A Clinical Research Patient-Centric Framework: Prevention and Reduction of Financial Toxicity Risk

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Medical billing practices are complicated; clinical research is complex. Human subjects protection regulations do not mandate the level of detail a research site should provide a participant related to medical billing that aligns with the high-level information in the cost section of the informed consent document. Regulations only require sites to provide information regarding potential additional costs or items promised free due to participation but do not state how to provide the information (U.S. Food & Drug Administration, 2014). Furthermore, industry experts attest to the importance of transparent processes around coverage analysis, internal budgeting, and charge capture to mitigate site risk of clinical research billing (CRB) non-compliance and improve financial transparency (Hurtado & Longspaugh, 2017; Meade, 2019).

The Problem

Research sites with medical billing practices are at risk for CRB non-compliance under the False Claims Act, and violations have serious ramifications (Bennington & DeBra, 2020; U.S. Department of Justice, 2021). Centers for Medicare and Medicaid Services (2008) have rules and guidelines regarding billing requirements when submitting claims for charges associated with routine costs in qualifying clinical trials. Financial toxicity impacts patients seeking healthcare services by leading to unexpected financial burdens, distress, or decreased satisfaction (Bach, 2019; Chino & Zafar, 2019). Best practices and processes around documenting financial responsibility and capturing charges for study-related items and services exist across the industry and differ across sites (Meade, 2019). High-level details regarding costs are written in the cost section of the informed consent document and signed by the participant when consenting to participate in a clinical research study (OHRP, n.d.).

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.

Driving Research Questions

- 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?
- How does informing the participant help the site demonstrate financial transparency and reduce its risk of CRB non-compliance?

Methodology

Problem-based learning, the virtuous business model, secondary data sources around financial toxicity, CRB non-compliance risk, financial transparency, and research participant satisfaction drivers contributed to the methods in the applied doctoral project. After completing the literature review, the researcher identified a need to gather more concise data. This need led to developing and distributing a pilot survey to further

explore best practices and processes around the concepts in the driving research questions. The researcher worked with the partner organization to develop survey questions based on the following themes:

- Coverage Analysis
- ICF
- Budgeting & Financial Navigation
- Satisfaction Surveys
- General Medical Billing Information
- Miscellaneous Comments

The partner organization agreed to serve as a third party to disseminate the survey and forward de-identified responses to the researcher. The survey was distributed to clients familiar with clinical research billing compliance requirements at multiple research sites across the United States. De-identified responses were provided to the researcher for analysis.

Analysis

Limitations to the study included the short timeframe to collect data and the uncertainty of the number of respondents. The researcher analyzed the de-identified responses according to themes. A common theme showed that 94% of sites develop a coverage analysis during study start-up, but only 75% include a detailed billing grid with charge details. Responses showed that 37% provide more information about medical billing than what is included in the informed consent document. However, only 19% said they provide additional details or a breakdown of costs. No details regarding what type of information or examples were provided by respondents. Furthermore, the financial toxicity of the clinical research participant was not commonly addressed in the published literature reviewed and is not widely discussed across sites. Willenberg (2021) addresses the need to understand the impact of financial toxicity on participants and determine best practices to address this issue.

Another significant theme showed that none of the respondents conducted research participant satisfaction surveys at any interval. Satisfaction surveys are essential for organizational development needs to assess areas that require improvement or change (Bolman & Deal, 2017). Additionally, medical billing outcomes are drivers of satisfaction that impact sites (Blackman, 2021). This theme identified the need to include participant satisfaction surveys in operational research processes. Another similar theme was the minimal inclusion of medical billing practice information provided to patients.

The survey results and gaps identified in the literature review guided the researcher to determine what steps were necessary to resolve knowledge deficits and begin to tie best practices with existing internal processes. Incorporating new discoveries with existing best practices led to the recommended solution as a starting point.

Recommended Solution

This study identified areas where additional research is necessary regarding financial toxicity and its impact on clinical research participants and the research sites. There is also a need to develop best practices and benchmarks around surveying clinical research participants regarding satisfaction. An important lesson learned in this study was that sites are not connecting the dots between industry best practices and internal processes outside of research operations.

The PBL process, concepts of the virtuous business model, secondary research, the researcher's personal experience, input from the partner organization, and an analysis of results from the third-party distributed survey contributed to the proposed site-level solution in this study. The recommended solution is a patient-

centric, five-step process merging multiple best practices and internal processes into one framework identified as the prevention and reduction of financial toxicity (PRoFT) risk framework. A patient-centric approach puts the participant's needs first (Florence, n.d.). The driving research questions guided the development of the PRoFT Risk Framework. Steps in the PRoFT risk framework merge best practices and internal processes to create a holistic approach to prevent and reduce financial toxicity risk. Additionally, the efforts of the PRoFT Risk Framework address the deficit regarding participant satisfaction surveys, financial transparency, and risk of CRB non-compliance while helping sites benchmark metrics for baseline and improvement.

Implementing the PRoFT risk framework approach of preventing and reducing financial toxicity risk will vary across sites based on infrastructure and needs. A gap analysis will guide the site in determining the appropriate change management plan needed for success. Sites should also review infrastructure and continually identify additional needs or improvements.

Conclusion

A clear, meaningful strategy around implementing the PRoFT risk framework approach to prevent and reduce financial toxicity risk, clinical research participant satisfaction surveys, and establishing metrics to benchmark results will aid in determining return on investment. The clinical research industry is changing rapidly; innovative and impactful change is necessary to protect the research site's integrity, reduce clinical research billing non-compliance, and prevent and reduce financial toxicity for the clinical research participant. Foremost, sites should take a patient-centric approach in clinical research by prioritizing the patient's needs and outcomes.

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