

The BIGGEST Public Health Experiment Ever:

The 1954 Field Trial of the Salk Poliomyelitis Vaccine

Introduction

Background

Polio, or poliomyelitis, is a *crippling and potentially deadly infectious disease*. It is caused by the **poliovirus**.

The virus spreads from person to person and can *invade an infected person's brain and spinal cord*, causing paralysis.

Time Line

Localized paralytic polio epidemics began to appear in Europe and the United States around 1900s.

Effective vaccines were developed in 1950s and have been used around the world since then, allowing some richer countries to eliminate the disease entirely in the 1960s and 70s.

Video Clip

BBC: <http://www.medicine.mcgill.ca/epidemiology/hanley/bios601/CourseStudies/BBCpieces.mp4>

U-Michigan: <https://www.youtube.com/watch?v=5BfxpdzwXLA>

1954 Field Trial

- **OBSERVED CONTROL**

- Case: vaccination all children in the 2nd grade
Control: the 1st and 3rd grade children
- Pros:
 - same geographic location
 - observed concurrently in time
- Cons:
 - different ages (take average)
 - uncertainty in the diagnostic process
 - bias in physician's expectations
 - selective effect of using volunteers.

- **RANDOMIZATION + PLACEBO CONTROL**

- Randomize vaccine / placebo to all 2nd grade volunteers
 - Pros:
 - minimize the previously mentioned bias
 - placebo injection -- small risk
 - double blind
 - Cons:
 - parents' concerns on children receiving ineffective salt solution
 - ethical issue
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TABLE 1. Summary of Study Cases by Diagnostic Class and Vaccination Status (Rates per 100,000)

STUDY GROUP	STUDY POPULATION	ALL REPORTED CASES		POLIOMYELITIS CASES							
		No.	Rate	Total		Paralytic		Nonparalytic		Fatal polio	
				No.	Rate	No.	Rate	No.	Rate	No.	Rate
All areas: Total	1,829,916	1013	55	863	47	685	37	178	10	15	1
Placebo control areas: Total	749,236	428	57	358	48	270	36	88	12	4	1
Vaccinated	200,745	82	41	57	28	33	16	24	12	—	—
<u>Placebo</u>	201,229	162	81	142	71	115	57	27	13	4	2
Not inoculated*	338,778	182	54	157	46	121	36	36	11	—	—
Incomplete vaccinations	8,484	2	24	2	24	1	12	1	12	—	—
Observed control areas: Total	1,080,680	585	54	505	47	415	38	90	8	11	1
Vaccinated	221,998	76	34	56	25	38	17	18	8	—	—
<u>Controls**</u>	725,173	439	61	391	54	330	46	61	8	11	2
Grade 2 not inoculated	123,605	66	53	54	44	43	35	11	9	—	—
Incomplete vaccinations	9,904	4	40	4	40	4	40	—	—	—	—

Source: Adapted from Francis (1955), Tables 2 and 3.

* Includes 8,577 children who received one or two injections of placebo.

** First- and third-grade total population.