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Reviews of books and studies

Bégaud B. (Ed.): *Analyse d'incidence en pharmacovigilance; application à la notification spontanée*. 103pp. Edition Arme-pharmacovigilance, Bordeaux, 1991.

Arme-Pharmacovigilance is a lively association established in France in 1989, devoted to methodological research in drug adverse reaction monitoring ("pharmacovigilance"). To its credit it includes both manufacturers and independent members, but it is attached very firmly to one of the excellent regional centres handling drug monitoring in France, that at Bordeaux. The industrial contribution enables it to employ professional staff, while the link to the monitoring system ensures its independence of thought.

The present volume, edited by Bernard Bégaud, sets out the tools currently available for estimating the incidence of adverse reactions, insofar as these are applicable to spontaneous reporting systems. Sensibly, it begins by defining in what terms the magnitude of an adverse reaction problem can be defined, making essential distinctions between such concepts as rate, ratio, incidence and prevalence, which are often confused. Thereafter it goes on to consider how the numerator and the denominator should be estimated. An example built around a fictitious drug is dealt with in detail to show how the scope of a problem can be delineated in terms of the population sub-groups involved, the geographical distribution of the events and their development over time. Finally there is a long statistical section (which is hard going but unavoidable) and some intelligent considerations of phenomena such as the Type II error, i.e. the failure to identify an existing fact.

Very much of this is good sense and it is well thought out and presented. If one is to raise any criticism of the book it is that (perhaps because of restrictions of space) it does not go sufficiently far on two issues fundamentally affecting estimates of incidence.

The first of these is the under-reporting rate. True, the authors do on p. 19 note that it is difficult to estimate how much information is hidden for this reason, while the iceberg analogy (on page 9) is allowed to suggest visually that seven-eighths of the problem is below the surface. In reality, however, things are much, much worse; one optimist attached to a successful A.D.R. reporting system has estimated that up to 5% of suspected adverse reactions do get reported; a realist may well find that the proportion is well under 1%. It is indeed true that it is difficult to estimate the size of the problem, but methods have been applied (involving the comparison of the A.D.R. record of the same drug in different systems, or the study of reporting in individual doctors' practices) and it is important to apply them further in every country. A decade ago, certainly, the reporting rate in

France does not seem to have been more than 2%; it has developed strongly since then, but even today one must have to apply a substantial multiplier.

One's other reservation applies to the denominator, which tends to be based on prescriptions or on sales data. Again one needs to avoid a dangerous fallacy, namely that patient compliance is 100%. Even in some critical indications, patients take only half of what is prescribed for them. For that reason the denominator is much smaller than it is often thought to be. Here too the literature provides plenty of evidence of what can be done to estimate the compliance rate, and it could usefully be reviewed here.

These two aspects are matters which deserve to be developed in additional chapters in future editions of this book. It is already a thoughtful and thought-provoking piece of work. With a little more input of the same quality it could very well become the pharmacovigilante's bible.

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Harold C. Sox Jr., Marshal A. Blatt, Michael C. Higgins and Keith I. Marton: *Medical Decision Making*. Butterworth, London, 1988.

In the preface it is stated that the "purpose of this book is to help students of medical practice learn to make good decisions despite uncertainty" using decision analysis. The book sets out to explain the methodology of decision analysis and to show how it can be used to improve medical decision making.

The early chapters of the book are concerned with "making a diagnosis", i.e. the collection of information and its analysis, the choosing of the appropriate test(s) and the accurate interpretation of the test results. The authors discuss the relevance of conditional, prior and posterior probabilities and their relationship to each other (Bayes' theorem) in making a diagnosis and outline several different formulations of Bayes' theorem which may be used to improve the accuracy of diagnosis. The remaining chapters explain how to make choices in clinical practice. The technique of expected value decision making is described. This involves the use of several quantitative methods which involve both clinician and patient in choosing the decision alternative with the highest expected value. The final chapter deals with cost effectiveness and cost-benefit analyses.

The book is carefully constructed to provide the reader with a step-by-step explanation of decision analysis. Within each chapter there are frequent summaries with numerous clinical examples from everyday practice to illustrate the point being explained in the text. Each chapter also has its own glossary of new terms introduced in the text and critical references relating to the content, which are particularly useful. In summary, the book achieves its aims of clearly defining decision analysis and its possible relevance to clinical practice.

There have been many publications [1-4] over the last 20 years referring to the usefulness, or otherwise, of decision analysis but the method has yet to achieve

widespread acceptance amongst clinicians. This book certainly provides a comprehensive review of the methodology of decision analysis and an understanding of several of the techniques discussed in the book (e.g. decision trees and utility assessment) would benefit all clinicians whether or not they accept the concept of decision analysis. However, apart from the question of whether decision analysis is a meaningful clinical tool or not, in the current climate of medical cut-backs, its use which requires time and computer facilities [2], will be likely to remain restricted only to interested clinicians and researchers.

Finally, although I noted that one of the authors is a medical student, I feel a certain level of clinical experience is necessary to fully understand the methods of decision analysis. Therefore this book may serve to confuse rather than help the inexperienced medical student, especially if used without guidance. Indeed even the authors themselves agree that there is “no substitute for a wide-ranging clinical *experience*” but that “the ability to use experience to reason effectively can be learned”. I rest my case.

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References

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- 2 Pauker SG, Kassirer JP. Decision analysis. *N Engl J Med* 1987;316:250–258.
- 3 Feinstein AR. The haze of Bayes, the aerial palaces of decision analysis and the computerised Ouija board. *Clin Pharmacol Int* 1977;21:482–496.
- 4 Dix D. Decision analysis. *N Engl J Med* 1987;317:387.

Alan Pollock and Mary Evans: *'Surgical Audit'*. Butterworth, 1989. £19.50, ISBN 0 407 00823 3.

In a period of accountability, when focuses are on outcomes and the appropriate use of resources and when governments, health administrators and hospital managers are seeking value for money, quality assurance can be seen as one of the most important tools that health professionals and health providers have available to demonstrate their worth and to ensure their contribution in decision and policy making.

In this environment, a book such as “Surgical Audit” is therefore both timely and most appropriate. The title, however, may be slightly misleading as the book touches upon a much wider area than audit alone and, although references are specifically made to surgery and the authors indeed have this as their background, the book is equally suitable as providing the rationale and framework for audit and quality control in other clinical areas.

Of general interest are those chapters giving the history, the evolution and the definition of audit as well as chapters dealing with ethical aspects, quality of life and patient satisfaction. The book is throughout extremely well written, chapters are of appropriate length, each with a limited but relevant list of references. This will be specifically useful for those non-surgical readers who will use this book to focus on specific aspects of quality assurance in general.

Of special merit is the section "Audit of Outcome", which it is a novelty to find in a book since previous works have mainly focussed on the structure and process aspects of quality assurance and not sufficiently on outcome. Although few surgeons will disagree that improved outcome is what they honestly see themselves as striving towards in their everyday work, actually measuring, comparing and evaluating the outcome of clinical practice requires a specific methodology and there are many pitfalls in drawing conclusions. This section of the book touches upon most of the areas such as random controlled trials, quality of life after surgery, mishap and malpractice. This section of the book is a valuable contribution to the emerging focus on outcome in general.

As an example of the outcome approach, the classical study from the United States, the SENIC study (the Study on Efficacy of Nosocomial Infection Control) is given. The conclusion of this study still holds that the key factor for reduction of the rate of surgical wound infection appears to be feedback to individual surgeons. There are many European initiatives along the same lines, and the SENIC results are a little out of date (carried out in the mid-seventies) and this example could have been of more value if balanced against other similar initiatives.

On this note comes the only minor criticism of an excellent book which is that it obviously has its basis in the English language literature and therefore pays little reference to the novel and very exciting initiatives in this area carried out in, for example, Spain, Italy and Scandinavia. In future editions, of which there will probably be many, more emphasis should be given to getting a wider coverage, and the book would also benefit from including more direct examples of successful strategies.

In summary, the book is an excellent work, giving a comprehensive introduction not only to surgical audit but the quality assurance in general, and can absolutely be recommended for clinicians, health administrators, policy makers and health economists.

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