

As a result, the investigators felt they knew enough about it to begin—last September—a routine program of GG administration to every new patient at Willowbrook. One injection is given on admission, and a second four months later. The best dosage range appears to be 0.01 or 0.02 ml. per pound. The program has cut the incidence of icteric hepatitis among patients by 80-85 per cent, according to Dr. Krugman. A similar reduction in the icteric form of the disease has been accomplished among the employees, who began getting routine GG earlier in the study.

The Willowbrook results also have paid off for the armed forces, Dr. Krugman said. Troops going to areas of endemic hepatitis, such as Vietnam, now routinely get 0.05-ml./pound of GG on much the same schedule as used at Willowbrook. The same regimen also has been applied to Peace Corpsmen.

There still is no vaccine against hepatitis, Dr. Krugman said, but the Willowbrook experiments are aiding in many attempts to isolate the hepatitis virus. "One cc. of serum taken from our subjects early in the disease is enough for a year's isolation work in most laboratories," he said. At least four other laboratories in the country, in addition to his own, are trying to isolate the Willowbrook hepatitis virus. "Since it seems to be naturally attenuated," said Dr. Krugman, "it would appear to be the best starting material toward a vaccine."

Study Criticized in 1965

The Willowbrook hepatitis study was a target for criticism long before Senator Thaler precipitated the current excitement about it. In the spring of 1965, Dr. Henry K. Beecher of Harvard used it as one of many examples of "questionable ethical studies"—the question lying largely in the matter of "experimentation on a patient not for his benefit but for that, at least in theory, of patients in general."

Again last summer, Dr. Beecher, who is a Professor of Research in Anesthesia, cited the Willowbrook study among 22 examples in an article in the *New England Journal of Medicine*. Of the study he wrote, "There is no right to risk an injury to one person for the benefit of others."

By way of reply, Dr. Krugman said that he was "certain from the outset" that there would be criticism of the program. "We set it up very carefully . . . and in accordance with the World Medical Association's Draft Code of Ethics on Human Experimentation." That code, more commonly known as the Declaration of Helsinki, has been endorsed by a large number of national medical organizations, including the American Medical Association and seven other medical groups in the U.S.

On the matter of informed consent,

Dr. Krugman said he believes the investigation has "been more than cautious" in obtaining written parental consent only after they understood the program to their apparent satisfaction. For instance, he said, "we decided at the start to use no wards of the state, although by law the administrator of Willowbrook could have signed consent for them."

Still, the obtaining of consent at Willowbrook has not been without controversy. Dr. Jack Hammond, administrator of the institution, said the "biggest fuss" arose more than a year ago over a "complete misinterpretation . . . of an unfortunate coincidence."

The circumstances were set up by the closing of Willowbrook in late 1964 to all new admissions because of overcrowding. Parents who applied for their children to get in were sent a form letter over Dr. Hammond's signature saying that there was no space for new admissions and that their name was being put on a waiting list.

New Patients Were Admitted

But the hepatitis program, occupying its own space in the institution, continued to admit new patients as each new study group began. "Where do you find new admissions except by canvassing the people who have applied for admission?" Dr. Hammond asked.

So a new batch of form letters went out, saying that there were a few vacancies in the hepatitis research unit if the parents cared to consider volunteering their child for that.

In some instances the second form letter apparently was received as closely as a week after the first letter arrived. "All of a sudden," Dr. Hammond recalled, "we had parents' meetings, calls from local politicians, calls from family physicians . . . all sorts of kicks."

Canvassing the parents by letter "obviously was open to misinterpretation, so we stopped it more than a year ago," Dr. Hammond said.

But the repercussions have not stopped. Most recently an educator who works in rehabilitation programs for the mentally retarded, Jack M. Gootzeit, Ed.D., appeared on a New York City television news program to charge that the form letters constituted a "high-pressure method" of obtaining consent from parents "desperate to institutionalize their child."

In the midst of the current ruckus, Dr. Hammond happily recalls one instance in which an incipient investigation of the Willowbrook hepatitis project reached what he called a "logical conclusion."

"Senator [Robert F.] Kennedy sent a man around to check on the program," the administrator said. "I sent him to Dr. Krugman for a full explanation, and he went away satisfied that everything was what we said it is."