

Author(s) (year)	Study objectives	Methods	Participants	Main results
Tsutsumi <i>et al.</i> (2018)	Examine the ability of the BJSQ (recommended by the SC program) to predict workers needing long-term sick leave	Questionnaire (longitudinal)	14,178 workers (7,356 men, 7,362 women) at an independent financial services company (administrative employees, temporary transferred persons, overseas employees, absentees and dispatched employees were excluded)	<p>Implementation: The prevalence of those identified as under high levels of stress by the BJSQ was 5.6% for men and 15.0% for women</p> <p>Utility: Workers who were identified as under high levels of stress by the BJSQ (based on SC program implementation manual assessment criteria) had a significantly high risk for long-term sick leave</p> <p>Challenges: Effects of three elements of the SC program need to be confirmed. 1. Reducing the risk for mental health issues through implementation of routine survey for workers and returning the results to workers. 2. Preventing mental health issues through screening for those under high levels of stress and providing interviews by physicians. 3. Reducing psychological stress reactions by improving the work environment (including education for management and supervisors). Because risk for sick leave in those under high levels of stress rapidly increased after 2–3 months, occupational health staff needs to consider measures for those under high levels of stress immediately after SC implementation</p>

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Table 1.
Implementation and
effects of the Stress
Check Program:
literature incorporated
in this systematic
review (18 papers)

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Asai <i>et al.</i> (2018)	Implementation of the SC program during its first year and investigation of the utility of each element with anticipated effects under the SC program	Questionnaire (cross-sectional)	3,891 full-time workers	<i>Implementation:</i> At workplaces with ≥ 50 workers, 52.5% reported they had been notified of the SC program implementation, and the examination rate was 92.0%. In addition, 14.2% were under high levels of stress, of which 18.6% requested an interview with a physician. Overall, 3.3% of workers that received the SC experienced improvements to their work environment <i>Implementation:</i> The SC implementation rate was low (34%). The most common reason for not implementing the SC was because of the "obligation to make efforts." In regard to scheduling group analysis, among 10 workplaces (after excluding those without a plan), eight workplaces (80%) indicated they would implement group analysis <i>Challenges:</i> Administrative complications, such as considerations regarding privacy and financial burden, were also cited as issues that inhibited implementation SC.
Takeishi <i>et al.</i> (2017)	Investigate implementation status of the SC in small-scale workplaces in Saitama Prefecture	Questionnaire (cross-sectional)	38 small-scale workplaces in Saitama Prefecture	

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Saito <i>et al.</i> (2019)	Clarify mental health measures and implementation of SC in small-scale workplaces along with related factors and obtain suggestions for future promotion	Questionnaire (cross-sectional)	Workplaces with 30–50 workers in Aichi Prefecture (290 independent companies and 331 branches)	<i>Implementation:</i> The SC implementation rate was higher in branches (56%) compared with independent companies (15%) <i>Efforts:</i> In workplaces with mental health staff, SC implementation was more advanced compared with workplaces without such staff. Assigning dedicated staff in small-scale workplaces would be useful to promote SC
Ishimaru <i>et al.</i> (2018)	Examine if conducting SC simultaneously with the annual health examination improved the SC examination rate	Questionnaire (cross-sectional)	31,356 workers who used both the SC service and the annual health examination	<i>Implementation:</i> The total SC examination rate was 90.8%. The examination rates of workers aged ≥ 30 years, those with occupations such as transportation and postal services, and workplaces with 50–999 workers, were high. However, the examination rates for medical and welfare-related jobs and workplaces with $\geq 1,000$ workers were low <i>Efforts:</i> If the SC date was close to the annual health examination, the examination rate increased by about 1.7–3.8 (odds ratio); implementing the SC close to the annual health examination may improve the examination rate
Muratani (2017)	Compare sex and age groups, and administrative/educational staff to clarify workplace stress	Questionnaire (cross-sectional)	683 workers at a school (university and junior college)	<i>Implementation:</i> 531 people underwent the SC (examination rate of 78%); 11 % were under high levels of stress

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Nakatani (2017)	Examine the necessity of improvements to the work environment through analysis of workers under high levels of workplace stress	Questionnaire (longitudinal)	1,009 full-time workers who received an SC two years in a row (830 men, 179 women)	<i>Implementation:</i> The SC examination rate was 100% in 2016 and 99.6% in 2017. Among 1,009 workers who completed the SC in both years, 5% were under high stress in both years, 6% in 2016, and 6% in 2017; 83% were not considered under high stress <i>Implementation:</i> In surveys that used the BJSQ based on the evaluation criteria of the SC Program implementation manual, the prevalence of those under high levels of stress was 16.7% with the 57-item version and 15.5% with the short version (23 items) <i>Utility:</i> High-stress screening using the cut-off values from the implementation manual had 60.5% sensitivity and 88.9% specificity when K6 score of ≥ 13 was used as the outcome indicator <i>Challenges:</i> Among those under high levels of stress, less than half presented psychological a stress reaction equivalent to a severe mental disorder <i>Implementation:</i> 92.5% of medical facilities had a system to implement occupational health interviews for those who were deemed under high-level stress and wanted an interview with a physician
Tsutsumi <i>et al.</i> (2017)	Examine the ability of the BJSQ recommended to identify workers who present psychological stress reactions equivalent to severe mental disorders	Questionnaire (cross-sectional)	1,650 workers registered with an online survey company	
Wada <i>et al.</i> (2018)	Clarify the situation of occupational health activities for medical staff	Questionnaire (cross-sectional)	214 medical facilities in Kanto Region	

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Author(s) (year)	Study objectives	Methods	Participants	Main results
Adachi <i>et al.</i> (2018)	Verify the correlation between screening criteria for an interview with a physician and psychological health	Questionnaire (cross-sectional)	368 workers (288 men, 80 women) at an independent company	<i>Utility</i> : Correlation between BJSQ stress reaction scale score (total of 29 items) and CES-D score was examined. There was strong correlation (Spearman's rank correlation coefficient = 0.800, $p < 0.001$) <i>Utility</i> : A survey that included BJSQ items was conducted and its relationship with voluntary retirement examined. Individual job satisfaction measured with the BJSQ, and satisfaction with work and life at the workplace level had a significant negative correlation with voluntary retirement <i>Utility</i> : BJSQ items that are strongly correlated with job satisfaction were examined for each gender. For men, the significance of work, control at work, support from superiors, job aptitude and workload were significantly correlated with job satisfaction. For women, significant factors were job aptitude, significance of work and workload
Takahara (2018)	Examine concrete clues to improve workplaces by implementing a multivariate analysis including objective workplace indicators	Questionnaire (longitudinal)	1,895 workers including non-regular workers at an independent company	
Adachi (2017)	Gain an understanding of situations in workplaces to achieve work engagement and prepare essential documents to examine approaches in occupational fields	Questionnaire (cross-sectional)	368 workers (288 men, 80 women) at an independent company	<i>Utility</i> : Using the BJSQ items at the baseline, deterioration in job aptitude and related factors for the subsequent four years were examined. Levels of physical burden, job satisfaction and support from superiors were significantly correlated with deterioration in job aptitude
Higuchi <i>et al.</i> (2015)	Analyse longitudinal BJSQ data and examine items that would impact on subsequent work	Questionnaire (longitudinal)	661 male workers at a machine manufacturing plant	

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Shimura <i>et al.</i> (2018)	Examine the relationship between sleep-related issues and stress reaction in the SC	Questionnaire (cross-sectional)	884 workers at 10 workplaces	<i>Utility:</i> Using structural equation modelling that combined sleep-related issues (measured with the Pittsburgh Sleep Quality Index) with factors of stress at work and support from others in the BJSQ showed that 55.2% of psychological and physical stress reaction was explained by these factors <i>Utility:</i> Physicians providing interviews may not be familiar with mental disorders; therefore, a support tool to accurately assess risk for mental health issues is necessary <i>Effects:</i> Workers who reported both SC and improvements to their work environment had significantly lower psychological stress reactions compared with those who did not report either
Ito (2017)	Develop a simple and convenient depression assessment scale (Ji test)	Questionnaire (cross-sectional)	91 new patients at a clinic	<i>Effects:</i> Immediate feedback was provided to participants using an online system that provided individual results and advice on stress, related factors and measures based on responses to the questionnaire Compared with before use of this system, motivation to implement stress coping and awareness of the features of stress management were improved. Motivation to implement stress coping was maintained for two months, which led to maintenance of psychological health
Inamura <i>et al.</i> (2018)	Examine the link between implementation of SC based on the SC Program, improvements to the work environment, psychological stress reactions and work performance	Online survey (longitudinal)	3,891 workers registered with an online survey company (part-time workers were excluded)	
Ito <i>et al.</i> (2016)	An online SC program that provided individual results and advice for decreasing stress, influencing factors and current measures was examined as to whether this approach promoted motivation to implement stress coping	Questionnaire (longitudinal)	371 workers voluntarily participated in a survey that used an online SC program and provided responses to three rounds of the survey	

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Author(s) (year)	Study objectives	Methods	Participants	Main results
Shintani <i>et al.</i> (2018)	Interviews with all employees performed after SC, and training was provided based on its content, to verify whether this approach improved factors associated with stress and stress reactions	Questionnaire (longitudinal)	All 168 workers (134 men, 34 women) at a food manufacturing company	<i>Effects:</i> This study investigated if implementing interviews for all employees, stress self-care training for individual employees and training for management and supervisors after SC improved factors associated with stress and stress reactions. Factors associated with stress increased role-related conflict and reduced skill usage. Physical stress reactions were reduced but psychological stress reactions were not <i>Efforts:</i> It is important to provide mental health training for employees by offering interviews to all employees as a follow-up to the SC and by using the contents of the SC

Note(s): SC: stress check; BJSQ: Brief Job Stress Questionnaire; CES-D: Center for Epidemiologic Studies Depression Scale

Table 1.

workplace improvement), and “examination rate”, to refer to the proportion of workers who underwent stress checks among those who were expected to do so.

Implementation rate of the Stress Check Program

Asai *et al.* (2018) conducted an online survey with 3,891 full-time workers across Japan to clarify the implementation status of the Stress Check Program in its first year. They found that among respondents working at enterprises with ≥ 50 workers, 52.5% had received notification of the implementation of the Stress Check Program. Stratified analyses based on respondents' demographics revealed that notification of program implementation was more common among workers aged 40–49 years and those in manufacturing positions. An analysis based on the scale of enterprises showed that larger enterprises had more workers who received notification. That study also reported that 12.1% of workers at small-scale enterprises had received a notification of the implementation of the Stress Check Program from their employer.

In addition, two reports examined small-scale enterprises. Takeishi *et al.* (2017) conducted a survey of 38 small-scale enterprises in Saitama Prefecture and reported a low implementation rate of stress checks (13 workplaces, 34%). The most common reason for not implementing the Stress Check Program in small-scale enterprises was because they were only obliged to make “reasonable efforts.” Saito *et al.* (2019) examined the implementation rate of stress checks in small-scale enterprises in Aichi Prefecture by dividing them into independent companies ($n = 290$) and branches of companies with multiple locations ($n = 331$; e.g. offices, branches, sales offices). The results showed that the implementation rate of stress checks was 15% for independent enterprises and 56% for branches, which clearly showed a difference based on enterprise size. That study also reported that enterprises with mental health staff had significantly higher implementation rates of stress checks than enterprises without mental health staff.

Examination rate of stress checks

The nation-wide survey by Asai *et al.* (2018) showed that among workers who were notified of the Stress Check Program, 92.0% actually underwent stress checks at enterprises with 50 or more workers, and 84.7% underwent stress checks at small-scale enterprises. Ishimaru *et al.* (2018) used data for 31,156 workers who received both a stress check from an occupational health agency and a routine health checkup, and they reported that 90.8% of workers had received a stress check. In terms of the scale of enterprises, stress checks were reported by 91.1% of workers at enterprises with ≥ 50 workers and 87.3% of workers at small-scale enterprises. In addition, that study reported the examination rate varied based on workers' attributes. A higher examination rate was reported among workers aged ≥ 30 years, those with occupations such as construction, transportation and postal services and those in enterprises with 5–999 workers compared with workers aged 1–29 years, those in manufacturing jobs and those in enterprises with 1–49 workers. However, those in occupations such as medical and welfare services and who worked in enterprises with $\geq 1,000$ employees had significantly lower examination rates compared with those in manufacturing jobs and enterprises with 1–49 workers. In addition, stress checks implemented on dates closer to routine health checkups had higher examination rates.

Muratani (2017) reported the stress check examination rate was 78% in an academic institution (a university and junior college) with 683 staff. Nakatani (2017) reported that the examination rate of stress checks implemented over two years at corporate groups that included multiple occupations (e.g., sales, manufacturing, and distribution) was 100% in 2016 and 99.6% in 2017. However, the examination rate for workers at each workplace was not reported in the two papers that examined small-scale enterprises (Saito *et al.*, 2019; Takeishi *et al.*, 2017).

Prevalence of workers under high levels of stress

Asai *et al.* (2018) reported that among workers who received a stress check, the prevalence of workers who were identified as under high levels of stress was 14.2% in enterprises with ≥ 50 workers and 14.4% at small-scale enterprises. Tsutsumi *et al.* (2017) conducted an online survey involving 1,650 workers. They reported that the prevalence of workers under high levels of stress as determined using the BJSQ (Shimomitsu, 2000) based on the assessment criteria indicated in the Stress Check Program Implementation Manual (Ministry of Health, Labour and Welfare, Japan, 2015) (referred to as the Manual) and according to the Industrial Safety and Health Act was 16.7% with the 57-item version and 15.5% with the 23-item (short) version. In addition, Tsutsumi *et al.* (2018) conducted a prospective cohort study with 14,718 workers at a financial service company (7,356 men, 7,362 women) and reported that the prevalence of workers under high levels of stress calculated with similar assessment criteria (57-item version of the BJSQ) was 5.6% for men and 15.0% for women. The survey of the academic institution (university and junior college) found that 11% of staff was under high stress (Muratani, 2017). In addition, the study focussed on stress checks among workers at corporate groups (sales, manufacturing and distribution) concluded that among 1,009 full-time workers who received stress checks in 2016 and 2017, 5% were under high stress in both years, whereas 6% were under high stress in 2016 and 6% reported high stress in 2017 (Nakatani, 2017). That study also reported that 83% of workers were not under high stress in either year.

Implementation rate of interviews with physicians

Asai *et al.* (2018) found that among workers who received a stress check, 2.6% requested an interview with a physician at enterprises with ≥ 50 workers, whereas no workers made such request at small-scale enterprises. That study also reported that among those who were identified as under high stress, 18.6% of those at enterprises with ≥ 50 workers requested physician interviews, whereas no workers small-scale enterprises made such a request.

In this study, workers were asked for the reasons why not they requested an interview with a physician at enterprises. The followings were the reasons that workers with high stress did not see a doctor: did not receive notice, 19%; forgot to request 1%; had no time, 20%; felt no need, 29%; did not know how useful the interview was, 36%; the problem was solved, 1%; did not think they had stress, 3%; thought they could cope with by themselves, 14%; felt no special need because they consulted on a regular basis, 4%; already saw a doctor, 4%; did not want to let the company know the results, 10%; were anxious about the fact that they saw a doctor being introduced to the company, 11%. Wada *et al.* (2018) surveyed 214 medical facilities in the Kanto region and examined implementation of interviews with physicians for those with high levels of stress. They found that 92.5% of medical facilities indicated they had a system ready to implement interviews with occupational physicians for those identified as under high stress that wished to have such a meeting.

Implementation rate of group analysis and work environment improvement

In the national survey by Asai *et al.* (2018), 3.3% of workers who received a stress check reported that their work environment was improved. The survey by Takeishi *et al.* (2017) that targeted small-scale enterprises found that eight of the 10 companies surveyed (80%) indicated that they would “implement” group analysis.

Utility and validity of tools for stress checks

Eight of the 18 reviewed papers examined the utility and validity of the BJSQ for the Stress Check Program (Table 1). Three papers examined the relationship between BJSQ scores and mental health indicators, three examined the relationship between the BJSQ and work-related factors and two discussed the necessity of supplementary tools.

Relationship between BJSQ scores and mental health indicators

Adachi and Inaba (2018) examined the relationship between scores on the BJSQ stress response scale (total of 29 items) and the Center for Epidemiological Studies-Depression scale (a depression self-assessment scale) in a cross-sectional study involving 368 workers at an enterprise (288 men, 80 women). That study revealed a strong correlation between the scores for the two scales (Spearman's rank correlation coefficient = 0.800, $p < 0.001$).

Tsutsumi *et al.* (2017) changed the assessment criteria (i.e., the cutoff value) to screen for high stress using the BJSQ as indicated in the Manual (Ministry of Health, Labour and Welfare, Japan, 2015) and examined the screening efficiency of the Kessler Screening Scale for Psychological Distress (Furukawa *et al.*, 2008; Kessler *et al.*, 2002), with a score of 13 or higher (equivalent to a severe mental disorder) being the outcome indicator. The results showed that when the cutoff value (stress responsescore of ≥ 77) in the Manual was used, the prevalence of those with high stress was 16.7%, with sensitivity of 60.5%, specificity of 88.9%, Youden index of 0.504, positive predictive value of 47.3% and negative predictive value of 93.8%. The highest screening efficiency (highest Youden index) was observed when the cutoff value was lowered to 65, where the prevalence of those with high stress increased to 32.3% and the positive predictive value dropped to 33.0%.

Similarly, Tsutsumi *et al.* (2018) examined the relationship between presence/absence of high stress at baseline (determined based on the assessment criteria in the Manual (Ministry of Health, Labour and Welfare, Japan, 2015) and long-term sick leave of ≥ 1 month during the following year (obtained from human resources data) using a Cox proportional hazards model. The results showed that compared with those who were not under high stress, those with high stress had a long-term sick leave risk due to subsequent mental health issues. The hazard ratios (adjusted for age, years of work, occupation, position, and receiving an interview with occupational health staff after the stress check) were 8.68 for men and 3.67 for women. The equivalent population-attributable risk proportion was 30.1% for men and 25.6% for women.

Relationship between BJSQ scores and work-related factors

Takahara (2018) conducted a survey that included items from the BJSQ with 1,895 temporary workers from a single company and examined the relationship between scores for these items and workers' voluntary retirement. They found that personal-level job satisfaction, workplace-level satisfaction and life satisfaction, as measured by the BJSQ, had a significant negative correlation with voluntary retirement.

Adachi (2017) examined BJSQ items that were strongly related to job satisfaction for 368 workers at a single company (288 men, 80 women) based on sex. The results showed that for men, factors that were significantly correlated with job satisfaction were the significance of work, control at work, support from superiors, aptitude in work and the amount of work. For women, aptitude at work, significance of work and the amount of work were significantly correlated with job satisfaction.

Higuchi *et al.* (2015) used BJSQ items at a baseline assessment for 661 male workers at a machine manufacturing factory to examine factors related to deterioration in respondents' job adaptability in the subsequent four years. They found that levels of physical burden, job satisfaction and support from superiors were significantly related to deterioration in job adaptability.

Necessity of supplementary tools

Shimura *et al.* (2018) used structural equation modelling, in which sleep-related issues (identified with the Pittsburgh Sleep Quality Index) were added to factors of stress and support at work drawn from the BJSQ. They showed that 55.2% of psychological and

physical stress could be explained through these factors. Those authors argued for the importance of also addressing sleep-related issues in stress checks. Ito (2017) noted that because the physicians that conduct interviews with those under high levels of work stress are not necessarily familiar with mental disorders, a support tool to accurately evaluate the risk for mental health issues is necessary. Therefore, that study proposed the use of a depression screening test (Ji test) that could be easily used in the Stress Check Program.

Effects of the Stress Check Program

Among the 18 papers reviewed, three examined the effects of the Stress Check Program (Table 1). One paper examined the effects of improvements in the work environment, one examined the effect of the method by which the stress check results were shared with individuals and the last paper examined the effects of other combined approaches.

Imamura *et al.* (2018) examined the links between implementation of improvements to the work environment through the Stress Check Program, stress responses and work performance. That study included data for 3,891 full-time workers that completed surveys before and after the Stress Check Program (November 2015 and February 2016) (the same subjects as used in the national survey by Asai *et al.* (2018)). A follow-up survey was conducted one year later, in which participants were interviewed about to whether they received a stress check at their workplace and if there had been any improvements to their work environment. Participants were divided into groups based on whether they had completed stress checks and experienced work environment improvements: “neither” (53.9%), “stress check only” (40.5%), “improvement to work environment only” (3.0%) and “both” (2.6%). Possible differences in changes to psychological stress responses and work performance scores were examined. The “both” group had significantly lower stress responses compared with the “neither” group. Imamura *et al.* (2018) concluded that implementation of the stress check as mandated by the Stress Check Program alone may not be effective in reducing the stress responses of workers and may be more effective in combination with improvements to the work environment.

In terms of sharing the stress check results with workers, Ito *et al.* (2016) reported on sharing the results of a questionnaire that involved 371 workers at an information technology (IT) company using an Internet-based system. Respondents’ stress status, related factors, individual stress management results and related advice were immediately provided by the system based on their answers to a questionnaire. That study showed that when the stress check results were conveyed to respondents using this system, respondents were more aware of the characteristics of stress management and more motivated to implement measures compared with before the intervention. The desire to implement measures continued for two months, and this maintained motivation impacted the maintenance of psychological health. A reason for this result may be that it was effective to have information in the individual report such as: the importance of having repertoires of measures for coping with stress on a daily basis, meaning multiple measures could be used as appropriate when individuals faced various stress-related factors and stressful situations; advice on how changes in mood and perspective could be useful in reducing work-related stress and specific examples that could be incorporated to everyday situations.

In another combined approach, Shintani *et al.* (2018) examined improvements in stress-related factors and stress responses after implementing the stress check following several strategies: interviewing all workers, providing stress self-care training for individual workers and providing training for managers and supervisors. Participants were workers at a food manufacturing company (168 total: 134 men, 34 women). In terms of stress-related factors, they reported role-related conflicts increased and skill use declined. With regard to stress responses, there was improvement in physical stress responses but no improvement in

psychological stress responses. The reason for the lack of improvement in stress-related factors may have been related to insufficient sorting of detailed tasks, which could have led to inefficient use of workers' skills.

Discussion

Implementation of the Stress Check Program

This review showed the implementation rate of the Stress Check Program was 53% at enterprises with ≥ 50 workers and 12–56% at small-scale enterprises. However, the national survey by Asai *et al.* (2018) was conducted in the early December of 2016, and numbers from any subsequent surveys were not included. Therefore, implementation rates for the following three years (2017–2019) may be expected to be higher (Asai *et al.*, 2018). According to the report on the implementation of the Stress Check Program prepared by the Ministry of Health, Labour and Welfare based on the reports submitted by enterprises to labour standards inspection offices (2017) (Ministry of Health, Labour and Welfare, Japan, 2017a), the Stress Check Program was implemented at 82.9% of enterprises in which it was mandated. In a survey that included workers at small-scale enterprises, which are not legally mandated to implement the Stress Check Program, implementation rates tended to be underestimated (Imamura and Kawakami, 2017); therefore, caution is needed when evaluating the program implementation rate in small-scale enterprises. However, implementation rates tended to be low in small-scale enterprises, especially small-scale independent enterprises (Saito *et al.*, 2019). The official report on the Stress Check Program implementation (2017) (Ministry of Health, Labour and Welfare, Japan, 2017a) presented implementation rates for each type of enterprise, which were particularly low in the hospitality and entertainment, cleaning and animal husbandry areas.

Within the scope of the survey, the examination rate of the stress check exceeded 90% in workplaces with ≥ 50 or more workers and 80% in workplaces with < 50 workers. In terms of occupation, the examination rate was particularly low for medical workers (Saito *et al.*, 2019) and educators (Muratani, 2017).

Although stress levels may depend on the individual workplace, 10–15% of workers on average were identified as under high levels of stress. However, only a limited number of workers received an interview with a physician. According to the 2017 Ministry of Health, Labour and Welfare report (Ministry of Health, Labour and Welfare, Japan, 2017a), among all those examined (examination rate of 78.0%), only 0.6% received an interview with a physician.

According to the survey by (Asai *et al.*, 2018), 3.3% of workers that received a stress check reported that their work environment had improved (Asai *et al.*, 2018). If workers were not involved in these changes to the work environment, it is likely that many workers may be unaware of improvements to their work environment, which could have resulted in underestimation of workplace improvements. In a subsequent national survey (Ministry of Health, Labour and Welfare, Japan, 2017b), the implementation rate was reported as 69% for enterprises with ≥ 50 workers and 58.3% overall. In the same survey, more than 70% of workplaces conducted group analyses using the stress check results, but specific details are unknown. In the survey of workplaces across Japan conducted by Kawakami (2012), the proportion of workplaces where any measures to improve the work environment were implemented after the stress checks increased from 37.0% in 2016 to 44.2% in 2017. However, many of these measures were “reporting and providing explanations to management,” whereas only 4–7.5% of workplaces implemented “participatory improvements to the work environment” that were considered effective in reducing workers' stress.

Implementation rates, examination rates and use of results for group analysis (including those separated by the scale of enterprises and industry) are important indicators in the distribution of

the Stress Check Program, and a further detailed survey is necessary. The reviewed literature showed that to further promote the Stress Check Program among small-scale enterprises, it is important to increase implementation efforts, such as tackling projects by appointing someone in charge of promoting mental health (Saito *et al.*, 2019) and implementing a stress check with routine health checkups (Ishimaru *et al.*, 2018). The literature also showed the necessity of managing the financial burden and other complexities, such as privacy in implementing stress checks, while making sure that the subsidy system is well known (Takeishi *et al.*, 2017).

Utility and validity of tools used for stress checks

The BJSQ has a certain level of validity for mental health-related outcomes (Adachi and Inaba, 2018; Tsutsumi *et al.*, 2017; Tsutsumi *et al.*, 2018) and work-related outcomes (Adachi, 2017; Higuchi *et al.*, 2015; Takahara, 2018). Specifically, the fact that a high level of stress has over a 25% population-attributable risk for mental health-related sick leave (Tsutsumi *et al.*, 2018) indicated that the BJSQ is a valid measure to identify high-risk groups for mental health issues. Although there is no evidence since the Stress Check Program started, the “Job Stress Assessment Diagram” that was prepared based on BJSQ responses to visualize health risks associated with job stressors has shown positive effects on the improvement of work environments (Kobayashi *et al.*, 2008; Tsutsumi *et al.*, 2009), and was used as a tool for group analysis in many studies.

Overall, the effectiveness of the Stress Check Program has not been shown for stress-related factors that are not identified by the Job Stress Assessment Diagram (i.e. factors other than workload, control at work and support at work). It is therefore necessary to examine whether unused items could be useful to understand high stress and inform measures to improve work environments. Although they may differ between industries, “subjective physical burden,” “job satisfaction,” “significance of work,” and “aptitude at work” (for which the link with work-related factors has been shown) may be items that could provide useful information for stress-related measures (Adachi, 2017; Higuchi *et al.*, 2015; Takahara, 2018). However, further empirical findings are needed.

Screening of those under high levels of stress by the BJSQ using assessment criteria as specified in the Manual (Ministry of Health, Labour and Welfare, Japan, 2015) is considered useful (Tsutsumi *et al.*, 2017). However, among those identified as under high stress, less than half presented psychological stress responses equivalent to a severe mental disorder; therefore the ability to screen individuals during implementation of the Stress Check Program has limitations. It is necessary to verify if it is useful to consider sleep-related issues (Shimura *et al.*, 2018), combining the BJSQ with supplementary tests (e.g. an assessment scale for depression (Ito, 2017)) and other related tools.

Effects of the stress check program

Reducing the risk for mental health issues through conducting routine surveys of workers and sharing the results. A previous randomized controlled trial did not support the idea that providing feedback from stress surveys to workers reduced the risk for mental health issues (Kawakami *et al.*, 1999; Ketelaar *et al.*, 2013). The present review found one study that showed that sharing individual results and providing advice to improve issues using an IT-based system improved awareness of stress management and motivation to implement measures (Ito *et al.*, 2016). However, that study was a before-and-after trial conducted without controls. Whether the immediacy of feedback from a stress check and the validity of advice can contribute to its effectiveness need to be verified in further studies.

Screening of those under high levels of stress and interviews with physicians. No available study investigated the effect of interviews with physicians for those under high levels of stress following a stress check. There are few studies worldwide that have shown the

effectiveness of screening for mental disorders such as depression following stress checks. Wang *et al.* (2007) reported that intensive care by trained social workers and experts following screening was effective (Wang *et al.*, 2007). Considering the low implementation rates of interviews with physicians in the Stress Check Program in Japan, interviews with physicians are unlikely to be effective in the present system that targets those under high levels of stress.

It is difficult to demonstrate the effectiveness of the secondary preventative functions of the Stress Check Program within current mandatory frameworks, but measures for managing those under high levels of stress at risk for mental health-related sick leave are necessary. The studies we reviewed recommended tools such as, self-care using existing points of contact with workers, preliminary interviews with public health nurses (Masuzawa *et al.*, 2018), frameworks for ex-post actions that could be passed onto experts and the creation of a simple manual that includes the previous options. In addition, re-examination of procedures for interviews with physicians including requests filed by workers was proposed to create a system where stress-related consultation was easy for workers.

Interviews with workers and self-care training related to the Stress Check Program (Shintani *et al.*, 2018) could be designed to fit the capacity of workplaces and occupational health staff within the framework of comprehensive mental health measures. The cost of measures for workplace stress is also being examined, which can be used as a further reference in reviewing the system (Yoshimura *et al.*, 2013).

Reducing psychological stress responses through improvement of the work environment based on group analysis (including education for management and supervisors). A combination of a stress checks and improvements in the work environment may reduce workers' psychological stress responses (Imamura *et al.*, 2018). As the Stress Check Program started, no study has verified the effect of the program on workers' mental health by using group analysis of stress check results. However, some studies verified the effects of improvements in the work environment implemented based on the stress check results using the occupational stress model within a similar framework (Egan *et al.*, 2007; Lamontagne *et al.*, 2005; Montano *et al.*, 2014). The present results are consistent with these reports.

What the relevance of the stress check program is as implemented in Japan to other countries

The Japanese Stress Check Program focuses on prevention of mental health problems by combining an annual stress survey that aims to decrease the risk for mental health problems by increasing workers' awareness of their own stress and allowing group analysis to improve the workplace psychosocial environment. The major strategy for improving worker mental health in European countries is risk assessment and management of psychosocial factors at work (e.g. Psychosocial Risk Management Excellence Framework: PRIMA-EF) (International Labour Organization, 2012; Leka *et al.*, 2011). This approach focuses on the psychosocial work environment. The ordinal procedure for the psychosocial risk assessment at work is conducted by using an anonymous survey, and the report is summarized based on the group. Compared with national policies and programs to prevent occupational stress conducted in other countries (Brookes *et al.*, 2013; Daniels *et al.*, 2012; Mackay *et al.*, 2004; Malachowski *et al.*, 2017), Japan's program is unique in that individual workers are identified (for screening purposes) and group analysis is not mandatory.

It may reflect a culture of paternalistic approach of Japanese occupational health system, in which employers are expected to protect employees' health and welfare (Kawakami and Tsutsumi, 2016). Such individualized approach could be easily adopted by the countries with similar cultural backgrounds and/or occupational health systems, such as general health examination at workplace (Kang *et al.*, 2017). It is also interesting to see the effects of the Stress Check System in the countries sharing common occupational health issues (Tsutsumi, 2019).

However, the effect of the program needs to wait for the future evaluation on the longer-term impact of the program.

Conclusions

The aim of the 13th Occupational Safety and Health Program (2018–2022) (Japan Ministry of Health, Labour and Welfare) is to increase the proportion of workplaces that perform group analysis using the results of stress checks and utilize the results to 60% or higher (Ministry of Health, Labour and Welfare, Japan, 2018). The results of group analysis can be used at various levels, such as comparisons of overall enterprises with the national average, comparisons between departments and improvements in the work environment based on the results. As discussed earlier, implementation of improvements in the work environment as part of the Stress Check Program was observed in a number of workplaces; however, few workplaces had made improvements based on stress check results. Improvements in the work environment that are linked with the Stress Check Program need to be further promoted. Further efforts are needed to narrow the gap between evidence and implementation, including improving guidance manuals and introducing different methods based on successful cases to increase the on-site implementation potential of the Stress Check Program.

The Japanese Stress Check Program contrasts with risk management of psychosocial factors at work as a strategy for improving workers' mental health proposed by international bodies such as the World Health Organization and the International Labor Organization. These strategies target the psychosocial work environment rather than psychosocial stress among individual workers. Although the effectiveness of the Japanese program needs further evaluation, future developments of the program would provide insight for national policies on psychosocial risks/psychosocial stress at work.

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Work functioning impairment in the course of pharmacotherapy treatment for depression

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This study investigated the association between the duration of pharmacotherapy treatment for depression, or discontinuation from treatment, and work functioning impairment. This was a retrospective cohort study examining 30,409 workers. Work functioning impairment was assessed using a questionnaire, and treatment status was assessed using medical claims data. Odds ratios (ORs) of workers with severe work functioning impairment compared with healthy workers (control group) were calculated using logistic regression analysis. Continuous medical treatment was associated with severely impaired work functioning regardless of treatment period [continuous medical treatment; 4 months <: OR = 3.2, 4 months ≥, 10 months <: OR = 2.6, 10 months ≥, 14 months <: OR = 2.3, 14 months ≥, 16 months <: OR = 2.3, which are all statistically significant ($p < 0.05$)]. Workers who initially received pharmacotherapy treatment but discontinued in <11 months had a significantly higher OR (treatment discontinuation period; 3 months <: OR = 2.3, 3 months ≥, 8 months <: OR = 2.0, 8 months ≥, 11 months <: OR = 3.0), while those who discontinued at ≥11 months did not (OR = 1.4, 95% CI 0.6–3.5). The sensitivity analysis excluding participants with at least one psychiatric comorbidity other than depression did not change the final result. It is important for the occupational health practitioners and attending psychiatrists to follow up in cooperation with each other, paying attention to the decrease in work functioning in addition to the symptoms.

Patients with depression are likely to experience many years lived with disability (YLDs). This is a global health issue because major depressive disorder (MDD) is among the five leading causes of YLDs worldwide, contributing 34.1 million of the total YLDs (805 million) as of 2016¹. Depression reduces quality of life and affects work performance quality^{2,3}. Presenteeism, defined as working while sick, is associated with reduced productivity and is a topic gaining increasing attention. A study found 6.4% of workers met the criteria for 12-month MDD, which is associated with 27.2 lost work days per sick worker per year and, in the United States, an overall loss of 225 million work days and \$36.6 billion⁴. Based on total health-related costs due to absenteeism, presenteeism, and medical and pharmaceutical expenses, mental health disorders, including depression, comprise the largest burden of disease in the United States⁵ and Japan⁶. Our past study revealed that the presenteeism costs due to mental and behavioural disorders were \$948 per 1000 full-time equivalent per year⁶. The other study revealed that sickness presence accounted for an average of 45.1 work days lost per employee per year⁷.

Undiagnosed and untreated depression had caused enormous socio-economic losses such as a decrease in labor force and an increase in social security costs due to the severity and chronicity of depression⁸. It has been shown that mild depression should be an intervention target because it has a high risk of becoming severe^{9,10}. It is important to detect and treat depression during its early stages. Proper treatment throughout the acute phase can relieve related symptoms, and achieve remission and a return to full functioning and quality of life^{10–13}. It is also strongly recommended to continue pharmacotherapy after remission following successful acute phase

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treatment for preventing relapse^{11,14}. American Psychiatric Association guidelines recommend treating patients with primary depression with the same dose of antidepressants as used in the acute phase, for 4–9 months or longer after remission, and assuming good and consistent control of depression symptoms^{11,15}. Meanwhile, discontinuation and dose reduction of antidepressant drugs in the early phases can increase the risk of exacerbating symptoms; early discontinuation of antidepressants results in a 77% increase in the risk of relapse and recurrence of depression in two years¹⁶. In order to decide the treatment policy, it is important not only to monitor the patient's psychiatric status but also to evaluate functional impairment and quality of life¹¹.

Many depressed patients present with cognitive dysfunction such as slowed thoughts, poor concentration, distractibility, and reduce capacity to process information¹¹. Understanding the type and extent of cognitive dysfunction is important in assessing the course of treatment. Attending physicians can evaluate functional impairment for their patients, and neuropsychological testing can be performed in the hospital¹⁷. However, it is difficult for the attending physician to intervene if the treatment is interrupted. If the patients were workers, the occupational health staff such as occupational physician and occupational health nurse can intervene with them in the workplace. Workers with depression tend to appear disabilities as work functions. Therefore, if the work functioning can be evaluated, it will be possible to find the timing of intervention by the occupational health staff. We previously developed and validated a self-administered questionnaire using the work functioning impairment scale (WFun) for assessment¹⁸. We also verified that the results of WFun assessments were correlated with the results of fit-to-work assessments conducted by occupational health nurses¹⁹.

Clinical treatment aims not only to relieve related symptoms, but to help patients recover their social functioning. Work functioning is an important social function for workers with depression. Information on the degree of work functioning in each phase of the treatment process is useful when deciding the necessity of cooperation between the occupational health staff and the attending physician, and when the attending physician decides the treatment content. However, to the best of our knowledge, there are no reports on changes in work functioning impairment based on treatment duration and discontinuation.

The purpose of this study is to describe the degree of work functioning impairment according to the course of pharmacotherapy treatment for depression (Objective 1: the duration of pharmacotherapy treatment, and Objective 2: the duration of discontinuation from pharmacotherapy treatment).

Methods

This was a retrospective cohort study of 45,404 workers, from 13 companies in Japan. All 13 companies were manufacturers (five pharmaceutical, six automobile-related, one nonferrous metals, and one precision equipment).

Data collection and ethical approval. The participants completed the WFun questionnaire between July and October 2015. The objectives of the study were explained to the participants, who were informed that participation was voluntary and that only the researchers, who were unaffiliated with the companies, would have access to the data. Ultimately, of the 45,404 workers, 33,415 (73.6%) participated.

We obtained participants' medical claims data from the companies' health insurance unions retrospectively, back to 15 months before the WFun questionnaire was given. These claims contained information on the date of any visits to a medical institution (outpatient or inpatient), the name of the institution, the disease(s), treatment/medication(s), and medical expenditures. Because Japan has a universal health insurance system, these claims data contained complete records on services used by the participants and covered under the system.

All methods were carried out in accordance with relevant guidelines and regulations. All data were labelled with unique codes assigned to each participant for personal information protection. Informed consent including implied consent was obtained from all subjects. The study was approved by the Ethics Committee of University of Occupational and Environmental Health, Japan (H26-026).

Measurements for treatment of depression with pharmacotherapy. Medical claims data were used for determining whether the participants had visited medical institutions and received pharmacotherapy treatment for depression there each month within the 15 months prior to their completing the WFun questionnaire. Participants were determined to have received pharmacotherapy treatment if they satisfied both of the following two inclusion criteria and one exclusion criteria:

We included by two criteria as follow.

1. International Classification of Diseases 10 (ICD 10) codes F30–F39 (mood [affective] disorders) was given as the disease name.
2. Antidepressants and/or psychoneurotic drugs (therapeutic category of drugs in Japan: 117) were prescribed²⁰.

We excluded workers who had International Classification of Diseases 10 (ICD 10) codes F30 (Manic episode) or F31 (Bipolar affective disorder) given as the disease name of the claims data. A total of 126 participants had F30 (Manic episode) or F31 (Bipolar affective disorder), and we excluded their data in the final analysis.

Based on information obtained from medical claims data and WFun, the participants were divided into five categories in accordance with their duration of pharmacotherapy treatment (Objective 1) and duration of discontinuation from treatment (Objective 2). Detailed definitions are provided below and in Fig. 1.

Objective 1: Association between the duration of pharmacotherapy treatment for depression and work functioning impairment.

Objective 1: Relationship between the duration of pharmacotherapy treatment for depression and work functioning impairment

Months prior to completing the WFun questionnaire	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	*
WFun conducted in July 2015	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15
WFun conducted in August 2015	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15
WFun conducted in September 2015	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15
WFun conducted in October 2015	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15
Continuous pharmacotherapy treatment period																
(1) control group (healthy workers)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(2) <4 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	○
(3) 4 to <10 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	○
(4) 10 to <14 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	○
(5) 14 to <16 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	○

WFun: work functioning impairment scale

* month in which WFun was conducted

○ pharmacotherapy treatment for depression

- no pharmacotherapy treatment for depression

Objective 2: Relationship between the duration of discontinuation of pharmacotherapy treatment for depression and work functioning impairment

Months prior to completing the WFun questionnaire	15	14	13	12	11	10	9	8	7	6	5	4	3	2	1	*
WFun conducted in July 2015	Apr-14	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15
WFun conducted in August 2015	May-14	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15
WFun conducted in September 2015	Jun-14	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15
WFun conducted in October 2015	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15	Mar-15	Apr-15	May-15	Jun-15	Jul-15	Aug-15	Sep-15	Oct-15
Discontinuation period after continuous pharmacotherapy treatment																
(1) control group (healthy workers)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(2) <3 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(3) 3 to <8 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(4) 8 to <11 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
(5) 11 to <14 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

WFun: work functioning impairment scale

* month in which WFun was conducted

○ pharmacotherapy treatment for depression

- no pharmacotherapy treatment for depression

Figure 1. Definitions of the five categories of the study objectives.

1. control group (healthy workers with no pharmacotherapy treatment): those who had received no related treatment within 15 months preceding the WFun
2. continuous pharmacotherapy treatment (< 4 months)
3. continuous pharmacotherapy treatment (4 to < 10 months)
4. continuous pharmacotherapy treatment (10 to < 14 months)
5. continuous pharmacotherapy treatment (14 to < 16 months).

A total of 315 participants were not classified under any of the above categories because they had received irregular pharmacotherapy treatment. Accordingly, we excluded their data in the final analysis.

Objective 2: Association between the duration of discontinuation of pharmacotherapy treatment for depression and work functioning impairment.

1. control group (healthy workers with no pharmacotherapy treatment): those who had received no related treatment within 15 months preceding the WFun
2. treatment discontinuation period (< 3 months)
3. treatment discontinuation period (3 to < 8 months)
4. treatment discontinuation period (8 to < 11 months)
5. treatment discontinuation period (11 to < 14 months).

A total of 546 participants were not classified under any of the above categories because they had received irregular pharmacotherapy treatment. Accordingly, we excluded their data in the final analysis.

Outcome measurements. WFun is a self-administered questionnaire developed using the Rasch model¹⁸. It assesses the severity of work functioning impairment and has been validated in accordance with the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN). Items of WFun and the scoring method was shown in Table 1. A higher total suggests greater work functioning impairment due

	Options and score of each option				
	Not at all	≥ 1 days a month	About 1 day a week	≥ 2 days a week	Almost every day
Items of Work Functioning Questionnaire (WFun)					
(1) I have not been able to behave socially	1	2	3	4	5
(2) I have not been able to maintain the quality of my work	1	2	3	4	5
(3) I have had trouble thinking clearly	1	2	3	4	5
(4) I have taken more rests during my work	1	2	3	4	5
(5) I have felt that my work is not going well	1	2	3	4	5
(6) I have not been able to make rational decisions	1	2	3	4	5
(7) I have not been proactive about my work	1	2	3	4	5

Table 1. Items of Work Functioning Questionnaire (WFun) and the scoring method. The total score is the sum of the scores of all items. The score range is 7 to 35 points. A high score means that the work impairment is large.

to health problems. A total of ≥ 21 points suggests severely impaired work functioning: a previous study found approximately 20% of employees had a WFun score of 21 points, and an assessment by occupational health nurses found these people were likely to have severely impaired work functioning and that they demonstrated high detectability with an area under the ROC curve of 0.83¹⁹. Cronbach's alpha coefficient for the seven items of WFun was 0.92 in this study.

Other measurements. We used a self-administered questionnaire to determine the participants' sex, age, job type and job title. Age in years was categorised into five groups (< 30 , 30–39, 40–49, 50–59, and ≥ 60 years), as was job type (clerical and administrative support, sales, research and development, production line, and other), while job title was categorised as manager or rank-and-file employee.

Statistical analysis. In addressing each of the two objectives indicated above, we performed logistic regression analyses using each category as an explanatory variable and a total WFun score of ≥ 21 points as an outcome variable. Using the category of no pharmacotherapy treatment (healthy workers) as a reference, we calculated the OR (and 95% CI) for each category. Stata version 14.2 (StataCorp LLC; TX, USA) was used for analyses, with significance set at < 0.05 .

Sensitivity analysis. Many patients can be expected to have at least one psychiatric comorbidity and this can quite significantly alter work functioning. Sensitivity analysis was performed in order to confirm that the results did not change even if these individuals were excluded. We excluded participants below (exclusion criteria) and performed logistic regression analyses in the same way.

Exclusion criteria.

1. International Classification of Diseases 10 (ICD 10) codes F00–F09 (organic, including symptomatic, mental disorders) was given as the disease name. F00–09 includes F00 (Dementia in Alzheimer disease) and F01 (Vascular dementia).
2. International Classification of Diseases 10 (ICD 10) codes F10–F19 (mental and behavioural disorders due to psychoactive substance use) was given as the disease name. F10–F19 includes F10 (mental and behavioural disorders due to use of alcohol) and F11 (mental and behavioural disorders due to use of opioids).
3. International Classification of Diseases 10 (ICD 10) codes F20–F29 (schizophrenia, schizotypal and delusional disorders).

Results

Participants' characteristics. Among the 33,415 participants, we were unable to obtain the medical claims data of 2,533 participants and 473 did not answer at least one of the seven WFun questions. After excluding them, we had data from 30,409 participants for analysis.

Table 2 shows the participants' characteristics. Male employees comprised 85% of the participants, and the largest proportion of participants (32%) were 40–49 years old, followed by 30–39 (24%), 50–59 (22%). Participants primarily worked in research and development (20%), clerical and administrative support (18%), and sales (18%).

Objective 1. Table 3 shows the association between the duration of pharmacotherapy treatment for depression and work functioning impairment.

	N	%
Sex		
Men	25,882	85
Women	4527	15
Age (years)		
≤ 29	5681	19
30–39	7448	24
40–49	9786	32
50–59	6621	22
≥ 60	873	3
Job type		
Clerical and administrative support	5423	18
Sales	5390	18
Research and development	5939	20
Production line	2845	9
Other	10,569	35
Missing	243	1
Job title		
Manager	5394	18
Rank-and-file employee	15,555	51
Missing	9460	31

Table 2. Participants' characteristics.

	N	WFun score		WFun score ≥ 21	OR	95% CI		p value
		Mean	SD					
(1) Control group (healthy workers)	29,564	14.7	6.4	20	Reference			
(2) Continuous medical treatment (4 months <)	63	19.1	8.1	44	3.2	1.9	5.2	<0.001
(3) Continuous medical treatment (4 months ≥, 10 months <)	58	18.7	8.1	40	2.6	1.5	4.4	<0.001
(4) Continuous medical treatment (10 months ≥, 14 months <)	33	18.5	7.8	36	2.3	1.1	4.6	0.024
(5) Continuous medical treatment (14 months ≥, 16 months <)	250	17.9	7.3	37	2.3	1.8	3.0	<0.001

Table 3. Number of workers, mean WFun score, and proportion of workers with a high WFun score (21 points or more), and logistic regression analyses for Objective 1: association between the duration of medical treatment for depression and work functioning impairment. OR odds ratio, CI confidence interval.

Continuous medical treatment was associated with severely impaired work functioning regardless of treatment period [continuous medical treatment; 4 months <: OR = 3.2, 4 months ≥, 10 months <: OR = 2.6, 10 months ≥, 14 months <: OR = 2.3, 14 months ≥, 16 months <: OR = 2.3, which are all statistically significant ($p < 0.05$)].

Objective 2. Table 4 shows the association between the duration of discontinuation from pharmacotherapy treatment for depression and work functioning impairment.

Workers who initially received pharmacotherapy treatment but discontinued in < 11 months had a significantly higher OR (treatment discontinuation period; 3 months <: OR = 2.3, 3 months ≥, 8 months <: OR = 2.0, 8 months ≥, 11 months <: OR = 3.0), while those who discontinued at ≥ 11 months did not show a significantly higher risk of work functioning impairment (OR = 1.4, 95% CI 0.6–3.5).

A sensitivity analysis was performed on both objectives 1 and 2. The results excluding participants with at least one psychiatric comorbidity other than depression did not change (Supplementary Table S1, S2).

Discussion

This study investigated the association between the duration of pharmacotherapy treatment and work functioning impairment as well as the association between the duration of discontinuation from pharmacotherapy treatment and work functioning impairment. Continuous medical treatment was associated with severely impaired work functioning regardless of treatment period. Further, workers who initially received pharmacotherapy treatment but discontinued in < 11 months had a significantly higher OR compared to healthy workers (control group), while those who discontinued at ≥ 11 months did not (OR = 1.4, 95% CI 0.6–3.5).

	N	WFun score		WFun score ≥ 21	OR	95% CI		p value
		Mean	SD	%				
(1) Control group (healthy workers)	29,564	14.7	6.4	20	Reference			
(2) Treatment discontinuation period (3 months <)	81	17.9	6.8	37	2.3	1.5	3.7	<0.001
(3) Treatment discontinuation period (3 months \geq , 8 months <)	48	19.1	5.8	33	2.0	1.1	3.6	0.026
(4) Treatment discontinuation period (8 months \geq , 11 months <)	21	19.2	6.8	43	3.0	1.3	7.1	0.014
(5) Treatment discontinuation period (11 months \geq , 14 months <)	23	16.2	6.7	26	1.4	0.6	3.5	0.481

Table 4. Number of workers, mean WFun score, and proportion of workers with a high WFun score (21 points or more), and logistic regression analyses for Objective 2: association between the duration of discontinuation from medical treatment for depression and work functioning impairment. *OR* odds ratio, *CI* confidence interval.

The present results have several implications for future interventions. First, in this study, the risk of experiencing severe work functioning impairment was higher even with ≥ 1 year of antidepressant treatment. While most recent systematic reviews have shown antidepressant treatment improves functional outcomes, one reported that 60% of patients had persistent functional impairment even 6 months after symptom remission²¹. Job performance is also improved over time following symptom amelioration²². These results are consistent with the present findings. Based on these findings, if the symptoms were recovered by the treatment of antidepressants but the work function was deteriorated, it may be necessary to consider a side effects of antidepressants or a cognitive impairment due to causes other than depression such as Alzheimer's disease.

Second, in addition to symptom amelioration, job-related functioning and performance are important for continued employment. Our study suggests the importance of monitoring patients for ≥ 1 year after finishing treatment (Table 4), assuming work performance is only restored after recovery from symptoms. The risk of work functioning impairment is markedly higher, particularly in the acute phase (<4 months as shown in Table 3), wherein the risk is threefold that of healthy controls. It is therefore important to assess workers' degree of recovery from impairment after starting treatment, even if their symptoms have remitted. Additionally, given that severe work functioning impairment (WFun ≥ 21 points) can increase the risk of taking sick leave in the future, such assessments are important for preventing depression-related work leave²³.

Third, in the present study, the risk of severe work functioning impairment remained high for about 1 year after discontinuation of antidepressant treatment (Table 4). This is the first study to assess work functioning following treatment discontinuation. To deter workers' impatience with their recovery, attending psychiatrists or occupational physicians should explain the likelihood of being at an increased risk of work functioning impairment for ≥ 1 year after discontinuing antidepressant treatment. This explanation may give motivation to seek medical assistance when experiencing a symptom relapse. Additionally, Japanese companies with >50 employees are legally obliged to employ corporate healthcare professionals, mainly occupational physicians, in the workplace. In these companies, importance should be placed on collaboration between the attending psychiatrist and healthcare professionals via the patient, and these healthcare professionals should follow-up patients after the patients discontinue antidepressant treatment.

The present study has a number of strengths. It is the first study to investigate work functioning impairment in employees across several phases of antidepressant treatment for depression by comparing findings with healthy workers who have never received such treatment. The study also examined work functioning impairment across several phases after discontinuation of pharmacotherapy treatment for depression. Additionally, this study used a large-scale, workplace cohort and was based on mutually exclusive and collectively exhaustive medical claims data obtained via Japan's universal health insurance system.

The study does also have some limitations. First, we did not obtain information on the responsiveness of treatment for depression and the reason for discontinuation of treatment. We could not evaluate the effects of these situations on work functioning.

Second, we did not assess depression severity. We therefore did not account for its effect on work functioning impairment. However, a recent systematic review reported, based on several studies, that although antidepressant treatment ameliorates functional outcomes, the severity of depression at the start of treatment does not affect this amelioration². We were also unable to examine non-pharmaceutical treatments, such as psychotherapy, concurrent with pharmacotherapy; therefore we did not evaluate the effects of such treatments. Additionally, we did not examine other aspects, such as the effects of job styles at certain workplaces, with relation to work performance. Finally, because the study population comprised employees from companies listed on the First Section of the Tokyo Stock Exchange, and thus generally representing those of higher socioeconomic status, care should be taken in generalising the findings. Furthermore, roughly half were pharmaceutical company employees and therefore likely have greater medical knowledge than the general public. People with higher socioeconomic attributes, such as higher education levels, are also more accepting of mental health services²⁴. The proportion of participants who had depression but were not using such services was therefore likely lower than that in the general population. This limitation should be taken into account when interpreting the results. Those taking oral antidepressants accounted for 2.7% of all participants, which is similar to the proportion in

a large-scale survey on mood (emotional) disorders among general residents in Japan (in which the 12-month prevalence of depression was 2.1%)²⁵.

Conclusions

The present study showed an association between the duration of pharmacotherapy treatment and work functioning impairment as well as the relationship between the duration of discontinuation from treatment and such impairment. Patients were found to be at an increased risk of severe work functioning impairment for ≥ 1 year after discontinuing antidepressants. It is important for the occupational health practitioners and attending psychiatrists to follow up in cooperation with each other, paying attention to the decrease in work functioning in addition to the symptoms.

Data availability

The analysis presents clinical data of a large-scale workplace-based cohort with ongoing follow-up examinations. This project constitutes a major scientific effort, therefore data are not made available for the scientific community outside. Interested researchers make their requests to the leader of the Collabo-Health Study (Tomohisa Nagata; tomohisa@med.uoeh-u.ac.jp).

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Author contributions

T.N. played a lead role in the study design and the writing of the manuscript, and he contributed to the data interpretation and the data analysis. Y.F. conducted the data analysis, contributed to results interpretation and reviewed drafts of the manuscript. M.O. (Makoto Ohtani) contributed to the study design and data interpretation. K.F. conducted the analysis of receipt data. M.N., S.K., M.O. (Makoto Okawara) and K.M. reviewed drafts of the manuscript. All authors had final approval for submitted and published version of the paper.

Competing interests

The authors declare no competing interests.

Additional information

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ORIGINAL ARTICLE

Developing a global occupational health and safety management system model for Japanese companies

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Abstract

Objectives: To develop and validate a global occupational health and safety management system (OHSMS) model for Japanese companies.

Methods: In cooperation with a Japanese company, we established a research team and gathered information on occupational health and safety (OHS) practices in nine countries where the target company operated manufacturing sites. We then developed a model hypothesis via research team meeting. The model hypothesis was introduced to local factories in Indonesia and Thailand as trial sites. We evaluated the roles of the company headquarters, the implementation process, and any improvements in OHS practices at the sites. Based on the results, a global OHSMS model was formalized for global introduction.

Results: The model consisted of both headquarters and site roles. These roles were well-functioning, and OHS at the sites improved. Two issues concerning the functioning of the headquarters were identified: the need to establish a reporting system to the headquarters and the need to support the improvement of specialized human resources. By improving the model hypothesis to address these issues, the model was formalized for global introduction.

Conclusions: The global OHSMS model was based on the use of methods and specialized human resources relevant to each region and their common objectives, as well as evaluation indicators based on the minimum requirements of the company headquarters. To verify the effectiveness of this model, the experiment should be extended to other countries.

KEYWORDS

global OHSMS, Japanese companies, performance audit, reporting system, specialized human resources

1 | INTRODUCTION

The globalization of economic activities has also seen the expansion of Japanese companies abroad. A survey of Japanese companies and their overseas subsidiaries and business

activities found that there were 24 959 overseas subsidiaries of Japanese companies as of July 2017.¹ Regarding occupational health and safety (OHS) for workers in Japan, staff in charge of OHS generally provide the necessary services in compliance with local laws and regulations. However,

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developing and emerging countries often lag far behind developed countries in terms of OHS training for professionals, and practices in these countries do not always keep pace with the development of laws and regulations of their home country.

Large companies in Europe and the United States typically apply global standards, which usually have stricter requirements than local regulations, to local sites, as well as complying with local OHS laws and regulations.^{2,3} They often establish a unified OHS management system (OHSMS) whereby each site is required to meet common requirements, and this system is typically controlled and managed by the company's OHS department located at its headquarters.⁴ Furthermore, most OHSMSs also include international standards or company standards that reflect the laws and practices of the area in which the company's headquarters is located.⁴

In addition to considering the requirements in the location of the company's headquarters, which is involved in personnel allocation and investment decision-making through capital relationships, as part of risk management and corporate social responsibility strategies, Japanese companies, as well as Western companies, need to improve their OHS standards at their subsidiaries, regardless of location.^{4,5}

When considering OHS practices based on Japanese regulations, it should be noted that Japanese OHSMSs are based on minimizing requirements and assume that the resources and personnel are adjusted to the actual situation in each region as much as possible to achieve the same objective. Thus, we call our system a “global OHSMS for Japanese companies.”

In developing a global OHSMS for Japanese companies, it is necessary to gather information on the OHS environments in the target countries and regions where overseas subsidiaries are located and to establish a system that enables both the involvement of the company headquarters and the autonomous efforts of local sites. Thus, we developed an “Information Collection Check Sheet for OHSMSs at Overseas Plants” as a tool for efficient information gathering,⁶ and investigated the actual conditions regarding, for example, OHS regulations and human resource development in a number of countries.^{7–10}

In this study, we developed a global OHSMS model for Japanese companies and confirmed its validity via cooperation with the headquarters of a global Japanese manufacturing company that produces construction equipment.

2 | METHOD

2.1 | Research team

We established a research team that consisted of two experienced occupational physicians (OPs: SK, KM) working at a Japanese branch of a US-based global company, two chief

OPs (YK, MS) with Japanese-based global enterprises, and the chief OP (SN) and two in-house OPs (KH, NF) from the target company, which is described below.

2.2 | Target company

The target company is a manufacturer of construction and mining equipment that has 12 production sites in Japan and 31 overseas sites. Of the overseas sites, 18 are located in five Asian countries, including China, seven are located in five European countries, including Russia, five are located in the United States, and one is located in Brazil. The company has approximately 60 000 employees worldwide, of which 60% are non-Japanese employees working at the overseas sites.

The company produces a diverse range of products, and total sales in the 2016 fiscal year were approximately 1.8 trillion yen. The possible health hazards for workers include noise, heat, dust, organic solvents, and bad posture. Company management displayed a clear willingness to promote both OHS and OHS investment in all workplaces, including its overseas sites.

2.3 | Model development process

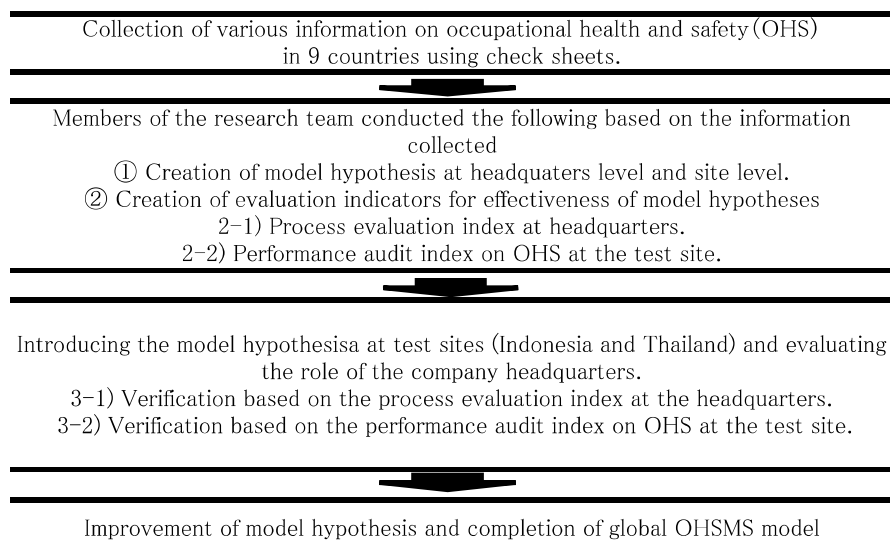
The model was developed in four steps: (a) information gathering; (b) establishing the model hypothesis and developing evaluation indicators; (c) introducing the model hypothesis at test sites and evaluating the roles of the company headquarters; and (d) improvement of the model hypothesis based on the results of the pilot implementation and completion of the global OHSMS model.

2.3.1 | Information gathering

Because most European sites exist in countries that are members of the European Union, the OHS requirements are considered to be similar across these sites. Therefore, to better understand the overall picture of the similarities and differences among the overseas sites, we surveyed nine countries from various continents, including Japan.

To conduct the survey, we visited each of the nine countries following a literature and Internet search and gathered information using the “Information Collection Check Sheet for OHSMS at Overseas Plants”.⁶ Members of the research team visited the Japanese Embassy, local administrative agencies such as the Ministry of Health, Labor and Welfare, ISO (International Organization for Standardization) accreditation bodies, and institutions that train OHS experts, such as universities, in each country. We conducted interviews with representatives in each location that lasted for about 2–3 hours. If sufficient information was not obtained during the initial visit, we returned to the site as many times as necessary. A flow chart of the survey procedure is shown in Figure 1.

FIGURE 1 This figure shows the flow of this research for about 6 years



2.3.2 | Establishing the model hypothesis and developing evaluation indicators

We conducted a meeting of the research team to establish a model hypothesis based on the information obtained. Following a brainstorming session with members of the research team, we created the categories at headquarters level and site level respectively. To establish a hypothesis based on a global OHSMS perspective, we clarified that it will be implemented at the headquarters and sites on the premise of utilizing the basic policy and OHSMS.

Then, we created evaluation indicators for headquarters and test sites to confirm the validity of the model hypothesis. Evaluation indicators were also developed based on the ideas presented by the research team members during the discussion. The evaluation indicators made it possible to evaluate the level of improvement in detail and to describe what kind of reach (state) each criterion is specifically. Headquarters adopted process evaluation and test sites created performance audit on OHS.

2.3.3 | Introducing the model hypothesis at test sites and evaluating the roles of the company headquarters

We conducted a pilot implementation of the global OHSMS for Japanese companies in Indonesia and Thailand based on the model hypothesis. While the sites in these countries had already introduced a number of OHS initiatives, there was considerable room for improvement, mainly in the field of occupational health. For example, neither the established OHS practices based on laws and regulations nor the risk management system addressing hazardous factors not covered by laws and regulations were satisfactory. The training system in these two countries was relatively clear, and it was easy to obtain specialized human resources from major

universities and administrative agencies. Furthermore, these countries were selected because local management was committed to introducing the OHSMS.

Based on the hypothesis, we gained an understanding of the OHS conditions at the sites in these countries through an interview and field patrol with local health and safety personnel. Then, the research team presented proposals to the site management teams regarding the measures necessary to address OHS issues that had been identified. In cases where the site personnel required assistance from OHS experts, we introduced local experts to management, and also recommended the use of OHS experts when it was necessary to provide education and training for workers.

Then, we evaluated the effects of our intervention after a period of time. The research team examined the functions and roles of the company headquarters and evaluated after developing efforts to test sites. The evaluation result of the company headquarters was determined by the members of the research team. Evaluation of the local sites was based on previously determined evaluation indicators (performance audit consists of evaluation items and criteria). Members of the survey team discussed the audit results with the top management and safety and health managers of the target factory and discussed until the audit team and the audited organization were satisfied.

2.3.4 | Improvement of model hypothesis based on the results of the pilot implementation and completion of the global OHSMS model

We reviewed the results of the performance audit and evaluation following the pilot implementation. Then, we reviewed the model hypothesis, discussed any necessary improvements, and completed the global OHSMS model.

3 | RESULTS

3.1 | Information gathering

The results of the survey of OHS systems in nine countries, including Japan, are as follows.

3.1.1 | Laws on OHSMS and status of specialized human resources

Regarding presence of laws and guidelines on OHSMS, Japan, Thailand, and China welcomed the introduction of an OHSMS.

Regarding professionals mainly responsible for OHS activities, OPs were active in Japan, Indonesia, Germany, and Brazil. Safety Officers are active in Thailand and China. In the United Kingdom, family physicians, and in the United States, Safety Professionals and Industrial Hygienists have been the main activities.

Regarding legal requirements concerning the appointment and utilization of expert personnel in OHS, Japan, Indonesia, Germany, and Brazil are all legally required to appoint OPs. Japan, Thailand, China, and Germany have legal obligations regarding the appointment of safety managers or safety officers.

Regarding status of training specialized human resources on OHS, OPs in Japan and Indonesia were able to obtain qualifications by receiving more than 50 hours (Japan) and 56 hours (Indonesia) of training. Different levels of SOs were developed in Thailand and China. OP specialists were trained in Germany, the United Kingdom, the United States, and Brazil. Although there is no requirement to employ specialist staff such as OPs and safety officers, the responsibilities of businesses are stipulated, and specialist personnel are employed in the United Kingdom and the United States (see Table 1).

3.1.2 | Status of major programs related to occupational health

Regarding presence of law of risk assessment for harmful factors, Japan, Germany, the United Kingdom and Brazil have to conduct and personal exposure monitoring for hazardous work is conducted in the United States.

Regarding evaluation of health effects by hazardous work, employers are obliged to carry out evaluation of health effects by hazardous work in all countries except for Myanmar. There are those in which health checks and laboratory standards are regulated by law (eg, China) and those where they are selected by specialized personnel (eg, Indonesia, Thailand, and Germany).

Regarding fit for work programs, all countries except for Myanmar have laws and regulations prescribing pre-deployment health checks for workers engaged in hazardous work. The United States is only required when a worker returns to work after injury.

Regarding management of personal information, personal health information is only shared between the workers and medical professionals, and only health-related information that is relevant to the workers' employment is conveyed to employers. In Myanmar, OHS legislation is not well-developed, and there is no clear provision for any of the above practices (see Table 2).

3.2 | Establishing the model hypothesis and developing evaluation indicators

3.2.1 | Model hypothesis

We assumed a model consisting of two levels of practices at the company headquarters and at each manufacturing site. In the headquarters, the following eight practices were implemented at the headquarters level: "formulation and dissemination of health and safety policies by the CEO (Chief Executive Officer)," "establishment of a global safety and health conference," "determination of OHSMS standards," "formulation and notification of global standards," "formulation and notification of performance audit standards," "training of auditors and conduct performance audit," "support for securing and fostering appropriate human resources at each site," and "technical support in the case of a shortage of specialized resources."

Of these, the global standards issued by the headquarters of Japanese companies included those used to promote the autonomous activities of the organization and to acquire budget funding. To facilitate verification of the introduction of global standards, we developed the following global standards: "risk assessment," "chemical substance management," and "facilities and personal protective equipment standards."

The components of an OHSMS that were developed and applied at each site are as follows: "formulation of the basic policy," "specialized human resources in OHS or utilization of external resources," "companies' global standards and regulations compliance," "promotion of autonomous activities," and "internal audit and continuous improvement."

The OHSMS at each site was based on the Occupational Health and Safety Assessment Series (OHSAS) 18001 in consideration of an integrated review with ISO 14001 and the possibility of future global integrated authentication. At the time of the development of the model hypothesis, ISO 45001 (which is similar to OHSAS 18001) was expected to become an ISO standard in the near future. Therefore, it was decided to replace OHSAS 18001 with ISO 45001 when it was made official.

3.2.2 | Evaluation indicators

To evaluate the global OHSMSs of Japanese companies, we decided to use process evaluations at the headquarters level and performance audits at the test sites. Process evaluation

TABLE 1 Laws on OHSMS and status of specialized human resources of nine countries using the information collection check sheet

No	Country name	Presence of laws and guidelines on OHSMS	Professionals mainly responsible for OHS activities	Legal requirements concerning the appointment and utilization of expert personnel in OHS	Status of training specialized human resources on OHS
1	Japan	Yes	OPs	The obligation to appoint an OP and the establishment of SM, HM, etc. are stipulated by laws and regulations at business establishments of a certain size or more.	OP qualifications can be obtained by taking education of 50 hours or more based on the standards of laws and ordinances.
2	Indonesia	No	OPs	There is an obligation to provide therapeutic medical services by an OP who directly employed in workplaces of a certain size or more.	OP qualifications can be acquired by taking education of 56 hours or more based on the standards of laws and ordinances. Certified specialist OPs are cultivated at several domestic universities.
3	Thailand	No There is a management system standard called TIS 18001, but there is no obligation to certify.	SOs	OHS activities are structured to focus mainly on SOs. There are five levels of SO. Specialized OPs perform special health examination.	The number of certified OPs being trained is not large. SO has been trained in 86 facilities as of February 2015.
4	China	No Safety production standardization exists as a framework for promoting OHS activities, and applicable business sites need to comply with these requirements.	SOs	Establishment standards for SOs are determined. Only institutions that have qualified doctors who are certified by the government can conduct special health checkups.	SOs can be in charge of graduation above the vocational school or those who received a certain training. There are no certified OPs, but public health doctors (medical departments) are being trained at universities throughout the country.
5	Myanmar	No	None	None	None
6	Germany	No	OPs	There is an obligation to appoint an OP, a SO. Those persons in charge can be an employee or an external expert.	OPs and SOs are trained.
7	United Kingdom	No	Family Doctor	There is no obligation to appoint an OP. There are cases where external consultants are utilized to satisfy the requirements specified by laws and ordinances.	Family doctor is playing the role of OP. There are qualified OPs.
8	United State of America	No	SPs His	There is no obligation to appoint a person in charge of OHS experts.	CSP (Certified SP) and CIH (Certified IH) are cultivated. Specialized OPs are cultivated at several domestic universities, and there is a specialist medical system certified by academic societies.
9	Brazil	No	OPs External experts	There is an obligation to appoint safety engineers, occupational health nurses, OPs.	Training of specialist OP is being conducted.

Abbreviations: HM: hygiene manager; IH: industrial hygienist; OHS: occupational health and safety; OHSMS, occupational health and safety management system; OP: occupational physician; SM:safety manager; SO: safety officer; SP: safety professional.

TABLE 2 Status of major programs related to Occupational Health of nine countries using the information collection check sheet

No	Country name	Presence of Law of RA for harmful factors	Evaluation of health effects by hazardous work	Fit for work program	Management of personal information
1	Japan	Yes There are RA and chemical substance RA guidelines.	There is an obligation for SME. For each harmful factor, inspection items are stipulated by law.	There is an obligation of GME (before deployment, regular, special worker). There are guidelines on support for returning to mental health disabled people. Efforts are under way to support work and treatment compatibility at the same time.	The results of GME are obliged to be preserved by the operator for 5 years. Personal information is provided to business operators after processing by OPs and other.
2	Indonesia	No	There is an obligation for SME. Details of inspection items are not stipulated by laws and regulations.	There is a judgment classification of GME. More concrete judgment criteria and post correspondence according to health condition are defined for each employment classification.	No regulations concerning Personal information are stipulated.
3	Thailand	No	There is an obligation for SME at the time of employment and change of workplace. The details of inspection items are not stipulated in laws and ordinances.	If there is a finding on the result of SME by workers, arrange for the workers to receive medical treatment immediately and investigate the cause for prevention.	The employer shall record the results of all SME of workers engaged in hazardous work in the personal medical examination notebook.
4	China	No	SME must be carried out for workers engaged in hazardous work at the time of employment and at the time of changing workplaces. Inspection items are stipulated for each harmful factor by law. Standards of the executing agency are stipulated.	If a company finds a health hazard resulting from that job, it is necessary to relocate the workplace of that worker properly.	It is necessary to prepare and preserve health management records including data on health aspects concerning individuals such as worker's work history, past records that touched on occupational disease harm.
5	Myanmar	No	None	None	None
6	Germany	Yes There is an obligation to conduct RA.	There is an obligation to conduct SME.	There is an obligation to conduct GME(before deployment, regular, special worker). A list of OI and WRD exists and OP advises.	Individual medical information and health information can be confirmed only by OPs.
7	United Kingdom	Yes There is an obligation to conduct RA. Management itself places emphasis on self-management of business operators.	There is an obligation to conduct SME. Details of inspection items are not stipulated by law.	Fit note, which is the application form for official leave of compensation, is used at the time of reinstatement from sick leave. Workers first consult with their superiors and employers, and consideration is often given to employment on that basis.	The results of SME are to be managed by the business operator. Results of health examination will be notified to individual workers as well.

(Continues)

TABLE 2 (Continued)

No	Country name	Presence of Law of RA for harmful factors	Evaluation of health effects by hazardous work	Fit for work program	Management of personal information
8	United State of America	No Using the results of PEM, voluntary RA and measures based on the results are required.	There is an obligation to conduct SME for special work obtained by law.	At the time of reinstatement after occupational accidents or labor diseases, it is required to prepare a workplace where businesses can arrange by referring to the opinion written on the doctor's medical certificate at the time of reinstatement.	The results of SME are managed by the company (in-house personnel in charge). The results of GME (voluntary implementation) are managed only by individual workers and are not notified to business operators.
9	Brazil	Yes The risk of hazardous work inside the workplace is identified by experts in occupational health and safety outside the company.	There is an obligation to conduct SME.	OPs conduct assessment of job aptitude and state opinions to companies.	Only workers and OPs can view the results of SME and GME.

Abbreviations: GME, general medical examination; MH, mental health; OI, occupational injury; OP, occupational physician; PEM, personal exposure monitoring; PI, personal information; RA, risk assessment; SME, specific medical examination; WRD, work-related disease.

items at the headquarters level were “expression of company-wide basic policy on health and safety,” “development and dissemination of company-wide global standards required to be implemented at each site,” “opportunities for information sharing among staffs in charge of OHS at each site,” and “establishment of indicators for performance audits conducted from the headquarters standpoint and training of auditors.”

The performance audits at the test sites were conducted over 2 days by four researchers at each site. The audit team proposed the scoring system in relation to the performance audit evaluation (evaluation items and criteria) to top management and the OHS manager at the test site, and the scores were determined based on mutual agreement. Evaluation items at the test site were based on the following 12 items after discussion among research team members: (1) introduction of management systems, (2) appointment of personnel in charge of safety and health, organizational positioning, and job authority, (3) competency of personnel in charge of safety and health, (4) description in the management system of specialized resources (people/organizations) in relation to safety and health, (5) compliance, (6) risk assessment, (7) risk reduction measures, (8) evaluation of health of workers exposed to harmful factors, (9) evaluation of job aptitude and suitability for employment (fit for work), (10) management of personal information, (11) emergency preparedness in relation to OHS functions, and (12) prevention of recurrence of work-related illnesses. Each evaluation criteria was scored on a 10-point Likert scale ranging from “0: Procedure (criterion) does not exist” to “9: Procedure (criterion) is executed reliably and continuously until it reaches a level that is a model both inside and outside the company” (see Table 3).

3.3 | Introducing the model hypothesis at test sites and evaluating the roles of the company headquarters

3.3.1 | Test site in Indonesia

Problems before introduction of model hypothesis

We conducted the first performance audit at the Indonesian test site in August 2013. The audit showed that this site complied with laws and regulations, that an OHSMS had not been introduced, and that there were problems regarding a number of occupational health practices including risk assessment, chemical substance management, and health checks.

Specific activities to improve (September 2013 to May 2016)

After being introduced to global policies and draft global standards, professional staff from the company's headquarters provided education and training for workers. We also assisted site personnel in obtaining advice from local OHS experts.

TABLE 3 Trends in evaluation indicators before and after interventions in Indonesia and Thailand (test sites)

Evaluation item	Site in Indonesia		Site in Thailand	
	Aug.2013	Jun.2016	Jun.2013	Aug.2016
(1) Introduction of management system	2	5	2	3
(2) Appointment of the persons in charge of safety and health, organizational positioning, job authority	3	5	3	4
(3) Competency of person in charge of safety and health,	3	5	3	5
(4) Description in the management system of specialized resources (people/organization) for safety and health	2	5	2	3
(5) Compliance	4	5	4	5
(6) Risk assessment	3	4	0	3
(7) Risk reduction measures	2	3	0	3
(8) Evaluation of health effects of workers exposed to harmful factors	2	4	2	4
(9) Evaluation of job aptitude and consideration of employment (fit for work)	0	4	0	3
(10) Management of personal information	4	4	0	5
(11) Labor during crisis management function that takes safety and health into consideration	4	5	3	5
(12)Prevention of recurrence after occurrence of work-related illness	4	4	2	4

Definition of numbers: 0: Procedure (criteria) does not exist. 1: There is a procedure (criteria) but it has not been introduced. 2: There are procedures (criteria) and some have been introduced. 3: There is a procedure (criteria) but there is a significant issue that needs to be addressed before it can be introduced. 4: There is a procedure (criteria) but there is a minor issue that needs to be addressed before it can be introduced. 5: Procedure (criteria) is clearly executed. 6: Evaluation of effectiveness of procedure (criteria) is continually performed (there is a mechanism). 7: Procedures (criteria) are executed (reliably and continually) and have achieved consistent results. 8: The procedure (criteria) has been (reliably and continually) executed and has achieved high results. 9: Procedure (criteria) is (reliably and continually) executed, and it is at a level whereby it is a model inside and outside the company.

Improvements after implementation and evaluation

We conducted a second performance audit in June 2016, and the results from before and after the implementation of the model hypothesis were compared. OHSAS 18001 certification, which is an international standard for OHS management, was acquired in January 2014, and practices from the Japanese-based sites such as “Safety Dojo,” KY (danger prediction), and 5S (Sorting, Setting-in-Order, Shining, Standardizing, and Sustaining the Discipline) activities were implemented at the Indonesian site. The test site entered into a consultancy contract with the Department of community medicine, University of Indonesia, and under the guidance of an occupational medicine expert, hazard identification was performed and a hazard list (eg, the creation of a noise map) was compiled. Then, risk assessment was undertaken based on the hazard list. The relevant aspects of the health-check process for workers engaged in hazardous work were also reviewed. Selection and education in the use of personal protective equipment was carried out and a professional OP was hired.

As a result of these efforts, the following six evaluation items improved by 2 points or more. (1) introduction of management systems, (2) appointment of personnel in charge of safety and health, organizational positioning, and job authority, (3) competency of personnel in charge of safety and health, (4) description in the management system of specialized resources (people/organizations) in relation to safety and health, (8) evaluation of health of workers

exposed to harmful factors and (9) evaluation of job aptitude and suitability for employment (fit for work). These efforts resulted in changes in the site's scores, as shown in Table 3.

3.3.2 | Test site in Thailand

Problems before introduction of model hypothesis

We conducted the first performance audit at the site in Thailand in June 2013. The audit showed that safety and health management was being carried out under ISO 14001, and that there was compliance with the relevant laws and regulations. However, we found some problems regarding the development of risk management processes based on risk assessment and occupational health practices such as chemical substance management and health checks. A safety officer was hired and provided with appropriate training, including training in occupational health.

Specific activities to improve (July 2013 to July 2016)

We did not seek support for the expert personnel, but we did explain the global policy and the global standard plan, and the specialist staff at the company headquarters continued to implement risk assessment training. Because the safety officer who was hired did not have sufficient knowledge and experience, we recommended external training.

Improvements after implementation and evaluation

We conducted a second performance audit in August 2016. OHSAS 18001 certification was obtained in April 2015, and existing practices from the Japanese-based factories were implemented. Furthermore, a health and safety officer was placed in the manufacturing department, and existing workplace hazards were identified and a hazard list was created. Health checks for workers engaged in hazardous work were reviewed by the new safety officer. The health-check procedure was amended based on recommendations from an external OP. The in-house safety officer worked with external labor health agencies and began to use the results of the health checks to determine fit for work.

As a result of these efforts, the following eight evaluation items improved by 2 points or more. (1) Competency of personnel in charge of safety and health, (2) risk assessment, (3) risk reduction measures, (4) evaluation of health of workers exposed to harmful factors, (5) evaluation of job aptitude and suitability for employment (fit for work), (6) management of personal information, (7) emergency preparedness in relation to OHS functions and (8) prevention of recurrence of work-related illnesses. These efforts resulted in changes in the site's scores, as shown in Table 3.

3.3.3 | Evaluation of the company headquarters

The Japanese headquarters published global safety and health policies from April 2011 to August 2016. These outlined the company's behavioral standards, and global safety and health policies were transmitted to domestic and overseas business sites. It was decided that annual global health and safety meetings would be held and that OHSAS 18001 (now ISO 45001) or equivalent management system standards would be introduced. Performance audit related to OHS were also formulated, and initiatives to systematically audit a number of domestic and overseas business sites each year in accordance with the appropriate standards were implemented. Regarding the training of auditors, staff with relevant knowledge and experience were selected from within the company, and on-the-job training was provided. Efforts were made to secure and nurture specialized talent in each country to fulfill contracts between local institutions and overseas affiliates. If difficulties arose in dealings with a specific country, an OHS expert from Japan was dispatched to the site. Regarding global standards, guidelines for risk assessment, personal protective equipment, and chemical substance management were formulated and communicated.

The eight practices included in the model hypothesis at the company headquarters level were discussed and examined by the research team, who evaluated the degree to which each item had been achieved. Discussion continued until a unanimous decision was reached in relation to each item. As

a result, the following nine practices were identified as the roles of headquarters. To establish and disseminate basic policy on health and safety by CEO. To establish global safety and health conference. To determine OHSMS standard. To formulate and notify global standards for OHS. To formulate and notify performance audit standards. To train auditors and conduct performance audits. To evaluate the competence and expertise of employed professionals and provide support to secure and develop specialized human resources as necessary. To provide technical support in the case of shortage of specialized resources. To clarify the reporting route to the headquarters of activities related to OHS at the site.

3.4 | Improvement of model hypothesis based on the results of the pilot implementation and completion of the global OHSMS model

As a result of the pilot implementation, the effectiveness of the model hypothesis was generally confirmed, with two issues being identified by the research team. First, it was deemed necessary to clarify the reporting mechanism to enable the company headquarters to better understand and compare the situation at each site. Second, the local professionals who were appointed lacked sufficient knowledge and experience in relation to the hygiene and health sectors.

As mentioned previously, safety awareness processes that are unique to Japanese companies, such as "Safety Dojo" and KY, were also introduced to overseas sites. However, when the research team first developed the model hypothesis and evaluation indicators, we did not see the need to evaluate these activities. Therefore, they were excluded from the evaluation in the pilot implementation. After these issues were addressed, the global OHSMS model for Japanese companies was completed, as shown in Figure 2.

The global OHSMS model included the following features: the inclusion of OHSAS 18001 (now ISO 45001), which is an international management system standard, the announcement of the policy by the CEO, the establishment of a coordination system between the company headquarters and local sites, the use of local expertise to collaborate with universities and other institutions, education and training of personnel, compliance with laws and regulations, preparation of in-house global OHS standards, and performance audits. After obtaining approval from management at the headquarters in Japan, the company finalized the global OHSMS model and decided to implement it globally.

4 | DISCUSSION

We developed a global OHSMS model in four steps to enable a common standard of OHS practice at all of a company's sites, including overseas sites.

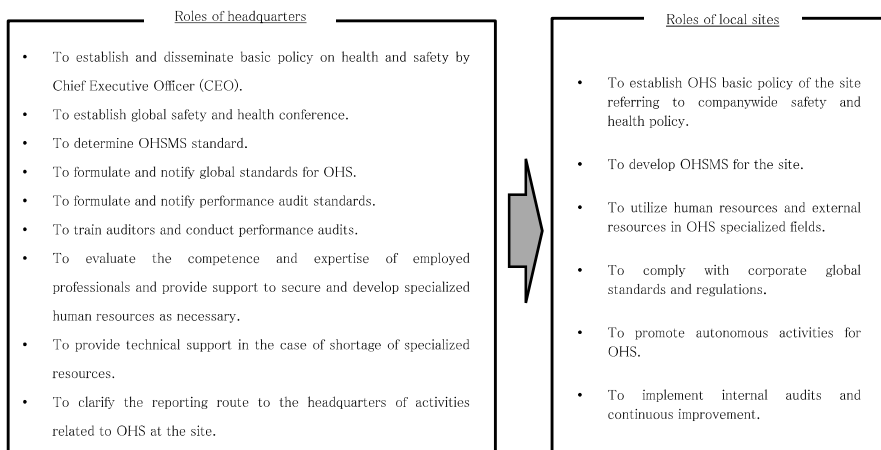


FIGURE 2 This figure shows the global OHSMS model for Japanese companies newly developed by this research group

In the first step, based on a previous study,⁶ it was necessary to gather detailed information on OHS activities, which are conducted in accordance with each country's laws and regulations and the available human resources in terms of OHS professionals. Therefore, the research team gathered information in advance using the Internet, visited each country selected in the study sample, and gathered information on site by conducting interviews with various stakeholders.⁷⁻⁹

In the second step, it was necessary to develop and verify a model for an OHS system that could be used at overseas sites. Therefore, the research team discussed the information that had been compiled and developed a model hypothesis based on the results. In addition, evaluation indicators were developed. Furthermore, we emphasized the promotion of autonomous practice and human resource development at each site.

In the third step, it was necessary to select overseas sites to test the model hypothesis and verify the effects, and to undertake pilot implementations. In addition, it was necessary to enumerate the efforts that were necessary on the part of the Japanese headquarters. Therefore, based on the information relating to each country gathered during the first step,⁷⁻⁹ and with the cooperation of the management of the company, two countries, Indonesia and Thailand, were selected for pilot implementations.

In the fourth step, based on the results obtained from the pilot implementations, the research team verified the validity of the model hypothesis and evaluation indicators. Finally, we improved the model based on our findings following the above process.

4.1 | Pilot implementation in two countries (Indonesia and Thailand)

Based on the theory assumed at the research team meeting, we conducted pilot implementation in Indonesia and Thailand. In the results using the evaluation indicator, the six and eight items have significantly improved in Indonesia and Thailand, respectively.

The common weakness was observed in occupational health programs, such as evaluation of health of workers exposed to harmful factors and evaluation of job aptitude and suitability for employment (fit for work) before implementation. One of the success factors at the pilot sites was evaluating the existing OHS expertise and improving it by obtaining advice external experts or enhancing skills of internal experts with training.⁵ In addition, the implementation of risk assessment and risk reduction was not sufficiently implemented at the sites. Therefore, when introducing the global OHSMS, it was considered important to strengthen risk assessment education,⁵ provide company-wide guidelines,⁴ and secure experts who completed comprehensive OHS training.⁵

4.2 | Headquarters functions and roles promoting the global OHSMS model

In order to support the introduction of the global OHS model, the headquarters played several significant roles.⁵ Among them, OHS policies by CEO and the OHS global conference, which brings together representatives from around the world, show the direction of the company and it is presumed that it was effective for information sharing and network construction.^{4,5} It is also speculated that the common safety and health system was established at sites around the world by recommendation of obtaining the certification of the international standard of OHSMS (ISO45001¹¹).

Performance audit that evaluates OHS activities with common items clarifies the characteristics and issues of each business site, and it offers opportunities for improvement of OHS activities.^{3,12} The process and report of the performance audit should be accepted not only by the headquarters of Japan but also by the management of local business sites. The performance audit team was composed mainly of members of the research team who had auditor experience in the past.¹² Since audits require conversations in English, they may need to have certain language skills as well as OHS knowledge.

Since the performance audit was extremely important for the operation of the global OHSMS model and verification of the effects,^{5,12} it should be considered to secure competent auditors by training inside resources contracting with outside ones.

4.3 | Reporting system to the health and safety department in headquarters regarding performance audit results

The evaluation of the performance audit identified two issues regarding the model hypothesis. In relation to the company headquarters' reporting system, each site currently reports to the manufacturing department, but not to the health and safety department. To enable an understanding of the OHS situation at each site and an evaluation of the effectiveness of the global standards, it is necessary to build a regular business reporting line to the company headquarters' health and safety department.

4.4 | Need for utilization of occupational health experts

To promote autonomous practices based on the minimum standards contained in the model hypothesis, it is essential to use specialized OHS resources.² While such specialized resources are used in Europe and the United States,^{13,14} most Asian countries only have access to limited resources. The legal obligations in relation to the appointment of specialized staff also vary widely among countries.

Of the countries in which the model was introduced, Indonesia is required to appoint a doctor who has undergone a short period of training.⁷ This legal requirement already existed at the time of the pilot implementation. However, the level of expertise was not considered sufficient, and was greatly improved by using an OP who undertook systematic training to obtain a professional qualification.

Meanwhile, in Thailand, the placement of a safety officer with an undergraduate degree from a faculty of public health is mandatory,⁸ and this was already in place at the time of the pilot implementation. However, this requirement did not provide the officer with sufficient experience, and therefore the existing occupational health programs need further improvement.

Thus, in this model, it is desirable to select experts who are familiar with the local situation (eg, OPs and certified experts) in each country. This means that this need will be secured as a special resource in the occupational health field, and its effect will be clarified by recognizing it as a requirement. In developing countries, where it is difficult to obtain specialized resources, it is necessary to consider support from company headquarters and/or neighboring countries.

4.5 | Necessity of evaluation of practices to increase workers' awareness

Some practices were not subject to evaluation in the performance audits. These included Safety Dojo and KY¹⁵ activities. In Japan, major safety practices must comply with various laws and regulations, and until risk assessment becomes mandatory,^{16,17} measures must be developed to increase safety awareness. Thus, many overseas sites are making significant efforts in areas other than risk management. It is necessary to promote risk assessment, prioritize risks in the workplace, and strategically promote risk reduction. In addition, voluntary efforts to raise awareness of the health and safety of workers are also important.¹⁸ A performance audit evaluates such efforts, and therefore improvements are essential, and are also a feature of the proposed management system.³

4.6 | Necessity of management leadership

Managing a global OHSMS requires leadership from top management¹⁹ and this initiative was implemented with strong support from top management. They recognized that OHS issues at their overseas sites involved numerous risky practices. Thus, recognition and cooperation from top management at the company headquarters is indispensable for successful implementation at the local sites.

4.7 | Characteristics of a global OHSMS model for Japanese companies

Our global OHSMS model has the following features: (a) it introduces ISO 45001 as the framework for the OHSMS¹¹; (b) the standard issued by the company headquarters is the minimum standard, including the basic global policy for OHS; (c) it uses the most appropriate professionals in the area; and (d) it includes a performance audit to confirm the effectiveness of the system and to provide opportunities for improvement.

To enable Japanese companies to establish consistently sound OHS practices at all sites, including overseas sites, we propose to introduce a management system that serves as an overall framework. ISO 45001 is a global standard,¹¹ and each country has appropriate resources such as a certification body. Furthermore, from the viewpoint of the company, it is advantageous if it possesses the possibility of integrated authentication with other ISO systems (eg, ISO 14001 and ISO 9001). However, by only introducing ISO 45001, we do not believe that OHS practices at overseas sites will improve to the level required. The introduction of ISO 45001 by Japanese companies is considered to be merely a "necessary condition" for the development of global OHS activities, including at overseas sites.^{4,5}

Regarding the items issued by the company headquarters, these are limited to understanding the situation at each site and enabling comparisons, and by the need to secure OHS budget allocations. In countries where detailed requirements are already set out in various laws and ordinance,¹⁷ there may be discrepancies and duplications between the company headquarters' standards and local laws and customs. For example, if health checks are mandatory in Japan, inconsistencies will arise in Western countries where health-check results are not used to determine a worker's ability to perform certain tasks because of privacy concerns. In addition, if measurement of the working environment is mandated, duplication occurs (such as requiring both practices in the country of management) based on personal exposure measurements. Thus, the company headquarters needs to act consistently in accordance with the global OHSMS model.

Under the proposed model, it is necessary to conduct performance audits on a regular basis, for example, every three years. This will ensure that conformity with standards is monitored, as well as the degree of conformity. Continuous improvement can also be evaluated. Therefore, it is essential that quality is maintained via performance audits conducted by internally trained auditors. If a global OHSMS model for Japanese companies is introduced and the understanding of the necessary internal standards by experts and staff in charge of OHS at each site is improved, then it will also be possible for them to act as auditors.

4.8 | Limitations

This model was established in relation to a specific company, and its validity was only confirmed in two emerging countries. Therefore, it is necessary to verify its effectiveness via full implementation throughout all of the company's overseas sites and through its application in other industries.

5 | CONCLUSION

The validity of our global OHSMS model was confirmed by the fact that company headquarters' roles functioned properly under the model, while OHS practices at the test sites were improved as a result of the intervention. We will further evaluate the effectiveness of the model by introducing it to all of the major manufacturing sites of the target company and by extending it to other companies in the near future.

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DISCLOSURE

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AUTHOR CONTRIBUTIONS

SK, KM, YK, and MU conceived the ideas, KH and NF collected the data, NP analysed the data and advised the revision of idea, and KM and SN led the writing.

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調査報告

中華人民共和国の安全衛生に関するリスクマネジメントの制度と実態

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抄録：目的：中国の安全衛生に関するリスクマネジメントの制度と実態を明らかにする。**方法：**学術情報の検索エンジンを用いた文献検索と、インターネットによる一般情報検索を行った。その後、現地の公衆衛生大学院、健康診断や作業環境測定などを実施している職業衛生技術サービス機関、日系企業の現地事業場を訪問し、得られた情報を、法体系、専門人材、作業環境測定、健康診断、職業病、職業衛生技術サービス機関ごとに整理した。**結果：**安全生産法や職業病予防治療法などにより、安全衛生に関する事項が定められていた。安全管理者や衛生管理者の制度は存在していたが、産業医や産業保健看護職の制度はなく、企業に医療職の選任義務はない。一般健康診断は法令で定められていないが、特殊健康診断や作業環境測定は、企業外の職業衛生技術サービス機関での実施と判定が事業者には義務付けられていた。職業病は増加傾向であり、その約80%がじん肺であった。職業衛生技術サービス機関は、専門スタッフを雇用し、政府からの認定がなければ、健康診断等のサービス提供ができなかった。**考察・結論：**衛生や健康の専門知識について、企業内部と外部機関との格差が大きいことが特徴であり、企業の安全衛生活動が形骸化しやすいなどの問題が発生しやすい。そのため、事業場における公衆衛生医師の活用や、中国の安全衛生に関するリスクマネジメント制度

を理解した日本の専門家による支援が重要である。
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目 的

海外に進出している日系企業の総数（拠点数）は75,331拠点と、前年より3,711拠点（約5.2%）の増加となり、過去最多を更新している¹⁾。日系企業がグローバルに事業展開する際には、現地での社会的責任を果たすためにも、日本人のみならず現地労働者の安全や健康の確保が重要となる。その際、現地の安全衛生に関する情報が必要となるが、著者らはそのような情報を効率的に収集することを目的に開発した「海外事業場の労働安全衛生体制構築のための情報収集チェックシート」²⁾を用いてインドネシア共和国³⁾とタイ王国⁴⁾における調査結果を報告した。

日系企業の海外拠点の中で、中華人民共和国（以下、中国）は32,349拠点と全体の約43%を占め、第2位の米国8,606拠点（約11%）の約3.8倍¹⁾と、最大の進出先となっている。また、中国は急速な工業化に伴い、職業病の発生可能性が世界で最も高い国との報告があり⁵⁾、中国に製造拠点を持つ日系企業にとって、現地の安全衛生は優先度の高い問題である。

中国の安全衛生に関する最近の情報として、安全衛生に関連する法令と制度^{6,7)}、2016年から2020年の5年間計画⁵⁾、中国版労働安全衛生マネジメントシステムといえ

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る安全生産標準化⁸⁾が報告されている。しかし、日系企業の本社が現地の事業場を支援するための具体的な情報は、言語の問題もあり入手は容易でない。

また、安全衛生関係法令の改正の度に、事業者等に対する規制や罰則は強化され、法令違反した事業者に対して、罰金だけでなく、当該作業の中止や事業場の閉鎖も法律で定められた。2018年9月には、日系企業の最多海外拠点数である上海（10,043拠点）¹⁾を有する江蘇省から、安全生産リスクの高い企業や環境基準未達などの企業に対して、今後3年間で1,000社を閉鎖する目標を定めたと公表があった⁹⁾。最新の安全衛生関連情報を収集し、現地の実態に応じて適切にリスクを低減することは、安全衛生の問題だけに留まらず、中国における事業継続の観点から経営上の大きな課題でもある。

今回、中国の安全衛生に関する情報を収集する過程で、安全衛生のリスクマネジメントについて情報が得られた。中国に製造拠点をもち多くの日系企業においても有益な情報と考えられるため、その内容について、調査を行うこととした。

方 法

1. インターネット調査

ILO や中央労働災害防止協会のHP等のインターネット上の一般情報に加えて、学術情報の検索エンジン（医中誌、Pubmed、Google Scholar）を用いた検索（検索式の例：“安全衛生” AND “中国”，“Occupational safety and health” AND “China”）を行い、安全衛生のリスクマネジメントに関する情報を収集した。

2. 訪問調査

インターネット調査で得られた情報の確認と詳細情報を収集するため、また安全衛生に関するリスクマネジメントの実態を確認するため、現地の安全衛生に関する専門機関と日系企業の現地事業場を対象とした。調査チームのネットワークを用いて訪問依頼を行い、協力の得られた機関に対して、2016年11月から2018年11月にそれぞれ1～2回訪問した。調査はインタビュー形式で実施し、活動内容などに応じて調査日数は、専門機関半日～1日、日系企業の現地事業場2日～4日とした。

1) 専門機関

事前のインターネット調査で、特殊健康診断と作業環境測定は、企業外の政府認定機関でのみ実施できることが明らかになったため、これらの実施機関と、そこで働く専門人材を育成する教育・研究機関を訪問した。

①公衆衛生大学院

2016年11月の訪問当時、35名の教授を中心に136名の教員と1,117名の学生を擁する中国の代表的な公衆衛生大学

院である。環境保健科学、社会医学・衛生管理、疫学・生物統計、公衆衛生の4分野の中に15の小分野が分けられている。卒業生の多くは政府機関に就職するが、一部は外資系企業などで産業医として活動している。

②職業病臨床研修センター

大学付属機関であり、中毒科、じん肺科、放射線科、職業健診科の4科をもつ。特殊健康診断の実施数は、年間約25万人と上海全体の約4割に相当し、職業病の診断数は上海の約80%を占めている。また、職業病に関する診断基準や診察ガイドラインを策定するための研究、若手医師に対する職業病の診療トレーニング等の教育を行っている。

③労働安全衛生研究所 職業病予防協会

健康診断で採取した血液尿検査や作業環境測定を実施している機関である。分析・測定などの国際的な第三者認定であるISO/IEC17025を取得している。

2) 日系の製造業の中国拠点

ブルドーザー、油圧ショベル、ダンプトラックなどの建設機械・鉱山用機械の開発・設計を行っており、日本本社が発信した安全衛生方針に従い、日本国内・海外で活動を推進している企業を対象とした。華北地域にある2つの事業場と、華中地域にある2つの事業場を訪問した。4つの事業場の労働者数は約250～1,100名である。

結 果

1. 法体系

中国における主要な安全衛生に関する法律として、中華人民共和国安全生産法（以下、安全生産法）と、中華人民共和国職業病予防治療法（以下、職業病予防治療法）が存在する。安全生産法は生産安全と事故の防止・減少を目的に、職業病予防治療法は主に職業病の予防を目的に、共に2002年に制定され、その後度々改正されている。

これらの法律に基づき、日本の内閣に相当する國務院が制定する行政法規、各部・委員会が制定する部門規則があり、具体的な技術・基準規範として、JIS（Japanese Industrial Standards：日本工業規格）に相当する標準が存在する。標準は2～3文字のアルファベットと数値の数字で表記されるが、これは中国語ピンイン音の頭文字である「G：国家（Guojia），B：標準（Biaozhun），T：推奨（Tuijian）」の略であり、労働安全衛生に関する業界標準はAQ：安全（An Quan）と示される。

2. 専門人材

A 産業医・産業保健看護職

1) 医師の種類

中国の医師は、病院内で患者の診察・治療を行う臨床医師、CDC（Centers for Disease Control and Prevention）

や衛生局など主に行政機関に属する公衆衛生医師、漢方を専門とする中医師の3つに大別される。5年間の医学部教育カリキュラムは、臨床医師が、基礎医学2年、公衆衛生0.5年、臨床医学2.5年であり、公衆衛生医師が、基礎医学1.5年、公衆衛生2.5年、臨床医学1年と、在学中のカリキュラムが異なるため、受験生は医学部に入学する段階でどの医師になるか選択する必要がある。それぞれの医師免許も異なり、公衆衛生医師が臨床医師のように診療業務に従事することはできない。労働衛生における役割は、臨床医師は健康診断の診察を行い、公衆衛生医師は、日本の企業外労働衛生機関に相当する職業衛生技術サービス機関に所属することが多い。

2) 選任義務と活動内容

中国には産業医制度はなく、事業場に医師や看護職の選任義務もない。しかし、今回訪問した日系企業では、臨床医師や看護師を雇用して、企業内診療所で体調不良者の対応や、健康診断の結果に基づいて保健指導や食堂メニューの減塩化等の活動を行っている事業場があった。

B 安全管理者

1) 選任義務

安全生産法に基づき、鉱業、建設施工業、危険物の生産取扱い、金属精錬事業、道路運輸事業では、安全生産管理組織の設置もしくは専任の安全管理者の配置が必要である。その他の製造業では、労働者が100名を超える場合では、同様に安全生産管理組織の設置もしくは専任の安全管理者の配置が必要であるが、労働者が100名以下の場合には、兼任の安全管理者や安全生産管理の外部委託も可能である。

2) 安全管理者の種類

安全管理者は認証する行政区分に応じて、市、省、国の3つのレベルに大別される。市や省レベルの安全管理者の受験資格は、専門学校以上の学歴と、安全に関する1年以上の業務経験であり、約3日間の研修受講後に試験に合格する必要がある。その後も定期的な研修受講が必要である。

国家レベルの安全管理者と言える登録安全管理者に関する制度が2004年より開始された。受験資格は、専門学校卒で7～9年の安全に関する実務経験、大学卒業で3～5年の実務経験などである。試験内容は、安全生産法と関連知識、安全生産管理知識、安全生産技術、安全生産事故判例分析の4科目である。選択式と記述式の問題から構成され、各科目の試験時間は150分である。合格率が20%以下となった年もあり、日本の労働安全コンサルタント¹⁰⁾に相当するものと考えられる。

C 衛生管理者

国家安全監督管理総局による「建設プロジェクトの職業病危害リスク分類管理目録の発行に関する通知(2012年5月31日付け安監総安健[2012]73号)」で、職業病の

危害が重大と分類された職場では、職業病予防治療法に基づき、衛生管理組織の設置と専任の衛生管理者の配置が必要である。職業病の危害が重大な業務は、主に化学品の製造、鉱物産業、金属精錬・圧延加工作業などであり、自動車等の輸送機器や電子機器などを含めた一般機器の製造は、職業病の危害が存在する職場として取り扱われる。職業病の危害が存在する職場で労働者が100名を超える場合は、同様に衛生管理組織の設置と専任の衛生管理者の配置が必要であるが、100名以下の場合には、衛生管理者は兼務でもよい。衛生管理者は、安全管理者と同様に、研修受講後に市や省に認定・登録され、その後も継続的な研修受講が必要である。しかし、登録安全管理者に相当するような国家レベルの高度専門人材制度は現在のところ存在しない。

3. 職業病危害要因の測定と現状評価

職業病予防治療法及び「作業場所職業衛生監督管理規定」(国家安全監督管理総局令47号)に基づき、職業病の危害が存在する職場では、職業病危害要因の測定が必要であり、職業病の危害が重大な職場は、職業病危害要因の現状評価の実施も追加で必要である。

A 職業病危害要因の測定

1) 概要

職業病の危害が存在する職場では、少なくとも毎年1回、日本の作業環境測定に相当する職業病危害要因の測定(以下、作業環境測定とよぶ)を実施しなければならない。作業環境測定は、政府衛生部門の認証を受けた職業衛生技術サービス機関が実施しなければならない。測定・分析方法に関して物質ごとに標準に詳細な内容が定められている。事業者は、作業環境測定の結果を記録し、所轄衛生行政部門に報告すると共に、労働者へ公表しなければならない。作業環境測定の結果が国の基準に満たない場合は、直ちに改善措置を講じなければならない。基準に満たなければ、当該作業の再開はできない。

2) 職業ばく露限界値

職業ばく露限界値(OEL: occupational exposure limits)は、2007年に改定された「職場における有害因子の職業ばく露規制値第1部: 化学的有害因子(GBZ 2.1-2007)」と「職場における有害因子の職業ばく露規制値第2部: 物理的有害因子(GBZ 2.2-2007)」に定められている。前者には化学物質339種類、粉じん47種類、生物学的因子2種類(昆虫病原糸状菌の1種である白きょう病菌、枯草菌から細胞外に分泌されるサブチリシン)、後者には11種類の物理的因子(超高周波、高周波電磁界、低周波電磁界、レーザー、マイクロ波、紫外線、暑熱、騒音、振動、地下作業場または炭鉱における温湿度と風速、高負荷作業)が規定されている。高負荷作業は具体的に定義されていないが、業務は肉体労働強度レベルに応じて4つに

(Ⅰ：パソコン入力作業など、Ⅱ：一般的な物の運搬など、Ⅲ：重量物運搬など、Ⅳ：強度の高い切削業務など)分類され、性別なども加味した、最大心拍数や勤務日の最大総エネルギー消費量が定められている。

化学物質のOELとして以下の3つが採用されている。1つ目は、時間・荷重平均許容濃度PC-TWA (Permissible Concentration-Time Weighted Average) で、一般的な1日8時間、週40時間労働における平均濃度と定義されている。2つ目は、最大許容濃度MAC (Maximum Allowable Concentration) であり、いかなる場合においても、超過してはならない上限値である。3つ目は、短時間許容濃

度－暴露限界PC-STEL (Permissible Concentration-Short Term Exposure Limit) で、たとえ8時間の労働時間における時間・荷重平均濃度がPC-TWA以下でも、1日の作業の時間においても超過してはならない15分間の時間・荷重平均濃度である。日本で管理濃度が定められており、中国の「職場における有害因子の職業ばく露規制値第1部：化学的有害因子 (GBZ 2.1-2007)」でも規定されている代表的な化学物質に関して、中国のOELと日本の許容濃度¹⁾を比較したところ、多くの物質で、中国のOELは許容濃度以下であった (表1)。

表1. 代表的な化学物質に関する中国の職業ばく露限界値と日本の許容濃度の比較

物質名	中国 (2007年)			日本 (2018年)
	MAC	PC-TWA	PC-STEL	許容濃度
アクリロニトリル		1	2	4.3
エチルベンゼン		100	150	217
エチレンオキシド		2		1.8
塩素	7.5			1.5
カドミウム及びその化合物		0.01	0.02	0.05
五酸化バナジウム		0.05		
コバルト及び無機化合物		0.05	0.1	0.05
コールタール		0.2		
シアン化カリウム		1	3	5 *
シアン化水素	1			5.5
四塩化炭素		15	25	31
ジクロロメタン		200		170
臭化メチル		2		3.89
水銀及びその無機化合物		0.02	0.04	0.025
スチレン		50	100	85
テトラクロロエチレン		200		検討中
トリクロロエチレン		30		135
ニッケル化合物 (ニッケルカルボニルを除く)		1		0.01 (水溶性)
ニッケルカルボニル	0.002			0.1 (水溶性でないもの)
パラ-ニトロクロロベンゼン		0.6		0.007
砒素及びその化合物		0.01	0.02	0.64
フッ化水素	2			0.0003~0.003**
マンガン及びその化合物		0.15		2.5*
硫化水素	10			0.2
硫酸ジメチル		0.5		7
アセトン		300	450	0.52
イソプロピルアルコール		350	700	470
エチルエーテル		300	500	980*
キシレン		50	100	1200
クレゾール		10		217
クロルベンゼン		50		22
酢酸エチル		200	300	46
酢酸ノルマル-ブチル		200	300	720
酢酸ノルマル-プロピル		200	300	475
酢酸メチル		200	500	830
シクロヘキサノール		100		610
シクロヘキサノン		50		102
トルエン		50	100	100
二硫化炭素		5	10	188
メタノール		25	50	3.13
メチルエチルケトン		300	600	260
				590

単位はすべて mg/m³

* 最大許容濃度、常時この高度以下に保つこと

** 過剰発がん生涯リスクレベル10⁻³~10⁻⁴の評価値

表 2. 職業病危害要因の現状評価に関する項目

項目	内容
事業場の基本的情報	事業内容, 立地場所, 使用物質とその使用量, 職員配置
全体的なレイアウト	労働者の位置, 職場内の危険な場所と安全な場所
製造工程・設備配置	生産設備や製造プロセス, 機械の自動化
建物内の衛生	建物の構造, 暖房, 換気, 空調, 照明
労働災害	職業上の危険の種類と分布, 接触時間や操作方法
職業保護具及び緊急救助施設	局所排気装置等の設置, 緊急救助施設の種類の, 数量, 設置場所
産業衛生サーベイランス	過去 3 年間の健康診断の結果, 職業病の症例有無
個人用保護具	有害物質に応じた保護具の種類, 数量, 性能
工場外の施設	事務所, 休憩場所, 食堂, トイレ, 診療所
労働衛生管理	職業衛生管理組織や職員の設置, 管理計画と実施
過去の作業環境評価に対する対応	

B 職業病危害要因の現状評価

職業病危害が重大な職場は, 作業環境測定に加え, 少なくとも 3 年に 1 回の職業病危害要因の現状評価 (以下, 作業環境評価とよぶ) を実施しなければならない。作業環境評価は, 日本では法令で定められていない制度であるが, 「事業者の職業上の危険の状況を評価するための技術的ガイドライン (AQ/T4270-2015)」では, 職場における職業病の危険性とそのばく露レベル, 職業病予防施設その他の職業病予防対策と効果, および労働者への健康影響に対する職業病の危険性の包括的評価と定義されている。

評価項目として, 製造機器等のレイアウト, 個人用保護具, 健康診断の結果等が確認項目として定められており (表 2), 書類調査と現場訪問により, 工場内のハザードを特定し, リスク評価した後に, リスク低減策を提案する。今回訪問した企業では, 公衆衛生医師をリーダーとした 4 名のメンバーが, 3 日間かけて実施していた。作業環境評価も, 作業環境測定と同様に, 政府衛生部門の認証を受けた職業衛生技術サービス機関が実施しなければならない。作業環境評価の結果を所轄衛生行政部門に報告しなければならない。

4. 健康診断

1) 概要

中国では日本の一般健康診断に相当する健康診断は法律に定められていない。しかし, 職業病予防治療法及び職場における職業衛生監督管理規定 (国家安全監督総局令 49 号) に, 日本の特殊健康診断に相当する職業病健康診断 (以下, 特殊健康診断) の実施が事業者には義務付けられている。

特殊健康診断の実施時期は, 労働者が当該職場に就く前, 在職中定期的, その職場を離れる時であり, その費用負担は事業者が行わなければならない。特殊健康診断を実施できる機関は, 政府衛生部門により承認を受けた

職業衛生技術サービス機関のみであり, 診察は臨床医師によって行われる。就業前の健康診断を受診していない労働者に対する当該有害業務従事の禁止や, 業務による健康障害が生じた場合の労働者の配置転換が義務付けられている。労働者の職歴, 職業病の危害に触れた過去の記録, 職業上の健康診断の結果と職業病の診療などの各個人に関する健康面のデータを含んだファイルを作成し, 規定の期限通りに適切に保存しなければならない。労働者は退職する際に, 自己の健康診断結果のファイルのコピーを要求する権利を有する。

2) 基本的な健康診断項目

健康診断の項目や在職中の健康診断の実施頻度は, 業務内容により異なり, これらは「産業衛生モニタリングのための技術仕様 (GBZ 188-2014)」に定められている。健康診断の基本項目は, 労働者の基本情報 (性別, 年齢, 職歴, 家族歴など), 一般生理学的検査 (血圧, 身長, 体重など), 自覚症状, 内科検査, 神経系検査, その他の専門検査, 臨床検査 (血液検査, 尿検査, 胸部レントゲン検査, 心電図検査など) からなり (表 3), 「産業衛生モニタリングのための技術仕様 (GBZ 188-2014)」の付属文書 B には, 各健診項目の測定方法が細かく記載されている。例えば血圧測定では, 測定前に被験者を 5 分休ませる, 仰臥位もしくは座位で測定する, 右上肢の衣服がない状態で少し外転させ肘は心臓と同じ高さにする, カフの下端は肘から約 2 cm ~ 3 cm の距離に置く, 橈骨動脈の拍動音が消失するまでカフを膨張させる, 3 回測定した平均値を被験者の血圧とする, 各測定間隔は 30 秒以上あける等である。

3) 健康診断の対象業務

健康診断の実施対象となる有害要因は, 化学物質 (58 種類), 粉じん (6 種類), 物理的要因 (6 種類), 生物学的要因 (2 種類), 特殊作業 (9 種類) に分類されている (表 4)。各有害業務に関して, 在職中定期的に実施する健康診断の項目を基本に, 職場に就く前, 当該職場を離

表 3. 基本的な健康診断項目

検査項目	検査内容
労働者の基本情報	氏名, 性別, 生年月日, 職歴, 生活歴, 家族歴など
一般生理学的検査	血圧, 心拍数, 呼吸数, 身長, 体重, 栄養状態など
自覚症状	神経系, 呼吸器系, 心血管系, 消化器系, 造血・内分泌系, 泌尿器系, 筋骨格系, 眼・耳鼻咽喉系, 皮膚
内科診察	皮膚粘膜, 表在リンパ節, 甲状腺 呼吸器検査: 胸郭の形状, 呼吸音など 心血管検査: 心拍数, 心雑音など 消化器系検査: 腹部の形状, 肝臓・脾臓の大きさ・硬さ
神経一般検査	意識, 精神状態, 腱反射, 深部感覚など
その他の専門検査	眼科検査: 視力など 口腔内検査: 歯肉・歯の状態など 耳の検査: 一般聴覚検査など 鼻・咽頭の検査: 鼻中隔, 咽頭, 扁桃など 皮膚検査: 色素沈着, 発疹, 水疱など
臨床検査	血算: ヘモグロビン, 赤血球数, 白血球数および分類, 血小板数 尿検査: 色, pH, 比重, 尿中タンパク, 尿糖など 肝機能検査: ALT, γ -GTP, 総ビリルビン, 総蛋白など 胸部レントゲン検査: 心電図 肺機能検査: 肺活量, 努力性肺活量, 1秒率, %肺活量 腎機能検査: 血清クレアチニン, 血中尿素窒素

表 4. 健康診断の実施対象業務

分類	対象物質・業務
化学物質	鉛とその無機化合物 テトラエチル鉛 水銀とその無機化合物 マンガンとその無機化合物 ベリリウムとその無機化合物 カドミウムとその無機化合物 クロムとその無機化合物 酸化亜鉛 ヒ素 アルシン（水素化ヒ素） リンとその無機化合物 リン化水素 バリウム化合物（塩化バリウム, 硝酸バリウム, 酢酸バリウム） バナジウムとその無機化合物 トリアルキルスズ タリウムとその無機化合物 ニッケルカルボニル フッ素とその無機化合物 ベンゼン（工業用トルエン, キシレンもベンゼンを参考にして実施する） 二硫化炭素 四塩化炭素 メタノール ガソリン 臭化メチル 1,2-ジクロロエタン ノルマルヘキサン ベンゼンのアミノ化合物およびニトロ化合物 トリニトロトルエン ベンジジン

	塩素
	二酸化硫黄
	窒素酸化物
	アンモニア
	ホスゲン
	ホルムアルデヒド
	モノメチルアミン
	一酸化炭素
	硫化水素
	塩化ビニル
	トリクロロエチレン
	クロロプロペン
	クロロブレン有機フッ化物
	トルエンジイソシアネート
	ジメチルホルムアミド
	シアン化合物とニトリル化合物
	クレゾール、カテコール、レゾルシノール、ヒドロキノンなどのフェノール化合物
	ペンタクロロフェノール
	クロロメチルエーテル〔ビス（クロロメチル）エーテルも参考にして実施する〕
	アクリルアミド
	ジメチルヒドラジン
	硫酸ジメチル
	有機リン系殺虫剤
	カルバメート系殺虫剤
	ピレスロイド系殺虫剤
	酸ミストまたは酸無水物
	職業性喘息の原因物質
	コークス炉からの放散物質
粉じん	遊離シリカ粉じん
	石炭粉じん
	アスベスト粉じん
	その他の無機粉じん
	コットンダスト（亜麻、柔らかい麻、ジュータダストを含む）
	有機粉じん
物理的要因	騒音
	振動
	高温
	高気圧
	紫外線
	マイクロ波
生物学的要因	ブルセラ菌
	炭疽菌
特殊作業	電気工事
	高所作業
	圧力容器作業
	結核の予防および管理業務
	肝炎の予防および管理業務
	職業自動車運転
	VDT 作業
	高地作業
	航空乗務

れる時、緊急時、に実施する健康診断の項目が決まっている。

特定の業務に従事することにより、一般的な労働者よりも職業上の健康リスクが高く、職業病に罹患する可能性や健康影響を受ける可能性の高い状態を職業禁忌症と呼び、健康診断の結果、職業禁忌症と判断された場合は、当該業務への従事を避けなければならない。各健康診断

でそれぞれ職業禁忌症が定められている。日本と中国の健康診断項目を比較するために、代表的な有害要因と思われる、ベンゼン（特定化学物質）、メタノール（有機溶剤）、鉛（重金属）、遊離ケイ酸粉じん（じん肺）、騒音（物理的要因）、自動車運転（特殊作業、職務適性）に関する在職中の健康診断項目を示す（表5）。

表 5. 代表的な健康診断項目

	ベンゼン	メタノール	鉛	遊離ケイ酸粉じん	騒音	自動車運転
職業禁忌症 造血系疾患	網膜神経障害 視神経症 器質性中枢神経障害	中等度貧血 ポルフィリン症 多発性末梢神経障害	活動性結核 慢性閉塞性肺疾患 肺機能障害を伴う疾患	騒音以外要因による恒久的感音性難聴（500 Hz, 1,000 Hz, 2,000 Hz いずれかで 25 dB 以上の純音気導閾値） 伝音声難聴（平均周波数の聴力損失が 41 dB 以上） 騒音敏感（就業前の各周波数の聴覚損失が 25 dB 以下であり、騒音作業従事 1 年以内に 3,000 Hz, 4,000 Hz, 6,000 Hz のいずれかの周波数で聴覚閾値が 65 dB 以上）	両眼の遠見視力 大型：両目<0.1（裸眼）および<1.0（矯正） 小型：両目<0.1（裸眼）および<0.8（矯正） 両耳の平均聴覚閾値> 30 dB 血圧 大型：収縮期血圧≧140 mmHg および拡張期血圧≧90 mmHg 小型：Ⅱ度Ⅲ度のコントロール不良な高血圧 赤緑色盲、器質性心疾患、てんかん、振戦麻痺、くる病、向精神薬を長期間使用している者	
自覚症状	頭痛、めまい、疲労、不眠、記憶喪失、皮膚粘膜出血、月経異常などの神経系・血液系に焦点を当てる	網膜および視神経症、器質性神経障害の症状に焦点をあてる	貧血や以下のような神経系および消化器系の一般的な症状に焦点を当てる：頭痛、めまい、疲労、不眠症、過敏性、多夢、記憶喪失、四肢の痺れ、腹痛、食欲不振、便秘など	咳嗽、胸痛、呼吸困難、喘鳴、咯血その他の症状に焦点を合わせる	中耳・外耳疾患の既往、聴覚に影響を与える可能性のある外傷歴・薬剤歴・中毒歴・病歴・家族歴、騒音ばく露歴	職業禁忌に関する病歴、喫煙の有無、薬物の注射、依存性向精神薬の長期使用歴および治療歴に焦点を当てる
身体検査	内科診察	内科診察 神経一般検査 眼科検査・眼底検査	内科診察：消化器系と貧血に焦点を当てる 神経一般検査	内科診察（呼吸器系および心血管系に焦点を当てる）	内科健診 耳科検査	内科診察 外科診察*：身長、体重、頭、首、手足、筋肉、骨に焦点を当てる 眼科検査：深視力、視野、暗順応、色識別 耳科検査
臨床検査（必須）	血算（細胞形態や分画に注意） 尿検査 心電図 血清 ALT 肝臓・脾臓の超音波検査	血算 尿検査 心電図 肝機能 肝臓・脾臓の超音波検査	血算 尿検査 心電図 血中鉛または尿中鉛	胸部 X 線 高圧撮影（後前方向）またはデジタルエックス線検査 心電図検査 肺機能検査	気導純音聴力検査 心電図	血算 尿検査 心電図検査 気導純音聴力検査
臨床検査（選択）	尿中 trans, trans-ムコン酸 尿中フェノール 骨髄穿刺	視野検査	尿中 δ-アミノレブリン酸（δ-ALA） 赤血球遊離プロトポルフィリン（ZPP） 赤血球遊離プロトポルフィリン（FEP） 神経筋電図検査	血算検査 尿検査 血清 ALT	骨導純音聴力検査 音響インピーダンス検査 耳音響放射検査 聴性誘発反応検査	複雑反応検査** 速度推定検査 ダイナミックビジョン検査
実施頻度	1 年	3 年（推奨）	血中鉛<400 μg/L または尿中鉛<70 μg/L：年 1 回 血中鉛 400 μg/L ～600 μg/L、または尿中鉛 70 μg/L ～ 120 μg/L：3 ヶ月に 1 回 血中鉛または尿中鉛の測定	生産ダスト分類 ・ 1 級：2 年に 1 回 ・ 2 級以上：1 年に 1 回 など	8 時間の等価騒音レベル ・ 80 dB 以上 85 dB 未満：2 年に 1 回 ・ 85 dB 以上：年に 1 回	大型：1 年に 1 回 小型：2 年に 1 回

* 各関節の可動域の確認など主に整形外科で実施される診察と考えられる。
**被験者の前にある赤色のランプが点灯したら右足のスイッチを踏み、緑色のランプが点灯したら右手の応答器、黄色のランプが点灯したら左手の応答器を押す。他の色のライトが点灯した時や、音が聞こえた時は、足や手のスイッチを押さない

5. 職業病

1) 職業病の定義と分類

職業病予防治療法の第 2 条に、職業病は「労働者が作中に粉塵、放射性物質とその他有毒・有害物質に触れるなどの要因により患った疾病」と定義され、「職業病の分類と目録」により 10 大分類 128 種類に分類されている（表 6）。その他 3 種類は、金属熱、地下労働者の滑液包炎、搔爬作業者の大腿静脈血栓症症候群・大腿動脈閉塞またはリンパ閉塞である。

中国における職業病の統計は、12,212 件（2005 年）から 29,972 件（2014 年）と増加し、その約 80% がじん肺で

表 6. 職業病の分類

- 1 じん肺（12 種類）及びその他の職業性呼吸器疾患（6 種類）
- 2 職業性皮膚疾患（8 種類）
- 3 職業性眼疾患（3 種類）
- 4 職業性耳鼻咽喉口腔疾患（4 種類）
- 5 職業性化学物質中毒（59 種類）
- 6 物理的因子による職業病（7 種類）
- 7 放射線による職業性疾患（10 種類）
- 8 職業性感染症（5 種類）
- 9 職業性がん疾患（11 種類）
- 10 その他（3 種類）

ある。しかし、データ欠損率が高く全体像を正確に把握することは困難であり¹²⁾、実際にはこの報告数よりも多いと考えられている。

2) 職業病の診断

職業病の診断は、政府衛生行政部門によって認定された医療衛生機関が行う。機関の認定条件は、診断に必要な検査機器と専門医に加え、適切な品質管理システムを有することである。2016年11月に確認した際には、上海、北京、武漢の3か所にある総合病院付属職業病センターと、15の中国疾病対策予防センター付属職業病防止病院の合計18機関が職業病の診断資格を有していた。職業病の診断では、労働者の職歴、有害要因にばく露された期間及び濃度、診察所見及び補助的検査の結果等を総合的に分析し、3名以上の職業病専門医（3年以上の実務経験があり、試験に合格したもの）により診断しなければならない。

6. 職業衛生技術サービス機関

作業環境測定・現状評価や健康診断を実施する機関は、政府により認定されなければこれらのサービスを提供することはできない。なお、組織体制、試験に合格したスタッフ数、設備や品質管理等により、甲級、乙級、丙級と3つにランク付けされる。甲級は、国務院およびその関連部署により認定された機関であり、原子力施設など特殊業務を含め、中国全土でサービスを提供することができる。乙級は、省およびその関連部門により認定された機関であり、所属省、自治区、直轄市でサービスを提供できる。丙級は所属する区、市等でサービス提供できるが、一部制限がある。

考 察

安全衛生関係法令で規定されているものを日中で比較すると、安全管理者や衛生管理者の制度、作業環境測定や特殊健康診断の実施は共通していた。一方、日本だけ認められるものとして、産業医や労働衛生コンサルタントなど衛生に関する専門人材制度、一般健康診断の実施があり、中国だけ認められるものとして、職業病危害要因の現状評価（作業環境評価）があった。

中国では、作業環境測定や特殊健康診断を、企業外の職業衛生技術サービス機関で実施しなければならず、企業内に産業医や産業保健看護職などの医療の専門家の選任義務はなく、専門医などの衛生に関する高度専門人材育成制度もない。そのため、衛生や健康の専門知識について、企業内部と行政機関や職業衛生技術サービス機関等の外部機関との格差が大きいことが特徴であり、企業側からみると、そのことによる問題が発生する。

まず、作業環境測定結果に基づいて職場環境を改善す

ることが難しい点である。中国では、基準内であれば措置の規定はないが、基準外であれば直ちに改善措置を講じなければならない。しかし、作業環境測定結果が基準外だった場合に、職場の状況や作業内容をよく理解した専門家から、助言が得られにくい。

健康診断においては、職業禁忌症への対応など判定結果に基づく事後措置が義務付けられている。この健診の判定結果は、社内に産業医等の専門家がいらないため、基本的には外部機関の判定に従わざるをえない。しかし、提供されるサービスの質への懸念が存在するにも関わらず、企業側がその質を判断することは困難である。日系企業のある事業場で、騒音健康診断で配置転換した労働者の健康診断の結果を確認したところ、気道純音聴力検査で、両耳とも 500 Hz, 1,000 Hz, 2,000 Hz は約 25 dB, 3,000 Hz, 4,000 Hz, 6,000 Hz は 90~100 dB であり、前回（1年前）とほぼ結果は変わらなかった。しかし、1年前の健康診断の結果に対するコメントは、職業病の疑いがあるため、職業病の危険に対する個人の保護（耳栓着用）の強化を推奨するであったが、今回は、騒音以外の原因による恒久的感音性難聴であり職業禁忌症に該当するため職場異動を推奨とあった。この結果の解釈を、訪問調査先の専門家に尋ねたところ、政府の認定機関であるため一定の基準を満たしているが、機関のレベル格差の大きさが問題との回答が得られた。

また、日本では作業環境測定の結果、第1~3管理区分の3つに分類され各管理区分に応じて講ずべき措置が定められており、特殊健康診断では、作業内容や作業環境測定結果等を把握した上で、健康診断の結果を企業内で柔軟に解釈することが可能である。しかし、中国では、これらの結果が基準内か基準外かで企業の講ずべき対応が大きく異なるため、安全衛生担当者の関心は、作業環境測定や健康診断の結果が基準に合致するか否かに集まりやすい。そのため、検査結果がかりうじて基準内だったとしても、政府が認定した機関で基準内と判断されれば問題ないと、安全衛生上のリスクを過小評価する懸念や、法令や外部機関からの指示を遵守すること自体が重要視され、安全衛生活動が形骸化しやすいという問題がある。

今後中国で、職業上の健康問題として重要になると考えられるのは、職業性がんなどの潜伏期間の長い疾患である。中国の特殊健康診断の実施義務は、当該業務から離れる際までであり、日本のように、過去に従事させたことのある労働者や、健康管理手帳のように離職後の健康診断の実施制度がない。中国のOELは日本の許容濃度より厳しい物質が多かったが、発がん性のあるヒ素は日本の方が厳しかった（表1）ことから、このような物質への対応は現時点では十分ではないと考えられる。

また、2014年に安全生産法が改正された際に、生産事

故につながる設備に関するリスクマネジメントを実施することが事業者には義務付けられた。職業病予防法では、事業者が職業病の危険のある化学物質等を提供する場合、製品の特性、主成分、有害要因、健康影響、安全上の注意点、職業病の予防および研究治療措置が記載された取扱説明書も提供しなければならず、「化学品リスク評価の一般原則（GB/T 34708-2017）」「GHS ラベルおよび化学物質の安全データシートのための理解可能な試験方法（GB/T 34714-2017）」が2018年5月1日より適用された。このため、リスクマネジメントの対象が生産事故につながる設備だけでなく、化学物質にも拡大される可能性がある。さらに、職業病として、筋骨格系疾患、長時間労働に伴う健康障害、精神疾患が掲載されていないことが問題視されており⁷⁾、今後職業病として認定されるようになる、その対応の必要性が顕在化される。

職業衛生技術サービス機関や専門家がより経済的に発展した地域に集約することが知られているため⁶⁾、大都市から離れた場所に事業場を有する日系企業ほど、これらの問題に対するリスクはより大きくなる。その対策として、事業場において公衆衛生医師を積極的に活用することが考えられる。公衆衛生医師の一部は、安全衛生の知識を有し、外資系企業等で産業医として活動しているため、日系企業の現地事業所でも、同様に検討できるであろう。また、日本本社等からの専門家による支援も考えられるが、その際、日中の安全衛生は異なる点もあるため、中国の安全衛生制度を理解する必要がある。本研究の限界として、訪問した専門機関は全て同じ都市に位置しており、日系企業の4つの現地事業場は同一企業であるため、一般化できない可能性がある。

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利益相反自己申告：申告すべきものなし

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Systems and actual practices of occupational safety and health risk management in the People's Republic of China

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Abstract: Objectives: To investigate the systems and actual practices of occupational safety and health risk management in China. **Methods:** First, we gathered basic information through a literature review using an academic search engine (Japan Medical Abstracts society, Pubmed, and Google Scholar), as well as a general search on the Internet. Next, we conducted field surveys at a graduate school for public health, providers of occupational health services (e.g. medical examinations, working environment measurements), and local workplaces of a Japanese construction machinery company in China. This information was analyzed in terms of legal framework, professional staff, working environment measurements, medical examinations, occupational diseases, and occupational health service providers. **Results:** Health and safety-related matters have become codified in Chinese workplaces as a result of safety laws and measures to prevent occupational diseases. While the country does have safety and hygiene officers, they lack official frameworks for occupational physicians and nursing professionals. The employers are not obligated to appoint medical professionals. While general medical examinations are not provided for under Chinese law, businesses are obligated to bring in external providers of occupational safety to perform special medical exams and working environment measurements. Occupational diseases are on the rise; pneumoconiosis comprises roughly 80% of cases. In addition, occupational health technical service providers have specialized staff and are not permitted to perform medical examinations or other services without government accreditation. **Discussion/Conclusion:** There are great disparities in specialist knowledge about health and hygiene between company staff and external organizations, thus running the risk of corporate health and safety policies existing only on paper. This issue demands greater utilization of public health physicians in Chinese workplaces and support from Japanese professionals who understand how occupational safety and health risk management operate in China.

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Cardiovascular and cerebrovascular diseases risk associated with the incidence of presenteeism and the costs of presenteeism

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Abstract

Objectives: The objective of this study was to estimate a risk of cardiovascular and cerebrovascular diseases for each worker and to determine whether this risk is associated with the incidence and costs of presenteeism, absenteeism, and medical/drug treatments.

Methods: Established risk equations were used to estimate the 10-year probability of developing coronary artery disease and ischemic stroke in male workers aged 40–65 years who were recruited from four pharmaceutical companies in Japan. The incidence of presenteeism was defined as existence of presenteeism for the past a month, and the incidence of absenteeism was defined as existence of sick-leave for the past three months by a self-administered questionnaire. Each cost was calculated based on the human capital method. Data on medical/drug treatments were collected from health insurance claims.

Results: The risks were calculated for 6047 workers. Individuals at moderate and high risk of coronary artery disease had a significantly higher rate of presenteeism and absenteeism than workers at low risk. Workers at moderate and high risk of ischemic stroke also had a significantly higher rate of presenteeism and absenteeism than workers at low risk. Mean costs for absenteeism and medical/drug treatments increased with the risk of developing coronary artery disease or ischemic stroke, while costs for presenteeism did not.

Conclusions: To prevent the costs of presenteeism, workers not only at high risk but also at low and moderate risk of developing cardiovascular and cerebrovascular diseases should receive health care services.

KEYWORDS

absenteeism, coronary artery disease, cost, ischemic stroke, presenteeism, risk equation

Koki Kimura and Tomohisa Nagata contributed equally.

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1 | INTRODUCTION

Employee illness results in both medical expenses and productivity loss from disability, absenteeism, and presenteeism. The role of health in productivity management has gradually garnered attention from government agencies and employers in Japan, where the working population is shrinking and aging.¹ Studies have shown that a detailed breakdown of costs by medical condition is required for decision-making in the field of employee health,^{2,3} and we previously reported that the burden of presenteeism was greater than that of medical expenses and absenteeism in Japanese workers.⁴ The importance of health management measures targeting a decline in productivity that is attributable to presenteeism is becoming increasingly recognized in Japan.

Presenteeism has been associated with a stressful work environment⁵ and modulated by individual worker risk factors⁶ and the incidence of chronic illnesses.⁷ To reduce presenteeism, measures should incorporate both a population approach and a high-risk approach. In the high-risk approach, the employees at high risk of presenteeism should be identified and treated individually. In Japan, employers are obligated to conduct general periodic health examinations for all workers under the Industrial Safety and Health Act,⁸ while additional health assessments require cumbersome procedures to protect employees' personal information.⁹ The general health examination therefore offers an effective opportunity to identify employees at high risk of presenteeism.

The costs of cardiovascular and cerebrovascular diseases constitute a great burden, and account for half of all causes of death and one-quarter of work disability causes in the working population in Japan.¹⁰ Since employees are now expected to work more years than in the past because of the shrinking workforce, more individuals are projected to develop these diseases prior to retirement.¹¹ Furthermore, the health effects of long working hours have become a major social issue, and cardiovascular and cerebrovascular diseases are regarded as the main adverse health effect of long working hours and industrial accidents.¹² For these reasons, the Ministry of Health, Labour and Welfare has placed an emphasis on testing for and preventing these diseases.¹³

Studies have reported that medical and absenteeism costs increase with disease-related risks,^{14–17} and that the costs of presenteeism are also associated with a number of health risk factors and with the sum of risk factors identified in each employee.^{7,18–22} These may also include non-physical factors, such as the refusal to use safety belts or dissatisfaction with life.²² The costs of presenteeism may therefore not reflect the risk of cardiovascular and cerebrovascular diseases accurately. To the best of our knowledge, there are no published

studies that correlate these risks with presenteeism. Such data would be an important resource for managing health and productivity in the workplace.

Risk equations have been developed to estimate the 10-year probability of coronary artery disease and ischemic stroke in Japanese individuals.²³ This probability can be calculated from age, sex, smoking status, systolic blood pressure, antihypertensive medication use, diabetes mellitus, and cholesterol levels; these data can be obtained from standardized laboratory tests and questionnaires during the general periodic health examinations. Coronary artery disease and ischemic stroke are major diseases in Japan. We hypothesized that employees at high risk of cardiovascular and cerebrovascular diseases, as estimated by the risk equations for coronary artery disease and ischemic stroke, would exhibit greater presenteeism than employees deemed at lower risk. We hypothesized as well that employees at high risk would exhibit greater absenteeism and medical/drug costs than employees deemed at lower risk. The purpose of this study was to examine the association between the 10-year probability of developing these diseases and the incidence or costs of presenteeism, as well as the association with medical/drug treatment and absenteeism. By clarifying these associations, it is possible to estimate the effect and economic impact of preventing cardiovascular and cerebrovascular disease, and to clarify the characteristics of the target population for preventing presenteeism.

2 | MATERIALS AND METHODS

We conducted a cross-sectional study of male employees aged 40–65 years in four pharmaceutical companies and their health insurance society. This age group was selected because the minimum age for the applicability of the risk equation method²³ estimating the 10-year probability of coronary artery disease and ischemic stroke is 40 years, and 65 is a retirement age. The predicted probability of incident coronary artery disease within 10 years and the predicted probability of ischemic stroke within 10 years were calculated for each employee by combinations of age, sex, smoking status, systolic blood pressure, cholesterol levels, antihypertensive medication use, and use of medications to control diabetes.²³ These data were obtained from the standardized laboratory tests and health questionnaires administered to employees in 2014 in each participating company.

We divided the subjects into three groups according to the probability of incident coronary artery disease. We defined the workers whose probabilities were less than 0.5% as “low-risk,” the workers whose probabilities were 0.5%–2.0% as “moderate-risk,” and the workers whose probabilities were more than 2.0% as “high-risk.” The cutoff points were set

by reference to low-density lipoprotein cholesterol management target-setting.²⁴ We also divided the probability of incident ischemic stroke into three categories using the same definition.

This study was approved by the ethics committee of the University of Occupational and Environmental Health, Japan, Kitakyushu, Japan (H26-026 Date: 7/August/2019).

We designed a web-based, self-administered questionnaire about presenteeism and absenteeism in 2014. We asked participants whether they had experienced health issues at work over the preceding month. If the answer was yes, we asked whether the symptoms affected the quality and quantity of their work, in comparison with productivity during periods without symptoms. The quality and quantity were scored on a 0–10 scale.^{22,25} When participants had no health issues or indicated that their health issues had not affected the quality and quantity of their work at all, we defined the situation as “no presenteeism.” When participants indicated that their health issues did affect their work to any degree, we defined the situation as “presenteeism,” and the incidence of presenteeism was defined as existence of “presenteeism.” We calculated the presenteeism costs using the following formula⁴:

$$\begin{aligned} \text{Presenteeism costs} = & \text{JPY}3,300 \times 8 (\text{working hours per day}) \\ & \times (1 - \text{quantity } (0 - 10) \times \text{quality } (0 - 10) / 100) \\ & \times (\text{days with symptoms in a year}) \end{aligned}$$

The mean payroll per person per hour was set at 3,300 Japanese Yen (JPY) and based on the average in large manufacturing companies in 2014 in Japan.²⁶

We asked participants how many sick-leave days they had taken over the preceding 3 months. All subjects of this study were full-time employees, and they were guaranteed a sufficient sick leave according to their years of service. The salary was guaranteed by the company or health insurance unions depending on the number of days off. If the answer was none, we defined the situation as “no absenteeism.” All other answers were scored as “absenteeism,” and the incidence of absenteeism was defined as existence of “absenteeism.” We calculated the absenteeism costs using the following formula⁴:

$$\begin{aligned} \text{Absenteeism costs} = & \text{JPY}3300 \times 8 (\text{working hours per day}) \\ & \times (\text{sick-leave days in a year}) \end{aligned}$$

We received inpatient medical and pharmaceutical claims, outpatient medical claims, and outpatient pharmaceutical claims data for all participants from the health insurance unions, which covered the period between 1 April 2014 and 31 March 2015. The claims did not include dental treatments or over-the-counter drug expenses. We defined the sum of

inpatient medical and pharmaceutical claims, outpatient medical claims, and outpatient pharmaceutical claims as medical/drug costs. We excluded employees who spent more than 10 million JPY in medical expenses during that period to avoid the influence of catastrophic events.

2.1 | Statistical analysis

We first calculated descriptive statistics (percentages, means, and standard deviation) in each risk category. Logistic regression was used to calculate the odds ratio of each incidence of presenteeism and absenteeism comparing each category of coronary artery disease and ischemic stroke risk. We calculated the odds ratio adjusted for occupation (categorical variables) and body mass index (continuous variable), which were not used for estimating the 10-year probability of coronary artery disease and ischemic stroke. Next, we compared absenteeism, presenteeism, and medical/drug costs between the three categories. Statistical analysis was conducted using the Kruskal-Wallis test, and post-hoc multiple comparisons were made using the Mann-Whitney U test with Bonferroni corrections. All tests were two-tailed, with differences reported as significant if $P < .05$. All analyses were performed in SPSS version 25 (IBM SPSS, Armonk, NY, USA) and Stata version 16 (StataCorp, College Station, TX, USA).

3 | RESULTS

We sent an e-mail solicitation for questionnaires to 11 774 male employees aged 40–65 years in four companies, and 6,581 individuals (56%) responded. We excluded 530 employees for missing data and four employees who experienced catastrophic events that required extensive medical treatment (more than 10 million JPY in medical expenses). The number of employees eligible for inclusion in the analysis was 6047. The numbers of employees in each coronary artery disease risk category (low, moderate, and high) were 2374, 1808, and 1865, respectively. The numbers of employees in each ischemic stroke risk category were 2319, 1628, and 2100, respectively. Table 1 lists the characteristics of study participants, stratified by each category.

Regarding coronary artery disease, the incidence of presenteeism (defined as existence of presenteeism for the past a month) was recorded for 19%, 22%, and 27% of participants at low, moderate, and high risk, respectively (Table 2). The incidence of absenteeism (defined as existence of sick-leave for the past three months) was recorded for 17%, 21%, and 30% of participants at low, moderate and high

TABLE 1 Demographic characteristics of the study population

	Total		Coronary artery disease risk						Ischemic stroke risk					
			Low risk N = 1125		Moderate risk N = 4004		High risk N = 918		Low risk N = 2319		Moderate risk N = 3014		High risk N = 714	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age ^a														
40-49	3,107	51	1,125	100	1,866	47	116	13	2,319	100	780	26	8	1
50-59	2,679	44	0	0	2,022	50	657	72	0	0	2,183	72	496	69
60-65	261	4	0	0	116	3	145	16	0	0	51	2	210	29
Occupation														
Clerical administrative support	830	14	148	13	559	14	123	13	299	13	436	14	95	13
Sales	2,507	41	403	36	1,643	41	461	50	970	42	1,213	40	324	45
Research and development	1,036	17	218	19	701	18	117	13	460	20	480	16	96	13
Production line	521	9	84	7	361	9	76	8	180	8	263	9	78	11
Other	1,153	19	272	24	740	18	141	15	410	18	622	21	121	17
Smoking ^a														
Yes	1,669	28	0	0	1,202	30	467	51	501	22	822	27	346	48
Treatment for hypertension ^a														
Yes	1,171	19	0	0	483	12	688	75	0	0	659	22	512	72
Treatment for diabetes mellitus ^a														
Yes	266	4	0	0	73	2	193	21	0	0	79	3	187	26
Treatment for hyperlipidemia ^a														
Yes	965	16	83	7	554	14	328	36	172	7	523	17	270	38
Body mass index (kg/m ²)	23.9	3.2	22.9	2.5	23.8	3.1	25.7	3.6	23.2	2.8	24.1	3.2	25.2	3.5
Systolic blood pressure (mmHg) ^a	121	14	115	9	121	14	127	15	115	11	123	14	127	15
Diastolic blood pressure (mmHg)	77	10	73	8	78	10	82	11	74	9	79	10	81	11
Total cholesterol (mg/dL)	202	32	197	28	204	31	204	37	202	31	205	31	194	33
Low-density lipoprotein cholesterol (mg/dL)	123	29	118	25	124	30	123	32	124	29	124	29	114	29
High-density lipoprotein cholesterol (mg/dL)	58	14	60	13	59	15	53	14	58	14	59	15	55	14

(Continues)

TABLE 1 (Continued)

	Total		Coronary artery disease risk						Ischemic stroke risk					
			Low risk N = 1125		Moderate risk N = 4004		High risk N = 918		Low risk N = 2319		Moderate risk N = 3014		High risk N = 714	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Triglycerides (mg/dL)	127	99	97	50	124	84	175	165	114	74	130	106	155	126
Fasting blood glucose (mg/dL)	97	16	92	8	96	14	108	27	93	10	97	15	109	27
Glycated hemoglobin (HbA1c, %)	5.5	0.6	5.3	0.3	5.4	0.5	5.9	0.9	5.3	0.4	5.5	0.6	5.9	0.9

^aThese variables were used to calculate the risk of coronary artery disease and ischemic stroke.

risk, respectively. Workers at moderate and high risk also had a significantly higher risk of incidence of presenteeism than workers at low risk (OR: 1.18; CI: 1.00-1.40 for moderate-risk workers and 1.46 [CI: 1.18-1.81] for high-risk workers). Workers at moderate and high risk had a significantly higher risk of incidence of absenteeism than workers at low risk (odds ratio [OR]: 1.29; 95% confidence interval [CI]: 1.08-1.53 for moderate-risk workers and 2.11 [CI: 1.69-2.63] for high-risk workers).

Regarding of ischemic stroke, the incidence of presenteeism was recorded for 20%, 23%, and 25% of participants at low, moderate, and high risk, respectively. The incidence of absenteeism was recorded for 19%, 22%, and 31% of participants at low, moderate and high risk, respectively. Workers at moderate and high risk also had a significantly higher risk of incidence of presenteeism than workers at low risk (OR: 1.17; CI: 1.02-1.33 for moderate-risk workers and 1.24 [CI: 1.01-1.51] for high-risk workers). Workers at moderate and high risk of ischemic stroke had a significantly higher risk of incidence of absenteeism than workers at low risk (OR: 1.23; CI: 1.07-1.41 for moderate-risk workers and 1.94 [CI: 1.59-2.36] for high-risk workers).

The mean presenteeism costs per person per year in groups at low, moderate, and high risk for coronary artery disease were JPY 322 418, JPY 341 768, and JPY 337 277, respectively (Figure 1). Only the high-risk and low-risk groups differed significantly ($P < .01$). The mean absenteeism costs per person per year in groups at low, moderate, and high risk for coronary artery disease were JPY 35 388, JPY 47 697, and JPY 75 059, respectively. All risk groups differed significantly ($P < .001$). Mean medical/drug costs per person per year in the high-risk group were highest (JPY 240 486), followed by costs in the moderate-risk group (JPY 133 820) and in the low-risk group (JPY 97 816). There was a significant cost difference between all risk groups ($P < .001$).

The mean presenteeism costs per person per year in groups at low, moderate, and high risk for ischemic stroke were JPY 330,213, JPY 353 118, and JPY 295 122, respectively (Figure 2). The three risk groups differed significantly in the Kruskal-Wallis test ($P = .031$) but not in the post-hoc multiple comparisons test (Mann-Whitney U-test with Bonferroni correction). The mean absenteeism costs per person per year in groups at low, moderate, and high risk for ischemic stroke were JPY 38 729, JPY 50 733, and JPY 79 792, respectively. All risk groups differed significantly. Mean medical/drug costs per person per year in the low-, moderate-, and high-risk groups were JPY 90 838, JPY 157 818, and JPY 252 531, respectively. The three groups differed significantly ($P < .001$).

4 | DISCUSSION

We sought to associate the probability of developing coronary artery disease and ischemic stroke with the incidence of presenteeism and absenteeism, as well as with the annual mean cost per employee of presenteeism, absenteeism, and medical/drug treatments. Presenteeism and absenteeism were higher in workers at moderate and high risk of coronary artery disease and ischemic stroke. The mean costs of absenteeism and medical/drug treatments were higher in the high-risk groups, and presenteeism costs were higher in the group at high risk for coronary artery disease but not ischemic stroke. Overall, the costs of presenteeism were much higher than those of absenteeism or medical/drug treatments, which is consistent with the findings of our previous study.⁴ As far as we know, this is the first study to assess the association between risks of cardiovascular and cerebrovascular diseases calculated with risk equations and presenteeism, absenteeism, and medical/drug treatment simultaneously.

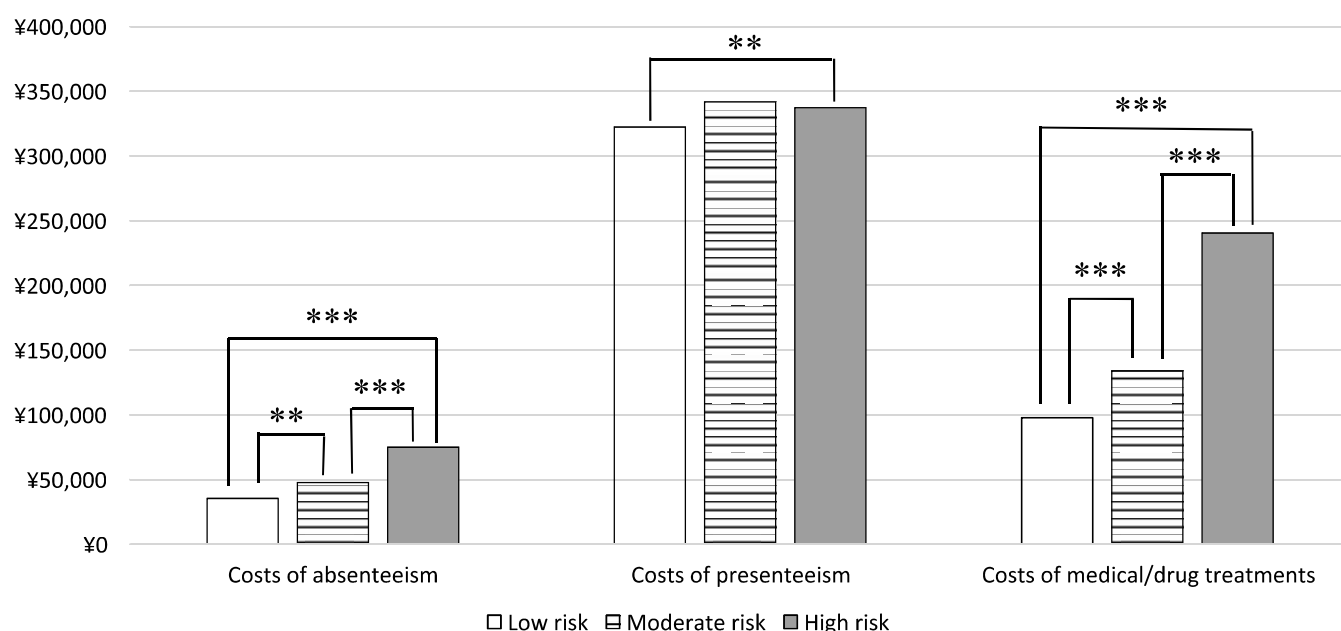
TABLE 2 Adjusted odds ratio of incidence of presenteeism and absenteeism by risk category

	Incidence of presenteeism ^a				Incidence of absenteeism ^b			
	Proportion (%)	Adjusted odds ratio ^c	95% confidence interval	<i>p</i> value	Proportion (%)	Adjusted odds ratio ^c	95% confidence interval	<i>P</i> value
Coronary artery disease								
Low risk	19	ref			17	ref		
Moderate risk	22	1.18	1.00-1.40	.048	21	1.29	1.08-1.53	.005
High risk	27	1.46	1.18-1.81	<.001	30	2.11	1.69-2.63	<.001
Ischemic stroke								
Low risk	20	ref			19	ref		
Moderate risk	23	1.17	1.02-1.33	.022	22	1.23	1.07-1.41	.003
High risk	25	1.24	1.01-1.51	.039	31	1.94	1.59-2.36	<.001

^a The incidence of presenteeism was defined as existence of presenteeism for the past a month by a self-administered questionnaire.

^b The incidence of absenteeism was defined as existence of sick-leave for the past three months by a self-administered questionnaire.

^c Adjusted for occupation (categorical variables) and body mass index (continuous variable).

**FIGURE 1** Mean costs of absenteeism, presenteeism, and medical/drug treatments per person per year (Japanese Yen in 2014) stratified by risk of coronary artery disease. ***P* < .01; ****P* < .001

Our findings of increased absenteeism and medical/drug treatments in the high-risk group are in accordance with those of studies that reported that absenteeism or medical/drug costs increased as the number of cardiometabolic risk factors increased,¹⁴⁻¹⁷ and suggest that employers would benefit from reducing absenteeism and medical/drug treatments to intervene in high-risk individuals identified from health examinations.

The percentage of employees displaying symptoms that cause presenteeism is reported to be approximately 16%–22%^{4,27} among workers in large Japanese companies. Therefore, identifying individuals at high risk and offering

them treatment measures would constitute an effective approach. In Japan, employers are required to implement intervention measures in occupational health after general health examination. Since studies have shown that presenteeism increases as the number of risk factors for cardiovascular and cerebrovascular diseases increases,^{7,18-22} we examined the feasibility of screening individuals at high risk of presenteeism using the disease risk factors that can be identified by the general health examination. We found that presenteeism was higher in individuals at high risk of coronary artery disease and ischemic stroke, suggesting that this approach is effective. This result contradicts the fact that costs of

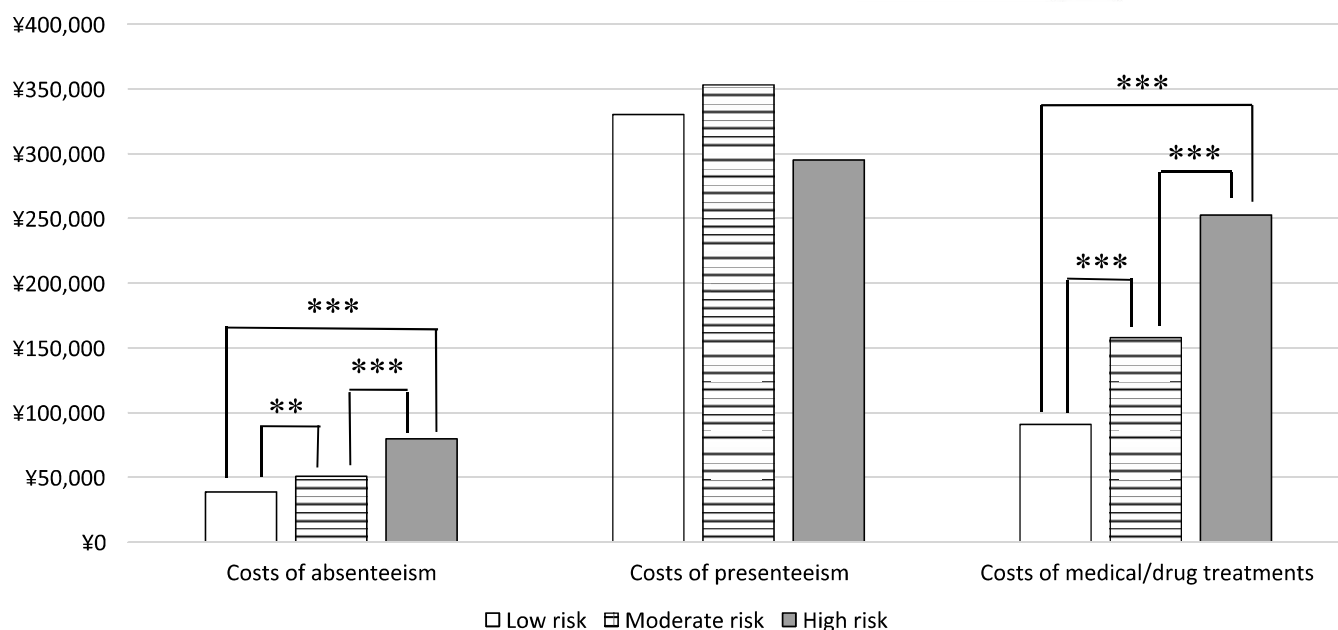


FIGURE 2 Mean costs of absenteeism, presenteeism, and medical/drug treatments per person per year (Japanese Yen in 2014) stratified by risk of ischemic stroke. ** $P < .01$; *** $P < .001$

presenteeism were not higher according to rising the risk of coronary artery disease and ischemic stroke. Presenteeism costs are calculated not only by the existence of presenteeism but also by factors that affect the work. A past study revealed that the highest cost burdens of presenteeism from chronic illness were related to mental (behavioral) health conditions.⁴ Although the rate of co-morbidity between cardiovascular and cerebrovascular disease and depression is relatively high at around 20%,²⁸ the risk factors for those diseases are not exactly the same. There might be many people with mental health illness in the low or moderate risk group of cardiovascular and cerebrovascular diseases as those in the high-risk group. In addition to this, the amount of presenteeism costs for people with symptoms of mental illness is higher than for other symptoms.⁴ For that reason, costs of presenteeism in workers at low and moderate risk for both coronary artery disease and ischemic stroke may contain costs of presenteeism related to mental health conditions. Costs of presenteeism in workers at low and moderate risk should not be neglected since it involves much higher than costs of absenteeism or medical/drug. These findings also indicate that employers should consider investing in countermeasures against presenteeism, such as interventions to relieve stressful conditions in the workplace.

This study has several limitations. First, we used data from employees of large pharmaceutical companies. The smoking rate was 28% among the subjects of this study (mostly 40–59 year old men). According to the National Health and Nutrition Survey,²⁹ which is a representative sample of the general population in Japan, smoking rate was 44.2% among men in their 40s and 36.4% in men in their 50s in the 2014

survey. The subjects in this study may be healthier than the general population. However, since this study calculates the absolute risk of cardiovascular and cerebrovascular diseases using data from lifestyle and blood tests, the results of this study can be used in other groups. The future study is needed to confirm reproducibility of this results in small and medium enterprises and other industries. This study was conducted only among men, and it will be necessary to consider it among women in the future. Second, we could not calculate the costs of over-the-counter drugs, but as sales of such drugs in Japan total only JPY 94 billion, compared with JPY 985 billion for prescription drugs,³⁰ we estimate that the influence of the former is small. Third, dental claims were not included in the medical/drug costs. Again, as dental costs are estimated at only 6.8% of total expenditure for medical care,³¹ we surmise that their influence on our findings is negligible. Fourth, this study was cross-sectional, so we were unable to estimate whether programs aimed at preventing cardiovascular and cerebrovascular diseases reduce the economic burdens of presenteeism, absenteeism, and medical/drug treatments. Determining the efficacy of prevention programs would require intervention studies.

Despite the limitations, our study adds to the literature assessing health-related costs in the context of cardiovascular and cerebrovascular diseases. The findings could assist employers in developing effective strategies for the promotion of workplace health and human capital, especially in Japan.

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DISCLOSURE

Approval of the research protocol: This study was approved by the ethics committee of the University of Occupational and Environmental Health, Kitakyushu, Japan, and was conducted in full accordance with the World Medical Association Declaration of Helsinki. **Informed consent:** We explained the study protocol and obtained opt-out consent. **Registry and the registration no. of the study/trial:** N/A. **Animal Studies:** N/A. **Conflict of interest:** None declared.

AUTHOR CONTRIBUTIONS


TN and KM conceived and coordinated the project. KK, TN, and MO completed the data analysis. KK and TN drafted the initial manuscript. MN, S.K, YF, and KM revised the manuscript. All authors commented on drafts of the report.

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遠隔機器を用いた労働者の健康管理：産業保健領域における 遠隔機器を用いた健康管理のシステマティックレビューと 遠隔産業医面接に関する法制度の現状

Workers' Health Management by Using Remote Devices: Systematic Review of Health
Management by Using Remote Devices in Occupational Health and Current Status of
Legal System for Remote Occupational Interviews

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＜要 約＞

遠隔機器を用いた産業場面での健康管理の中で、特に労働者の健康管理に資する現在までの知見をシステマティックレビューの形式で整理した。和文は医学中央雑誌web版を、英文はPubMedを使用し、和文は「産業保健」もしくは「産業衛生」と「面接」もしくは「面談」と「遠隔」を、英文は「Occupational Health」 and 「Telehealth」を検索キーワードとし、2000年以降の総説、原著論文、症例報告・事例および学会報告に限って検索した。結果、和文15本、英文18本の計33本を組み入れた。遠隔機器を用いた健康管理では、減量支援やメンタルヘルス対策において一部効果が報告されているものの、効果検証を行った報告は少ないことが明らかとなった。さらに、産業医等の医療職による遠隔面談（面接）については、ストレスチェックや過重労働について幾つかの指針が示されているものの、その他については明文化されたものはなく、医療サービスなどの周辺領域で適用されている法令な

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