

A Framework for Workflow-based Clinical Research Billing Disambiguation

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Abstract

Medicare received authorization in 2000 to reimburse for routine costs incurred in association with patients participating in clinical research. However, we hypothesize that the inability to accurately differentiate standard from investigational care has resulted in under-coding of potentially reimbursable clinical events. To address this problem, we have initiated the development of a methodology for constructing computational clinical workflow models that can be employed to aid in the disambiguation of routine versus research costs.

Introduction

In 2000, a presidential executive memorandum explicitly authorized Medicare to reimburse for “routine patient care costs associated with clinical trials”¹. However, members of the Association of American Medical Colleges (AAMC) have expressed concern regarding the ability to accurately differentiate charges incurred from standard of care treatment versus research protocol activities¹, and as a result, the Centers for Medicare and Medicaid Services (CMS) is currently undertaking an initiative to clarify these definitions. We hypothesize there is significant under-coding associated with standard of care treatments provided for clinical research subjects due to uncertainties over billing compliance. Consequently, in the specific context of cardiology research, we have iteratively developed a novel workflow-based framework to:

1. Identify the critical activities and decision points that can be used to define standard of care treatments for research patients;
2. Construct a computational workflow model based on these findings that can aid in the disambiguation of charges associated with standard of care and research protocol activities.

Methods

We have initiated a pilot project in collaboration with the perioperative care teams at the Richard M. Ross Heart Hospital at the Ohio State University Medical Center (OSUMC) to assess the efficacy of our methods for developing computational workflow models.

Workflow Studies

A combination of ethnographic observations, time-motion studies and semi-structured interviews are being conducted to identify critical activities and de-

cision points. In addition, clinical practice standards and guidelines from the National Guideline Clearinghouse (NGC)² and UpToDate³ will be processed using the MedLEE⁴ natural language processing engine. The goal is to generate a computational representation of the major standard-of-care concepts contained in the guidelines and augment it with locally relevant workflow practices.

Data Warehouse “Meta-Model”

Using an ontology-anchored abstraction layer developed for the OSUMC Information Warehouse, we will correlate the computational workflow representation model with quantitative data-driven metrics. Two critical components of this proposed framework are the capability to (1) create conceptual and semantic linkages between the clinical workflow, data entry and physical storage, and (2) perform trend analyses.

Computational Workflow

Finally, we will adapt the methodologies implemented in the SAGE Guideline Model⁵, most notably the use of activity graphs generated with Protégé-2000 to construct computational clinical workflow models integrating the results of the preceding framework components.

Conclusion

The development and implementation of a data-driven computational clinical workflow model can potentially improve our understanding of standard of care processes and associated billing practices. Our future work includes adapting the current methodologies to research-specific clinical data, workflows and protocols, which should aid in disambiguating standard of care treatments for research subjects.

References

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