



Statistical Methods in Healthcare

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 WILEY

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– Frederick W. Faltin

To Jonathan, Alma, Tomer, Yadin, Aviv and Gili
– Ron S. Kenett

To Anna, Giacomo and Lorenzo
– Fabrizio Ruggeri

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Foreword

Twenty-five years ago we launched an interesting experiment, ‘The National Demonstration Project for Quality Improvement in Healthcare’. It was a modest experiment bringing together twenty-one healthcare providers with twenty-one top industrial companies to explore whether industrial quality methods would work in healthcare settings. The results of this experiment were published as *Curing Health Care: New Strategies for Quality Improvement*. The statistical methods used by most of these healthcare providers were fairly basic tools of quality improvement; yet, many of the improvements were significant.

Looking back this many years later, there was no reason to be surprised by these results. Statistical methods had been used in many areas of healthcare for almost as many years as statistical methods had been used by any organization. Florence Nightingale was one of the first honorary members of the American Statistical Association, an organization that celebrated its 150th anniversary twenty-two years ago. Her pioneering work using clear, simple graphical methods to discover causes of death in hospitals during the Crimean War and alter British barracks was well known and celebrated. Basic, simple statistical methods to explore, understand and present data are as effective in healthcare applications as in any other endeavour.

But somehow, the science of quality control and quality improvement had passed healthcare by. Starting with Shewhart’s control chart in 1924, statistical quality control had progressed quickly during the Second World War, and had been widely adopted and used by post-war Japan to become a leading producer of high-quality products. It had been rediscovered in the United States in the 1980s, and widely applied throughout the world in the 1980s and 1990s by companies in almost every competitive industry. Healthcare had evolved many methods of quality assurance, risk management and quality measurement, for the most part independent of what was happening in industry.

In some areas of healthcare, particularly in drug and medical device development and production, sophisticated methods had been created and widely used. Researchers in biostatistics, biometrics and clinical trials had developed and employed some of the most advanced statistical methods, and in turn contributed much to the statistical literature. These methods, however, did not seem to translate easily to the practice of continuous quality improvement in hospital-based care or general clinical practice. There was a considerable gap between what we knew how to do and what we were doing.

The National Demonstration Project evolved into the Institute for Healthcare Improvement, and the growing network of healthcare providers became increasingly adept in learning from sources outside of healthcare, adapting these methods to healthcare applications, and sharing encouraging results with each other. It was not only the statistical tools. The healthcare organizations picked up the methods of putting these tools to use in a scientific approach to improvement using PDSA (Plan-Do-Check/Study-Act), Juran's Quality Improvement Steps, Motorola/General Electric's Define-Measure-Analyse-Improve-Control (Six Sigma Quality), and full-scale implementations of the Toyota Production System (Lean).

Healthcare organizations around the world have formed collaboratives, networks and not-for-profit organizations to share these methods and statistical tools. Thousands of doctors, nurses and other practitioners now routinely attend healthcare quality conferences and daily participate in online courses, web-based sharing and local working groups. Organizations such as the Institute for Healthcare Improvement have tried to structure some of this learning through devices such as IHI's *Improvement Roadmap* and the Open School, but there has not been a simple place to find the statistical tools used in healthcare improvement until now.

Faltin, Kenett and Ruggeri have brought together leading researchers and practitioners in statistical methods to provide a wealth of methods in one place. Starting with some of the most sophisticated methods used in the development of pharmaceutical products and medical devices, and ending with applications to healthcare management, they have managed to cover amazing ground. The chapters on control charts bring together some of the best methods of statistical process control (SPC) in healthcare, and even cover some of the abuses in the use of control charts. The chapter 'Six Sigma in Healthcare' gives a remarkably thorough discussion of both Six Sigma and how it is being applied by many healthcare organizations in Europe and the USA.

But this book goes much further than the typical statistics text and addresses serious policy issues such as kidney allocation and offers advanced statistical methods as an approach to this critical problem. Another critical issue in healthcare, vaccine safety evaluation, is also addressed. In this time of crises in healthcare costs, the economics of healthcare is becoming a major issue. Here too, statistical methods have a large part to play.

The core of healthcare is, of course, clinical outcomes. Statistical methods play a critical role in outcomes analysis. Bias in modelling and monitoring health outcomes are addressed in a chapter by Grigg. Biggeri and Catelan discuss disease tracking. Guglielmi, Ieva, Paganoni and Ruggeri address process indicators and outcome measures in an important area, and Negri gives an excellent discussion of the special tool of meta-analysis.

We no longer need to discuss the value of statistical tools and quality improvement methods in healthcare. The value has been demonstrated thousands of times. What is needed is a comprehensive compilation of these tools in one place written by careful, knowledgeable authors. We should all be grateful to Faltin, Kenett and Ruggeri for providing it.

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Preface

This book has its origins in the confluence of two realizations. First, that the availability and quality of healthcare is the defining issue of our time. And second, that statistics as a discipline pervades every aspect of the healthcare field.

Statistical Methods in Healthcare illustrates the spectrum of statistical applications to healthcare. From pharmaceuticals to health economics, drug product development to facilities management, clinical outcomes to electronic medical records, risk assessment to organ allocation, statistics has permeated every corner of healthcare. Accordingly, we have assembled here an array of chapters, prepared by a broadly international group of leading authors, which address all of these topics, and many more. Our objective was not to touch upon every area of statistical application in healthcare – that would be impossible. Rather, our purpose has been to span, as best we can, the diverse domains to which statistics has been applied and, thereby, to contribute to the evolution of statistical methods in healthcare applications.

The book consists of 23 chapters organized in five parts:

Part One: Statistics in Development of Pharmaceutical Products

This part consists of chapters dealing with clinical trials, pharmacometrics, risk management in drug product development, statistical aspects in current regulatory guidelines, and future challenges in drug development.

Part Two: Statistics in Outcomes Analysis

The second part deals with monitoring healthcare and diseases, a detailed case study on the treatment of acute myocardial infarction patients, and a chapter dedicated to meta-analysis.

Part Three: Statistical Process Control in Healthcare

Applications of statistical process control in healthcare are gaining widespread acceptance.

In this part we present examples from healthcare, clinical studies and applications of Six Sigma in healthcare.

Part Four: Applications to Healthcare Policy and Implementation

This part is focused on aspects of policy and implementation, including healthcare economics, benchmarking, vaccination policy and allocation procedures in kidney transplant surgery.

Part Five: Applications to Healthcare Management

This final part covers various aspects of healthcare delivery as a service, including payment procedures, electronic medical records and facilities management.

Not surprisingly, such an effort has been the work of contributors from many fields. *Statistical Methods in Healthcare* integrates contributions from statisticians, economists, physicians, epidemiologists, operations researchers, actuaries and managers, among others. The outcome captures perspectives from all of these disciplines, providing an integrated interdisciplinary view reflecting the richness and complexity of healthcare applications.

Our hope and belief is that this collective effort will prove valuable to those in a wide array of professions which in some way touch upon healthcare. Not only statisticians, but researchers, physicians and administrators will find here statistical applications with detailed examples representing a variety of problems, models and methodologies. Students and practitioners alike will discover opportunities to innovate via the use of statistical methods.

We'd like to acknowledge and thank the many people whose contributions have made this work possible. These include, first and foremost, our esteemed colleagues who have contributed chapters to the work, and the outstanding editorial, production and copy-editing teams at Wiley, who followed up our work together on *The Encyclopedia of Statistics in Quality and Reliability* with another successful outing. And of course, our thanks go especially to our families, for their patience with us while we were preoccupied or otherwise disengaged throughout the duration of this project.

This book includes an accompanying website www.wiley.com/go/statistical_methods_healthcare

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