Strong data management knowledge and skills are a requirement for every DNP. This unique text focuses on fostering the rigorous, meticulous data management skills that can improve care experience, health outcomes, and cost savings worldwide. It provides a knowledge base, describes the regulatory and ethical context, outlines a process to guide evaluation, presents a compendium of resources, and includes examples of evaluation of translation. It takes the DNP student step by step through the complete process of data management, including planning, data collection, data governance and cleansing, analysis, and data presentation. Moreover, the text continues the process of establishing a sturdy clinical data management (CDM) skill base by presenting techniques for ongoing project monitoring after analysis and evaluation are concluded.

A progressive case study illustrates multiple techniques throughout each chapter, enabling students to apply what they have learned to their own DNP projects. The book features information from professors who are highly experienced in teaching CDM as well as a renowned scholar of population health analytics. The text provides very specific examples of techniques using SPSS software that is familiar to graduate nursing students. Chapters include objectives, references, and examples from translation projects to assist students to learn and apply chapter content.

Key Features:

- Meets the specific data management needs of the DNP student from planning to presentation
- Presents a wide selection of data display options through frequent illustrations of SPSS data
- Uses a progressive case study to illustrate multiple techniques and methods throughout chapters
- Provides substantial content necessary for the DNP student to rigorously evaluate DNP innovations/projects
- Includes very specific examples of the application and utility of these techniques using software that is familiar to graduate nursing students
Clinical Analytics and Data Management for the DNP
Martha L. Sylvia, PhD, MBA, RN, is assistant professor at the Johns Hopkins University School of Nursing with a joint appointment in the School of Medicine, and an associate faculty member of the Welch Center for Prevention, Epidemiology, and Clinical Research. She is the director of the Population Health Analytics Core, a unit that is jointly sponsored by Johns Hopkins HealthCare; Johns Hopkins Welch Center for Prevention, Epidemiology, and Clinical Research; and the Division of General Internal Medicine. Dr. Sylvia currently participates in four research projects with Johns Hopkins University, including serving as the principal investigator on Calculating Cost Savings for Care Management Programs (Johns Hopkins HealthCare) and as principal investigator on An Evaluation of The Access Program (TAP) at East Baltimore Medical Center (Johns Hopkins Community Physicians and Urban Health Institute). She has published eight peer-reviewed research papers; has presented internationally on data management and predictive analytics in Australia, Germany, Japan, and Malaysia; and has presented nationally at the American Association of Colleges of Nursing (AACN) Doctoral Conference, America’s Health Insurance Plans (AHIP), and the American Society of Health Risk Management, among many others. Dr. Sylvia developed and has taught 3 years of both sections I and II of the Clinical Data Management course in the Doctor of Nursing Practice (DNP) program at Johns Hopkins. She has over 10 years experience in clinical analytics and 10 years clinical nursing experience in acute care medical–surgical nursing, provider office staff nursing, case management, management of community and health plan case management services, and executive leadership of a community-based free clinic for the uninsured.

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Clinical Analytics and Data Management for the DNP

Martha L. Sylvia, PhD, MBA, RN
Mary F. Terhaar, DNSc, RN
This book is dedicated to Amy, an admirable nurse and lovely niece.
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Foreword

Clinical Analytics and Data Management for the DNP is a most welcome addition to the available resources for nurses in advanced practice and executive roles. The book is unique. It aims to provide nurses with the analytic skills needed to transform practice at the systems level, and thereby improve outcomes by gathering, managing, and applying well-analyzed data. These skills are essential if DNPs are to rigorously evaluate innovative projects and if their work is to have impact.

In addition to introducing DNP students to the management of clinical and administrative data, including financial data, the book will be very useful for practicing DNP nurses and faculty.

The authors have intentionally designed a practical yet scholarly approach to analysis of clinical data and how to manage it. The book has been developed using their years of experience teaching in the DNP program at Johns Hopkins School of Nursing. The book reflects their cumulative learning through developing, implementing, and evaluating a novel approach to teaching clinical data management.

The chapters are arranged in a logical manner to build understanding and skills. Beginning with basic statistical concepts and power analysis, the reader is led through planning for data collection and developing an analysis plan, to data governance and creating the data set. The subsequent chapters address exploratory and outcomes data analysis; the concluding chapters focus on summarizing results of project evaluation and ongoing monitoring. Whether data are collected and analyzed for a specific project or gathered from multiple existing sources for a new project, these approaches are crucial if the project outcomes are to be credible.

The progressive case study illustrates multiple techniques and methods students can apply to their projects. More important, however, is the mastery of these techniques and methods for use by practitioners after graduation. The role of the practicing DNP requires an ability to translate evidence into practice in large organizations—that is, into clinical standards, quality improvement initiatives, and innovative management programs. DNPs with strong data management skills add value to organizations by documenting advances in clinical care, in the efficiency of care processes, and in the cost-effectiveness of programs.

Health care organizations are shifting from a fee-for-service model to a value-based model. Value-based health care focuses on costs, quality, and, most important, outcomes. The goal is high-quality and high-value care, with a reduced need for high-cost services. Central to this shift is the organization’s ability to use data to measure the use of services, the quality of care, and patient satisfaction. The ability to define, measure, analyze, and demonstrate an improvement is central to the role of the DNP in health care’s pursuit of value.
FOREWORD

We are proud of the leadership and creativity Martha Sylvia and Mary Terhaar have demonstrated in designing courses, curriculum, and this book. They have carefully thought through the competencies needed by graduates of DNP programs if they are to fulfill their potential to be effective leaders of systems-level changes that will improve patient care and outcomes.

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Preface

We are committed to the success of the DNP as a credential and to the success of the students who earn it. Our program prepares students to capably apply evidence to address important clinical problems and then evaluate the impact of their efforts. For 8 years we have taught students to adopt a posture of inquiry in their work, to use evidence to tackle important problems, and to rigorously evaluate their efforts. This approach prepares graduates to continually improve practice, to deliver outcomes, and to establish solid, credible programs of translation and improvement.

As faculty, we practice what we preach. We continuously evaluate the outcomes of our teaching and the work of our students. In that tradition, we conducted a review of the initial 38 capstone projects completed by DNPs in our program and determined that the evaluation component of the capstone needed to be more rigorous and data driven. In a review of the broader DNP curriculum, we identified and exploited opportunities to introduce content that would provide DNP students with the tools they needed to improve the data-driven components of the capstone project. Gap analysis revealed the need to strengthen plans for data collection, cleansing and manipulation, governance, analysis, and reporting. We decided to add an analytics course and set out to find a text to help us do so.

In the search for a text, we were surprised to find none that fully addressed the complexity of using clinical, operational, and financial data sets in various combinations to evaluate the impact of quality improvement and translation activities. Certainly, high-quality research and statistics texts are available and useful as a foundation for design and significance testing. Although essential, existing texts are not sufficient to prepare the DNP and other health professionals to translate evidence into practice and evaluate impact.

Absent a good text to guide the course, we set out to develop the content ourselves. Initially, Clinical Data Management (CDM) was offered as an elective, and course evaluations were favorable. More importantly, students who took CDM were more capable, comfortable, and independent in the analysis of their translation projects. We learned from their experiences, refined the course, and established CDM as a requirement for all DNP students. Evaluations improved, students succeeded and provided additional helpful feedback, and CDM was expanded to two courses in the second year of the program. Publications that resulted from the capstone projects increased, and graduates became increasingly successful in continuing the work of translation and evaluation they learned in the program. For example:

- Erik Southard used evidence and technology to provide consultation support to communities across rural Indiana, where psychiatric professionals are in short supply. He documented a decreased mean time to consult from 16.2 hours to 5.4 hours (Southard, Neufeld, & Laws, in press).
Mariam Kashani and her colleagues added family risk and history of premature heart disease to risk assessment based on the Framingham Risk Score. As a result, 48% of 114 patients originally classified as low to moderate risk were reclassified as high risk, and 72% of those were found to have dyslipidemia, 35% had hypertension, 20% were prediabetic, and 61% evidenced atherosclerosis on carotid intima media thickness (Kashani, Eliasson, Vernalis, Bailey, & Terhaar, 2013).

Lina Younan used evidence to establish handoff procedures that reduced errors of omission during intershift handoff (n = 90) from a mean of 4.96 errors per patient handoff at baseline to 2.29 per patient handoff postintervention (p < .000; Younan & Fralic, 2013).

Bernadette Thomas made modifications to the electronic health record and used scorecards to increase chronic kidney disease screening (from 38% to 46%, p = .049), diagnosis (from 11% to 20%, p = .000), and use of appropriate medications among patients with diabetes (from 63% to 67%, p = .000) at a statewide federally qualified health center in Connecticut (Thomas, 2011).

All of these students tackled problems important to their organizations and communities. The analytics they applied allowed confidence in the conclusions they drew and all achieved statistically significant improvements.

This is the point at which we decided to write a text. We had developed content and a process useful to our students and faculty. We tested the text’s value and reported an increase in capstone publications. We believe the content will be useful to others: to students, faculty leading other programs, and the organizations that employ DNPs. We want to share the evidence we collected to direct planning, gathering, entry, transforming, cleansing, governing, analyzing, and reporting of data. We invite schools of nursing with DNP programs that require scholarly projects to adopt and improve this process in support of establishing consistent, rigorous, well-evaluated translation. We want research to reach practical application expeditiously so the triple aims of quality, experience, and value can be attained (Berwick, Nolan, & Whittington, 2008) and so society can yield the return on its investment in basic research.

In the words of Charles-Guillaume Étienne, “One is never served so well as by oneself.” We set out to write the text that could extend the success our students have earned. We hope it is helpful to all who seek to improve practice and outcomes through the judicious application of evidence and rigorous evaluation of the results.

Martha L. Sylvia
Mary F. Terhaar

REFERENCES


Acknowledgments

I would like to give a special thank you to everyone at Johns Hopkins HealthCare and Johns Hopkins University who have contributed to my clinical analytic journey: those who have mentored me, those who worked beside me, and especially those on my team of amazing analysts, past and present, from whom I learn every day. And to my husband Michael, thank you for all of your support and encouragement throughout this process.

Martha L. Sylvia

We want to recognize the community of scholars that is Johns Hopkins Nursing. It has been a once-in-a-lifetime opportunity to develop a new program in partnership with amazing educators, researchers, administrators, and clinicians. Each has made the program stronger and helped our faculty to develop students and curricula for the demands of care, quality, and value.

We thank Dean Hill for her courageous leadership. At a time when great uncertainty surrounded creation of a doctorate in nursing practice, Dean Hill challenged us to offer a program whose graduates would make Johns Hopkins University proud. She encouraged her faculty to lead, not follow, and her challenge freed us to undertake this work.

We especially thank our students for the challenges they present. The problems they undertake to solve press us to develop tools and processes to ensure both rigor and success. The populations they serve and the communities with whom they collaborate make great innovation possible. We celebrate your accomplishments and are pleased to contribute to your success.

Martha L. Sylvia
Mary F. Terhaar
CHAPTER 1

Introduction to Clinical Data Management

MARY F. TERHAAR

TRANSLATION

Timely application of strong science in the provision of direct patient care; management of health care systems; and education of clinicians, providers, and administrators are all compelling needs today in clinical data management (CDM). Science promises reduced suffering, improved quality of life, and increased productivity of individuals in societies. The challenge is to establish effective, disciplined mechanisms for translation that are accompanied by vigilant monitoring, rigorous analytics, and critical evaluation as innovation is brought to scale. These strategies are integral to delivering the innovation and reform that research findings proscribe, and every step on this path depends on data and analytics.

The purpose of this book is to describe a process and a set of strategies to be used to promote consistent, quality evaluation of the impact of translation. To adopt this approach builds a base of support for the work. This approach directs formation of a comprehensive plan that can be reviewed and approved prior to beginning any translation activity and then monitored throughout execution. It increases the quality of evaluation because it reduces error in data collection, measurement, and analysis. This, in turn, increases confidence of the team in its own potency, confidence of decision makers in the outcomes accomplished, and support within the organization for a program of translation. Because translation is central to the role of the Doctor of Nursing Practice (DNP), this text focuses on the DNP and presents examples of DNP work, data, and evaluations.

THE DOCTOR OF NURSING PRACTICE AS TRANSLATOR AND ANALYST

The DNP is a relatively new practice doctorate intended to improve outcomes for individuals receiving health care; for systems providing that care; and for professionals engaged in care, consultation, management, leadership, and the policy process. DNPs make their mark by accelerating the translation of robust evidence to improve outcomes. The value of the degree is judged by the results achieved.
The work of the DNP must be strong, scholarly, and significant. It must conform to accepted standards of researchers, clinicians, statisticians, and academics alike in order for the work to achieve its mark; the credential to endure; and for those who earn it to have lasting impact.

A set of core skills focusing on translation, collaboration, and evaluation is required for the DNP to be effective. Effective translation requires critical understanding and selection of evidence, careful planning, meticulous execution, reliable measurement, and robust evaluation. Knowledge of research design, program implementation, project management, statistics, epidemiology, professional and research ethics, data management, and analytics is the key (Sylvia & Terhaar, 2014).

THE CONTEXT OF DISCOVERY AND INNOVATION

Movement of science from the bench to the bedside brings significant change in context. Researchers formulate questions based on extensive study of existing knowledge; pose hypotheses for testing; control conditions in which these hypotheses are tested; select or develop measurement strategies that assure specificity and precision; and gather comprehensive data sets that ensure robust, generalizable conclusions can be derived. The hallmarks and the context of research are precision and control. Investigators maximize the effects of the variable(s) of interest, minimize the effects of extraneous variables, and control interactions known to impact the research question. The result is confident conclusions about relationships between variables and causality. The goal is new knowledge—discovery.

Translators operate in a different environment: the practice environment. They identify problems to solve, performance to improve, processes to refine, and conventions to question. Here, opportunity for innovation exists with minimal opportunity for control, and time is often critical. There is a calculus that seeks to minimize time to solution, as well as risk and error. Solution rather than discovery is the goal. Effective application of knowledge is the key.

Regardless of context and purpose, both research and translation require rigorous evaluation—the former to assure proper conclusions and generalizability of findings, the latter to determine applicability of research findings to a particular population and setting. This book provides a base of knowledge, describes the regulatory and ethical context, outlines a process to guide evaluation, presents a compendium of resources, and delineates examples of evaluation of translation efforts.

CLINICAL DATA MANAGEMENT

[CDM is] [t]he process of planning, designing, collecting, cleansing, manipulating, analyzing, and reporting data generated in the assessment, development, delivery, and evaluation of health-related interventions, products, and services. (Sylvia & Terhaar, 2014)

Pharmaceutical companies employ CDM to evaluate sets of data from clinical trials (Lu & Su, 2010). Considered a distinct phase in clinical research by some, CDM produces reliable data and reduces time of a drug progressing from development to trial, and ultimately to market (Krishnankutty, Bellary, Kumar, & Moodahadu, 2012).
Within the context of translation, CDM is most effectively seen not as a phase, but as a thread that crosses all activities of the work and promotes confidence in both process and outcome. Whether the work of teams, researchers, statisticians, or DNPs, CDM consistently refers to efficient and effective decision support using clean, reliable data.

The following paragraphs describe the procedures of CDM. Chapter by chapter, each introduces one component along with the foundational knowledge required for its deployment, tools to facilitate the work being described, and examples from translation projects.

Chapter 2: Basic Statistical Concepts and Power Analysis

In this chapter, the language of CDM is introduced and some elementary knowledge from statistics and research is reviewed. Types of measurement and levels of data are explained. Power analysis is outlined, emphasizing its critical importance to rigorous evaluation and manner of determination. Decisions about sample size and formation are presented in detail. Chapter 2 is not a statistics text, but a review of content vital to understanding the remainder of this book and to successful CDM in support of translation.

THOUGHTFUL PLANNING

Chapter 3: Preparing for Data Collection

Prior to completing the data analysis plan, a decision must be made about the sources of data to be used during the analytic phase of the DNP project. These sources are used to collect data for descriptive information and outcomes measurement. Feasibility, quality, specificity, and utility of primary data are compared to secondary data. Here, the logic for selecting either source is described and the implications for evaluation are reviewed.

Chapter 4: Developing the Analysis Plan

The first step in any data analysis is the creation of a data analysis plan that guides the entire project. A comprehensive process for planning analysis, including a description of considerations with respect to key decisions, is presented. Highlighted are the needs for descriptive data about the population, units of measurement, and the use and composition of comparison groups. In addition, outcome measures, calculations to derive scores, and other metrics are outlined. The construction and the sensitivity of measures that precisely evaluate the attainment of project aims are considered.

Chapter 5: Data Governance and Stewardship

The ethical responsibilities of those engaged in human subjects research are well understood and articulated. Although many in practice do not consider translation to be research, those who engage in this work need to adhere to the same...
requirements for protection of human subjects and peer review. Translators, like researchers, need do no harm. This chapter presents the critical importance of data governance and stewardship as one means to assure compliance with standards for professional ethics. The history, regulations, structures, and processes in place within each organization that impact the project, its execution, and the work of CDM are considered.

CAREFUL AND EFFECTIVE ACTION

Chapter 6: Creating the Analysis Data Set

High-quality results depend on high-quality data. This chapter explains the process of going from initial data collection or from the collection of secondary data to creation of a final analysis data set. This procedure includes importing data into statistical software, cleansing the data, manipulating the file and/or data, and creating a final analysis data set and data dictionary. Throughout the entire operation and any ongoing analysis, syntax is used as a method for documenting actions taken on the data and the decision process leading to those actions.

Chapter 7: Exploratory Data Analysis

Exploratory data analysis (EDA) is both a method for the investigation of data as well as a set of recommended tools and techniques with the fundamental tenet being that the data need to be explored and understood in their most basic form to the point of meaningful information (Smith & Prentice, 1993). This activity encompasses exploration of each variable individually and in meaningful combinations, as well as developing an understanding of the population and/or events of interest. It is necessary to carry out this EDA process prior to the analysis of outcomes measures. In conducting the EDA, the goal is to analyze data without expectations or assumptions. Thus, unexpected findings can be revealed. Chapter 7 considers the EDA as a strategy to create meaning from the collected data and to provide the structure and preparatory information needed to refine and execute the data analysis plan.

Chapter 8: Outcomes Data Analysis

Outcomes data analysis (ODA) is the final step in data management. Of all the phases of data management, ODA is perhaps the easiest after all the work that has gone into preparing and analyzing the data to this point. If the translational project does not use groups for comparison, then analysis of outcomes may be solely descriptive or may use a comparison to some type of benchmark or predetermined goal. If the translational project plan uses some type of comparison group, then statistical testing is done to determine the success of outcomes compared to another group or the same group at a different point in time. This chapter reviews execution of the analysis plan and evaluation of outcomes.
Chapter 9: Summarizing the Results of the Project Evaluation

Reporting of results is done within a defined structure; however, the content within that structure and the choice of format and mechanisms for delivery are chosen based on the primary interest of the target audience. Therefore, Chapter 9 describes the basic elements that need to be compiled for the reporting of results. Yet, variation is expected in the actual communication and presentation of this information based on the targeted audience and message.

Chapter 10: Ongoing Monitoring

Data management should be thought of as an ongoing feedback loop where data gathered, analyzed, and evaluated are used to continuously inform decisions and improve processes. As procedures are modified, deleted, or continued to achieve the desired outcome, the data must continue to be gathered and monitored to understand ongoing effects of the intervention and make decisions to further ensure that the best possible results are achieved. This chapter introduces the many tools that can be used to understand intervention techniques and outcomes, including statistical process control charts, run charts, and benchmarks. All of these can be used as part of broader, ongoing, continuous quality-improvement efforts to ensure that gaps in the intervention are met with effective responses and areas of weakness are addressed across the life span of the intervention.

CONCLUSION

The critical importance of improving practice and outcomes through the application of evidence has been significantly emphasized and resourced through collaborative efforts of the Robert Wood Johnson Foundation (RWJF) and the Institute of Medicine (IOM, 2010). Thousands of clinicians, educators, and administrators from around the globe have gathered to learn from experience, share strategy, and disseminate successes that target innovations and meaningful improvements in care, health, and cost (Berwick, Nolan, & Whittington, 2008). Scholarly journals, publications, and affiliations have developed the science and the practice of improvement and implementation. Johns Hopkins Hospital and its partners have cultivated processes and tools to be used by clinicians in the application of evidence in practice (Dearholt et al., 2012) and to support the work of translation (White & Dudley-Brown, 2012). Universities and clinicians providing direct care have designed models to promote timely, effective translation and system-wide collaborative change (Pronovost et al., 2006).

Health care professionals around the globe embrace the challenge of achieving the triple aim to improve performance: care experience, outcomes, and cost (Berwick et al., 2008). In presenting this treatise on CDM, the authors strive to set a standard for DNP practice that guides robust evaluation of the work of translation. If this new academic preparation of clinical nurse specialists, administrators, anesthetists, practitioners, midwives, informaticians, executives, and educators achieves its intended goal, the triple aim of improved care, health, and cost will be that much closer. Without meticulous CDM, this certainly remains out of reach.
REFERENCES


