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Trust in physicians and definitive diagnosis time among Japanese patients with specific intractable diseases: A cross-sectional study

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SUMMARY Trust in physicians is an important metric in shared decision-making. Many patients with rare diseases experience misdiagnosis or delayed diagnosis because of difficulties in diagnosis or access to specialists. What impact do these have on trust in physicians? This study focused on patients with rare diseases, evaluated the effects of a delayed diagnosis and misdiagnosis on trust in physicians, and clarified the backgrounds of patients who have experienced delayed diagnoses. Patients with any of the 334 intractable diseases in Japan were registered, and a questionnaire survey was conducted on 1,000 valid registrations. Scores were calculated on a five-point Likert scale, and Cronbach's alpha coefficient was calculated to determine internal consistency, which was 0.973. Independent sample t-tests and analysis of variance were used to compare average trust scores based on patient demographics. The mean trust in physician score of patients who waited ≤ 1 year until definitive diagnosis was 47.66 ± 11.69, while those of patients who waited > 1 year was 45.07 ± 11.63 (p = 0.004). The average trust scores of patients with or without a misdiagnosis were 46.69 ± 11.96 and 47.22 ± 11.65 (p = 0.550), respectively. Among patients with time to a definitive diagnosis of > 1 year, 62.8% had a period from symptom onset to initial hospital visit of > 1 year. A longer time to definitive diagnosis lowered the degree of trust in physicians. Many patients who experienced delayed diagnoses also had a long time from symptom onset to the initial medical visit. This aspect is important for understanding the background of patients who experienced delayed definitive diagnoses.

Keywords delayed diagnosis, misdiagnosis, rare diseases, shared decision-making, symptoms

1. Introduction

The conventional relationship between patients and physicians is a passive-active relationship between a helpless patient suffering from an illness and a physician trying to save the patient. Physicians use their knowledge and skills to select treatment methods that effectively restore health and relieve pain. Subsequently, information is provided to the patient, but the mainstream perspective assumes that the patient would agree with the physician's choice or so-called paternalism (*1*). However, in recent years, shared decision-making (SDM) has been established, in which physicians and patients share information and deepen mutual understanding to make appropriate treatment decisions (*2*). This patient-centered approach to medicine is described as one in which "physicians seek to enter the patient's world and see the disease through the patient's eyes" (*3*). The patients make their final medical decision based on all of the information provided by the physician. Various mechanisms are believed to influence this important decision-making process. One of these is the patient's trust in their physician. Trust in physicians is an important metric when implementing SDM (*2*).

When a patient visits a hospital, an appropriate diagnosis is promptly made, and the patient selects a treatment approach from several options provided by a physician. In other words, SDM is conducted sincerely, and the patient is involved in the decision-making. This process is acceptable for patients in today's advanced medical care. However, there are diseases for which this process is unclear due to the difficulty of diagnosis and treatment methods. One of these is rare diseases. It can take a long time to reach a definitive diagnosis for many rare diseases owing to the difficulty of diagnosis and the lack of access to specialists (*4,5*). Furthermore, treatment options are limited, and patients face many challenges (*4,6*). Even under such circumstances, sincere SDM should still be implemented, but can trust in physicians, which mainly influences this mechanism, be maintained at a high level? Alternatively, what types of changes will occur in that trust? Although the individual prevalences

of these diseases are small, rare diseases represent a significant public health challenge in terms of the cumulative number of patients since there are thousands of rare disease cases worldwide (*1,5*). Few studies have examined trust in physicians among patients with rare diseases. The first purpose of this study was to evaluate how delayed diagnosis or misdiagnosis of rare diseases affects patients' trust in physicians. The International Rare Diseases Research Consortium (IRDiRC) has been working to improve international collaboration and take action to reduce the time required for patients with rare diseases to receive a definitive diagnosis after visiting a medical institution (*4*). Reducing the time to a definitive diagnosis of a rare disease as much as possible is important in improving a patient's quality of life (QOL) and implementing SDM. In addition to evaluating changes in trust in physicians, we also aimed to understand the backgrounds of patients who experienced a delayed diagnosis. In this study, we evaluated patients with rare diseases with a definitive diagnosis of any of the 334 diseases specified as intractable in Japan (*7*).

2. Materials and Methods

This study was conducted in August 2022 using the Rakuten Insight patient panel. A questionnaire survey was conducted on 1,000 patients with a definitive diagnosis of any of the 334 diseases specified as intractable in Japan. The data used in this study were outsourced to Rakuten Insight, Inc., and were obtained using their panel. All data obtained from Rakuten Insight, Inc. were anonymized before analysis. In addition, the data were unconnected and completely anonymized. We did not have access to the anonymization correspondence table or any personal identifiable information. Therefore, this study was exempted from ethical approval by the Research Ethics Review Committee of the Graduate School of Health Innovation, Kanagawa University of Human Services, as the study used a fully anonymized questionnaire survey (notification number SHI No. 52). Participants were informed about the purpose of the research and their participation implied consent.

A 13-item questionnaire was used to obtain a trust score that indicated the patient's degree of trust in their physicians. A questionnaire survey was conducted among physicians currently treating the patients. Questionnaire responses were given scores of 5, 4, 3, 2, and 1 for the options of "extremely strongly agree", "strongly agree", "somewhat agree", "somewhat disagree", and "disagree completely". These were calculated on a five-point Likert scale. Trust analysis was conducted by calculating Cronbach's alpha coefficient for internal consistency of trust in physicians.

Independent sample *t*-tests and analysis of variance were used to compare the average trust scores by sex, age group, marital status, educational background, and occupation. Trust in doctors' scores was used as the dependent variable, and sex, age group, marital status, educational background, and occupation as independent variables. The *t*-test was conducted for average physician trust scores according to the presence or absence of a misdiagnosis experience. $P < 0.05$ was considered statistically significant. Patients with a misdiagnosis were asked to provide free responses to specify which diagnosis they were given in cases where a definitive diagnosis was not made.

The IRDiRC has set the goal of ensuring that everyone with a rare disease receives an accurate diagnosis, care, and available treatment within 1 year by 2027 (*4*). Since no standard definition of a delayed diagnosis exists, this consortium's guidelines were used as a standard. We divided patients into two groups: those with a time to a definitive diagnosis of ≤ 1 year and those with > 1 year and calculated the respective average physician trust scores. We further divided the two groups into four categories according to the presence or absence of misdiagnosis, calculated the respective physician trust scores, and conducted analyses of variance.

We asked, "When did you start to suspect this disease?" from the time of definitive diagnosis. Patients were divided between those with a period of ≤ 1 year from that date to the date of definitive diagnosis and those with > 1 year. These two categories are presented using a pie graph.

Answers to the question, "How long did it take from the time you felt something was wrong with your body until you went to the hospital for the first time?" were used to divide patients between those with a time to a definitive diagnosis of ≤ 1 year and those with > 1 year. These two categories are presented in a pie graph. This study used IBM's SPSS statistical software ver. 28 for statistical analysis.

3. Results

A questionnaire survey was conducted on 1,000 patients diagnosed with any of Japan's 334 diseases specified as intractable. Table 1 shows the characteristics of the participants. Men comprised 60.4% of participants. The most common age group was 30–49 years, accounting for 35.0%. Married participants comprised 63.1% of the total population. The most common educational level was university graduate, accounting for 39.2% of the total. By occupation, those employed by companies were the most common (34.7 %), followed by those unemployed (31.9 %).

Table 2 shows the number and percentage of patients with major specified intractable diseases who participated in this survey and the number and percentage of patients registered with specified intractable diseases reported by the Ministry of Health, Labor, and Welfare in 2020 (*8*). According to a Ministry of Health, Labor, and Welfare report, Parkinson's disease was the most registered intractable disease, accounting for 13.8% of all

registrations. However, in the present survey, the disease prevalence was low, accounting for only 2.9%. The overall registration profile was similar to the Ministry of Health, Labor, and Welfare data.

Table 1. Characteristics of the study sample

Characteristic	Categories	Number	Percentage (%)
Sex	Male	604	604
	Female	396	396
Age	< 29 years	18	18
	30–49 years	350	350
	50–59 years	295	295
	60–69 years	242	242
	> 70 years	95	95
Marriage	Married	631	631
	Others	369	369
Education background	Junior school	21	21
	High school	299	299
	Professional school	134	134
	Junior college	94	94
	Bachelor degree	392	392
	Master degree and above	54	54
	Other	6	6
Occupation	Company employee	347	347
	Self-employed	79	79
	Government employee	35	35
	Teacher	20	20
	Contract worker / Temporary worker	52	52
	Part-time job	88	88
	Student	3	3
	Unemployed	319	319
	Other	57	57

We asked 13 questions about patients' trust in their physicians (Table S1, *http://www.irdrjournal.com/action/getSupplementalData.php?ID=144*). The average patients' physician trust scores were calculated using a Likert scale. Trust in these question items was evaluated using Cronbach's alpha for internal consistency. The result was 0.973, indicating a sufficiently explainable internal consistency level for these question items. The overall average score was 47.10 (total score of 65.00). This trust score was used in subsequent research.

We compared average trust scores according to sex, age, marital status, educational level, and type of occupation using an independent *t*-test or analysis of variance to investigate the influence of each characteristic on trust in physicians by category (Table 3). Significant differences were observed regarding age ($p = 0.005$) and marital status ($p = 0.012$). For age, subsequent multiple regression analysis (Bonferroni method) showed that the trust in physicians score of those aged 30–49 years was significantly lower than that of those aged 60–69 ($p = 0.008$). Previous studies have focused on sociodemographic characteristics when investigating physician trust scores (*9-13*). Among these, a statistically significant difference has been reported in the respective trust scores of age and marital status (*13,14*). This trend was repeated in the present study in patients with specified intractable diseases.

The time to definitive diagnosis in patients with specified intractable diseases in Japan is shown

Table 2. Major patients with specified intractable diseases registered in this survey

Specified intractable disease	This survey		Data from the Japanese MHLW*	
	Number	Percentage	Number	Percentage (%)
Ulcerative colitis	223	22.3	140,574	13.6
Systemic lupus erythematosus	57	5.7	64,468	6.2
Sjögren's syndrome	49	4.9	17,628	1.7
Crohn's disease	49	4.9	47,633	4.6
Posterior longitudinal ligament ossification	37	3.7	36,401	3.5
Idiopathic dilated cardiomyopathy	30	3.0	20,387	2.0
IgA nephropathy	30	3.0	12,699	1.2
Parkinson's disease	29	2.9	142,375	13.8
Multiple sclerosis/neuromyelitis optica	29	2.9	21,437	2.1
Moyamoya disease	27	2.7	13,894	1.3
Myasthenia gravis	25	2.5	25,416	2.5
Eosinophilic sinusitis	25	2.5	13,404	1.3
Polycystic kidney disease	24	2.4	11,935	1.2
Behcet's disease	23	2.3	15,537	1.5
Sarcoidosis	21	2.1	16,138	1.6
Dermatomyositis/polymyositis	20	2.0	24,894	2.4
Idiopathic thrombocytopenic purpura	17	1.7	18,793	1.8
Idiopathic femoral head osteonecrosis	17	1.7	20,003	1.9
Spinocerebellar degeneration (excluding multiple system atrophy)	16	1.6	27,365	2.6
Systemic scleroderma	15	1.5	27,647	2.7
Retinitis pigmentosa	14	1.4	23,979	2.3
Anterior hypopituitarism	13	1.3	18,653	1.8
Primary biliary cholangitis	13	1.3	17,993	1.7
Pustular psoriasis (disseminated)	11	1.1	2,058	0.2
Idiopathic interstitial pneumonia	11	1.1	17,589	1.7

*Excerpt from an example of a health administration report by the Ministry of Health, Labor, and Welfare in 2020 (*http://www.mhlw.go.jp/toukei/list/36-19.html*).

in Table S2 (*http://www.irdrjournal.com/action/getSupplementalData.php?ID=144*). The time to definitive diagnosis was ≤ 1 year in 78.2% of patients. Furthermore, 21.8% of all patients had a time of > 1 year. Patients aged > 21 years comprised 3% of all patients. The data showed that patients with intractable diseases required a long time to obtain a definitive diagnosis. Subsequently, we investigated patients who were misdiagnosed before the definitive diagnosis, and the results showed that those who were misdiagnosed comprised 22.8% of the total. A *t*-test was used to compare the average trust scores of patients with or without a misdiagnosis, and the results showed no significant differences. Table 4 shows the major intractable diseases in patients with time to a definitive diagnosis of > 1 year. The ratio of each disease to this study's total number of registrations is also shown. Sjögren's syndrome and ulcerative colitis each accounted for 17 cases. Regarding Sjögren's syndrome, the percentage of registered cases was relatively high (34.69 %). Among the diseases with at least 10 cases, eosinophilic sinusitis and polycystic kidney disease were high (48.00% and 41.67%, respectively). Additionally, ankylosing spondylitis had a high probability. However, there is a need to further expand the scale of the study in the future to make a clear judgment because the number of cases was small.

Table S3 (*http://www.irdrjournal.com/action/getSupplementalData.php?ID=144*) shows the results of the free responses from patients who experienced misdiagnosis and were asked to specify the misdiagnosis. Depending on the disease, patients experienced multiple misdiagnoses before a definitive diagnosis. Figures 1A and 1B show a pie graph depicting the time to definitive diagnosis for patients who experienced misdiagnosis and

Table 3. Comparison of trust in doctors score based on participants' characteristics

Characteristic	Categories	Trust in doctor scores (mean ± SD)	*p* value
Sex	Male	47.55 ± 11.51	0.131
	Female	46.40 ± 12.02	
Age	< 29 years	47.56 ± 9.55	0.005*
	30–49 years	45.24 ± 11.73	
	50–59 years	47.54 ± 12.10	
	60–69 years	48.53 ± 11.70	
	> 70 years	48.80 ± 10.07	
Marriage	Married	47.81 ± 11.53	0.012*
	Others	45.88 ± 11.96	
Education background	Junior school	49.38 ± 10.97	0.548
	High school	46.33 ± 11.93	
	Professional school	46.72 ± 12.47	
	Junior college	46.69 ± 11.03	
	Bachelor's Degree	47.48 ± 11.62	
	Master's degree and above	48.65 ± 10.63	
	Other	52.50 ± 13.52	
Occupation	Company employee	46.18 ± 11.95	0.574
	Self-employed	46.20 ± 10.95	
	Government employee	47.06 ± 11.06	
	Teacher	47.55 ± 11.01	
	Contract worker / Temporary worker	46.04 ± 12.63	
	Part-time job	48.73 ± 10.80	
	Student	49.67 ± 13.28	
	Unemployed	47.97 ± 11.76	
	Other	47.16 ± 12.27	

*Statistical significance: $p < 0.05$; independent sample *t*-test and ANOVA performance for comparison of means.

Table 4. Highest number of patients with rare diseases with a definitive diagnosis exceeding 1 year

Diseases	Number of patients	Number of registrations	Percentage (%)
Sjögren's syndrome	17	49	34.69
Ulcerative colitis	17	223	7.62
Crohn's disease	14	49	28.57
Systemic lupus erythematosus	13	57	22.81
Eosinophilic sinusitis	12	25	48.00
Polycystic kidney disease	10	24	41.67
IgA nephropathy	9	30	30.00
Posterior longitudinal ligament ossification	8	37	21.62
Parkinson's disease	7	29	24.14
Idiopathic dilated cardiomyopathy	6	30	20.00
Anterior hypopituitarism	5	13	38.46
Moyamoya disease	5	27	18.52
Multiple sclerosis/neuromyelitis optica	5	29	17.24
Spinal muscular atrophy	4	9	44.44
Muscular dystrophy	4	9	44.44
Idiopathic interstitial pneumonia	4	11	36.36
Sarcoidosis	4	21	19.05
Behçet's disease	4	23	17.39
Ankylosing spondylitis	3	3	100.00
Amyotrophic lateral sclerosis	3	4	75.00
Malignant rheumatoid arthritis	3	8	37.50
Ligamentum flavum ossification	3	8	37.50
Pustular psoriasis (disseminated)	3	11	27.27
Spinocerebellar degeneration (excluding multiple system atrophy)	3	16	18.75
Idiopathic femoral head osteonecrosis	3	17	17.65
Myasthenia gravis	3	25	12.00

those who did not. Patients who did not experience a misdiagnosis and had a time to a definitive diagnosis of > 1 year were 18.1% of the total. In comparison, patients who were misdiagnosed and had time to a definitive diagnosis of > 1 year were 34.2% of the total.

Subsequently, we used the IRDiRC guidelines as a standard to divide patients with time to a definitive diagnosis of ≤ 1 year and > 1 year and calculated the average physician trust score for each group (Table 5). The results showed that the physician trust score for patients with time to a definitive diagnosis of > 1 year was significantly lower than that for patients with a time of ≤ 1 year ($p = 0.004$). Additionally, we compared the physician trust score among patients with time to a definitive diagnosis of ≤ 1 year and > 1 year according to whether the patient experienced a misdiagnosis. There were no significant differences in physician trust scores among patients with time to a definitive diagnosis of ≤ 1 year, according to the experience of misdiagnosis. However, patients with time to a definitive diagnosis of > 1 year who experienced a misdiagnosis had the lowest physician trust scores. We performed an analysis of variance of the average physician trust scores between these four groups, and the results showed statistically significant differences.

Subsequently, we asked, "When did you start to suspect this disease, starting from the time of definitive diagnosis?" We divided the answers to this question between patients with time to a definitive diagnosis of ≤ 1 year and those with a time > 1 year and presented the results in a pie graph (Figure 1B and 1C).

The results showed that the number of patients with no suspicion of their underlying disease from the beginning was the highest for both categories. The number of patients who suspected the disease for > 1 year was 28.9%, higher than that of those who suspected the disease for ≤ 1 year. Therefore, patients who experienced a delayed diagnosis had suspected their disease for > 1 year but took a long time to reach a definitive diagnosis.

The answer to the question, "How long did it take from the time you felt something was wrong with your body until you went to the hospital (for the first time)?" was divided into two categories: time to a definitive diagnosis of ≤ 1 year and > 1 year, and investigated. The

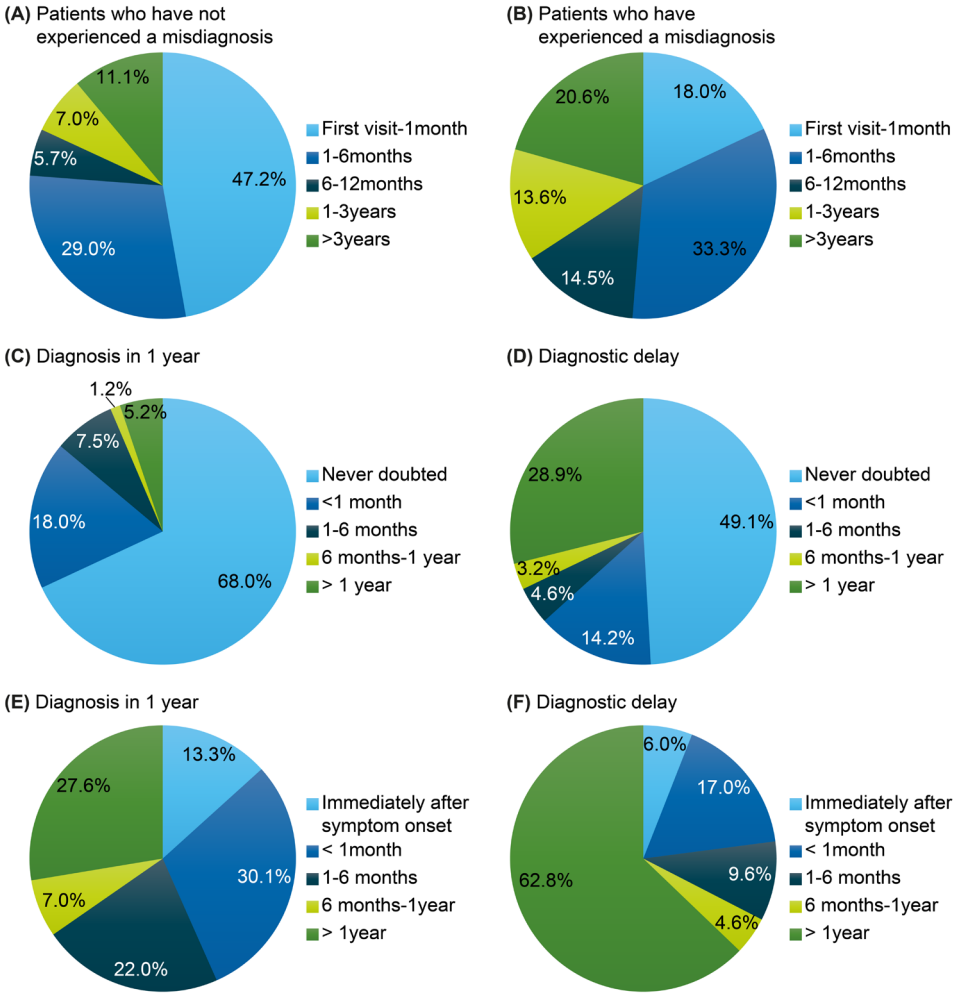

Figure 1. (A) and (B) reflect the period to a definitive diagnosis of patients who have or have not experienced misdiagnosis; (C) and (D) note the period patients suspected the disease before a definitive diagnosis; (E) and (F) reflect the period between symptom onset and first hospital visit.

Table 5. Comparison of trust in doctors between the period of definitive diagnosis and misdiagnosis

Period until definitive diagnosis	Categories	Trust in Doctor Score (mean ± SD)	*p* value
First visit ≤ 1 year	All	47.66 ± 11.69	0.004*
> 1 year	All	45.07 ± 11.63	
First visit – 1 year	Without misdiagnosis experience	47.63 ± 11.63	0.035*
First visit – 1 year	With misdiagnosis experience	47.79 ± 11.72	
> 1 year	Without misdiagnosis experience	45.35 ± 11.72	
> 1 year	With misdiagnosis experience	44.56 ± 11.72	

*Statistical significance: $p < 0.05$; independent sample *t*-test and ANOVA performance for comparison of means.

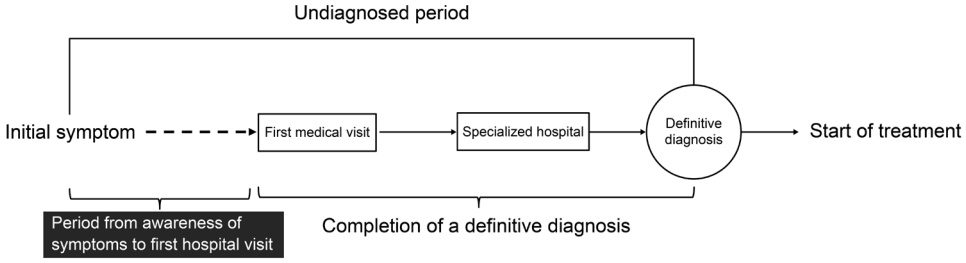

Figure 2. Diagram of the process from initial symptoms to a definitive diagnosis.

results are presented in Figures 1E and 1F.

For the category with time to a definitive diagnosis of > 1 year, patients who responded that the time from when they felt something was wrong with their body to the first hospital visit was > 1 year comprised 62.8% of the total. This was higher than the 27.6% in the category with a time to a definitive diagnosis of ≤ 1 year. Patients who experienced a long time from the initial hospital visit to a definitive diagnosis reported a long period from when they felt something was wrong with their body to the first hospital visit.

4. Discussion

Access to an appropriate diagnosis is difficult for rare diseases, and delays frequently occur (*4*). Patients face many difficulties because of delayed diagnosis. To solve this problem, the IRDiRC aims for everyone with a rare disease to have an accurate diagnosis and receive prompt care and available treatments by 2027 (*4*). From the perspective of SDM, it is important to maintain a relationship of trust between the physician and patients, from diagnosis to available treatment.

The first important achievement of this study is that we clarified the changes in patient's trust in physicians during the period leading to definitive diagnoses in patients with rare diseases. We used the IRDiRC statement as a standard and compared the physician trust scores of patients with time to a definitive diagnosis of ≤ 1 year and those with > 1 year. Physician trust scores declined significantly when the time to definitive diagnosis was > 1 year. The time to definitive diagnosis had a greater influence on the degree of trust in physicians than the presence or absence of a misdiagnosis experience. These results will be of great interest. On the other hand, many patients who experienced a misdiagnosis had a time to a definitive diagnosis of > 1 year. In other words, misdiagnosis prolongs the time to a definitive diagnosis. This result demonstrates the difficulty of definitively diagnosing rare diseases. If a rare disease is suspected, one solution is to use the domestic medical network and prepare a medical environment where an appropriate diagnosis can be made. Furthermore, efforts to create networks of information on a global scale by organizations such as IRDiRC are anticipated in the future. In this study, 28.9% of patients with time to a definitive diagnosis of > 1 year were suspected of having an intractable disease for > 1 year. Patients experienced a long time to definitive diagnosis; however, it was suspected to be an intractable disease from their symptoms. We hope that our future in-depth follow-up interviews with patients with intractable diseases will provide a more detailed interpretation of this observation.

The second important achievement of this study is that we clarified that patients with time to a definitive diagnosis of > 1 year included those with a period from symptom onset to the initial hospital visit of > 1 year. Many studies have focused on shortening the time from the initial hospital visit to a definitive diagnosis in patients with rare diseases. It is important to use the above-mentioned information network to establish a system that can appropriately test for rare diseases; however, the undiagnosed period includes the period from symptom onset to the time of hospital visits. In other words, giving patients a strong motivation to see a physician as soon as possible after the first symptoms appear is important to improve the QOL of patients with rare diseases (Figure 2). In the future, we would like to clarify why patients took a long time from the symptom

onset to the initial hospital visit in additional in-depth interviews; however, one possibility is that the diagnosis was delayed because of the patient's residence locations or physical disabilities. Spreading awareness of remote diagnoses and eliminating disparities in medical care between rural and urban areas may improve this.

Finally, we showed that a delay in definitive diagnosis reduces patients' trust in physicians. In other words, avoiding diagnosis delays may help maintain trust in physicians and promote SDM. Furthermore, we showed that motivating patients to visit the hospital as soon as possible after symptom onset is necessary to improve the QOL of patients with rare diseases. In addition, the time to diagnosis may be further shortened if the government and related medical services encourage people to visit medical institutions and support such actions.

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