Validation of a Questionnaire to Screen for Shift Work Disorder

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Study Objective: At least 15% of the full-time work force is shift workers. Working during the overnight hours, early morning start times, and variable or rotating schedules present a challenge to the circadian system, and these shifts are associated with adverse health and safety consequences. Shift work disorder (SWD), a primary (circadian rhythm) sleep disorder indicated by excessive daytime sleepiness and/or insomnia associated with a shiftwork schedule, is under-recognized by primary care physicians. We sought to develop and validate a questionnaire to screen for high risk of SWD in a shift working population.

Design: Shift workers completed a 26-item questionnaire and were evaluated by a sleep specialist (physician) who diagnosed them as either positive or negative for SWD. The physician assessment of SWD was guided by a flow chart that operationalized the ICSD-2 criteria for SWD.

Setting: 18 sleep clinics in the USA.

Patients or Participants: 311 shift workers.

Interventions: Not applicable.

Measurements and Results: Responses to the items in the questionnaire were entered into a series of discrimination function analyses to determine the diagnostic value of the items and the fewest number of questions with the best predictive value. The function was then cross-validated. A final 4-item questionnaire has 89% positive predictive value and 62% negative predictive value (sensitivity = 0.74; specificity = 0.82).

Conclusions: This Shiftwork Disorder Screening Questionnaire may be appropriate for use in primary care settings to aid in the diagnosis of SWD.

Keywords: Sleep, nightshift, circadian rhythm, sleepiness, insomnia

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INTRODUCTION

Shiftwork, including extended duration shifts and other variable and non-standard hours, comprises approximately 15% of the full-time workforce in the United States,[1] almost 23% of the workforce in Japan,[2] 16% in Australia,[3] 18 % in the United Kingdom, and 13% in France.[4] In the United States,[1] approximately 8 million people regularly work overnight hours,[5] and approximately 20 million people are estimated to have unusually early work start times (between 02:30 and 07:00).[6]

Working at night or during unusual hours presents specific physiological challenges to sleep-wake and alertness rhythms. Shift workers' sleep-wake schedules are often out of phase with their endogenous circadian rhythms.[7,8] Most workers on permanent night shift do not fully adapt to the shifted sleep-wake schedule required for their work.[9-13]

Night workers, in particular, are highly prone to vehicular accidents.[14,15] Decreased alertness, cognitive ability, and vigilance,[16,17] which are likely underlying causes of vehicular accidents, also lead to a substantially higher rate of injuries, industrial accidents, and quality-control errors on the job,[18] as well as a general decline in work capacity[19] and a higher rate of reported actual and near-miss injuries.[20]

Shift work is also associated with a number of adverse health outcomes, including cardiovascular disease, diabetes, gastrointestinal problems, mood disturbances, and cancer.[21] Night shift workers are reported to have higher body mass index,[22,23] elevated cholesterol,[22] and elevated triglyceride levels[22] when compared to day workers. Gastrointestinal problems include an increased rate of peptic ulcers in night and rotating shift workers compared with day workers,[24] and the risk of developing cardiovascular disease was increased by 40% in shift workers.[25] Shiftwork has also been associated with increased rates of depression[26] and is thought to intensify existing mood disorders.[21] Finally, nurses who had performed shift work for many years were significantly more likely to develop breast[27,28] and colon cancers.[29] In fact, the International Agency for Research on Cancer, a part of the World Health Organization, concluded that shift work is probably carcinogenic to humans.[30]

The most commonly reported symptoms of shift work are sleep disturbance and excessive sleepiness. There is, however, a wide range in the severity of these symptoms. Some shift workers have extreme difficulty maintaining optimal sleep-wake functioning while performing a shift-work schedule, even while employing appropriate countermeasures, and should be considered for a diagnosis of shift work disorder (SWD).

SWD is a primary sleep disorder, in the category of Circadian Rhythm Sleep Disorders.[31] It is characterized by excessive sleepiness and/or insomnia temporally associated with the shift schedule. Although the SWD diagnostic criteria have been in place for more than 20 years, the prevalence of the disorder has only recently been defined. Drake and colleagues have suggest-

ed that the prevalence of SWD is at least 10% of those working night and rotating shifts.[24]

SWD has been poorly diagnosed and most likely under-recognized in primary care settings partly because of lack of standardized screening tools.[21,32] Furthermore, individual vulnerability to the adverse health and safety consequences of shift work is not well understood, in part due to the lack of an appropriate screening instrument that identifies those with SWD. The aim in the present study was to develop a questionnaire to assess SWD in a shift working population, suitable for use in clinical practice and research, and validated against clinical diagnosis by sleep specialists in accredited sleep clinics.

METHODS

Participants

Shift workers (n = 311) were recruited to complete the screening questionnaire and to be evaluated by a physician in an accredited sleep clinic. In order to maximize the ability to capture those with and without SWD, we recruited participants in two ways. First, shift workers were recruited from the general population via internet advertising (R; n = 156). Second, flyers at sleep clinics solicited shift workers who were at the clinic for previously scheduled appointments (W; n = 155).

Individuals were eligible to participate in the study if they were aged 18 to 65 years, were not currently being treated by a physician at a sleep clinic for shift work disorder, and, in the past month, worked a non-standard shift schedule (started before 07:00 or after 14:00, rotated, or regularly included hours outside of the standard 07:00 to 18:00 work day). The study protocol was approved by the Partners Human Research Committee. Focus groups were conducted in December 2009, and physician diagnoses on clinic visits were completed from March to October 2010 (spring, summer, and fall).

Questionnaire Development

A previous study assessing the risk of sleep disorders in 4,957 North American police officers[33] provided an opportunity to develop a preliminary version of a SWD questionnaire based on The International Classification of Sleep Disorders, Second Edition (ICSD-2) criteria.[31] A broad range of questionnaire items for the current project were initially generated and compiled from the police study.

A factor analysis reduced the 37 questions regarding insomnia and excessive sleepiness on the police-focused version of the survey to 24 items that best predicted the final outcome. The 24 items were presented in 10 individual interviews of shift workers to determine the most appropriate questions for discriminating between individuals with and without SWD.[34] Shift workers who reported working full-time, aged 18 to 65, were recruited from the general population for these interviews. To be considered shift workers, work had to be scheduled during the habitual hours of sleep, including night shifts, evening and early morning shifts, and rotating shifts,[31] and they were required to meet one of the following criteria: (a) begin work between 14:00 and 17:59; (b) begin an 8- to 10-hour shift between 19:00 and 04:00; (c) have frequently rotating shifts; or (d) start work between 04:00 and 07:00. They were required to work these shifts an average of 5 times per month for ≥ 3 months.

During the interviews (approximately 60 min), shift workers were asked open-ended questions about their job, the impact of shift work on their life, and their interpretation of the survey questions. Questions were revised based on feedback from shift workers and on the ability of the shift workers to interpret the questions. We also ensured that the items in the questionnaire included all symptoms associated with SWD, as self-reported by the shift working sample.

The final questionnaire consisted of 26 items assessing the following: demographics and work schedule details, insomnia while working non-standard shifts, excessive sleepiness while working nonstandard shifts, and insomnia and excessive sleepiness while on a break (i.e., at least 1 week in the last year) from nonstandard shifts (e.g., vacation or standard day shifts). Nonstandard shifts were defined on the questionnaire as those that start before 07:00 or after 14:00, rotate, or regularly include hours outside of the standard 07:00 to 18:00 work day. Response categories for all items except demographics were on a 4 or 5 point Likert scale (see Supplemental Material, Figure S1).

Diagnostic Process

We also conducted 2 focus groups consisting of board-certified sleep specialists (n = 8; 4 per group) to help us better understand how physicians interpret the ISCD-2 criteria and, in practical terms, how they make the diagnosis of SWD. The focus group physicians gave us feedback on a flow chart we developed; the flow chart did not provide any additional guidance outside ICSD-2 criteria. To clarify the diagnosis process, we provided each clinic with a flow chart that operationalized the ICSD-2 criteria for SWD (Figure 1). The flow chart was used to standardize among clinics across the study the clinical evaluation and diagnosis of the disorder. Furthermore, the evaluating physicians did not see the questionnaire that volunteers completed.

Sleep Clinics

The study was conducted across 18 sleep clinics in the United States. All clinics were certified by the American College of Sleep Medicine. The clinics were located in California (Sacramento), Florida (Altamonte Springs, Orlando), Georgia (Macon), Illinois (Chicago, Maryland (Catonsville, Frederick, Westminster), Massachusetts (Brighton, Framingham, Worcester), Pennsylvania (Darby, Lafayette Hill), South Carolina (Charleston, Columbia), Texas (Waco), and Virginia (Portsmouth).

Protocol

Participants completed the questionnaire prior to their appointment with a sleep physician, either at home (R) or in the sleep clinic waiting room (W). Each participant then met individually with a sleep physician who performed a routine clinical evaluation and diagnosis of SWD according to ICSD-2, without access to participant questionnaire data. The diagnosis flow chart was provided to each clinic (Figure 1). Physicians were required to report diagnosis according to the likelihood of SWD (definite, probable, possible, or not likely) and whether a comorbid sleep disorder was present (definite, probable, possible, or not likely), as well as to identify the comorbid sleep disorder(s).
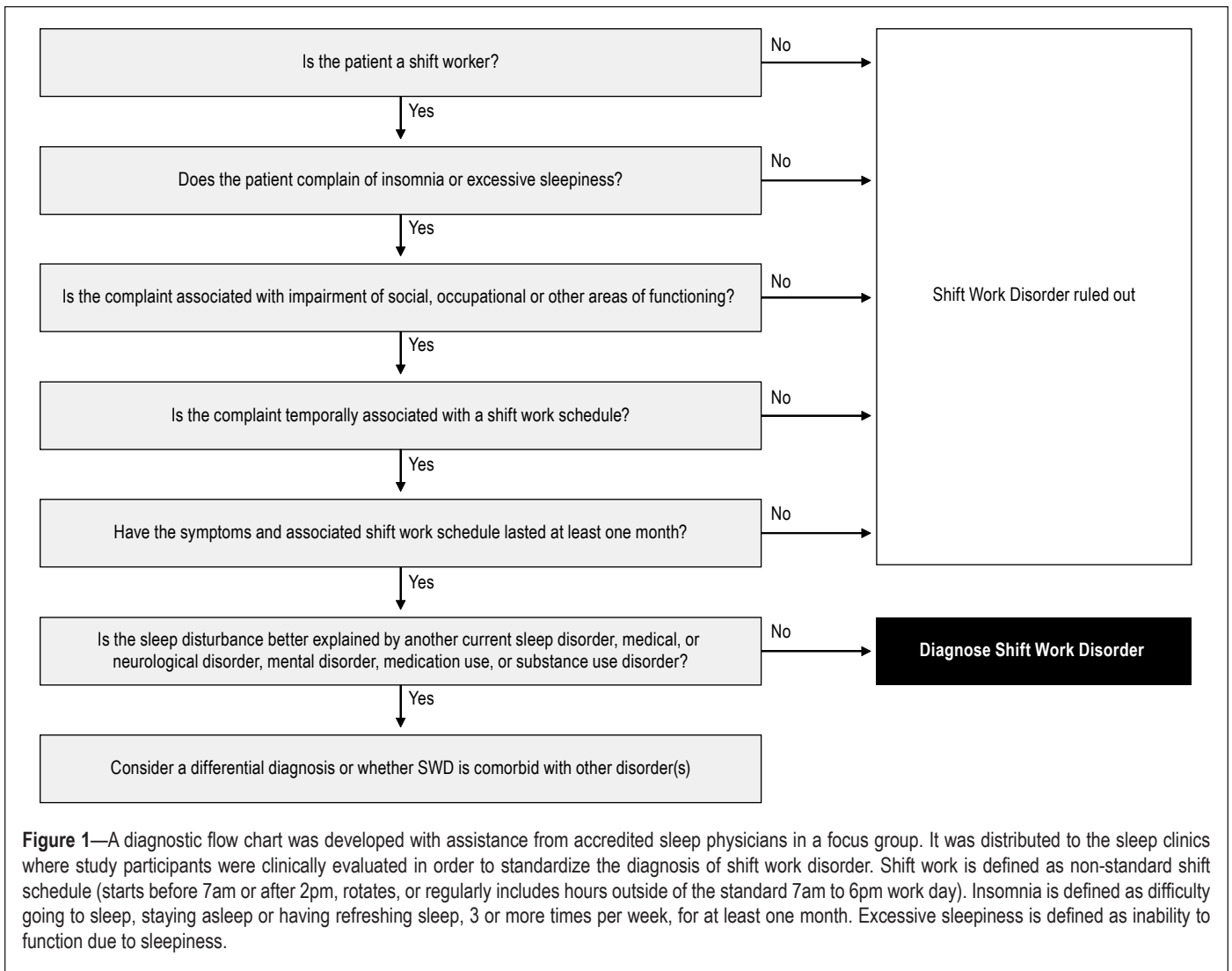
Figure 1—A diagnostic flow chart was developed with assistance from accredited sleep physicians in a focus group. It was distributed to the sleep clinics where study participants were clinically evaluated in order to standardize the diagnosis of shift work disorder. Shift work is defined as non-standard shift schedule (starts before 7am or after 2pm, rotates, or regularly includes hours outside of the standard 7am to 6pm work day). Insomnia is defined as difficulty going to sleep, staying asleep or having refreshing sleep, 3 or more times per week, for at least one month. Excessive sleepiness is defined as inability to function due to sleepiness.

Analysis

The responses to the items in the questionnaire were entered into a series of discrimination function analyses (DFAs) to determine the diagnostic value of the questionnaire items taken together and to identify the smallest number of items contributing significantly to the discriminant function(s). DFA is an analysis of choice for identifying predictors of categorical criterion variables where predictors may be considered non-categorical. It generates a "discrimination function" which may be used to classify new cases into the various criterion categories. However, the predictive value of variables identified by DFA may be inflated by specific characteristics of the validating sample. Use of the function in a new sample may not yield as effective a discrimination as suggested by the original analysis. For this reason, it is essential to cross-validate the findings from the initial DFA with a new sample to determine the likely "true" effectiveness of the function.

For the purposes of cross-validation, the sample was randomly divided into 2 subgroups: an analysis sample (75%) and a cross-validation sample (25%). The random selection was conducted separately for the participants diagnosed as definitely or probably having SWD and those classified as not likely or definitely not having SWD. The final composition and size of samples used in any given analysis was affected by the presence of participants with missing data on one or more questions. T-tests, χ^2, and Fisher exact tests were conducted to compare demographics between the analysis and cross validation samples.

To establish the discriminant values of individual items within the questionnaire, t-tests were conducted comparing the individuals in the analysis sample in binary SWD risk groups (type I error rate set at a Bonferroni adjusted $\alpha = 0.002$). The function was then cross-validated with the cross-validation sample and its adequacy determined by Press's Q test. Receiver operating characteristic (ROC) curves were established for the final questionnaire to determine its sensitivity and specificity. Statistical analysis was conducted with SPSS version 18.0 (SPSS Inc., Chicago, IL, USA).

RESULTS

Sample Characteristics and Clinical Evaluations

A total of 311 (males = 166, females = 124, unknown = 21) shift workers completed the study. Mean (+ SD) age was 41.5 + 12.1 years: 156 shift workers were recruited from the general population (R), and 155 were recruited at previously scheduled sleep clinic appointments (W). The majority of participants started working shifts more than one year ago (82%), with almost half of those (39%) having worked shifts > 5 years.

Table 1—Participant characteristics and physician diagnosis of SWD following clinical evaluation

	Analysis group	Cross-validation group	Total sample	P
N	232	79	311	
Age, Mean ± SD (range)	41.4 ± 12.1 (21-75)	42.0 ± 12.4 (19-67)	41.5 ± 12.1 (19-75)	0.67
Sex, n (%)				0.11
Women	87 (37.5)	37 (46.8)	124 (39.9)	
Men	130 (56.0)	36 (45.6)	166 (53.4)	
Not known/not reported	15 (6.5)	6 (7.6)	21 (6.8)	
Duration of shift work, n (%)				0.85
< 1 year	41 (17.7)	16. (20.3)	57 (18.3)	
1 year to < 5 years	97 (41.8)	37 (46.8)	134 (43.1)	
≥ 5 years	94 (40.5)	26 (32.9)	120 (38.6)	
Frequency of shift work, n (%)				0.43
6-7 times per week	31 (13.4)	9 (11.4)	40 (12.9)	
5 times per week	87 (37.5)	27 (34.2)	114 (36.7)	
4 times per week	59 (25.4)	16 (20.3)	75 (24.1)	
3 times per week	32 (13.8)	15 (19.0)	47 (15.1)	
Less than 3 times per week	14 (6.0)	4 (5.1)	18 (5.8)	
Not known/Not reported	9 (3.9)	8 (10.1)	17 (5.5)	
SWD diagnosis, n (%)*				0.82
Definitely	91 (39.2)	34 (43.0)	125 (40.2)	
Probably	62 (26.7)	18 (22.8)	80 (25.7)	
Not likely	49 (21.1)	15 (19.0)	64 (20.6)	
Definitely not	30 (12.9)	12 (15.2)	42 (13.5)	0.98
Definitely or Probably	153 (65.0)	52 (65.8)	205 (65.9)	
Not likely or Definitely not	79 (34.0)	27 (34.2)	106 (34.1)	

*Diagnosis of SWD by sleep physician.

Most participants worked non-standard shifts 5 times per week (37%), 24% worked non-standard shifts 4 times per week, and 15% worked them 3 times per week (see Table 1). Of the sample, 40% reported typically working night shift (start work 19:00–03:59), 30% reported typically working evening shift (start work 14:00–18:59), 15% typically reported working early morning shifts (start work 04:00–06:59), and the remainder were unknown or rotating.

Participants assigned to the cross-validation group (n = 79) were not significantly different from the analysis group (n = 232) in mean age, number of years working shifts, mean number of shifts worked per week, or SWD diagnosis (P > 0.05).

Clinical evaluations were performed in 18 clinics in 17 cities (number of evaluations, percentage): Altamonte Springs, FL (24, 8%); Brighton, MA (24, 8%); Catonsville, MD (5, 2%); Charleston, SC (11, 4%); Chicago, IL (44, 14%); Columbia, SC (33, 11%); Darby, PA (4, 1%); Framingham, MA (8, 3%); Frederick, MD (7, 2%); Lafayette Hill, PA (43, 14%); Macon, GA (3, 1%); Orlando, FL (12, 4%); Portsmouth, VA (20, 6%); Sacramento, CA (26, 8%); Waco, TX (37, 12%); Westminster, MD (3, 1%), Worcester, MA (7, 2%). The physician-assigned SWD diagnosis categories of the 311 participants are shown in Table 1.

After randomly dividing the subjects, the analysis sample consisted of 232 participants (153 diagnosed as likely or definitely with SWD and 79 diagnosed as not likely or definitely not with SWD). The cross-validation sample of 79 consisted of 52 diagnosed as likely or definitely with SWD and 27 diagnosed as not likely or definitely not with SWD (see Table 1).

Questions Included in Final Discriminant Function Analyses

Of the original 26 items in the questionnaire (see Supplemental Materials, Figure S1), only 16 were used in subsequent discriminant function analyses. Questions 1 and 4 were demographic and not appropriate as discriminators. Questions 19-25 were applicable only to participants who had at least one week's break from non-standard shift work in the previous year, as indicated by a positive response to Question 18. Only 179 of the total of 232 participants in the analysis sample answered Question 18 in the positive. The remainder either did not take at least one week's holiday in the past year or did not answer the question. A preliminary stepwise discriminant function analysis with the 179 participants, with all questions included, yielded a significant function (Wilks λ = 0.662, χ^2 = 72.44, P < 0.001) discriminating the low and high risk groups, with questions 11, 13, 15, and 26, but not questions 19-25, contributing significantly to the function. Questions 19-25 were, therefore, excluded from subsequent discrimination function analysis to avoid further reduction in sample sizes.

Standard Discriminant Function for Predicting Membership of the Four Diagnostic Categories

Standard multiple discriminant function analysis of the analysis sample yielded one significant discriminant function (Wilks' λ = 0.450, χ^2 (72) = 131.927, P = 0.001). The function only yielded 52.2% overall correct classification. While the overall correct classification was poor, the primary sources of errors of classification were in misclassifications between

the "definitely" and "probably" subcategories for those diagnosed as "positive" for SWD and between the "not likely" and "definitely not" subcategories for those considered negative for SWD. This suggested that a more effective approach would be to combine the subcategories to form 2 clinical evaluation categories.

Differences between the Two Diagnostic Groups on Individual Questions

Individuals who were diagnosed as either definitely or likely to be suffering from SWD were more inclined to experience insufficient sleep, excessive sleepiness, and a tendency to doze off at work while working non-standard shifts (Table 2). The participants tended to have problems falling asleep and staying asleep, as well as waking up too early. Their overall quality of sleep tended to be unsatisfactory. They had a reduced sense of well-being while they were awake and experienced decreased physical and mental functioning. The positive group tended to doze off while commuting (not driving).

Therefore, only Questions 7 to 15, individually significantly discriminated between the 2 populations. Nonetheless, it is possible that some of the remaining questions may operate as suppressor (moderating) variables in a discriminant function analysis and were, therefore, included in all subsequent discriminant analyses.

Discriminant Function for Predicting Membership of the Two Major Diagnostic Categories: Standard Discriminant Function Analysis

Standard discriminant function analysis of the 185 participants in the analysis sample that had complete data yielded a significant discriminant function (Wilks' $\lambda = 0.646$; $\chi^2 = 76.13$; df = 17; P < 0.001), with an overall correct classification of 75.1%. This was a considerable improvement on the overall correct classification from the function seeking to discriminate the original 4 diagnostic categories. The percentage of false positives (15.9% falsely classified as positive for SWD) was less than false negatives (29.5%; falsely classified as negative for SWD). The receiver operating characteristics for this function were: sensitivity = 0.71; specificity = 0.84; positive likelihood ratio = 4.44; negative likelihood ratio = 0.35; positive predictive value = 90%; and negative predictive value = 60%. The results suggest that the full function was reasonably sensitive, with the probability of an individual having SWD when he/she was classified as having SWD at 0.90. On the other hand, the probability that an individual did not have SWD when he/she was classified as *not* having SWD was only 0.60, reflecting a higher risk of false negatives.

Stepwise Discriminant Function Analysis

To determine the minimum number of predictors required to significantly discriminate between the diagnostic categories, a stepwise regression analysis was carried out. This resulted in a significant function (Wilks' $\lambda = 0.681$; $\chi^2 = 67.65$; df = 4, P < 0.001), with positive loadings from questions 11, 13, 15, and 26, with question 26 being a suppressor variable, and yielding 76.4% correct classification (see Table 3).

The reduced function with only 4 variables performed as well as the full function with 16 variables. The receiver oper-

ating characteristics for this function were: sensitivity = 0.74; specificity = 0.82; positive likelihood ratio = 4.11; negative likelihood ratio = 0.32; positive predictive value = 89%; and negative predictive value = 62%. Again, the function yielded higher false negatives. The probability that the participant was *diagnosed as* NOT suffering SWD (Negative) when the function predicted that he/she was *not* suffering from SWD (low risk) was 0.62. In contrast, where the function predicted that the participant was suffering from SWD (high risk), the probability that he was *diagnosed as* suffering from SWD (Positive) was 0.89.

Final Discriminant Function

To cross-validate the final discriminant function, a standard discriminant function analysis was first carried out with only the 4 variables extracted in the stepwise analysis. The resulting function (Wilks' $\lambda = 0.70$; $\chi^2 = 66.75$; df = 4, P < 0.001) yielded the same proportion of cases correctly identified identical to that generated in the stepwise analysis.

Fisher's classification coefficients and the structure matrix for the discriminant function with 4 variables provide the correlation between each question and the function are given in Table 4. The strongest contributor to the function was Question 11. Participants who scored high on the function tended to wake up too early and not be able to go back to sleep when on non-standard shifts. They tended to have a poor sense of well-being (Question 13) and to doze off at work (Question 15). Finally, the negative coefficient for Question 26 in the structure matrix might indicate that participants scoring high on this question were at a lower risk of suffering from SWD. However, χ^2 (Table 2) shows that Question 26, on its own, did not discriminate the groups, with a P value of 0.95. This suggests that Question 26 entered the equation as a suppressor variable, possibly for Question 15 with which it has a significant correlation of 0.25 (P = 0.001; see Supplemental Material, Table S1). Of some interest is the finding that Question 3, asking participants when they started working non-standard shifts, did not on its own or in combination with other variables, contribute to discrimination between the diagnostic groups, suggesting that extent of shift-work exposure may not be a major factor in the development of SWD.

Cross-Validation

The function was cross-validated with 61 participants from the cross-validation sample with complete data (see Table 5). The resulting function correctly classified 63.9% of cases, resulting in shrinkage of 12.5%. However, the resulting classification was still better than chance, with a Press's Q test yielding a $\chi^2 = 4.714$; df = 1; P < 0.001. Thus, the discriminant function with just 4 variables provided a significantly better than chance agreement with clinical diagnosis of SWD. The following are the receiver operating characteristics for the cross-validation classification: sensitivity = 0.68; specificity = 0.57; positive likelihood ratio = 1.59; negative likelihood ratio = 0.56; positive predictive value = 75%; and negative predictive value = 48%.

Factors Underlying the Discriminators

Although stepwise discriminant analysis indicates that only 4 questions were sufficient to generate a function that discriminated those diagnosed as positive for SWD from those

Table 2—Differences in responses to individual questions between physician-assigned SWD diagnostic categories

Question	Definitely or Probably SWD (n = 205)	Not likely or definitely not SWD (n = 106)	P[a]
	Diagnostic category, assigned by sleep physician		
Q2. Frequency of shift work, n (%)			0.27
6-7 times per week	27 (13.2)	13 (12.3)	
5 times per week	79 (38.5)	35 (33.0)	
4 times per week	47 (22.9)	28 (26.4)	
3 times per week	31 (15.1)	16 (15.1)	
Less than 3 times per week	11 (5.4)	7 (6.6)	
Not known/Not reported	10 (4.9)	7 (6.6)	
Q3. Started working non-standard shifts, n (%)			0.26
Less than 1 month ago	1 (0.5)	3 (2.8)	
1-6 months ago	16 (7.8)	11 (10.4)	
7-12 months ago	15 (7.3)	11 (10.4)	
1-5 years ago	89 (43.4)	45 (42.5)	
More than 5 years ago	84 (41.0)	36 (34.0)	
Not known/Not reported	0 (0.0)	0 (0.0)	
Q5. Age, mean ± SD	42.1 ± 11.8	40.5 ± 12.7	0.29
Q6. Gender, n (%)			0.26
Male	104 (50.7)	37 (34.9)	
Female	87 (42.4)	62 (58.5)	
Not Known/Not reported	14 (6.8)	7 (6.6)	
Q7. Overall amount of sleep, n (%)			< 0.001
Sufficient	14 (6.8)	18 (17.0)	
Slightly insufficient	45 (22.0)	37 (34.9)	
Somewhat insufficient	84 (41.0)	40 (37.7)	
Very insufficient	60 (29.3)	11 (10.4)	
Not known/Not reported	2 (1.0)	0 (0.0)	
Q8. Experience sleepiness, n (%)			< 0.001
None	10 (4.9)	12 (11.3)	
Mild	70 (34.1)	64 (60.4)	
Considerable	104 (50.7)	24 (22.6)	
Intense	19 (9.3)	6 (5.7)	
Not known/not reported	2 (1.0)	0 (0.0)	
Q9. Problem falling asleep at bedtime, n (%)			< 0.001
No problem	40 (19.5)	44 (41.5)	
Minor problem	63 (30.7)	35 (33.0)	
Considerable problem	70 (34.2)	22 (20.8)	
Serious problem	32 (15.6)	5 (4.7)	
Not known/not reported	0 (0.0)	0 (0.0)	
Q10. Problem staying asleep, n (%)			< 0.001
No problem	34 (16.6)	31 (29.2)	
Minor problem	66 (32.2)	45 (42.52)	
Considerable problem	72 (35.1)	25 (23.6)	
Serious problem	33 (16.1)	4 (3.85)	
Not known/Not reported	0 (0.0)	1 (0.9)	
Q11 Problem with waking up too early and not being about to get back to sleep, n (%)			< 0.001
No problem	35 (17.1)	37 (34.9)	
Minor problem	61 (29.8)	46 (43.4)	
Considerable problem	77 (37.6)	18 (17.0)	
Serious problem	32 (15.6)	5 (4.7)	
Not known/Not reported	0 (0.0)	0 (0.0)	
Q12. Overall quality of sleep, n (%)			0.0002
Satisfactory	30 (14.6)	19 (17.9)	
Slightly unsatisfactory	41 (20.0)	43 (40.1)	
Somewhat unsatisfactory	83 (40.5)	31 (29.2)	
Very unsatisfactory	51 (24.9)	12 (11.3)	
Not known/Not reported	0 (0.0)	1 (0.9)	

[a]t-tests were used for continuous data, χ^2 for categorical data unless cell population was < 5 (Fisher exact).

Table 2 continues on the following page

Table 2 (*continued*)—Differences in responses to individual questions between physician-assigned SWD diagnostic categories

	Diagnostic category, assigned by sleep physician		
Question	Definitely or Probably SWD (n = 205)	Not likely or definitely not SWD (n = 106)	P[a]
Q13. Sense of well-being during the time you were awake, n (%)			< 0.00
Normal	40 (19.5)	46 (43.3)	
Slightly decreased	62 (30.2)	38 (35.8)	
Somewhat decreased	76 (37.1)	16 (15.1)	
Very decreased	25 (12.2)	2 (1.9)	
Not known/Not reported	2 (1.0)	4 (3.8)	
Q14. Physical and mental functioning during the time you were awake, n (%)			< 0.001
Normal	46 (22.4)	51 (48.1)	
Slightly decreased	80 (39.0)	35 (33.0)	
Somewhat decreased	63 (30.7)	13 (12.3)	
Very decreased	16 (7.8)	6 (5.7)	
Not known/Not reported	0 (0.0)	1 (0.9)	
Q15. Doze off at work, n (%)			0.002
Not at all	59 (28.8)	50 (47.2)	
Slight chance	73 (35.6)	38 (35.9)	
Moderate chance	48 (23.4)	11 (10.4)	
Highly likely	25 (12.2)	7 (6.6)	
Not known/Not reported	0 (0.0)	0 (0.0)	
Q16. Doze off while driving after a non-standard shift, n (%)			0.29
Not at all	89 (43.4)	55 (51.9)	
Slight chance	64 (31.2)	24 (22.6)	
Moderate chance	23 (11.2)	9 (8.5)	
Highly likely	16 (7.8)	6 (5.7)	
Not applicable	12 (5.9)	11 (10.5)	
Not known/Not reported	1 (0.5)	1 (1.0)	
Q17. Doze off while commuting (not driving), n (%)			0.09
Not at all	58 (28.3)	33 (31.1)	
Slight chance	35 (17.1)	24 (22.6)	
Moderate chance	36 (17.6)	17 (16.0)	
Highly likely	36 (17.6)	8 (7.6)	
Not applicable	40 (19.5)	24 (22.6)	
Not known/Not reported	0 (0.0)	0 (0.0)	
Q26. Doze off while driving after at least two days off from work, n (%)			0.95
Not at all	103 (50.2)	54 (50.9)	
Slight chance	41 (20.0)	20 (18.9)	
Moderate chance	9 (4.4)	6 (5.7)	
Highly likely	5 (2.4)	3 (2.8)	
Not applicable	7 (3.4)	8 (7.5)	
Not known/Not reported	40 (19.5)	15 (14.2)	

[a]*t*-tests were used for continuous data, χ^2 for categorical data unless cell population was < 5 (Fisher exact).

that were diagnosed as negative for SWD, a number of other questions individually significantly discriminated between the diagnostic groups (see Table 2). The likely reason that these questions were not included in the reduced function is that they shared common relevant variance with the questions included. The matrix of significant correlations is given in the Supplemental Material, Table S1.

The correlation matrix was subjected to a principal components analysis with varimax rotation to determine the component structure underlying these correlations (see Supplemental Material, Table S1). In the rotated solution, there were 6 components with eigenvalues > 1.0. The Scree test suggests one major component accounting for 28.62% of the variance (Figure 2, Supplemental Material, Table S2).

Component 1 appears to be a factor reflecting sleep disturbance and associated sense of mental and physical well-being, with high loadings (correlations between each question and the component greater than 0.40) from Questions 7-16. It is reasonable to assume that any predictive value of these questions, other than 11, 13, and 15, are represented by these 3 questions in the discriminant function.

The 4 questions determined by the discriminant function to make up the final questionnaire are shown in Supplemental Materials (Figure S2). The questions are weighted by their discriminant function classification coefficients. To assess an individual's risk of SWD, the number associated with the response to each question is multiplied with the classification function coefficients listed in Table 4 and the constant added,

Table 3—Classification outcomes for step-wise discriminant function analysis

Clinical Evaluation[a]	Predicted Group Membership[b]		
	Low risk	High risk	Total
Negative for SWD, n (%)	54 (81.8)	12 (18.2)	66 (100)
Positive for SWD, n (%)	33 (26.4)	92 (73.6)	125 (100)

76.4% of original grouped cases correctly classified. [a]Physician assigned categories based on clinical evaluation. Negative for SWD consisted of physician assigning "Possible" or "Not likely." Positive for SWD consisted of physician assigning "Definite" or "Probable." [b]Predicted group membership indicates result according to screening survey.

Table 4—Fisher's classification coefficients and structure matrix for the discriminant function providing the correlation between each question and the function

Question	Classification Function Coefficients		Structure matrix for the discriminant function[a]
	Low Risk	High Risk	
Q11. Problem with waking up too early and not being about to get back to sleep	1.576	2.240	0.808
Q13. Sense of well-being during the time you were awake	1.305	2.406	0.595
Q15. Doze off at work	1.204	1.615	0.425
Q26. Doze off while driving after at least two days off from work	0.949	0.412	-0.194
Constant	-5.189	-8.859	

[a]The values in the Structure Matrix column give the correlation between each variable and the function. Thus, Q11 contributes the major proportion 66% of the variance in the function scores ($r^2 = 0.808^2 = 0.65$). Note, however, that the proportion contributed by each question includes any shared predictive value with the other questions. Hence, the total variance accounted for by all questions will exceed 100%.

Table 5—Classification outcomes from cross-validation of the final discriminant function with four variables using 61 participants

Clinical Evaluation[a]	Predicted Group Membership[b]		
	Low Risk	High Risk	Total
Negative for SWD, n (%)	12 (57.1)	9 (42.9)	21 (100)
Positive for SWD, n (%)	13 (32.5)	27 (67.5)	40 (100)

63.9% of original grouped cases correctly classified. [a]Physician assigned categories based on clinical evaluation. Negative for SWD consisted of physician assigning "Possible" or "Not likely." Positive for SWD consisted of physician assigning "Definite" or "Probable." [b]Predicted group membership indicates result according to four questions reduced from screening survey.
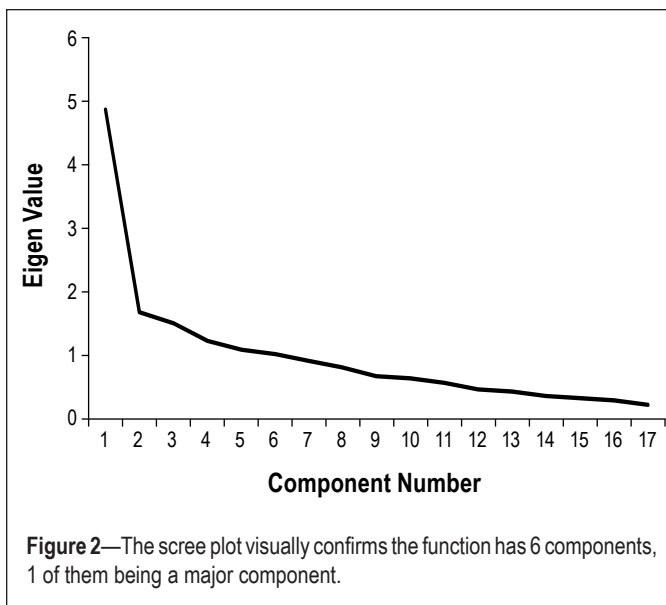
Figure 2—The scree plot visually confirms the function has 6 components, 1 of them being a major component.

for each column. The resulting score in the High Risk of SWD column are then compared with the resulting score in the Low Risk of SWD column. The higher of the two column scores indicates the individual's risk. For example, if the high risk score is higher than the low risk score, then the individual is at risk for SWD. If the low risk score is higher, then the individual is not considered at risk for SWD. This function can be easily programmed into a standard spreadsheet program.

Insomnia versus Excessive Sleepiness Symptoms

In those clinically diagnosed with SWD, 53.2% of participants responded to the question on the final 4-question survey indicating that they had a considerable or serious problem with waking up too early and not being able to get back to sleep while working non-standard shifts, indicating sleep maintenance insomnia. On the final 4-question survey, 35.6 % of participants responded to the question that they had a moderate chance of or were highly likely to doze off at work during a non-standard shift, indicating excessive sleepiness; 23.4% of participants indicated both insomnia and excessive sleepiness symptoms.

Comorbid Disorders

Of the total participants who were diagnosed as positive for SWD, 56% (115/205) were identified as "definitely" or "probably" having another (comorbid) sleep disorder, with 68% (78/115) of the comorbidities identified as sleep apnea. Shift workers that were recruited from the population (R) were less likely to be diagnosed with SWD than those who visited the sleep clinic on their own (W) ($\chi^2 = 9.42$, P = 0.0021). Those who visited the sleep clinic on their own (W) were more likely to be identified as having a comorbid sleep disorder compared to shift workers recruited from the general population ($\chi^2 = 5.54$, P = 0.019). Comorbidities included conditions other than sleep disorders such as hypothyroidism, overweight and obesity, anxiety, and depression.

DISCUSSION

We have developed and validated the first questionnaire screening instrument for SWD. The four-item questionnaire

correctly identified 76.4% of cases diagnosed to have SWD by a sleep physician, with 89% positive predictive value and 62% negative predictive value (sensitivity = 0.74; specificity = 0.82). This level of accuracy is comparable to other sleep disorders screening tools[35,36] and standard screening tools to identify risk of psychiatric conditions.[37,38]

Consistent with the ICSD2 criteria for SWD, we found the reduced set of four questions assessed both of the hallmark symptoms of the disorder. One question relates to an insomnia complaint characteristic of sleeping at an adverse circadian phase.[39] Two questions relate to daytime excessive sleepiness and impaired well-being. The final question relates to the occurrence of sleepiness following days off from work, isolating the symptoms of SWD to those that are temporally associated with the non-standard work schedule.

As sleep disturbances are common in shift workers, the diagnosis of more serious cases that meet criteria for SWD may be challenging. Moreover, the primary symptoms of SWD, insomnia, and excessive sleepiness, are also associated with many other maladies and sleep disorders.[21] The minimal criteria for SWD includes a primary symptom of either insomnia or excessive sleepiness that is temporally associated with the work schedule.[31] In screening shift workers for sleep disorders, it is essential and often challenging to distinguish between those symptoms associated with or independent of their shift work schedule. In a survey of 673 healthcare professionals, they indicated two-thirds of the cases of SWD are missed or undiagnosed.[40] Therefore, this questionnaire to identify those at high risk for SWD will be very beneficial.

Shift workers with SWD experience persistent insomnia and/or excessive sleepiness.[41] The disorder negatively affects almost every aspect of the shift worker's work and home life[42] and is associated with neurological changes.[43] A recent literature review of individual differences indicated that younger shift workers, males, and those that score low on morningness may be more tolerant to shift work.[44] Other factors that may increase a shift worker's susceptibility to SWD include genetically based vulnerability to insomnia[45-47] and genetic polymorphisms such as that of the *Per3* gene that influence sensitivity to sleep loss.[48] The length of a shift worker's intrinsic period may also influence the ability to adapt to shift work, with periods longer or shorter than 24 hours significantly decreasing tolerance.[49] Until these vulnerabilities are more fully explored, and their association with SWD is determined, our newly validated questionnaire provides a useful method of identifying high risk SWD cases based on self-reported sleep-wake symptoms.

Limitations

In drawing conclusions about the utility of the final four-question screening tool, several caveats should be noted. Although we piloted these questions with almost 5,000 police officers and conducted individual interviews with shift workers to develop the questions for general shift workers, the discriminant functions generated are limited to the questions we chose to include. Additionally, the validity of the function for discriminating between the diagnostic classes is limited by the accuracy of the clinical diagnoses made by physicians; the latter leading to misclassifications that may be due to misdiagnoses of cases. To attempt to control for the variation among

physicians and standardize the diagnosis, we limited our study to only sleep specialists at accredited sleep clinics and provided an ICSD-2 criteria-based diagnosis flowchart. To increase the generalizability of the study, we used 18 clinics in multiple geographic regions of the United States. We cannot exclude the fact that participants having just answered a questionnaire addressing symptoms of excessive sleepiness and insomnia might have affected their interaction with the physician.

Because SWD is a symptom-based diagnosis, we cannot totally exclude the issue of circularity in our validation process, as each clinic was provided with a flow chart that operationalized the ICSD-2 symptomatic criteria for SWD. No objective diagnostic test is available for SWD; hence clinical evaluation according to the specified diagnostic criteria remains the current approach in clinical practice. Circularity, however, does not appear to have been a significant factor in our study. For example, item 8 on the screening tool is a question regarding excessive sleepiness, one of the diagnostic criteria for SWD, and has the fifth highest loading on the major component in the Principal Component Analysis (Supplemental Material, Table S1), but it does not appear as a predictor in the discrimination function analysis. We speculate that this is because excessive sleepiness alone is not a major contributor to distinguishing SWD from other sleep disorders—that is, its unique contribution to SWD is not substantial, and its contribution (if any) is represented by other variables with which it correlated, possibly item 15 ($r = 0.55$) or item 13 ($r = 0.46$). Therefore, if circularity was substantially affecting the results, one would expect that the outcome of a clinician querying a patient about excessive sleepiness and a questionnaire item on this symptom would be highly interrelated and hence become a part of the final questionnaire. The outcome of the analysis we conducted demonstrates that other unique items on the questionnaire more accurately predicted SWD.

Although we attempted to obtain an approximately equal distribution of those diagnosed with and without SWD, positive diagnosis was overrepresented in our sample. Physicians participating in the study may have had a greater tendency towards a positive diagnosis of SWD given their knowledge of the overall aims of the study. The prevalence of SWD in our sample of shift workers (65.9% diagnosed by a clinician as either definitely or probably having SWD) may have also been influenced by the broad range of the non-standard shift types represented in our study sample. Nevertheless, we used well-established methods and statistical techniques to analyze the data, including cross validation. We were, however, limited in the number of participants that could be used to cross-validate the results.

Furthermore, almost one-quarter of our sample did not report having at least one week break from working non-standard shifts (e.g., one week of vacation or one week of standard daytime shifts). This limited our ability to distinguish between excessive sleepiness and/or insomnia symptoms associated with a shift working schedule and the persistence or absence of those symptoms when shift work is not occurring. The lack of a break (vacation, etc.) may be characteristic of some types of shift workers and thus makes a definitive clinical diagnosis of SWD more difficult in those individuals.

The sensitivity and specificity of the instrument in different settings (e.g., primary care clinic versus sleep clinic) remain to be

investigated. Future studies should also consider validating the survey against physiological measures. Nocturnal multiple sleep latency tests and daytime polysomnography have been used in past research for study entry criteria and to assess severity.[50] It is strongly advised that the results of the classification, at least for the cross-validation sample, be validated against these objective physiological indices of the primary symptoms of SWD.

This Shiftwork Disorder Screening Questionnaire may be appropriate for use in primary care and sleep clinic settings to aid in the diagnosis of SWD. The tool may also be used in research studies to assess the risk of adverse health, safety, and performance outcomes associated with SWD and in the development of appropriate interventions.

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DISCLOSURE STATEMENT

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Table S1—Matrix of significant correlation among questions

r	2	3	5	6	7	8	9	10	11	12	13	14	15	16	17	26
2		0.12*	0.12*													
3			0.34**											-0.19*		
5						-0.18*	-0.18*		-0.13*	-0.14*						
6											0.16*		-0.15*			
7						0.49**	0.33**	0.40**	0.41**	0.58**	0.50**	0.47**	0.38**	0.18*	0.19*	
8							0.27**	0.32**	0.30**	0.44**	0.46**	0.45**	0.55**	0.30**	0.26**	0.17*
9								0.50**	0.52**	0.42**	0.43**	0.38**	0.12*	0.15*		0.18*
10									0.67**	0.48**	0.39**	0.43**	0.18*	0.17*	0.14*	
11										0.48**	0.41**	0.40**	0.24**	0.13*		
12											0.59**	0.50**	0.35**	0.24**	0.22**	
13												0.73**	0.35**	0.26**	0.22**	0.12*
14													0.35**	0.32**	0.20**	0.18*
15														0.31**	0.28**	0.25**
16															0.32**	0.58**
17																
26																

Question number (column header); Questions number (row label)

*P < 0.05, **P < 0.001.

Table S2—Sums of squares of loadings on six principal components with eigenvalues greater than 1.0 after rotation[a]

Component	Extraction Sums of Squared Loadings — Cumulative %	Rotation Sums of Squared Loadings[b]		
		Total	% of Variance	Cumulative %
1	28.616	3.164	18.614	18.614
2	38.568	2.853	16.780	35.395
3	47.488	1.651	9.711	45.105
4	54.789	1.434	8.436	53.542
5	61.095	1.211	7.126	60.668
6	67.002	1.077	6.335	67.002

[1]Principal components analysis with varimax rotation was used to determine the component structure. After rotation, six components had eigenvalues greater than 1.0. [b]The sum of squares of loadings indicate the total variance in the variables accounted for by each factor, before and after rotation of the axes.

Table S3—Loadings of each questionnaire item on the principle component analysis-derived component (Component 1) (Loadings below 0.400 not included)

Question	Loading: correlation between the variable and Component 1
Q2. Times per week working a non-standard shift	
Q3. Started working non-standard shifts	
Q5. Age	
Q6. Gender	
Q7. Overall amount of sleep	0.699
Q8. Experience sleepiness	0.673
Q9. Problem falling asleep at bedtime	0.651
Q10. Problem staying asleep	0.673
Q11. Problem with waking up too early and not being about to get back to sleep	0.645
Q12. Overall quality of sleep	0.766
Q13. Sense of well-being during the time you were awake	0.781
Q14. Physical and mental functioning during the time you were awake	0.777
Q15. Doze off at work	0.565
Q16. Doze off while driving after a non-standard shift	0.500
Q17. Doze off while commuting (not driving)	
Q26. Doze off while driving after at least two days off from work	

Extraction Method: Principal Component Analysis. Rotation Method: Varimax with Kaiser Normalization.Rotation converged in 7 iterations.

Please read each question carefully before answering. Where necessary, answer the question to the best of your recollection. Although it is hoped that you will answer all of the questions, you may skip over any questions which you choose not to answer.

SECTION A

1. In the past month, did you typically work a non-standard shift schedule (starts before 7am or after 2pm, rotates, or regularly includes hours outside of the standard 7am to 6pm work day)?

☐ *YES*   ☐ *NO*

IF YES, GO TO QUESTION 2. IF NO, Discontinue participation.

2. On average, how many times per week do you work the non-standard shift? ☐

3. When did you start working non-standard shifts? (fill in the bubble)
○ *Less than 1 month ago*
○ *1-6 months ago*
○ *7-12 months ago*
○ *1-5 years ago*
○ *More than 5 years ago*

4. a. For non-rotating shifts, what time do you typically <u>start</u> a non-standard shift?
☐ : ☐   AM   PM   (circle one)

 b. For non-rotating shifts, what time do you typically <u>end</u> a non-standard shift?
☐ : ☐   AM   PM   (circle one)

5. What is your age? ☐ *years*

6. What is your gender? ☐ *M* ☐ *F*

SECTION B

7. In the past month, <u>while working non-standard shifts</u>, your *overall amount of sleep* was

○ Sufficient	○ Slightly insufficient	○ Somewhat insufficient	○ Very insufficient

8. In the past month, did you *experience sleepiness* <u>while working non-standard work shifts</u>?

○ None	○ Mild	○ Considerable	○ Intense

9. In the past month, <u>while working non-standard shifts</u>, did you have a *problem falling asleep at bedtime*?

○ No problem	○ Minor problem	○ Considerable problem	○ Serious problem

1

Figure S1—A 26-item screening questionnaire was administered to 311 shiftworkers.

10.   In the past month, <u>while working non-standard shifts</u>, did you have a *problem staying asleep*?

| ○ No problem | ○ Minor problem | ○ Considerable problem | ○ Serious problem |

11.   In the past month, <u>while working non-standard shifts</u>, did you have *a problem with waking up too early and not being able to get back to sleep*?

| ○ No problem | ○ Minor problem | ○ Considerable problem | ○ Serious problem |

12.   In the past month, <u>while working non-standard shifts</u>, your *overall quality of sleep* (no matter how long you slept) was

| ○ Satisfactory | ○ Slightly unsatisfactory | ○ Somewhat unsatisfactory | ○ Very unsatisfactory |

13.   In the past month, <u>while working non-standard shifts</u>, your *sense of well-being during the time you were awake* was

| ○ Normal | ○ Slightly decreased | ○ Somewhat decreased | ○ Very decreased |

14.   In the past month, <u>while working non-standard shifts</u>, your *physical and mental functioning during the time you were awake* was

| ○ Normal | ○ Slightly decreased | ○ Somewhat decreased | ○ Very decreased |

15.   In the past month, how likely were you *to doze off at work* <u>during your non-standard shift</u>?

| ○ Not at all | ○ Slight chance | ○ Moderate chance | ○ Highly likely |

16.   In the past month, how likely were you *to doze off while driving* <u>after working a non-standard shift</u>?

| ○ Not at all | ○ Slight chance | ○ Moderate chance | ○ Highly likely | ○ Not applicable |

17.   In the past month, how likely were you to *doze off while commuting (**not driving**)* <u>after working a non-standard shift</u>?

| ○ Not at all | ○ Slight chance | ○ Moderate chance | ○ Highly likely | ○ Not applicable |

SECTION C

18.   *In the past year, did you have at least a one week break from working non-standard shifts (for example, one week of vacation, or one week of standard daytime shifts)?*

☐ *YES*   ☐ *NO*

If YES, GO TO QUESTION 19. If NO, GO TO 27.

2

Figure S1 (*continued*)—A 26-item screening questionnaire was administered to 311 shiftworkers.

19. <u>During your break from non-standard shifts</u>, *your overall amount of sleep* was

| ○ Sufficient | ○ Slightly insufficient | ○ Somewhat insufficient | ○ Very insufficient |

20. <u>During your break from non-standard shifts</u>, did you *experience sleepiness during the time you were awake?*

| ○None | ○ Mild | ○ Considerable | ○ Intense |

21. <u>During your break from non-standard shifts</u>, did you have *a problem falling asleep at bedtime*?

| ○ No problem | ○ Minor problem | ○ Considerable problem | ○ Serious problem |

22. <u>During your break from non-standard shifts</u>, did you have *a problem with staying asleep?*

| ○ No problem | ○ Minor problem | ○ Considerable problem | ○ Serious problem |

23. <u>During your break from non-standard shifts</u>, your *overall quality of sleep* (no matter how long you slept) was

| ○ Satisfactory | ○ Slightly unsatisfactory | ○ Somewhat unsatisfactory | ○ Very unsatisfactory |

24. <u>During your break from non-standard shifts</u>, *your physical and mental functioning during the time you were awake* was

| ○ Normal | ○ Slightly decreased | ○ Somewhat decreased | ○ Very decreased |

25. <u>During your break from non-standard shifts</u>, how long was the *time delay you experienced in getting to sleep at bedtime*?

| ○ No delay | ○ Slightly delayed | ○ Somewhat delayed | ○ Very delayed |

SECTION D

26. How likely are you to *doze off or fall asleep while driving* <u>after at least two days off from work</u>?

| ○ Not at all | ○ Slight chance | ○ Moderate chance | ○ Highly likely | ○ Not applicable |

27. THANK YOU FOR PARTICIPATING. YOUR COOPERATION IS MUCH APPRECIATED.

3

Figure S1 (*continued*)—A 26-item screening questionnaire was administered to 311 shiftworkers.

1	In the past month, <u>while working non-standard shifts</u>, did you have *a problem with waking up too early and not being able to get back to sleep*?				
	1.No problem	2.Minor problem	3.Considerable problem	4.Serious problem	
2	In the past month, <u>while working non-standard shifts</u>, your *sense of well-being during the time you were awake* was				
	1. Normal	2.Slightly decreased	3.Somewhat decreased	4.Very decreased	
3	In the past month, how likely were you *to doze off at work* <u>during your non-standard shift</u>?				
	1.Not at all	2.Slight chance	3.Moderate change	4.Highly likely	
4	How likely were you to *doze off or fall asleep* while driving <u>after at least two days off from work</u>?				
	1.Not at all	2.Slight chance	3.Moderate change	4.Highly likely	5.Not applicable

Figure S2—The final shift work disorders screening questionnaire consists of 4 questions.