Abstract Title: Cancer Center's Experience with Insurance Denials for Clinical Trial Participation after ACA Mandate

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Describe the background of the problem:

Enrollment into cancer clinical trials for adults is a challenge; 97% of patients do not participate in clinical trials despite nearly one-third of American adults indicating a willingness to participate if asked.¹,² Lack of adequate enrollment to cancer clinical trials limits the generalizability of the results, causes trials to be cancelled prematurely and increases the length of time required to get effective treatments into widespread practice.³,⁴ One identified barrier to clinical trial enrollment is lack of insurance coverage for clinical trial participation. The 2010 Patient Protection and Affordable Care Act (ACA) includes a provision requiring coverage for clinical trial participation as of January 1, 2014. Nonetheless implementation of the law may lag enactment.

Provide metrics or goals hoped to be achieved with the solutions to address the problem:

We initiated a study of cancer organizations to assess the impact of this legislation on trial enrollment and to identify barriers to mandate implementation. Surveying organizations to evaluate the manner in which health insurance coverage for clinical trial participation is ascertained may lead to improving organizational processes for increasing trial enrollment. Specifically, we will: (1) assess the number of patients enrolled to clinical trials January 1, 2014 to December 31, 2014, (2) describe specific institutional processes for precertification, and (3) identify the degree to which individuals are interested in participating in barrier reduction intervention teams.

Describe the solutions or methods implemented:

We used a convenience sample of cancer organizations from professional society listservs (American Society of Clinical Oncology, Association of American Cancer Institutes, Oncology Nursing Society) to solicit participation in an on-line survey. An initial screening survey was used to identify qualified individuals to respond to a more detailed survey. The detailed survey is currently being administered. The University of Kansas-Lawrence, Human Subjects Committee exempted this project.

Describe the outcome of the solutions implemented or show data representing a change whether positive or negative.

The initial survey was sent to 1,412 individuals who are members of at least one of the participating organizations. These represented cancer centers, but also sponsors and CROs. We received 309
responses with the majority of respondents (63.6%) reported having experienced insurance denials. Of the centers that responded, 78.2% reported having a precertification process.

<table>
<thead>
<tr>
<th>Did your cancer program/institution/practice experience insurance denials for patients participating in clinical trials in 2014?</th>
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<td>Yes (n=107)</td>
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*309 due to 15 individuals not responding

Show lessons learned, others to involve in the future, changes to the methods to achieve a better outcome.

- Insurance denial for obtaining treatment via a clinical trial persists despite the ACA mandate, potentially limiting treatment options for patients with cancer.
- Detailed survey results are expected to provide guidance in the design of a “best practice” for performing precertification.

References