Cancer Center and Community Research Program Experience with Insurance Denials for Clinical Trial Participation after ACA Mandate

Christine Mackay, RN, MSA, CCRP¹, Kaitlyn Antonelli², Suanna Bruniooge², Shellie Ellis, MA, PhD²

¹University of Kansas Cancer Center, ²American Society of Clinical Oncology

Introduction

Lack of certainty and uniformity about insurance coverage impacts clinical trial participation, access to care and healthcare disparities. Since January 1, 2014, the 2010 Patient Protection and Affordable Care Act (ACA) requires most insurance providers to cover routine costs associated with clinical trial participation. However, implementation of the law may be incomplete. A comprehensive assessment of implementation of the ACA provision has not been reported.

We initiated a study of organizations conducting cancer clinical trials to describe factors associated with insurer’s denial of cancer clinical trial coverage, particularly the precertification process. Understanding how insurance coverage for clinical trial participation is ascertained may lead to improving organizational processes, thus increasing trial enrollment.

Methods and Materials

Individuals who are part of a professional society listserve or email list from the American Society of Clinical Oncology’s Community Research Forum, Association of American Cancer Institutes’ Clinical Research Initiative, Oncology Nursing Society’s research nurses special interest group and the Midwest Cancer Alliance, were emailed an invitation to participate in an online screening survey. This 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.

Results

The initial survey was sent to 1,412 individuals associated with at least one of the participating organizations. These individuals represented cancer centers and community-based research programs. We received 309 responses. After removing duplicates and incomplete entries, 252 responses were analyzed (Figure 1).

Of those responding, 158 (62.7%) reported experiencing an insurance denial for patients participating in clinical trials in 2014 (Figure 2). Sites performing precertification are more likely (69.3% vs. 41.7%, $\chi^2=14.9, p=0.001$) to experience denials (Figure 3). Sites with state laws or agreements experienced similar rates of denials as states without (82.3% vs. 85.1%, $\chi^2=50.7, p=0.001$) (Figure 4).

After controlling for volume of enrollment and presence of a state law or agreement mandating coverage already in place, sites with a precertification process were three times more likely to experience denials than sites without a precertification process (OR 3.04, 95% CI 1.55-5.99) (Table 1).

Discussion

The objective of this study was to describe the implementation of the ACA’s mandate requiring insurance companies to cover routine costs for participation in cancer clinical trials. We found that denials persist and that precertification is significantly associated with experiencing denials.

Although 62% of sites experienced denials, we do not know what proportion of individual participants were denied. Planned analyses of our second survey may inform this discussion. Denials may persist after the ACA mandate because some insurers remain exempt from both state and federal mandates, i.e. self-insured plans or Medicaid.

There are 2 possible reasons for the association between conducting precertification and experiencing denials. First, sites who do not conduct precertification may not be aware that patients are experiencing denial. Alternatively, the precertification process itself may be engendering higher levels of scrutiny from the insurers than what might otherwise be provided. When alerted to a “clinical trial”, insurers may evaluate individual coverage elements rather than evaluating whether the specific policy provides coverage. Planned analyses of subsequent survey results will clarify how sites with and without a precertification process experience denials.

Although sites in states where laws or agreements exist reported similar rates of denials as sites without similar regulations, this finding was not significantly related to experiencing insurance denials. Nonetheless future research should assess the degree to which these laws are enforced.

This study has several limitations. As a convenience sample of people associated with specific email lists, the results cannot be generalized to all sites conducting cancer clinical trials. As with all survey data, self-reported data is subject to recall bias.

Conclusions

• Insurance denials for obtaining treatment through a clinical trial persist despite the ACA mandate, especially for sites seeking precertification approval, potentially limiting treatment options for patients with cancer.
• A comprehensive evaluation of the implementation of federal requirements for insurance companies to cover clinical trial participation is needed.

Next Steps

• Evaluate the responses from the detailed survey to better understand the processes sites are using to perform precertification and learn how they respond to an initial denial.
• Detailed survey results are expected to provide guidance in the design of “successful practices” for performing precertification.
• Use data related to denials and delays to inform ongoing advocacy with insurance companies and policy makers to ensure adequate access to care and to decrease health disparities.

Collaborators

Association of American Cancer Institutes-Clinical Research Initiative
Midwest Cancer Alliance
Oncology Nursing Society

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<thead>
<tr>
<th>Table 1</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
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<tbody>
<tr>
<td>Precertification Process</td>
<td>3.04</td>
<td>1.55-5.99</td>
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<td>Enrolled Patients</td>
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<td>State Law or Agreement</td>
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