Cioms Guidelines

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Report of CIOMS Working Group on Vaccine Safety Springer
In recent years public expectations for rapid identification and prompt management of emerging drug safety issues have grown swiftly. Over a similar timeframe, the move from paper-based adverse event reporting systems to electronic capture and rapid transmission of data has resulted in the accrual of substantial datasets capable of complex analysis and querying by industry, regulators and other public health organizations. These two drivers have created a fertile environment for pharmacovigilance scientists, information technologists and statistical experts, working together, to deliver novel approaches to detect signals from these extensive and quickly growing datasets, and to manage them appropriately. In following this exciting story, this report looks at the practical consequences of these developments for pharmacovigilance practitioners. The report provides a comprehensive resource for those considering how to strengthen their pharmacovigilance systems and practices, and to give practical advice. But the report does not specify instant solutions. These will inevitably be situation specific and require careful consideration taking into account local needs. However, the CIOMS Working Group VIII is convinced that the combination of methods and a clear policy on the management of signals will strengthen current systems. Finally, in looking ahead, the report anticipates a number of ongoing developments, including techniques with wider applicability to other data forms than individual case reports. The ultimate test for pharmacovigilance systems is the demonstration of public health benefit and it is this test which signal detection methodologies need to meet if the expectations of all stakeholders are to be fulfilled.

Field Trials of Health Interventions Springer Nature
Written by epidemiologists, ethicists and legal scholars, this bookprovides an in-depth account of the moral problems that often confrontepidemiologists, including both theoretical and practical issues. The topicscovered include informed consent, privacy and confidentiality protection, thebalancing of risks and benefits, ethical issues in the study of vulnerablepopulations, the institutional review board system, and professional education.The solid, up-to-date analyses of these issues will be very helpful toepidemiologists in their practice, research and teaching. They encourage thelatest developments in the field and include detailed bibliographies.

Research Ethics in Exercise, Health and Sports Sciences **Oxford University Press**
L. Gostin ; L. Jordan
Ethics and Research on Human Subjects Inst of Clinical Research
The growing globalization of medical research and the application of new biotechnologies in morally contested areas has forced a revision of international ethical guidelines. This book examines the controversies surrounding biomedical research in the twenty-first century from a human rights perspective, analyzing the evolution and changes in form and content of international instruments regulating the conduct of biomedical research. The approach adopted is comparative and includes an evaluation of human rights and UK and US law on embryonic stem cell research, the HIV/AIDS trials in the developing world, the Alder Hey Inquiry and the human radiation and nerve gas experiments on human subjects in the US and the UK. This is the first book to analyze some of the major issues in biomedical research today from an international, comparative human rights perspective.

Ethics in Clinical Research Routledge
At any point in the drug development process, systematic reviews and meta-analysis can provide important information to guide the future path of the development program and any actions that might be needed in the post-marketing setting. This report gives the rationale for why and when a meta-analysis should be considered, all in the context of regulatory decision-making, and the tasks, data collection, and analyses that need to be carried out to inform those decisions. There is increasing demand by decision-makers in health care, the bio-pharmaceutical industry, and society at large to have access to the best available evidence on benefits and risks of medicinal products. The best strategy will take an overview of all the evidence and where it is possible and sensible, combine the evidence and summarize the results. For efficacy, the outcomes generally use the same or very similar predefined events for each of the trials to be included. Most regulatory guidance and many Cochrane Collaboration reviews have usually given more attention to assessment of benefits, while issues around combining evidence on harms have not been as well-covered. However, the (inevitably) unplanned nature of the data on safety makes the process more difficult. Combining evidence on adverse events (AEs), where these were not the focus of the original studies, is more challenging than combining evidence on pre-specified benefits. This focus on AEs represents the main contribution of the current CIOMS X report. The goal of the CIOMS X report is to provide principles on appropriate application of meta-analysis in assessing safety of pharmaceutical products to inform regulatory decision-making. This report is about meta-analysis in this narrow area, but the present report should also provide conceptually helpful points to consider for a wider range of applications, such as vaccines, medical devices, veterinary medicines or even products that are combinations of medicinal products and medical devices. Although some of the content of this report describes highly technical statistical concepts and methods (in particular Chapter 4), the ambition of the working group has been to make it comprehensible to non-statisticians for its use in clinical epidemiology and regulatory science. To that end, Chapters 3 and 4, which contain the main technical statistical aspects of the appropriate design, analysis and reporting of a meta-analysis of safety data are followed by Chapter 5 with a thought process for evaluating the findings of a meta-analysis and how to communicate these.

Current Challenges in Pharmacovigilance Cambridge Law Handbooks
Records the papers and commentaries, with an edited discussion, presented at an international consultation convened by the Council for International Organizations of Medical Sciences (CIOMS) to guide revision of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects. The Guidelines, first issued in 1982 and then revised in 1993, are being updated and expanded to address a number of new and especially challenging ethical issues. These include issues raised by international collaborative trials of drugs in developing countries, especially expensive drugs, and the use of placebo controls in randomized clinical trials. Others arise from the complexity of research in human genetics, including stem-cell research, and in reproductive biology. Throughout, particular attention is given to the difficult questions that arose during the heated debate over trials in developing countries, of short-duration zidovudine (AZT) therapy to reduce perinatal transmission of HIV. The International Ethical Guidelines for Biomedical Research Involving Human Subjects set out a code of research ethics that is widely used by ethical review committees and other bodies responsible for reviewing and overseeing the ethical design of studies and conduct of research. The revision of the Guidelines is being coordinated by CIOMS, in collaboration with WHO. The consultation centered on seven specially commissioned papers, authored by international experts that explore some of the more difficult issues in depth. Each is followed by an invited commentary, often expressing opposing views, and a summary of the issues or conclusions that emerged during the subsequent debate. The first paper, on justice in international research, deals with the question of whether proposals for research to be conducted in a developing country should make provision for future access of the population involved to the interventions under investigation. Also considered are questions that arise when research uses populations in developing countries to investigate interventions that will be of exclusive benefit to the industrialized world. Case studies of recent drug trials and their research protocols are discussed to illustrate circumstances in which use of populations in developing countries is justified or constitutes exploitation. Ethical challenges of the randomized controlled trial are considered in the second paper, which includes a discussion on the equitable distribution of benefits and risks, the use of placebo for controls, and the obligation to ensure that the participation of controls does not compromise their medical care or endanger their health. A paper on informed consent in international health research considers how cultural factors influence communication and language in the informed-consent process and respect for privacy and confidentiality in the research. Subsequent papers address issues in genetics research and reproductive biology, including the moral status of fetuses and the use of embryos in research, and examine the contribution which international human rights instruments can make in the application of the general principles of ethics to research involving human subjects. The final paper gives an overview of capacity building and the role of communities in international biomedical research.

Proceedings of the Xxvth CIOMS Conference, Geneva, Switzerland 7-9 Who Publications Centre USA
The aim of this book is to provide research ethics committee members with a resource that focuses on research ethics issues in Africa. The authors are currently active in various aspects of research ethics in Africa and the majority have been trained in the past by either the Fogarty International Center or Europe and Developing Countries Clinical Trial Partnership (EDCTP) sponsored bioethics training programmes .

Practical Aspects of Signal Detection in Pharmacovigilance Routledge
This book is a collection of fictionalised case studies of everyday ethical dilemmas and challenges, encountered in the process of conducting global health research in places where the effects of global, political and economic inequality are particularly evident. It is a training tool to fill the gap between research ethics guidelines, and their implementation 'on the ground'. The case studies, therefore, focus on 'relational' ethics: ethical actions and ideas that emerge through relations with others, rather than in regulations. This work was published by Saint Philip Street Press pursuant to a Creative Commons license permitting commercial use. All rights not granted by the work's license are retained by the author or authors.

Principles of Good Clinical Practice AFRICAN SUN MeDIA
Research Ethics in Exercise, Health and Sports Sciences puts ethics at the centre of research in these rapidly expanding fields of knowledge. Placing the issues in historical context, and using informative case studies, the authors examine how moral theory can guide research design, education, and governance. As well as theoretical analysis, key practical concerns are critically discussed, including: informed consent anonymity, confidentiality and privacy plagiarism, misappropriation of authorship, research fraud and ‘whistleblowing’ ethics in qualitative research vulnerable populations trans-cultural research. Providing an accessible and robust theoretical framework for ethical practice, this book challenges students, researchers and supervisors to adopt a more informed and proactive approach to ethics in exercise, health and sports research. This insightful text will be of great interest to those taking a kinesiology, human movement, sport science or sport studies degree course.

Ethics and Epidemiology Cioms Publication
This review considers ethical challenges to research design and informed consent in biomedical and behavioral studies conducted in resource-poor

settings. A review of the literature explores relevant social, cultural, and ethical issues in the conduct of biomedical and social health research in developing countries. Ten case vignettes illustrate ethical challenges that arise in international research with culturally diverse populations. Recommendations for researchers and policy-makers concerned about ethical practices in multinational studies conducted in resource-poor settings are also listed.

Final Report of CIOMS Working Group II. Oxford University Press, USA

"Resolution WHA41.17 adopted by the Forty-first World Health Assembly, 13 May 1988" -- p.1.

Report of CIOMS Working Group X Cioms Publication

I. Defining "research"--II. Issues in study design . -- III. Harm and benefit -- IV. Voluntary informed consent -- V. Standard of care -- VI. Obligations to participants and communities -- VII. Privacy and confidentiality -- VIII. Professional ethics.

Science, Ethics, and Governance SAGE

This is a collection of Ruth Macklin's previously published articles on ethics in global health and research. The articles range from a chapter in a book published in 1989 to a journal article currently in press. The essays fall into two broad categories: policy and practice, and multinational research.

The Cambridge Handbook of Health Research Regulation International Ethical Guidelines for Health-Related Research Involving Humans

This Dictionary presents a broad range of topics relevant in present-day global bioethics. With more than 500 entries, this dictionary covers organizations working in the field of global bioethics, international documents concerning bioethics, personalities that have played a role in the development of global bioethics, as well as specific topics in the field.The book is not only useful for students and professionals in global health activities, but can also serve as a basic tool that explains relevant ethical notions and terms. The dictionary furthers the ideals of cosmopolitanism: solidarity, equality, respect for difference and concern with what human beings- and specifically patients - have in common, regardless of their backgrounds, hometowns, religions, gender, etc. Global problems such as pandemic diseases, disasters, lack of care and medication, homelessness and displacement call for global responses.This book demonstrates that a moral vision of global health is necessary and it helps to quickly understand the basic ideas of global bioethics.

Guidelines for Preparing Core Clinical-safety Information on Drugs World Health Organization

This textbook provides a brief history of human experimentation and reviews various theories of ethics from which the principles and rules that govern this research are derived. All relevant international documents and national regulations, policies and memoranda are referred to extensively to assist in addressing issues that regularly arise during the course of research involving human subjects. It includes case examples and exercises and is of interest to students and experienced researchers.

International Ethical Guidelines on Epidemiological Studies World Health Organization

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Ethics and Epidemiology Government Printing Office

This guide offers a practical step-by-step approach and algorithm to aid immunization professionals and decision-makers in determining the best course of action if additional vaccine safety data is needed. The guide provides a structured process for evaluating whether significant knowledge gaps exist, whether passive safety surveillance is adequate, and if not, methods for and practical aspects of conducting active vaccine safety surveillance. The guide also includes an essential vaccine information source list for evaluating the extent of data resources and several case studies for review. With more vaccine solutions available and opportunities for earlier availability of new vaccine products in resource-limited countries (e.g. vaccines against rotavirus, human papillomavirus or pneumococci) as well as new products that address diseases endemic in those countries only (e.g. malaria, dengue among others), generating reliable data about specific safety concerns is becoming a priority for all countries. This CIOMS publication--more than any other in recent history--has focused on the special needs of the country level organizations responsible for developing strategies and implementing new vaccination programs into resource-limited environments.

Casebook on Ethical Issues in International Health Research Pharmaceutical Press

Before new interventions can be used in disease control programmes, it is essential that they are carefully evaluated in "field trials", which may be complex and expensive undertakings. Descriptions of the detailed procedures and methods used in trials that have been conducted in the past have generally not been published. As a consequence, those planning such trials have few guidelines available and little access to previously accumulated knowledge. In this book the practical issues of trial design and conduct are discussed fully and in sufficient detail for the text to be used as a "toolbox" by field investigators. The toolbox has now been extensively tested through use of the first two editions and this third edition is a comprehensive revision, incorporating the many developments that have taken place with respect to trials since 1996 and involving more than 30 contributors. Most of the chapters have been extensively revised and 7 new chapters have been added.

Biomedical Research Ethics Routledge

This text aims to be a one-stop source for guidance and checking the rules for proper conduct of clinical trials, as well as providing a historical perspective of the clinical research landscape. Good Clinical Practice guidelines provide an international quality standard for the regulation of clinical trials. They include standards on how clinical trials should be conducted, provide assurance of safety and efficacy of newly developed drugs and protect human rights. Principles of Good Clinical Practice describes the ethical principles and regulatory requirements that influence the current and future conduct of clinical research. As well as providing essential information on clinical trial design and pharmacovigilance, coverage also includes: informed consent; investigator and sponsor responsibilities; site monitoring; institutional review boards and dependent ethics committees; clinical trial registration and reporting; quality assurance; and future implications for good clinical practices. Principles of Good Clinical Practice will be a definitive text for Clinical Development personnel at pharmaceutical companies, Contract Research Organizations (CROs), PharmD and postgraduate pharmacy students, and medical, pharmacy and drug company libraries

Evidence Synthesis and Meta-Analysis for Drug Safety World Health Organization

Examining the theoretical and empirical status of applied ethics, this volume demonstrates how a pluralistic and democratic society can deal with ethical issues in the light of its moral conscience. The volume first sets the stage for a conception of applied ethics as applications of transnational civil ethics, based both on a discourse theory of knowledge (Apel, Habermas), and on an activities and capabilities approach (Aristotle, Sen). It then examines how applied ethics relates to important theoretical discussions in philosophy such as constructivism, virtue ethics, hermeneutic and deliberative theory. The contributors discuss applied ethics in light of globalization and identify recurring dilemmas as well as the problem of universal norms. They close by considering two aspects of the institutional point of view - republicanism, and contractarianism and constitutional economics.