CONTEXTUAL INQUIRY FOR MEDICAL DEVICE DESIGN

MARY BETH PRIVITERA

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FOREWORD BY THOMAS FOGARTY

The USA has long been the leaders in the development of new technology in the field of medicine, these reasons are multifactorial. This leadership is now under challenge. This book gives insight into basic concepts of how we can maintain our leadership role. The authors give suggestions and pathways that will serve the readers well in maintaining interest and leadership in medical technology. The book covers the subject well. It is written with insight and experience.

Dr. Tom Fogarty
Chairman, Director, Founder of The Fogarty institute for Innovation
National Inventors Hall of Fame for invention of the balloon embolectomy catheter
Presidential National Medal of Technology and Innovation 2014
Mountain View, CA, USA

FOREWORD BY PETER CURRY

Bard Medical Division (BMD) of CR Bard Inc. is a developer and producer of wide ranging critical care products, selling in excess of $700M, globally. Our product development process has embraced the use of contextual inquiry as an essential component to understanding value in the eyes of our customers. It has impacted the development and design of devices used in the treatment of urinary diseases and devices used to precisely control and manage patient temperature after critical life-threatening injury and illness. Our work with Mary Beth and her team has had a significant impact on our development process and directly improved customer satisfaction. We have recently redesigned and launched a product using the contextual inquiry process and a typical response from new and existing customers is "this is exactly what we've been asking for" or "this solution is very intuitive"; which is exactly what we are trying to achieve – organizing extensive customer inputs, derived from intense study of the 'use-environment', into valuable innovation. The products developed using contextual inquiry are having immediate impact on clinicians and patients as well as others in the hospital that make decisions on what to use. In these examples, this commitment to our patients and value to our customer would not have been possible without taking a methodical approach in studying clinical practice as presented in this book.

BMD has worked collaboratively with Mary Beth over the past few years. Her ability to combine objectivity and creativity is a fresh approach to innovation and has improved the early design end of our pipeline. The chapters of this book represent the process she has developed over the course of her career, working collaboratively with the medical device industry and training young professionals. It highlights the relationship between developing a clear understanding of user needs and developing information that informs device design. It is focused on industry practice and incorporates agency requirements.

As engineers, we quickly gravitate to looking for solutions first. Applying the principles highlighted in the chapters that follow, you will

understand the importance of, first, answering the "WHY" questions before developing "HOW/WHAT" solutions that often get confused with as starting point of design. Following contextual inquiry and listening to its outputs has shown success in product design for us.

Peter Curry
President, Bard Medical, Inc.
A division of CR Bard
Atlanta, GA, USA

FOREWORD BY WILLIAM S. BALL

Like industry, innovative approaches to medical product design are growing within our universities and colleges daily. The environment is perfect as it combines the efforts of many fields by talented faculty and enthusiastic students who are only bound by the limits of their creativity and ability to innovate. However, to find the right mixture for success requires a serious effort to identify a methodical approach that can turn "imagination into magic." Mary Beth's research in the area of contextual inquiry and the fuzzy front end of design provides us an excellent example of how best to promote medical device innovation across our campus. This book represents years of her dedicated practice both within the academy and as a consultant to the medical device industry. I am very proud of her contribution and her inclusion of our university's Academic Health Center as a true collaborative partner bridging the academic environment with the medical device industry.

Mary Beth's career at our university was in fact groundbreaking from the very start. She was recruited from the college of design to join the engineering faculty of the University of Cincinnati's Department of Biomedical Engineering under my leadership as a full faculty in medical device design. Her role was to integrate design into our developing undergraduate curriculum in medical device innovation. In this role she never disappointed and in fact far exceeded expectations. She rapidly recognized the need for a more experiential and productive approach to the craft, and set the bar for other programs nationally to follow. Over the years, I have watched her bring together the community and its needs with physicians and researchers in the College of Medicine to the benefit of her students, the university and industry. This book comes as no surprise. It highlights the practices she has developed and taught to collaborating biomedical engineering, business and industrial design students as well as faculty in many other disciplines. The book includes detailed descriptions of sound research methodology coupled with a fresh and innovative approach to collaboration. Lastly, the case studies presented offer a validation of the methods presented that can have a lasting impact throughout the device development process.

The University of Cincinnati prides itself on collaboration. This book represents all that our institution has to offer: solving real-world problems

through world-class research, building on our local resources to connect with a national and international community, while incorporating innovative pedagogy. This book best exemplifies what we refer to as *Cincinnati Smart,* and Mary Beth represents with pride the very best in what we have to offer. Even better, I have no doubt we are just at the beginning of an important career, with the best yet to come!

William S. Ball, MD
Professor of Biomedical Engineering, Radiology and Pediatrics
Vice-President for Research
Interim Vice-President for Health Affairs and
Dean College of Medicine
University of Cincinnati
Cincinnati, Ohio, USA

FOREWORD BY ARTHUR PANCIOLI

This book contains an in-depth explanation of the contextual inquiry practice and highlights the flexibility of the methodology. When we created our "medical device engine" in the Department of Emergency Medicine and brought together clinicians and experts in contextual inquiry wonderful things happened. Our faculty greatly enjoyed the process of explaining their procedural techniques while specifically highlighting areas of challenge. The clinicians often felt that their processes or techniques had room for improvement, however, they did not have the tools to delineate where the improvements could be found. Working with and observing the clinicians in their clinical arena and debriefing with them frequently, the experts in contextual inquiry were able to extract the gems of understanding that led to device improvement. This process often led to multiplicative benefits as one improvement often brought to light other opportunities for progress. The synergy was remarkable and I am grateful to have had the opportunity to observe the power of this team work and practice.

As readers consider engaging in this type of work you may discover that physicians and other clinical personnel have reservations when they are asked to participate in a process that is predicated on the direct observation of their practice. This was an issue that we encountered in virtually every clinical arena that we explored. Navigating this concern requires a clear explanation of the process, the ground rules and the goals. The case studies from the University of Cincinnati demonstrate the effectiveness of our efforts and success within the academy. The design team involved, under Mary Beth's direction, will always be welcome in our clinical environment. The results of these studies, especially the procedure maps that were generated, provide a truly unique opportunity for learning and represent an amazing dissection of these clinical processes. The depth of analysis and the ability to communicate the intricacies of clinical procedures was simply fascinating.

Finally, I am hopeful many more medical device manufacturers, especially those who design for emergency medicine, take up the practice presented in this book as a proven methodology that improves device design.

Arthur Pancioli, MD
Professor and Chairman
Department of Emergency Medicine
University of Cincinnati, College of Medicine,
Cincinnati, OH, USA

PREFACE

Deep understanding can only be gained through direct experience. The apprentice works alongside a master to gain the skills and knowledge to eventually execute a task on their own; they do more than just ask questions, they observe, absorb and internalize until they understand the nuances that separate adequate from exceptional. Contextual Inquiry (CI) takes on this model by embedding the design team within a users environment. This method is commonly used in consumer products and in the design of software interfaces but is more challenging in medical applications because of limits in access and logistics.

Medical device development involves understanding a complex web of interactions, tasks, and users. Product development teams are challenged to obtain a deeper level of understanding that can only be gained by direct exposure to the user and their environment. The contextual inquiry (CI) methodology provides the research tools and framework to enter the clinical environment and execute observations. These techniques are proven methods that provide a positive and tangible impact in the development of medical devices in every step of the development process.

This book describes the processes of conducting CI in a health care environment, it explains when in the design process it is appropriate to employ the various tools, and provides case studies to illustrate potential applications of CI. This research methodology integrates observation and interview techniques commonly used in existing product development and applies them to this complex use environment. The methodology is consistent with the best practice publication, AAMI TIR 51 Contextual Inquiry. Case studies from the medical device industry are provided which will illustrate and explain main concepts and values.

My objective in writing this book is to share knowledge and experience from the field in the hope that others may accept the methods in their practice ultimately improving medical device design globally.

ACKNOWLEDGMENTS

This book is the result of over 2 decades of practice in the medical device industry and 15 years as serving as a biomedical engineering faculty member at the University of Cincinnati, which included a unique experience while working directly in the Department of Medicine. The methods presented have evolved over the years and have been influenced by many individuals along the way.

I personally thank those in the design community who over many meetings and conferences openly shared and collaborated with me on this text. Their case studies highlight the value of the CI process and their objective feedback has helped assure this test provided actionable guidance through the process. Key contributors to this book include Tor Alden, Steve Wilcox, Beth Loring, Jim Rudolph and Sean Hagen.

Likewise the University of Cincinnati Medical Device Innovation and Entrepreneurship Program students and faculty deserve recognition. The students continue to surprise me with their creativity; their energy is contagious and helped motivate me to write this text. The faculty, Bala Haridas and Jeff Johnson, along with amazing support from Linda Moeller, the academic advisor, have provided the foundation for this outstanding program.

The University of Cincinnati, Department of Emergency Medicine, enabled the formation of a professional team dedicated to collaborating more closely and professionally with the medical device industry; this initiative that brought clinicians, design faculty, and industry together is a truly novel means for improving medical device design. This book would not be possible without this significant commitment to advancing care.

Most of the visuals represented in this book have been either designed or influenced by Kyrsten Sanderson. Kyrsten served as a leader for our professional team and I am grateful to have had the opportunity to work with her. Likewise, Cecilia Arredondo has contributed to the practice through suggesting visual representation of emotion and through her research that introduced playful medical device design.

Thanks to Elsevier for seeing value in its publication with excellent support from program editors, Fiona Geraghty and Natasha Welford.

Lastly, and most importantly, I thank my husband and our three exceptional daughters. Their support for me is endless and very much appreciated.

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