Revised Cioms International Ethical Guidelines For Health

Ethics Dumping

Grand Challenges in Pharmaceutical Medicine: Competencies and Ethics in Medicines Development

Human Experimentation and Medical Ethics

Biomedical Research Ethics

Research Ethics in Africa

The National Bioethics Advisory Commission

Ethics and Research on Human Subjects

Ethical Issues in International Biomedical Research

Integrating Clinical Research 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 used to illustrate the ethical dilemmas that are to be faced in situations in which research on one group 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 controls for, and the obligation to ensure that the participation of these populations is voluntary. 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. Supersedes the 1991 International Guidelines for Ethical Review of Epidemiological Studies. Its core consists of 24 guidelines with commentaries. A section outlines the historical background and the revision process, and includes an introduction, an account of earlier instruments and guidelines and a statement of general ethical principles. An Appendix lists the items to be included in a revised code of conduct for research involving human subjects. Also included in the appendices is the World Medical Association's 2008 Declaration of Helsinki. [Ed.].100 Questions (and Answers) About Research Ethics by Emily E Anderson

Research Definitions and Application of Terms for Vaccine Pharmacovigilance

SMQs

100 Questions (and Answers) About Research Ethics

About Research Ethics by Emily E Anderson

Amy Corneli is an essential guide for graduate students and researchers in the social and behavioral sciences. It identifies ethical issues that individuals must consider when planning research studies as well as provides guidance on how to address ethical issues that might arise during research implementation. Questions such as assessing risks, to protecting privacy and vulnerable populations, obtaining informed consent, using technology including social media, negotiating the IRB process, and handling data ethically are addressed in this book. The third edition expands new material on managing research ethics, including an appendix which provides a comprehensive list of resources. Case studies of recent drug trials and their research protocols are used to illustrate the ethical dilemmas that are to be faced in situations in which research on one group 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 controls for, and the obligation to ensure that the participation of these populations is voluntary. 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. Supersedes the 1991 International Guidelines for Ethical Review of Epidemiological Studies. Its core consists of 24 guidelines with commentaries. A section outlines the historical background and the revision process, and includes an introduction, an account of earlier instruments and guidelines and a statement of general ethical principles. An Appendix lists the items to be included in a revised code of conduct for research involving human subjects. Also included in the appendices is the World Medical Association's 2008 Declaration of Helsinki. [Ed.].100 Questions (and Answers) About Research Ethics by Emily E Anderson

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institutional disruption, and an overall climate of fear and distrust. Invariably, the countries most affected by outbreaks have limited resources, under-developed legal and regulatory structures, and health systems that lack the resilience to deal with crisis situations. Countriespecific and public health professionals may be forced to weigh and prioritize potentially competing ethical values in the face of severe time and resource constraints. Therefore, it is imperative for policymakers, health providers, researchers, and funders to plan for outbreak situations by anticipating and preparing for the critical ethical issues likely to arise. In addition to setting forth ethical principles applicable to infectious disease outbreaks generally, it shows how these principles can be adapted to different epidemiological and social circumstances. The definitive reference guide to designing scientifically sound and ethically robust medical research, including legal, ethical, and social issues. The CIOMS was established in 1995 to advise various government entities on issues arising from research on human biology and behavior. During its five-year tenure, NBAC submitted six reports to the White House containing 120 recommendations on several complex bioethical issues including the cloning of human beings and embryonic stem cell research. This study assesses NBAC's contribution to policymaking by tracking the response to NBAC's recommendations from the president, Congress, government, societies and foundations, other organizations, and national and international groups. It is essential that such principles be 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, these planning protocols have very 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. 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 clinical research. 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 describe 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 pharmaceutical practice, they also provide insight into the ethical and regulatory landscape of the clinical research industry. The book reviews the role of 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. It is one of the foremost historians of contemporary science. . . . His book is at once a guide to primary sources for the history of medical 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. 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 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. At any point in the drug development process, systematic reviews and meta-analysis provide important information to guide 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 at large to have evidence on benefits and risks to the best available data and medical professionals. The proposed 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 meta-analysis of 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 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 wider reviews 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 approach and results presented, are written in a manner that anyone with a meta-analysis background can follow and use them to evaluate the findings of a meta-analysis and how to communicate these. This report from the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO covers the activities and outputs of the CIOMS/WHO Working Group on Vaccine Pharmacovigilance (2005–2010). This working group brought together experts from both industrialized and emerging countries representing regulatory agencies, vaccine industry, national and international public health bodies including WHO and CIOMS, academia and clinical care, contributing from their different perspectives. The report covers general terms and definitions for vaccine safety and discusses the application of such harmonized tools in vaccine safety surveillance and studies. As well, the report highlights case definitions for adverse events typically reported for vaccines. The report is addressed to those engaged in vaccine safety data collection and evaluation, and will also make a useful reading for others who want to familiarise themselves with vaccine safety terminology. The use of human subjects in medical and scientific research has given rise to troubling questions. How should human subjects be selected for experiments? What should they be told about the research in which they are involved? How can their privacy be protected? When is it permissible to deceive them? How do we deal with subjects such as children, fetuses, and the mentally infirm, for whom informed consent is impossible? In this book, Dr. Robert J. Levine reviews federal regulations, ethical and legal principles and policies, and responsible research practices in the conduct of human subject research and clinical trials. His book is an essential resource and reference for everyone involved in clinical research, including institutional review boards, scientists, philosophers, lawyers—addressing the ethical issues involved. [Levine's] experience as a clinician, IRB chairman, writer and editor of a journal devoted exclusively to issues faced by IRBs makes him uniquely qualified to bring together the legal, ethical, and practical dimensions. . . . [The book] is sophisticated but readable. . . . [and] should be on every IRB administrator's desk and in every medical ethics library.---Norman Post, M.D., The New England Journal of Medicine [Levine's] work will be of interest to historians of science, as well as philosophers and ethicists who care about the conduct of clinical research in the late twentieth century and a pioneering secondary source about that history.---Daniel M. Fox, Bulletin of the History of Medicine [You will be charmed by the [book's] elegance and lucidity and . . . persuaded of its relevance to doctors in any country.---Alex Paton, British Medical Journal "Should be of wide interest to those keen to see advances in medical research brought into general medical practice."--Gilbert Drenn, issues in Science and Technology [his book] is a resourceful and comprehensive reference book, and it is one of the most useful texts on ethics of clinical research.
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. The aim of this publication is to brief drug regulatory authorities, scientific institutions and pharmaceutical companies worldwide about the development, purpose and appropriate use of Standardized MedDRA Queries (SMQs) in drug surveillance. Two papers in this publication are to assist in the rational use of search queries in the identification and retrieval of potentially relevant individual case safety reports from a database and to harmonize presentation of search results. It also includes examples to illustrate the structure and content of end product. This consensus report of the CIOMS DILI Working Group aims to provide a critical framework and essential set of tools to detect, diagnose, and manage DILI during drug development and in the post-marketing setting. The report is intended for clinical and basic pharmaceutical industry investigators who capture, analyze, and communicate liver safety data in drug development. It is also intended for regulatory scientists and expert consultants who comprehensively evaluate new products and emerging biomarkers for their association with DILI risk and for health care professionals who monitor and manage patients treated with potentially hepatotoxic drugs in clinical practice. This document assists policy-makers, health care providers and researchers to understand key concepts in health ethics and to identify basic ethical questions surrounding health and health care. It illustrates the challenges of applying ethical principles to global public health and outlines practical strategies for dealing with those challenges. The document is divided into four main parts. The first part explores key concepts in health ethics and explains common terms, theories and principles. The second part examines the main challenges in the practice of health ethics from the perspective of global public health. These issues provide the reader with a concrete understanding of the various ethical obstacles that may arise in public health, health research, and the provision of health care services. The third part describes practical strategies for dealing with these challenges and the key actors involved in developing ethical frameworks. Finally, the fourth part explains why health ethics is important to WHO, and how WHO supports Member States in building capacity in health ethics. The 2014-2015 Ebola epidemic in western Africa was the longest and most deadly Ebola epidemic in history, resulting in 28,616 cases and 11,310 deaths in Guinea, Liberia, and Sierra Leone. The Ebola virus has been known since 1976, when two separate outbreaks were identified in the Democratic Republic of Congo (then Zaire) and South Sudan (then Sudan). However, because all Ebola outbreaks prior to that in West Africa in 2014-2015 were relatively isolated and of short duration, little was known about how to best manage patients to improve survival, and there were no approved therapeutics or vaccines. When the World Health Organization declared the 2014-2015 epidemic a public health emergency of international concern in August 2014, several teams began conducting formal clinical trials in the Ebola affected countries during the outbreak. Integrating Clinical Research into Epidemic Response: The Ebola Experience assesses the value of the clinical trials held during the 2014-2015 epidemic and makes recommendations about how the conduct of trials could be improved in the context of a future international emerging or re-emerging infectious disease events.