

1.5 ± 1.2, respectively), followed by publication through the media (0.9 ± 1.1) and communication via company websites (0.4 ± 0.8).

67.3% of respondents considered that disclosure of the safety risk management plan was useful, with the expectation that this would make it easier to gain the cooperation of healthcare professionals and patients in ensuring effective implementation, and by reason of the public significance of ensuring the transparency of post-marketing activities. Concern was expressed over the potential of explicit scientific language to provoke unnecessary misunderstanding and unrest among patients, and over the need to tailor the language in such disclosures for lay people.

#### Other comments

Among the numerous comments, notable responses included the need to establish a single integrated mechanism to communicate drug information to healthcare professionals and patients; the need to consider benefit-risk balance and the accurate comprehension of risks during risk communication; the expectation that the media should be a responsible party not only in always-negative but also positive involvement with responsibility in public risk communication; and the need for official guidelines and a regulatory department specialized in direct communications with healthcare professionals, taking into account the seriousness of the risk.

#### Discussion

Here, we comprehensively investigated drug company perspectives on current risk communications for drug safety. To our knowledge, this is the first such study conducted in Japan.

The response ratio of 70% was considered sufficient to ensure the external validity of the survey results, and was additionally strengthened by the following considerations. More than 10 of the targeted companies are considered to be currently inactive or to have reduced post-marketing pharmacovigilance activities because their products are generic, legacy, or licensed out to other companies, and accordingly might not have responded to the survey. Foreign capital companies account for 25.6% of all member companies of the JPMA (Japan Pharmaceutical Manufacturers Association 2013), which is consistent with the ratio of domestic to foreign capital among the firms responding to this survey. Responses were predominately from large-scale companies with more than one thousand regular employees, which account for the majority of pharmaceutical companies selling newly developed pharmaceutical products in Japan. Many respondents appeared to be sufficiently experienced in the area of pharmacovigilance to provide adequate answers.

#### Contents

To be successful, messages for risk communications need to convey a balance of multiple conflicting requirements: they need to be written in a clear, simple and comprehensive manner on topics that are relevant and important, and yet at the same time they need to be brief (Seligman and Osborne 2009; Mazor et al. 2005). We found that many companies prioritized the strength of evidence and place a high value on comprehension, probably because of their intent to ensure the credibility of the message. This appears to reflect the principle that the effectiveness of risk communication depends on the creditability of the message (Bahri and Harrison-Woolrych 2012b). Aspects at the next ranking level, 'Stratification of patients with regard to harm' and 'Number of people affected by harm', likely include the expectation of behavioral changes in medical practice as a consequence of the communication. This question lacked an option of 'mention of what should be done differently' since the Media Doctor rating criteria lack it; nevertheless, the comments of several respondents regarding the question on the creation of messages emphasized the importance of the outcome of message transmission, indicating that pharmaceutical companies are likely to next focus on the effectiveness of message transmission. The EU and US guidelines clearly recommend that communication plans include the assessment of effectiveness, such as quantification of behavioral changes, survey of comprehension, and reductions in adverse event reporting (Edwards and Chakraborty 2012; The US Food and Drug Administration 2009; European Medicines Agency 2013). The Japanese regulations for the provision of DHCP letters, in contrast, requires a pharmaceutical company to assess only the distribution of the communication materials to medical institutions and practitioners in the communication plan. Unlike the EU and US plans, therefore, the Japanese communication plan does not address 'true effectiveness' (Pharmaceuticals and Food Safety Bureau 2011a). The introduction of risk management planning in Japan, although delayed until April 2013, urges the Japanese regulatory community to change the poor methodology of the current method of assessing communication practices (Pharmaceuticals and Food Safety Bureau 2012).

#### Targets

Stakeholders and the message to be communicated in risk communications vary depending on the type of harm/risk. Communication with the most prioritized targets, physicians and pharmacists, was considered mostly successful, indicating that drug companies focused intensively on these two occupations, as evidenced by the considerable time allocated to them shown in the other question item. Patients were rated as third; however, risk communication with patients was rated as less successful

than that with the reference in-company division in this survey. Drug companies in Japan communicate with patients in an indirect and unidirectional fashion via healthcare professionals, patient-oriented handouts, and corporate websites. Direct-to-consumer advertisements are legally prohibited, and drug company activities and publications directed to patients are strictly regulated. Given the comparatively small work-time allocation to patients, the high prioritization given to patients as communication targets in this survey therefore likely represents corporate policies and conceptual but unsubstantial patient-oriented attitudes.

We found the lower ranking of the regulatory authority as a communication target to be inconsistent with the finding that the regulatory authority received the largest work-time allocation. Pharmaceutical companies are required to consult the regulatory authority when commencing regulatory actions involving risk communication activities which target healthcare professionals and the public. We speculate that the drug companies may be concerned about being seen as excessively authority-oriented, with a view to subsequent publication of the survey results. Additionally, risk communications with the regulatory authority were all rated successful or better. We speculate that respondents might have censored their responses by selecting the socially "harmless" answer 'successful' to telegraph that they had no particular concerns in their relationship with the regulatory authority.

### Measures

Generally, DGPs obtained a good appraisal, particularly in terms of readability and contents. As respondents pointed out, however, they are poorly recognized by the public; in a survey of 1,707 people who had undergone a regular physical examination, for example, only 2% had experienced accessing a DGP and only 15% were in fact actually aware of them, and an initiative to attract patient attention to this material is therefore warranted (Suka 2011). Consistent with the US medication guides, the scope of drugs requiring the preparation of DGPs is limited (The US Food and Drug Administration 2011). However, more than half of respondents supported extension of the preparation of DGPs to all prescription drugs, as does the UK Patient Information Leaflet (Committee on Safety of Medicines 2005). In Japan, prescription drugs are dispensed with a consumer medication information (CMI) sheet, which includes a small picture of the drug in its dosage form and a brief description of its usage, dosage and adverse reactions. These are prepared by the dispensing pharmacy, which primarily sources them from non-authorized drug information databases maintained by private claims reimbursement computer system vendors. In this regard, a survey of the US CMI sheets reported that the

contents were of low quality, and urged their improvement (Kimberlin and Winterstein 2008; Raynor et al. 2007). In contrast, DGPs provide several pages of rich and detailed content for patient self-instruction and are developed by the supplying pharmaceutical company and reviewed by the regulatory authority at the expense of national insurance subscribers and patients, although many are currently in disuse. Utilization of DGPs as legitimate source documents for the preparation of CMIs at dispensing pharmacies is strongly recommended. Achieving this will require that all information in individual DGPs for all prescription drugs become publicly available through an official online database with easy accessibility using the Standard Generalized Markup Language.

Our survey respondents also positively noted the efficiency and effectiveness of drug information websites run by the pharmaceutical companies. Although some respondents expressed concern that the information posted on company-run websites is likely to be partial and one-sided (Davis et al. 2007), one study reported that lay people considered that the credibility of information on regulatory agency and pharmaceutical company websites was comparable (Kim 2011). The low usability of the PMDA website noted in our survey appears to result from its tangled, multiroute, multistep path from the home page to target information, and from the awkwardly organized, overlapping information and PDF regulatory documents attached to many webpages. This should be improved by usability testing from the perspective of the public, without influence by the regulatory perspective (Bahri and Harrison-Woolrych 2012b; European Medicines Agency 2013). The significance and importance of internet use in searching and querying drug information was shown in our separate surveys, which found that 37.4% of community pharmacists had utilized company-run websites and that 43% of people who received regular health checkups had had a chance to browse for drug information on the Internet (Suka 2011). The very major importance of official, integrated, and strategic web-based provision of drug information should therefore be acknowledged. The EMEA websites may be referenced as sophisticated examples, and the EU is also planning to establish a single consolidated online database for drug information (European Medicines Agency 2013).

The respondents appreciated the significance of direct communication of risk information by the regulatory agency, especially in case of emergency. Current Japanese regulatory advisories, including revision of label information, issuance of DHCP letters, and other safety notifications often require intensive and sometimes contentious preliminary discussion, followed by tough negotiation before agreement between the regulatory authority and

pharmaceutical company is reached. These likely represent the most resource-consuming tasks on both sides. The risk communication measures implemented by drug companies under the strict oversight of the regulatory agency may therefore take considerable time until the dispatch of key risk messages can proceed, which might in turn impair the timeliness of risk mitigation actions, and also compromise the effectiveness and transparency of communications. Indeed, in July 2011, coincidentally after the close of this survey, the PMDA launched a new website "On information concerning the risks of drugs under evaluation" within its "Pharmaceuticals and Medical Devices Information Homepage", similar to the Drug Safety Communication by the US FDA (Pharmaceuticals and Food Safety Bureau 2011b; Seligman and Osborne 2009). Further effective utilization of direct and rapid communication by the regulatory agency is desirable.

The media were recognized as and expected to play an essential role in emergency risk communications by the pharmaceutical company side. This expectation was in contrast to the lower success rating for communications targeted to mass media, and the smaller resource allocation to them. The effectiveness of risk minimization activities such as DHCP letters is reportedly influenced by whether the risk receives wide media publicity (Weatherby et al. 2001; Urushihara et al. 2011; Waller et al. 2006). However, the legitimate role of the media in risk communications has been questioned as their interests differ from those of pharmaceutical companies and regulatory agencies. If the media is conceived of as a public organ of society, rather than a private institution that seeks mere demagoguery and sensation, then its provision of well-balanced, evidence-based media coverage of safety issues may be expected to maximize benefits and ameliorate harms for patients and the public, although admittedly this remains an ongoing challenge (Bahri 2010; Waller et al. 2006). The advantage of the UK's scientific media in improving the quality of reporting of drug information via the general media should be acknowledged (Czarnecki 2008; Mebane 2005).

Safety risk management planning was eventually implemented in April 2013 in Japan, following the issuance of local guidance for risk management plans for pharmaceuticals in April 2012, which supplements the ICH E2E "pharmacovigilance planning" guideline (Pharmaceuticals and Food Safety Bureau 2012). Most global companies have therefore already experienced the development and implementation of safety risk management plans, whereas domestic companies likely have little or no such experience. More than half of the respondents in this survey agreed with disclosure of the outlines of risk management plans, mostly owing to a likely grudging acceptance of transparency. Disclosure of safety risk management plans is planned to commence in 2013 and is

also expected to facilitate understanding and cooperation with practitioners and patients. However, as our respondents noted, tailoring the information to the expected audience is essential, given its potential to both maximize the effectiveness of the information and minimize anticipated confusion among patients as well as healthcare professionals (Bahri and Harrison-Woolrych 2012b).

#### Limitations

The results of this survey likely represent the partial and one-sided views of the responding pharmaceutical companies, and comprehensive and impartial investigations among other important stakeholders should accordingly follow. Owing to the anonymity of the study process, it was not possible to identify non-responding companies and thereby determine the extent of selection bias. The possibility exists that only those companies which actively express their opinion on a routine basis dominated this survey results. This survey did not target generic drug makers since they generally rely on the marketing authorization holders of the original drugs and do not play a central role in risk communication activities. Further, the answers derived from the survey may be biased toward those considered socially desirable, out of concern of criticism after the publication of this survey and subsequent to internal review within companies before the answers were returned. Even considering the above limitations, the high return rate appears sufficient to ensure representativeness in Japan, although the results would not be applicable to companies located in other countries, which have different medicosocial national systems.

#### Conclusions

We conducted a survey to better understand current risk communications by drug companies located in Japan. Risk communications operate at two levels, to the individual patient and to the general public. For both levels, to be successful implementation, credible messaging is necessary not only about risks, but also the benefit-risk balance of the particular drug as well as its outcome evaluation. This notion appears to be well accepted by the pharmaceutical industry in Japan. Direct communication by the regulatory agency and mobilization of mass media channels may enhance the speed and effectiveness of emergency risk communications, but the utilization and quality control of these communications appear premature and should be further explored. Internet websites are heavily utilized to provide risk information by regulatory agencies, pharmaceutical companies and other concerned parties, but the current provision of information on drug safety is highly disparate, occurring in various forms at multiple websites. Establishment of a comprehensive, integrated website as a 'one-stop portal' should

therefore be considered for maintaining transparency and sufficient circumstantiality. Such a portal would be complete with a user-oriented guide and be connected with a single national repository of 'authorized' information. This would maintain the standardized quality of and ease of accessibility to information for audiences with varying IT skills. 'Official' drug information storage at a single national repository might facilitate the transparency of drug information at the population level, such as in media publicity, and might also satisfy individual patient needs during consultation at a doctor's office, as well as in pharmacological training at dispensing pharmacies.

## Additional files

**Additional file 1: Outline of the survey questionnaire (English translation).**

**Additional file 2: Media Doctor Australia rating instrument for Adverse Effects.**

## Competing interest

HU is a paid consultant for Eli Lilly Japan. The other authors have no potential conflicts of interest to declare. This research was supported by a research grant from the Ministry of Health Labor and Welfare for Medicines and Medical Devices Regulatory Science Multidisciplinary Research Project (Grant Numbers H21-lyaku-lppan-020 and H24-lyaku-lppan-001). The funder had no role in study design, collection, analysis and interpretation of data, decision to publish, or preparation of the manuscript.

## Authors' contribution

Conceived and designed the study: HU, GK, HM, ST, KO, HS. Carried out the study: HU, HS. Analysed the data: HU. Wrote the first draft of the manuscript: HU. Contributed to the writing of the manuscript: GK, HM, ST, KO. Agree with the manuscript results and conclusions: GK, HM, ST, MY, TN, KK, TM, KO, HS. Jointly developed the structure and arguments for the paper: MY, TN, KK, TM. Made critical revisions and approved the final version: MY, TN, KK, TM, HS. All authors reviewed and approved of the final manuscript.

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# Reading comprehension of health checkup reports and health literacy in Japanese people

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## Abstract

**Objectives** To determine the reading comprehension of health checkup reports in the context of health literacy (HL) in Japanese people.

**Methods** A web-based survey was conducted among 424 Japanese adults aged 35–59 years. Participants were asked to read specifically designed health checkup reports and then answer a series of questions to examine whether they accomplished the fundamental purposes of health checkup reports (recognition of the problems, recognition of the risk of illness, recognition of the need for preventive action, and motivation for preventive action). HL was simultaneously

measured using the 14-item health literacy scale (HLS-14), the 11-item Lipkus scale (Lipkus-J), and the Newest Vital Sign (NVS-J).

**Results** About 70 % of the study subjects misread the normal/abnormal classification for at least one items. Those with lower HLS-14 scores were significantly less likely to recognize the problems, the risk of illness, and the need for preventive action for the examinee, and also less likely to express their willingness to take preventive action in compliance with the doctor's advice after having received the health checkup report. Compared with the HLS-14 scores, the Lipkus-J and NVS-J scores showed hardly any association with the reading comprehension of health checkup reports.

**Conclusion** All examinees do not always have an adequate level of HL. HL may be the major determinant of reading comprehension of health checkup reports. For more effective health checkups, health promotion service providers should become aware of the existence of examinees with inadequate HL and address the problem of misreading health checkup results.

**Keywords** Reading comprehension · Health checkup report · Health literacy · Japan

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## Introduction

Multiphasic health checkups are annually conducted according to the law in community and worksite in Japan. Every examinee receives a piece of paper that conveys his/her health checkup results within a few months after the health checkup. Health promotion service providers expect the examinees to read their health checkup reports and act on the doctor's advice written there. Although Japan has

one of the most educated populations in the world [1], well-educated people do not always have an adequate level of health literacy (HL). It may be more complicated that it looks for ordinary (non-medical) people to understand their health checkup reports that notify measurement data and professional comment with a lot of technical jargons. Unfortunately, epidemiological evidence to support the reading comprehension of health checkup reports has been scarce so far.

To what extent people seek, understand, and use health information depends on their HL level [2, 3]. Recently, a number of instruments have become available to measure HL in Japanese speakers [4–9]. In the absence of a gold standard, composition and content vary widely across these instruments, and they seem to measure different constructs of HL. There have been no studies that simultaneously measured HL using two or more instruments in a Japanese population. Accordingly, little is known about the discrepancy between existing measures of HL.

To produce the effect expected from health checkups, health checkup results must be notified in a way that is understandable to all examinees regardless of their HL level. It is important to determine the reading comprehension of health checkup reports in the context of HL in a possible target population. We conducted a web-based survey among middle-aged Japanese people to investigate to what extent they could read specifically designed health checkup reports [10]. HL was simultaneously measured using the following three instruments: the 14-item health literacy scale (HLS-14) [6], the 11-item Lipkus scale (Lipkus-J) [7], and the Newest Vital Sign (NVS-J) [8]. These instruments, consisting of 14, 11, and 6 questions, respectively, capture different aspects of HL and enable users to obtain a single index value for HL. Moreover, these instruments are designed for self-completion by respondents and are ideally suited for use in both paper-based and web-based surveys. In this study, we analyzed the relationship between the reading comprehension of health checkup reports and the three types of HL measures in Japanese people.

## Methods

### Subjects

A web-based survey was conducted in June 2013 among 424 Japanese adults aged 35–59 years [10]. An online research company (MACROMILL, INC., Tokyo, Japan) contracted to create web questionnaire forms and collect responses ( $n = 400$ ). The company has a nationwide research panel of more than 1 million registrants. At the time of the survey, the registrants aged 35–59 years totaled

534,582 (221,815 males and 312,767 females). Recruitment e-mails were sent to 20,000 eligible registrants aged 35–59 years who were randomly selected from each age and gender stratum. Applicants for participation in the survey were accepted in the order of receipt until the number of participants reached the quotas (40 people aged 35–39 years, 80 people aged 40–49 years, and 80 people aged 50–59 years for each gender). All participants voluntarily agreed to complete the survey. Those with serious health conditions and medical professionals were excluded through a prescreening process. Finally, a total of 424 valid responses were obtained. The study protocol was approved by the ethics committees of the Jikei University School of Medicine and has been conducted in accordance with the Guidelines for Epidemiological Studies by the Ministry of Health, Labour, and Welfare and the Ministry of Education, Culture, Sports, Science, and Technology.

### Measures

#### Health literacy

HL was simultaneously measured using the HLS-14, the Lipkus-J, and the NVS-J. These instruments were developed to measure different constructs of HL and were validated in Japanese people [6–8].

The HLS-14 [6] consists of 5 items for functional HL, 5 items for communicative HL, and 4 items for critical HL. The functional HL items ask about basic skills to read instructions or leaflets from hospitals or pharmacies. The communicative HL items asked about more advanced skills to obtain information about disease and treatment and use the obtained information in everyday situations. The critical HL items asked about more advanced skills to analyze information about disease and treatment critically. Respondents choose one of 5 options (1: strongly agree/disagree to 5: strongly disagree/agree) in response to each statement. The scores on the items were summed up to give the HLS-14 score (range 14–70 points) for each respondent.

The Lipkus-J [7, 11] consists of 3 general numeracy questions to measure understanding of percentages, frequency, and probability and 8 expanded numeracy questions to assess the ability to comprehend numerical risk information that are represented as percentages, frequencies, and probabilities in medical scenarios. For each question, respondents perform a simple calculation and answer the calculation result by means of giving figures or choosing one of the options. The number of the correct answers was counted as the Lipkus-J score (range 0–11 points) for each respondent.

The NVS-J [8, 12] is designed to assess the ability to understand and act on health information. Subjects are given a specially designed ice cream nutrition label and

are asked 6 questions about it. For the first four questions, respondents derive relevant information from the nutritional label and perform a simple calculation to get a specific numerical answer. For the fifth question, respondents judge whether a person allergic to peanuts can eat the ice cream, referring to the nutrition label, and for the sixth question, they explain the reason for the judgment. The number of the correct answers was counted as the NVS-J score (range 0–6 points) for each respondent.

Higher scores indicate having better HL for all measures.

#### Reading comprehension of health checkup reports

There is no established methodology for assessing reading comprehension of personal health information like health checkup reports. In this study, participants were asked to read specifically designed health checkup reports and then answer a series of questions to examine whether they accomplished the fundamental purposes of health checkup reports.

#### Preparation of health checkup report examples

Prior to the web-based survey, we collected health checkup report samples from 20 healthcare facilities throughout Japan. Based on the review of health checkup report samples, we found five distinctive features of health checkup reports and then prepared five representative examples for the web-based survey [10].

Participants in the web-based survey were randomly divided into four groups (53 males and 53 females, respectively). Each group was assigned two of the five health checkup report examples: one example was a standard and another example had some different features which may be influential in reading the health checkup report. There were two kinds of health checkup report examples that were considered as the standard. These health checkup report examples had the same form while they were applied different coding systems (alphabet grades vs. Japanese grades). The health checkup report example with alphabet grades is shown in Fig. 1. The health checkup report example with Japanese grades looked the same as that of the Fig. 1, except that the grades were expressed in the Japanese codes. Two groups were assigned the health checkup report example with alphabet grades as a standard (presented in different orders) and the other two groups were assigned the health checkup report example with Japanese grades as a standard (presented in different orders). When we preliminarily compared the answers to the questions about the health checkup report example with alphabet grades and those of the health

checkup report example with Japanese grades, no significant differences were found between them. Moreover, there were no significant differences between the two groups in which the same health checkup report example was presented as a standard in different orders (i.e., order effects). Therefore, in this study, the answers to the questions about the health checkup report example with alphabet grades and those of the health checkup report example with Japanese grades were combined and analyzed together.

As shown in the Fig. 1, the health checkup report example consisted mainly of findings and advice. A hypothetical case of metabolic syndrome was embedded in every health checkup report example. Physical measurements and clinical laboratory data were listed on the right side of the document. Abnormal findings were pointed out in the following 7 items: (1) body composition (waist circumference 87.5 cm) graded C or 'follow-up required', (2) blood pressure (under treatment) graded F or 'under treatment', (3) liver function (alanine aminotransferase 46 U/l,  $\gamma$ -glutamyl transferase 81 U/l) graded C or 'follow-up required', (4) serum lipid (triglyceride 369 mg/dl, HDL cholesterol 37 mg/dl) graded C or 'follow-up required', (5) blood glucose (hemoglobin A1c 6.3 %) graded D or 'precise reexamination required', (6) uric acid (uric acid 7.1 mg/dl) graded C or 'follow-up required', and (7) electrocardiogram (left ventricular hypertrophy) graded C or 'follow-up required'. A doctor's advice on the abnormal findings was written in the text box on the left side of the document. The doctor recommended the examinee to improve current lifestyle, especially diet and alcohol; to continue antihypertensive therapy; to have a precise reexamination for blood glucose; to have a 6-month follow-up examination for serum lipid; and to have a regular checkup next year to monitor the items that were classified as abnormal in this health checkup report. Overall, the health checkup results indicated that the examinee held multiple metabolic risk factors, which is called metabolic syndrome, and thus had to take appropriate measures to minimize his risk of illness.

#### Assessment of reading comprehension

Generally, health checkup reports are served on examinees for the purpose of notifying them what problems they have (recognition of the problems), to what extent their problems may induce seriously ill (recognition of the risk of illness), and what measures they must take to minimize their risk of illness (recognition of the need for preventive action), and consequently encouraging their willingness to take preventive action in compliance with their doctor's advice (motivation for preventive action). In this study, the assessment of reading comprehension



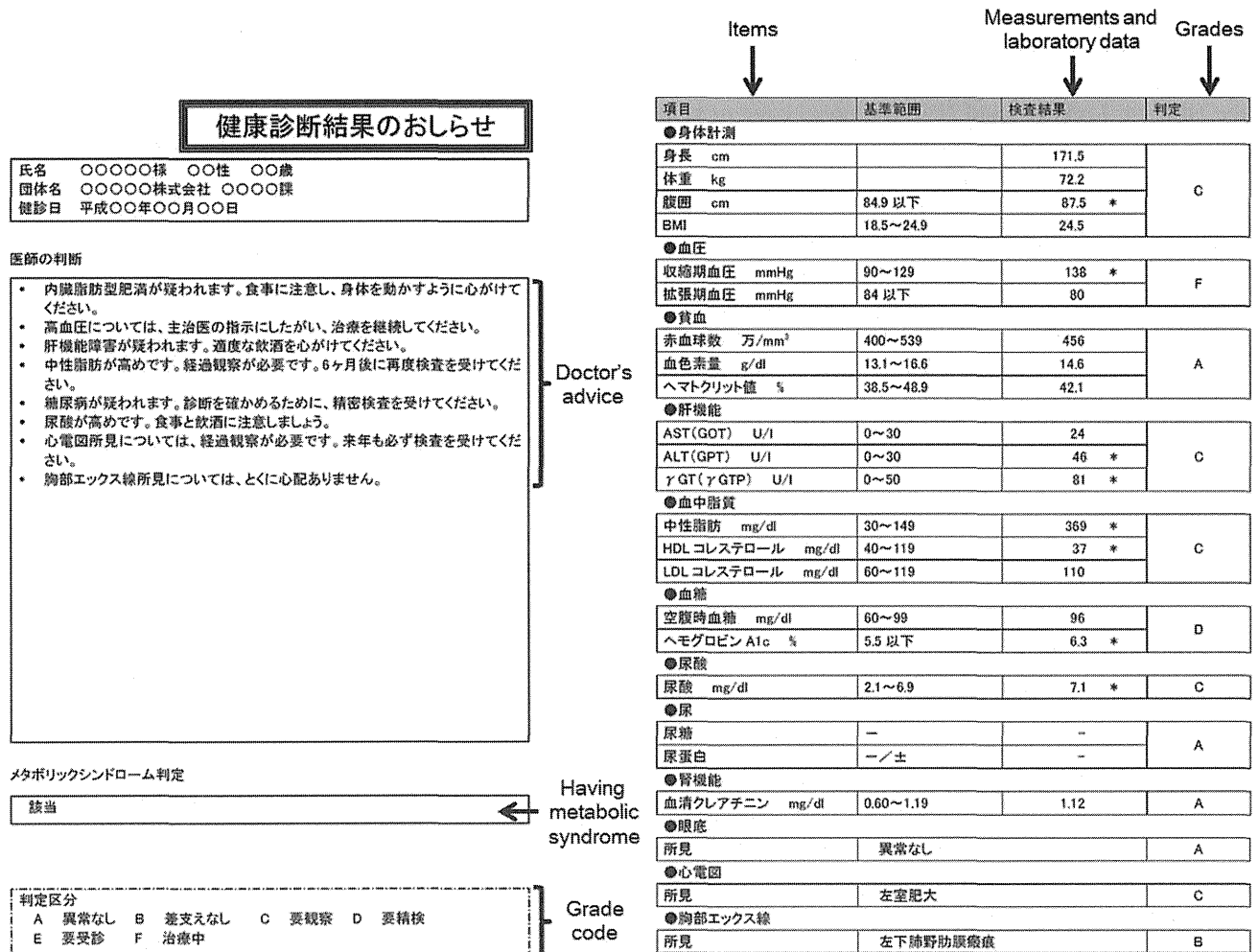


Fig. 1 Health checkup report example used in the web-based survey

focused on addressing these fundamental purposes of health checkup reports.

To examine whether participants accomplished the first purpose (recognition of the problems), they were asked to point out all the items that were classified as abnormal in the health checkup report. A list of 12 items was displayed and corresponding items were checked. As for the second and third purposes (recognition of the risk of illness and the need for preventive action), participants were asked to rate how much they agree or disagree with the following statements on a 5-point scale: I think that this examinee (1) has an increased risk of illness, (2) will get seriously ill unless he takes measures, (3) will recover his health if he takes measures, and (4) should take appropriate measures. As for the fourth and final purpose (motivation for preventive action), participants were asked to rate how much they agree or disagree with the following statements on a 5-point scale: If I were this examinee and received this health checkup report, I would (1) have a precise

reexamination, (2) have a 6-month follow-up examination, (3) improve current lifestyle, and (4) have a regular checkup next year.

Participants were also asked to assess the comprehensibility of the health checkup report. According to the consumer information rating form [13], participants rated how easy or hard the health checkup report was to (1) read, (2) understand, (3) remember, (4) locate the point, and (5) keep for future reference on a 5-point scale.

#### Statistical analysis

Median and interquartile range (IQR) were calculated for the HLS-14, Lipkus-J, and NVS-J scores and were compared using Mann-Whitney test (between two groups) or Kruskal-Wallis test (between three or more groups). Spearman correlation coefficients ( $\gamma$ ) were calculated to determine the associations between the HLS-14, Lipkus-J, and NVS-J scores. To examine whether the

HLS-14, Lipkus-J, and NVS-J scores were related to the reading comprehension of health checkup reports, the study subjects were divided into two groups according to the HLS-14, Lipkus-J, and NVS-J scores above or below the median, respectively. Responses were recategorized into three groups for comparison: strongly disagree/disagree, uncertain, and agree/strongly agree; very difficult/difficult, neutral, and easy/very easy. The distribution of responses was compared between the higher and lower scoring groups using Chi-square test. All statistical analyses were performed using the SAS ver. 9.2 (SAS Institute, Cary, NC, USA). Significant levels were set at  $p < 0.05$ .

## Results

### Subjects

Table 1 shows the characteristics of the study subjects. Of the 424 subjects, 46.7 % had completed higher education (university or higher), 68.9 % were married, and 73.8 % had some occupation. Those who reported having a health checkup every year accounted for 62.0; 10.1 % had every 2 years, 5.7 % had every 3–4 years, and 22.1 % had every 5 years or less. According to the 2011 national census [14], the percentage of the Japanese population aged 35–59 years with university degrees was 21.3 %, considerably lower than that of this study, whereas the percentages of married and employed population were 71.3 and 74.8 %, respectively, almost equal to that of this study.

### Health literacy

Figure 2 shows the distribution of the HLS-14, Lipkus-J, and NVS-J scores. The HLS-14 scores were approximately normally distributed with a median of 50 (IQR 10) points. Higher HLS-14 scores were associated with being female ( $p < 0.001$ ), being more highly educated ( $p < 0.001$ ), having no occupation ( $p < 0.001$ ), and having good economic status ( $p = 0.002$ ). The distribution of the Lipkus-J scores was left-skewed with a median of 10 (IQR 2) points; 47.1 % of the study subjects got a perfect score. Higher Lipkus-J scores were associated with being male ( $p < 0.001$ ), being older ( $p = 0.006$ ), being more highly educated ( $p < 0.001$ ), and being an employee ( $p = 0.008$ ). The distribution of the NVS-J scores was left-skewed with a median of 4 (IQR 2) points. Higher NVS-J scores were associated with being older ( $p = 0.034$ ), being more highly educated ( $p = 0.028$ ), and having good economic status ( $p = 0.007$ ).

When the associations between these three measures were examined, the Lipkus-J scores and the NVS-J scores

**Table 1** Characteristics of the study subjects

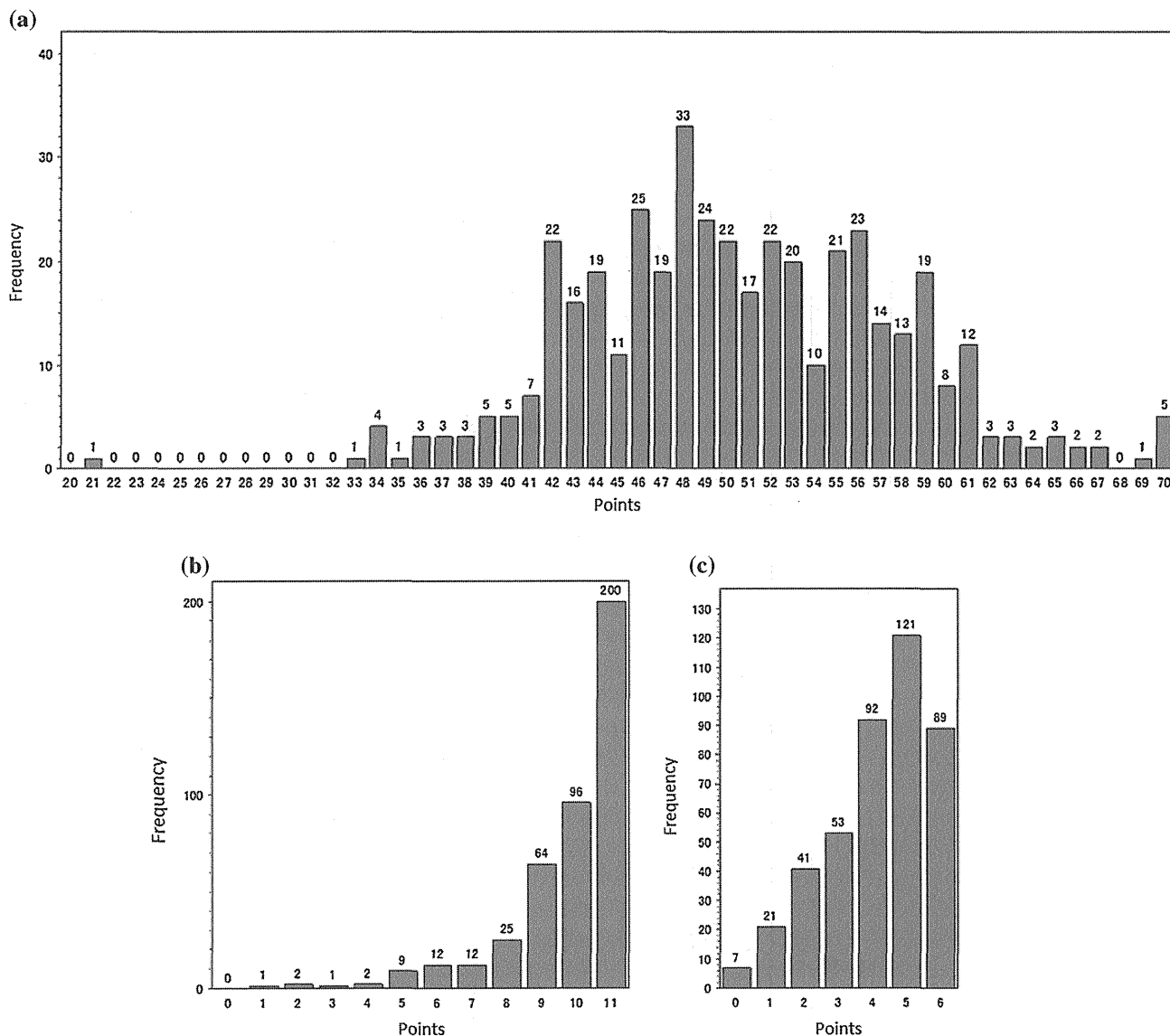
	<i>n</i>	%
Age		
35–39 years	88	20.8
40–44	92	21.7
45–49	76	17.9
50–54	99	23.3
55–59	69	16.3
Gender		
Male	212	50.0
Female	212	50.0
Education		
Compulsory education	10	2.4
High school	119	28.1
Junior college/vocational school	96	22.6
University or higher	198	46.7
Missing	1	0.2
Marital status		
Unmarried	132	31.1
Married	292	68.9
Occupational status		
No occupation	111	26.2
Self-employed	75	17.7
Temporary or part-time employee	60	14.2
Regular full-time employee	178	42.0
Household income		
<2.0 million yen <sup>a</sup>	31	7.3
2.0–5.9	176	41.5
6.0≤	166	39.2
Missing	51	12.0
Self-rated economic status		
Very poor	97	22.9
Poor	116	27.4
Moderate	134	31.6
Good	77	18.2

<sup>a</sup> 1 million yen was about 9,000 US dollars at the time of the survey

were moderately correlated with each other ( $\gamma = 0.42$ ,  $p < 0.001$ ). Meanwhile, the HLS-14 scores showed significant but weak correlations with the Lipkus-J scores ( $\gamma = 0.21$ ,  $p < 0.001$ ) and the NVS-J scores ( $\gamma = 0.21$ ,  $p < 0.001$ ).

### Reading comprehension of health checkup reports

Table 2 shows the recognition of the problems. For the 7 items classified as abnormal, 25.0–52.4 % of the study subjects, respectively, misread the normal/abnormal classification, whereas for the 5 items classified as normal, almost all (93.9–99.1 %) gave the right answers. Overall,



**Fig. 2** Distribution of the HLS-14 (a), Lipkus-J (b), NVS-J (c) scores

those who could correctly point out all the items classified as abnormal accounted for 27.1 % in the study subjects. This percentage was 36.5 % in the HLS-14 higher scoring group compared with 18.8 % in the lower scoring group ( $p < 0.001$ ); 33.0 % in the Lipkus-J higher scoring group compared with 21.9 % in the lower scoring group ( $p = 0.010$ ); 36.7 % in the NVS-J higher scoring group compared with 17.8 % in the lower scoring group ( $p < 0.001$ ).

Table 3 shows the recognition of the risk of illness, the recognition of the need for preventive action, and the motivation for preventive action. As for the first 2 statements assessing their recognition of the risk of illness, 77.6 and 78.3 % of the study subjects, respectively, agreed; whereas 11.1 and 10.4 %, respectively, expressed

disagreement. As for the second 2 statements assessing their recognition of the need for preventive action, 73.8 and 74.1 % of the study subjects, respectively, agreed; whereas 9.4 and 9.4 %, respectively, expressed disagreement. As for the latter 4 statements assessing their motivation for preventive action, those who expressed their willingness to have a precise reexamination, to have a 6-month follow-up examination, to improve current lifestyle, and to have a regular checkup next year in compliance with the doctor's advice accounted for 64.2, 61.6, 73.8, and 83.0 %, respectively, in the study subjects. These percentages in the HLS-14 higher scoring group were significantly higher than those in the lower scoring group. As for the Lipkus-J, there were no significant differences between the higher and lower scoring groups. As for NVS-J, a significant

**Table 2** Recognition of the problems

	HLS-14				<i>p</i>	Lipkus-J				<i>p</i>	NVS-J				<i>p</i>
	≤50		51≤			≤10		11			≤4		5≤		
	( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 214)	(%)	( <i>n</i> = 210)	(%)	
Body composition <sup>a</sup>	90	40.2	112	56.0	0.001	90	40.2	112	56.0	0.001	80	37.4	122	58.1	<0.001
Blood pressure <sup>a</sup>	136	60.7	149	74.5	0.003	142	63.4	143	71.5	0.076	128	59.8	157	74.8	0.001
Anemia	222	99.1	198	99.0	1.000	221	98.7	199	99.5	0.626	213	99.5	207	98.6	0.369
Liver function <sup>a</sup>	126	56.3	156	78.0	<0.001	132	58.9	150	75.0	<0.001	125	58.4	157	74.8	<0.001
Serum lipid <sup>a</sup>	119	53.1	148	74.0	<0.001	124	55.4	143	71.5	<0.001	115	53.7	152	72.4	<0.001
Blood glucose <sup>a</sup>	155	69.2	163	81.5	0.004	157	70.1	161	80.5	0.014	143	66.8	175	83.3	<0.001
Uric acid <sup>a</sup>	120	53.6	147	73.5	<0.001	127	56.7	140	70.0	0.005	119	55.6	148	70.5	0.002
Urine	218	97.3	195	97.5	0.908	218	97.3	195	97.5	0.908	206	96.3	207	98.6	0.135
Renal function	220	98.2	196	98.0	1.000	218	97.3	198	99.0	0.291	208	97.2	208	99.0	0.285
Fundoscopy	222	99.1	200	100.0	0.500	223	99.6	199	99.5	1.000	212	99.1	210	100.0	0.499
Electrocardiogram <sup>a</sup>	112	50.0	133	66.5	<0.001	124	55.4	121	60.5	0.285	107	50.0	138	65.7	0.001
Chest X-ray	209	93.3	189	94.5	0.608	214	95.5	184	92.0	0.130	200	93.5	198	94.3	0.722
All the items classified abnormal	42	18.8	73	36.5	<0.001	49	21.9	66	33.0	0.010	38	17.8	77	36.7	<0.001

The number of subjects who answered the normal/abnormal classification correctly was counted

<sup>a</sup> This item was classified as abnormal in the health checkup report

**Table 3** Recognition of the risk of illness, recognition of the need for preventive action, and motivation for preventive action

		HLS-14				<i>p</i>	Lipkus-J				<i>p</i>	NVS-J				<i>p</i>
		≤50		51≤			≤10		11			≤4		5≤		
		( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 214)	(%)	( <i>n</i> = 210)	(%)	
I think that this examinee...																
...has an increased risk of illness	Disagree	31	13.8	16	8.0	0.011	25	11.2	22	11.0	0.711	27	12.6	20	9.5	0.165
	Uncertain	32	14.3	16	8.0		28	12.5	20	10.0		29	13.6	19	9.0	
	Agree	161	71.9	168	84.0		171	76.3	158	79.0		158	73.8	171	81.4	
...will get seriously ill unless he takes measures	Disagree	30	13.4	14	7.0	0.007	25	11.2	19	9.5	0.578	28	13.1	16	7.6	0.102
	Uncertain	32	14.3	16	8.0		28	12.5	20	10.0		27	12.6	21	10.0	
	Agree	162	72.3	170	85.0		171	76.3	161	80.5		159	74.3	173	82.4	
...will recover his health if he takes measures	Disagree	24	10.7	16	8.0	0.004	20	8.9	20	10.0	0.354	24	11.2	16	7.6	0.337
	Uncertain	49	21.9	22	11.0		43	19.2	28	14.0		38	17.8	33	15.7	
	Agree	151	67.4	162	81.0		161	71.9	152	76.0		152	71.0	161	76.7	
...should take appropriate measures	Disagree	28	12.5	12	6.0	0.007	22	9.8	18	9.0	0.520	25	11.7	15	7.1	0.222
	Uncertain	44	19.6	26	13.0		41	18.3	29	14.5		37	17.3	33	15.7	
	Agree	152	67.9	162	81.0		161	71.9	153	76.5		152	71.0	162	77.1	
If I were this examinee, I...																
...would have a precise reexamination	Disagree	39	17.4	22	11.0	<0.001	33	14.7	28	14.0	0.856	32	15.0	29	13.8	0.539
	Uncertain	60	26.8	31	15.5		50	22.3	41	20.5		50	23.4	41	19.5	
	Agree	125	55.8	147	73.5		141	62.9	131	65.5		132	61.7	140	66.7	
...would have a 6-month follow-up examination	Disagree	38	17.0	26	13.0	<0.001	40	17.9	24	12.0	0.176	36	16.8	28	13.3	0.383
	Uncertain	69	30.8	30	15.0		54	24.1	45	22.5		53	24.8	46	21.9	
	Agree	117	52.2	144	72.0		130	58.0	131	65.5		125	58.4	136	64.8	
...would improve current lifestyle	Disagree	24	10.7	12	6.0	<0.001	24	10.7	12	6.0	0.118	25	11.7	11	5.2	0.002
	Uncertain	58	25.9	17	8.5		43	19.2	32	16.0		47	22.0	28	13.3	
	Agree	142	63.4	171	85.5		157	70.1	156	78.0		142	66.4	171	81.4	
...would have a regular checkup next year	Disagree	13	5.8	8	4.0	<0.001	13	5.8	8	4.0	0.302	14	6.5	7	3.3	0.005
	Uncertain	42	18.8	9	4.5		31	13.8	20	10.0		35	16.4	16	7.6	
	Agree	169	75.4	183	91.5		180	80.4	172	86.0		165	77.1	187	89.0	

difference between the higher and lower scoring groups was found in the willingness to improve current lifestyle and have a regular checkup next year.

We further examine the relationship between the reading comprehension of health checkup reports and the HLS-14 scores by gender and by age group. Although the number of subjects was too small to provide the necessary statistical power, the recognition of the problems, the recognition of the risk of illness, the recognition of the need for preventive action, and the motivation for preventive action seemed related to the HLS-14 scores in both male and female and in both younger (35–44 years old) and older (45–59 years old) age groups.

Table 4 shows the comprehensibility of the health checkup report. Those who answered that the health checkup report was easy to read, understand, remember, locate the point, and keep for future reference accounted for 67.5, 65.1, 37.7, 54.2, and 65.3 %, respectively, in the study subjects. These percentages in the HLS-14 higher scoring group were significantly higher than those in the lower scoring group. As for the Lipkus-J, a significant difference between the higher and lower scoring groups was found in the difficulty of locating the point. As for the NVS-J, a significant difference between the higher and lower scoring groups was found in the difficulty of understanding and locating the point.

## Discussion

Simply providing information is not enough to stimulate preventive action. It is vital to confirm that people can actually understand the information they need. Unfortunately, there have been no attempts to examine reading comprehension of personal health information like health checkup reports. This is the first study that determined the reading comprehension of health checkup reports in the context of HL in Japanese people. In the absence of established methodology, the assessment of reading comprehension was performed in terms of accomplishing the following fundamental purposes of health checkup reports: (1) recognition of the problems, (2) recognition of the risk of illness, (3) recognition of the need for preventive action, and (4) motivation for preventive action.

The items classified as abnormal were marked with signs clearly and were also mentioned in the doctor's advice in the health checkup report. Beyond our expectation, those who could correctly point out all the items classified as abnormal accounted for only 27.1 % in the study subjects. More than one-third of the study subjects misread the normal/abnormal classification for the 7 items classified abnormal, respectively. The health checkup report used for the assessment represented a hypothetical

case of metabolic syndrome that differed from the actual condition of the study subjects. The difference between hypothetical and actual data may confuse them and may affect their responses to some extent. However, it is worth noticing that quite a few examinees may misread the items classified as abnormal that require appropriate measures to minimize the risk of illness.

In spite of the misreading of health checkup results, about 75 % of the study subjects agreed with the statements about the increased risk of illness and the need for preventive action for the examinee. Accordingly, most subjects expressed their willingness to take preventive action in the compliance with the doctor's advice after having received the health checkup report. These results do not support our hypothesis that only people who can identify their own problems will recognize their increased risk of illness and their need for preventive action, and consequently intend to take preventive action. Annual multiphasic health checkups have been firmly established in Japan, and people are likely to know full well that they should work at their health promotion subsequently to health checkups. Even though examinees cannot understand the details of health checkup results, they might have a vague sense that they must take appropriate measures to minimize their risk of illness.

Those who expressed their willingness to have a precise reexamination and a 6-month follow-up examination accounted for 64.2 and 61.6 %, respectively, which were relatively lower than that of improving current lifestyle (73.8 %) and having a regular checkup next year (83.0 %). This result is consistent with the findings in the national cancer screening programs that the percentages of examinees having a precise reexamination among those with abnormal findings ranged from 63.6 % of colon cancer to 83.5 % of breast cancer [15]. Many factors affect the likelihood that examinees with abnormal findings will revisit for diagnosis and follow-up. As mentioned above, part of the examinees who cannot understand the details of health checkup results will take preventive action, but the misreading of health checkup results may be one of the causes of lack of revisits.

The measurement of HL of the study subjects confirms our expectation that all examinees do not always have an adequate level of HL. In the analysis of the relationship between reading comprehension of health checkup reports and three types of HL measures, those with higher HLS-14 scores were significantly more likely to recognize the problems, the risk of illness, and the need for preventive action for the examinee, and also more likely to express their willingness to take preventive action in compliance with the doctor's advice after having received the health checkup report. Meanwhile, as for the Lipkus-J and the NVS-J, significant differences between the higher and

**Table 4** Comprehensibility of the health checkup report

	HLS-14				<i>p</i>	Lipkus-J				<i>p</i>	NVS-J				<i>p</i>
	≤50		51≤			≤10		11			≤4		5≤		
	( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 224)	(%)	( <i>n</i> = 200)	(%)		( <i>n</i> = 214)	(%)	( <i>n</i> = 210)	(%)	
<b>Read</b>															
Difficult	21	9.4	16	8.0	0.002	20	8.9	17	8.5	0.405	21	9.8	16	7.6	0.061
Neutral	68	30.4	33	16.5		59	26.3	42	21.0		60	28.0	41	19.5	
Easy	135	60.3	151	75.5		145	64.7	141	70.5		133	62.1	153	72.9	
<b>Understand</b>															
Difficult	30	13.4	21	10.5	<0.001	33	14.7	18	9.0	0.088	29	13.6	22	10.5	0.023
Neutral	70	31.3	27	13.5		55	24.6	42	21.0		59	27.6	38	18.1	
Easy	124	55.4	152	76.0		136	60.7	140	70.0		126	58.9	150	71.4	
<b>Remember</b>															
Difficult	64	28.6	60	30.0	<0.001	67	29.9	57	28.5	0.122	59	27.6	65	31.0	0.316
Neutral	91	40.6	49	24.5		82	36.6	58	29.0		78	36.4	62	29.5	
Easy	69	30.8	91	45.5		75	33.5	85	42.5		77	36.0	83	39.5	
<b>Locate the point</b>															
Difficult	35	15.6	27	13.5	<0.001	39	17.4	23	11.5	0.026	36	16.8	26	12.4	0.023
Neutral	88	39.3	44	22.0		77	34.4	55	27.5		76	35.5	56	26.7	
Easy	101	45.1	129	64.5		108	48.2	122	61.0		102	47.7	128	61.0	
<b>Keep for future reference</b>															
Difficult	19	8.5	11	5.5	<0.001	20	8.9	10	5.0	0.051	17	7.9	13	6.2	0.135
Neutral	81	36.2	36	18.0		69	30.8	48	24.0		67	31.3	50	23.8	
Easy	124	55.4	153	76.5		135	60.3	142	71.0		130	60.7	147	70.0	

lower scoring groups were found in the recognition of the problems, but not in the recognition of the risk of illness, the recognition of the need for preventive action, or the motivation for preventive action, besides a few exceptions (the willingness to improve current lifestyle and have a regular checkup next year in relation to the NVS-J). The HLS-14 is a more comprehensive measure that covers all three levels of HL (functional, communicative, and critical) compared with the Lipkus-J and the NVS-J. The results of this study suggested that basic literacy and numeracy skills (i.e., functional HL) may contribute to the recognition of the problems, but more advanced skills (i.e., communicative HL and critical HL) are required for the recognition of the risk of illness, the recognition of the need for preventive action, and the motivation for preventive action.

Those who found no difficulty in reading understanding, remembering, locating, and keeping the health checkup report were more frequently observed in the HLS-14 higher scoring group. Those with adequate HL may be able to read their health checkup reports easily and utilize the information for their health promotion. Meanwhile, those with inadequate HL may have trouble in reading their health checkup reports and in some cases, may misread the information, which may affect their compliance with doctor's advice. Every examinee is notified of his/her health checkup results in written form according to the law in Japan. Further studies should be conducted to redesign the present health checkup reports to be understandable to all examinees regardless of their HL level.

This study provides the first step towards elucidation of the reading comprehension of health checkup reports in Japanese people. On the contrary, it has a number of potential limitations. First, the study subjects were selected from a nationwide panel of an online research company. Applicants for participation in the survey were accepted in the order of receipt until the number of participants reached the quotas. Unfortunately, we have no information about the number of subjects who would participate in the survey if we had not set the quota. As described in the "Results" section, the study subjects included highly educated people twice as many as in the Japanese population. Those who were more interested in health and more familiar with health information were likely to agree to complete the survey. The distribution of HLS-14 scores in the study subjects is quite similar to that obtained from our previous paper-based survey in a Japanese healthcare facility [6], but the selection bias may have influenced the results to some extent. Second, the web-based survey was self-administered, and thus the accuracy of responses must depend on their understanding of questions and their motivation to answer questions accurately. Although the understandability of wording were checked prior to the web-based survey, it is almost impossible to eliminate the information bias completely. Third, the method of assessing reading

comprehension of health checkup reports was not fully validated. Similar performance-based assessments are commonly used for user-testing of written medicine and health information [16, 17]. The significant relationship between the reading comprehension of health checkup reports and the HLS-14 scores seems to support the validity of our assessment method, but further studies are needed to confirm the validity in other populations. Fourth, cross-sectional data were used, and thus causality cannot be inferred. Nobody doubts that HL is the major determinant of reading comprehension of health checkup reports. On the other hand, those who have read their health checkup reports may take an active interest in their health, which may enhance their HL level. It is possible that reading comprehension of health checkup reports and HL will be reciprocally enhanced. However, none of the three HL measures was significantly related to the frequency of health checkups in the study subjects. Health checkup experience seems to have only a limited effect on HL, if any.

## Conclusion

Japanese people are supposed to have annual health checkups, and every examinee is notified of his/her health checkup results in written form. However, all examinees do not always have an adequate level of HL. After reading a specially designed health checkup report, about 70 % of the study subjects misread the normal/abnormal classification for at least one items. Those with lower HLS-14 scores were significantly less likely to recognize the problems, the risk of illness, and the need for preventive action for the examinee, and also less likely to express their willingness to take preventive action in compliance with the doctor's advice after having received the health checkup report. HL may be the major determinant of reading comprehension of health checkup reports. For more effective health checkups, health promotion service providers should become aware of the existence of examinees with inadequate HL and address the problem of misreading health checkup results.

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**Conflict of interests** The authors declare that they have no conflict of interest.

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◎ みてわかる薬学

図解



医薬品情報学

編集

NTT 東日本関東病院薬剤部長 折井孝男

改訂  
3  
版

南山堂

医薬品に関するコミュニケーションは古くて新しいテーマである。患者は、医薬品の効能・効果、使用上の注意、副作用\*などについて、古来より家族、近隣住民、医療専門職などに相談してきた。また、今日では、インターネット上のホームページ、個人ブログ、FacebookやTwitterのようなソーシャルメディアなどの情報までも積極的に活用して、情報収集・情報交換をするようになってきた(e-patient)。

さらに、近年、医薬品においては、患者との協力関係のもとでの処方と使用のプロセスを重視する「コンコーダンス」モデル（「患者指導からパートナーシップへ」）が注目されている。その医療における選択の「共有決定 shared decision making」では、医薬品の有効性（ベネフィット）と安全性（リスク）について、患者と医療専門職の双方向性のコミュニケーションが重要な役割を持つ。

本項では、ベネフィットとリスクのバランス（科学的不確実性）、コンコーダンスなどを説明したうえで、医薬品とリスクコミュニケーションについて述べる。

### A ベネフィットとリスクのバランス(科学的不確実性)

一般的に「ベネフィット」は便益・利益と訳され、医療においては、医薬品の処方を受けたり、外科手術を受けたり、何らかの医療サービスを受けた結果、期待される好ましいアウトカム（効能・効果）をいう。一方、「リスク」は、好ましくないアウトカム（結果）を総称した幅広い概念である\*\*。医療においては、例えば、医薬品の副作用で胃腸障害が一過性に出るような軽い事象から、外科手術後に意識が戻らず植物状態になってしまうような深刻な事象まで含む。最も重要なことは、あらゆる医療サービス（投薬、手術、検査など）には、一定の「リスク」があることを理解することである（100%安全な医療サービスはなく、必ずリスクを伴う）。

図3-10-1に、医薬品におけるベネフィットとリスクのバランス、すなわち「科学的不確実性」の考え方について図示した。ベネフィットが大きく、リスクの少ない選択肢（右下）が最良のバランスで患者\*\*\*にとって最も受け入れやすい。一方、ベ

\* 厳密には薬物有害反応（ADR）。

\*\* リスクはある価値を失う確率である。したがって、アウトカムに対する価値評価が異なれば、リスクの定義も異なってくる（value-focused thinking）。

\*\*\* 本項では、患者・国民・消費者・市民を略して「患者」とする。

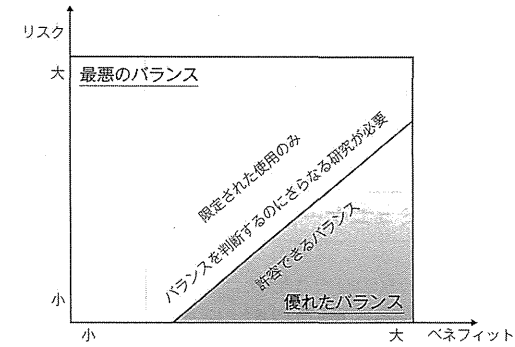


図3-10-1 医薬品のベネフィットとリスクのバランス（科学的不確実性）

ネフィットが小さく、リスクの大きい選択肢（左上）は最悪のバランスで受け入れにくい。両者とも患者にとって選択決定するのが容易である。一方で、その両者の間に、「許容できるバランス」、「バランスを判断するのにさらに検討が必要なもの」、「一定の条件下で限定された使用のみ許されるもの」を位置づけることができるが、これらをベネフィットとリスクの秤にかけて患者が選択の意思決定することは複雑で困難である。

### B 医療の「共有決定」と「コンコーダンス」

近年、医療で注目されている概念に「共有決定 shared decision making/ 科学的根拠に基づく患者選択 evidence-based patient choice」がある。これは、患者と医療専門職が両者で科学的根拠に基づく情報を双方向に共有し合い、医療を選択決定していくパートナーシップのかたちをいう。これは、インフォームド・コンセント（説明と同意）やインフォームド・チョイス（説明と選択）より、さらに発展したかたちとされる。

表3-10-1に、この「共有決定」の類似概念を整理した。医薬品においては、患者との協力関係（共同作業）のもとでの処方と使用のプロセスを重視する「コンコーダンス」(Marinker, 1997) モデルがある。これまでの処方せんの指示に従って患者が医薬品を服用するコンプライアンスの考え方から変遷しつつある。コンコーダンスモデルは、患者と医療専門職とのパートナーシップに基づき、両者で医薬品について情報を共有したうえで治療決定を行う。近い概念として「アドヒアランス」も服薬の継続性の視点からよく用いられている。

図 3-10-2 に、英国 Medicine Partnership Group によるコンコーダンスの柱を示した。わが国の高血圧治療ガイドライン<sup>1)</sup>でも、コンコーダンスを「疾病について十分な知識をもった患者が自己の疾病管理にパートナーとして参加し、医師と患者が合意に達した診療を行うことを指す」とある。表 3-10-2 には、同ガイドラインの「医療者と患者が共通の理解に到達しパートナーとして治療を行う方法」を示した。

### C リスクコミュニケーション

このような医療の「共有決定」、「コンコーダンス」の成立には、医薬品の有効性（ベネフィット）と安全性（リスク）について、患者と医療専門職の双方向性のコミュニケーションが重要な役割を持つ。医薬品においては、そのベネフィットとリスクに関する正確な情報を、患者と医療専門職などの利害関係者（ステークホルダー）の間で共有し合い、相互（双方向性）に意思疎通を図ることを「〈ベネフィット〉リスクコミュニケーション」（本来はベネフィット・リスクコミュニケーションである）という。患者が共有決定に関して独立した判断ができるように、必要な情報を患者と医療専門職が共有するために意図されたコミュニケーションである。リスクコミュニケーションにより、必要かつ適切な情報共有がなされることで、患者意識が高められ、状況理解が進み、患者の「よりよい意志決定」が促進される。なお、これには患者と医療専門職との間の、情報の透明性と信頼性の確保が大前提である。

リスクコミュニケーション概念の定義は、時代とともに変遷が見られる。当初の一方向性の「技術的なリスクメッセージ提供の段階」〔1975～1984年（昭和50～59年）〕から、「説得のためのメッセージの工夫の段階」〔1985～1994年（昭和60～平成6年）〕、そして「対等な立場でコミュニケーションをはかる段階」〔1995年（平成7年）～〕を経て、現在では上記の定義に至っている。一見似ている概念として、広報 public affairs や宣伝 public relations (PR) におけるコミュニケーションがあるが、リスクコミュニケーションとは情報の「正確性に対する責任」や「曖昧さの排除」において異なる。リスクコミュニケーションの特徴は、ベネフィットとリスクに関して均衡（バランス）のとれた適正な理解を患者に促すとともに、医療者の側にも患者の心理プロセスへの意識の高まりを求めるものである。

またリスクコミュニケーションの最終ゴールは、情報共有（例えば、患者による疾患と服薬の理解、医療者による患者の背景や心配の理解）、信念変容（患者による服薬の誤解、医療者による一方向的な治療方針の決定などから、協力的な治療に向けた目標の共有へ）、行動変容（共有した目標に向けて医療者・患者が協力して治療に取り組む）である。

医療者からの単なる情報提供（「ただ言うだけ just-say-it」）で終わらせるのではなく、双方向的なコミュニケーションによって医療者と患者がともに変わりながら、協力関係を築き、目標の達成に向かうことが求められている。

表 3-10-1 共有決定 shared decision making の類似概念

<ul style="list-style-type: none"> <li>・ Evidence-based patient choice (Hope, 1996)</li> <li>・ Informed (shared) decision making (Towle and Godolphin, 1999)</li> <li>・ Patient-centred care (Stewart et al., 1995)</li> <li>・ Concordance (Marinker, 1997)</li> <li>・ Participation and partnership (Coulter, 1997)</li> <li>・ Informed consent (Gigerenzer, 2002)</li> </ul>	<ul style="list-style-type: none"> <li>・ Autonomy (Schneider, 1998)</li> <li>・ Consumer involvement and consumerism (Entwistle et al., 1998)</li> <li>・ Expert patient (Kennedy and Rogers, 2001)</li> <li>・ Evidence-informed patient choice (Entwistle et al., 1998)</li> </ul>
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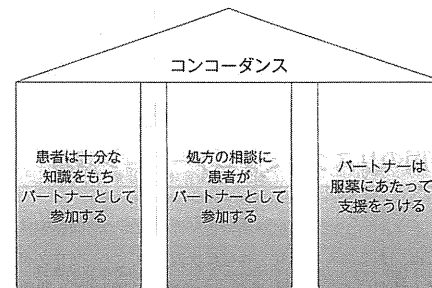


図 3-10-2 医薬品のコンコーダンスモデル  
(英国 Medicines Partnership Group)

表 3-10-2 医療者と患者が共通の理解に到達しパートナーとして治療を行う方法

- ・ 患者と高血圧のリスクおよび治療の効果について話し合う。
- ・ 治療計画について、書面および口頭で明確に説明する。
- ・ 治療計画を患者の生活習慣に合わせる。
- ・ 患者の配偶者および家族に、高血圧および治療計画に関して情報を提供する。
- ・ 家庭血圧測定や、飲み忘れ防止法などの行動論的方法を活用する。
- ・ 副作用によく注意し、必要に応じて用量変更、薬剤の切り替えを行う。
- ・ 1日の服薬錠数、服薬回数を減らし、合剤の使用を含め、処方箋を簡素化する。
- ・ 服薬忘れとその要因について話し合う。
- ・ 服薬継続、受診継続、生活習慣修正を支援するシステムを提供する。
- ・ 生涯にわたる治療の費用と効果を説明する。

(文献1)より引用

### D 医薬品のリスクコミュニケーションの動き(米国)

米国では、2004年（平成16年）にCOX2阻害薬のロフェコキシブ（米国での商品名 Vioxx）が心筋梗塞や脳卒中などの心血管イベントのリスク増加のために自主回収・販売中止に至ったのを直接の契機として、米国食品医薬品局（FDA）に対して、新薬の早期承認を重視するあまり、安全性を軽視しているのではないかという懸念が広がった。