# The Detection of New Adverse Drug Reactions

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with a guest chapter contributed by
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STOCKTON PRESS

Softcover reprint of the hardcover 1st edition 1985 978-0-333-36886-2



First published 1985

Published in the United Kingdom by
THE MACMILLAN PRESS LTD
Houndmills, Basingstoke, Hampshire RG21 2XS
and London
Companies and representatives throughout the world

British Library Cataloguing in Publication Data
Stephens, M.D.B.
The detection of new adverse drug reactions.
1. Drugs – Side effects
I. Title
615'.704 RM302.5
ISBN 978-1-349-07252-1 ISBN 978-1-349-07250-7 (eBook)
DOI 10.1007/978-1-349-07250-7
Published in the United States and Canada by
Stockton Press
15 East 26th Street, New York, NY 10010

Library of Congress Cataloging in Publication Data
Stephens, M.D.B., 1930–
The detection of new adverse drug reactions.
Bibliography: p.
Includes index.
1. Drugs — Side effects. 2. Drugs — Toxicology.
I. Talbot, J.C.C. II. Title.
RM302.5.S74 1985 615'.7042 85–2834
ISBN 978-0-943818-33-7

# Contents

# Foreword

We stand on the threshold of what has been called 'the second pharmacological revolution'. During the past three decades major therapeutic advances have been made, but they may well be overshadowed by those of the rest of the century, as new molecular biochemical discoveries, and techniques for genetic engineering, permit control of viral, psychiatric, malignant and autoimmune disease. Tragically, however, this optimistic prediction is threatened by ill-advised yet widespread public fear of, and indeed hostility to, new drugs, fostered by a variety of consumer and media lobbies who have not yet understood that a chemical's therapeutic efficacy is inevitably associated with unwanted effects, particularly if used unwisely.

Many books have been written about the design of clinical trials and determination of therapeutic efficacy of drugs, but little has been published on the systematic detection, quantification and evaluation of adverse drug reactions. This process should begin, of course, with the earliest administration of a drug to man, and continue throughout its controlled clinical trials, but is likely only to identify relatively common or bizarre adverse effects. Less common, but nevertheless important, unwanted effects will be recognised only when it is prescribed for larger numbers of patients, usually after it has been marketed, and when its use, therefore, is less closely supervised.

Dr Stephens has been closely involved in the practical problems of adverse drug reaction monitoring for many years, and this book represents an important contribution to the subject which I believe will be of value to all involved in the scientific assessment of drug treatment.

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# Preface

This book sets out to describe the problems involved in the detection of new adverse drug events both before and after a drug reaches the market and the various methods available to overcome these problems. The methods cover the collection, storage and assessment of the information. It is hoped that it will be found useful to those involved in clinical trials, whether clinician or pharmaceutical scientist. For the latter it is also hoped that he or she will find sufficient information and referenced papers to be able to set up a drug surveillance unit within a pharmaceutical company.

The withdrawal from the market of numerous drugs over the last two years has prompted changes in the regulations in many countries and, therefore, in turn has caused, and will cause, great changes within the pharmaceutical industry.

The most important change will be the realisation that equal effort and money will need to be put into both sides of the cost–benefit ratio in the clinical research of a new drug. At the time of writing, many changes are afoot and, in order to keep this book up to date, an additional chapter entitled *Update* has been included and contains the latest changes as well as references to papers that have only recently come to my attention.

I have resisted the temptation to stray into the more fascinating and controversial areas, such as the law on liability and compensation for drug injury or the history of various established adverse drug reactions, but I hope that the bibliography will have covered these gaps.

All opinions mentioned in this book are my own, unless specifically stated as being otherwise. It should not be presumed that any views or practices described here are those of the Glaxo Group or any of its subsidiary companies, unless stated.

*Bishop's Stortford, 1984* M.D.B.S.

# Acknowledgements

Whenever there has been need of statistical advice I have run to either D. Robinson or J. Forster at Glaxo Group Research, Ware, and evidence of this is seen in almost every chapter. Dr C. Bulpitt guided my first faltering footsteps in the world of controlled clinical trials and his influence has spread into many aspects of the book. The whole area of form design and postmarketing surveillance results from close collaboration with the late Dr J. Jackson of Clinical Data Monitoring, Glaxo Group Research, and I am deeply indebted to his help over the years.

I would not have dared to venture into the field of regulations but for the help of many people:

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| United Kingdom | Dr R.G. Penn |
| United States of America | Dr J. Dodds, Dr W.I.H. Shedden |
| France | Dr M. Rynikiewicz |
| Germany | Dr M. Hadoke, Frau G. Menck |
| Italy | Dr M. Pugina |
| Japan | Dr H. Kurihara |

I am also very indebted to members of my own Drug Surveillance Department: Dr J. Talbot for his chapter on handling data, Ms M. Woods for indexing, Mrs B. Long for proof–reading and most of all to Mrs M. Rear to whom any praise for the layout and presentation of the manuscript is due.

It is also a pleasure to thank:

1. Dr Emmanueli of Farmitalia Carlo Erba for permission to publish his revised algorithm (August 1983).
2. Dr A. Ruskin for his two algorithms on drug–event association and drug–death association.
3. Dr J.A. Lewis of ICI and Elsevier Biomedical Press for permission to reproduce his statistical tables on the numbers of patients required for PMS.

4. Drs S.N. Ciccolunghi, P.D. Fowler and M.J. Chaudri for the use of the 'Ciccolunghi–Fowler–Chaudri Method'.
5. Dr B.D. Dinman and *JAMA* for permission to reproduce his tables of risk 'The reality and acceptance of risk', JAMA, 1980, **244** (11), pp. 1226–1228, © 1980, American Medical Association.
6. Dr E.S. Snell and the members of the ABPI for permission to publish the results of the 1981 survey.
7. Dr C. Stevenson for help with the design of the skin ADR form.