A Clinical Research Patient-Centric Framework:

Prevention and Reduction of Financial Toxicity Risk

Mitigating Clinical Research Billing Non-Compliance through a Patient-Centric Framework

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Abstract

Research sites with medical billing practices are at risk for Clinical Research Billing (CRB) non-compliance under the False Claims Act, and violations have serious ramifications.[8] Centers for Medicare and Medicaid Services (CMS) have rules and guidelines regarding billing and claims processing requirements when submitting claims.[3] Financial toxicity impacts patients seeking healthcare services through unexpected financial burdens, distress, or decreased satisfaction.[1] Best practices around processes to justify and document financial responsibility during the study start-up process and then the capture of charges for study-related items and services exist across the industry but often differ across sites.[6] Clinical research and medical billing combined may increase site and participant risk of financial toxicity and CRB non-compliance.

Problem Statement

High-level details regarding costs are written in the informed consent document and signed by the participant when consenting to participate in a clinical research study.[7] **The problem is a clinical research participant does not generally have enough detailed information to know how the actual medical bills they may receive translate to the high-level details written in the cost section of the informed consent document.**

Research Questions

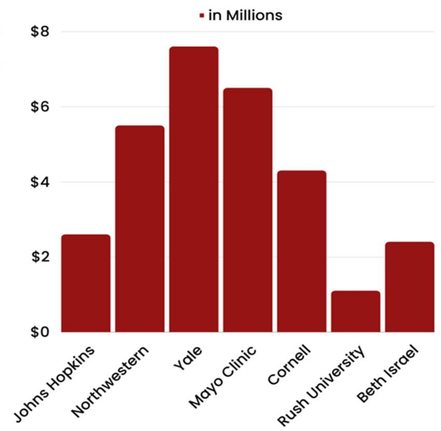
1. What steps should a site take to educate participants about medical bills they may receive due to study participation to decrease their risk of financial toxicity and increase their satisfaction?
2. How does informing the participant help the site demonstrate financial transparency and reduce its risk of CRB non-compliance?

Method

1. Review: Multiple secondary sources around financial toxicity, clinical research billing non-compliance, financial transparency, participant satisfaction drivers, and the virtuous business model.
2. Pilot Survey: Best Practice Approaches to Reducing Financial Toxicity for the Clinical Research Study Participant and the Enrolling Organization.
3. Pilot Survey Design: Open and close-ended questions.
4. Survey Distributor: Partner organization.
5. Solution-Orientation: Problem-based learning.
6. Analysis: Secondary data and de-identified survey responses.
7. Categorization: Key themes.

Consequences of Clinical Research Billing Non-Compliance[2]

Cases of Improper Clinical Trials Billing



Key Themes

Coverage Analysis, **Informed Consent**, **Budgeting and Financial Navigation**, **Satisfaction Surveys**, **General Medical Billing**, and **Miscellaneous Comments**.

Key Findings

- ❖Lack of consistent processes across sites relating to clinical research billing non-compliance mitigation and financial transparency, except for the coverage analysis development process.
- ❖According to survey results, 94% of the sites develop a coverage analysis during study start-up.
- ❖Limited research exists regarding financial toxicity and the connection to clinical research.
- ❖Only 19% of responses answered yes to providing some sort of breakdown of costs to study participants.
- ❖Limited sites conduct research participant satisfaction surveys, although billing outcomes are a key driver for the patient experience.
- ❖Only 6% of respondents provide information about site medical billing practices.
- ❖Sites are not connecting the dots between site financial outcomes and participant financial outcomes.

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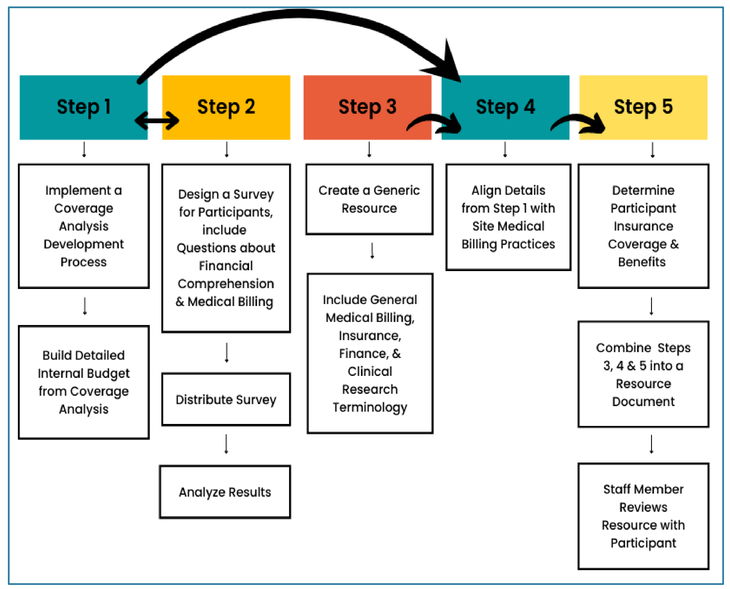
Solution

A patient-centric, site-level, 5-step process merging best practices and internal processes.



Conclusion

Several findings validated the need for additional research regarding financial toxicity and its impact on the clinical research participant.[9] Furthermore, there is a need to distribute research participant satisfaction surveys and measure financial understanding. Additionally, there is a need to establish and implement best practices aimed at the prevention and reduction of financial toxicity risk.[4]

❖A patient-centric approach considers the needs of the participant first.[5]

❖Implementation of the PRoFT Risk Framework will vary across sites based on current infrastructure and require planning and change management initiatives.

References

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