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Randomized Trials vs Epidemiology?

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Randomized trials vs epidemiology?

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Epidemiology

A branch of medical science that deals with the incidence, distribution, and control of a disease in a population (Merriam Webster's *10th Collegiate Dictionary* 2001)

The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems (Last's *Dictionary of Epidemiology*, 4th ed, 2001)

\EpiVsCT\EpiDefn

Biostatistics

A discipline of the biological sciences concerned with the application of mathematical-statistical theory, principles, and practices to the observation, measurement, and analysis of biological phenomena. syn: biometry (Meinert's *Clinical Trials Dictionary*; 1996)

\EpiVsCT\Biostat

Epidemiologist and trialist

Epidemiologist: An investigator who studies the occurrence of disease or other health-related conditions or events in defined populations (Last, *Dictionary of Epidemiology*; 2nd ed)

Trialist: One who specializes in the design and conduct of trials; one concerned with procedural and policy issues related to the design, conduct, and analysis of trials (Meinert, *Clinical Trials Dictionary*, 1996)

\EpiVsCT\EpiVsCT

The epidemiologist vs the trialist

- The epidemiologist is concerned with causality; the trialist with determining whether a treatment works
- The epidemiologist is an observationist; the trialist is an interventionist
- The epidemiologist is an "absolutist"; the trialist is a relativist

\EpiVsCT\Trialist

Randomized trials vs epidemiology

64 dollar question

Where is the intellectual home for trialists?

Answer: It should be in epidemiology but is it?

\EpiVsCT\Question

Schools of Public Health with clinical trials courses

No of schools: 27

Schools with ≥ 1 CT course listing: 19

4 with 3 courses

6 with 2 courses

9 with 1 course

By department

10 Biostat

3 Epi

6 Epi and Biostat

\EpiVsCT\Courses

JHU and Tulane Epi Departments course listings

JHU

Epi

88 courses

2 courses with CT in title

Biostat

81 courses

0 courses with CT in title

Tulane

Epi

16 courses

0 courses with CT in title

Biostat

18 courses

0 courses with CT in title

\EpiVsCT\JHU&Tul

Randomized trials vs epidemiology

2002 Am Journal of Epi

341 articles
4 relating to trials

13 involving kids
1 CT and kids

\\EpiVsCT\EpiJour

PhD dissertations

JHU (1991 - 2002)
232 total
10 re CTs

U of Washington (1990 - 2002)
132 total
3 re trials

Tulane (1992 - 2002)
52 total
0 re trials

\\EpiVsCT\Thesis

General epi texts pages devoted to CTs

	Total	Pages CTs
Gordis (2000)	308	26
Rothman & Greenland (1998)	738	2
Szklo & Nieto (1998)	494	0
Schoenback & Rosamond (1999)	572	4
Morton et al (2001)	208	5
Kleinbaum et al (1982)	529	1
Lillienfeld & Stolley (1994)	371	20
Trichopolous & MacMahon (1996)	347	7
Timmreck (1998)	508	3
	4,075	68

\\EpiVsCT\Textbook

Randomized trials vs epidemiology

Pediatric trials via PubMed

	Total #	#	Pediatric trials	
			%	% RCT
1966 - 70	6,277	517	8.2	1.8
1971 - 75	10,024	803	8.0	2.1
1976 - 80	14,501	982	6.8	2.6
1981 - 85	21,858	1,410	6.5	3.4
1986 - 90	35,574	2,285	6.4	3.7
1991 - 95	60,970	3,980	6.5	3.9
1996 - 00	91,579	6,522	7.1	3.6
2001	18,079	1,272	7.0	4.1
2002	15,703	1,120	7.1	4.4
	274,565	18,891	6.9	3.6

\EpiVsCT\CT&Kids

Pediatric rule

Rule issued by FDA in 1998 requiring that adult drugs prescribed for children must be tested in children

Overtaken by court challenges in 2002; groups argued that the FDA overstepped its authority because the "rule" gave the FDA oversight over off-label prescriptions

\EpiVsCT\PedRule

The science of clinical trials?

Science: Knowledge or a system of knowledge covering general truths or the operation of general laws especially as obtained and tested through scientific methods (Webster's 10th Collegiate)

Is the science of clinical trials contained in epidemiology as we know it today?

What do we call that science? Trialology?

\EpiVsCT\SciTrial

Randomized trials vs epidemiology

The 64 dollar question answered?

Trialist by training and disposition have more in common with epidemiologists than any of the other medical sciences, therefore, epidemiology is the logical home for trialists

\EpiVsCT\Home

Factors working against a homecoming

- "Youth" of the field
- Trials are just another kind of epidemiological study
- Mind set in departments of epidemiology
- Trials are a measure of last resort
- Terminology
- Definition of epidemiology

\EpiVsCT\Problems

Toward a broader definition of epidemiology

An observational and evaluative (experimental and intervention) medical science concerned with the cure, prevention, amelioration, or elimination of disease and related adverse health conditions by study of the patterns and distribution of disease and related adverse health conditions to determine source and cause and by study to assess the relative merit of different control or treatment procedures.

Or Last rewritten

The study of the distribution and determinants of health-related states or events in specified populations *through observation, intervention, or experimentation*, and the application of this study to control of health problems

\EpiVsCT\NewDefn