Symposium Report: "Problems with the HPV Vaccine" -- Reports from Japan and Overseas--

March 2016

#### 1. 230 Participants

On November 23rd, 2015 at Tetsumon Memorial Hall, The University of Tokyo, the symposium "Problems with the HPV Vaccine -- Reports from Japan and Overseas" was co-hosted by Medwatcher Japan, the Representative of Japan Cervical Cancer Vaccine Sufferers Organization and the Executive Committee for Public Medical Symposiums. 230 people attended, including victims of the HPV vaccine, citizens, doctors, pharmacists and lawyers.

# 2. Part 1 Keynote Lectures

In Part 1 of the symposium, lectures were delivered by Dr. Louise Brinth of Frederiksberg Hospital in Denmark who has examined many victims of the HPV vaccine, Professor Kusuki Nishioka, Director of the Institute of Medical Science at Tokyo Medical University, and Shunpei Yokota, Professor Emeritus at Yokohama City University.

(1) Dr. Brinth explained that a Gardasil immunization program for girls aged 12 was launched in Denmark in 2009, and that the change in schedule from three doses to two doses took place from August 2014. She also said that between 2009 and 2015, a total of 1,651,152 vaccinations were administered. Of this, 1,586 led to reports of adverse effects and 543 of these cases were severe. Denmark currently has HPV Information Centers in 5 regions. Dr. Brinth and her colleagues are working in the biggest center and have examined 300 people between 2011 and November 2015.

She then introduced three published theses. Concerning POTS (Postural Orthostatic Tachycardia Syndrome), suspected to be an adverse effect linked to the HPV vaccine, Dr. Brinth explained that victims' symptoms were varied and included, in order of prevalence, orthostatic intolerance, nausea, headache, fatigue, palpitations, cognitive dysfunction, skin lesions, segmental dystonia, neuropathic pain, sleeping disorder and muscle weakness. She said that whether or not the victim had been diagnosed with POTS, all symptoms occurred at almost the same rate, and most of the cases that were suspected to be adverse effects linked to the HPV vaccine had fulfilled the diagnostic criteria for myalgic encephalomyelitis. Dr. Brinth then pointed out the need for definitive biomarkers and for Japan and Denmark to conduct further research under a common goal.

In November 2015, the EMA (European Medicines Agency) released the assessment report stating that there is no evidence that the HPV vaccine causes CRPS (chronic regional pain

syndrome) or POTS. The <u>Danish Health Authority</u> adopted these results, and the government allocated a budget of 7,000,000 kroner or 123,600,000 yen to investigate adverse effects over the next 3 years.

- (2) On the topic of adverse effects linked to the HPV vaccine, Professor Nishioka explained that autonomic nervous system and endocrine-related disorders, cognitive dysfunction and emotional disturbance, impaired sensation and movement disorders occur one after another and as time proceeds. He defined these disorders as "a new syndrome with clinical features that worsen with time and appear in a variety of clinical situations" and pointed out the need to interpret them as a syndrome after HPV vaccination, called HANS (HPV Vaccination Associated with Neuro-immunopathic Syndrome). Professor Nishioka also mentioned that there was a problem with the EMA report concluding that the available evidence does not support that CRPS and POTS are caused by HPV vaccinations. He stated that an epidemiological study that investigates the relation between the occurrence of conventional diseases and HPV vaccination doesn't make any sense. He then indicated that in order to respond to adverse effects that cannot be interpreted as conventional disease concepts it's necessary to draw upon lessons learned from SMON cases that should also be described as an origin of drug-induced sufferings.
- (3) Emeritus Professor Yokota introduced some characteristics of patients' conditions based on the results of an analysis by the Japan Medical Research Foundation into 88 victims suffering from adverse effects linked to the HPV vaccine. He once again indicated the need to interpret such effects as a new syndrome entity (HANS) and the problem in setting them aside as one conventional disease concept. Based on symptomatic examinations stating that many symptoms tend to overlap and manifest themselves in a short period of time, he also explained that even the hypothalamus could be assumed to be a responsible lesion.

Professor Yokota explained that the causal link between HANS and the HPV vaccine is clinically obvious because cases are occurring after HPV vaccination, they are only occurring among young women and not among men, above all that a group of symptoms are occurring one after another, forming one entire syndrome and that these apply to many cases. He also stated that based on immunological mechanism involved, there are questions on the effectiveness of the HPV vaccine and that it is incorrect to assume that in 10 years' time Japan would become prone to cervical cancer if HPV vaccination were scrapped altogether.

## 3. Part 2 Reports of the Situations of Victims

In Part 2, there were reports of the situations of victims in Japan as well as overseas.

(1) From Japan, Ms. Toshie Ikeda, Secretary General of the Japan Cervical Cancer Vaccine Sufferers Organization introduced a video on the serious adverse effects among victims in

Japan. She then highlighted areas including inadequate government explanations, how the seriousness of such adverse effects had impacted victims' daily lives and future paths, and of course treatment. As of the end of November 13 branch offices had been established, with 465 registered members and 2100 consultations held.

(2) Video letters were shown from overseas. <u>Sara</u>, a victim of the HPV vaccine, and her mother <u>Charlotte</u> from Denmark talked about how they went to Switzerland in search of better treatment after Sara started experiencing a range of adverse effects including impaired memory and how, although Sara's walking has somewhat improved, their endless nightmare continues.

The next video letter from the UK introduced Ms. Freda Birrell who is a facilitator for a group of victims of the HPV vaccine. 5 people, including Ms. Amanda Dew, then talked about how they and their families had been affected. The stories gave touching accounts of how the lives of victims and their families had been turned upside down following HPV vaccination, including a victim who began sleeping for 23 hours a day after being vaccinated.

#### 4. Part 3 Panel Discussion

(1) In Part 3, in addition to the three doctors who delivered keynote lectures in Part 1, Dr. Hirokuni Beppu, a Medwatcher Japan member and neurologist, Dr. Kiyoshi Uchide, an obstetrician and gynaecologist, Ms. Mika Matsufuji who heads the Japan Cervical Cancer Vaccine Sufferers Organization and Ms. Nanami Sakai, a victim of the HPV vaccine, joined a panel discussion facilitated by Medwatcher Japan member Professor Kunihiko Kumamoto and Ms. Masumi Minaguchi, Secretary General of Medwatcher Japan.

Beginning the discussion, Ms. Sakai took to the platform in a wheelchair. She explained her symptoms and how she had no choice but to change her future path after suffering adverse effects linked to the HPV vaccine. Having seen the video letters in Part 2, she reiterated how the victims' symptoms and situations are the same in Japan and overseas.

- (2) Next, short presentations were held on the necessity and effectiveness of the HPV vaccine, in order to share background information on the discussion.
- ① Dr. Uchide indicated that only a small fraction of HPV virus infections develop into cervical cancer. He then said that the HPV vaccines (Cervarix, Gardasil) are said to be effective because they reduce CIN2 and CIN3 (cervical dysplasia, precancerous stage) and not cervical cancer itself, but as outcome measures of effectiveness, these have little credibility. He explained that this is mentioned in clinical guidelines developed by a Health Labor and Welfare Ministry research team and that the most effective way to prevent death from cervical cancer is early detection and treatment.

- ② Dr. Beppu pointed out how HPV vaccine advocators are misleading public with relative risk reduction. He argued as follows: they claim that HPV vaccine will protect people from becoming precancerous condition (CIN2/3) with 98-100 %, which sounds as if cervical cancer was almost totally preventable by this vaccine. But in reality, it reduces the absolute risk by only 0.7%, or to put that another way, the NNT (number needed to treat) is as large as 143.
- ③ Professor Kumamoto explained that in addition, when a frequency of occurrence is low, like adverse effects linked to the HPV vaccine, various symptoms that are characteristics of adverse effects should not be separated one by one. He then said when comparing inoculated and non-inoculated individuals in such a manner, even though differences exist in their frequency of occurrence, unfortunately epidemiological data can emerge stating that there are no differences.
- (3) In response, Ms. Matsufuji pointed out that there have been almost no explanations available on the necessity and efficiency of the vaccine, let alone the dangers. After the symposiasts exchanged opinions, a discussion was held with the audience. Some of the audience's questions were related to the WHO's recommendations concerning the HPV vaccine. Ms. Minaguchi pointed out that there is a serious conflict of interest between the WHO and other international organizations like Bill & Melinda Gates Foundation and GSK.

### 5. Ending

The symposium lasted for over 4 hours from 1:30PM to 5:40PM. It was a fulfilling event in which the problems surrounding the HPV vaccine were examined from various perspectives. Some people still believe that damage caused by the HPV vaccine is only occurring in Japan but the symposium confirmed once again that the seriousness of the adverse effects and situations of victims is basically the same in Japan and overseas.

The symposium once again showed that according to investigations into the effectiveness and necessity of the vaccine, the balance between the vaccine's risks and benefits had collapsed. The ultimate goals of research and clinical findings into the HPV vaccine's risks were also shared.

Introductions to the speakers and organizing groups, as well as Power Point slides for each presentation and transcriptions of the video letters have been uploaded in the references section. Please refer to them for further information.

However, please be aware that these materials were prepared for use as supplementary information to the oral presentations made during the symposium. Any unauthorized reprints or citations are strictly prohibited.

To conclude, we wish to express our sincerest gratitude to Dr. Louise Brinth, Professor Nishioka and Professor Emeritus Yokota who kindly delivered keynote lectures in Part 1, to the victims overseas who prepared the video letters, to the staff who supported the event and to all those who attended. Thank you very much.