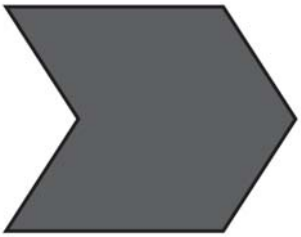

Chapter 1

Introduction

Patrick J. Bryant

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Evidence-Based Medicine

Evidence-based medicine focuses on the scientific method as the key source of knowledge in making clinical decisions. Research shows that when we use experience as the primary knowledge source to make clinical decisions, we tend to overestimate efficacy and underestimate risk factors of a specific drug or procedure.[1] This leads to variation in services and treatment, resulting in inappropriate care, lack of care, and increase in health care costs. An approach to making clinical decisions has emerged within the medical discipline called evidence-based medicine. Evidence-based medicine is an attempt to provide something other than just experience of the practitioner in making clinical decisions. David Sackett, one of the pioneers in this area, originally coined the term "evidence-based medicine" while teaching medical students; he essentially defined this term as:

> *"The conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients, while integrating clinical experience with the best available evidence from a systematic search."*[2]

Sources of Knowledge

As mentioned, evidence-based medicine utilizes the scientific method as a key source of knowledge for clinical decision making. However, in addition to the scientific method, there are four other sources of knowledge.[3] Each source or method presents potential problems that are discussed below.

Key Idea

Evidence-based medicine focuses on scientific method as the key source of knowledge to make clinical decisions.

1. **Reference to tradition** – accepting certain truths as givens. Problem: many traditions are not evaluated for validity nor tested against potentially superior alternatives.
2. **Reference to authority** – placing trust in those who are authorities or experts on an issue. This can be useful where scientific evidence is weak or unavailable. Problem: this method minimizes the need for critical analysis and confirmation of validity and does not encourage testing of potentially superior alternatives.
3. **Trial and error** – applying multiple attempts to find a solution by chance. Used when no other basis for making a decision exists. Problem: this method results in a haphazard and unsystematic process to obtain knowledge that is generally not shared, limited in scope, and time consuming; it also prevents identifying/confirming the best solution.
4. **Logical reasoning** – involving *deductive reasoning*—a systematic method for drawing conclusions by using a series of three interrelated statements. Problem: deductive reasoning only produces a hypothesis that still requires testing since usefulness is dependent upon the truth of the premises developed. **Example**—all living things must die (major premise), humans are living things (minor

premise); therefore, all humans must die (conclusion). Logical reasoning also involves *inductive reasoning* or developing generalizations from specific observations. Problem: quality of the knowledge derived from inductive reasoning is dependent upon how well specific observations represent the general situation. To be absolutely certain of the conclusion, one must observe all possible examples of the event, and that is rarely possible. **Example**—edema decreases with application of ice to an injured ankle. After numerous observations of this phenomenon, one concludes cold reduces fluid infiltration in body tissues.

5. **Scientific method** – applying a logical sequential process to develop a conclusion. This process involves identifying the problem, organizing collection of data, objectively analyzing the data, and interpreting the findings. The goal is to enable other researchers to reproduce the results that confirm validity. This is the most rigorous process for obtaining new knowledge. Problem: complexity and variability of components (e.g., nature/environment, unique psychosocial and physiological capacities of individuals) introduce uncertainty into interpretation and generalization of data.

The Problem

Although the best evidence comes from the scientific method, medical practice continues to focus on the other four sources of knowledge. The result is variation in medical practice patterns and variation in treatment for virtually the same patient with the same disease state.[4] In addition, a gap exists between new research findings and incorporating these findings into clinical practice.

Key Idea

Although the best evidence comes from the scientific method, medical practice continues to focus on less accurate sources of knowledge.

As a result, the most recent scientifically developed knowledge is not being applied to clinical practice. The scientific method, our best source of knowledge, is not being maximized to ensure the best patient care.

Several evidence-based medicine processes have been developed; however, these processes tend to be complex, labor intensive, inconsistent in rigor, and variable in determining the quality of evidence. Morever, these processes are generally developed by physicians for diagnostic minded physicians and not for the analytically minded pharmacy practitioner. These practitioners need a time-sensitive decision making process that allows them to make *firm* decisions and recommendations based on results of rigorously conducted clinical trials while incorporating their own clinical judgment. **Figure 1.1** illustrates how the practitioner must use caution in developing a recommendation and/or decision when this type of evidence does not exist.

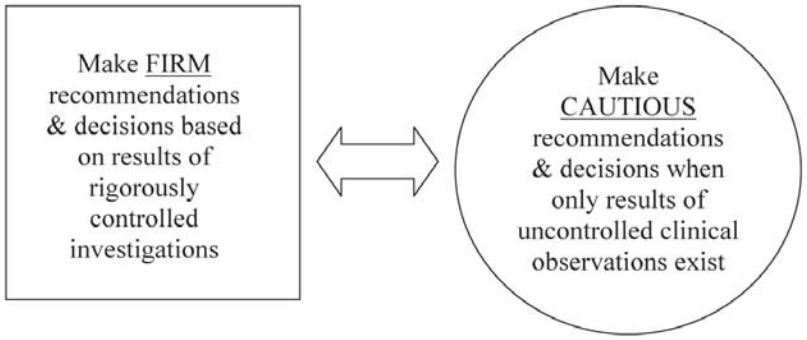

Figure 1.1: Explanation of Differences in Firm and Cautious Recommendations Based on Trial Type

Key Idea

Practitioners need a time-sensitive decision making process that leads to evidence-supported decisions and recommendations.

The Solution

The University of Missouri–Kansas City School of Pharmacy Drug Information Center developed the 5-Step Evidence-Based Medicine Process that has been taught as a required course to Doctor of Pharmacy (Pharm.D.) students for the last 10 years. This process exhibits the following characteristics:

- Offers less complexity
- Offers time-sensitive decision making support by alleviating time-intensive methods
- Maintains rigor
- Categorizes quality of the evidence in a simple, straightforward, and logical manner
- Provides a process designed specifically for pharmacy practitioners making drug therapy decisions

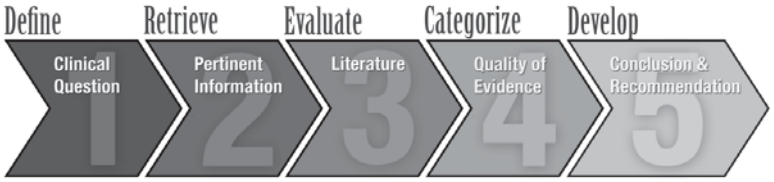

Figure 1.2: 5-Step Evidence-Based Medicine Process

This process involves five steps as illustrated in **Figure 1.2.** **Step one** is defining the clinical question. Defining the clinical question is essential in providing direction to the remaining four steps of this evidence-based medicine process. This step may be the hardest one in the process because it involves the conversion of a clinical problem into an answerable clinical question. A well-constructed answerable clinical question clearly presents the true clinical problem, provides guidance to pertinent evidence, and suggests the format of the recommendation to solve the problem.

Step two involves searching the literature for articles associated with this clinical question. The assumption is that the reader has completed a basic literature retrieval course. A comprehen-

sive discussion of resources for searching the literature is beyond the scope of this book. Furthermore, most practitioners are too busy to conduct extensive and sophisticated database searches to ensure a comprehensive review of the pertinent literature. For this reason, the practitioner must rely on specialists in drug information centers and health system libraries to conduct the searches for them. Specific references will be identified for readers who want a review of searching processes.

Step three is evaluating literature found. Again, the assumption is that the reader has completed at least a basic critical evaluation course with some exposure to biostatistics. Although it is not a requirement to understand the evidence-based medicine process presented in this book, those readers without this background or those desiring a "refresher" review can refer to additional resources identified throughout the book.

Step four is determining the quality of identified and critically evaluated evidence. Several different hierarchies of evidence are available to accomplish this step.[5–15] The categorization system presented in this book provides a simple, straightforward, and logical approach, which incorporates a modified technique to determine the quality of evidence originally described in Drs. Sandra Cook and Gordon Guyatt's 1992 seminal work.[1] This fourth step serves as a bridge to the fifth step.

Step five is developing a conclusion and recommendation with supporting justification. This step involves the creation of a specific recommendation statement supported by the efficacy, safety, and other special considerations/special populations provided by the evidence. Cost of therapy is also factored into this final recommendation.

How This Book Will Help You

This book is not a text book, but rather a "how to" or self-development type resource. The book teaches the practitioner how to incorporate the 5-Step Evidence-Based Medicine Process into daily drug therapy decision making.

Key Idea

This book is not a text book, but rather a "how to" or self-development type resource.

A consistent goal has been to develop an evidence-based medicine process that is simple enough to integrate into practitoners' thought processes without giving up any rigor or quality associated with good clinical decision making. Based on results of studies to determine the effectiveness of this process, this goal has been accomplished over the last 9 years of development.[16] Now, that same evidence-based medicine process is made available to the practitioner through this book.

The format has been carefully considered, allowing the reader to complete the book within a couple of evenings and immediately incorporate the process into current clinical practice. In addition, the reader is encouraged to use this book as a resource while applying the 5-Step Evidence-Based Medicine Process in practice.

Key Idea

The format allows the reader to complete the book in a couple of evenings and immediately incorporate the process into current clinical practice.

Chapter 2: Basics for Interpretation is a high-level review of basic tools and concepts associated with study design and selected biostatistic principles. Emphasis is placed specifically on the more pertinent knowledge in these two areas that is required to understand and effectively perform the Evidence-Based Medicine Process. For instance, only four biostatistic concepts are discussed:

1. Significance
2. Power

3. Types of data
4. Appropriate statistical tests for the type of data undergoing analysis

For a more comprehensive review of biostatistics, the reader should refer to the suggested references.

The actual 5-Step Evidence-Based Medicine Process is described in Chapters 3 through 7. Each chapter addresses a specific step in the process. Examples are provided to further illustrate the concepts being taught. In addition, figures and tables are included to reinforce visual learning of the concepts.

Key Idea

The actual 5-Step Evidence-Based Medicine Process is described in Chapters 3 through 7 with each chapter addressing a specific step in the process.

Chapters 8–10 identify special considerations and describe clinical pharmacy practice applications for this process. Chapter 10 has been devoted to the differences in practicing evidence-based medicine with dietary supplements compared to conventional pharmaceuticals. The use of evidence-based medicine practice with dietary supplements is an area requiring greater attention. This chapter is an attempt to address that need.

At the end of this book, you will find a glossary of evidence-based medicine terms to assist in learning the language associated with this discipline. In addition, there is a section dedicated to forms and tables used by our students during the initial stages of learning the 5-Step Evidence-Based Medicine Process. This section is appropriately named Evidence-Based Medicine Tools and will hopefully be a help.

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