

Distribution Differences of Medical and Clinical Research and Clinical Trial Information by Hospital Size in Japan

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Abstract

It is known that information regarding clinical research/trials is not easily available to the public in Japan. To improve the current clinical research/trial information portals, we could consider combining them with intelligible clinical information; moreover, we could explore how best to provide trial-related information to patients and medical professionals. To this end, we conducted a questionnaire survey; self-administered questionnaires were administered by post to medical facilities in Japan. The responses to a few questions were statistically significant with regard to the distribution of clinical research/trial information. We confirmed that several medical facilities have provided clinical research/trial information to the public. However, we need to consider the distribution of the information content expected by the patients and citizens. For greater awareness, it is necessary that medical facilities consider the method of information delivery from the viewpoints of patients and citizens, regardless of whether they are a small or large facility.

Keywords: Medical informatics; Questionnaires; Clinical research; Clinical trials; Information distribution; Internet; Hospital information system; Information services

Introduction

The Japan Primary Registries Network (JPRN) comprises the Ministry of Health, Labour and Welfare (MHLW), a portal site operated by National Institute of Public Health (NIPH) [1] and three data providers: the University Hospital Medical Information Network (UMIN CTR) [2], the Japan Pharmaceutical Information Center-Clinical Trials Information (JapicCTI) [3] and the Japan Medical Association-Center for Clinical Trials (JMACCT CTR) [4]. The JPRN portal site was recognised as a World Health Organization (WHO) primary registry in 2008 and also provides data collection, management and display functions in Japanese and English. Several challenges with the portal websites such as not being easy to use have been pointed out by the clinical research/trial activation committee [5].

The Clinical research/trial activation five-year plan, 2012 in the MHLW, and Ministry of Education, Culture, Sports, Science and Technology (MEXT), assumes that Japanese citizens and patients can use the information and novel findings of Japanese clinical research/trials through accessible websites [6]. Therefore, to improve the present portal site for clinical trials, we could possibly combine the present portal site for trials with intelligible clinical information; moreover, we could explore how best to provide patients and medical professionals with trial information (such portal sites do not necessarily focus on clinical trials, but offer general medical information to patients and citizens) [5,6].

To understand the current state of distribution of general medical information or clinical research/trial information from medical facilities, a survey needs to be conducted among medical professionals. Our purpose is that the modification of the present Japanese clinical trial search portal site would address users' requests for a more user-friendly and convenient website for all users, including patients and their families, medical professionals, pharmaceutical companies, and researchers. Promoting participation in clinical trials and a greater understanding of clinical research would also be beneficial to the public. Some research article have been published that are associated

with this project [7,8]. After this survey, a prototype of the system that citizens and patients can easily access/use for information could be created and evaluated; this system should be useful for medical professionals as well.

Methods

This study protocol and questionnaire were approved by the institutional review board of the NIPH (approved number NIPH-IBRA#12029) on December 11, 2012. Self-administered questionnaires were delivered to medical professionals by post between January and February 2013. Intended respondents were the individuals in charge of the departments responsible for the distribution of information in various medical facilities. In total, 327 facilities, which were national centre hospitals (6 facilities), National Hospital Organization hospitals (145 facilities), national and private university hospitals (168 facilities) and other hospitals (8 facilities), participated in this study (Table 1). The questionnaire comprised items such as socio-demographic information (age, gender and profession), hospital information (type of facility, number of beds), 9 questions regarding the availability and distribution of general medical information, 19 questions regarding the availability and provision of clinical research/trial information and 13 questions regarding desired methods of distribution of clinical research/trial information in the future.

This study was analysed to determine the distribution of general medical information or clinical research/trial information whether hospital size is a small or large.

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Statistical analysis

The number of beds were categorised to establish the definitions for the 2 groups: 42 small facilities (less than 100 beds and out-patient facility alone) and 107 large facilities (300 or more beds). Categorical variables were dummy coded. All results were presented as proportions or means. The Pearson chi-square test and Fisher's exact test were used to compare the proportions. The two-sample t test was used to compare the means of the number of staff or the number of staff × number of days. Data were analysed using statistical analysis software (STATA 12.1 for Windows, State Corp LP, Texas, USA). The significance level (alpha) of the hypothesis test was 95% (i.e. p values <0.05 were considered statistically significant).

Results

In total, 165 medical facilities responded to questionnaires (response rate, 50.5%), and these were analysed in this study. The respondents comprised 94 (62.7%) males and 56 (37.3%) females. In addition, most respondents belonged to the age group of 50-59 years (55 respondents, 36.7%). Moreover, the most commonly reported profession of respondents was pharmacist (73 respondents, 49.0%). The types of facilities were National Hospital Organization hospitals (73 facilities), university hospitals (65 facilities), national centres (4 facilities) and other hospitals (11 facilities) (Table 1).

Distribution of general medical and clinical research/trial information

General medical information (Other than clinical research/trials): Responses to the two questions 'Do you have any services that provide general medical information and are there any specific departments that collect and provide general medical information' revealed no statistically significant differences between both groups based on the number of beds. The number of large facilities (more number of beds) which had websites providing information regarding general medical information was higher compared with other types of facilities (p = 0.038) (Table 2).

Clinical research/trial information: Responses to the questions do you have any services that provide clinical research/trial information, do you have any website that collects clinical research/trial information and do you have any website that provides clinical research/trial information revealed statistically significant differences between both groups (p<0.001). A small number of both large and small facilities reported that they received evaluations (feedback) from users (Table 2).

Resources for website management regarding general medical or clinical research/trial information

Current system of information distribution: The mean number of staff involved in the website's administration was 4.81 for the general medical information website and 3.52 for the clinical research/trial website. The most common answer regarding questions on operation or management of the clinical research/trial website was by them (Table 3).

Future information distribution regarding clinical research/trials: In case of you collect and provide information yourself at your facility, the mean value of staff × days per month required to collect and distribute this information was 19.61. In case of other facilities centrally collect and provide information. You just use and distribute that information, the mean value of staff × days per month required to

Socio-demographic factors	Number of valid cases	%	(n)
Gender	150/165 (90.9%)		
Male		62.7	(94)
Female		37.3	(56)
Age at survey	150/165 (90.9%)		
20-29 years		2.7	(4)
30-39 years		26.0	(39)
40-49 years		32.7	(49)
50-59 years		36.7	(55)
60-69 years		2.0	(3)
70-79 years		0.0	(0)
≥80 years		0.0	(0)
Profession	149/165 (90.3%)		
Medical doctors /Dentists		15.4	(23)
Nurses		1.3	(2)
Nurses and CRC		2.0	(3)
Pharmacists		49.0	(73)
Pharmacists and CRC		12.8	(19)
CRC		7.4	(11)
Technologists		0.7	(1)
Office worker		11.4	(17)
Type of facility	150/165 (90.9%)		
National centres		2.7	(4)
National hospital organisations		48.7	(73)
University hospitals		43.3	(65)
Other hospitals		5.3	(8)
Number of beds	149/165 (90.3%)		
Outpatient services only		0.7	(1)
0-19		0.0	(0)
20-99		7.4	(11)
100-299		20.1	(30)
≥300		71.8	(107)

Table 1: Respondent demographics
Medical professionals survey in 2013. CRC: Clinical Research Coordinator

collect and distribute this information was 11.71 (Table 3). Both large facility and small facility were not statistically significant.

Nature of the desired information distribution in future regarding clinical research/trials: When providing clinical research/trial information (conducted at our facility) to medical professionals such as doctors and the Clinical Research Coordinator (CRC), which is the desirable method for information distribution. For this, the most common response was by the website, which revealed statistically significant differences (p = 0.013) between both groups. However, the proportion of other answers distribution on leaflet, in conversation unnecessary and others revealed no statistically significant differences between both groups.

When providing clinical research/trial information (conducted at our facility) to patients and their families, which is the desirable method for information distribution. For this, the most common response in large facilities was by the website, which revealed statistically significant differences (p<0.001) between both groups. The proportion of the other answers Distribution on leaflet, in conversation, Unnecessary and Others revealed no statistically significant differences between both groups. Further, the responses Distribution on leaflet and in conversation were the most common results in terms of ideal ways to provide this information (Table 4).

Discussion

With the spread of Internet technology, several internet users often

Question	Number of beds (0-299) Groups#		Number of beds (≥300) Groups		Pearson chi-square	
	%	(n)	%	(n)	p value	
[General medical information]						
Do you have any services? (n = 147)	87.8	(36)	93.4	(99)	0.267	
Are there any specific departments that collect or provide? (n = 144)	30.0	(12)	42.3	(44)	0.175	
Do you have a website? (n = 147)	46.3	(19)	65.1	(69)	0.038	*
[Clinical research/trial information]						
Do you have any services? (n = 148)	45.2	(19)	87.7	(93)	0.000	***
Are there any specific departments that collect or provide? (n = 147)	28.6	(12)	62.9	(66)	0.000	***
Do you have a website? (n = 147)	33.3	(14)	79.1	(83)	0.000	***
With regard to your website, do you collect evaluations (feedback) from users? (n = 96)	0.0	(0)	18.8	(15)	0.059	

Table 2: Differences in general medical information or clinical research/trial information between large and small facilities
The Pearson chi-square test and Fisher's exact test (* p < 0.05, ** p < 0.01, *** p < 0.001) were used.
(#) including outpatient services only.

Question	Number of beds (0-299) Groups#		Number of beds (≥300) Groups	
	Mean staff	n	Mean staff	n
Current system of information distribution				
What is the number of staff for operation or management? [site's administrators]	5.69	16	4.51	46
Website creation [site's administration method]				
By yourself	11.2	5	2.6	20
By part-time staff	-	0	1.0	1
By IT sub-contractor	3.2	11	6.6	17
Others (include a combination of the above)	-	0	6.3	7
[Clinical research/trials information website]				
What is the number of staff for operation or management? [site's administrators]	2.23	13	3.73	77
Website creation [site's administration method]				
By yourself	1.7	6	3.8	46
By part-time staff	9.0	1	2.0	3
By IT sub-contractor	2.0	4	3.3	18
Others (include a combination of the above)	-	0	5.0	9
Question	Number of beds (0-299) Groups#		Number of beds (≥300) Groups	
	Mean (staff × day)	n	Mean (staff × day)	n
Future distribution of clinical research/trial information				
What amount of invisible resources do you need to do this?				
You collect and provide information yourself at your facility	23.79	29	18.22	87
Other facilities centrally collect and provide information. You just use and distribute that information.	15.38	29	10.45	84

Table 3: The number of resources used for website management regarding general medical information or clinical research/trial information
(#) including outpatient services only.

search for health information [7-10]. In this study, 70% responding medical facilities acknowledged that the most common method for distribution of general medical information was through the Internet. In addition, more than 50% respondents used brochures, posters and newsletters. In most facilities, general medical information was provided in a combination of ways. This allows the organisation to satisfy the information needs of patients and citizens who do not use the internet [9,11]. On the other hand, 77% medical facilities in this study acknowledged that they provided a service of clinical research/trial information and 83% of those facilities confirmed that the most

common method for distribution of clinical research/trial information was through the internet. In addition, >50% facilities used posters. Users seeking information regarding rare diseases (specific diseases) frequently use the Internet [10,12]; however, patients make their decisions regarding participation in trials using different methods (poster, leaflet website or email to medical professionals) [11,13]. It is difficult to determine which media is the best way of distributing information.

On the basis of the results of this survey, not many facilities (particularly among the small ones) had a system in place to receive

feedback regarding their website from users (patients and citizens). The access log analysis is a way to understand the behaviour of Internet information seekers [12-15]. Website evaluations are accessible and user-friendly, and therefore, this provides a good opportunity to receive feedback directly from the patients and citizens; however, after receiving such feedback, it needs to be verified with regard to the contents of the information provided and the actual information asked from users [14,16,18]. This study suggested that the quality of general medical information was better than that of clinical research/trial information. On the basis of the degree of dissemination of information from the website, it may also have an impact on public awareness regarding clinical research/trials. Accessible organisations such as consumer organisations should aggressively promote and disseminate such websites through various media channels [17,19], and it could be effective in increasing patients awareness regarding clinical research/trials.

Further, for website (general medical information) management, the number of staff in small facilities was slightly higher than in large facilities. Moreover, the professions of these staff members varied among various facilities. For several facilities, Information Technology

(IT) sub-contractors or the facility's own staff may be in charge of website creation. On the other hand, for website (clinical research/trial information) management, the number of staff in large facilities was slightly higher than in small facilities. The staff members' professions also varied among various facilities. CRC is familiar with the clinical research/trial information and is involved in website operation. For many of the facilities, IT sub-contractors or their own staff members are in charge of website creation. The number of medical professionals in a Japanese hospital is usually proportionately greater than the number of beds [18,20]. According to this study, in Japan, the work load is higher for websites run by small facilities compared with those run by large facilities because large facilities have more resources (staff) than the smaller ones. Therefore, large facilities can easily afford the creation, operation and management of their own websites. One possible reason for this may be that there is no scope for expansion of clinical research/trial information in human resources departments. Therefore, IT sub-contractors and facility staff need to co-operate with each other in order to create or update websites according to patients' opinion or feedback [19,21].

Question	Number of beds (0 - 299) Groups#		Number of beds (≥ 300) Groups		Pearson chi-square	
	%	(n)	%	(n)	p value	
What is a good method of distributing information to medical professionals?						
Website	59.5	(25)	80.0	(84)	0.010	*
Leaflet distribution	52.4	(22)	59.1	(62)	0.461	
Word of mouth	23.8	(10)	34.3	(36)	0.216	
Unnecessary	2.4	(1)	1.9	(2)	0.854	
Others	4.8	(2)	6.7	(7)	0.663	
What is a good method of distributing information to patients and their families?						
Website	27.5	(11)	73.8	(79)	0.000	***
Leaflet distribution	80.0	(32)	72.9	(78)	0.377	
Word of mouth	55.0	(22)	43.9	(47)	0.231	
Unnecessary	0.0	(0)	0.9	(1)	0.540	
Others	2.5	(1)	3.7	(4)	0.712	
Which organisations should proactively inform about the clinical trial/research website?						
Each facility and institute	47.6	(20)	54.2	(58)	0.469	
Organisational headquarters	31.0	(13)	30.8	(33)	0.989	
Research Institute, National Centre for Global Health and Medicine	14.3	(6)	15.9	(17)	0.808	
Pharmaceutical companies	23.8	(10)	35.5	(38)	0.169	
Medical conferences and academic institutions	9.5	(4)	27.1	(29)	0.020	*
National and local public organisations	16.7	(7)	20.6	(22)	0.589	
PMDA (Pharmaceuticals and medical devices agency)	47.6	(20)	54.2	(58)	0.469	
Others	0.0	(0)	4.7	(5)	0.154	
What do you think is the best way to disseminate clinical research/trials information for compliance awareness for patients?						
At your institution	54.8	(23)	50.0	(53)	0.601	
Publicity through reliable media, such as television or newspapers	45.2	(19)	61.3	(65)	0.075	
Government-led education	31.0	(13)	38.7	(41)	0.379	
Internet	42.9	(18)	34.9	(37)	0.367	
School education and lifelong learning	11.9	(5)	35.9	(38)	0.004	**
Others	0.0	(0)	2.8	(3)	0.271	

Table 4: Questions regarding future methods for the desired manner of information distribution regarding clinical research/trials. The Pearson chi-square tests and Fisher's exact tests ($p < 0.05$, $**p < 0.01$, $***p < 0.001$) were used. (#) including outpatient services only.

When information regarding clinical research/trials has been distributed through a website, each facility or Pharmaceuticals and medical devices agency (PMDA) [20,22] should pro-actively provide the necessary details and information. Several respondents replied that a specific organisation should centrally archive medical information (including the general medical information), and each facility should share this information using links or other methods. A good example of such a website is the website of the National Health Service (NHS) in the United Kingdom (NHS Choices), which provides easy access to both general medical information as well as clinical research/trial information [21-24]. If each hospital can link to the one-stop portal site such as NHS Choices website through their hospital website, the accessibility and quality of information would improve for all citizens, patients and medical professionals. It is considered that many facilities desire to provide guarantee of accuracy and quality control, with the use of standardised items, regulation for presentation of information and toolkit and professional guidance. The consistent use of certified assessments such as Health On the Net Code (HONCode) [23,25], Japan Quality Health Care Organization [24,26] and Japan Internet Medical Association [25,27] would help to ensure the reliability of the website. Several studies have pointed out that quality is a problem on the Internet [26,28]. Nevertheless, good quality information on reliable websites which are recommended by doctors (medical professionals) could satisfy the information needs of patients [27,29]. Further, several information providers believe that when sharing information, the national research institutes or the government should collect and manage detailed clinical research/trial information regarding national guidelines in the future. However, few limitations of the website mentioned here include the fact that it is not linked to hospitals or associations, not many individuals from the general population know that the information exists or how to access it and that patients and citizens are not aware of the existence of the useful information [28-31]. It could be considered that the National Institute of Public Health may play a role in information management. We have not found clearly how to promote the clinical research/trials in this study. However, it is a challenge a greater understanding the clinical research/trials. It needs to increase the opportunities to learn the clinical research/trials especially for the public. It would be one of the good examples that there is a guideline for clinical research/trials information distribution regardless of hospital size.

Conclusions

We confirmed that several medical facilities provide clinical research/trial information to the general population. We found that awareness regarding clinical research/trial information provided on a website was different between small and large facilities. However, it is necessary to consider the distribution of the content of information which is required by the patients and citizens. For greater awareness, it is necessary that medical facilities consider the method of information delivery from the viewpoint of patients and citizens, regardless of whether they are a small or large facility.

On the basis of several opinions regarding this, the current portal site, i.e. the clinical research/trial information search portal site, needs improvement for its function in the National Institute of Public Health. We believe that this website would benefit from being well-known to many medical facilities as one of the choices of information distribution, which would in turn centralise clinical research/trial

information in Japan.

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