Experts were all associated with significantly higher participation and interest in clinical trials.

Having a Second Opinion had the highest association with clinical trial consideration (107 of 168) and participation (58 of 107).

We should be encouraged by the high rate of clinical trial participation among those who have discussed studies with outside experts (62%) and their oncologist (60%), which suggests that making the discussion of clinical trials standard practice will increase enrollment rates.
The Internet was reported as the primary way patients learned about trials.

We interpret concerns with randomization (56%) as a fear of receiving an inferior protocol: a form of study risk. Therefore perceived risk (33% + 56%) is the primary reason for declining to participate in a clinical trial in this cohort.

DISCUSSION

BACKGROUND

Enrollment in clinical trials is widely acknowledged to be insufficient to support progress against cancers (3-5%). As drug discovery accelerates, the evaluation bottleneck will get worse:
Thousands of new agents, instead of hundreds, but the same number of patients and the same un-addressed obstacles to enrollment, which are undoubtedly delaying innovations.

ASSUMPTIONS

Patients are risk-adverse; tend to delay treatment decisions, which favors use of familiar, standard protocols when they get sick or need therapy.

To patients, participation in a clinical trial is a treatment decision. As such, study protocols must compare favorably to other study protocols and available standard therapies: be reasonable / appropriate treatment decisions for their clinical setting.

SETTING-BASED TRIAL DESIGN & DESCRIPTIONS

Rationales for participation - based on potentially meeting clinical needs and treatment objectives in common clinical settings - should be described clearly in study protocols ...

... basing study designs and descriptions on the objective of meeting needs and treatment goals (for ethical reasons), with awareness also of patient biases and hopes (for practical reasons):

Setting-Based Clinical Trial Design & Descriptions (continued)

A few examples:

a) Alternatives to expectant management (watch & wait):

Agents and protocols with low / reversible / transient toxicity such as immunotherapy, or select targeted agents.

b) First primary therapy:

Head-to-head studies comparing frequently prescribed protocols where there's genuine uncertainty about which is superior. (CHOP-R versus CVP-R versus RIT for example)

c) Refractory disease setting:

Protocols of agents that may overcome drug resistance.

NEW TOOLS AND STANDARDS

Biospecimen-based studies are needed to address patient and disease heterogeneity.

Accounting for patient and disease variables could reduce risk (real and perceived) of study participation, making participation in a trial more attractive to patients than standard medicine.

STREAMLINE ENROLLMENT

- Refer patients to centers that can capture and store tissue that support biospecimen-based research.
- Make discussion of clinical trials common practice; utilize waiting room time, web-based videos .
- Raise awareness among patients that study participation can be an appropriate treatment decision.
- We might reward or provide national recognition to physicians who refer patients to clinical trials.
- We might form an independent committee (NCI/non-profit-based) to identify trials appropriate to different clinical settings in order to make study consideration more feasible for general oncologists and also to minimize risk to patients from sponsor- or investigator bias.

Finally, a guiding principle for patients and drug sponsors is SELF INTEREST. We each need incentives:
Sponsors to innovate; patients to participate.

The keys to progress include:

- Fund and support the shared infrastructure and adoption of research standards;
- Expedite biomarkers discovery and validation in order to make study participation safer - minimizing what patients fear most: unproductive toxicity, particularly of a type that burns treatment bridges;
- Provide commercial incentives to do targeted drug development and assessment on selected patients - stratified research (orphan drug program as model?);
- Patients to contribute tissue and to enroll in trials (research partners);
- Study design that makes trial participation a smart treatment decision

Patients Against Lymphoma

Non-Profit | Independent | Evidence-based
www.Lymphomation.org

3774 Buckwampum Rd, Riegelsville, PA 18077

Tel: 610-346-8419 | Email: Support@Lymphomation.org