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日米 NCDB ワークショップ

米国側報告



*A multidisciplinary program of the  
American College of Surgeons*

## **Summary Report and Recommendations: Japan / USA NCDB Workshop**

Tokyo, February 27-28, 2007

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### **INTRODUCTION**

The following report summarizes the findings and impressions of the delegation from the American College of Surgeons (ACoS), Commission on Cancer staff that attended the Japan/USA Workshop was held in Tokyo at the National Cancer Center, February 27-28, 2007. This delegation was lead by Dr. David P. Winchester, FACS, Medical Director of Cancer Programs of the American College of Surgeons, and included senior staff members of the National Cancer Data Base, Andrew K. Stewart, MA and E. Greer Gay, RN, PhD. The workshop was co-sponsored through funds available from a Japanese Health and Labor Sciences Research grant, and a Ministry of Health, Labor and Welfare cancer research grant.

### **REPORTS AND PRESENTATIONS**

Members of the delegation from the American College of Surgeons and Japanese participants presented and discussed a broad range of experiences and findings regarding registry operations, data standards, clinical surveillance studies and quality of cancer care during the course of the two-day workshop.

The ACoS delegation reviewed the development and maturation of the National Cancer Data Base during its 15 years of operations. This was followed by specific discussions regarding data standardization efforts in the United States and how these impacted registry operations and data management. Comparisons between hospital based registry data and population-based data were provided to emphasize that collaboration and standardization can result in high levels of agreement across data sets. An outline of the history and events that have shaped American privacy laws was provided as a context for understanding the privacy regulations that are part of HIPAA, the regulatory framework guiding release and use of medical information in the United States. Clinical findings from studies of breast, colon, pancreas, and gastric cancers using data from the NCDB were presented. Finally, recently developed initiatives focusing on assessing quality of cancer care and audit/feed-back reports were presented.

Presentations from the Japanese participants closely mirrored those from the ACoS. Each of the Japanese registry systems (population, hospital, and JNCDB) presented descriptive outlines of their scope of operations and plans for the future. A representative from among the software vendors addressed issues and challenges of interoperability among medical information systems,



and how the cancer registration systems might interface with these efforts. Representatives from each of the participating medical specialty organizations presented a combination of operational descriptions of their proprietary clinical registry systems and descriptive clinical findings from the data collect through these registries. Finally, a review of the current interpretation of the Japanese patient privacy laws and how these were being considered within the medical and cancer surveillance community was provided.

## **BACKGROUND**

Cancer registration activities in Japan have their roots in public health surveillance activities stemming from concerns regarding long-term effects from radiation exposure following the close of Second World War, notably in Hiroshima and Nagasaki. Since their initial establishment in the late 1950's the breadth and scope of cancer surveillance and cancer registration have grown to include the establishment of a Japanese Association of Cancer Registrars, and most recently a legislative mandate in the form of the Cancer Control Act of 2006. Malignant neoplasms have been the leading cause of death in Japan since 1981, accounting for 241.7 deaths per population of 100,000, far more than the next two leading causes, heart disease (121.0/100,000) and cerebrovascular diseases (103.4/100,000).<sup>1 2</sup> Though cancer is a significant health concern in Japan, it is not a mandated as a reportable disease.<sup>3</sup>

Broad efforts to collect surveillance population-based and clinical cancer information exist in Japan. Among these are the epidemiological, population-based registry efforts that collect 25 items on diagnosis, initial treatment, and follow-up information, and is organized at the Prefecture level, and includes one metropolitan area. Individual academic medical societies also operate clinical registries that collect in-depth information, usually between 200-300 variables for site-specific cancers. Finally, hospital-based registries collect approximately 60 items on diagnosis, initial treatment, and follow-up with the intent to evaluate patterns and quality of care. Participation in the hospital-based registries has recently increased from 30 hospitals within the Japanese Association of Clinical Cancer Centers to include an additional 286 designated cancer care hospital.

Hospital-based cancer registration activities in Japan are increasingly linked to Ministry of Health, Labor and Welfare policy decisions as this ministry expands its recognition and expected functions/roles of Designated Cancer Care Hospitals. Established standardized data sets among hospital-based registries include patient demographic information, histo-pathology, initial treatment, and follow-up information are in place. Leaders of the population-based registry activities clearly understand the importance of further standardizing the cancer registration process and increasing the capacity of hospital-based cancer registration activities in support of the 2006 Cancer Control Act. At the forefront of the population-based registries interests rests the question of ascertaining incidence and survival statistics. Incidence rates are based on a limited sample (~25%) of the Japanese population and are believed to significantly under-represent the actual cancer burden in the country.

In contrast, the medical specialty societies have each established proprietary disease specific registry systems that are dependent upon voluntary participation by treatment facilities. The breast cancer registration system collects data from over 350 centers and the ObGyn registry from more than 250 programs. Coverage of reported cases is variable to, for example, 40% of expected prostate cancer cases thought to be reported to the Prostate Cancer Registry. Nonetheless, clinical surveillance of cancer presentation, treatment, and survival is well established in Japan and through the efforts of the individual specialty societies these registries yield an abundance of important and useful information.

The JNCDB project has adopted an integrative view, recognizing the strengths and shortcomings of the population, hospital and disease specific registry systems. The population-based registries lack treatment information that is carefully collected through the disease specific registries, which in turn do not have access to routine or accurate survival or vital statistics. In addition, the potential synergy resulting from the ability to exchange surgical and radiation oncology treatment data available in departmental and radiation oncology databases maintained within hospital settings is seen to be significant. The common thread is the hospital setting where diagnoses are made and treatment is provided, which places a substantial premium on the successful implementation and integration of IT infrastructure registry operations.

## CHALLENGES

Though exempt from the JPIPA (Articles 16, 23, and 50)<sup>4</sup>, the population-based cancer registries are not complete, standardization is lacking, and follow-up occurs in only a few of these registries. The disease specific registries have incomplete follow-up information, and since the passage of the JPIPA, these registries have been forced to regroup and consider alternative mechanisms by which to protect patient privacy. In some cases this has resulted in the suspension of data collection. The hospital-based cancer registries have other data collection problems. First data collection is performed separately by each discipline, and is frequently recorded by the physician, who has limited available time to dedicate to these data collection efforts.

Establishment of a Japanese cancer registry system has been hindered by the passage of the JPIPA - Law No. 57, 2003. This law protects the rights and interests of individuals by clarifying responsibilities of government and setting a high standard of care for handling personal information for companies in the *medical*, financial credit, and telecommunications industries.<sup>5</sup> Additionally, a 'privacy scare' in which concerns regarding loss of personal information resulting in cases of billing fraud, and other misuse of personal data are perceived to be widespread in Japan.<sup>6</sup> Finally, the social stigma attached to the diagnosis of cancer, and the potential impact the exposure of this information may have on personal or professional lives acts as a further deterrent to fostering public support for a cancer registries in Japan.<sup>7</sup>

Most of the registries in Japan have elected to use HASH functions common to many database software operating systems to circumvent the restrictions of JPIPA. This has provided a technical short-term solution and has allowed each registry system to continue operations as before.

Each registry – population, hospital, and disease specific - openly acknowledged these challenges and clearly recognized that the Japanese cancer registry systems:

- Lacked standardized data sets and operations;
- Limited integration of clinical data bases and wider hospital IT infrastructure;
- Viewed government mandates as sets of confounding directives.

## OPPORTUNITIES

The Cancer Control Act, approved in June 2006, to be implemented in April 2007, presents a critical opportunity for cancer registration in Japan. This Act calls for a cancer control implementation plan at the prefectural and national level, cancer prevention and early detection, equalizing cancer care quality, cancer research and the creation of an advisory board that includes representatives of cancer patients and their families.<sup>8</sup> This Act and other efforts ongoing since

April 2004 that began with the Third-Term Comprehensive 10 Year Strategy for Cancer Control have forged a way towards creating a means to implement a synchronized cancer registry system that has the potential to address the issues facing the current registries while at the same time accommodating the individual purposes of each registry.<sup>9</sup>

Specifically, this Act provides the basis for addressing both standards within and among the agencies engaged in cancer surveillance, and privacy concerns that are a current concern:

### Standards

- The establishment of Japan's National Cancer Center provides a locus from which defining the need for, the purpose of, and the dissemination of value in cancer registry can be articulated. The advisory board is a means to involve:
  - Patients and family members;
  - The Quality of Life Policy Bureau, part of the Cabinet office of the Government Statistical Organization Chart<sup>10</sup>;
  - Representatives from the Japanese Ministry of Health, Labor, and Welfare;
  - Hospitals;
  - Medical societies.
- The National Cancer Control and Information System (NCC-CIS), established in October 2006, provides:
  - Training for tumor registrars, which should relieve some of the burden experienced by physicians responsible for data entry;
  - A forum through which the registries can meet on equal terms, define common standards for data collection, reporting and definitions – similar to role in the USA played by the North American Association of Central Cancer Registries;
  - Development of standards for computer software, and interoperability between medical IT systems;
  - Increasing the number of hospital-based cancer registries, at the very least in designated cancer care hospitals that will move efforts forward to provide a system through which quality of care can be evaluated and improved at the local level through feedback mechanisms on practice and outcomes.

The Cancer Control Act, if viewed broadly, contains all the necessary directives to enable the broad number of agencies interested in population and clinical surveillance of the cancer burden and its care in Japan to work together towards a common goal. This Act provides the legal framework for consensus building and standardization of registry education, operations, and education; data collection and transmission standards; and even interoperability with other medical information systems.

Similar efforts have been ongoing in the United States for almost two decades and were initiated among agencies as a means to improve cancer surveillance, but are not directly supported by legislative mandate. Much of the incentive toward adoption of standards has been driven by a combination of limited human resources and uncertain financial resources. To achieve the current level of harmonization within the registry community in the United States has required significant political will and intellectual infrastructure. The fact that Federal, State, and private agencies continue to work diligently and effectively together to maintain high levels of agreement regarding education, operations and data standards in the face of continuing budgetary pressures is a significant indication of the value of these consensus processes.

## Privacy

The government statistical system of Japan has two major official statistical laws; the Statistics Law and the Statistical Reports Coordination Law. Under these laws, three types of surveys are permitted: designated statistics, notified statistics, and approved statistics.<sup>11</sup> Cancer surveillance activities in Japan should be classified as designated statistics, which are those surveys necessary for the formulation of basic government policies. As such, it might be reasonable for a representative of the cancer surveillance community to press for an active liaison role with, or representation on, the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) statistics council, and thus elevate the visibility and recognition of the cancer registry system.

The Health Promotion Act of 2002 and the Basic Act for Anti-Cancer Measure (6/16/2006) affords the opportunity for surveillance of cancer in Japan while also providing an exemption from the JPIPA for the population-based cancer registry. This has not been the case for the hospital-based nor medical society-based registries.<sup>12</sup> However, a case could be made for collecting patient cancer data on practice and outcome through establishing a "Purpose for Use" that the requisite data would facilitate the mandates required under the Cancer Control Act of 2006; i.e., "equalizing cancer care quality" and "cancer research." This, of course, presumes that the data will be accurate, under security control, and appropriate and necessary supervision over the employees that handle the data occur (Articles 19, 20, and 21, JPIPA). Population-based registries should work with hospital and disease specific registries to explore the development of appropriate legal mechanism to facilitate access to and use of selected patient identifiers.

## **SUMMARY**

Much of what is needed for the further development and integration of cancer data bases in Japan are or can be in place. The three main types of registry systems can work together to accomplish that goal, success comes with a unified approach. A legal framework exists to support standardization of data items and definitions, software, development of a trained cohort of registry professionals and placing them in the hospitals. Public awareness of the value of cancer registration is greatly needed. Efforts to make cancer a reportable disease are paramount. Working within the framework of established laws is possible.

## **RESPECTFULLY SUBMITTED**

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