## Patient Compliance in Medical Practice and Clinical Trials

Stores -

**Editors** 

Joyce A. Cramer, B.S.

Project Director, Epilepsy Research Epilepsy Center Department of Veterans Affairs Medical Center West Haven, Connecticut; and Department of Neurology Yale University School of Medicine New Haven, Connecticut

Bert Spilker, PH.D., M.D.

Director, Project Coordination, Burroughs Wellcome Company Research Triangle Park, North Carolina Adjunct Professor of Pharmacology and Clinical Professor of Medicine University of North Carolina Clinical Professor of Pharmacy University of North Carolina School of Pharmacy Chapel Hill, North Carolina





## Contents

	I. Introduction to the Topic of Patient Compliance	
1.	Overview of Methods to Measure and Enhance Patient Compliance Joyce A. Cramer	3
2.	Failure to Refill Prescriptions: Incidence, Reasons,and RemediesRichard A. Levy	11
3.	Interaction of Compliance and Patient Safety	19
4.	Partial Compliance as a Source of Variance in Pharmacokinetics and Therapeutic Drug Monitoring Julie M. Backes and Jerome J. Schentag	27
5.	Methods of Assessing and Improving Patient Compliance in Clinical Trials Bert Spilker	37
6.	Impact of Risk Communication on Accrual, Regimen, and Follow-up Compliance Louis A. Morris and Ivan Barofsky	57
	II. Special Patient Populations	
7.	Compliance with Pediatric Medical Regimens Michael A. Rapoff and Martha U. Barnard	73
8.	Behavioral Strategies to Increase Compliance in Adolescents Barbara A. Cromer	99
9.	Improving Compliance in the Older Patient: The Role of Comprehensive Functional Assessment Norma J. Owens, E. Paul Larrat, and Marsha D. Fretwell	107
	III. Monitoring Techniques for Specific Therapies	
10.	Monitoring Compliance with Antiepileptic Drug Therapy Joyce A. Cramer and Richard H. Mattson	123
11.	Monitoring Compliance: The Sine Qua Non of Assessing Therapeutics in the Elderly R. John Dobbs, Sylvia M. Dobbs, and J. Dickins	139

## CONTENTS

12.	Aerosol Inhaler Monitoring of Asthmatic Medication Sheldon L. Spector and Helen Mawhinney	149
13.	Validity of Standard Compliance Measures in Glaucoma Compared with an Electronic Eyedrop Monitor Mae E. Gordon and Michael A. Kass	163
14.	Compliance With Treatment of Hyperlipoproteinemia in Medical Practice and Clinical Trials Wolfgang HH. Kruse	175
15.	Clinical Correlates of Antidepressant Compliance Frederick W. Engstrom	187
16.	Oral Contraceptive Compliance and Its Role in the Effectiveness of the Method Linda S. Potter	195
17.	Compliance to Diabetes Regimens: Conceptualization, Complexity, and Determinants Russell E. Glasgow	209
18.	Developing More Clinically Meaningful Definitions of Medication Compliance Seth A. Eisen	225
19.	Patient Computers to Enhance Compliance with Completing Questionnaires: A Challenge for the 1990s Bengt Dahlström and Sven-Åke Eckernäs	233
	IV. Analytical Issues and Approaches	
20.	Statistical Approach to Subgroup Analyses: Patient Compliance Data and Clinical Outcomes Frank L. Hurley	243
21.	Regulatory View: Use of Subgroup Data for Determination of Efficacy Russell Katz	251
22.	Biometric Issues in Measuring and Analyzing Partial Compliance in Clinical Trials Joerg Hasford	265
23.	Antihypertensive Drug Trials: Contributions from Medication Monitors Peter Rudd, Shaheda Ahmed, Valerie Zachary, Carol Barton, and Delphine Bonduelle	283
24.	Patient Compliance as an Explanatory Variable in Four Selected Cardiovascular Studies John Urquhart	301

xii

## CONTENTS

25.	Clinical Trial Prerandomization Compliance (Adherence) Screen Jeffrey L. Probstfield	323
26.	Patient Selection Bias in Analyses Using Only Compliant Patients Joseph F. Collins and Walter Dorus	335
27.	Variability of Antiepileptic Medication Concentrations and Compliance Ilo E. Leppik	349
28.	Intent-to-Treat Policy for Analyzing Randomized Trials: Statistical Distortions and Neglected Clinical Challenges Alvan R. Feinstein	359
	V. Perspectives on Health Care and Research	
29.	V. Perspectives on Health Care and Research Epidemiological and Community Approaches to Patient Compliance Lawrence W. Green, Patricia Dolan Mullen, Rhonda B. Friedman	373
29. 30.	Epidemiological and Community Approaches to Patient Compliance Lawrence W. Green, Patricia Dolan Mullen,	373 387
	Epidemiological and Community Approaches to Patient Compliance	

.