

Division of Clinical Research and Development

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General Summary

Clinical study is a strategy and a science for implementing 1) efficient diagnosis, treatment, and prevention, 2) the discovery of etiology, and 3) understanding pathophysiology. Baron Kanehiro Takaki prevented beriberi by a change in diet based on evidence obtained from clinical study. Thus, we at The Jikei University School of Medicine have a responsibility to carry on and expand his passion using epidemiology and biostatistics to save lives and maintain peace in the world. However, most clinicians are busy treating patients. In addition, modern epidemiology and biostatistics have been changing along with computer science. Therefore, we have established the Division of Clinical Research and Development as a project base to support clinical studies at The Jikei University School of Medicine. Our mission is to find *veritas* in a complicated clinical world and to contribute to society with our findings. To accomplish our mission, education and promotion are major strategies.

Research Activities

The Jikei clinical research course

From May 2007 through March 2008, we held 21 seminars about strategies for clinical studies for health-care practitioners at The Jikei University. In 2007, small-group study courses targeting postgraduate students will be started from the principles of epidemiology and biostatistics by reading textbooks and by analyzing real clinical data using STATA software and designing clinical studies. Our goal is for postgraduate students to develop the skills to construct hypotheses, design protocols, monitor trials, and analyze data.

Consulting for clinical studies

1. Inside The Jikei University: Most clinical departments
2. Outside The Jikei University: Tokyo Women's Medical University

As shown in the publication section, we published several articles in English by collaborating with clinical departments. For fiscal year 2007 we accelerated the process from consultation to paper submission. Next year, we are planning to launch a clinical data-pooling system in our division to support high-quality prospective clinical studies.

Umbilical cord blood study

We hypothesized that exposure of fetuses to low concentrations of hazardous heavy metals during pregnancy can cause changes in the behavior and intelligence of children. We have started to collect umbilical cord blood to measure heavy metals and have sent

questionnaireS to ask about daily habits and the condition of children after birth. We have finished enrollment, since we could collect more than 1,000 samples of umbilical cord blood. We have finished measuring levels of heavy metals in umbilical cord blood and collected questionnaires from when the children were 2 years old. In addition, we are performing a study of twins to examine the genetic and environmental effects on children's behavior.

Molecular epidemiology

Genes of epidermal growth factor beta in cancer cells obtained from clinical specimens were sequenced, and several mutations of the epidermal growth factor receptor were confirmed to generate tumors in vitro. Moreover, we found that the combination of mutation and phosphorylation might be a prognostic indicator.

Diagnosis of complication in diabetes mellitus

We could draw receiver operating characteristics curves with high sensitivity and high specificity for diagnosing complications of diabetes mellitus.

Global environmental change and human health

We have been dedicated to research on global environmental change and human health with the Japanese government.

Homeland security

Preventing acts of terrorism is one of our missions. An extreme example of prevention may be homeland security. We attended a workshop on "G8 Forensic Epidemiology" in London. We have held a series of lectures on national security affairs and crisis management for the Cabinet and have advised the Deputy Chief Cabinet Secretary for Crisis Management.

To assess communication capacity between remote locations, governments, ministries, and the cabinet under extraordinarily stressful conditions during national crises, the Biosecurity 2007 tabletop exercise was held in October 2007 at The Jikei University School of Medicine. It was the largest biosecurity exercise of its kind in Japan. The scenario was that an ecoterrorist group had released the severe acute respiratory syndrome virus, a CDC category C agent, as well as anthrax, a CDC category A agent, at different sites on the same day as an overt act of bioterrorism.

Publications

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