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[Original]

A Retrospective Cohort Study among Iron-Steel Workers in Anshan, China: Exposure Assessment

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Abstract: Although adequate assessment of exposure is needed in epidemiological studies among foundry workers, previous studies are often lacking in this aspect. We conducted a retrospective cohort study of a Chinese iron and steel company with a 14-yr follow up during 1980－1993. Exposure assessment was performed for a single job, i.e., the current job for the active worker and the longest job for the retired or deceased worker as of the end of the follow-up, which was allocated as the surrogate of lifetime job and was applied to a job-exposure matrix. Of the 147,062 cohort members, 52,394 males (43%) and 5,291 females (21%) were exposed to any of 15 hazardous factors such as dust, silica, PAHs (polycyclic aromatic hydrocarbons), CO (carbon monoxide) and heat. In 2,104 randomly selected samples, the exposure assessment of exposed workers based on a single job was found to be 12－14% lower than the real situation. This study suggests that the exposure assessment is valuable in evaluating the health effects among the foundry workers, despite some limitations such as underestimation of exposure assessment and the lack of data regarding smoking and drinking habits.

Key words: foundry, cohort study, job exposure matrix, multiple exposures.

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Introduction

Although proper assessment of exposure is a key issue in retrospective epidemiological studies, exposure to specific harmful agents has not always been assessed in most large-scale cohort studies of iron-steel workers, and job titles or job categories have been used as a surrogate measure of exposure to such agents [1−3]. Such a study method is prone to exposure misclassification in a random or non-differential manner, and a causal association may be missed [4].

In general, iron and steel founding consists of three major processes. They include the following: 1. molding or coremaking using sand and binding materials, 2. metal smelting in furnaces or cupola with coke, limestone and fluxes at extremely high temperature and pouring molten iron and steel into the molds, and 3. fettling as a final process to remove sand and excess metal from the castings. The workers are exposed to a variety of chemical and physically harmful agents in the processes [5].

The purpose of this paper is to describe the procedure of the exposure assessment and to evaluate its validity, i.e., how correct the results of the exposure assessment would be reflected in the real situation of exposure to the hazardous agents, with randomly selected subjects in a Chinese large-scale cohort study.

Methods and Resources

Overview of the study

The general characteristics of the study method, i.e., setting, definition of cohort and of reference groups, confirmation of vital status, and statistical analysis, and the results of the estimated mortality risks were described elsewhere [6].

Briefly, of the 121,846 male and 25,216 female steelworkers studied, 13,363 and 597 died, respectively, during the 14-yr follow-up period (from January 1, 1980 through December 31, 1993) in a Chinese iron-steel company, Angang for short, in the city of Anshan in northeastern China. In the computerized personnel data file in Angang, we collected the only-one-job information of one worker from the file, i.e., the longest job for the retired workers, and the current job for the active workers as of December 31, 1993. Standardized Mortality Ratios (SMRs) and Standardized Rate Ratios (SRRs) were calculated for evaluation of the mortality risks. SMR analysis showed increasing 'dose-response' trends between exposure and mortality for all causes of death and all major categories of diseases, both in males and females. SRR analysis showed that exposure to the 15 hazardous factors mentioned below increased mortality risks for all causes, all neoplasms, and some diseases among the males, while adjusting for confounding factors. Combined exposure to PAHs (polycyclic aromatic hydrocarbons) and two or more dusts increased the risk of lung cancer (SRR = 654 [95% CI: 113−3,780]) and other malignancies, which supports the proposition that foundry work has adverse health effects, including carcinogenic risk [6]. In this paper, we described the method of exposure assessment and evaluated whether or not the current jobs and the last jobs could be surrogate measures of the lifetime jobs for the active workers and for the retired/left workers, respectively, as of the time of the setting of the cohort.

Procedure of job exposure matrix establishment

A workshop-, job title- and exposure matrix method (Job Exposure Matrix, JEM) was applied for the exposure assessment in this study. The workers at Angang engaged in a total of 1,583 job titles in 836 workshops of about 90 factories or facilities allocated by the coding manual of the computerized personnel data file [7]. The manual was used as the standard job dictionary for establishing the JEM. The following information and documents were also used to establish the JEM by the occupational hygienists of the Angang Occupational Hygiene Institute:

1. The dictionary of job-workplace/calendar year/pollution levels for various dusts and benzo(a)pyrene (BaP) at 385 workplaces by 5-year periods in 1956－1990: Based on the 82,867 historical monitoring records of dusts and BaP which were collected in 1956－1992, most of the job titles with heavy exposure in the coding manual have been included in the dictionary [7, 8].
2. The standard of jobs receiving compensation for exposure to occupational hazards at Angang: This contained 2,755 job titles originally specified for the purpose of compensating workers with exposure to dusts, mercury, lead, benzene, manganese, sulfur dioxide, carbon disulfide, nitrogen oxide, PAHs, radiation and high temperature (heat) [9].
3. Research reports of studies conducted by the Angang Labor Hygiene Research Institute (ALHRI): This listed the major jobs or worksites with occupational exposure to dusts [10－12], BaP [13], coke oven emission [14], carbon monoxide (CO) [15] and heat [16].

The hygienists at ALHRI re-evaluated the exposure status for the 836 workshops and 1,583 job titles in the coding manual, because the above information was collected for different purposes. For those workshops or job titles without historical exposure data mentioned above, the hygienists made exposure estimates taking into consideration workplaces or job titles with similar working conditions. As a result, the following 15 hazardous factors were evaluated: silica dust, iron dust, cement dust, welding dust, asbestos, coal dust, wood dust, grinding dust, other dusts, heat, CO, PAHs, oil mist, acid mist and benzene. Exposure to each of these 15 factors was evaluated as a dichotomous variable (yes or no) by linking the JEM with the only-one-job information for each worker. It should be noted that even white-collar workers could be classified as being exposed to some risk factors if they ordinarily worked at worksites involving these factors.

Validation study of exposure assessment and smoking and drinking behavior

Since the exposure to the factors were evaluated by the only-one-job, there remained the possibility of misclassification of exposure to the factors. If a worker had exposure to any factors in jobs other than the allocated job, the exposure would not be counted for either currently active workers or for workers who had retired or left the company. To assess the differences in the exposure rates between the condition when using the only-one-job for the JEM and that when using the all-the-jobs that each worker had experienced, we randomly

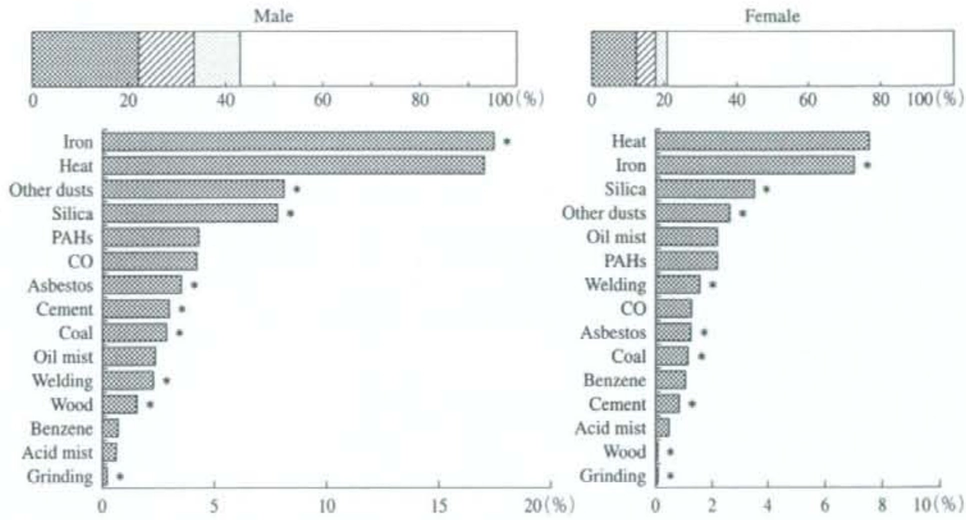

Fig. 1. Status of exposure to harmful agents among 147,062 Chinese iron-steel workers (Upper: Proportion of workers by number of exposed factors in males (N = 121,846) [left] and females (N = 25,216) [right]; Lower: Proportion of workers with harmful exposure by the factors in males (N = 52,394) [left] and females (N = 5,291) [right]).

: one; Male (N=26,796), Female (N=3,168), : two; Male (N=14,037), Female (N=1,296),
: three or more; Male (N=11,561), Female (N=827), : none; Male (N=69,452), Female (N=19,925).
*: Classified as dust.

selected 2,104 subjects from a previous case-control study [8]. The indicators for comparison were rate 1, i.e., the proportion of exposures to the factors obtained by applying the JEM to only-one-job, and rate 2, i.e., the proportion of exposures to the factors obtained by applying the JEM to all-jobs-experienced.

Further, to evaluate the difference in smoking and drinking rates among the workers exposed to each factor, the proportion of current smokers and current drinkers was calculated for the 756 male controls of the case-control study. Statistical significance of the difference in the rates between the exposed and non-exposed workers was tested with Chi-square test. Cancer cases in the 2,104 subjects were excluded, because it is generally accepted that smoking and drinking rates are higher in lung cancer and stomach cancer patients. Females were also excluded because of the small number.

Results

Figure 1 shows that male workers were two times more exposed to the 15 risk factors evaluated than female workers (43.0% *vs.* 21.0%). Of the male workers, 21,175 (17.4%) were exposed to iron dust, 20,729 (17.0%) to heat, 9,542 (7.8%) to silica and 5,245 (4.3%)

Table 1. Working period in different jobs among randomly selected workers at Angang of China

	Male (N = 1,942)		Female (N = 162)	
	Length (years)	%	Length (years)	%
Lifetime job	29.7	100.0	24.8	100.0
Longest job	21.2	71.4	18.8	75.8
Current job	16.6	55.9	16.6	66.9

The average ages in the sample were 59.5 and 54.9 for males and females, respectively

These were 8 − 10 years older than those of the cohort members

N = 2,104

to PAHs. Of the female workers, the corresponding numbers were 1,786 (7.1%), 1,918 (7.6 %), 891 (3.5%) and 563 (2.2%), respectively. Some workers, both male and female, had exposure to three or more of the factors.

Among the 2,104 randomly selected samples, the average lengths of lifetime work were 29.7 years for males and 24.8 years for females (Table 1). The average lengths of their longest job were 21.2 years for males and 18.8 years for females, which accounted for 71.4 % (21.2/29.7) and 75.8% (18.8/24.8) of the lifetime working years, respectively. Current jobs accounted for 55.9% and 66.9% of the lifetime working years for males and females, respectively. It should be noted that the average ages in the sample were 59.5 for males and 54.9 for females; these were 8 − 10 years older than those of the cohort members.

Table 2 shows that rate 1, the proportion of workers exposed to the factors using the only-one-job information among the 2,104 subjects randomly sampled, was lower than rate 2, the proportion of workers exposed to the factors using the all-jobs-experienced information for the same 2,104 subjects. The differences between the rates were a total of 14.0% in males and 12.4% in females. As for the workers with exposure to each factor, the highest difference in males and females were 9.6% and 6.8% for heat, respectively. Rate 1, the surrogate exposure rate in the cohort study, may be underestimated compared to rate 2, the actual exposure rate.

Table 3 shows the distribution of smokers and drinkers by the exposure status based on the case and control allocation among the 756 male controls. The total numbers of current smokers and current drinkers were 514 (68.0%) and 373 (49.3%), respectively. As for both smoking rates and drinking rates, the differences due to numbers of exposure and of dust exposure were not statistically significant either by the only-one-job method or by the all-jobs-experienced method.

Table 2. Differences in expression of exposure rates by the method of exposure assessment among randomly selected workers at Angang of China

	Male (N = 1,942)			Female (N = 162)		
	Rate 1	Rate 2	Rate 2 − Rate 1	Rate 1	Rate 2	Rate 2 − Rate 1
Number of exposure factors						
None	61.9	47.9	–	87.7	75.3	–
One or more	38.1	52.1	14.0	12.3	24.7	12.4
One	21.2	23.2	2.0	9.3	15.4	6.1
Two	9.0	12.3	3.3	1.9	4.9	3.0
Three or more	7.9	16.6	8.7	1.2	4.4	3.2
Number of dust exposures						
None	68.3	55.1	–	92.0	81.5	–
One or more	31.7	44.9	13.2	8.0	18.5	10.5
One	27.0	32.7	5.7	6.8	14.8	8.0
Two	4.3	9.3	5.0	1.2	2.5	1.3
Three or more	0.4	2.9	2.5	0.0	1.2	1.2
Exposure factors						
Silica dust	7.0	13.0	6.0	1.2	4.3	3.1
Iron dust	16.1	23.8	7.7	3.7	9.3	5.6
Welding dust	1.2	1.8	0.6	1.2	2.5	1.3
Coal dust	2.3	4.4	2.1	0.6	1.9	1.3
Cement dust	2.4	4.2	1.8	0.6	0.6	0.0
Grinding dust	0.2	0.5	0.3	0.0	0.0	0.0
Asbestos	2.4	3.6	1.2	0.6	1.2	0.6
Wood dust	1.8	2.5	0.7	0.0	0.6	0.6
Heat	16.1	25.7	9.6	2.5	9.3	6.8
Carbon monoxide	6.3	11.3	5.0	1.2	3.1	1.9
PAHs	4.3	7.8	3.5	3.1	4.3	1.2
Oil mist	2.5	3.6	1.1	1.9	3.7	1.8
Acid mist	0.5	0.6	0.1	0.0	0.0	0.0
Benzene	0.5	0.6	0.1	1.2	2.5	1.3

Rate 1: Exposure rates of 2,104 subjects of a case-control study which were evaluated by applying the JEM to only one job, i.e., the longest job for the retired, deceased and workers who left the company, and the current job for the active workers

Rate 2: Exposure rates of 2,104 subjects of a case-control study which were evaluated by applying the JEM to all jobs experienced

N = 2,104

Discussion

Impact of the use of job exposure matrix in the epidemiological study

We established the JEM based on information and documents including 82,867 working environment monitoring records with support by industrial hygienists, and performed exposure assessment in 836 workshops and 1,583 job titles. For each of the 147,062 members, exposure to the 15 harmful factors were successfully allocated as a dichotomous variable.

Table 3. Differences in proportions of current smokers and drinkers by the method of exposure assessment among randomly selected workers at Angang of China

	Assessed by only-one-job information			Assessed by all-jobs-experienced information		
	Total	Current smokers N = 514	Current drinkers N = 373	Total	Current smokers N = 514	Current drinkers N = 373
Number of exposure factors						
None	491 (100)	330 (67.2)	240 (48.9)	391 (100)	259 (66.2)	183 (46.8)
One	153 (100)	103 (67.3)	72 (47.1)	181 (100)	125 (69.1)	92 (50.8)
Two	60 (100)	46 (76.7)	34 (56.7)	86 (100)	60 (69.8)	42 (48.8)
Three or more	52 (100)	35 (67.3)	27 (51.9)	98 (100)	70 (71.4)	56 (57.1)
Number of dust exposure						
None	545 (100)	368 (67.5)	263 (48.3)	454 (100)	303 (66.7)	212 (46.7)
One	180 (100)	124 (68.9)	96 (53.3)	234 (100)	160 (68.4)	123 (52.6)
Two	27 (100)	20 (74.1)	12 (44.4)	47 (100)	33 (70.2)	27 (57.5)
Three or more	4 (100)	2 (50.0)	2 (50.0)	21 (100)	18 (85.7)	11 (52.4)

No significant associations were found between proportions of current smokers and drinkers and proportions of workers with the status of exposure by Chi-square test
N = 756 (males only), (%)

Therefore, the current study allows for the evaluation of more detailed exposure-response relationships with less chance of misclassification of exposure than previous studies using only job titles or job categories [1−3, 17−21].

JEMs are widely used in epidemiological studies. Types of assessments include dichotomous (yes or no) [22], semi-quantitative (low, medium and high) [23, 24], and quantitative (point estimates of exposure levels, e.g., [mg/m^3]) [25]. Although a quantitative approach is undoubtedly likely to ensure less uncertainty and misclassification of exposure of the study subject, some problems, such as less availability of sufficient monitoring data in retrospective studies, may be involved [4]. It is noted that less precise measures are quite certain in some studies for epidemiologically examining etiologic hypotheses [26]. For the workers at Angang, only-one-job was available for each cohort member in the computerized personnel file, so it was feasible to dichotomously allocate the 147,062 subjects to exposure to the 15 agents as surrogates of exposures in the lifetime jobs.

Exposure status of the Chinese iron and steel workers

At Angang, multiple exposure is common among the workers. At least 21% of the male workers (N = 25,598) were exposed to two or more risk factors, such as iron dust, heat, silica, PAHs, CO and asbestos. On the other hand, almost 80% of the females (N = 19,925) were not exposed to any factor. Our results of exposure assessment were very close to those of previous reports at Angang and other Chinese iron and steel foundries [10−16, 27]. Thus, the exposure rates assessed in this study may reflect the average exposure status of workers throughout China.

When the number of total exposures is considered, the exposure rates and combinations of major harmful agents may greatly increase the diversity for different exposure subgroups. Most of the factors are weakly correlated, but the co-exposures to other hazards must be noted when evaluating the health effects for an individual hazard, such as silica dust, iron dust, asbestos, other dusts, heat, CO and PAHs. When considering the health effects of the agents, e.g., cancer risk, careful attention should be paid to the interpretation of the impact of correlations, such as additive or synergistic effects and confounding. As mentioned above, we reported that combined exposure to PAHs and two or more dusts significantly increased the risk of lung cancer (SRR = 654 [95%CI: 113−3,780]) among the male workers [6]. These results were consistent with previous studies, which indicated the accuracy of exposure assessment in this study.

In the results mentioned above, the exposure rates evaluated by all-jobs-experienced, rate 2, were higher than those evaluated by only-one-job for the case-control subjects, rate 1. Since the decreases in exposure rate with the only-one-job method were 14.0% in males and 12.4% in females, the results of the exposure assessment may include misclassification of exposed workers as non-exposed. Thus, as a surrogate measure of lifetime exposure, the assessment with the only-one-job method may underestimate somewhat the real situation of exposure status among them.

Limitations of the study

In the current study, we did not consider the exposure dose of the substances. The exposure dose depends on several factors, such as concentration level in the workplace, length of exposure, and status of wearing personal protective equipment, all of which are time-dependent. Thus, caution must be exercised when interpreting the results of health effects of the agents, e.g., cancer mortality risk [6].

Smoking and drinking information were not available for each member in the study, so that careful attention is also required when evaluating the health effects of the agents. According to our sampling survey summarized in Table 3, the smoking and drinking rates were almost the same between the exposed and non-exposed group. Thus, it would be valid to compare the health effects of the 15 hazardous factors without adjusting for the difference in smoking and drinking rates between them.

Conclusions

We conducted a retrospective cohort study with exposure assessment using JEM among Chinese iron-steel workers. There was a large amount of accumulated historical exposure data to provide sufficient objective information for establishing a valid JEM. The exposure rates and multiple exposure status of the 15 major occupational hazards were completely assessed with the JEM for the 147,062 steel workers, and the distribution of the exposures was described. The limitation of the study is that the exposure assessment was based on only-one-job as a surrogate measure of the lifetime job, but this method is valid because there is only a slight difference between the estimate and the actual situation in the sampling survey. Thus, our study provides valuable information for evaluating the adverse health effects of occupational hazards among iron and steel workers.

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中国鞍山市某製鉄業労働者の後ろ向きコホート研究：曝露評価

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要　　旨： 製鉄業従事者の疫学研究では適切な曝露評価が必要とされるが，先行研究ではこれをしばしば欠いて来た．我々は1980～1993年の14年間の追跡を伴う中国の某製鉄所における後ろ向きコホート研究を行った．その際，先ず生涯職種の代用指標として，追跡終了時に現役だった場合はその時点の職種，退職または死亡していた場合は最も長く従事した職種を労働者ごとに特定し，次に，それを職業曝露連関表に当てはめて，曝露評価を実施した．合計147,062名のコホート構成員の内，男性52,394名(43%)と女性5,291名(21%)が粉じん，シリカ，PAH(多環系芳香族炭化水素)，一酸化炭素，温熱など15種類の作業要因のいずれかへの曝露を有していた．2,104名の無作為抽出標本における単一職種曝露評価の結果と実際に従事したすべての職種での結果とを比較したところ，前者の曝露者の割合は後者より12～14%低くなっていた．本研究では，曝露の定性評価による過小推定および喫煙と飲酒習慣に関する情報の欠損という限界はあるものの単一職種による作業曝露連関表を用いた曝露評価の有効性が示唆された．

キーワード： 製鉄業，コホート研究，作業曝露連関表，重複曝露．

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The development and regulation of occupational exposure limits in Japan

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Abstract

The Ministry of Health, Labor and Welfare, on an administrative basis, establishes and supervises the Administrative Concentration Level, which can be viewed as an Occupational Exposure Limit (OEL) legally binding employers to maintain a good working environment. The Japan Society for Occupational Health, on a scientific basis, establishes the Recommended OELs, which can be viewed as a reference value for preventing adverse health effects on individual workers. In the case of carcinogens, Reference Values are recommended instead of OELs, corresponding to lifetime excessive risk of 10^{-3} and 10^{-4}. The former is based on monitoring of the ambient working environment (area monitoring) while the latter is based on the monitoring of the individual worker. The two OELs influence each other in the course of establishment.

1. Introduction

Japan is currently in the process of recovering from the major economic slowdown that started in the 1990s. It boasts the second most technologically powerful economy in the world after the United States. With a population of 127 million (M), the labor force (66.7 M) by occupation is composed of agriculture 5%, industry 25%, and services 70%. Industry is characterized as among the world's largest and technologically advanced producers of motor vehicles, electronic equipment, machine tools, steel and nonferrous metals, ships, chemicals, textiles, and processed foods (Central Intelligence Agency). The wide array of chemicals manufactured (for both industrial and consumer use) spans organic/inorganic chemicals, dyes, paints, pharmaceuticals, cosmetics, detergents, fertilizers, and plastics. Chemical production depends primarily on domestic demand but export (roughly 1.5 times the level of import) has been increasing since the mid 1990s (Ministry of Economy, Trade and Industry, 2002).

The Ministry of Health, Labor and Welfare (MHLW) is the government authority that regulates occupational exposures in the working environment. The MHLW, together with its umbrella of prefectural (regional) Labor Bureaus and Labor Standards Inspection Offices, has jurisdiction over the Administrative Control (AC) Level for various exposures, the supervision/oversight of workplaces in implementing exposure measurements and remedial actions when measurement data indicate excessive exposures.

The Japan Society for Occupational Health (JSOH) is a non-governmental academic society of occupational health professionals (academicians and practitioners) with a membership of ca. 7500 (Japan Society for Occupational Health; Takahashi, 2000). The Committee for Recommendation of Occupational Exposure Limits of JSOH is a permanent subcommittee within the Society delegated with the said purpose and assessment of carcinogenicity.

Hence, in principle, the two authorities are distinct by type (governmental/scientific) and purpose (regulation/

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recommendation), yet they are not completely independent of each other because membership may overlap in expert committees between the two parties and attention is paid to the position of the other party in the course of discussions. The aim of the present paper is thus to overview how occupational exposure limits of chemical substances are developed and implemented in Japan, with particular focus on the complementary role of the pertinent bodies.

2. Procedure of Occupational Exposure Limit development

The Industrial Safety and Health Law (ISH Law) of Japan (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002; Ministry of Health, Labor and Welfare, ISH Law) stipulates "Working Environment (WE) Management" as one of the core management activities designated for occupational health. Like many countries, the ultimate responsibility of WE and other management activities is borne by the employer. The premises of the WE Management rest on implementing WE Measurement by a qualified WE Measurement Expert (an employee of the company or via purchase of service from a third party) with reference to the AC Level specified for the respective substances.

In practice, the actual measurement data are compared with the AC Level, and according to their comparative status, employers are required to take the necessary measures to maintain or improve the WE as laid down by the ISH Law and subordinate regulations/rules. Hence, the AC Level is the Recommended Occupational Exposure Limit (OEL) with legal binding power. This should be viewed in contrast with the Recommended OEL issued by JSOH, which has no legal binding power but is considered to be a voluntary guidance value. There are differences in the rationale for establishing AC Level and Recommended OEL as well. However, as noted throughout the present paper, the two values often influence each other.

2.1. Administrative Control level

The AC Level, in combination with the various procedures for WE Measurement enforced in Japan, is unique (Sakurai, 2003). Unlike many other countries, the entire system is based on monitoring of the ambient working environment rather than monitoring of individual workers. Briefly, WE Measurement incorporates: (1) A-measurement implemented in a designated Unit Work Area (UWA) accounting for distribution of harmful substances and range of movement of workers within the area of the workshop concerned; and (2) B-measurement implemented at the time and point observed to entail the highest exposure. The actual procedure for A-measurement requires measurement during regular operation, at the height of 50–150 cm above the floor (workers' respiratory zone) of at least 5 intersection points of grid-lines drawn of 6 m or less drawn within a designated UWA. Air sampling should be continued for at least 10 min per sampling point, and for 2 days in principle (Sakurai, 2003; Ministry of Health Labor and Welfare, 2001a).

The distribution of measurement values will closely fit a log-normal curve, which provides the basis for adopting the following criteria. From the distribution of measurement values, Measurement Value 1 (E_A1) is calculated as the estimated upper 5-percentile value, and Measurement Value 2 (E_A2) as the estimated arithmetic mean value (Ministry of Health Labor and Welfare, 2001b; Labor Standards Bureau, Ministry of Health Labor and Welfare, 2004).

When only A-measurement is conducted, the A-measurement data are compared directly with the AC level to determine the following categories of outcome: Control Class (CC) 1 [Dai-ichi Kanri Kubun] is defined as $E_A1 <$ AC level. This is interpretable as 95% of the measurement values falling short of the AC level and indicates that the WE is good and should be maintained. CC 3 [Dai-san Kanri Kubun] is defined as $E_A2 >$ AC level. This is interpretable as more than half of the measurement values exceeds the AC level (because of the arithmetic mean > median on the distribution curve) and indicates that the WE is inappropriate, and employers are required to take immediate necessary measures for improvement. CC 2 is the intermediate range corresponding to $E_A2 <$ AC level $< E_A1$. This indicates that the WE is neither good nor inappropriate and employers should make effort for improvement.

When B-measurement is conducted, the B-measurement data (C_B) are compared with the AC level or 1.5 times the AC level. Hence, if $C_B <$ AC level, then the workplace is CC 1 (see indication above). If $C_B > 1.5 \times$ AC level then CC 3 (see indication above). If AC level $< C_B < 1.5 \times$ AC level, then the workplace is CC 2 (see indication above). B-measurements should always be combined with A-measurements, and in doing so, the poorer AG level for either A- or B-measurement is prioritized. Other detailed conditions are also regulated for WE Measurement, e.g., the type of worksite mandated to implement these procedures, the particular substance to be measured, periodicity of measurement, length of keeping records, and specific methods to analyze samples (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002; Ministry of Health, Labor and Welfare, ISH Law).

The current List of AC levels (Table 1 shows the format of the List but data are excerpted for benzene only) shows values for 81 chemical substances (Ministry of Health Labor and Welfare, 2001b). To reiterate, AC levels are established and updated by an expert meeting assembled ad hoc when deemed necessary by the MHLW in consideration of accumulation of scientific knowledge. This expert

Table 1
Excerpt from the List of Administrative Control (AC) Levels (MHLW)

Name of type and substance	AC Level (25 °C, 1 atmospheric pressure)
Benzene	10 ppm (until March 31, 2005) 1 ppm (from April 1, 2005)

meeting is not exclusive of but often involves the relevant members of JSOH. As a general rule, the expert meeting will discuss both the recommended OELs by JSOH and the Threshold Limit Values (TLV) by the American Conference of Governmental Industrial Hygienists (ACGIH) to finally adopt its own value. Amendments to the List of AC Level (examples are given for benzene in Table 1 and silica in the text) will become effective as of April 1, 2005.

Because employers are required to maintain documented records of the WE measurement and evaluation where the legal designation applies, the MHLW has been able to monitor the distribution of CC (CC 1, 2, and 3) for a variety of designated substances on a nation-wide scale. On average, the proportion of CC 1 achieved has increased substantially among the workplaces, i.e., during the period 1995 ($N=102{,}679$ worksites)—2002 ($N=188{,}897$ worksites), the respective changes in proportion were an increase from 87.0 to 89.7% for CC 1, a decrease from 8.4 to 6.3% for CC 2, and a decrease from 4.6 to 4.0% for CC 3 (Karasawa, 2005).

2.2. Recommended OELs

The JSOH, through the aforementioned permanent subcommittee, recommends OELs "as reference values for preventing adverse health effects on workers caused by occupational exposures." The subcommittee meets periodically to choose substances requiring recommendation and, more importantly, discuss the scientific information on health and exposure regarding the substance. It will ultimately produce a proposal document (new or update) on the recommended OEL and classification of carcinogenicity for the substance in question. The JSOH carefully expresses 10 points of reservations regarding how the OELs should and should not be used. A noteworthy reservation regarding OELs can be found in clause 6, which states: "Because OELs do not represent a definitive borderline between safe and hazardous conditions, it is not correct to conclude that working environments above OEL are the direct and sole cause of health impairment in workers, or vice versa" (The Japan Society for Occupational Health, 2004).

Similar to ACGIH, the recommended OELs include chemical substances and physical agents, as well as biological exposure indices. Specifically, for chemical substances, exposure concentration is defined as "the concentration of a chemical substance in air which will be inhaled by a worker during a job without the use of protective respiratory equipment." Hence, in contrast to the AC Level, personal sampling is the presupposed method of measurement for making reference to the Recommended OELs. In addition, because OELs are set at conditions under which no skin absorption will take place, substances that may be absorbed through the skin at significant levels are designated by "S" marks in the tables listing specific OEL values.

OEL-Mean (OEL-M) is defined as "the reference value to the mean exposure concentration at or below which adverse health effects caused by the substance do not appear in most workers working for 8 h a day, 40 h a week under a moderate workload (The Japan Society for Occupational Health, 2004)." Exposure above OEL-M should be avoided even where duration is short or work intensity is high. The List of OEL-M values of 2004 (Table 2 shows the format of the List but data are excerpted for benzene only) includes 206 chemical substances.

For some substances, an OEL-Ceiling (OEL-C) [defined as "the reference value to the maximal exposure concentration of the substance during a working day at or below which adverse health effects do not appear in most workers"] is recommended mainly because the toxicity in question can induce immediate adverse effects such as irritation or suppressive effects on the central nervous system (The Japan Society for Occupational Health, 2004).

3. Examples

3.1. Benzene

For carcinogens, JSOH affirms that concentration levels corresponding to lifetime excessive risk should not be recommended as OELs but rather as Reference Values (RV)s. In the case of benzene, RVs were recommended after it was designated as Group 1 for carcinogenicity or human carcinogen (The Committee for Recommendation of Occupational Exposure Limits, 1997). Consequently, in the Table of OELs (Table 2), benzene is annotated for being included in the List of RV (Table 3) and is denoted with the "S" mark for possible absorption through the skin, and indicated as a carcinogen.

The rationale for establishing the RV for benzene adopted the basic logic used conventionally by JSOH and data derived from the literature, which can be summarized as follows: (1) risk was estimated from the findings of the cohort study by Pliofilm (The Committee for Recommendation of Occupational Exposure Limits, 1997; Rinsky et al., 1987); (2) exposure was estimated by Paustenback's method (The Committee for Recommendation of Occupational Exposure Limits, 1997; Paustenback et al., 1992); (3) extrapolation was made from the average relative risk

Table 2
Excerpt from OEL for chemical substances (JSOH)

Substance [CAS No.]	Chemical formula	OEL	Skin absorption	Class of carcinogenicity	Class of sensitizing potential		Year of proposal
		ppm			Airway	Skin	
Benzene [71-43-2]	C_6H_6	Separate table[a]	S	1			1997

[a] See Table 3.

Table 3
Reference Values (RV)s corresponding to an individual excess lifetime risk of cancer, excerpt (JSOH)

Substance	Individual excess lifetime risk of cancer	Reference value (ppm)	Method of estimation	Year of estimation
Benzene	10^{-3}	1	Average relative risk model	1997
	10^{-4}	0.1		

Separate table indicated in Table 2.

model by WHO (The Committee for Recommendation of Occupational Exposure Limits, 1997). Exposure to benzene at 1 ppm for 40 yrs was calculated to cause excessive mortality risk (EMR) of 0.762×10^{-3} (95%CI $0.621-0.98$ 7×10^{-3}) for leukemia. This is translatable to 1.31 (1.01–1.61) ppm for 10^{-3} EMR and 0.13 (0.10–0.16) ppm for 10^{-4} EMR. Considering 40 yrs of exposure, the RV was thus determined to be 1 ppm to suppress lifetime risk below 10^{-3} and 0.1 ppm to suppress lifetime risk below 10^{-4} (The Committee for Recommendation of Occupational Exposure Limits, 1997).

As exemplified by benzene, RVs have been calculated corresponding to EMR of cancer of 10^{-3} and 10^{-4}, although the precise logic and factors used to establish RV differ by substance, e.g., for asbestos the average exposure period was assumed for the those 16–65 yrs old of age (or 50 yrs of exposure) (The Committee for Recommendation of Occupational Exposure Limits, 2000).

3.2. Respirable Crystalline Silica

Respirable Crystalline Silica (RCS) is currently regulated by an AC Level expressed in the following formula: E (in mg/m^3) $= 2.9/(0.22Q + 1)$, where Q is the proportion of free silicate in percent. In the case of $Q = 100$, equivalent to 100% pure silica dust, the formula will produce a value of $E = 0.13\ mg/m^3$. The revised AC Level of silica will be expressed in the following formula (effective as of April 1, 2005): E (in mg/m^3) $= 3.0/(0.59Q + 1)$, where Q is the proportion of free silicate in percent. In the case of $Q = 100$, equivalent to 100% pure silica dust, the formula will produce a value of $E = 0.05\ mg/m^3$.

The former formula was originally adapted from the formula designated for respirable dust (dusts containing more than 10% free silica) as the Recommended OEL by JSOH. Hence up to March 31, 2005, the two OELs were expressed by exactly the same formula. Recently, JSOH upgraded RCS to Group 1 for carcinogenicity (or carcinogen) (The Committee for Recommendation of Occupational Exposure Limits, 2001; Takahashi, 2003). JSOH is currently discussing a revision of the Recommended OEL value.

4. Harmonization within Japan and with other countries

The AC Level is established by a National Expert Meeting (NEM) authorized by the MHLW and has legal binding power once it is issued. In one of its official documents, the MHLW explicitly states that the NEM, in the course of establishing the AC Level, shall take into due account the OELs recommended by JSOH as well as the OEL designated by ACGIH. On the other hand, JSOH, and the Committee for Recommendation of Occupational Exposure Limits in particular, aspires to conduct its own evaluation. During preparation for recommended OELs, committee members will seriously consider the OELs by ACGIH as one of the most reliable source of information [the recommended OEL-M is analogous to the TLV-TWA (and OEL-C to TLV-STEL) by ACGIH]. However, JSOH makes every effort to add its own perspective, particularly by taking into account recent and domestic publications.

Table 4 shows the OEL values (AC Level and Recommended OEL) adopted for selected organic solvents in Japan along with the TLV-TWA by ACGIH. The close values are indicative of the aforementioned efforts for achieving harmonization within the country as well as the international norm, in particular, that of ACGIH.

On the other hand, it has been acknowledged that there is lack of coherence between the system of AC Level, which is based on area sampling, and that of the Recommended OEL, which is based on personal sampling. The justification widely accepted is that the former method is effective to reduce the average level of exposure as a group of workers (conceptualized as "WE management") (Sakurai, 2003). Furthermore, as mentioned earlier, if CC 1 [Dai-ichi Kanri Kubun] is achieved, 95% of the measurement values will fall

Table 4
Comparison of OELs for selected organic solvents[a]

Substance	AC Level[b] [MHLW]	Recommended OEL (or RV when indicated) [JSOH]	TLV-TWA[c] [ACGIH]
Benzene	10 ppm (until March 31, 2005) 1 ppm (from April 1, 2005)	RV = 1 ppm (10^{-3} Lifetime Risk) RV = 0.1 ppm (10^{-4} Lifetime Risk)	0.5 ppm
Xylene	100 ppm (until March 31, 2005) 50 ppm (from April 1, 2005)	50 ppm	100 ppm
Toluene	50 ppm	50 ppm	50 ppm

[a] See text for acronyms.
[b] Date is shown for only the substances scheduled for amendment effective as of April 1, 2005. For other OELs, current values effective at the time of manuscript submission are shown.
[c] By American Conference of Governmental Industrial Hygienists, 2003.

short of the AC level, which would restrict exposure to the safer side. In contrast, the latter method is effective to reduce the level of exposure of the individual worker (Sakurai, 2003). Moreover, the two values influence each other in the course of discussion on their establishment and produce close values.

For occupational carcinogens, JSOH has long considered that "the classification of occupational carcinogens proposed by the International Agency for Research on Cancer (IARC) is appropriate" but "in principle." Therefore the current classification scheme for carcinogens adopted by JSOH closely resembles that of IARC. However, here again, the system is headed towards introducing more original reasoning and justification by JSOH. Aside from the OEL-M and OEL-C, JSOH will estimate a reference value corresponding to an individual excess lifetime risk of cancer due to exposure to a Group I carcinogen, but "only when scientifically reasonable information is available" (The Japan Society for Occupational Health, 2004).

5. Enforcement and communication (recognition) of OEL

In the ISH Law, an array of penalties is designated for violation of specific provisions therein. For example, if an employer fails to implement WE measurement when the worksite is actually required to implement such procedures (Article 65-1 of the ISH Law, same here after), the employer is subject to a fine or imprisonment (Article 119-1). However, the penalty is seldom executed in practice. Due to good awareness of the ISH Law in general, most employers abide by this provision. Of further importance is the provision on the result of the WE measurement, in particular, if CC 1 is not achieved. In this case, the ISH Law stipulates that employers must take necessary procedures including improvement of facilities and equipment and health examinations, etc (Article 65-2.1). However, there is no penalty for breach of this provision. Concerned parties acquire essential information via documents, e.g., law books (Department of Safety and Health, Ministry of Health, Labor and Welfare, 2002), guidebooks (Labor Standards Bureau, Ministry of Health Labor and Welfare, 2004), and official notices from the government. Increasingly, such information is accessed via websites of the MHLW and prefectural Labor Bureaus. Full provisional records of the related national committees are also web-accessible in most instances, which greatly enhances the transparency of the decision process.

Once every year JSOH publishes in its official journal *Sangyo Eiseigaku Zasshi* (in Japanese) newly recommended OELs and evaluation of carcinogenicity as proposals. Their summaries are published in its official English journal, Journal of Occupational Health. The full text of both journals is available on the Internet (http://joh.med.uoeh-u.ac.jp/). It should be noted that, after a proposal is made on any of these issues by JSOH, one year is allowed for concerned parties to raise opinions/objections before the proposal is finalized. JSOH will review the opinion, respond accordingly, and officialize the proposal in due course. In some instances industry will raise objections as to the feasibility of the proposed OEL, but such cases are rare.

6. Conclusion

To reiterate, the AC Level value controlled by the MHLW and the OEL value recommended by JSOH stem from contrastive premises, the former on area monitoring and the latter on individual monitoring. Although it has been acknowledged that the "dual premises" lack coherence, such criticism has not gained momentum. However, the reasoning is not straightforward and is prone to cause confusion among practitioners. As both values tend to converge over time, the obvious question is then, whether the dual premises can be justifiably maintained in the long run. It is only natural that the ultimate value of the system will depend on the extent to which the health of workers can be adequately protected from exposure to hazardous substances and conditions. For further improvement, the complementarity of the system should be scrutinized carefully and periodically, harmonization with international norms should be given weight, and more scientific (epidemiologic and experimental) evidence should be acquired from domestic studies.

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