Patients' Views on Reference to Clinical Data

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In order to survey patients' views on reference to clinical data for research purposes, an anonymous self-administered questionnaire was distributed to Aichi Cancer Center Hospital patients in 1995. All eligible first-visit outpatients (97 persons), randomly selected revisit outpatients (99 persons), and all eligible inpatients in a good condition at discharge except six cases (97 persons), responded to the questionnaire. Out of 293 patients (115 males, 174 females and 4 unspecified), 85.3% (standard error 2.1%) considered that hospitals should make active efforts to improve their health care and treatment skills. And 88.1% (standard error 1.9%) answered that reference to their own clinical data to improve health care and treatment skills was "preferable" or "don't mind". J Epidemiol, 1997 ; 7 : 17-19.

Reference to clinical data is essential not only for clinical studies, but also for health research on etiology and prevention of diseases. Innumerable studies in both fields have been conducted, and have provided useful information for health care providers and patients. However, increasing attention to patients' privacy protection has begun to arouse restrictions on the use of clinical data even for research purposes. There are many arguments for or against the restrictions 1-9, but it has rarely been reported how patients themselves view this problem. This paper reports Japanese patients' views on use of clinical data gathered in hospitals.

MATERIALS AND METHODS

This study was done at the same time as a questionnaire survey on information needed for cancer care services. Since the details have been described in another paper 9, the outline is only briefly described here. An anonymous self-administered questionnaire was distributed at Aichi Cancer Center Hospital to three groups of patients: first-visit outpatients, revisit outpatients, and inpatients. For first-visit outpatients, the questionnaire was handed out consecutively on four days in November 1995. All eligible patients excluding those with visual acuity problems participated in the study. For the revisit outpatients, the questionnaire was handed out at random at registration points by four nurses and one doctor, on one day in October 1995. For the inpatients, the questionnaire was handed out consecutively two or three days before discharge and collected one day before or on the day of discharge during October and November 1995. The subjects were all eligible cases in a good condition, six cases; two cases due to sudden discharge, one due to being too old, one due to taking the questionnaire home and not returning it, and one due to losing the chance, did not participate.

Table 1 shows the age and sex of the subjects. The questionnaire was collected from 97 first-visit outpatients, 99 revisit outpatients, and 97 inpatients, totalling 293 patients: 115 males (39.2%), 174 females (59.4%) and 4 unspecified (1.4%). The male:female ratio was slightly higher than that among all first-visit outpatients 1988-93 where 29.2% were male and 70.8% female. The mean age of the subjects was 50.8 years for first-visit outpatients, 59.5 years for revisit outpatients, and 57.5 years for inpatients.

In the text, percentage responses are shown with their standard error calculated by $\sqrt{(p(1-p)/n)}$, where p is the percentage, and n is the number of subjects. Significance tests for differences in percentage were performed by Fisher's exact test using SAS Procedure FREQ 9. Mantel-Haenszel chi-square method 10 was adopted for the comparisons between sexes adjusted by age group (younger than 60 years vs 60 years or over).

RESULTS

Table 2 shows patients' views on use of clinical data for
Table 1. Age distribution of the respondents.

| Age | M | F | Total |
|-----|---|---|-------|
| 18-29 | 2 | 8 | 10 |
| 30-39 | 6 | 12 | 18 |
| 40-49 | 2 | 16 | 18 |
| 50-59 | 7 | 12 | 19 |
| 60-69 | 9 | 12 | 21 |
| 70+ | 8 | 3 | 11 |
| Unknown | 0 | 0 | 0 |
| Total | 34 | 63 | 97 |

M: male, F: female
*Total* includes sex-unknown individuals

Table 2. Percentage responses to the question on use of clinical data, according to sex and age.

| Question | Male | Female | All subjects |
|----------|------|--------|--------------|
|          | Ages<60 | Ages<60 | Ages<60 |
|          | 60s | Total | Ages<60 | 60s | Total | Ages<60 | 60s | Total |
| Do you think hospitals should make active efforts to improve their health care and treatment skills? | | | | | | | | | |
| Yes | 91.3 | 85.5 | 87.8 | 47 | 46 | 47 | 88.8 | 80.6 | 85.3 |
| No | 2.2 | 2.9 | 2.6 | 3.5 | 0.0 | 2.3 | 3.1 | 1.6 | 2.4 |
| I can't answer | 6.5 | 11.6 | 9.6 | 8.8 | 25.4 | 14.4* | 8.1 | 17.8 | 12.3 |

Do you think hospitals should study the clinical data of patients to improve their health care and treatment skills? | | | |
| Yes | 87.0 | 89.9 | 88.7 | 90.4 | 84.7 | 87.9 | 89.4 | 87.6 | 88.4 |
| No | 3.0 | 1.4 | 0.9 | 1.8 | 3.4 | 2.3 | 1.2 | 2.3 | 1.7 |
| I can't answer | 13.0 | 8.7 | 10.4 | 7.9 | 11.9 | 9.8 | 9.3 | 10.1 | 9.9 |

Do you mind if medical staff (doctors, nurses, etc.) use your clinical data to improve their health care and treatment skills? | | |
| Yes, very much | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.3 |
| Yes, slightly | 0.4 | 1.9 | 0.9 | 1.8 | 3.4 | 2.3 | 1.2 | 2.3 | 1.7 |
| No | 28.3 | 27.5 | 27.8 | 32.5 | 32.2 | 32.2 | 31.1 | 29.5 | 30.4 |
| No, preferable | 63.0 | 60.9 | 61.7 | 57.9 | 47.5 | 54.6 | 58.6 | 55.0 | 57.7 |
| I can't answer | 8.7 | 8.7 | 8.7 | 7.9 | 16.9 | 10.0 | 8.1 | 12.4 | 9.9 |

Under the condition that your private information such as name would not go out from the hospital, do you mind if your clinical data is used to improve health care and treatment skills throughout Japan? | | |
| Yes, very much | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Yes, slightly | 4.3 | 2.9 | 3.5 | 10.5 | 6.8 | 9.2 | 8.7 | 4.7 | 6.8 |
| No | 19.6 | 27.5 | 24.3 | 29.8 | 35.6 | 31.6 | 26.7 | 31.8 | 28.7 |
| No, preferable | 67.4 | 58.0 | 61.7 | 53.5 | 39.0 | 48.3 | 57.8 | 48.8* | 53.9** |
| I can't answer | 8.7 | 11.6 | 10.4 | 6.1 | 16.6 | 10.9* | 6.8 | 14.7 | 10.6 |

*Total* includes the subjects with unknown age.

Significant tests (Fisher's exact test) were done between age groups in the columns of "Male" and "Female", and between the sexes in the column of "All subjects". Mantel-Haenzel method was used for the column of "Total" of "All subjects". *P<0.05, **P<0.01.

research purposes, as well as the expectation that it is the hospital's duty to improve health care and treatment skills. Those who did not circle any answer of each question were included into "I can't answer". It was found that 85.3% ± 2.1% of the respondents considered hospitals should make active efforts to perform this duty. The percentage was higher in those aged
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less than 60 years than in those aged 60 years or over; the difference was significant in females. Those who considered that hospitals should utilize the clinical data of their patients were 88.4% ± 2.1%

Although six patients (2.0% ± 0.8%) expressed discomfort, 88.1% ± 1.9% answered that they did not mind for research-aimed use of their own clinical data by medical staff to improve the hospital's health care and treatment skills. To be noted is that 57.7% ± 2.9% evaluated it preferable. Four of the above six patients were first-visit outpatients, one a revisit outpatient, and one an inpatient.

For the purpose of improving health care and treatment skills throughout Japan, slightly more patients, twenty subjects (6.8% ± 1.5%) expressed slight discomfort, and none, serious discomfort. Twelve of the twenty patients group, five from the revisit outpatients group, and three from the inpatients group. However, 82.6% ± 2.2% did not mind in the use of their own clinical data under the condition that their privacy would never be violated. The majority (53.9% ± 2.9%) evaluated the use preferable, and the percentage was significantly higher in males than in females after age group adjustment (p<0.01).

DISCUSSION

There are no arguments that respect for patients' privacy is very important in health care. However, the duty to improve health service sometimes touches on and may include many privacy issues, and there have been no studies on patients' views about this problem. Interestingly, the results documented here stood for the use of clinical data under the condition or assumption that the data remain confidential, i.e., privacy is not violated.

Even when those who answered "I can't answer" were included in the percentage calculation, more than 80% of respondents sought hospitals' efforts to improve health care and treatment skills, and approved of the use of their individual clinical data for this purpose. Although the fact should not be neglected that a few respondents objected to the use of their individual clinical data, it could be said that medical staff are expected by the nationals to improve health care by using clinical data, as long as patients' privacy is not violated.

Since the contents of health care are expanding to provision of information concerning disease prevention, the patients' views documented in this study could be similarly applicable to health science researches including etiological studies.

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