# MEDICAL TECHNOLOGY MANAGEMENT PRACTICE

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**Anthony Y. K. Chan** graduated in Electrical Engineering (B.Sc. Hon.) from the University of Hong Kong in 1979, completed a M.Sc. degree in Engineering from the same university and worked as an electrical project engineer. He completed a Master of Engineering Degree (M.Eng.) in Clinical Engineering from the University of British Columbia in Canada in 1987. He also holds a Certificate in Hospital Services Management from the Canadian Hospital Association. Anthony was the manager and director of biomedical engineering in a number of Canadian acute care hospitals. He is currently the Program Head of the Biomedical Engineering Technology Program at the British Columbia Institute of Technology. He is a professional engineer and a certified clinical engineer.

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*By*

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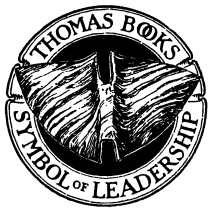


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*To my wife Elaine*
*and*
*my parents, Chung Ping Chan and How Fong Chan*

# PREFACE

With continuous rapid advancement, technology has infiltrated into all parts of everyday life. Modern health care delivery and medicine are increasingly dependent on technology in the diagnosis and mitigation of illnesses, in disease prevention, and in health promotion. Medical technology is one of the driving forces in shaping the direction of health care. However, it is also a primary factor for the escalating cost in the health care delivery system. For these reasons, it is important for managers to master the arts and methodologies in medical technology management so that technology can be used appropriately, effectively, and efficiently.

This book studies the medical technology life cycle from the user's perspective, starting from technology acquisition to disposal. It takes a practical approach to analyze medical technology management in clinical settings. General practices are described throughout the book, concepts are reinforced with real-life examples, and practical tools are used for illustration whenever possible. An overview of the medical technology development and standards is also included in the last two chapters to provide the readers with a general concept to relate standards and regulatory control in technology development to medical technology management practice. This book is written for readers who already have a general understanding of the health care environment and are interested in getting a practical understanding of managing medical technologies. Such readers may include but are not limited to health administrators, technology planners, biomedical engineers and technologists, and supervisors and managers of technology-intensive departments. The contents are grouped into twelve chapters. Below is a brief description of each chapter:

- Chapter 1 provides an overview of technology management and introduces the systems approach to study medical technologies.

- Chapter 2 lists the benefits of managing technology using a systems approach and identifies the different phases of the technology life cycle.
- Chapter 3 discusses maintenance of medical technology including demand maintenance and preventive maintenance and the essential elements of establishing a cost-effective technology maintenance program.
- Chapter 4 describes the required infrastructure to provide effective support of medical technology. It also analyses the advantages and disadvantages of various technology support models such as in-house support, maintenance contract, self-insurance, and regional services.
- Chapter 5 outlines the importance of medical device incoming inspections and documentation and analyzes criteria for such processes. It also lists the minimum requirements of a medical equipment management database system and reviews management information that can be extracted from such database.
- Chapter 6 introduces the concept of quality improvement and covers the essential elements of a medical technology risk management program including hazard report handling, incident investigation, and training.
- Chapter 7 describes the organization, roles, and responsibilities of key stakeholders in hospital-level technology planning, assessment, prioritization, and acquisition.
- Chapter 8 introduces technology budgeting using the life cycle cost-of-ownership approach. It also discusses various financing options in technology acquisition.
- Chapter 9 leads the readers through the tendering and evaluation process in technology acquisition. It includes specification preparation, pre-purchase evaluation, and formulation of award documents.
- Chapter 10 evaluates the criteria for technology replacement and disposal of medical devices.
- Chapter 11 explores medical device standards and the standard development process. It also provides an overview of medical device regulations in the area of device risk classification and regulatory control.
- Chapter 12 gives an overview of the essential components of

design assurance and risk management in medical device development.

It is hoped that this text will enlighten readers to start using a systematic life cycle approach to manage medical technology so that appropriate technologies are used safely, effectively, and efficiently for the better of mankind.

I am indebted to my two young daughters, Victoria and Tiffany, who should have received more of my attention if I were not engaged in writing this book. I am deeply indebted to my good friend, Euclid Seeram, whose encouragement and constant reminder had made this book a reality. A number of people have contributed ideas in this book, especially Ken Yip and Stephan Bauer. I extend my special appreciation to the Biomedical Engineering Department of the Vancouver General Hospital which allowed me to include their forms and procedures in the book. Last but not the least, I want to thank Michael Thomas for agreeing, without hesitation, to publish this book upon receiving my proposal two years ago.

Anthony Y. K. Chan

# CONTENTS

# MEDICAL TECHNOLOGY MANAGEMENT PRACTICE

# Chapter 1

# INTRODUCTION TO MEDICAL TECHNOLOGY MANAGEMENT



## 1 OVERVIEW OF HEALTH TECHNOLOGY MANAGEMENT

Modern health care delivery and medicine are increasingly dependent on technology in the diagnosis and mitigation of illnesses, in disease prevention and in health promotion. On one hand, medical technology can be viewed as tools to improve the quality of life of individuals. On the other hand, it is considered by some as a culprit of the upward spiraling cost of health care. Nonetheless, it is one of the driving forces that shape the direction of modern health care delivery. For these reasons, it is important to manage medical technology so that it can be used appropriately, effectively, and efficiently.

Managing medical technology requires the expertise and infrastructure to address the challenges in different phases throughout the life of the technology. The "Technology Life Cycle" starts in the development phase of the technology, undergoes validation, goes through acquisition and utilization, and then terminates when it is being replaced or abandoned. This book studies the medical technology life

cycle from the user's perspective, starting from technology acquisition. An overview of the development phase of medical technology at the end of the book provides the reader with a general idea of the processes involved in the design assurance, hazard analysis, and regulatory control of medical technology development.

## 1.1 Systems Approach to Health Technology Management

In simple terms, a system may be viewed as a group of things or parts or processes working together under certain relationships. A system transforms a set of input into a set of output entities. Within a system there are aspects, variables, or parameters which mutually act upon each other. A closed system is self-contained on a specific level and is separated from and not influenced by the environment, whereas an open system is influenced by the environmental conditions by which it is surrounded. Figure 1–1 shows an example of a system. The elements within the system and their relationships as well as the environment can affect the performance of the system. A more complicated system may contain multiple numbers of subsystems or simple systems.

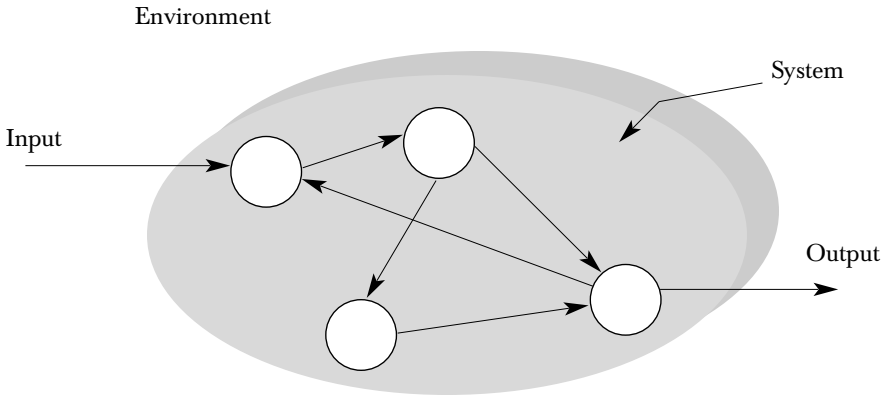


Figure 1–1. Example of a System.

In analyzing a large complex system, one can break down the system into several smaller subsystems with the output from one subsystem connected to the input of another. A basic subsystem comprises of input, output, and processes as shown in Figure 1–2. The process that

takes the output and feed it back into the input in order to modify the output is called a feedback process. A system with feedback is called a closed loop system, whereas a system without any feedback is called an open loop system. Most systems that we encounter contain feedback paths and hence are closed loop systems.

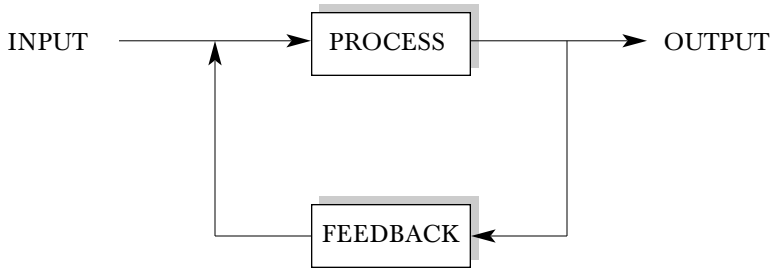


Figure 1–2. A Closed Loop System.

Listening to a radio is an example of a simple closed loop system. The input to the system is the broadcast in the form of electromagnetic wave that is received by the radio. The radio processes the received signal and produces the audible sound such as music. If the music (the output) is not loud enough, the listener will turn up the volume to increase the sound level. In doing so, the listener becomes the feedback process that analyzes the loudness of the music and produces the action to turn up the volume.

Figure 1–3a shows the block diagram of an asynchronous (fixed rate) pacemaker. The pulse generator produces a pulse at a predetermined rate (e.g. 60 pulses per minute). These pulses are transmitted to the ventricle of the heart via a lead wire and an electrode to stimulate the ventricle to contract. Pulses are sent to the heart irrespective of the natural heart activities. Figure 1–3b shows a demand pacemaker. In addition to the pulse generator, the lead, and electrode, the natural contraction signal from the heart is sensed and transmitted back to the pacemaker. With the feedback, the pacemaker is able to skip sending stimulation to the heart if it is detected to be beating on its own. The fixed rate pacemaker in this example is an open loop system, whereas the demand pacemaker is a closed loop system.

A systems approach is a generalized technique to understand organized complexity. It provides a unified framework and instigates a way