In June 2002, Japan’s Ethical Guidelines for Epidemiologic Research were announced as the culmination of a four-year project by epidemiologists, clinicians, ethicists, experts in law, and the media as representatives of the general public.1 In this report, we review the events that contributed to these published guidelines and, in particular, how governmental ministries and the Japan Epidemiological Association (JEA) played a role in the development of these published guidelines.

Currently in Japan, there exist two sets of ethical guidelines for epidemiologic research: a national governmental set of guidelines and the JEA set of guidelines. While the JEA guidelines, which were announced in October 2002, apply to all JEA members, the governmental guidelines apply to all studies that employ epidemiologic methodology.

Even though the governmental guidelines were revised in December 2004, this review primarily focuses on the first governmental ones issued in 2002 and describes a history of events that led up to them.
PART I: An initial JEA survey and its history (1991-1996)

The year of 1991 was a milestone year for epidemiology, particularly in Japan. In January, the JEA held its first scientific meeting at the National Cancer Center, Tokyo. Second, the Council for International Organizations of the Medical Sciences (CIOMS) released its international guidelines for the ethical review of epidemiologic studies. They were immediately translated into Japanese by a lawyer, Tadahiro Mitsuishi. Since then, several Japanese epidemiologists have examined the ethical implications of epidemiologic research.

At the same time, Gordon Guyatt of McMaster University, Canada, published a noteworthy article, entitled “Evidence-based medicine,” in which he proposed several key concepts based on clinical epidemiology. This article initiated and promoted an EBM (evidence-based medicine) movement worldwide. Evidence of this rising boom was early seen in a research project conducted in Japan between 1990 and 1991 funded by the Ministry of Labour on the prevention of work-related diseases including cardiovascular diseases. This study was unique in that it was the collaborative project between physicians and epidemiologists. This project led several health policy makers and clinical researchers to recognize the significance of epidemiology. Under these circumstances, the formal introduction of EBM by governmental agencies in 1996 stimulated a successive “epidemiology boom” among clinicians and policy-makers alike.

In Japan, several large community-based cohort studies were conducted throughout the 1980s and 1990s by mainly epidemiologists. Among them, one national collaborative cohort study, entitled “The Japan Collaborative Cohort Study (JACC) Study for Evaluation of Cancer Risk” was first funded in 1988 by the Ministry of Education, Science and Culture and the Science (currently the Ministry of Education, Culture, Sports, Science and Technology: MEXT). Several JEA researchers carried out a survey in 1993 on whether or not informed consent had been conducted in this study. The results of this survey, reported in 1996 at the International Epidemiologic Association (IEA), demonstrated that (1) informed consent for health questionnaires was carried out in all cohorts, but methods varied; (2) informed consent for the collection of blood was obtained in 28 of 34 cohorts (78%); and (3) this collaborative study group decided that specimens collected without consent should not be used. Combined, these results reflect a trend among many epidemiologists at that time: the primary concern was informed consent over protection of personal information.

PART II: Discussion of the protection of personal information (1997-2000)

Following the JACC study, the Japanese Young Epidemiologists Society (JYES), a division of the JEA, continued to discuss the issue of informed consent in epidemiologic research at JEA conferences in 1996, 1997, and 1998. Their discussions resulted in the establishment of a working group on “Development of Ethics Guidelines for Informed Consent in Epidemiologic Research” (hereinafter refer to as the “Tamakoshi Group” after the principal investigator, Akiko Tamakoshi) in April 1998. The Tamakoshi Group, funded by the MHW, consisted primarily of epidemiologic researchers affiliated with the JYES and also included experts from the fields of bioethics and law.

Several significant events took place in Japanese society when the Tamakoshi Group was conducting their investigation (April 1998 - March 2000). Particularly beneficial to epidemiology was the MHW Health Sciences Council’s ranking of “the promotion of EBM and the utilization of information technology” as an area of focus in May 1999. Their acknowledgement emphasized the value of epidemiologic and clinical epidemiologic research, the basis of EBM. At the same time, the field of epidemiology was slightly strained by events leading up to the Personal Information Protection Bill. This bill was based on the a document published by the Organization for Economic Cooperation and Development (OECD) in 1980: The Recommendation of the Council Concerning Guidelines Governing the Protection of Privacy and Trans-Border Flows of Personal Data (hereinafter, the “Eight OECD Principles”).

In July 1999, the Advanced Information and Telecommunications Society Promotion Headquarters (in Japanese, Kodo jo no tsushin shakai suishin honbu), led by the prime minister, established an investigating committee on personal information protection. In November 1999, their interim report, “Modality of the Personal Information Protection System in Japan (in Japanese, Wagakuni niokeru kojin no hogo shisutemu no arikata nitsuite),” indicated a need to draft a basic law on personal information protection. The government formulated the national committee in February 2000 to submit the bill to the ordinary session of the Diet in spring 2001. This committee interviewed parties that were interested in this issue from February through August 2000 in a fashion of “hearing.”

At the same time, the field of epidemiology was hit hard by several newspaper articles on ethical problems related to epidemiologic research. A major Japanese newspaper published a story in November 1999 entitled “Genetic Analysis without Permission,” linking genetic analysis to the drawing of blood at mass screenings. Similar reports ensued, raising the level of social criticism regarding improper handling of personal information in epidemiologic research.

Under these circumstances, the MHW organized several working groups such as a committee to assess the practical use of statistical data in the field of public health (chairman: Masahiro Takaishi, in Japanese, Tokei joho no kodo riyo no seidoteki na kenshin ni kansuru kentokai). These working groups collected data primarily on foreign cancer registries while also assessing domestic problems. However, the contributions of epidemiologic research to society continued to go unrecognized by the public. In light of this, the MHW also funded a working group on the “Assessment of Epidemiologic Research in terms of...
Table 1. A brief history of events related to Japan's ethical guidelines for epidemiologic research (1980-2003).

| Year | Event |
|------|-------|
| 1980 | Europe's OECD proposing recommendation of the council concerning guidelines governing the protection of privacy and transborder flows of personal data. |
| 1982 | The CIOMS releasing the international ethical guidelines for biomedical research involving human subjects. |
| 1989 | Establish a three-year project on the ethical issues in preventive medicine (Principle Investigator: Shinichi Yamamoto). |
| 1990 | Formation of the research project funded by the Ministry of Labour on the prevention of work-related diseases including cardiovascular diseases in Japan. |
| 1991 | January: The JEA holding its first scientific meeting at the National Cancer Center in Tokyo. The CIOMS releasing the international guidelines for ethical review of epidemiologic studies. In Canada, Guyatt publishing a report entitled "Evidence-Based Medicine" in the ACP (American College of Physicians) Journal Club. |
| 1992 | A survey conducted with the purpose of the process of informed consent in the large-scale study "The Collaborative Cohort Study for Evaluation of Cancer Risk" (The survey results were later reported at the ISEA conference in Nagoya in August 1998). |
| 1995 | November: The CIOMS releasing the international ethical guidelines for biomedical research involving human subjects. |
| 1996 | January: The JEA holding its first scientific meeting at the National Cancer Center in Tokyo. |
| 1998 | January: The CIOMS revising the international ethical guidelines for biomedical research involving human subjects. |
| 1999 | May: The Health Science Council presented "The MHLW future modality towards the 21st Century." |
| 2000 | January: JEA setting up the ad hoc committee on ethical issues (Chair: Yutaka Inaba). Formation of the MHLW Health Sciences Working Group on "Assessment of epidemiologic research in terms of contributions to health policy" (Principal investigator: Takeshi Nakayama). |
| February | Establishment of the National Committee in charge of the Personal Information Protection Bill. "Hearing" from parties of interest (March through August 2000). |
| March | The Advanced Medical Technology Assessment Panel of the MHLW Health Sciences Council on "Assessment of epidemiologic research in terms of contributions to health policy." The JEA releasing a public statement on the need to explain the relationship between epidemiologic research and personal information to the public. |
| April | A draft of Guidelines for Informed Consent in Epidemiologic Research on "Health Promotion" (Principal investigator: Akiko Tamakoshi). |
| May | The MHLW Health Sciences Working Group revising the international ethical guidelines for biomedical research involving human subjects. |
| June | The MHLW, MEXT, and METI publishing the Ethical Guideline for Human Genome and Gene Analysis Research. |
| July | The Diet stalling on enacting a law for personal information protection. |
| August | The JEA publishing the ethical guidelines for the conducting of epidemiologic research (in Japanese, "Ekigaku kenkyu o jisshi suruniaten no rinri shishin"). |
| September | The MHLW, MEXT, and MEI releasing the Ethical Guidelines for Human Genome and Gene Analysis Research. The Diet stalling on enacting a law for personal information protection. |
| October | The JEA announcing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| November | The JEA preparing to release its second ethical guidelines for epidemiologic research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| December | The JEA releasing an ethical proclamation for conducting of epidemiologic research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). The MHLW revising the international ethical guidelines for biomedical research involving human subjects. |
| January | The JEA announcing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| April | The MHLW Health Sciences Council revising the national guidelines for ethical review of epidemiologic studies. The JEA announcing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| May | The JEA releasing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| June | The JEA announcing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
| July | The JEA releasing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |
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| December | The JEA releasing an ethical proclamation for conducting of epidemiologic research. The MJC releasing the Ethical Guidelines for Epidemiologic Research (in Japanese, "Ekigaku kenkyu ni okeru rinri shishin"). |

Note: AJMC: Association of Japanese Medical Colleges CIOMS: the Council for International Organizations of the Medical Sciences JEA: International Epidemiological Association JIA: Japan Epidemiological Association JIES: Japanese Young Epidemiologists Society MEIT: Ministry of Economy, Trade and Industry MEXT: Ministry of Education, Culture, Sports, Science and Technology MHLW: Ministry of Health, Labour and Welfare OECD: Organization for Economic Cooperation and Development. In 2000, the Ministry of Health and Welfare (MHW) and the Ministry of Labour combined to form the Ministry of Health, Labour and Welfare (MHLW). The Ministry of Education, Science and the Science and Technology Agency combined to form the Ministry of Education, Culture, Sports, Science and Technology.
Contributions to Health Policy” (principal investigator: Takeo Nakayama, in Japanese, *Ekigaku kenkyu no gyoseiteki sokumen karano hyoka ni kansuru kenkyu*) in January 2000. This group examined the political utility of epidemiologic research from the perspective of social accountability (Table 2). At the same time, the JEA set up the ad hoc committee on ethical issues (chairperson: Yutaka Inaba). This committee prompted the JEA to release a public statement on the need to explain the relationship between epidemiologic research and personal information protection to the public (in Japanese, *Kojin joho no kaihatsu ni kansuru ho seibi ni kansuru seisou* [in Japanese]) in March 2000.14,15 This statement led to a degree of controversy when a group of citizens, including several lawyers representing patient rights, requested that the JEA provide a clear description of their rationale.

Soon after in April 2000, the Tamakoshi Group proposed a draft of guidelines for Informed Consent in Epidemiologic Research Version 1.0 (in Japanese, *Ekigaku kenkyu ni okeru information konsenso ni kansuru gaidorain*).16 This draft of guidelines, which focused on observational studies, stressed the apparent need for informed consent.

Following these events, in the fiscal year 2000, the Ministry of Health, Labour and Welfare (MHLW, formerly MHW) organized two nationwide efforts to examine the ethical implications of epidemiologic research: (1) An ad hoc committee under the auspices of the Advanced Medical Technology Assessment Panel of the Health Sciences Council examined privacy protection in scientific studies using epidemiologic methodology (hereinafter referred to as “the former ad hoc committee”); and (2) the MHLW Grant Research Project for the Study of Ethical Ramifications and Personal Data Protection in Researches and Programs Using Epidemiologic Methods which was led by Eiji Maruyama, a professor of law at the Kobe University Graduate School of Law.

**PART III: The Inter-Ministry Joint Committee proposes a set of guidelines (2001-2002)**

As a result of the then-rising controversy surrounding the Personal Information Protection Bill announced the basic principles of the future bill (in Japanese, *Kojin joho kihon hosei ni kansuru taiko*). Epidemiologists and the MHW, however, noted that the contents of this report, which were highly influenced by the Eight OECD Principles, could restrict epidemiologic research.17,18

### Table 2. Epidemiology in the 21st Century: A proposal of requirements.

1. To comply with relevant laws and guidelines including personal information protection
2. To conduct research in close collaboration with society
3. To utilize information adequately
4. To provide results that meet the expectation of society and further foster their trust
5. To conduct research responsibly as an epidemiologist
6. To present findings to society in a public way

These requisites were proposed by the MHW Working group on “Assessment of Epidemiologic Research in terms of Contributions to Health Policy” (April 2000) (in Japanese)

### Table 3. Ethical proclamation for conducting epidemiologic research by the Japan Epidemiological Association

1. Research with the aim to reveal the truth
2. Research respecting the human rights of all subjects
3. Research using the most suitable methods to achieve its objectives
4. Research maintaining all social norms
5. Research always opening to society

(January 2002 http://wwwsoc.nii.ac.jp/jea/main/sengen.html accessed October 23, 2004, in Japanese)
In April 2001, as the Diet failed to enact the bill for personal information protection, which was claimed to be a "restricting media law" by people in the mass media, the Maruyama Group proposed their draft, "Guidelines for Personal Information Protection and Bioethical Issues in Epidemiologic Research (in Japanese, Ekiyaku teki shuho o mochita kenkyu nado niokeru seimeirinri mondai oyobi kojin joho hogo no arikata ni kansuru shishin)." This draft was neither finalized nor put into effect partly because clinical researchers were concerned about its influence. However, the Maruyama group's draft prompted the MHLW to create a second ad hoc committee for the development of ethical guidelines specific to epidemiologic research under the auspices of the Science and Technology Panel of the MHLW Health Sciences Council. Likewise, in August 2001, the MEXT created a sub-committee on epidemiologic research under the Council for Science and Technology. This same MEXT sub-committee was in charge of finalizing the draft created by the AJMC sub-committee (the AJMC also falls under the jurisdiction of the MEXT).

The MHLW ad hoc committee and the MEXT sub-committee combined to form the Inter-Ministry Joint Committee (IMJC) in September 2001. The IMJC consisted of clinical researchers, epidemiologists, lawyers, and media representatives. Through the collaborative efforts of these two ministries, which collected public comments and held a total of three meetings, the IMJC succeeded in publishing the Ethical Guidelines for Epidemiologic Research. This set of guidelines took effect in June 2002. Although these guidelines are not legally binding, both the MHLW and MEXT, which provide the bulk of government funding for scientific research, strongly recommend that all studies using epidemiologic methodology conform to these guidelines.

The JEA and its members have contributed to the development of the IMJC's set of guidelines in several ways. Before the announcement of the ethical guidelines, the JEA announced ethical proclamation for epidemiologic research in January 2002 (Table 3). However, in an attempt to supplement this set of guidelines, the JEA developed their own set of guidelines in October 2002 (in Japanese, Ekiyaku kenkyu o jisshite suruniatatteno rinri shishin). According to these guidelines, the JEA established an "Ethics and Review Board" in both eastern and western Japan.

CONCLUSION: The need to assess the process of developing ethical guidelines

This report has reviewed a selection of historical events related to the development of the Ethical Guidelines on Epidemiologic Research published in 2002, which were the first ethics guidelines in this field. Although these guidelines had been planned to be revised after 5 years, the revision was facilitated and published in December 2004 because the Protection of Personal Information Act will take effect in April 2005. The authors did not address the revision process of these guidelines, but it needs to be examined elsewhere. Further studies are required to clarify problems specific to the contents of these guidelines. For instance, an in-depth study is needed that can critically evaluate the developmental procedures of guidelines. In particular, the problem of consistency among guidelines needs to be resolved. This is necessary not only for the proper administration of these guidelines, but to provide society with an agreed-upon set of guidelines.

Since the release of the Ethical Guidelines for Epidemiologic Research, the issue of personal information protection has increasingly gained attention. The Protection of Personal Information Act was enacted in May 2003 by a draft amendment of the Personal Information Protection Bill. This law states that scientific researchers are relieved of their duties prescribed for "the (commercial) handling of personal information," but are, at the same time, obligated to release information to the public. This legislation, in other words, asks researchers to grapple with the development of ethical guidelines. Epidemiologists need to bear in mind that the development process of ethical guidelines should be an interdisciplinary and public effort. Yokomato and Nudesima have suggested a lack of social consensus regarding the development of medical research guidelines in Japan. This argument is based on the following perspectives: (1) original members of the governmental review board were primarily academics and experts selected by the national government; (2) the review process was not fully open to all interested parties; and (3) the board's decision often does not reflect the views of all relevant parties. Time is insufficient to discuss all aspects of the issue, and each party has its own vested interests. Despite these limitations, however, an interdisciplinary approach can foster a more substantive and effective process for the development of guidelines. This review serves as a first step to raising the level of efficiency and efficacy of the development of future guidelines and their revision.

Ethical guidelines for epidemiologic research must ensure the highest standards of ethical research while also preserving the promotion and growth of our field. In developing effective guidelines, epidemiologists must address questions, including "What is epidemiology in terms of methodology?" and "What is its role in society?" Epidemiologists also need to convey their acquired knowledge to academics, professionals, legislators, the media, and the general public. Only by facilitating an informative relationship with society, will epidemiologists be able to cultivate greater understanding and acceptance of this field.

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