line with a previous study[23] and confirmed by an additional result that no significant interaction term between year and income was found in the GEE analyses for cessation. As for relapse, when the tobacco price increased, it was only significantly associated with prevention of relapse in the lowest income subgroup (figure 2).

Further, we observed no effect modification of the price increase on either cessation or relapse by sex in this study (figures 1 and 2), which is in line with the results from a review paper that reported no clear evidence for differential effects by sex.[9] This is possibly because this study did not include the younger generation who are likely to stop smoking when specific events occur such as pregnancy or childcare.[27] As for number of cigarettes smoked per day, the price increase was not significantly associated with increased cessation in the subgroup of heavy smokers (31 or more cigarettes smoked per day), although the point estimate was positive. In all other subgroups of fewer cigarettes smoked per day, the price increase was significantly associated with cessation (figure 1).

Interestingly, differential impacts of the price increase on relapse were observed according to baseline characteristics such as recent quitter or long-term quitter, level of household income and self-rated health. Consistent with previous studies,[28] recent quitters were more likely to relapse than long-term quitters. However, we found that, when the price increased (figure 2), it was significantly associated with prevention of relapse among recent quitters; the same was not true for long-term quitters, although the relapse rate among recent quitters was high, even in 2009–2010 (15.0%). Similarly, quitters with very poor self-rated health had a significantly higher association with relapse than those with excellent health. When the price increased, it was only significantly associated with prevention of relapse in the very poor health subgroup, although point estimates of <1 AOR were observed in all other health subgroups. Taken together, our findings suggest the existence of several high-risk subgroups (eg, heavy smoker and short-term quitter) for tobacco control.

Policy implications

During the period 2009–2010, smoking prevalence decreased (from 27.2% to 24.5%) at the same time as the 2010 tobacco price increase. However, in 2011, there was a slight increase to 25.1%. The notion of 'hardening' among smokers must also be taken into consideration. After some smokers who were less dependent and found it easier to quit have done so, the remaining smokers may become less likely to quit over time, that is, hardening.[20] However, since the trend of the period was not significant for either cessation or relapse in both weighted and unweighted analyses, no evidence of a hardening in smokers was obtained. The entire distribution of smoking volume shifted down over time (table 1). This might be a key step in moving towards cessation. Although this study did not investigate long-term cessation, it is important to determine whether smokers successfully quit in the long term or not. Further studies to investigate long-term changes including cessation or reduction in the number of cigarettes smoked per day will be required in the future.

In recent years, the price of tobacco in Japan has been considered very low according to the affordability index.[29] Cigarettes were more affordable in Japan than in any other developed countries surveyed in 2009; the price of a pack of 20 cigarettes could be earned in 11.5 min compared with 30 min in many other countries.[29] After the 2010 price increase, this figure rose slightly (to around 16 min) but remained low compared with other countries.

Our current findings suggest that we need to consider the stages of tobacco control policy in Japan. The early stages of public health interventions, such as health information campaigns, often cause health equity problems.[30] The *inverse equity hypothesis*[31] avers that such interventions disproportionately benefit the wealthy, so there is an initial increase in inequality (early stage). Deprived sections of society catch up after the affluent have gained maximum benefit (late stage). Although the tobacco price increased in 2010 in Japan, the low price may mean that the 'early stage' of the tobacco price intervention will continue. Further price increases may thus be necessary to alleviate health inequalities.

In the Japanese health promotion strategy, Health Japan 21 (Second version), government ask for reduction of both smoking prevalence and health in equality (including smoking inequality).[32] This study identified high-risk populations for tobacco control, that is, groups that are less sensitive to tobacco price increase, although they may respond to further higher tobacco price increases. Since some subgroups are less likely to quit smoking or continue to not smoke, even if the tobacco price is increased by up to 37%, and furthermore respond slowly to price increases, additional tobacco control measures targeting the high-risk subgroups may be required.

Limitations

There are several limitations to the study. First, the smoking variables were self-reported without biomarker validation; however, the quality of the self-reporting was generally high.[33 34] Second, unmeasured factors such as tax avoidance and product substitution based on a wide price range may have biased the estimated effect.[1 35] However, tax avoidance is likely to be low in this setting; Japan's island nation status makes it difficult to avoid tax across national borders. Although low-price tobacco products (eg, the cheap Echo brand) gained market share in Japan after 2010, according to the tobacco industry's reports,[36] the increase was small (0.5% from 2010 to 2011). Therefore, the impact of product substitution may be trivial. Third, we considered the income of the respondents and their spouses, if available, since the income of other family members could not be obtained from the survey. It should be noted that household income, as defined in this study, probably underestimated household income.[15]

What this paper adds

What is already known on this topic?

- The impact of tobacco price increases on smoking behaviour in different social groups has been investigated; mixed results have been reported for differences in gender, occupation and education subgroups.
- Since few previous studies focused on the impact of price on relapse, longitudinal studies that have examined the effect of tobacco price on both cessation and relapse are scarce.

What this study adds?

- Of all the factors surveyed, only the tobacco price increase in 2010 was significantly associated with cessation (100% increase) and relapse (40% decrease).
- The tobacco price rise was associated with favourable smoking changes in nearly all population subgroups.

CONCLUSION

Since recent quitters are likely to relapse,[6 28] it is important to enhance both promotion of cessation and prevention of relapse. We confirmed that tobacco price rises were significantly associated with increasing cessation among smokers and decreasing relapse among quitters concurrently.[1] Furthermore, this price rise was associated with favourable smoking changes in nearly all population subgroups; a large differential impact was not observed across the various subgroups.

Acknowledgements The authors thank Dr J Mortimer for her English language editing.

Contributors TT conceptualised and designed the study, drafted the initial manuscript and revised it, and approved the final manuscript as submitted. TF and TS supervised the data analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted.

Funding This work was supported by the Ministry of Health, Labour and Welfare (grant; Comprehensive Research on Life-Style Related Diseases including Cardiovascular Diseases and Diabetes Mellitus (H25–010)) and the Ministry of Education, Culture, Sports, Science, and Technology (grant-in-aid for Young Scientists B: number 15K19256).

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The Ministry of Health, Labour and Welfare, Japan, does not make all the raw data publicly available. However, data are available on request under the 33th article of the Japanese Statistical Law, at Examination Analysis Office, Planning Division, the Statistics and Information Department, Minister's Secretariat, the Ministry of Health, Labour and Welfare, Japan.

REFERENCES

1 International Agency for Research on Cancer. *IARC handbooks of cancer prevention tobacco control volume 14: effectiveness of tax and price policies for tobacco control*. Lyon, France: WHO Press, 2011.
2 Eriksen M, Mackay J, Schluger N, *et al*. *The Tobacco Atlas, fifth edition: revised, expanded, and updated*. Atlanta, USA: American Cancer Society, 2015.
3 International Agency for Research on Cancer. *IARC handbooks of cancer prevention tobacco control volume 13: evaluating the effectiveness of smoke-free policies*. Lyon, France: WHO Press, 2009.
4 Ross H, Blecher E, Yan L, *et al*. Do cigarette prices motivate smokers to quit? New evidence from the ITC survey. *Addiction* 2011;106:609–19.
5 Dunlop SM, Perez D, Cotter T. Australian smokers' and recent quitters' responses to the increasing price of cigarettes in the context of a tobacco tax increase. *Addiction* 2011;106:1687–95.
6 Wakefield MA, Bowe SJ, Durkin SJ, *et al*. Does tobacco-control mass media campaign exposure prevent relapse among recent quitters? *Nicotine Tob Res* 2013;15:385–92.
7 Tauras JA. Public policy and smoking cessation among young adults in the United States. *Health Policy* 2004;68:321–32.
8 Amos A, Greaves L, Nichter M, *et al*. Women and tobacco: a call for including gender in tobacco control research, policy and practice. *Tob Control* 2012;21:236–43.
9 Thomas S, Fayter D, Misso K, *et al*. Population tobacco control interventions and their effects on social inequalities in smoking: systematic review. *Tob Control* 2008;17:230–7.
10 Hill S, Amos A, Clifford D, *et al*. Impact of tobacco control interventions on socioeconomic inequalities in smoking: review of the evidence. *Tob Control* 2014;23(e2):e89–97.
11 Ito Y, Nakamura M. The effect of increasing tobacco tax on tobacco sales in Japan. *Jpn J Public health* 2013;60:613–18. (in Japanese).
12 Ministry of Health, Labour and Welfare. *Comprehensive survey of living condition of people on health and welfare*. Tokyo, 2014. http://www.mhlw.go.jp/toukei/list/20-21.html (accessed 1 Nov 2015) (in Japanese)
13 Ministry of Health, Labour and Welfare. *Longitudinal survey of middle-aged and elderly persons*. Tokyo, 2014. http://www.mhlw.go.jp/toukei/list/29-6.html (accessed 1 Nov 2015) (in Japanese)
14 Oshio T. The association between involvement in family caregiving and mental health among middle-aged adults in Japan. *Soc Sci Med* 2014;115:121–9.
15 Kachi Y, Otsuka T, Kawada T. Precarious employment and the risk of serious psychological distress: a population-based cohort study in Japan. *Scand J Work Environ Health* 2014;40:465–72.
16 Organization for Economic Cooperation and Development (OECD). *Growing unequal? Income distribution and poverty in OECD countries*. Paris: OECD, 2008.
17 Nishi N, Nakade M, Sarukura N, *et al*. Response rate and the related factors of National Health and Nutritional Survey. *Kosei no Shihyo* 2012;59:10–15. (in Japanese).
18 Little RJ, D'Agostino R, Cohen ML, *et al*. The prevention and treatment of missing data in clinical trials. *N Engl J Med* 2012;367:1355–60.
19 Hanley JA, Negassa A, Edwardes MD, *et al*. Statistical analysis of correlated data using generalized estimating equations: an orientation. *Am J Epidemiol* 2003;157:364–75.
20 Docherty G, McNeill A, Gartner C, *et al*. Did hardening occur among smokers in England from 2000 to 2010? *Addiction* 2014;109:147–54.
21 Katanoda K, Jiang Y, Park S, *et al*. Tobacco control challenges in East Asia: proposals for change in the world's largest epidemic region. *Tob Control* 2014;23:359–68.
22 Abadie A, Diamond A, Hainmueller J. Synthetic control methods for comparative case studies: estimating the effect of California's tobacco control program. *J Am Stat Assoc* 2010;105:493–505.
23 Tabuchi T, Nakamura M, Nakayama T, *et al*. Tobacco price increase and smoking cessation in Japan, a developed country with affordable tobacco: a national population-based observational study. *J Epidemiol* 2016;26:14–21.
24 Pfizer Japan Inc. *Internet survey for Japanese smokers before tobacco tax increase in 2010*. Japan: Pfizer Japan Inc, 2010.
25 Nakamura M, Oshima A, Ohkura M, *et al*. Predictors of lapse and relapse to smoking in successful quitters in a varenicline post hoc analysis in Japanese smokers. *Clin Ther* 2014;36:918–27.
26 Kanda H, Osaki Y, Ohida T, *et al*. Age verification cards fail to fully prevent minors from accessing tobacco products. *Tob Control* 2011;20:163–5.
27 Tabuchi T, Fujiwara T. Are secondhand smoke-related diseases of children associated with parental smoking cessation? Determinants of parental smoking cessation in a population-based cohort study. *Prev Med* 2015;73:81–7.
28 Hughes JR, Keely J, Naud S. Shape of the relapse curve and long-term abstinence among untreated smokers. *Addiction* 2004;99:29–38.
29 Eriksen M, Mackay J, Ross H. *The tobacco Atlas*. 4th edn. Atlanta, USA: American Cancer Society, 2012.
30 Frohlich KL, Potvin L. Transcending the known in public health practice: the inequality paradox: the population approach and vulnerable populations. *Am J Public Health* 2008;98:216–21.
31 Victora CG, Vaughan JP, Barros FC, *et al*. Explaining trends in inequities: evidence from Brazilian child health studies. *Lancet* 2000;356:1093–8.
32 Ministry of Health, Labour and Welfare. Health Japan 21 (Second). 2012. http://www.mhlw.go.jp/bunya/kenkou/kenkounippon21.html (accessed 1 Nov 2015) (in Japanese)
33 Ministry of Health, Labour and Welfare. *National Health and Nutritional Survey 2003*. Tokyo, 2005. http://www.mhlw.go.jp/bunya/kenkou/eiyou-chosa2-01/index.html (accessed 1 Nov 2015) (in Japanese)
34 Caraballo RS, Giovino GA, Pechacek TF, *et al*. Factors associated with discrepancies between self-reports on cigarette smoking and measured serum cotinine levels among persons aged 17 years or older: third National Health and Nutrition Examination Survey, 1988–1994. *Am J Epidemiol* 2001;153:807–14.
35 Wilson LM, Avila Tang E, Chander G, *et al*. Impact of tobacco control interventions on smoking initiation, cessation, and prevalence: a systematic review. *J Environ Public Health* 2012;2012:961724.
36 Tobacco Institute of Japan. *Cigarette statistics in Japan*. Tokyo, 2013. http://www.tioj.or.jp/data/index.html (accessed 1 Nov 2015) (in Japanese)

ADDICTION
SSA SOCIETY FOR THE STUDY OF ADDICTION
RESEARCH REPORT
doi:10.1111/add.13231

Awareness and use of electronic cigarettes and heat-not-burn tobacco products in Japan

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ABSTRACT

Background and Aims In addition to some electronic cigarettes (e-cigarettes), new heat-not-burn tobacco products Ploom and iQOS have recently begun to be sold by tobacco companies. These products are regulated differently in Japan, depending on whether the contents are liquid or tobacco leaf. Our objective was to estimate percentages of awareness and use of e-cigarettes and heat-not-burn tobacco products among the Japanese population, including minors. **Design and Setting** An internet survey (randomly sampled research agency panellists) with a propensity score adjustment for "being a respondent in an internet survey" using a nationally representative sample in Japan. **Participants** A total of 8240 respondents aged 15–69 years in 2015 (4084 men and 4156 women). **Measurements** Adjusted percentages of awareness and use of e-cigarettes (nicotine or non-nicotine e-cigarettes) and heat-not-burn products among total participants; product types and percentages ever used among e-cigarettes ever users. **Findings** Of respondents in Japan, 48% [95% confidence interval (CI) = 47–49] were aware of e-cigarettes and heat-not-burn tobacco products, 6.6% (95% CI = 6.1–7.1) had ever used, 1.3% (95% CI = 1.0–1.5) had used in the last 30 days and 1.3% (95% CI = 1.1–1.6) had experience of > 50 sessions. Seventy-two per cent (95% CI = 69–76) of ever users used non-nicotine e-cigarettes, while 33% (95% CI = 30–37) of them used nicotine e-cigarettes, which has the majority share world-wide; 7.8% (95% CI = 5.5–10.0) and 8.4% (95% CI = 6.1–10.7) of them used the new devices, Ploom and iQOS, respectively, with a relatively higher percentage among the younger population. **Conclusions** Approximately half the respondents in a Japanese internet survey were aware of e-cigarettes and heat-not-burn tobacco products, 6.6% had ever used. More than 70% of ever users used non-nicotine e-cigarettes, the sale of which is not legally prohibited, even to minors, in Japan, and 33% of them used nicotine e-cigarettes; 3.5% of never smoking men and 1.3% of never smoking women had ever used e-cigarettes. Corresponding figures for use in the last 30 days were 0.6% and 0.3%, predominantly non-nicotine e-cigarettes.

Keywords Awareness, electronic cigarettes, heat-not-burn tobacco products, iQOS Japan, Ploom, use.

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Submitted 7 May 2015; initial review completed 29 July 2015; final version accepted 10 November 2015

INTRODUCTION

Electronic cigarettes (e-cigarettes) are battery-operated devices that contain an inhalation-activated mechanism that heats a cartridge, producing vapour [1–4]. Since their first introduction to the market in 2004, a rapid growth has been seen in the global market and some organizations have expressed concern over their effects on health [2,4,5]. Some experts have suggested that these products could help smokers to move from combustible to non-combustible and less harmful sources of nicotine: nicotine e-cigarettes may help smokers to stop smoking compared with non-nicotine e-cigarettes, although this finding was based on a small number of studies [6].

Recently, transnational tobacco companies, such as Japan Tobacco (JT) and Philip Morris (PM), have entered the e-cigarettes market and are competing aggressively with the independent companies to gain market share [4,5]. In December 2013 JT started to sell a new heat-not-burn tobacco product, Ploom, that vaporizes tobacco leaf, and additionally acquired a leading UK e-cigarette company, Zandera Ltd, which owns the E-Lites brand [4]. PM developed a new heat-not-burn tobacco product, iQOS, that heats tobacco, and have been selling this product in

Japan since November 2014, sooner than other countries. Thus, recently, multiple types of these products have become available in the Japanese market-place, including nicotine e-cigarettes, non-nicotine e-cigarettes, Ploom and iQOS. These products are regulated differently in Japan, depending on the contents of liquid or tobacco leaf. The sale of nicotine e-cigarettes as a pharmaceutical product has been banned by the Pharmaceutical Affairs Act since 2010, because nicotine e-cigarettes deliver nicotine which is subject to control. However, non-nicotine e-cigarettes are available to the public, even to minors, because there is no regulation for non-nicotine e-cigarettes in Japan. Conversely, Ploom and iQOS are sold as tobacco products and regulated by the Tobacco Industries Act, an old but active law to promote the development of tobacco industries in Japan, because some components of these products are made by tobacco leaf. It is unclear what this regulatory situation means for the e-cigarettes market. However, the tobacco companies may intend to promote these products to young, non-tobacco users to create a new form of tobacco consumption in the face of declining cigarette use [7].

Although the World Health Organization (WHO) has recommended that governments conduct surveillance to assess e-cigarette use [5], there has been no surveillance in Japan. Furthermore, WHO also suggested that retailers should be prohibited from selling e-cigarette products to minors [5], but the sale of non-nicotine e-cigarettes is not prohibited legally, even to minors, in Japan. Therefore, our objective for this study was to estimate percentages of awareness and use of e-cigarettes and heat-not-burn tobacco products among the Japanese population (aged 15–69 years). Furthermore, we report on product types and the percentages ever used among ever users.

METHODS

Internet survey

The internet was estimated to be accessible to 82.8% of the Japanese population in 2013 [8]. This large proportion enables researchers to use the internet to engage numerous survey participants from a wider population range, in a shorter period of time, at lower cost, than conventional surveys such as in-person interviews and mail-outs.

The survey was conducted between 31 January and 17 February 2015 among the first 9000 respondents (actually 9055, including concurrent excess 55); i.e. 500 people aged 15–19 years and 800 people aged 20–29, 30–39, 40–49, 50–59 and 60–69 years for both sexes. They were invited to participate in the survey from a large survey panel managed by a major nation-wide internet research agency, Rakuten Research [9]. The overall size of the survey panel at the time of the survey was 2 278 733 people, of whom 53.9% were male. The panel members were skewed, but covered all social categories (such as education, housing tenure and marital status) defined by the Census in Japan. The age distribution of the survey panel was 1.2% for 10–19, 13.1% for 20–29, 34.0% for 30–39, 30.8% for 40–49, 14.5% for 50–59 and 5.0% for 60–69 years [9]. The survey panel consisted of people recruited initially through services managed by the research agency group. At the time of registration, they were required to provide information such as sex, age, occupation and residence, and to agree that they would participate in different research surveys.

In this survey, the panellists were asked about their awareness and use of e-cigarettes and heat-not-burn tobacco products with some demographic, socio-economic and health-related factors. The survey requests were sent by the research agency to the panellists, who were selected by each sex and age category using simple random sampling. The panellists who consented to participate in the survey accessed the designated website and responded to the survey. The panellists had the option to not respond to any part of the questionnaire and the option to discontinue the survey at any point. The survey was closed when the target numbers of respondents for each sex and age category were met. The participation rate [10] for the survey was 8.5% (9055 of 106 202).

Measures

Awareness and use of e-cigarettes and heat-not-burn tobacco products

Respondents who answered 'yes' to the question: 'Are you aware of e-cigarettes?' were considered to be aware of e-cigarettes and heat-not-burn tobacco products. Panellists were asked about their use of each of the following products: nicotine e-cigarettes, non-nicotine e-cigarettes, e-cigarettes with unknown nicotine content, Ploom and iQOS, using the question: 'Please choose your current status for each product', and the response options were 'never user', 'former non-regular user', 'former regular user' and 'current user'. The latter three responses were combined and defined as 'ever user' of each product. Respondents who reported ever use (at least once) of at least one type of product (of the above-mentioned five products) were considered ever users of these products. Regarding recent use and amount of usage according to previous studies reporting prevalence of e-cigarette use [11,12], in the present study we reported products used in the last 30 days and more than 50 sessions of ever use. Those who reported a number greater than zero (i.e. one to 30) for the question: 'During the past 30 days, on how many days have you used e-cigarettes?' were defined as products used in the last 30 days [11]. Ever users were asked: 'Approximately 15 puffs during10 minutes is defined as *one session*. How many

e-cigarette *sessions* have you had in your life?'. Those who answered 'more than 50 sessions' were defined as more than 50 sessions of ever use [11]. Before these questions, we added an explanatory note that e-cigarettes include nicotine or non-nicotine e-cigarettes, Ploom and iQOS.

Combustible tobacco (smoking status)

Panellists were also asked: 'Please choose your current status for paper-wrapped and roll-your-own cigarette separately', and the response options were 'never user', 'former non-regular user', 'former regular user' and 'current user'. Respondents who currently smoked combustible tobacco (paper-wrapped and/or roll-your-own cigarette) were considered current smokers. Those who reported former use and did not currently smoke either type of cigarette were considered former smokers. Those who had never smoked were considered never smokers.

Other variables

Area blocks (residence) defined by the National Population Mobility Survey conducted by the Japanese Ministry of Health, Labour and Welfare, marital status (married, never married, widowed and divorced), education [less than high-school, high school, technical or junior college, university (4 years) and graduate college], housing tenure (home-owner or not), occupation (regular employee, self-employed, executive officer, part-time/contract employee, full-time homemaker, retired, student and unemployed) and self-rated health (excellent, very good, good, fair, poor) were collected from the internet survey as well as a nationally representative survey (explained below).

Management of data discrepancies

Questions about the number of total household members were used to detect respondents with discrepancies. Respondents were asked for the total number of household members and each number of household members in each age group separately. Thus, we could identify any discrepancies in their responses ($n = 644$) to assess the data quality. In addition to discrepancies, artificial unnatural responses were found in some cases ($n = 274$); i.e. respondents who all chose the same option in some questions that had more than 10 items. Thus, we excluded respondents with discrepancies or artificial unnatural responses ($n = 815$) from our analyses.

Statistical analyses

Although internet surveys have several advantages compared to traditional surveys, their greatest potential drawback is that they may not be representative of the population of interest because the subpopulation with access to the internet may be specific. Previous studies have suggested that the adjusted estimates using inverse probability weighting (IPW) obtained from a propensity score (calculated by logistic regression models using basic demographic and socio-economic factors such as education and housing tenure) from an internet-based convenience sample provide similar estimates of parameters, or at least reduced the differences compared to probability sample-based estimates [13–15]. Therefore, IPW-adjusted estimates rather than simple internet survey estimates are presented as the main results in this study. To correct for the selectivity of internet-based samples, we used a probability sample that is representative of the Japanese population from the Comprehensive Survey of Living Conditions of People on Health and Welfare (CSLCPHW) [16]. Data from two surveys (internet survey and CSLCPHW) were pooled (combined) and used for a logistic regression model with all the above-mentioned covariates to estimate the probability of 'being a respondent in an internet survey', i.e. propensity score. Because internet surveys set an a priori sample size according to sex and age group stratification (sex × age groups = 12 strata), we calculated the propensity score separately for each stratum. Data from the 2010 CSLCPHW were used as this survey reported smoking status in minors which was not available in 2013. Detailed methods (e.g. participation rate and data management) are available in the Supporting information.

We presented unweighted and weighted percentages of awareness and use of e-cigarettes and heat-not-burn tobacco products among all the respondents according to sex, age group and smoking status. Furthermore, we showed percentages ever used of the above-mentioned five types of products among ever users, because in Japan these products have different legal regulation conditions. Adjusted percentages were shown with 95% confidence intervals (CIs) that were calculated by Wald and exact methods.

The study was reviewed and approved by the Research Ethics Committee of the Osaka Medical Center for Cancer and Cardiovascular Diseases. All statistical analyses were performed using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA).

RESULTS

After excluding respondents with a discrepancy, 8240 subjects remained. The characteristics of the study subjects before and after adjusting for 'being a respondent in an internet survey' are shown in the Supporting information, Table S1.

Table 1 shows the percentage (%) of awareness and use of e-cigarettes according to sex, age group and smoking status in Japan after weighting (see Supporting information, Table S2 for 'before weighting'). The distribution of smoking status according to sex and age group is also shown. After weighting, percentages of current smokers

Table 1 Adjusted percentages of e-cigarettes and heat-not-burn tobacco products used according to sex, age groups and smoking status (combustible tobacco) in Japan.

			Combustible tobacco,[a] current smoker (%)			*E-cigarettes and heat-not-burn tobacco products,[b] % (95% CI)*			
	n	*%*	*Unadjusted*	*Adjusted*	*Population-based survey[c]*	*Awareness*	*Ever use*	*Use in the last 30 days*	*Use of >50 sessions*
Both sexes	8240	100	13.4	20.5		48.0 (46.9, 49.1)	6.60 (6.06, 7.13)	1.29 (1.04, 1.53)	1.33 (1.08, 1.58)
Men									
Total	4084	49.6	18.9	31.5		53.2 (51.6, 54.7)	9.17 (8.29, 10.1)	1.70 (1.30, 2.09)	2.04 (1.61, 2.48)
Age groups (years)									
15–19	443	10.8	3.6	3.6	3.8	55.9 (51.2, 60.5)	5.75 (3.58, 7.91)	2.59 (1.11, 4.07)	1.14 (0.15, 2.12)
20–29	720	17.6	13.8	29.4	36.5	52.3 (48.6, 55.9)	12.5 (10.1, 14.9)	3.81 (2.41, 5.20)	1.69 (0.75, 2.64)
30–39	728	17.8	20.6	40.6	43.4	56.3 (52.7, 59.9)	12.7 (10.3, 15.1)	1.87 (0.88, 2.85)	3.13 (1.86, 4.39)
40–49	740	18.1	25.4	38.5	40.9	49.8 (46.2, 53.4)	11.3 (9.00, 13.6)	1.49 (0.62, 2.36)	3.40 (2.10, 4.71)
50–59	722	17.7	25.6	36.4	39.4	52.5 (48.8, 56.1)	5.32 (3.69, 6.96)	0.35 (0.00, 0.77)	0.87 (0.20, 1.55)
60–69	731	17.9	18.3	29.4	31.2	53.4 (49.8, 57.0)	6.12 (4.38, 7.85)	0.46 (0.00, 0.95)	1.64 (0.72, 2.56)
Smoking status									
Never smokers	2157	52.8				44.2 (41.9, 46.5)	3.51 (2.66, 4.36)	0.60 (0.24, 0.95)	0.10 (0.00, 0.25)
Former smokers	1155	28.3				52.7 (49.6, 55.8)	7.70 (6.04, 9.35)	1.75 (0.93, 2.56)	1.53 (0.77, 2.29)
Current smokers	772	18.9				66.2 (63.6, 68.7)	18.3 (16.1, 20.4)	3.20 (2.24, 4.16)	5.17 (3.96, 6.38)
Women									
Total	4156	50.4	8.0	9.7		42.9 (41.4, 44.4)	4.07 (3.47, 4.67)	0.88 (0.60, 1.17)	0.63 (0.39, 0.87)
Age groups (years)									
15–19	438	10.5	1.8	1.5	1.4	48.0 (43.3, 52.7)	3.09 (1.47, 4.71)	0.67 (0.00, 1.43)	0.00 (0.00, 0.84)
20–29	742	17.9	6.6	10.9	13.0	48.1 (44.5, 51.7)	7.10 (5.25, 8.95)	2.19 (1.13, 3.24)	0.97 (0.27, 1.68)
30–39	737	17.7	8.5	13.6	15.6	39.6 (36.1, 43.1)	4.37 (2.89, 5.84)	1.17 (0.39, 1.95)	0.49 (0.00, 0.99)
40–49	747	18.0	11.0	13.1	15.4	43.3 (39.8, 46.9)	3.63 (2.29, 4.98)	0.44 (0.00, 0.92)	0.50 (0.00, 1.01)
50–59	739	17.8	11.6	8.8	13.7	40.9 (37.3, 44.4)	2.92 (1.70, 4.13)	0.28 (0.00, 0.67)	0.57 (0.03, 1.11)
60–69	753	18.1	6.1	7.2	8.3	39.5 (36.1, 43.0)	2.93 (1.72, 4.13)	0.47 (0.00, 0.96)	0.96 (0.27, 1.66)
Smoking status									
Never smokers	3232	77.8				37.0 (35.3, 38.7)	1.25 (0.86, 1.64)	0.27 (0.09, 0.45)	0.10 (0.00, 0.21)
Former smokers	590	14.2				56.4 (52.5, 60.4)	8.94 (6.68, 11.2)	1.68 (0.66, 2.69)	0.92 (0.17, 1.68)
Current smokers	334	8.0				68.1 (63.5, 72.6)	18.5 (14.8, 22.3)	4.44 (2.44, 6.45)	4.24 (2.27, 6.20)

[a]Combustible tobacco include paper-wrapped and roll-your-own cigarette; [b]e-cigarettes and heat-not-burn tobacco products include nicotine e-cigarettes, non-nicotine e-cigarettes, e-cigarettes with unknown nicotine, Ploom and iQOS; [c]percentages of current smokers by age groups from a population-based survey, i.e. the CSLCPHW: in both sexes, figures for 15–19 years were from 2010 CSLCPHW and those for other years were from 2013 CSLCPHW. E-cigarettes = electronic cigarettes; CI = confidence interval; CSLCPHW = Comprehensive Survey of Living Conditions of People on Health and Welfare.

by age group became considerably closer to those of a population-based survey (CSLCPHW). Hereafter, we focused on the estimates after weighting in the study.

A total of 48.0% [95% confidence interval (CI) = 46.9–49.1] of respondents (both sexes) were aware of e-cigarettes and heat-not-burn tobacco products (53% for men and 43% for women). Although no large difference in awareness can be seen across age groups, current smokers (66–68%) were more aware of these products than never smokers (37–44%); 6.60% (95% CI = 6.06–7.13) of respondents (both sexes) had ever used these products (9.2% for men and 4.1% for women). With regard to age group, ever use of these products was relatively high among men aged 20–49 years (11.3–12.7%) and women aged 20–29 years (7.1%). While ever use among never smokers was 3.5% for men and 1.3% for women, ever use among current and former smokers was 18.3% and 7.7% for men and 18.5% and 8.9% for women, respectively; 1.29% (95% CI = 1.04–1.53) of respondents (both sexes) had used these products in the last 30 days (1.7% for men and 0.9% for women). The younger population had a relatively higher rate of use in the last 30 days, although the rate among female teenagers decreased to 0.7% after weighting. Use in the last 30 days among current smokers was 3.2% for men and 4.4% for women. Of the respondents (both sexes), 1.33% (95% CI = 1.08–1.58) had had > 50 sessions of ever use (2.0% for men and 0.6% for women). A relatively higher proportion of > 50 sessions ever use was observed among men aged 30–49 years (3.1% for those in their 30s and 3.4% for those in their 40s) and current smokers (5.2% for men and 4.2% for women). Regarding smoking status-stratified results, there is no difference between men and women.

The product types and the percentages ever used of e-cigarettes and heat-not-burn tobacco products among ever users are shown in Table 2. A total of 72.3% (95% CI = 68.6–76.1) of ever users used non-nicotine e-cigarettes in both sexes; 33.4% (95% CI = 29.5–37.4) used nicotine e-cigarettes (except for Ploom and iQOS) in total. Of these, 14.5% (95% CI = 11.5–17.4) used e-cigarettes with unknown nicotine content, while 7.8% (95% CI = 5.5–10.0) and 8.4% (95% CI = 6.1–10.7) used Ploom and iQOS, respectively. The sum of these percentages in the table rows exceeds 100% because of the use of multiple products. More than 30% of ever use of multiple products was observed in some categories, such as those respondents in the 20s age group and former smokers of both sexes (data not shown). In line with this, more than 10% of the younger population and former smokers used Ploom and iQOS, although the percentage of total subjects was not large (less than 2%; Supporting information, Table S2).

DISCUSSION

This is the first study, to our knowledge, to estimate awareness and use of e-cigarettes and heat-not-burn tobacco products in Japan. Among Japanese men and women aged 15–69 years, approximately half (48%) were aware of e-cigarettes and heat-not-burn tobacco products, 6.6% had ever used, 1.3% used in the last 30 days and 1.3% had more than 50 sessions of ever use. More than 70% of ever users used non-nicotine e-cigarettes, which are not regulated legally in Japan, while 33% used nicotine e-cigarettes, which are prohibited by pharmaceutical law in Japan but have a majority share world-wide [3,17]; 7.8% and 8.4% used the new devices, Ploom and iQOS, respectively. These devices have been developed recently by tobacco companies and are sold as tobacco products. This result may show the importance of the regulatory situation in Japan. Appropriate regulation for e-cigarettes and heat-not-burn tobacco products should vary by country, because there are large differences in both underlining tobacco control efforts and tobacco consumption across countries [5,18]. The feasibility at country level of these products' regulation will depend upon complex country-specific factors, including the existing regulatory frameworks. Because the Japanese government has prohibited nicotine e-cigarettes since 2010, these products might be relatively unused in Japan. The percentages trying products might reflect the differential regulations across the product categories.

Our estimated figures in the main results were obtained by adjusting the bias of 'being a respondent in an internet survey' using IPW methods [13–15]. After weighting, percentages of current smokers by age group became considerably closer to those of a population-based survey (CSLCPHW). This is natural, because adjustment procedures do what they are designed for: i.e. they achieve balance for the set of covariates used in constructing the weights. However, because combustible cigarette smoking has been associated strongly with use of e-cigarettes in various previous studies [1,3,12], this adjustment for smoking status was important to estimate use of e-cigarettes. According to this adjustment and previous knowledge of this method [13], we believe that IPW-based weighted estimates would be closer to those of the general population than unweighted estimates.

To the best of our knowledge, independent evidence on the use of e-cigarettes among the general population (including never smokers) was scarce. Awareness of e-cigarettes in Japan (48% in 2015, although the current study includes heat-not-burn tobacco products) was lower than that in the past in the United States (58% in 2011 [19], 78% in 2013 [12] and 90% in 2014 [4]) and higher than that in Indonesia (10.9% in 2011 [20]). Current smokers (66–68%) were more aware of e-cigarettes than never smokers (37–44%) in Japan, and similar results were

Table 2 Product types and the percentage ever used (%) (i.e. total ever users = 100%) of e-cigarettes and heat-not-burn tobacco products according to sex, age groups and smoking status in Japan (weighted results).

		Product types and the percentage ever used (95% CI) of e-cigarettes and heat-not-burn tobacco products				
	n	*Nicotine e-cigarettes*[a]	*Non-nicotine e-cigarettes*[b]	*E-cigarettes with unknown nicotine*	*Ploom (JT)*[c]	*iQOS (PM)*[c]
Both sexes	544	33.4 (29.5, 37.4)	72.3 (68.6, 76.1)	14.5 (11.5, 17.4)	7.8 (5.5, 10.0)	8.4 (6.1, 10.7)
Men						
Total	375	32.9 (28.1, 37.6)	71.7 (67.1, 76.2)	15.7 (12.0, 19.3)	7.9 (5.1, 10.6)	8.2 (5.4, 11.0)
Age groups (years)						
15–19	25	25.7 (8.8, 42.7)	89.7 (77.9, 100.0)	4.3 (0.0, 12.1)	18.0 (3.1, 33.0)	19.8 (4.3, 35.3)
20–29	90	38.9 (28.8, 49.0)	75.9 (67.1, 84.8)	6.1 (1.2, 11.1)	13.7 (6.6, 20.8)	11.8 (5.1, 18.5)
30–39	92	36.8 (27.0, 46.7)	64.0 (54.3, 73.8)	24.1 (15.4, 32.8)	12.6 (5.9, 19.4)	14.5 (7.3, 21.7)
40–49	83	27.8 (18.2, 37.4)	67.5 (57.5, 77.5)	17.8 (9.6, 26.0)	0.2 (0.0, 1.2)	0.0 (0.0, 4.4)
50–59	38	43.2 (27.6, 58.9)	65.4 (50.3, 80.4)	24.6 (11.0, 38.3)	1.8 (0.0, 6.0)	3.1 (0.0, 8.5)
60–69	45	17.1 (6.1, 28.2)	81.7 (70.4, 93.1)	12.1 (2.5, 21.7)	0.0 (0.0, 7.9)	0.8 (0.0, 3.3)
Smoking status						
Never smokers	63	23.4 (12.9, 33.8)	78.5 (68.4, 88.6)	14.5 (5.8, 23.1)	4.2 (0.0, 9.1)	3.6 (0.0, 8.2)
Former smokers	77	40.0 (29.0, 51.0)	72.5 (62.5, 82.5)	18.9 (10.1, 27.6)	15.9 (7.7, 24.1)	16.2 (7.9, 24.5)
Current smokers	235	33.1 (27.1, 39.1)	69.6 (63.7, 75.5)	14.9 (10.4, 19.5)	6.2 (3.1, 9.3)	6.8 (3.6, 10.0)
Women						
Total	169	34.7 (27.5, 41.8)	73.8 (67.2, 80.5)	11.9 (7.0, 16.7)	7.6 (3.6, 11.6)	8.9 (4.6, 13.2)
Age groups (years)						
15–19	14	19.9 (0.0, 41.2)	81.8 (61.2, 100.0)	8.3 (0.0, 23.1)	14.0 (0.0, 32.5)	16.3 (0.0, 36.0)
20–29	53	65.6 (52.8, 78.4)	70.7 (58.4, 83.0)	6.3 (0.0, 12.9)	16.2 (6.2, 26.1)	20.1 (9.3, 30.9)
30–39	32	25.6 (10.5, 40.7)	73.2 (57.9, 88.5)	16.1 (3.4, 28.9)	5.5 (0.0, 13.3)	5.5 (0.0, 13.3)
40–49	27	12.7 (0.2, 25.3)	71.5 (54.5, 88.5)	23.6 (7.6, 39.6)	0.0 (0.0, 12.8)	0.0 (0.0, 12.8)
50–59	22	28.3 (9.3, 47.4)	67.2 (47.4, 87.1)	6.0 (0.0, 16.0)	0.8 (0.0, 4.6)	0.0 (0.0, 15.4)
60–69	22	16.1 (0.8, 31.5)	86.7 (72.5, 100.0)	12.3 (0.0, 26.1)	2.1 (0.0, 8.1)	2.1 (0.0, 8.1)
Smoking status						
Never smokers	39	27.2 (13.2, 41.1)	77.8 (64.8, 90.8)	3.9 (0.0, 10.0)	1.7 (0.0, 5.6)	1.7 (0.0, 5.6)
Former smokers	55	39.0 (26.1, 51.9)	81.0 (70.6, 91.4)	11.8 (3.3, 20.4)	16.9 (7.0, 26.8)	17.4 (7.4, 27.5)
Current smokers	75	35.4 (24.6, 46.3)	66.5 (55.8, 77.2)	16.1 (7.7, 24.4)	3.9 (0.0, 8.3)	6.4 (0.9, 11.9)

[a]Sales are legally prohibited by the 'Pharmaceutical Affairs Act' in Japan: this product is available by import by an individual; [b]sales are not regulated legally even in minors in Japan; [c]sales are regulated legally by the 'Tobacco Industries Act' that aims at promoting sound development of the tobacco industry of Japan, although sales for minors are banned by this law. Sum of percentages in row exceeds 100% because of multiple use. E-cigarettes = electronic cigarettes; CI = confidence interval; JT = Japan Tobacco; PM = Philip Morris.

observed in Great Britain (41% for never smokers and 75–80% for current smokers; this study provided only smoking status-stratified results) [21]. In line with this, more current and former smokers had ever used e-cigarettes than never smokers. Both use in the last 30 days and more than 50 sessions use of e-cigarettes among current smokers were higher than those among never smokers. These results might be due to following reasons. First, although the effectiveness of e-cigarettes as smoking-cessation support has not been proven [2,5], e-cigarettes have been sold as smoking-cessation auxiliary goods. Secondly, because the term 'cigarette' had been used for 'e-cigarette' in marketing, smokers might have recognized the term 'e-cigarette' more frequently than never smokers.

Ever use of e-cigarettes in Japan (6.6%) was not much lower than that in the past in the United States (1% in 2009, 2–3% in 2010 [1] and 8.5% in 2013 [12]). E-cigarette use in the last 30 days in Japan (1.3%; although the current study includes heat-not-burn tobacco products) was higher than that in Indonesia in 2011 (0.3% for both sexes [20]) and equal to those in the United States in 2010 [1]. In the United States, use in the last 30 days increased to 2.6% in 2013 [12]. A similar trend in increased e-cigarettes use may occur in Japan from now on, so we need to continue to monitor access to e-cigarettes.

A total of 3.5% of never smoking men and 1.3% of never smoking women had ever used e-cigarettes and heat-not-burn tobacco products, predominantly non-nicotine e-cigarettes. This finding is not negligible, because never smokers form the majority of the population, accounting for more than half the people of Japan [16]. This ever use percentage among never smoking men in Japan was higher than that in Great Britain (0.5% in 2012 and 1.1% in 2014 for both sexes) [21,22] and the United States in 2013 (1.2% for both sexes), while among never smoking women, ever use (1.3%) was similar to that in the United

States in 2013 [12] and Great Britain in 2014 [22]. These percentages may become higher in the future, but they did not increase from 2010 to 2013 in the United States [12] or from 2013 to 2014 in Great Britain [22]. Because e-cigarettes were not used for the purpose of quitting smoking among never smokers [23], e-cigarette use among non-smokers must have some roots in the market. Some e-cigarette marketing strategies to attract never smokers may be carried out by e-cigarette industries in the same way as conventional tobacco companies [23].

There are several limitations to this study. First, data were self-reported without validation, but the reliability of self-reported smoking has generally been high in previous studies [24,25], although this has not been confirmed for e-cigarettes and heat-not-burn tobacco products. Respondents who had used these products in the last 30 days include both current users and some people who had tried these products once in the last 30 days. The figure of $>$ 50 sessions use includes both current and former use. Some users may check multiple categories for the product types used, even if they have used only one product. For example, some users of Ploom and iQOS may have also checked 'nicotine content unknown' if they do not know how much nicotine is in those brands. As for combustible tobacco use, because we did not apply the definition of ever smokers as respondents who had smoked $\geq$ 100 cigarettes in their life-time, someone who had smoked only one cigarette in their lives would be categorized as an ever smoker. These categorizations may result in some misclassifications of user status. Therefore, careful consideration of the data is necessary. Secondly, the total number of questions was slightly different according to the use status (category) of e-cigarettes, because some questions were added only for users, including questions about use in the last 30 days and more than 50 sessions of ever use. This might affect the response rate and underestimate the percentages of products used, if some users dropped out from the survey due to the excess burden of the questions. However, the difference in total number between users and non-users was made as small as possible. Furthermore, we offered relatively long survey periods for the internet survey and sent recall messages to non-responders in order to increase the response rate.

CONCLUSIONS

In Japan, approximately half the respondents were aware of e-cigarettes and heat-not-burn tobacco products, 6.6% had ever used, 1.3% used in the last 30 days and 1.3% had used for $>$ 50 sessions. More than 70% of ever users used non-nicotine e-cigarettes which are not regulated legally in Japan, while 33% used nicotine e-cigarettes, which have been prohibited by pharmaceutical law in Japan; 3.5% of never smoking men and 1.3% of never smoking women had ever used e-cigarettes and heat-not-burn tobacco products, predominantly non-nicotine e-cigarettes. According to WHO recommendations [5], we must continue to monitor awareness and use of e-cigarettes and heat-not-burn tobacco products in Japan. To implement an appropriate policy for these products, it is necessary to gather further evidence about both the harm and benefit of these products.

Declaration of interests

None.

Acknowledgements

This study was supported by the Ministry of Health, Labour and Welfare: Comprehensive Research on Life-Style Related Diseases including Cardiovascular Diseases and Diabetes Mellitus (H25-010 and H26-023). We thank Dr Julia Mortimer for her English language editing.

References

1. Pepper J. K., Brewer N. T. Electronic nicotine delivery system (electronic cigarette) awareness, use, reactions and beliefs: a systematic review. *Tob Control* 2014; **23**: 375–84.
2. Grana R., Benowitz N., Glantz S. A. E-cigarettes: a scientific review. *Circulation* 2014; **129**: 1972–86.
3. Hajek P., Etter J. F., Benowitz N., Eissenberg T., McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* 2014; **109**: 1801–10.
4. Eriksen M., Mackay J., Schluger N., Gomeshtapeh F., Drope J. *The Tobacco Atlas*, 5th edn, revised, expanded and updated. Atlanta, GA: American Cancer Society; 2015.
5. World Health Organization (WHO). Electronic Nicotine Delivery Systems: Report by WHO. Conference of the Parties to the WHO Framework Convention on Tobacco Control. Moscow, Russian Federation; 2014.
6. McRobbie H., Bullen C., Hartmann-Boyce J., Hajek P. Electronic cigarettes for smoking cessation and reduction. *Cochrane Database Syst Rev* 2014; **12**: CD010216.
7. Mejia A. B., Ling P. M. Tobacco industry consumer research on smokeless tobacco users and product development. *Am J Public Health* 2010; **100**: 78–87.
8. Ministry of Internal Affairs and Communication. Communications Usage Trend Survey, Tokyo, Japan; 2013. Available at: http://www.soumu.go.jp/menu_news/s-news/01tsushin02_02000072.html (Archived by WebCite® at http://www.webcitation.org/6arqSbmOG) (accessed 18 August 2015).
9. Rakuten Research. Monitor Profiles; 2015. Available at: http://research.rakuten.co.jp/en/ (Archived by WebCite® at http://www.webcitation.org/6arqdb38X) (accessed 18 August 2015).
10. American Association for Public Opinion Research (AAPOR). Standard Definitions: Final Dispositions of Case Codes and Outcome Rates for Surveys, 8th edn. Oakbrook Terrace, IL: AAPOR; 2015.
11. Giovenco D. P., Lewis M. J., Delnevo C. D. Factors associated with e-cigarette use: a national population survey of current and former smokers. *Am J Prev Med* 2014; **47**: 476–80.

12. King B. A., Patel R., Nguyen K. H., Dube S. R. Trends in awareness and use of electronic cigarettes among US adults, 2010–2013. *Nicotine Tob Res* 2015; **17**: 219–27.
13. Hoshino T. *Statistics for Observational Data and Survey Data—Causal Inference, Selection Bias and Data Fusion*. Tokyo: Iwanami Shoten; 2009.
14. Schonlau M., Soest A., Kapteyn A., Couper M. Selection bias in web surveys and the use of propensity scores. *Socio Meth Res* 2009; **37**: 291–318.
15. Berrens R., Bohara A., Jenkins-Smith H., Silva C., Weimer D. The advent of internet surveys for political research: a comparison of telephone and internet samples. *Policy Anal* 2003; **11**: 1–22.
16. Ministry of Health, Labour and Welfare. Comprehensive survey of living condition of people on health and welfare, Tokyo; 2010. Available at: http://www.mhlw.go.jp/toukei/saikin/hw/k-tyosa/k-tyosa10/index.html (Archived by WebCite® at http://www.webcitation.org/6arqpkcU1) (accessed 18 August 2015).
17. Etter J. F., Bullen C. Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy. *Addiction* 2011; **106**: 2017–28.
18. Eriksen M., Mackay J., Ross H. *The Tobacco Atlas*, 4th edn. Atlanta, GA: American Cancer Society; 2012.
19. King B. A., Alam S., Promoff G., Arrazola R., Dube S. R. Awareness and ever-use of electronic cigarettes among U.S. adults, 2010–2011. *Nicotine Tob Res* 2013; **15**: 1623–7.
20. World Health Organization Regional Office for South East Asia. Global Adult Tobacco Survey: Indonesia Report 2011; 2012. Available at: http://www.searo.who.int/entity/tobacco/data/gats_indonesia_2011.pdf (accessed 18 March 2015).
21. Dockrell M., Morrison R., Bauld L., McNeill A. E-cigarettes: prevalence and attitudes in Great Britain. *Nicotine Tob Res* 2013; **15**: 1737–44.
22. Action on Smoking and Health (ASH). Use of e-cigarettes in Great Britain among adults and young people; 2014. Available at: www.ash.org.uk/files/documents/ASH_891.pdf (accessed 21 March 2015).
23. Carroll Chapman S. L., Wu L. T. E-cigarette prevalence and correlates of use among adolescents versus adults: a review and comparison. *J Psychiatr Res* 2014; **54**: 43–54.
24. Caraballo R. S., Giovino G. A., Pechacek T. F., Mowery P. D. Factors associated with discrepancies between self-reports on cigarette smoking and measured serum cotinine levels among persons aged 17 years or older: Third National Health and Nutrition Examination Survey, 1988–1994. *Am J Epidemiol* 2001; **153**: 807–14.
25. International Agency for Research on Cancer. *IARC Handbooks of Cancer Prevention Tobacco Control, vol. 12: Methods for Evaluating Tobacco Control Policies*. Lyon, France: International Agency for Research on Cancer; 2008.

Supporting Information

Additional supporting information may be found of this article at the publisher's web-site.

Table S1 Basic characteristics of study subjects, unweighted and weighted distribution.
Table S2 Percentages of e-cigarettes and heat-not-burn tobacco products use according to sex, age groups and smoking status (combustible tobacco) in Japan, unweighted and weighted results.
Table S3 Product types and ever use of e-cigarettes and heat-not-burn tobacco products according to sex, age group and smoking status in Japan.
Appendix Supplementary methods and results.

小児における受動喫煙，$PM_{2.5}$の影響

Health effect of childhood passive smoking and $PM_{2.5}$

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Key words

受動喫煙，$PM_{2.5}$，小児，受動喫煙防止法，屋内全面禁煙

Summary

受動喫煙とは「他人のタバコの煙を吸わされること」である。子どもは主に家庭や自家用車内，飲食店で受動喫煙に曝されている。$PM_{2.5}$はタバコの煙の指標でもあり，日本では喫煙する室内の高濃度$PM_{2.5}$が問題である。たとえば，３人が喫煙するレストランは$PM_{2.5}$濃度が600 $\mu g/m^3$にもなる。タバコの煙は喫煙者本人だけでなく，タバコを吸わない周囲の人々の健康にも悪影響を及ぼす。子どもは親や環境を選べない。子どもは親や他人のタバコの煙から危害を加えられているのである。子どもを含む社会の成員すべての健康を守るため受動喫煙の防止に取り組むことが必要であり，屋内の全面禁煙化が求められる。タバコの煙から子どもを守るために，①家庭内を禁煙とする，②車の中を禁煙とする，③教育・啓発により家庭・車の禁煙化を促す，④両親など家族に受動喫煙の害を知らせる，⑤両親など家族が禁煙するのを支援する，そして⑥日本全国の屋内空間の全面禁煙を義務化する法律を制定することが必要である。

はじめに —小児における受動喫煙：どこで曝露されているか？

受動喫煙とは「他人のタバコの煙を吸わされること」である。子どもは主に家庭や自家用車内，飲食店で受動喫煙に曝されている。厚生労働省が実施した21世紀出生児縦断調査(2001年出生児)によると，子どもが生後６ヵ月時に父親の63%および母親の17%が喫煙しており，父親の38%および母親の12%は室内で喫煙していた[1]。現在，幼稚園や学校はほとんどの施設が屋内禁煙である一方，喫茶店や飲食店の多くは屋内禁煙となっていない[2)3)]。

I 受動喫煙の害

タバコの煙には発癌物質などの有害な化学物質が非常に多く含まれている。**図１**に科学的根拠に基づく，大人および子どもにおける受動喫煙の害(Tobacco Atlas 5th[4])を示す。受動喫煙により日本全体で少なくとも年間6,800人が死亡し[5]，心筋梗塞や肺癌などの病気にかかる者が増え，大人だけでなく子どもの呼吸器感染症・喘息などの発病や入院が増えることがわかっている[6)-8)]。親が室内で喫煙していると乳児の突然死が４倍増える[6]。短時間の受動喫煙であっても，害は即座に起こり蓄積される[6)9)]。

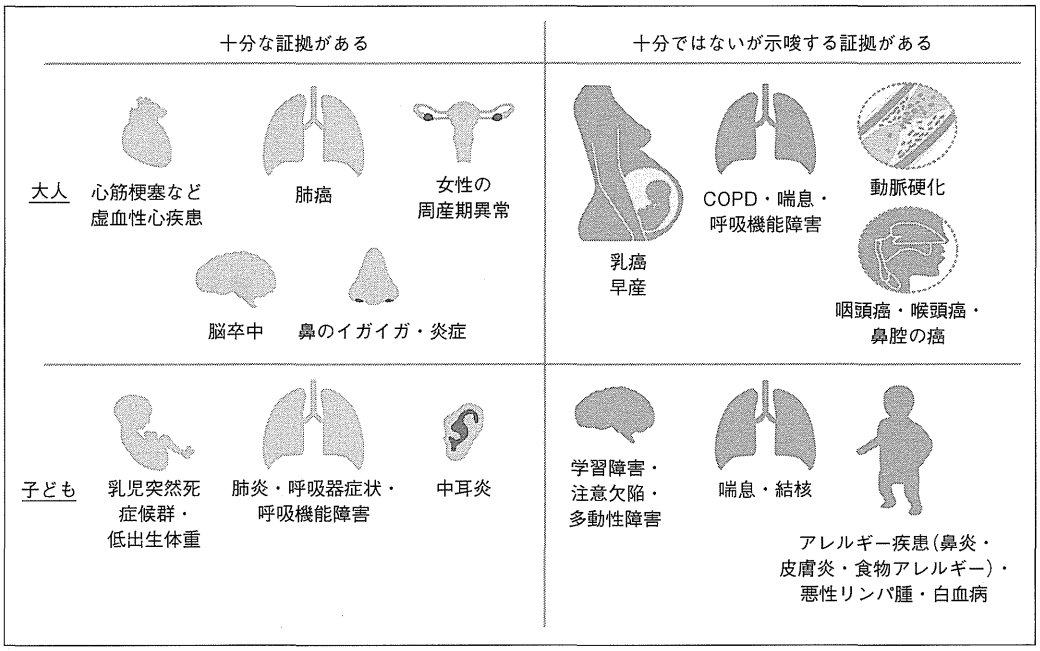

図1．大人および子どもにおける受動喫煙の害

(文献4より引用・改変)

II 受動喫煙とPM2.5

微小粒子状物質($PM_{2.5}$)とは，大気中に浮遊する小さな粒子のうち，粒子の大きさが2.5 μm以下の非常に小さな粒子のことである[10]。2013年には中国の北京市内が高い濃度の$PM_{2.5}$で覆われて視界がほとんどきかなくなり，九州でも高濃度の$PM_{2.5}$が観測されたことが話題になった。2014年の世界保健機関(WHO)の調査[11]によると，中国における大気の$PM_{2.5}$の年平均値は41.3 $\mu g/m^3$であり，日本では9.6 $\mu g/m^3$であった。

$PM_{2.5}$の健康影響に関して詳細は他稿に譲るが，米国の研究[12]で，大気中の$PM_{2.5}$値が10 $\mu g/m^3$増えると，心臓や肺の病気の死亡率が9％，肺癌死亡率が14％，全死亡率が6％増えると報告された。2005年，WHOは世界の大気汚染対策のために改訂版WHO Air Qualityガイドライン[13]を発表し，$PM_{2.5}$の年間平均レベルの第一の暫定的目標値として，35 $\mu g/m^3$を設定した(日平均値による第一暫定的目標値は75 $\mu g/m^3$)。ただし，この目標レベルでは$PM_{2.5}$の年平均10 $\mu g/m^3$(最も望ましいとされるガイドラインレベル)と比較すると死亡率が約15％高い[13]。2013年，日本の環境省は「健康影響が出現する可能性が高くなる濃度水準」を$PM_{2.5}$日平均値で70 $\mu g/m^3$と定め，70 $\mu g/m^3$を超えた場合には，不要不急の外出や屋外での長時間の激しい運動をできるだけ減らすこと，呼吸器系や循環器系疾患のある者・小児・高齢者などにおいては体調に応じてより慎重に行動することが望まれるとした[10]。

$PM_{2.5}$は大気汚染のほか，タバコの煙の指標としても使用できる。大気汚染および喫煙する室内における$PM_{2.5}$のレベルが明記されたWHO(China)による啓発画像を**図2**に示す。3人が喫煙するレストランは$PM_{2.5}$濃度600 $\mu g/m^3$であり，大気汚染の緊急事態レベル濃度500 $\mu g/m^3$よりも高い。またSempleらによる研究では，喫煙する家庭内の$PM_{2.5}$は，喫煙数が多ければ多いほど高くなり，その24時間平均値は約100 $\mu g/m^3$であった[14]。昼に家にいない労働者や学生における家庭での受動喫煙曝露の目安となる$PM_{2.5}$の夜間6時間平均値は，約200 $\mu g/m^3$であった[14]。一方，喫煙する車内では，

図2．大気汚染および喫煙する室内における$PM_{2.5}$のレベルを明記した啓発画像

＊：The 2014 Beijing Environment Report, Beijing Municipal Environmental Protection Bureau, released April 2015.

＊＊：Liu et al. A cross-sectional study on levels of second-hand smoke in restaurants and bars in 5 cities in China, Tobacco Control. 11 Dec 2009.

＊＊＊：Estimate.

（World Health Organization, China, 2015より引用・改変）

（巻頭グラビア p.10参照）

$PM_{2.5}$の1時間平均値は約750 $\mu g/m^3$と高かった[15]。喫煙で高くなった室内の$PM_{2.5}$が，WHOの24時間ガイドライン値の25 $\mu g/m^3$まで下がるには，中央値で2時間40分かかる[16]。

現在の日本では，大気の$PM_{2.5}$濃度は低く[11]，大気汚染レベルは比較的低いといえるため，大気汚染よりも屋内のタバコの煙に注意すべき状況だと考えられる。

Ⅲ 受動喫煙防止法の必要性

平成21年に厚生労働省によりまとめられた『受動喫煙防止対策のあり方に関する検討会報告書』では，受動喫煙は喫煙者による「他者危害」であることが指摘されている[17]。喫煙は個人の健康問題にとどまらず，他者に害を及ぼす大変な公共問題となっている[18]。他人に危害を加える権利は誰にもなく，誰もが受動喫煙の害から保護されるべきである[18]。特に，子どもは生まれる前から受動喫煙に曝露されており，生まれた後も自分で受動喫煙から逃げることができないため，社会的な受動喫煙を防止する取り組みが必要とされる。

世界の多くの国で，職場・公共の場所の受動喫煙防止対策が法律・条例などに基づき順次進められている[19][20]。世界各国から，受動喫煙防止法により心筋梗塞や脳卒中・喘息のための入院が減少したなど健康への好ましい影響が報告されている[20]-[23]。また，受動喫煙防止法の導入によって，公共の場所だけでなく家庭においても全面禁煙が促進される[24]。受動喫煙防止に取り組むことにより住民全体の健康を向上させることができる。日本では，2010年に神奈川県，2013年に兵庫県において受動喫煙防止条例が施行されたが，レストランなど職場の禁煙化は不十分である[25]。参考として**図3**に受動喫煙防止対策を進めるために筆者が取り組んでいる啓発キャンペーンの記事を示す。日本においても誰もが受動喫煙の害から守られるようにすべての空間で受動喫煙防止対策を進めていくことが求められている[20][26]。

おわりに ―子どもを受動喫煙の被害から守るには

国際対がん連合（UICC）は2008年『Protecting our children from second-hand smoke（たばこの煙から子どもたちを守るには）』[27]を出版し，その方法として以下の5点を挙げた。①家庭内の禁煙，②車の中の禁煙，③教育・啓発により家庭・車の禁煙化を促す，④両親など家族に受動喫煙の害を知らせる，⑤両親など家族が禁煙するのを支援する。この5点に加えて，日本全国の屋内空間の全面禁煙を義務化する法律を制定することを求めたい。

最後に，受動喫煙だけでなく健康格差へも話を広げたい。なぜなら，タバコは健康格差を拡大している代表的要

図3．広報みやこじま2015年6月号(上)と7月号(下)の記事(大阪市都島区公式広報誌)コラム「Dr. TABUCHIのそうだ！禁煙しよう！」
(http://www.city.osaka.lg.jp/miyakojima/category/2622-9-1-0-0.html より引用)
(巻頭グラビア p.11参照)

因の１つだからである。子どもが受動喫煙を受けるかどうかには社会格差が大きく影響している[1]。所得の低い社会的に不利な家庭の子どもほど多く受動喫煙に曝されているのである[1)28)]。社会疫学者マーモット博士は，健康格差を減らすために医療・社会政策に求められることの第一に「すべての子どもに人生のよいスタートを準備すること」を挙げた[29]。われわれは，子どもが人生のスタートから受動喫煙の害に曝されない社会を作っていかなければならない。ただし，タバコの害に曝されているのは子どもだけではない。子どもだけでなく喫煙者を含む社会の成員すべてをタバコの害から守るために，あらゆる屋内空間の全面禁煙化を進めて，喫煙者が禁煙しやすい・タバコを吸いづらい環境を整備していくことが必要である[25]。

※一部，大阪府立成人病センターがん予防情報センターホームページ用に執筆した内容を改変し，使用した。

文　献

1) Tabuchi T, Fujiwara T, Nakayama T, et al：Maternal and paternal indoor or outdoor smoking and the risk of asthma in their children；a nationwide prospective birth cohort study. Drug Alcohol Depend 2015；**147**：103-8.
2) 文部科学省：平成23年度社会教育調査，2012.
3) 厚生労働省：平成24年 労働者健康状況調査，2012.
4) Eriksen M, Mackay J, Schluger N, et al：The Tobacco Atlas(Fifth Edition) Atlanta, American Cancer Society, 2015.
5) 片野田耕太，望月友美子，雑賀公美子，他：わが国における受動喫煙起因死亡数の推計．厚生の指標 2010；**57**：14-20.
6) Department of Health and Human Services：The Health Consequences of Involuntary Exposure to Tobacco Smoking；A Report of the Surgeon General. Rockville, Centers for Disease Control and Prevention, 2006.
7) Hirayama T：Cancer mortality in nonsmoking women with smoking husbands based on a large-scale cohort study in Japan, Prev Med 1984；**13**：680-90.
8) Kanoh M, Kaneita Y, Hara M, et al：Longitudinal study of parental smoking habits and development of asthma in early childhood. Prev Med 2012；**54**：94-6.
9) Frey PF, Ganz P, Hsue PY, et al：The exposure-dependent effects of aged secondhand smoke on endothelial function. J Am Coll Cardiol 2012；**59**：1908-13.
10) 微小粒子状物質(PM_{25})に関する専門家会合：最近の微小粒子状物質(PM_{25})による大気汚染への対応．環境省 2013.
11) World Health Organization：Ambient (outdoor) air pollution in cities database 2014. 2014.
12) Pope CA 3rd, Burnett RT , Thun MJ, et al：Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution. JAMA 2002；**287**：1132-41.
13) World Health Organization：Air Quality Guidelines；Global Update 2005. 2006.
14) Semple S, Garden C, Coggins M, et al：Contribution of solid fuel, gas combustion, or tobacco smoke to indoor air pollutant concentrations in Irish and Scottish homes, Indoor Air 2012；**22**：212-23.
15) Jones IA, St Helen G, Meyers MJ, et al：Biomarkers of secondhand smoke exposure in automobiles. Tob Control 2014；**23**：51-7.
16) Semple S, Latif N：How long does secondhand smoke remain in household air；analysis of PM_{25} data from smokers' homes. Nicotine Tob Res 2014；**16**：1365-70.
17) 厚生労働省：受動喫煙防止対策のあり方に関する検討会報告書．2009.
18) Chapman S：Public Health Advocacy and Tobacco Control；Making Smoking History. Oxford, Blackwell Publishing Ltd, 2007.
19) Callinan JE, Clarke A, Doherty K, et al：Legislative smoking bans for reducing secondhand smoke exposure, smoking prevalence and tobacco consumption. Cochrane Database Syst Rev 2010；**14**：CD005992.
20) World Health Organization：WHO Framework Convention on Tobacco Control. Geneva, WHO, 2003.
21) Tan CE, Glantz SA：Association between smoke-free legislation and hospitalizations for cardiac, cerebrovascular, and respiratory diseases；a meta-analysis. Circulation 2012；**126**：2177-83.
22) Mackay D, Haw S, Ayres JG, et al：Smoke-free legislation and hospitalizations for childhood asthma. N Engl J Med 2010；**363**：1139-45.
23) International Agency for Research on Cancer World Health Organization：IARC Handbooks of Cancer Prevention, Tobacco Control, Volume 13；Evaluating the Effectiveness of Smoke-free Policies. Lyon, IARC, 2009.
24) Mons U, Nagelhout GE, Allwright S, et al：Impact of national smoke-free legislation on home smoking bans；findings from the International Tobacco Control Policy Evaluation Project Europe Surveys. Tob Control 2013；**22**：e2-9.

25) Tabuchi T, Hoshino T, Nakayama T : Are Partial Workplace Smoking Bans as Effective as Complete Smoking Bans? A National Population-Based Study of Smoke-Free Policy Among Japanese Employees. Nicotine Tob Res 2015. [Epub ahead of print]
26) 厚生労働省健康局長通知 健発1029第5号：受動喫煙防止対策の徹底について．厚生労働省，2012.
27) Hawthorne MA, Hannan LM, Thun MJ, et al : Protecting our children from second-hand smoke. Genova, International Union Against Cancer (UICC), 2008.
28) Pisinger C, Hammer-Helmich L, Andreasen AH, et al : Social disparities in children's exposure to second hand smoke at home ; a repeated cross-sectional survey. Environ Health 2012 ; **11** : 65.
29) Fair Society, Healthy Lives : Strategic Review of Health Inequalities in England Post-2010 ; The Marmot Review. London, UCL, 2010.

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Nicotine & Tobacco Research Advance Access published June 11, 2015

Nicotine & Tobacco Research, 2015, 1–9
doi:10.1093/ntr/ntv115
Original investigation

Original investigation

Are Partial Workplace Smoking Bans as Effective as Complete Smoking Bans? A National Population-Based Study of Smoke-Free Policy Among Japanese Employees

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Abstract

Introduction: Although complete workplace smoking bans are generally recommended rather than partial bans, the latter are widespread in many countries, especially Japan. Our objective was to compare complete workplace smoking bans and partial bans for associations with employee smoking and secondhand smoke (SHS)-related discomfort/ill-health. We also evaluated complete bans versus no ban and partial bans versus no ban.

Methods: Eleven thousand ninety eligible employees (weighted number: 34 353 241) aged 20–64 years in 2011 (response rate: 62.5%) were analyzed using a nationally-representative, population-based cross-sectional study. Adjusted prevalence ratios for self-reported current smoking and SHS-related discomfort/ill-health according to workplace smoke-free policies were calculated, using conventional regression and propensity score (PS) weighting (targeting population of average treatment effect among both treated [TET] and untreated [TEU]).

Results: Both conventional regressions and PS weighting analyses showed complete bans were significantly associated with lower prevalence of current smoking and perceived SHS-related discomfort/ill-health among nonsmokers than partial or no ban. In contrast, partial bans were not significantly associated with either outcome compared with no ban. Using several PS trimming levels, we found interesting differences between TET and TEU in a comparison between partial and no ban: that is, significant associations in TET estimations, but none in TEU estimations.

Conclusions: Although complete smoking bans were associated with lower levels of employee smoking and SHS-related discomfort/ill-health compared with no smoking ban, partial bans were not. Findings from PS weighting of TEU suggest that partial workplace bans may not be any more effective for Japanese employees than no ban. Therefore, complete bans may be strongly recommended for future implementation, but careful interpretation of the data is necessary because of the cross-sectional study design.

Introduction

Smoke-free policy is a key intervention in tobacco control.[1] Because there is no safe level of exposure to secondhand smoke (SHS), complete smoking bans are the only way to completely protect employees from SHS harm.[2–4] It is evident that national-level legislative smoking bans in countries such as Australia, England, and the United States are effective in reducing smoking prevalence and the SHS-related disease burden.[1,3,5,6] However, partial smoking bans

have been allowed and disseminated within the tobacco control legislation of many countries.[2,4,7] A partial ban could include designated ventilated smoking rooms or smoking areas separated by a wall.

In Japan, the Health Promotion Law allows partial bans as an option and the Workplace Smoke-free Guideline recommended a partial rather than a complete ban in 2003.[9–10] In addition, the tobacco industry has promoted the construction of designated smoking spaces as a way to sidetrack efforts to make workplaces entirely smoke-free.[11–13] Among Japanese workers, even among nonsmokers, there is support for partial rather than complete bans (54% vs. 35% in a workplace setting).[8] As a result, partial smoking bans are widespread.[14,15] Recently, complete smoking bans have been recommended, following ratification of the World Health Organization Framework Convention on Tobacco Control by the Japanese government in 2005. However, in 2007, 81.6% of privately-owned worksites with at least 10 employees in Japan did not have a complete smoking ban (having either a partial ban or no ban),[15] possibly because there is no national smoke-free legislation with penalty.

In previous studies, discomfort or ill-health due to workplace SHS was common.[1,3,16] SHS increased the rate of not only temporal discomfort like throat irritation but also acute disorders such as myocardial infarction.[1,3] A complete workplace smoking ban is a way to protect nonsmokers from the harmful health effects of SHS exposure, and to provide a supportive environment for employees who want to quit smoking.[1] However, there has been little evaluation of how the benefits of a complete ban compare with a partial ban, or the benefits of a partial ban versus no ban.[5]

Our objective was to compare complete and partial workplace smoking bans in terms of the association with employee smoking and SHS-related discomfort/ill-health. Similarly we evaluated complete bans versus no ban and partial bans versus no ban.

Methods

Data

We used data from a nationally representative population-based cross-sectional study: Survey on the Prevention of Industrial Accidents, conducted by the Japanese Ministry of Health, Labour and Welfare in November 2011.[17] According to the Japanese Economic Census 2009,[18] which was a complete-case survey for Japanese employees, of 1 058 505 business establishments (worksites) with at least 10 employees (excluding public offices), 13 276 worksites were randomly sampled across Japan. A worksite-level questionnaire (worksite survey) was sent to the person responsible for "industrial safety and health (Rodo-anzen-eisei)" at the worksite. To collect data from representative individual employees in Japan (employee survey), worksites were randomly selected, depending on the number of employees in the worksite (5, 10, 15, or 20 employees were sampled from worksites employing 10–29, 30–299, 300–499, or ≥500 employees, respectively). The selection was designed so that a sufficient number of samples for standard error calculation on all strata of industry and worksite scale variations would be obtained (further detailed methods are available on request). The Ministry of Health, Labour and Welfare calculated the survey weights to approximate total respondents in the entire distribution (comprising 42 710 457 employees with industry and worksite scale variations; Japanese Economic Census 2009) in Japan, additionally accounting for nonresponse and sampling probability. Data were used with permission from the Ministry of Health, Labour and Welfare. Analyses of national survey data were considered to be exempt from ethical review according to the Epidemiological Research Guidelines.

Variables

Workplace smoke-free policy (data from worksite-level questionnaire) was defined and categorized as (1) complete smoking ban (complete "indoor" smoke-free workspace which allowed an outdoor smoking space as an option), (2) partial smoking ban (smoking room and/or smoking corner allowed for smoking indoors), and (3) no smoking ban (neither complete nor partial). In the questionnaire, "smoking room" was defined as an independent designated room for smoking and "smoking corner" was defined as an indoor space for smoking divided by a wall or a partition such as a single-leaf screen.

The outcomes were (1) current smoker prevalence among total employees; and (2) prevalence of perceived SHS-related discomfort/ill-health at the workplace among nonsmoking employees. Current smoker was defined as a person who smoked cigarette regularly at the time of survey (yes or no). Respondents who did not smoke (nonsmokers) were asked: "Have you found that cigarette smoke in the workplace (SHS) has caused you discomfort or ill health in the last 6 months?" (perceived SHS-related discomfort/ill-health at workplace: yes or no).

The following characteristics were used as potential confounding factors. Characteristics of employee include: sex, age group (20–29, 30–39, 40–49, 50–59, or 60–64 years-old), full-time employment (yes or no), extra-working hours per month (0–44, 45–79, or ≥80 hours in October) and health checkup within the last year (yes or no). Characteristics of workplace include: size of workforce (10–29, 30–49, 50–99, 100–299, 300–999, or ≥1000 employees), industry ("forestry, mining and construction," "manufacturing," "electricity, gas, heat supply, water, information and communications," "transport and postal services," "wholesale and retail trade," "finance, insurance, real estate, goods rental and leasing," "scientific research, professional and technical services," "accommodation," "eating and drinking services," "other services," "education and learning support," and "medical, health care and welfare") and area block (Hokkaido, Tohoku, Kitakanto, Tokyoken, Chubu/Hokuriku, Chukyoken, Kinki, Chugoku, Shikoku, Kyushu/Okinawa).

Statistical Analyses

All analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC). Probability values for statistical tests were two-tailed and $P < .05$ was considered statistically significant. Survey weights were used for generalizability, and weighted results are shown.

Conventional Regression

The prevalence ratios (PRs) and 95% confidence intervals (CIs) for outcomes were calculated according to the workplace smoke-free policies (no ban was used as a reference category). Log-binomial regression models were used because the outcome was more than 10%.[19] In some instances, the models did not converge so we used log-Poisson models, which provide consistent but not fully efficient estimates of the PRs.[20]

Propensity Score Weighting

As complete workplace bans are not randomly implemented, we conducted propensity score (PS) analyses[21] to evaluate the association between smoke-free policies and outcomes. Characteristics of subjects differed according to workplace smoke-free policy (Table 1). PS weightings were used to account for differences. Procedures were repeated for the three combinations of policies (complete ban vs. partial ban, complete ban vs. no ban and partial ban vs. no ban),

Table 1. Basic Characteristics with Standardized Differences According to Workplace Smoking Ban Policies, Using Survey Weights (Before PS Weighting)

Characteristics	Complete smoking ban (weighted n = 8 156 369) %	Partial smoking ban (weighted n = 20 828 196) %	No smoking ban (weighted n = 5 368 676) %	Total (weighted n = 34 353 241) %	Standardized differences		
					Between C and P	Between C and N	Between P and N
Female sex	51.8	38.5	38.7	41.7	0.27	0.27	0.00
Age group							
20–29 years	23.1	18.1	16.6	19.1	0.13	0.17	0.04
30–39 years	30.5	28.2	31.4	29.3	0.05	−0.02	−0.07
40–49 years	25.5	28.0	22.6	26.6	−0.06	0.07	0.13
50–59 years	14.9	20.4	22.6	19.4	−0.14	−0.20	−0.05
60–64 years	6.0	5.3	6.9	5.7	0.03	−0.04	−0.07
Regular employee, Yes	76.7	77.1	81.1	77.6	−0.01	−0.11	−0.10
Extra working hours per month							
0–44	91.0	86.5	82.1	86.7	0.14	0.26	0.12
45–79	7.4	10.7	8.2	9.5	−0.12	−0.03	0.09
80 or more	1.6	2.8	9.8	3.6	−0.05	−0.31	−0.27
Health checkup within the last year, Yes	85.1	90.0	71.3	85.9	−0.15	0.34	0.49
Worksite scale (employee number)							
10–29	30.1	25.3	59.9	31.8	0.11	−0.63	−0.75
30–49	16.2	12.4	10.3	13.0	0.11	0.18	0.06
50–99	13.9	15.6	21.1	16.1	−0.05	−0.19	−0.14
100–299	22.3	26.0	2.8	21.5	−0.09	0.59	0.67
300–999	9.9	13.0	4.0	10.9	−0.10	0.22	0.32
1000 or more	7.6	7.7	1.8	6.8	0.00	0.24	0.24
Industries							
Forestry, mining and construction	5.4	4.7	12.3	6.0	0.03	−0.24	−0.27
Manufacturing	6.2	25.5	20.8	20.1	−0.55	−0.44	0.11
Electricity, gas, heat supply, water, information and communications	3.8	5.4	0.2	4.2	−0.07	0.17	0.23
Transport and postal services	0.9	7.3	10.7	6.3	−0.27	−0.37	−0.12
Wholesale and retail trade	15.8	23.8	17.0	20.8	−0.20	−0.03	0.17
Finance, insurance, real estate, goods rental and leasing	5.2	5.0	3.4	4.8	0.01	0.09	0.07
Scientific research, professional and technical services	3.4	2.9	2.5	3.0	0.02	0.04	0.02
Accommodations	0.7	2.1	0.8	1.6	−0.06	0.00	0.06
Eating and drinking services	3.4	6.9	7.2	6.1	−0.15	−0.16	−0.01
Services	16.0	9.9	14.0	12.0	0.18	0.05	−0.13
Education and learning support	9.3	1.3	1.9	3.3	0.31	0.29	−0.03
Medical, health care and welfare	29.9	5.3	9.3	11.7	0.68	0.54	−0.15
Area block							
Hokkaido	0.2	2.4	6.0	2.4	−0.10	−0.26	−0.16
Tohoku	1.6	4.1	11.2	4.6	−0.12	−0.36	−0.26
Kitakanto	2.9	4.8	3.4	4.1	−0.09	−0.02	0.06
Tokyoken	37.6	35.5	18.8	33.4	0.04	0.43	0.38
Chubu/Hokuriku	7.5	9.0	11.6	9.0	−0.05	−0.14	−0.09
Chukyoken	5.6	9.3	10.8	8.7	−0.14	−0.19	−0.05
Kinki	16.9	18.3	24.1	18.8	−0.04	−0.18	−0.14
Chugoku	5.3	6.3	2.7	5.5	−0.04	0.12	0.15

Table 1. *Continued*

Characteristics	Complete smoking ban (weighted n = 8 156 369) %	Partial smoking ban (weighted n = 20 828 196) %	No smoking ban (weighted n = 5 368 676) %	Total (weighted n = 34 353 241) %	Standardized differences		
					Between C and P	Between C and N	Between P and N
Shikoku	0.5	3.5	1.7	2.5	−0.13	−0.05	0.08
Kyushu/Okinawa	22.0	6.9	9.7	11.0	0.44	0.34	−0.10
Current smoker	25.0	36.9	43.9	35.1	NA	NA	NA
SHS-related discomfort/ill-health among nonsmokers	12.4	24.3	28.2	21.5	NA	NA	NA

C = complete smoking ban; P = partial smoking ban; PS = propensity score; N = no smoking ban; NA = not applicable; SHS = secondhand smoke. The number of missing values was 12 (weighted number: 40 634) for extra working hours, one (weighted number: 3352) for health checkup and seven (weighted number: 18 011) for current smoker. Unweighted numbers were 2066 for complete smoking ban, 7906 for partial smoking ban, 1118 for no smoking ban, and 11 090 for total.

because PS methods were only able to compare two groups.[22] PS (the probability of a workplace smoking ban for each employee ranging from 0–1) was calculated by multivariate logistic regression using all the previously listed potential confounders.[21] When assessing the effect of a treatment on an outcome, we are able to estimate three causal estimands of interest: the average treatment effect on the treated (TET), the average treatment effect on the untreated (TEU) and the average treatment effect (ATE).[23,24] The ATE represents the difference in outcome if everyone received the treatment compared to if everyone did not receive the treatment.[24] For future policy implications, it is important to distinguish between the TET and the TEU. To estimate the TET, each exposed individual received a weight of 1, while unexposed individuals were weighted by $e/(1-e)$, where e was the PS. To estimate the TEU, each unexposed individual received a weight of 1, while exposed individuals were weighted by $(1-e)/e$. To estimate the ATE, the exposed group weights were $1/e$, while the unexposed group weights were $1/(1-e)$, weighting each group to the combined sample.[24] Final weights were calculated by multiplying survey weights with PS weights.[25]

Because PS can have a wide range with no overlap between exposed and unexposed individuals, a methodological solution was a trimming to enable interpretation of data under exchangeability.[24] First, we restricted subjects with overlapping PS between the exposed and unexposed groups (as baseline population). Since the optimal level of trimming, that is, exclusion of the extreme 1%, 2%, or 10% of the PS distributions, was difficult to determine,[26,27] we conducted additional analyses using several levels of trimming (1%, 2%, 3%, 4%, 5%, and 10%).

To judge the success of each PS weighting in terms of creating groups that look similar on the observed covariates ("balance"), we used standardized differences; the difference in proportions between the exposed and counterpart groups divided by the standard deviation in the exposed group.[28] Because, generally, a standardized difference of 0.1 indicates a potentially meaningful imbalance,[28] the number (out of 39 covariates [total number of dichotomized and dummy variables; see Table 1]) of differences which exceeded 0.1 was counted as an indicator to evaluate the appropriateness of the "balance" achieved by PS weighting, compared with the number in the baseline before PS weighting. When PS weighting creates an acceptable "balance", "univariate" log-binomial regressions with PS weighting can be used for the final result. However, because all the differences were not completely adjusted by PS weighting and unacceptable "imbalance" might have remained in some categories (although there was no threshold), covariate-adjusted log-binomial regression with PS weighting was conducted for the final result.[29] Additional explanations are available elsewhere (Supplementary Data).[17,21]

Results

A total of 9664 worksites were available, giving a 72.8% response rate for the worksite survey. Of 18 075 employees selected for the individual employee survey, 11 296 (response rate: 62.5%) were available from 1245 worksites. Subjects without information on a workplace smoke-free policy (n = 10) were excluded from the analyses. Employees aged at least 65 years (n = 127) and at most 19 years (n = 69) were also excluded because we focused on adults of general working age in Japan. This left 11 090 subjects (weighted number: 34 353 241). Basic characteristics according to workplace smoke-free policy are shown in Table 1 (un-weighted distribution in Supplementary Table S1). A difference between groups was observed in some variables (ie, standardized difference exceeded 0.1). For example, the percentage of female or 20s age group was higher in the complete smoking ban group than other groups. The prevalence of current smokers was 25.0%, 36.9%, and 43.9% for complete, partial and no smoking ban, respectively.

Table 2 indicates the percentage of each smoking ban according to basic characteristics. In total, 23.7% of workplaces had a complete ban policy, 60.6% had a partial ban and the remaining 15.6% had no ban. The percentage of complete bans was higher in employees who were female, worked an extra 0–44 hours per month, worked in the education or medical industries, and lived in the Kyushu/Okinawa area.

Conventional Regression

Results of covariate-adjusted PRs for outcomes according to workplace smoke-free policy are shown in Table 3. Among total subjects, employees in smoke-free workplaces (PR [95% CI] = 0.74 [0.66, 0.84]) were significantly less likely to be current smokers than those in workplaces with no ban. However, those in workplaces with a partial ban (PR [95% CI] = 0.94 [0.86, 1.03]) were not. Among nonsmokers, employees in smoke-free workplaces (PR [95% CI] = 0.51 [0.42, 0.62]) were significantly less likely to perceive SHS-related discomfort/ill-health at workplace than employees with no ban, while employees in partial ban settings (PR [95% CI] = 0.97 [0.83, 1.13]) were not.