

Chapter 8.6

Novel Data Interface for Evaluating Cardiovascular Outcomes in Women

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ABSTRACT

This chapter discusses critical success factors in the design, implementation, and utility of a new construct and interface for data transfer with broad applicability to clinical data set management. In the context of a data coordinating center for evaluating cardiovascular outcomes in high-risk women, we detail and provide a framework for bridging the gap between extensible markup language (XML) and XML schema definition file (XSD) in order to provide greater accessibility using visual basic for applications (VBA) and Excel. Applications and lessons learned are discussed in light of current challenges to healthcare information technology management and clinical data administration. The authors hope that this approach, as well as the logic utilized and implementation examples, will provide a user-friendly model for data management

and relational database design that is replicable, flexible, understandable, and has broad utility to research professionals in healthcare.

INTRODUCTION

The transformation of clinical and translational science requires a visionary approach to management and sharing of information. This can best be accomplished by providing investigators with ubiquitous access to tools and processes that enhance the quality, availability, security, collection, and analysis of data. The informatics needs identified today for clinical and translational research will evolve and be rapidly augmented by new demands coupled to new capabilities. Therefore, the supporting information technology infrastructure needs to be flexible to respond to new challenges as they arise, and scalable to

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accommodate increases in demand, type, and complexity of data.

Researchers and practitioners conducting cutting edge investigation in healthcare information technology management and clinical data administration experience challenges in data and information management that are not confined to technology. Many of the obstacles pertain to ambiguous definition of terms, new concepts, processes, acronyms, and the plethora of research areas, issues, and trends that currently face information technology management and clinical data administration in the healthcare setting. Specifically, there is a need to better understand approaches, frameworks, and techniques for healthcare information technology management in order to develop and implement appropriate solutions that may have applicability to others, and to share lessons learned. The demand currently is for integrated systems of healthcare information. However, there is also a need for technologies and constructs that focus on the implementation, adaptation, development, and application of existing tools for clinical investigators, and their research teams, to facilitate the performance of small and medium sized research studies, specifically related to the collection, management, and security of human subjects study data.

There are a limited number of resources which detail models, frameworks, or case studies on how to facilitate creating integrated healthcare solutions for small and medium sized clinical investigations. In this chapter we will discuss one such approach, and techniques for healthcare information technology management solutions, utilizing as a model an innovative custom Excel construct system for data exchange established for a clinical Data Coordinating Center (DCC) at the University of California, Davis.

The University of California, Davis (UC Davis), Women's Cardiovascular Medicine Program, is the Data Coordinating Center for a national joint database involving a total of 6 study investigation sites nationwide. The sites include four

academic health centers, one clinical practice center, and one mobile community-based healthcare delivery program. The study was funded by the U.S. Department of Health and Human Services (DHHS)-Office on Women's Health (OWH) as part of an award entitled *Improving, Enhancing and Evaluating Outcomes of Comprehensive Heart Care in High Risk Women*.

The purpose of the study was to evaluate cardiovascular disease prevention, knowledge, risk awareness and clinical outcomes in women at high risk for cardiovascular disease due to race, ethnicity, rurality, and/or cardiac risk factor profile, and to compare outcomes at 6 and 12 months of patient follow-up. The intervention involved patient education and applying and utilizing Evidence-Based Guideline for Heart Disease Prevention in Women published by the American Heart Association at the time the study was initiated (Mosca, 2004). Each participating site collected patient demographic, survey, and clinical data. A total of over 1,300 women participated in the study. The joint analysis database developed for the study consisted of a collection of de-identified patient-specific data from human subjects enrolled at each of the 6 participating study investigation sites during a period spanning from January, 2006 to September, 2007.

The goal of the Data Coordinating Center (DCC) established and described below, was to manage the construct, design and implementation of the database, manage and coordinate data entry and upload to the database, create a joint database, attend to data validation, storage, integrity and security, secure access for statistical analysts and other project staff, and provide data backup, recovery and maintenance. The joint database was subsequently utilized for joint analysis of the project's outcomes as follows: 8 required clinical/survey/demographic outcomes and/or sub outcomes, and 5 optional outcomes and/or sub outcomes. Outcomes defined parameters in the following areas:

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