



Implementing common data elements across studies to advance research

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ABSTRACT

Challenges arise in building the knowledge needed for evidence-based practice partially because obtaining clinical research data is expensive and complicated, and many studies have small sample sizes. Combining data from several studies may have the advantage of increasing the impact of the findings or expanding the population to which findings may be generalized. The use of common data elements will allow this combining and, in turn, create *big data*, which is an important approach that may accelerate knowledge development. This article discusses the philosophy of using common data elements across research studies and illustrates their use by the processes in a developmental center grant funded by the National Institutes of Health. The researchers identified a set of data elements and used them across several pilot studies. Issues that need to be considered in the adoption and implementation of common data elements across pilot studies include theoretical framework, purpose of the common measures, respondent burden, teamwork, managing large data sets, grant writing, and unintended consequences. We describe these challenges and solutions that can be implemented to manage them.

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Introduction

Research findings establish new knowledge, validate previous findings, expand findings to a new population, and help build a body of knowledge on which practice (in a practice discipline such as nursing) is based. Challenges arise in building the knowledge needed for evidence-based practice partially because obtaining clinical research data is complicated, and many studies have small sample sizes. Combining data from several studies may have

the advantage of increasing the impact of the findings or expanding the population to which findings may be generalized. In addition, having standardized measures that can be shared will capitalize on the benefits of *big data* for enhancing scientific benefit. Big data is a broad term for any collection of data that is large and complex enough to become difficult to process.

Synthesizing findings across multiple studies is complex (Kim, Pressler, Jones, & Graves, 2008). The current manner in which data are collected to support knowledge generation can be a slow and expensive

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process (Boyd et al., 2011; Riley, Glasgow, Etheredge, & Abernethy, 2013). One way to increase the speed of accumulating data, incorporating findings, and reducing expense is for researchers to collect and report common data elements, which facilitates creating common databases (Riley et al., 2013). The purpose of this article is to discuss the philosophy of using common data elements across research studies and illustrate their use by the processes used in a National Institute of Nursing Research P20 Exploratory Center grant entitled Interdisciplinary Health Heart Center: Linking Rural Populations by Technology (NR011404). The P20 researchers identified a set of data elements and used them across several pilot studies. We also describe challenges that arose and solutions that can be implemented to manage them.

Definitions of Common Data Elements

The National Institutes of Health (NIH) is among the groups advocating that researchers use common data elements to facilitate comparing and combining data across studies, including data elements derived from electronic health records. The NIH definition of common data elements (CDEs) is “a data element that is common to multiple data sets across different studies” (<http://www.nlm.nih.gov/cde>; National Institutes of Health, 2014 a, b).

When designing research to answer a particular question, researchers select key concepts that are important to the question. In most cases, other researchers have also investigated the concepts and, over time, used multiple measures and methods to assess concepts. Data generated from the various methods may be similar but not necessarily equivalent. In contrast, CDEs are generated from the same set of instruments used to consistently measure a set of concepts of interest to many researchers. Comparison of data across studies is more accurate and relevant when researchers are investigating questions using the same data elements and measures.

CDEs

Several initiatives have been launched to create tools to collect common data. As a result, a variety of proposed sets of CDEs can be found on the Web. An example is the Quality of Life in Neurological Disorders, a set of self-report measures that assess health-related quality of life of adults and children with neurologic disorders. A collaborative, multisite group constructed these tools with a contract from the National Institute for Neurological Disorders and Stroke. Measures, which include English and Spanish versions, are available for use without permission and at no charge from their website (Northwestern University, 2013).

Another example is the PhenX Toolkit (Hamilton et al., 2011). To facilitate replication and validation

across studies, RTI International (Research Triangle Park, NC) and the National Human Genome Research Institute (Bethesda, Maryland) are collaborating on the consensus measures for Phenotypes and eXposures (PhenX) project. The goal of PhenX is to identify 15 high-priority, well-established, and broadly applicable measures for each of 21 research domains. PhenX measures are selected by working groups of domain experts using a consensus process that includes input from the scientific community. The selected measures are freely available to the scientific community via the PhenX Toolkit, thus providing the research community with a core set of high-quality, well-established, low-burden measures intended for use in large-scale genomic studies. The PhenX Toolkit website (release 5.8, <https://www.phenxtoolkit.org/>) contains 339 standard measures related to complex diseases, phenotypic traits, and environmental exposures (RTI International, 2014). The use of PhenX measures facilitates combining data from a variety of studies, stimulating investigators to expand a study design beyond easily accessible sample. All Toolkit content is available to the public at no cost.

In addition to creating tools, others have worked to catalog tools. An example is the National Cancer Institute's (NCI) Cancer Biomedical informatics Grid (caBIG). The purpose of this project, which was launched in August 2007, was to contend with various barriers to data exchange by addressing legal, regulatory, policy, proprietary, and contractual barriers. An assessment of the impact of caBIG (Board of Scientific Advisors Ad Hoc Working Group, 2011) found that the original goals were highly relevant to cancer research; however, caBIG was seen to have expanded beyond those goals to the implementation of an overly complex and ambitious collection of NCI-branded software tools. These tools have been fully adopted by only a few NCI-designated Cancer Centers, and tools from established commercial vendors have been found to be more useful. Although caBIG was retired, the project led to the development of a platform used to develop Grid-Enabled Measures database, a dynamic Web-based database for researchers (<https://www.gem-beta.org/public/About.aspx?cat=5>; NCI, 2012). The database was designed to allow users to collaborate in building consensus on the use of common elements and measures and to facilitate data sharing and harmonization. The database currently (as of November 4, 2014) has 891 measures of 343 concepts. Anyone can view the website, and all are invited to add and edit information, measures, and concepts.

These examples show a value in sharing CDEs as well as several processes that have been used to develop these CDEs. In addition, barriers to the use of CDEs are also illustrated, especially in the example of caBIG. The following examples later are from our experience on a smaller, college level when our center grant was under development and subsequently funded.

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