

Research article

## Attitudes of the Japanese public and doctors towards use of archived information and samples without informed consent: Preliminary findings based on focus group interviews

Atsushi Asai\*<sup>1</sup>, Motoki Ohnishi<sup>2</sup>, Etsuyo Nishigaki<sup>3</sup>, Miho Sekimoto<sup>4</sup>, Shunichi Fukuhara<sup>5</sup> and Tsuguya Fukui<sup>4</sup>

Address: <sup>1</sup>Department of Biomedical Ethics, School of Public Health, Kyoto University Graduate School of Medicine, Kyoto, Japan, <sup>2</sup>Quarantine station, The Kansai International Airport, Osaka, Japan, <sup>3</sup>Department of Psychology, Wakayama Medical College, Wakayama, Japan, <sup>4</sup>Department of General Medicine and Clinical Epidemiology, Kyoto University Graduate School of Medicine, Kyoto, Japan and <sup>5</sup>Department of Epidemiology and Health Care Research, School of Public Health, Kyoto University Graduate School of Medicine, Kyoto, Japan

E-mail: Atsushi Asai\* - [aasai@pbh.med.kyoto-u.ac.jp](mailto:aasai@pbh.med.kyoto-u.ac.jp); Motoki Ohnishi - [mot@kuhp.kyoto-u.ac.jp](mailto:mot@kuhp.kyoto-u.ac.jp); Etsuyo Nishigaki - [etsuyo@wakayama-med.ac.jp](mailto:etsuyo@wakayama-med.ac.jp); Miho Sekimoto - [mihoseki@kuhp.kyoto-u.ac.jp](mailto:mihoseki@kuhp.kyoto-u.ac.jp); Shunichi Fukuhara - [fukuhara@pbh.med.kyoto-u.ac.jp](mailto:fukuhara@pbh.med.kyoto-u.ac.jp); Tsuguya Fukui - [fkts@kuhp.kyoto-u.ac.jp](mailto:fkts@kuhp.kyoto-u.ac.jp)

\*Corresponding author

Published: 9 January 2002

Received: 24 October 2001

*BMC Medical Ethics* 2002, **3**:1

Accepted: 9 January 2002

This article is available from: <http://www.biomedcentral.com/1472-6939/3/1>

© 2002 Asai et al; licensee BioMed Central Ltd. Verbatim copying and redistribution of this article are permitted in any medium for any non-commercial purpose, provided this notice is preserved along with the article's original URL. For commercial use, contact [info@biomedcentral.com](mailto:info@biomedcentral.com)

### Abstract

**Background:** The purpose of this study is to explore laypersons' attitudes toward the use of archived (existing) materials such as medical records and biological samples and to compare them with the attitudes of physicians who are involved in medical research.

**Methods:** Three focus group interviews were conducted, in which seven Japanese male members of the general public, seven female members of the general public and seven physicians participated.

**Results:** It was revealed that the lay public expressed diverse attitudes towards the use of archived information and samples without informed consent. Protecting a subject's privacy, maintaining confidentiality, and communicating the outcomes of studies to research subjects were regarded as essential preconditions if researchers were to have access to archived information and samples used for research without the specific informed consent of the subjects who provided the material. Although participating physicians thought that some kind of prior permission from subjects was desirable, they pointed out the difficulties involved in obtaining individual informed consent in each case.

**Conclusions:** The present preliminary study indicates that the lay public and medical professionals may have different attitudes towards the use of archived information and samples without specific informed consent. This hypothesis, however, is derived from our focus groups interviews, and requires validation through research using a larger sample.

### Background

Medical research that is properly designed and carried out ethically brings great benefit to society. Ethically sound re-

search should therefore be encouraged and protected. There is, however, an inevitable tension between the requirements of research and the rights of individual re-

search subjects. [1]. Ethical issues in epidemiological studies attract worldwide ethical, professional and public concern.

In Japan, the interest in ethical issues as related to clinical medicine has become more widespread, although similar questions that beset epidemiological studies have been ignored for a long time. Since the 1990's, concerns about ethical issues in preventive medicine, especially in epidemiological investigations, have been gradually increasing among researchers in the field in question [2]. One study suggested that Japanese researchers engaged in epidemiological studies had identified protection of subjects' privacy, respect for subject autonomy and obtaining informed consent, the sharing of benefits that arise from research with the subjects involved, and risk minimization as significant ethical issues when conducting epidemiological investigations [3]. Despite such ethical awareness among researchers, two problematic epidemiological studies took place in the late 1990s. It was reported that both studies involved the analysis of several kinds of genes taken from biological samples that had been previously obtained during the course of other kinds of medical treatment. The genetic analysis was done without the informed consent of those involved and in one case, one researcher allegedly deceived a local research ethics committee by presenting a false report documenting that all samples were used after written informed consent was obtained [4]. These acts of misconduct have engendered intense social criticism, and the ethical attitudes of epidemiologists have been thrown into question. As a result, in 2000, guidelines relating to informed consent in epidemiological research were published by researchers working for the Ministry of Health and Welfare [5].

The ethical guidelines for epidemiological studies are based upon ideas of respect for persons, beneficence, non-maleficence, and justice, and articulate obligations to individuals, community, and society as a whole [1,6,7]. When individuals are to be the subjects of epidemiological studies, their informed consent -in general- must be sought. On the other hand, it has also been stated that with certain types of research it is neither feasible nor necessary to obtain informed consent, and that the use of certain records without consent is not necessarily an ethical violation if approval from the relevant research ethics committees has been obtained. [6]. For instance, in 1999, the Royal College of Physicians Committee on Ethical Issues in Medicine published recommendation declaring that non-intrusive research on human subjects which used only archived (existing) material such as medical records and biological samples that had been previously taken during the course of medical diagnosis or treatment, may be conducted without the informed consent of the individual patients or subjects under certain circumstan-

es. The waiver stipulated that the material was to be de-linked and made anonymous at the earliest possible stage, that there should be no inconvenience or hazard to the subjects involved. The recommendations also stated that there should be no ambiguity relating to the non-intrusive nature of the original procedures, and that the appropriate research ethics committees have reviewed and agreed upon the research protocol and specifically agreed to exempt the research from the requirement of individual informed consent [1].

The aforementioned ethical guidelines developed and published in Japan are in complete accord with other guidelines that govern the use of existing archived material such as medical records and biological samples taken during the course of medical diagnosis or treatment. When the question of harm is absent, and privacy is not threatened, no informed consent is required if the appropriate ethics committee has given their approval. However, there is less consensus among the general public concerning these questions. It was revealed that 20% of patients and 24% of rural inhabitants would accept the use of blood samples drawn for the purposes of medical examination without prior permission, for the purpose of epidemiological research, and 59% of the former and 46% of the latter would accept its use if the purpose of the research was explained to them [2].

No investigation has been done, however, to demonstrate why people would or would not accept such use of medical information or samples without specific informed consent. There has been little research examining the circumstances under which Japanese people would be willing to allow epidemiological investigators to use their private information and biological samples for research. We do not know whether or not Japanese laypersons approve of the kinds of ethical guidelines that are widely accepted among health care professionals. Given the limited data available to guide researchers, we used focus group interviews in this exploratory study, and attempted qualitative analysis of the results so that we could develop preliminary hypotheses regarding our research questions. This study used focus group interviews to explore the attitudes toward the application of existing archived material such as medical records and biological samples that had previously been taken during the course of medical diagnosis or treatment. We also attempted to compare the attitudes of the lay public with those of physicians who are involved in medical research.

In the following, we will present the results of our study and discuss their implications. Members of the lay public expressed diverse views towards the use of archived information and samples without specific and individual informed consent, and different views concerning their

control over personal privacy. The importance of the general public's trust in medical and epidemiological researchers was also revealed. It also emerged that the lay public and the medical profession seemed to have very different attitudes towards the use of the material under discussion without specific informed consent. Furthermore, some comments that the physician-researchers provided involved subtle but significant ethical issues, such as questions concerning the legitimacy of decisions made by research ethics committees, and the distinction between research and clinical practice.

**Methods and subjects**

We conducted three focus group interviews in November 2000, in Osaka. The first group comprised seven men from the general public, the second seven women from the general public, and the third was composed of seven male physicians. Each interview took approximately two hours. Inclusion criteria for the lay participants were as follows: they had to be aged between 35 and 55, married with children, an interviewee or his or her relatives had to have had experience of inpatient care during the preceding five years., The lay participants could not have close family members who were health care professionals.

Those who participated in the physician focus group had to be between 35 and 55, and be involved in both clinical practice and research activities. Recruitment of interview participants was conducted by investigators from the Japan Research Center working in the Osaka area, which is

a private institution for market research specializing in conducting group interviews and recruiting interviewees. The seven men and seven women from the general public were recruited by the investigators from their files of interviewees, independently of the authors. The participating physicians were recruited by the authors for the sake of convenience. Four of the authors (AA, MO, MS, SF) asked fellow physicians working in different institutions to recommend candidates to be subjects in this study and one author (AA) sent a formal letter of invitation to potential participants. All participants were asked to take part in a discussion about their attitudes, beliefs, and experiences with regard to medical research and medicine in general. All of them consented to join this study. An honorarium was paid to all participants.

Two trained professional facilitators from the Japan Research Center, who have appropriate training and experience, conducted the three sessions. All focus group interviews were audiotaped and shorthand was also taken with the consent of the participants. Participants completed a brief demographic questionnaire before the focus group interview began. The questions that were asked in the interviews are shown in Table 1 and Table 2. In general, focus group interviews are continued until no new information is obtained. However, no follow up sessions took place, owing to limited human and financial resources. Therefore, the results presented here should be regarded as preliminary.

**Table 1: A list of questions asked in the three focus group interviews**

Lay participants
Would you approve of the use of your medical records such as medical charts for research purposes?
Would you approve of the use of your medical records such as medical charts if you were asked your permission beforehand?
Would you approve of the use of your medical records for research purposes without your prior permission?
In your opinion, what are essential conditions that researchers must meet when they use your medical records for research purposes without your prior permission?
To whom do you think medical charts belong?
Would you like to get any feedback regarding the results of investigations for which researchers used your medical information?
How would you feel if you were aware that your medical information had been used for research purposes without your permission?
Would you approve of the use of biological samples that had been previously taken during the course of medical diagnosis or treatments and medical check-up you had, for research purposes without your prior permission?
Is there any difference between the use of your medical records such as medical charts and the use of biological samples that had been previously taken during the course of medical diagnosis or treatments and medical check-ups you had, for research purposes without your prior permission?

Audiotapes of the all interviews were transcribed. The transcripts were analyzed by three of the authors (AA, MO, EN). The authors read the transcripts several times, analysed them line by line, and replaced individual statements with general concepts or themes such as informed consent, privacy, and wrongs, so that all the issues rele-

vant to the attitudes and beliefs of the participants were identified. We did not necessarily aim to formulate comprehensive categories or develop theoretical frameworks because our primary objective in this study was to elicit information. Research team meetings and electronic communication was employed in order to discuss the accuracy

**Table 2: A list of questions asked in the three focus group interviews**

Physicians
<p>What kind of experience have you had with regard to medical research in which you used patients' medical information and biological samples that had been previously taken during the course of medical diagnosis or treatments and medical check-ups, for research purposes?</p> <p>Have you ever obtained informed consent from your patients when you used their information and samples? If you have done so, how?</p> <p>Have you ever given your subjects feedback regarding the results of your investigations based on their medical information or biological samples?</p> <p>What do you think of informed consent in epidemiological research that uses patients' medical information and biological samples that have been previously taken during the course of medical diagnosis or treatments and medical check-ups, for research purposes?</p>

of the lists of concepts and ethical issues identified. Research team discussions were also utilized to select interviewees' statements that were regarded as typical or representative. We repeated these processes until we reached consensus regarding the final presentation of the results.

All the focus group interviews in this study included discussions about the need for medical research, the use of placebos, attitudes towards double-blinded randomized control trials, and what motivated subjects to participate in medical research. These results will be reported separately elsewhere. The advantage of focus group interviews is that they include insights about attitudes and beliefs as the interaction among participants promoting rich discussion on controversial topics. The information obtained through focus group interviews can generate hypotheses about a target population although they have to be tested quantitatively by a survey to ensure their accuracy [8–11].

### Results

Table 3 shows demographic characteristics of participants in the focus group interviews. The female participants were aged between 35–55, four of them had part time jobs, and most of them had had experience of hospital care, either personally, or through contact with close family members who had been admitted. The male interviewees were aged between 35–55, all had full time jobs, three of them had had experiences of inpatient care themselves and all had had relatives who had been admitted to hospital. All physician participants were aged between 37–44, five of them were practicing internal medicine, one was working in intensive care, and one was an anaesthetist. The respondents had been practicing medicine from 12 to 17 years. We did not ask about their medical history or family history. What follows is a summary of the results of these three group interviews. Some typical statements of the participants are quoted as summarized by the authors.

### Laypersons

In response to the question, "Would you approve of the use of your medical records such as medical charts for re-

search purposes without your prior permission?" The participants' answers varied. The responses included positive approval, complying reluctantly with the current situation, requiring non-specific prior notice, wishing to secure veto power or the chance of opting out of having their medical information and biological samples used, and the insistence on individual informed consent. Participants who wished to help researchers to carry their investigations forward thought that informed consent was unnecessary. For example, one man stated:

*"It does not matter at all to me." (45-year old male)*

On the other hand, some participants seemed to give their consent somewhat reluctantly to the use of archived information and samples without informed consent. They felt that they could not but accept what researchers were doing or might do because of their unequal relationships with them. One woman stated:

*"I cannot help but accept researchers using my medical chart without my permission because I feel that the relationship between medical doctors and patients are socially unequal, with patients belonging to the lower rank." (52-year-old female)*

Others suggested that there might be a tacit understanding between patients and researchers in order to develop medical science and because of the existence of unspoken agreements about the importance of contributing to the public good. As one woman stated:

*"As a matter of fact permission has never been asked, but I think that they have been using our medical charts and blood samples. Such behavior brings about medical progress, so I think that there exists tacit agreement between the researchers and patients for the good of all of us." (48-year-old female)*

Some thought that although no individual informed consent was necessary, researchers conducting epidemiological studies were obliged to officially state that patients' medical records and blood samples were to be used for re-

**Table 3: Demographic characteristics of participants in focus group interviews**

		Female participants	Male participants	Physicians
	Number	7	7	7
	Age	35–54	35–55	37–44
Occupation	Full time	0	7	NA(not applicable)
	Part time	4	0	NA
	None	3	0	NA
Specialty	Internal Medicine	NA	NA	5
	Emergency/ICU	NA	NA	1
	Anesthesiology	NA	NA	1
Duration of practice (years)		NA	NA	12–17
Inpatient care	Interviewee him/ herself	5	3	NA
	Interviewee's relatives	6	7	NA

search purposes. They preferred to have the opportunity to opt out of epidemiological studies.

*"Ordinary hospitals as well as university-affiliated ones should make public that patients' medical charts and blood samples previously taken during the course of medical diagnosis or treatment are being used for research purposes. Those who do not want their medical charts or blood used in this way should be given a chance to say no."* (48-year-old female)

Protecting subjects' privacy, maintaining confidentiality, and communicating the outcomes of studies to research subjects were regarded as essential preconditions in order for researchers to be permitted to use archived information without the provision of specific informed consent. It seems that communicating the outcomes of studies to the public is also acceptable as a method of feedback. Promoting the public interest is also one important prerequisite of the ethical use of archived medical information without the specific informed consent of the participants. As some members of the focus group stated:

*"It would be no problem as long as they (researchers) do not make poor use of my medical charts or blood."* (40-year-old male)

*"I want to be privately or publicly told the results of studies in which the researchers used our information or blood."* (43-year-old-male)

*"It would be fine if the research served the interests of all and confidentiality was maintained."* (55-year-old male)

In addition, possible benefits to subjects in the distant future and the non-detrimental nature of the research were also important issues.

*"Using medical charts for research purposes would not offend me as long as my privacy was protected and it would be acceptable if it was likely that I might benefit from the results of the research."* (44-year-old female)

For some participants, however, the use of their medical records or blood samples without prior permission seemed a grave offence. These participants firmly insisted that researchers obtain individual informed consent from subjects.

*"Different people have different attitudes towards what kind of personal information should be made known to others. Even if a study is well-intended and conducted on behalf of the good of society personal permission should be obtained."* (44-year-old female)

*"Even if medical research is to be done in the best interests of society, I need to be asked for specific permission. I want to know what happens to my material whatever it is."* (35-year-old male)

The issue of ownership of medical records also arose. One of the participants claimed that medical charts belonged to patients, especially as it is the patient who pays the medical bill that results in the production of medical charts and blood samples.

*"Medical professionals and researchers do not have the right to use what belongs to me whenever they want."* (47-year-old female)

Trust in medical researchers was an important issue when judging how acceptable the use of archived records and samples without specific informed consent actually was.

Some doubted that researchers actually respected subjects, or were much interested in protecting their privacy.

The personalities of medical researchers also seemed to be an important issue.

*"There is no way for us to know whether or not our personal information is dealt with anonymously. We are so naive about what medical research is and how it proceeds. Such powerlessness and ignorance make me uncomfortable."* (44-year-old female)

*"Who looks at our medical record does matter to me."* (35-year-old male)

There was no basic difference in the participants' attitudes towards the use of existing medical records and the use of biological samples that had been previously taken during the course of medical diagnosis or treatment and regular health checks. No participants discussed issues regarding genetic research.

### **Physicians**

Inquiries with regard to use of medical records, especially the review of medical charts for research purposes seemed to take some of these participants by surprise. Those who had taken it for granted that they could access archived medical information without patients' permission were surprised by being questioned about whether or not this was in fact unethical. One participant asked the facilitator:

*"Are you suggesting that there are patients who might be made uncomfortable by our using their medical charts for research purposes?"* (39-year-old male)

All the physicians who participated had accepted existing ethical guidelines for epidemiological studies, which allowed that medical researchers could use archived medical information and biological samples without obtaining specific informed consent once permission from a research ethics committee was obtained, if subjects' confidentiality and privacy were maintained.

*"Permission provided from the research ethics committee is considered to be the equivalent of a patient's consent or permission."* (44-year-old male)

However, the actual procedure to obtain the permission for the use of medical records varied between hospitals. Participants from some university-affiliated hospitals reported that researchers could freely use archived medical records if they presented a document indicating the aims of their study, while a participant from other institutions said that researchers needed to obtain permission from a local research ethics committee to do so. No participants

suggested that individual informed consent had to be solicited from individual patients in order to use their archived medical information. One member of the focus group stated:

*"As a matter of fact, we do not have the tradition of obtaining consent from patients when we use their medical records."* (39-year-old male)

According to participants, the main issue about obtaining informed consent for the use of archived medical information was the difficulty in doing so.

*"In reality, it is almost impossible for us to get informed consent from every patient whose medical chart is to be used for research purposes. Even if we tried to contact all the subjects involved, I guess, we would not be able to get informed consent from more than 30% of them."* (39-year-old-male)

However, an effort was made to let patients know that biological samples that were taken during the course of medical diagnosis or treatment are likely to be used for research purposes in the future. For example, a formal notice saying that part of a patient's blood sample might be used for medical research had been posted on the walls of some hospitals. The medical participants of our study argued that it was not feasible to post notices indicating the specific aims of studies because the aims were often yet to be determined. However, whether or not such a general notice was worthy of being called informed consent was a matter of controversy among the participants in our study.

*"But, it cannot be regarded as obtaining informed consent."* (37-year-old male)

Opinions concerning the best way to obtain informed consent seemed to vary depending upon what kind of biological samples were taken. Individual informed consent was regularly obtained when tissues from organs such as the stomach were taken, but such was not the case for blood samples. Furthermore, as in the case of medical records, explanations about the studies in question were not offered to patients, nor was their consent sought.

*"We usually simply ask patients if we can use part of their blood samples for research purposes, but we have not told them about the details of the studies in question and the patients never ask questions about the studies."* (39-year-old male)

Rather than obtaining informed consent, patients were often given the opportunity to "opt out" of research studies.

*"In a hospital I know well, patients are asked to sign their names on a certain form and it is understood that patients who*

*do not do so are assumed to have given consent to the use of their blood samples for research purposes. "(43-year-old male)*

For the participating physicians, both clinical practice and research were indistinguishable. Both were essential for the care of patients.

*"We are allowed to look at a patient's medical chart for the purpose of diagnosis and treatment, but we are not permitted to look at the same chart for research purposes. Such a distinction does not make sense to me. For us, they are one and the same, distinguished only by motive. "(44-year-old male)*

One participant said with bewilderment that the boundary between a study requiring informed consent and the one not doing so remained obscure.

*"I certainly do not know the kind of investigation in which I would need to obtain informed consent from every subject. "(43-year-old male)*

Before the involvement of genetic analysis in research, researchers could use archived biological samples freely as the occasion demanded. Neither the procurement of blood samples from patients nor their use required researchers to obtain informed consent from patients.

*"In the past, we did not take the significance of informed consent seriously. "(39-year-old male)*

## Discussion

Our current preliminary study has provided several hypotheses: first, the general public is likely to have diverse attitudes towards the use of archived information and samples without specific informed consent. Some persons would be willing to allow medical researchers to use archived information and samples without such consent, while others claim that they should be asked for individual informed consent prior to the commencement of the study. The opportunity to opt out of having their medical information and biological samples used is also an option that some people wish to have. It seems that some hospitals in Japan have already provided their patients with such a choice. Second, it was suggested that protecting subjects' privacy, maintaining confidentiality, and communicating the outcomes of studies to research subjects were regarded as essential preconditions when allowing researchers to use archived information and samples for research purposes without specific informed consent. In addition, lay participants wanted general prior notice regarding the nature of the research in question and information about the researchers in charge. Third, some people were worried about investigators' ethical standards and uncertain about whether or not their privacy and confidentiality were properly protected by them. Fourth, al-

though the participating physicians thought that some kind of prior permission from subjects was desirable or necessary, the difficulties of obtaining individual informed consent were paramount. The physicians accepted the recommendations within the existing ethical guidelines in epidemiological research, but they were not certain about the circumstances under which individual informed consent was considered necessary, and how to actually obtain it. Finally, there emerged the possibility that the lay public and medical profession had sharply divergent attitudes towards the use of archived information and samples without informed consent.

It has been argued that no physical harm would occur if researchers used only archived medical records and samples that had been previously taken during the course of medical diagnosis, treatment or medical check-ups. When data or samples were delinked so that individual subjects cannot be identified even to the researcher, some believed that the possibility of psychological harm was eliminated [1]. It seems that some of our lay participants and all participant physicians shared this belief. On the other hand, some argued that there is a distinct difference between harms and wrongs and people can be wronged even when they do not suffer physical or psychological harm. For example, it is generally considered to be wrong when a person enters another's house without permission even if the intruder does nothing and leaves everything untouched. In this context, the wrong is the invasion of privacy without consent, which is known as trespass [12]. In our interviews, some lay participants who thought that prior individual informed consent, and the chance to opt out of research were essential, might have felt that they could have been wronged by a study that used archived medical records and samples without their own prior permission, even if the information and samples were dealt with anonymously. It follows that they might say something like "information about me is an aspect of myself, just as is the physical space that I live in and someone looking through it has intruded upon me as surely as if he or she had entered my home [12]." As one participant suggested, the gravity of the wrong depends upon how personal the information and data is.

Several questions remain: what implications does this range of opinion have on present and future research activities in epidemiology? To what extent should we consider possible moral wrongs beyond actual harm seriously? In what kinds of situations is individual informed consent required? These questions are crucial for those who are engaged in epidemiological investigations, because, as our physician focus group suggested, a considerable number of the investigators were uncertain about how to behave. In the following, we focus upon the ethical issues that arise from these questions. However, dis-

discussion in regard to ethical problems specific to genetic analysis of archived information and biological samples will not be included. This is because our interviewees did not discuss issues of genetic research in our study and also because ethical problems concerning genetic research are so complicated that they are beyond the scope of the current discussion.

Epidemiological investigations are indispensable to medical progress, which in turn brings people longer life of better quality. This is the ultimate goal of medicine. On the other hand, privacy is essential to us. It can be argued that protecting an individual's privacy is obligatory so as that every person can have a truly autonomous life with dignity, freedom, and security. No one can lead his or her life without anxiety or fear if others can easily invade his or her life and use his or her highly personal records or information without permission. Thus, protecting privacy and the progress of medical science are arguably of equal value and neither can be sacrificed for the sake of the other. Therefore, the most significant issue to consider is how to strike a balance between the requirements of research on behalf of social welfare and an individual's right to privacy. It would be wrong, therefore, to discontinue all investigations using archived medical information and biological samples on the grounds that such studies can ethically wrong people. By the same token, it would also be unacceptable for medical researchers to push ahead with their studies that could wrong people by violating an individual's privacy without a third party's ethical scrutiny. A better way of proceeding should give equal consideration to individual privacy and social welfare. In other words, the protection of privacy and the conduct of epidemiological research should both be restricted so that medical researchers and society in general can benefit. Entering someone's home is ethically wrong but this would not be the case if we did so with prior permission of the owner of the home. Therefore, in order to avoid wrongdoing, it is necessary for us to make those providing medical information or giving samples for diagnostic or therapeutic purposes aware that their medical records or biological materials may subsequently be used for research purposes in before such research takes place. Advance notices regarding aims, procedures, possible benefits and harms, expected outcomes of studies and the guarantee of privacy can give a research subject a chance of opting out of consent to have their medical information and biological samples used as well as their actively giving informed consent. The identities of researchers and others who will have access to subjects' information and samples should also be disclosed in order to enhance potential subject's trust in research projects and ease their anxiety regarding the abuse of privacy. As some lay participants indicated, providing information about how to communicate and how to provide the results to research

subjects could also increase the rate of consent to use their private information and biological material. It has been reported that such procedures for obtaining informed consent have not been widely employed, and our interviews with Japanese physicians confirmed this [1]. However, recent studies showed that more than 80% of Japanese patients would be willing to consent to have their medical information used for research purposes when asked [13]. Therefore, if the results hold true to actual situations, it is unlikely that a low response rate would become a big issue. In addition, the process of obtaining individual informed consent could also be regarded as a chance to facilitate understanding as to the importance of epidemiological studies. Better understanding of the significance of research may motivate subjects to cooperate with proposed investigations. We believe that obtaining informed consent could, therefore, give the researchers a higher response rate in the long run. We think that the requirement of informed consent and providing a chance for potential subjects to opt out of having their medical information and biological samples used is a fair restriction to impose on epidemiological investigations to protect individual privacy.

On the other hand, when a local research ethics committee determines that a certain epidemiological investigation is indispensable or urgently needed, and a delay caused by the insistence of obtaining individual informed consent will cause serious damage to public health and social welfare, research based on the use of archived information and biological samples without informed consent may be conducted. For example, an epidemiological study aiming to discover the pathogen of a lethal sweeping infection can be judged to be an emergency and any delay might result in more deaths. In such cases, individual rights to privacy should still be imposed and the researcher should conduct the investigations by delinking the information and samples. Nevertheless, it should be added that the fact that medical records and biological materials are already in the hands of researcher's hands does not lessen the gravity of using such results without permission. Therefore, whenever possible, it is ethically preferable for the investigators to try to obtain consent.

The outcomes of the present study also highlight the importance of the general public's trust in medical researchers and health care as a whole. As some of the lay participants mentioned, distrust in researchers' moral characters may be a problem when subjects consider taking part in research, and those who do not trust the researchers are very unlikely to consent to allow them to use their personal information and biological samples. In order to conduct research projects in a sound and ethical manner, we have already utilized local research committees and ethical guidelines in epidemiological research.

However, it may not be enough. What is equally important is ethics education for medical researchers to make them sensitive to ethical issues in research and the fundamental right to privacy. Research ethics committees would be hard pressed to prevent researchers who did not hesitate to deceive others and who carry out unethical studies violating one's privacy. Therefore, the formation of researchers who recognizes his or her moral obligation in doing research is essential.

Some statements made by those interviewed deserve close ethical analysis. Although both the Japanese lay participants and physicians expressed interesting attitudes and opinions concerning ethical issues we will focus on physicians' comments- in particular two statements. In our opinion, their comments relate to the most significant problems relevant to the ethics of epidemiological research. We also expect that the critical interpretation of these two statements will interest our readers, especially those who are researchers or physicians aware of the subtle but profound problems that they have when conducting research of the kind discussed here. What follows is only a preliminary discussion. However, a complete and thorough debate concerning the respective problems involved in the interviewees statements is beyond the scope of this paper, which basically attempts to report our empirical research. We think that the problems we briefly discuss should be debated more thoroughly in subsequent papers.

The statement "*Permission provided from the research ethics committee is considered to be the equivalent of a patient's consent or permission*" suggests that some researchers accept decisions made by the research ethics committee as unconditionally correct without critically reflecting upon them. It may be argued that some epidemiological researchers are unaware of the limitation of research ethics committees' functions. We should always ask whether or not the research ethics committee concerned, or indeed ethical guidelines published by different research societies actually represent individuals whose medical information and biological samples might be used without informed consent. Although we recognize that both research ethics committees and ethics guidelines regarding the conduct of epidemiological studies are certainly useful in evaluating the benefit/risk ratio of proposed investigations, and in assisting ethical reflection on study proposals, it does not necessarily follow that consensus reached in the committee or the guidelines are always correct. It is doubtful that every person's opinion or wishes regarding his or her privacy can really be considered when committees reach consensus, or when guidelines are drawn up [14].

Second, the statement "*We are allowed to look at a patient's medical chart for the purposes of diagnosis and treatment, but*

*we are not permitted to look at the same chart for research purposes. Such a distinction does not make sense to me. For us, they are one and the same, distinguished only by motive*" seems to suggest that some of physician-researchers would not or could not separate their epidemiological investigations for research purposes from everyday clinical practice. Such an attitude could be ethically problematic. Despite the fact that both research activities and clinical practice are aimed at benefiting people, it should be recognized that the main and primary purpose of research is different from that of daily clinical practice, which is supposed to serve the best interests of current and actual patients in the care of the physicians. The fundamental objective of research is to benefit future patients and communities at large and, historically speaking, medical researchers have either knowingly or unknowingly carried out research at the cost of current and actual patients in their care. Therefore, even when epidemiological investigations seem harmless to research subjects and the investigators are beneficently motivated, research activities should be regarded as distinct from clinical practice. In addition, we suggest that part of a researcher's motivation includes some degree of self interest, as his or her career and reputation will benefit from research that is successfully carried out. Hence, there are powerful reasons why research should be distinguished from daily clinical practice.

Our current investigation has several limitations. First, although the focus group interview is an important tool to explore participants' experiences, attitudes and beliefs, qualitative research methodology of this kind is used primarily to generate, rather than test, hypothesis [11]. We need to validate our findings through quantitative research with a nationally representative sample. Second, the lay participants that we interviewed were recruited from one city only, and it is possible that regional differences could affect our theories, and the attitudes expressed in the interviews may not be representative of the general public of Japan. Third, we did not ensure that our interviews provided all possible relevant hypotheses. Because of limited resources, we could not continue interview sessions until no new information was provided. Furthermore, our interviews did not focus on epidemiological studies that used genetic analysis. Therefore, our results and discussion may not be applicable to genetic research and the results we presented here should be perceived as preliminary.

## Conclusions

In conclusion, we discovered that the lay public expressed diverse attitudes towards the use of archived information and samples without specific informed consent and there was a strong possibility that the lay public and the medical profession had very different attitudes towards the use of such material without specific informed consent. These

focus group interviews, although preliminary, have several important implications about ethical conduct for epidemiological investigations. Our results naturally require validation through research into a larger sample.

### Competing interests

None declared

### Acknowledgements

The authors would like to thank Professor Akira Akabayashi and Professor Takeshi Nakayama for their useful suggestions and comments. This research was supported by research funds of the Department of Clinical Epidemiology, Kyoto University Graduate School of Medicine.

### References

1. Royal College of Physicians Committee on Ethical Issues in Medicine: **Research based on archived information and samples. Recommendations from the Royal College of Physicians Committee on ethical issues in medicine.** *J R Coll Physicians Lond* 1999, **33**:264-6
2. Inaba Y: **Ethics and epidemiology: Recent topics in Japan.** *J Epidemiology* 1996, **6**:S137-9
3. Subcommittee of Ethical Issues, Ethics and Epidemiology: **What ethical issues are Japanese epidemiologists facing? Results of a questionnaire study for members of the Monbusho research committee on evaluation of risk factors for cancer by large-scale cohort study.** *J Epidemiology* 1996, **6**:S141-6
4. **Analyzing patients' genes without informed consent and presenting a false report to a local research ethics committee.** *Asahi Shinbun (Newspaper)*; 2001, March 28
5. Kouseisho Kagakukenkyuuhi Hojokin; April 10, 2001: **Guidelines for informed consent in epidemiological research, version 1.0, Tokyo**
6. Beauchamp TL, Cook RR, Fayerweather WE, Raabe GK, Thar WE, Cowles SR, Spivey GH: **Ethical guidelines for epidemiologists.** *J Clin Epidemiology* 1991, **44**:151S-169S
7. Council for International Organizations of Medical Science (CIOMS): **International guidelines for ethical reviews of epidemiological studies, Geneva** 1991
8. Schattner P, Shmerling A, Murphy B: **Focus groups. A useful research method in general practice.** *Med J Aust* 1993, **158**:622-625
9. Kitzinger J: **Introducing focus groups.** *BMJ* 1995, **311**:299-302
10. Ellis PM, Butow PN: **Focus group interviews examining attitudes to randomized trials among breast cancer patients and the general community.** *Aust N J Public Health* 1998, **22**:528-31
11. Corbie-Smith G, Thomas SB, Williams MW, Moody-Ayers S: **Attitudes and beliefs of African American toward participation in medical research.** *J Gen Intern Med* 1999, **14**:537-546
12. Capron AM: **Protection of research subjects: So special rules apply in epidemiology?** *J Clin epidemiology* 1991, **44**:S81-S89
13. Hamajima N, Tajima K: **Patient's views on reference to clinical data.** *J Epidemiology* 1997, **6**:17-19
14. Asai A, Ohnishi M: **Ethical consideration in epidemiological studies.** *Journal of Japan Association of Bioethics* 2001, **1**:122-8

Publish with **BioMed Central** and every scientist can read your work free of charge

"BioMedcentral will be the most significant development for disseminating the results of biomedical research in our lifetime."

Paul Nurse, Director-General, Imperial Cancer Research Fund

Publish with **BMC** and your research papers will be:

- available free of charge to the entire biomedical community
- peer reviewed and published immediately upon acceptance
- cited in PubMed and archived on PubMed Central
- yours - you keep the copyright



Submit your manuscript here:

<http://www.biomedcentral.com/manuscript/>

[editorial@biomedcentral.com](mailto:editorial@biomedcentral.com)