

What Do Epidemiological Guidelines Say about Research in Emergency Situations?

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Disaster → Epidemiology

🌐 „the study of the distribution and determinants of disease in man” (MacMahon B., Pugh T. F, 1970, p. 1)



Disaster → Epidemiology

🌐 “The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control health problems” (Last J., 2001)



Disaster → Epidemiology

🌐 „The discipline of epidemiology, [...] provide the essential quantitative and analytical methods, principles of logical inquiry, and rules for evidence for: [...] **diagnosing, measuring, and projecting the health needs of community and populations;** determining health goals, objectives **and priorities;** **allocating and managing health care resources;** assessing intervention strategies and evaluating the impact of health services” (International Epidemiology Association, White, Henderson, 1976)



Disaster → Epidemics

**Epidemiological guidelines →
Disaster?**







Overview

- 🌐 How we constructed the sample of guidelines
- 🌐 Characteristics of the guidelines
- 🌐 What do epidemiological guidelines say about research in disaster and emergency?
- 🌐 Why do not they say almost anything?



1. HOW WE CONSTRUCTED THE SAMPLE

-  Inclusion and exclusion criteria
-  Searching strategy
-  Search results
-  Methods



1.1. INCLUSION AND EXCLUSION CRITERIA

👤 The goal: a sample of guidelines that might be used in all kinds of epidemiological or public health research by members of IRBs/RECs



1.1. INCLUSION CRITERIA

- 🌐 Guidelines introduce themselves as ethical guidelines for epidemiological or public health studies
- 🌐 Guidelines contain at least one paragraph defining the role of ethics review



1.1. EXCLUSION CRITERIA

- 🌐 General guidelines that regulate all kinds of research
- 🌐 Guidelines devoted to specific issue in epidemiological/public health research (i.e. HIV/AIDS research guidelines)

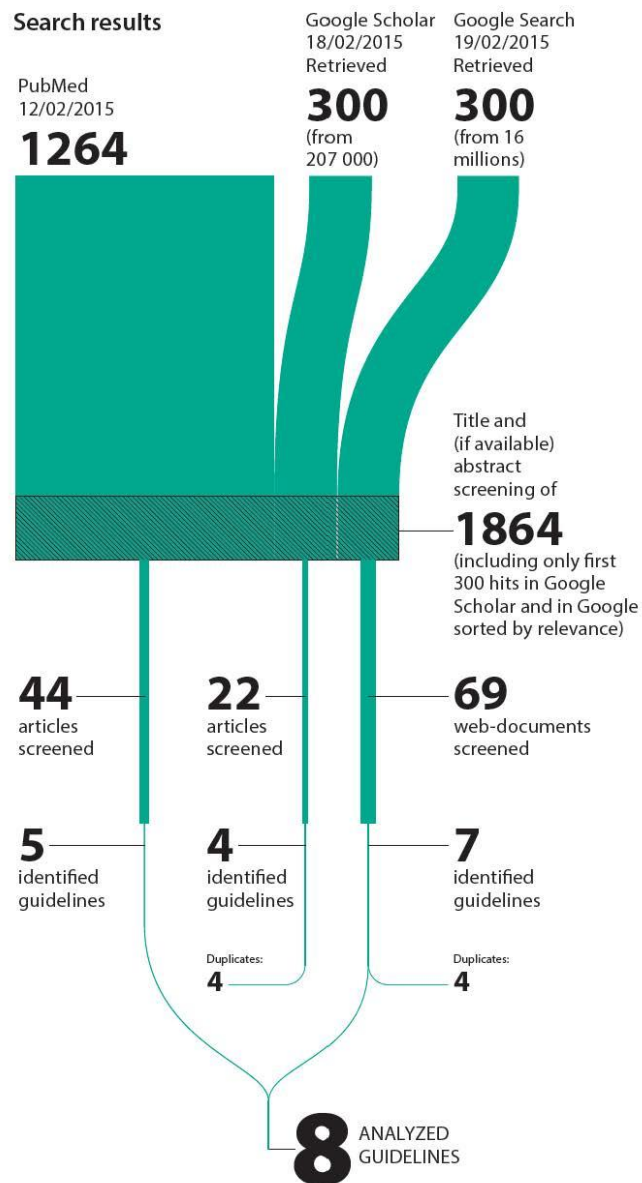


1.2. SEARCH STRATEGY

- 🌐 PubMed, Google Scholar and Google
- 🌐 Combinations of terms: code, guidelines, epidemiology and public health, ethics, research



1.3. RESULTS



1.3. RESULTS

Title	Organization	Year of latest version
Ethical Guidelines for Epidemiologists (IEF-EGE)	Industrial Epidemiology Forum	1991
American College of Epidemiology Ethics Guidelines (ACEEG)	American College of Epidemiology	2000
Good Epidemiological Practice. IEA Guidelines for proper conduct in epidemiological research (IEA-GEP)	International Epidemiological Association	2007
Guidelines for Good Pharmacoepidemiology Practices (GGPP)	International Society for Pharmacoepidemiology	2007
International Guidelines for Epidemiological Studies (CIOMS-IEGES)	Council for International Organizations of Medical Sciences, World Health Organization	2008
Ethical Guidelines for Epidemiological Research (JAPAN-EGES)	Ministry of Education, Culture, Sports, Science and Technology, Ministry of Labour and Welfare, Japan	2008
Ethical Guidelines for Observational Studies: Observational research, audits, and related activities. Revised edition (NEW-ZEALAND-EGOS)	National Ethics Advisory Committee, Ministry of Health, New Zealand	2012
Ethical Guidelines for Environmental Epidemiologists (EGEE)	International Society for Environmental Epidemiology	2012



1.4. METHODS

- Constant comparative method
- Important aspects of ethics review
- Five main categories
- Fifty eight subcategories



2. CHARACTERISTICS OF GUIDELINES

- 🌐 This is a heterogeneous set of documents
- 🌐 There are three main categories of guidelines:
 - 🌐 International documents issued by largely recognized professional organizations
 - 🌐 Professional guidelines establishing professional identity
 - 🌐 National, governmental guidelines supplementing national laws



3. WHAT GUIDELINES ACTUALLY SAY ABOUT RESEARCH IN EMERGENCY SITUATIONS

🌐 Two kinds of provisions/comments:

- 🌐 Referring directly to the disaster/emergency context of research
- 🌐 Referring indirectly to the disaster/health emergency context of research



3. WHAT GUIDELINES ACTUALLY SAY ABOUT RESEARCH IN EMERGENCY SITUATIONS

- 🌐 The analyzed guidelines do not say directly almost anything about research in emergency, disaster research and research in disaster.



3. WHAT GUIDELINES ACTUALLY SAY ABOUT RESEARCH IN EMERGENCY SITUATIONS

🔗 Key words: catastrophe, cataclysm, **disaster**, earthquake, **emergency**, **epidemic**, flood, **outbreak**, pandemic, **risk to public health**, **threat to public health**, war



3. WHAT GUIDELINES ACTUALLY SAY ABOUT RESEARCH IN EMERGENCY SITUATIONS

- 🌐 CIOMS GUIDELINES - The only guidelines, which contain paragraph *Research in emergency situation*



3. WHAT CIOMS GUIDELINES SAY

- 🌐 The design of different kinds of studies in emergency situation should be established in advance
- 🌐 The established studies protocol should be reviewed in advance by IRB/REC
- 🌐 In certain situations the informed consent might be waived by IRB/REC



3. WHAT DO GUIDELINES SAY (indirectly)?

Information policy

A4	Deviation from standard written informed consent form	ACEEG, EGEE CIOMS-IEGES, IEF-EGE, JAPAN- EGES (5)
A5	Withholding information, Deception of the subject, Debriefing	CIOMS-IEGES, IEF-EGE (2)
A8	Communication with community; community consultation and involvement	CIOMS-IEGES, JAPAN-EGES, EGEE (3)
A9	Communication of results to media and general public	CIOMS-IEGES, EGEE, IEF-EGE, (4)



3. WHAT DO GUIDELINES SAY (indirectly)?

🌐 Protection of subject

B6	Exceptional breach of confidentiality	ACEEG, EGEE (2)
B7	Waiver of informed consent (also in research utilizing existing personal information/specimen)	ACEEG, CIOMS-IEGES, EGEE, IEA-GEP, IEF-EGE, JAPAN-EGES, NEW-ZEALAND-EGOS (7)



3. WHAT DO GUIDELINES SAY (indirectly)?

🌐 Formal and operational requirements

D11	Fast-track review	EGEE, GGPP, IEF-EGE, JAPAN- IEGES (4)
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3. WHAT DO GUIDELINES SAY (indirectly)?

🌐 Different types of studies

E7	Studies using publicly available data	CIOMS-IEGES (1)
E8	Minimal risk	ACEEG, CIOMS-IEGES, JAPAN-IEGES, NEW-ZEALAND-EGOS (4)
E9	Studies using anonymized data/specimens	CIOMS-IEGES, GGPP, JAPAN-IEGES, GGPP (4)
E10	Studies without informed consent regulated by local laws	CIOMS-IEGES, GGPP, JAPAN-EGES, NEW-ZEALAND-EGOS (4)
E11	Public health, routine surveillance	ACEEG, CIOMS-IEGES, JAPAN-IEGES, NEW-ZEALAND-EGOS (4)
E12	Studies in emergency, acute communicable diseases	ACEEG, CIOMS-IEGES, JAPAN-EGES (3)
E13	Simple aggregation of records	JAPAN-EGES (1)



4. WHY DO GUIDELINES SAY ALMOST NOTHING?

- 🌐 In emergency situation doing research is wasting scarce resources
- 🌐 Research in emergency is not different than other kinds of epidemiological research
- 🌐 Emergency situations are too exceptional to formulate any general rules



4.1. EXCEPTIONALITY OF DISASTER

- 🌐 Disasters reveal vulnerability of human condition
- 🌐 Disasters make people helpless in hopeless situations



4.1. STRATEGIES IN HELPLESS AND HOPELESS SITUATIONS

- 🌐 Being indifferent (both victims and observers)
- 🌐 Crying or praying (compassion)
- 🌐 Being as rational as possible (disaster bioethics)



4.1. MEDICINE AND SALVATION

🌐 Byron Good: Medicine does not neglect the moral and spiritual dimension, it shapes „the experimental world of our moral lives by instrumental rationality, highly routinized procedures and both technical and technological management”



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🌐 Byron Good: „Sickness, death, and finitude are found in the corpse, in the human body. And salvation, or at least some partial representation of it, is present in the technical efficacy of medicine”

