Safety and Health at Work 10 (2019) 125–129

Contents lists available at ScienceDirect

Safety and Health at Work

journal homepage: www.e-shaw.org

Short Communication

Achievements, Problems, and Future Direction of the Quality Control Program for Special Periodic Health Examination Agencies in Republic of Korea

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ARTICLE INFO

Article history:
Received 12 December 2017
Received in revised form
5 June 2018
Accepted 27 November 2018
Available online 1 December 2018

Keywords:
Audiometric test
Biological monitoring
Pneumoconiosis
Quality control program

ABSTRACT

The ultimate goal of the quality control program for special periodic health examination agencies is to diagnose the health condition of a worker correctly, based on accurate examination and analysis skills, leading to protect the worker's health. The quality control program on three areas, chemical analysis for biological monitoring since 1995, and pneumoconiosis, audiometric testing since 1996, has contributed to improve the reliability of occupational health screenings by improving the issues including standardization of testing methods, tools, diagnostic opinions, and reliability of analysis for biological monitoring. It has contributed to improving the reliability of occupational health monitoring by rectifying the following issues associated with previous monitoring: absence of standardized testing methods, testing tools that are not upgraded, mismatching diagnostic opinions, and unreliable results of biological specimen analysis. Nevertheless, there are issues in need of further improvement such as lack of expertise or the use of inappropriate method for health examination, and passive and unwilling participation in the quality control. We suggested solutions to these problems for each area of quality control program. Above all, it is essential to provide active support for health examiners to develop their expertise, while encouraging all the health screening agencies, employers, and workers to develop the desire to improve the system and to maintain the relevance.

1. Introduction

The aim of the special periodic health examination is to protect workers' health by obtaining accurate assessments of the health conditions of workers exposed to hazards in the workplace. Republic of Korea is one of the countries that have implemented the special periodic health examination system similar to Japan, Germany, and Finland [1–3].

The Ministry of Employment and Labor ordered the Occupational Safety and Health Research Institute (OSHRI) to implement a quality control program to ensure the reliability of tests addressing social concerns such as pneumoconiosis diagnoses, determination of noise-induced hearing loss, and the analysis of biological samples. Subsequently, the OSHRI commenced a quality control program in 1995 for the analysis of biological samples. In 1996, quality control commenced for pneumoconiosis and audiometric test for accurate diagnoses of occupational lung disease and hearing loss. In 2002, the OSHRI added the spirometry test to the list of pneumoconiosis quality control items.

Over the past 20 years, there have been several revisions to the quality control system preceding the current version. At present, quality control test is performed once every 2 years. As of April 2017, there were 225 participants in pneumoconiosis and audiometric test quality control and 98 participants in the quality control of biological sample analysis. The authors reviewed the achievements of quality control systems for special periodic health examination agencies in Republic of Korea, identified current problems, and suggested solutions to improve the quality of each test.

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2093-7911/$ – see front matter
https://doi.org/10.1016/j.shaw.2018.11.003

2. Pneumoconiosis quality control

2.1. Achievements in pneumoconiosis quality control

Eighty-two agencies participated in the chest radiography program in 1996. The first spirometry test program was implemented in 2002; 225 agencies participated in the program as of April 2017. The proficiency in the chest radiography program was 72% in 2005; the level has maintained above 90% from 2009 and reached 100% in 2016 (Fig. 1). The proficiency in spirometry test was 72% in 2002; the proficiency has maintained above 90% since 2011 even though the criteria have become more demanding.

2.2. Problems in pneumoconiosis quality control

2.2.1. Examiners' lack of expertise

In the spirometry test program, a review of the data from 2015 and 2016 showed 44.2% adequacy in the "appropriateness of the health questionnaire and test opinions," which was the lowest score among all items (Table 1). This item requires the examiner to describe the cause of poor cooperation during the test and provide suggestions for improvement. The low score on this item implies that the examiners were unable to identify inadequate test results and analyze the causes of these results.

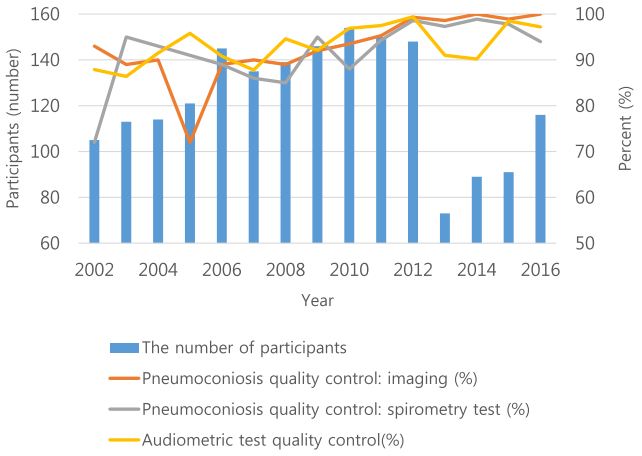

Fig. 1. The numbers and proficiency percentages of participants in the pneumoconiosis/audiometric test quality control program for special health examinations.

Table 1
Appropriateness of the spirometry test by evaluation item (2015–2016)

Evaluation item	Percent appropriateness (%)
Use of a disposable inline filter with optimal performance	97.3
Adequacy of adjustments	70.8
Adequacy of the health questionnaire and test opinions	44.2
Adequacy of the items shown on the result sheet	64.6
The number of appropriate tests performed per participant	68.1
Adequacy of the test (extrapolated volume of the test)	92.9
Adequacy of the test (coughing within 1 second, variable effort, or glottis closure)	74.3
Adequacy of the test (premature termination, or failure to reach the plateau)	77.0
Test repeatability	61.9

2.2.2. Inappropriate lung capacity prediction equation and selection of the best result

We found problems in the use of the lung capacity prediction equation. The Korean Academy of Tuberculosis and Respiratory Diseases and the OSHRI recommend the Choi equation to predict the normal lung capacity of a Korean adult [4]. However, a review of health examination data from 2015 and 2016 showed that only 6.9% of agencies used the Choi equation, 59.3% of the agencies used the Morris equation, and 15.2% of agencies used the Knudson equation [5,6]. There were 10 agencies that used the National Health and Nutrition Examination Survey III equation, which is a prediction equation for Caucasians based on a survey conducted in the United States [7]. Although it recommends a conversion factor of 0.88 for the application of this equation to Asians, no agency considered this factor [8]. In addition, two agencies used unidentifiable prediction equations. Furthermore, 20 agencies used different prediction equations with different types of equipment.

Mismatching criteria of selecting the best result was also problematic. The American Thoracic Society and European Respiratory Society recommend the maximum value for the forced vital capacity and forced expiratory volume in 1 second tests [9]. However, only 41% (84 out of 204) of the agencies followed the ATS/ERS recommendation to select the best result (Fig. 2).

2.3. Suggestions for improving pneumoconiosis quality control

The quality control program for special health examination agencies has contributed greatly to improving the reliability of occupational lung disease diagnoses. Nevertheless, there is a need for further improvements in the quality to build continuing trust.

An urgent issue is to improve the expertise of lung capacity examiners. Even if it is challenging to recruit staff and control the numbers of patients they examine, the agency should set up a system to assign specific staff for each test to improve levels of expertise. Meanwhile, it is imperative that the OSHRI develop tailored training programs and increase the capacity of the training programs to satisfy the needs of the participants in the quality control program.

The next important issue is to unify the type of prediction equation and selection criteria for the best results. At present, each health examination agency has its own prediction equation and criteria, which indicates that a worker's test result and diagnosis could differ depending on the medical facility they choose. The

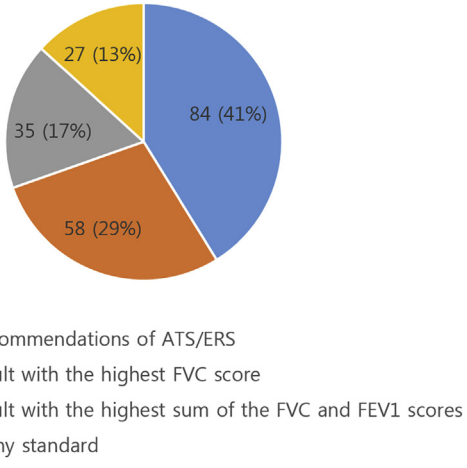

Fig. 2. The criteria used to select the best results from the spirometry test (2015–2016). ATS/ERS, American Thoracic Society/European Respiratory Society; FVC, forced vital capacity; FEV1, forced expiratory volume in 1 second.

Choi equation is highly recommended as the standard prediction equation for Koreans. However, the body types and circumstances that the equation is based on do not match current body types and circumstances as the Choi equation was developed in 2001. Another limitation is that the most recent statistics for analytical techniques are not applicable to the Choi equation. Thus, there is an urgent need to upgrade the Korean prediction equation. Moreover, as of February 2017, 210,214 foreign workers were employed in Republic of Korea under the employment permit system. Most are from Cambodia, Nepal, and Indonesia [10] and belong to different ethnic groups with unique physical features even though they share Asian characteristics [11]. Therefore, it is necessary to develop a prediction equation applicable to these foreign workers.

3. Audiometric test quality control

3.1. Achievements in audiometric test quality control

Since 2008, proficiency has been maintained at 90% or above (Fig. 1). Compared with previous studies, there were considerable improvements over the past 3 years (2014–2016) in the results from the acoustic calibration of audiometric testing equipment and ambient noise level in the audiometric test room [12,13]. Five out of 145 (3.4%) agencies exceeded the maximum permissible ambient noise level; only nine out of 145 (6.2%) agencies exceeded the tolerance for the acoustic calibration [14–16] (Tables 2 and 3).

3.2. Problems in audiometric test quality control

3.2.1. Ambient noise during on-site audiometric test

The maximum permissible noise level inside the audiometric test room was satisfactory in most locations (Table 2). However, it is necessary to control ambient noise in nonclinical locations, considering that most audiometric tests in Republic of Korea are on-site tests performed by health examiners who travel to workplaces. Currently, ambient noise during on-site audiometric test is not subject to quality control.

Table 2
The status of hearing booths for the quality control of audiometric test

Period	No. of participants	No. of failures‡	Percent failures (%)
2000–2003*	124	55	44.4
2004–2006*	158	22	13.9
2014–2016†	145	5	3.4

* American National Standards Institute S3.1-1999 applied.
† ISO 8253-1:2010 applied.
‡ Greater than the maximum permissible ambient noise level at any frequency.

Table 3
Clinical audiometers exceeding the permitted deviation from reference threshold levels for supra-aural earphones

Research period	n	Frequency of the permitted deviation* (%)	
		Left	Right
2000–2003	211	56 (26.5)	54 (25.6)
2004–2006	211	47 (24.0)	39 (19.9)
2014–2016	145	3 (2.07)	6 (4.14)

* Greater than the permitted deviation at any frequency; depending on the type of headphone, reference threshold levels from ANSI S3.6-1996 or ISO 389-9:2009 were applied.

3.2.2. Reliability of audiometric test

The results of the audiometric test from special health examinations in 2014 and 2015 revealed that a total of 86,817 workers were diagnosed with hearing loss and categorized as follows: C1, hearing loss that could develop into an occupational disease and requires further observation, but not severe enough to be classified as D1; C2, hearing loss that could develop into a nonoccupational disease and requires further observation; D1, occupational disease is suspected and requires health care; and D2, a nonoccupational disease that requires health care [17]. There were 8,016 workers with lower thresholds in the left ear in 2015 than in 2014 and 8,282 workers with lower thresholds in the right ear, with the exception of missing data (12 on the left and 5 on the right) at 4,000 Hz (Table 4).

3.3. Suggestions for improving audiometric test quality control

Problems such as a threshold change due to ambient noise as well as temporary hearing loss were more prominent during on-site examinations. These problems can be solved by performing an audiometric test only at medical facilities and not allowing on-site test. However, considering the current Korean situation, it is difficult to eliminate on-site health examination services completely. Thus, these problems can be solved by allowing on-site test for the first hearing test and performing the second hearing test (pure tone audiometry for 0.5–6.0 kHz) in the medical facilities.

At the same time, it is necessary to confirm previously whether the ambient noise during on-site examinations meets the acceptable ambient noise criterion (ISO 8253-1) at least once a day [18]. In addition, it is necessary for special health examination agencies to provide active training on the effects of ambient noise on test results for employers and employees.

To enhance the skill of the staff, special periodic health examination agencies are responsible for creating a work environment that allows longer employment of the staffs and training them to improve reliability of the task. It is also essential for agencies including the OSHRI to provide training courses on up-to-date audiometric test methods and criteria.

4. Quality control of biological sample analysis

4.1. Achievements in the quality control of biological sample analysis

The proficiency of participants ranged from 80% to 95% after the implementation of the quality control program of biological sample

Table 4
Changes in air conduction hearing thresholds among workers diagnosed with hearing loss (C1, C2, D1, or D2*) from 2014 to 2015

Decrement in air conduction thresholds at 4 kHz	Number of workers (N)	
	Left ear	Right ear
100 dB and above	35	35
70–100 dB	4	14
50–70 dB	54	60
40–50 dB	88	112
30–40 dB	250	272
20–30 dB	923	968
10–20 dB	6,662	6,821
Total	8,016	8,282

The number of workers who were diagnosed with C1, C2, D1, or D2 in 2014 and 2015 was 86,817.
* C1, hearing loss that could develop into an occupational illness and requires further observation, but not severe enough to be classified as D1; C2, hearing loss that could develop into a nonoccupational disease and requires further observation; D1, an occupational disease is suspected and requires health care; D2, a nonoccupational disease that requires health care [17].

analysis (1995–1999). The proficiency improved up to 99% in 2012 and maintained above 95% afterward (Fig. 3).

Starting from 87 participants in 1995, the number of participants reached up to 127 in 2007. A new regulation implemented in 2006 allowed the commissioned analysis of biological samples for agencies that do not expect many chemical hazard cases. As of 2017, the number of participants had reduced to 98, which represented 45% of all special health examination agencies.

4.2. Problems identified in the quality control of biological sample analysis

4.2.1. Ensuring the reliability of commissioned analysis agencies and the commissioning process

Currently, 55% of special health examination agencies commissioned all chemical analyses to other agencies. Approximately 39% of all biological monitoring samples were analyzed in commissioned agencies [19]. According to the current law, commissioned agencies can receive any sample for analysis once they pass at least one obligatory item and one subobligatory item. It should be noted that the reliabilities of the analytical results are not verified for items excluded from the quality control program. For example, most of the commissioned agencies apply for the least necessary items in the quality control program (e.g., urinary methylhippuric acid, hippuric acid, and lead and cadmium in the blood) and proceed to analyze other items without applying for those items in the program [19].

Furthermore, although the Korea Occupational Safety and Health Agency GUIDE H-60-2016 has been established as the manual for analysis commission and specimen transfer procedures [20], the analysis of some samples can be delayed due to the recommission processes. This can cause loss of stability of the analytes after the maximum duration from collection to analysis of samples [21], which can affect the reliability of the analytical results.

4.2.2. Lack of desire to apply for more items

Although the OSHRI announced that special health examination agencies should apply for one obligatory item and one or more subobligatory item, less than 20% of agencies applied for more than two subobligatory items during the last 5 years (Fig. 4). Until 2010, nonobligatory items were available for the participants, which were not included in the assessment of results of the quality control program. The participation rate for these items exceeded 44%, which was two times higher than the current rate.

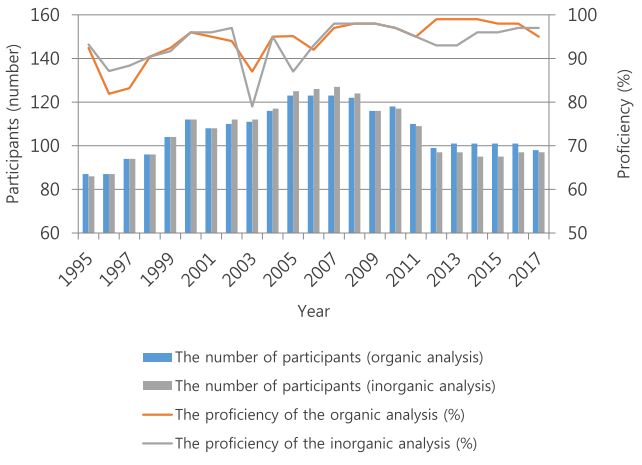

Fig. 3. Annual participation in and proficiency status of the biological sample analysis quality control program.

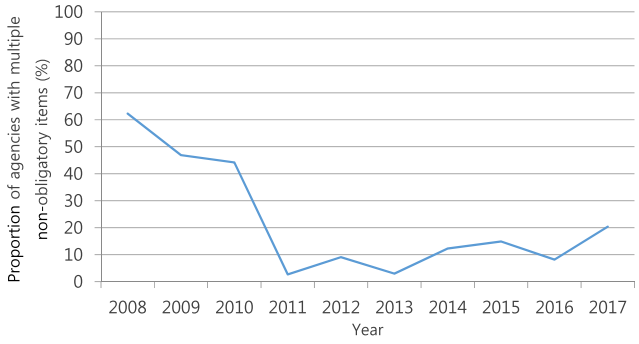

Fig. 4. Proportion of participating agencies with multiple nonobligatory items during the most recent 10 years.

4.3. Suggestions for improving quality control of biological sample analysis

It is imperative to enhance the quality management and reliability of commissioned agencies as they are responsible for more than 50% of biological monitoring data in the occupational health field. However, for analysis quality management, it is necessary to reinforce the quality control system such that the proficiency for each item is confirmed before the commissioned analysis. Information announced on a website regarding the qualification items for each agency will be a reference for other agencies when selecting a qualified commissioned agency. Guidelines for commissioning biological monitoring analyses also will be announced to all agencies to introduce the procedure of commissioning and procedures for sample transfer and storage.

While managing the commissioned agencies, it is necessary to search for strategies that provide financial and technical support for agencies with active analytical laboratories; the number of these agencies is gradually declining. For analysts to gain expertise and perform analyses in a stable work environment, it is crucial to establish strict regulations on the minimum number of analysts according to the analysis load of the agency and the minimum number of analyses per analyst through a further systematic study. Moreover, it is important to expand the number of methods and opportunities for analysis training for a variety of biological monitoring items.

Regarding a strategy to improve the lack of desire to apply for items, the implementation of nonobligatory items could be a solution. As formal evaluation results from quality control will include obligatory items only, the agencies can apply for active analysis items voluntarily. Moreover, the agency can earn additional points based on the evaluation results for the nonobligatory item in the periodic evaluation program for special health examination agencies. This will contribute to greater and more diverse participation in the quality control program to improve analytical quality.

5. Conclusion

It is evident that efforts by the OSHRI have greatly contributed to the increased reliability of chest radiography examinations, spirometry test, audiometric test, and biological sample analysis. These efforts need to be continued to maintain reliability. The most important tasks involve solving the aforementioned problems pertaining to the examiners' expertise, selection of the best results, using appropriate prediction equations for spirometry and on-site audiometric test, and the commissioned analysis agencies.

It is it is necessary to reach an agreement that meets the social expectations for the quality control program and minimizes

complaints from health examination agencies. They consider that the program is based on extremely strict regulations with limitations to increase test quality by systematic regulations alone. The ultimate goal of quality control is accurate health examinations for workers. This is feasible only if health examination agencies make a voluntary effort to improve reliability, not from coercion or regulations, but from a sense of responsibility and duty toward the workers.

The quality control program for occupational health examination agencies and systems is undergoing a transitional period. While traditional occupational diseases remain problematic, it is imperative to proactively address rapid changes in the industrial structure and new health hazards. Flexible responses are required for the development of new diagnostic methods and the improvement of diagnostic criteria based on new theories. The Ministry of Employment and Labor and the OSHRI will provide support to the system including active improvements and timely technical support to create a system that accommodates the present changes and meets approval from the society.

Conflicts of interest

The authors declare that they have no competing interests.

Acknowledgments

The authors acknowledge Occupational Safety Health Research Institute, Korea Occupational Safety and Health Agency to organize and support quality assurance program to protect the health of workers.

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