**Background – History of Polio and Vaccine Development**

This section includes much more information than students need. It combines information from several sources, though the most helpful sources were the Smithsonian’s polio website and the Marks and Monto articles.

Poliomyelitis virus primarily infects humans—and a few primates. About 75% of infected humans suffer no effects; almost all others have a mild short-term illness. In about 1 out of 150 cases, the virus weakens muscles, which can lead to paralysis and death. The virus is generally spread by hand-to-mouth ingestion, but can be spread from person to person through coughing in the air. Therefore, it is impossible to completely avoid the risk. Historical evidence exists for infections at least as far back as 1500 BC in Egypt, but major outbreaks with paralysis began in only about 1880 AD.

Ironically, a major factor in improving general human health—better sanitation—also brought a higher rate of serious polio. Before public sanitation systems, most infants were infected in their first year of life with weaker virus versions and had some residual protection from the mother. As areas improved personal hygiene and created sewers, babies were less frequently infected, and surviving polio strains became stronger. Thus, western Europe and the USA were first to report epidemics of paralytic polio, and the infected population shifted from primarily infants to school-age children and adults. Wealthier neighborhoods also had higher infection rates than poorer neighborhoods.

Almost all cases of polio occurred during warmer summer months. One major American epidemic occurred in 1916. There were 27,000 cases with 6,000 deaths across the US, concentrated in New York City with about 2,000 deaths. Quarantines were common; Pennsylvania required inspection of all children under 16 crossing the border from New York and New Jersey. Infection counts continued to increase through the 1950s, although better medicine and technology such as iron lungs reduced deaths. In the early 1950s, polio virus caused about 30,000 medical cases each year, with 1,000 to 2,000 annual deaths.

According to US census data, there are now about 50% more children than there were in 1950; the same rate of polio would cause tens of thousands of partially paralyzed children each year, with more than 1,500 deaths. According to CDC data, 1,500 annual deaths would be more than the mortality for childhood (ages 1–14) cancer or homicide or suicide. It would roughly equal the total for Sudden Infant Death Syndrome, which is considered a severe enough problem to change how babies sleep. Accidental injury would still cause more annual deaths, but polio would be known to all.

There was great interest in developing a vaccine that could prevent polio virus infections. One of the organizers was Franklin D. Roosevelt, who became paralyzed below the waist in 1921. The cause was diagnosed as polio (although modern review suggests Guillain–Barré syndrome instead). FDR continued to promote polio research, even as president; he helped establish the private charity National Foundation for Infantile Paralysis in January 1938. Between 1938 and 1955, the foundation (generally known as the March of Dimes) raised and spent $223 million on polio research and treatment—more than $2 billion when adjusted for inflation.

During attempts at a vaccine, two teams had progressed to human trials in 1935. Both trials were unsuccessful in preventing polio. Worse yet, both potential vaccines caused multiple cases of polio, including deaths. Other large-scale attempts were delayed by World War II and the need to establish higher thresholds of safety. Thus, the next promising vaccine trials began in the early 1950s. By 1953, researchers led by Jonas Salk had demonstrated that a properly created killed-virus vaccine had not caused polio and increased children’s resistance. In a killed-virus vaccine, the polio virus is treated with chemicals that destroy the ability to cause body damage. People injected got polio, but received a form that caused no damage; from this safe form, the body would develop immunity to all forms of polio, both safe and unsafe.

The Salk results looked promising, so the National Foundation began plans for a large-scale trial. There was some opposition, including several virus scientists who worried an improperly created vaccine could cause paralysis. (The virus scientists were correct. In 1955, after the results of the 1954 trial were announced, manufacturer Cutter Laboratories produced some improperly created vaccine doses. These doses caused about 170 cases of paralysis and 10 deaths. This manufacturing error does not change the effectiveness of properly killed virus, though.) Despite the scientists’ concerns, plans were developed in the fall of 1953.

Since schoolchildren had the highest incidence rate, the foundation decided to test on first through third grade students in 272 counties with relatively high incidence rates. The first plan—announced in November 1953—was observed control. All Grade 2 children whose parents consented would be vaccinated. Their polio rate would be compared against a control group of Grade 1 children, Grade 3 children, and Grade 2 children without parental consent. Placebo controls were considered, but placebos were thought to lower consent rates and introduce extra pain in the children.

To satisfy concerns about bias in evaluation, the foundation agreed to pay for an independent tabulation of results. That effort’s leader, Thomas Francis, started in December. Dr. Francis wanted a more statistical design with randomization. In this design—placebo control—parents in grades 1, 2, and 3 could choose to have their children participate. Half the participating children would receive vaccine shots; the control half would receive placebo shots.

On January 11, 1954, Francis convened an advisory meeting, the basis for this activity. The meeting included public health officials, clinical doctors, statisticians, and scientists. It did not include ethicists or parents, groups offered for student discussion. I added parents because that role allows students to consider their families individual belief. After this meeting and others in early 1954, some states switched to placebo control. Officials in 11 states implemented a placebo control study, with officials in 34 states remaining with observed control. (There were 48 states in 1954; the remaining three states had no test sites.) Monto’s 1999 article includes a map of participating areas on Page 15; nearby areas could be discussed.

Vaccinations occurred between April and June 1954, with monitoring through the summer—the season with the highest polio rate. Many parents chose not to participate. In placebo control areas, about 44% of children did not participate; in observed control areas, about 35% of eligible second-grade children did not receive vaccines. Retrospective analysis showed wealthier families were more likely to participate, at least partly because children in wealthier neighborhoods were more likely to contract a strong form of the virus. Overall, in placebo areas, about 200,000 children received vaccine, about 200,000 children received placebo, and about 330,000 children did not participate. In observed control areas, about 225,000 second-grade children received vaccine, about 125,000 eligible second-grade children did not participate, and about 725,000 first- and third-grade children served as controls. In total, more than 1,800,000 children were monitored through 1954.

Without computers, statistical analysis was much harder than it would be in the 21st century. People from the US Census Bureau and IBM assisted in the process, which included almost 2 million punch cards. Results listed included cases of paralytic and nonparalytic polio, combined from Monti (1999, p. 18). Because the placebo and observed designs were so different, results appear separately. In both designs, vaccination reduced polio incidence rate by at least 40%. The press release could begin, “The vaccine works. It is safe, effective, and potent.”

Placebo control Vaccinated 56 polio cases 28 per 100,000 children  
 Placebo 138 polio cases 69 per 100,000 children  
 Nonparticipating 153 polio cases 46 per 100,000 children

Observed control Grade 2 vaccinated 55 polio cases 25 per 100,000 children  
 Grade 2 unvaccinated 53 polio cases 43 per 100,000 children   
 Grades 1 and 3 391 polio cases 54 per 100,000 children

Results were announced April 12, 1955, in a nationally televised press conference. After the good news was announced, church bells rang. Plans commenced to vaccinate more children. The Cutter Laboratories incident delayed vaccination for about a month, but the campaign restarted with strict oversight from the federal CDC. By 1961, the US polio rate was less than 1 per 100,000; the last polio case originating in the USA occurred in 1979.

Polio vaccinations progressed around the world; the introduction of a single oral vaccine made the effort easier than Salk’s injections. Vaccination for polio and other diseases was so valued that vaccination truces were established in at least five civil wars (Peru, El Salvador, Angola, Afghanistan, and Sudan) to allow children to receive medicine. Polio has not been completely eliminated from the world, though the Global Polio Eradication Initiative is getting close; in 2018, there were only 133 confirmed paralytic polio cases worldwide.

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