The Scientific Method in Vaccine History

The scientific method is a disciplined, systematic way of asking and answering questions - there is no single model that can be applied in all situations. Certain qualities, however, must apply to all applications of the scientific method: it must attempt to answer a question; careful, controlled observations must form the basis of data collection; results must be reproducible: other investigators, using the same process, must be able to observe the same results.

**Observation**

Scientific investigations usually begin with an observation that points to an interesting question. One famous example of an observation that led to further investigation was made by Scottish biologist Alexander Fleming in the 1920s. After an absence from his lab, he returned and began to clean some glass plates on which he had been growing a certain kind of bacteria. He noticed an odd thing: one of the plates had become contaminated by mold. Curiously, the area around the mold looked free of bacterial growth. His observation indicated that a causal relationship might exist: the mold or a substance produced by the mold might prevent bacterial growth.

**Hypothesis**

A hypothesis is a possible solution generated by observation. In Alexander Fleming's investigation of antibiotic properties of mold, his hypothesis might have been something like, “If filtrates from a certain type of mold are introduced to bacteria, the bacteria will die.” Good hypotheses share several qualities -- begin with existing knowledge, involve a single problem and possible solution, and are testable and "falsifiable."

**Experiment/Testing**

Many modern scientific studies involve experimentation -- a test with a control group and an experimental group. The only difference between the groups is the single factor being tested -- known as the variable. The control group exists to provide a valid comparison to the experimental group. For instance, in an experiment testing Fleming's hypothesis, a scientist could introduce filtrates of mold to cultures of bacteria on glass plates. A control group would contain similar cultures of bacteria, but with no addition of mold filtrates. Both groups would be subject to exactly the same conditions. Any difference between the two groups would result from the variable, or the single difference between them: the introduction of mold filtrate to the bacterial cultures. Careful observations and recording of data are crucial during the testing phase of the scientific method.

**Conclusion**

A final step in the scientific methods involves analysis and interpretation of the data gathered during the testing phase. This allows the researcher to form a conclusion based on the data. A good conclusion takes into account all the data gathered and will reflect on the hypothesis, whether it supports the hypothesis or not.

**SCIENTIFIC METHOD IN ACTION --**

**Edward Jenner: The Importance of Observation**

Edward Jenner (1749-1823) was an English physician who tested the hypothesis that infection with cowpox could protect a person from smallpox infection. Cowpox is an uncommon illness in cattle, usually mild, that can be spread from a cow to a human via sores on the cow's udder. Smallpox, in contrast, was a deadly disease of humans killing about 30% of those infected. Jenner scratched some material from the cowpox sore on the hand of a milkmaid into the arm of James Phipps, the son of Jenner's gardener. Young Phipps felt poorly for several days, but made a full recovery. A short time later, Jenner scratched some matter from a fresh human smallpox sore into Phipps’s arm in an attempt to make him ill with smallpox. Phipps did not contract smallpox. Jenner's method of vaccination against smallpox grew in popularity and eventually spread around the globe. The World Health Organization eventually declared smallpox to be eradicated in 1980.

**Robert Koch: Steps to Identify the Cause of a Disease**

Robert Koch (1843-1910) was a German physician who helped establish bacteriology as a science. Koch made discoveries in identifying bacteria at a time when understanding of microbes was just emerging.
Koch and his colleague Friedrich Loeffler developed a method to identify a disease-causing agent. Scientists today follow these basic principles when trying to identify the cause of an infectious disease. Koch’s postulates are based on careful observations and reproducibility.

1. The microbe is present in each case of the disease.
2. The microbe can be taken from the host and grown independently.
3. The disease can be produced by introducing a pure culture of the microbe into a healthy host.
4. The microbe can be isolated and identified from the host infected in Step 3.

**Pearl Kendrick: Using Careful Controls**

During the 1930s, Pearl Kendrick developed a whooping cough (pertussis) vaccine that she hoped would be more effective than previous vaccines. An important part of showing the effectiveness of the vaccine involved a control group of children who did not receive the vaccine. This was something of an innovation at the time, but Kendrick knew that having a control group would add weight to her findings if the vaccine proved to be effective. The rate of pertussis disease in the control group would allow Kendrick to easily demonstrate whether or not her vaccine could reduce the rate of disease in the experimental group. Kendrick’s trial helped establish norms and expectations for future vaccine trials.

**Jonas Salk: A Double-Blind Randomized Trial**

The 1954 field trial of Jonas Salk’s inactivated poliovirus vaccine (IPV) enrolled a huge number of subjects—1.3 million children in all—in what is the largest medical field trial ever conducted. The Salk trial was a double-blind randomized experiment. This meant, first, that children were randomly assigned to either the control or the experimental group. “Double-blind” meant that no one knew whether an individual child received the polio vaccine or a placebo injection (salt water). The information about whether the child received the vaccine or the placebo was encoded in numbers on vials from which the injected material was taken, and it was linked to the child’s record. Only after the observation period was over and the result recorded—did the child develop polio during the observation period or not?—was the child’s experimental or control status revealed. The Salk vaccine trial successfully showed that the vaccine helped prevent paralytic polio, and licensure of the vaccine quickly followed. The disease that once paralyzed thousands of children has now been eliminated in the Western Hemisphere.

1. What are the three qualities to the scientific studies?

2. What are the qualities of a good hypothesis?

3. How did Edward Jenner test the observation of a milkmaid that had cowpox?

4. What was Robert Koch’s method of identifying the cause of a disease?

5. What was Pearl Kendrick’s contribution to the development of a scientific method for testing vaccines?

6. How did Jonas Salk’s method of testing his polio vaccine improve the way new vaccines are tested?