SUBMISSION BY

AUSTRALIAN AND NEW ZEALAND SOCIETY OF RESPIRATORY SCIENCE INC.

TO

SENATE COMMUNITY AFFAIRS REFERENCES COMMITTEE INQUIRY INTO

WORKPLACE EXPOSURE TO TOXIC DUST

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EXECUTIVE SUMMARY

The Australian and New Zealand Society of Respiratory Science (ANZSRS) is the professional body representing those working in the field of respiratory science. The Society has expertise in all areas of lung function assessment including aerosol medicine, spirometry and other methods of assessing lung function, in education and the setting of standards. The Society has recently successfully completed a Spirometry User's Guide for the Australian Government (Department of Health and Aging) in association with the Thoracic Society of Australia and New Zealand.

We are making this submission to draw attention to the following key areas:

1. Characterisation of dust must include discussion of particle size distributions, not just dust concentrations.
2. Pre-employment screening forms the basis for comparison and must include good quality lung function assessment – as a minimum good quality spirometry. This is not presently done well and tends to be limited to investigation of asthma alone.
3. The success of any respiratory function monitoring process for workplace exposure depends on suitable training of those performing spirometry, and other lung function assessment as required. This is commonly done poorly at the present time and hence the accuracy of diagnosis and the early recognition of adverse responses to exposure can be compromised.
4. Reports produced from lung function testing should have specifications, so as to preserve the quality of testing and ensure that reports are able to be interpreted consistently from site to site and from testing session to testing session.
5. ANZSRS is the repository of expertise in this field and would welcome consultation in establishing guidelines for lung function testing, training, interpretation and quality assurance of the assessments. We also have considerable expertise in the area of equipment standards and suitability.

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BACKGROUND

The Australian and New Zealand Society of Respiratory Science (ANZSRS) is the professional body representing those working in Respiratory Function Laboratories throughout Australia and New Zealand. Members work in public and private laboratories, in secondary tertiary and quaternary hospitals and universities. Many members are actively involved in teaching and research. The Society has as its aims the following

- *promoting education and training in respiratory science and excellence in respiratory measurement*
- *fostering the exchange of scientific and technical information between members*
- *facilitating dialogue with other professional societies*

Recent achievements of the Society include

- The development of a credential in Respiratory Science with a focus on respiratory function assessment (Certified Respiratory Function Scientist, CRFS)
- The development of a Spirometry Users Guide for the Commonwealth Department of Health and Aging, in association with the Thoracic Society of Australia and New Zealand (TSANZ)
- The establishment of a Spirometry Course endorsement programme which requires course content including handouts, reference material and assessments to be evaluated by an expert committee of the Society prior to being endorsed.
- The Annual Scientific Meeting of the Society attracts many eminent scientists/clinicians from around the world as guest speakers and is a highly regarded meeting in the international calendar.

The Society has hosted two international aerosol symposia as part of our annual scientific meetings and has considerable expertise in this field. The Society is also actively developing a voluntary registration process in parallel with the recent legislative changes in New Zealand requiring respiratory scientists to be registered. There is a joint project running at the present time with the National Asthma Council to develop a national training course in spirometry for General Practitioners.

We believe that, as a professional Society, we have both an interest and expertise relevant to sections b, c, d and e of the committee's terms of reference. Our submission focuses primarily on the quality of spirometry performance, the interpretation and the reporting of the results and the training required to achieve competence. This pertains to diagnostic and management aspects for those exposed to dusts in the workplace but also to historical reporting of progression of the consequences of dust exposure.

SUBMISSION

Section b. *The adequacy and timeliness of regulation governing workplace exposure, safety precautions and the effectiveness of techniques used to assess airborne dust concentrations and toxicity.*

The proportion of inhaled particles deposited in the respiratory tract depends on the geometry of the airway and on the particle sizes inhaled (Bates DV, 2005) Any regulations governing safety issues must include reference to particle sizes and distribution. It is not sufficient to consider only dust concentrations and chemical toxicity. This applies to not only dust generation, but also to the efficacy of safety equipment eg masks and filters. In general we believe this is well done presently with respect to particulates.

There has been a lot of work published categorising aerosols in terms of inhaled particle sizes and patterns of deposition in the lungs (Hallworth, 1993). ANZSRS has specific expertise in the area of aerosol inhalation.

Section c. *The extent to which employers and employees are informed of the risk of workplace dust inhalation.*

The provision of regular reports to employers and employees is an important way to reinforce the risks of exposure to dust inhalation in the workplace. By documenting the consequences of exposure and documenting the lack of consequences reinforces both the need for protective equipment to be used and that the equipment and practices in use are doing their job.

Any processes that are designed to inform employers and employees must include pre-employment screening for existing conditions that may make an employee more susceptible than usual to hazards in the workplace. Spirometry is well recognised as a valuable tool in the clinical evaluation of both early lung disease and accelerated rates of decline of lung function (Anthonisen *et al.*, 1986;Crapo, 1994;Tockman & Comstock, 1989). It is also well established that rates of change in respiratory function indices are very important in diagnosing and managing changes in lung function. Identification of rates of change also requires good quality spirometry before any disease process is established. Thus spirometry should be seriously considered as a minimum in pre-employment screening where there are work place exposure risks.

It is also important that the pre-employment screening investigation is matched to the exposure risks likely to be experienced. In many situations a comprehensive lung function assessment would be justified, as spirometry would lack the diagnostic power required obtaining a secure baseline against which changes can be measured.

Pre-employment spirometry would also help address the questions of contributions to airway and parenchymal lung dysfunction due to volitional practices, such as smoking, from workplace exposure to dusts.

Section d. *The availability of accurate diagnoses and medical services for those affected and the financial and social burden of such conditions.*

Spirometry provides very useful information regarding obstructive lung conditions, their development and progression (Anthonisen *et al.*, 1986;Crapo, 1994;Rosenstock, 1994;Tockman & Comstock, 1989). These conditions include asthma and chronic obstructive respiratory disease. This should provide the basis of employee monitoring. When used in isolation, spirometry is less effective as a diagnostic tool for interstitial lung conditions. Interstitial lung conditions include asbestosis, heavy metal diseases, and fibrosing alveolitis. They are commonly caused by inhalation of dusts. However, when correctly performed using appropriate methods and accurate instrumentation the results can be used as an indicator that more detailed investigation is required. More complex lung function tests such as the measurement of lung volume subdivisions (to identify air trapping in the lung and impairment of air movement within the lung) and diffusing capacity (to identify loss of ability to extract oxygen from the air in the lungs) are necessary to characterise interstitial processes and are also helpful in characterising obstructive conditions. These tests are readily available in teaching hospitals and many private laboratories. A case could be made that where particulate dust exposure is a risk, comprehensive lung function testing should form the basis of pre-employment screening.

The critical factor is early identification of deteriorating lung function. One of the difficulties in respiratory medicine is that the lungs have a large reserve in function, about 33% that can be eroded before there is any symptomatic evidence of deterioration. There is good evidence linking excess loss of lung function to cumulative dust and fume exposure (Oxman *et al.*, 1993). A loss of up to 20% of lung function, compared with predicted values for the individual, which is the commonly used threshold for abnormal results or waiting until an employee is affected by symptoms, is a very blunt approach to monitoring. Regular lung function testing will provide early detection of loss of function well before the results fall to 80% of predicted. This is important for people with lung function at the high end of the reference range for whom a 20% fall is very significant indeed. This also avoids problems with ethnic correction of the data. Many races have been suggested to require a reduction in Caucasian predicted values from 12% to 20% but there is a paucity of data defining this and few races have specific prediction equations available for them. Furthermore, the correction required will change with time through interracial mingling and environmental change. Prediction is based on height, as an index of chest volume, and this clearly depends on body proportions, which change between races and with anything that influences growth such as diet.

There has been a lot of work conducted internationally on standards for performance of all lung function tests. The American Thoracic Society (ATS), European Respiratory Society (ERS), American Association of Respiratory Care (AARC), British Thoracic Society (BTS) and other learned Societies have all developed and published guidelines for spirometry, lung volume measurement, diffusing capacity, provocation testing and cardiopulmonary exercise testing. ANZSRS has adopted the ATS guidelines and most laboratories operate to these standards. ATS and ERS guidelines have just been revised and reformulated as joint statements between ATS and ERS. The newly revised spirometry guideline has just been published (Miller *et al.*, 2005) and others can be found on the ATS website http://www.thoracic.org/statements.

There have been a number of studies presented at the ANZSRS Annual Scientific Meetings by members of the Society evaluating predicted equation sets for the Australian and New Zealand populations. This has lead to a much greater standardisation of equations in hospital laboratories across the country.

It is well established that the quality of spirometry performed in the primary care sector is not good (Eaton *et al.*, 1999;Schermer *et al.*, 2003;Enright *et al.*, 1991). The ATS has stated, in the context of spirometry, that "The largest single source of within subject variability is improper performance of the test" (ATS Position Statement, 1991) This poor quality of performance prompted the project within ANZSRS to formulate training expectations and the spirometry training course endorsement programme. The prescribed course syllabus includes instrumentation, performance of spirometry, choice of predicted equations, interpretation, quality assurance and infection control. Full details can be found at http://www.anzsrs.org.au/positionstatements.html. An important component of any training course is ongoing audit/quality assurance and training refresher courses (Enright *et al.*, 1991) and this is recommended in the ANZSRS statement.

This same problem with primary care spirometry quality is also the driver for the joint initiative with the National Asthma Council to develop the National Training Course with a focus on General Practitioner Spirometry.

A major concern with spirometry in the primary care sector is the lack of quality assurance. Instruments are sold to practices with the advice they never need calibrating. While this may be true, or more correctly the instrument is unable to be calibrated by the user, every instrument requires regular validation. This is rarely done well, if at all, outside lung function laboratories offering comprehensive investigations.

An important adjunct to spirometry training is the gaining of the CRFS credential by those working in the field. This is presently available, by examination, to members of ANZSRS. A prerequisite is that the person sitting the examination has a Bachelor of Science degree in a relevant field, or equivalent, plus a specified number of years of experience working in the field.

The ATS has developed detailed specifications for diagnostic and monitoring spirometers (ATS, 1995)

Section e. ***The availability of accurate records on the nature and extent of illness, disability and death, diagnosis, morbidity and treatment.***

Spirometric and other respiratory function results, including cardio-pulmonary exercise tests, are integral components of disability assessments eg Australian Medical Association guidelines.

The ATS makes specific recommendations regarding the report to be generated by a spirometer and this needs to be included in any regulations pertaining to the reporting of results. We would recommend that any lung function report should contain the following as a minimum and be of sufficient size that all information is easily read and can form part of a permanent record:

- Unique identifier for patient.
- Numeric data for specified parameters (eg FEV_1, FVC, FEV_6, FEF_{50}, FEF_{25-75}, PEF, FIF_{50}, FIF_{50}/FEF_{50}, PIF)
- Predicted values, % predicted and lower limit of reference range for each parameter selected. If testing is done before and after the administration of bronchodilator then % change should be included as well.
- Flow/volume and volume/time graphics

- Date of last calibration / validation check, date and time of test, operator name
- The prediction equation set used in generating the report must be identified.
- Comments regarding reproducibility and quality of test manoeuvres.

The utility and accuracy of an interpretation depends to a significant degree on the appropriateness of the prediction equations against which the results are gauged. The choice of these equations will vary from population to population and they must be chosen very carefully (ATS Position Statement, 1991).

It is in the area of serial monitoring that quality assurance plays a very critical role. The physician reviewing the test results must be able to have absolute confidence that the tests have been performed to the same standard every time. The data quality must be independent of any changes in equipment, changes of staff or the time since the person doing the testing has had refresher training. Only with these guarantees can the physician concerned know that any changes are due to changes in the patient's profile. Furthermore, it is the serial changes that are crucial to successful early detection and management of any disease process that may result from workplace exposure. Negative trends can be apparent even though the absolute measures are still within the reference ranges.

The need for consistency of approach is becoming increasingly important as the workforce becomes more mobile. Data from one area should be able to be compared with data from another area in the interest of gaining long term trending and separating pre-existing trends from current trends.

Any instrumentation used for monitoring respiratory function should have the capability of producing serial data reports either directly or via a computer interface.

SUMMARY

In summary ANZSRS wishes to stress the importance of incorporating the following into any legislative changes that may be sponsored following this committee's deliberations:

1. We believe it is important that any regulations defining dust concentrations and toxicity include reference to particle size distribution within the dust. This applies to both the workplace and to the efficacy of protective equipment.
2. Good quality baseline spirometry should be a minimum in pre-employment screening where there are workplace dust risks. Monitoring of workers should focus on the rate of change in spirometric indices rather than simply on absolute values.
3. There should be specified training expectations for those performing and interpreting spirometry in the workplace. It would be hoped that any courses being accepted as suitable are endorsed by ANZSRS.
4. There should be specifications provided for the reports produced so as to include a unique identifier for the patient, flow/volume and volume/time graphics as well as numerical data and the minimum data set to be reported. In the interests of quality assurance, reports should include predicted set in use, last calibration/validation date, operator name, time and date of test and an identifier for the instrument.
5. Instruments in use should be documented as meeting the standards defined by the ATS (ATS, 1995).
6. Instruments / software in use should be linked to appropriate predicted equation sets so as to provide consistency of approach when considering "percentage of predicted" data.
7. ANZSRS is the repository for expertise in the field of respiratory function testing and as such should be consulted in the formulation of guidelines surrounding the above recommendations.

GLOSSARY

Aerosols

Aerosols are suspension of fluid droplets that may or may not contain particulate material.

Airways

The airways are the tubes that lead to the gas-exchanging region deep in the lung itself. They do not allow for gas exchange but can become inflamed thereby preventing effective flow of air to the lung and compromising breathing.

ANZSRS

Australian and New Zealand Society of Respiratory Science. http:///anzsrs.org.au

Asthma

Asthma is an obstructive condition characterised by reversible airflow obstruction. A significant contributor to the airway narrowing is the constriction of the muscles lining the airway due to irritation by inhaled dusts and aerosols.

ATS

American Thoracic Society. http://www.thoracic.org

Calibration

Calibration is the act of setting an instrument to produce a standard output when a standard input is provided. For instance, setting the instrument to red a volume of 3.0 litres when 3 .0 litres is injected into it from an accurately standardised syringe. The need for regular calibration is defined by the design of the instrument with some needing calibration every session and others not being able to be calibrated by the user. This is quite distinct from validation.

Cardio-pulmonary exercise testing

This procedure measures the breathing and cardiac response to an exercise challenge along with measurement of oxygen consumption. This is particularly useful for assessing shortness of breath whether due to respiratory or cardiac dysfunction or simply lack of fitness. It is also an important test in assessing disability.

CRFS

Certified Respiratory Function Scientist. This is the credential offered by examination, 80% pass mark, by ANZSRS.

Diffusing capacity

A measure of the ability of the body to extract Oxygen from the air inhaled into the lungs. This is an important index when assessing interstitial lung disease.

Interstitial lung disease

Interstitial lung diseases are those diseases that result in a thickening of the membranes interposed between the blood and the air in the lungs. This happens in many conditions that arise from dust exposure and results in an impaired work capacity secondary to an inability to raise the amount of Oxygen able to be delivered by the blood to the muscles. This often results in stiffening and shrinkage of the lung.

Lung volume subdivisions

The matching of breathing to the demand for Oxygen requires that the lung has reserves of volume so that ventilation can be increased (at rest a healthy individual may breathe approximately 10 litres of air per minute but at maximal exercise may breathe 120 litres per minute). In lung disease this reserve is eroded by increases in the amount of air trapped in the lung (increased residual volume in emphysema) or loss of lung volume due to lung stiffening due to interstitial lung diseases (reduced residual volume and total lung capacity).

Obstructive lung disease

These are the conditions where airflow into and out of the lung is reduced due to muscle spasm (asthma), inflammation of airways (bronchitis) or airway collapse (emphysema).

Parenchyma

The parenchyma is the tissue of the lung itself as opposed to the airways.

Provocation testing

This is a test used to determine the sensitivity of the airways to irritation by inhaled agents. The provocation could be chemical (histamine, saline) or, physical (exercise). On occasions specific workplace agents can be used to test for sensitivity but this is a highly specialised procedure that has attendant high risk.

Quality Assurance

Quality Assurance is the total process that ensures test results are accurate, reproducible and consistent from one session and laboratory to another. A good Quality Assurance programme will also ensure the tests performed are appropriate to the question being asked and that the data reported provide the required information.

Spirometric indices

There are many indices of both expiratory and inspiratory airflow. The useful indices are those that describe the relationship between lung volume and airflow. All the numbers provided are efforts to describe the shape of this flow volume relationship.

Spirometry

Spirometry is the measurement of airflow into and out of the lung. Two core indices are measured namely the maximal volume of air that can be breathed out (FVC) and the amount of air that can be blown out forcefully in 1 second ($FEV_{1.0}$). This latter measure provides information about the state of the airways. The most useful information is the graphical representation of the relationship between the volume of air in the lungs and the rate at which the air can move out of the lungs – the Flow/Volume loop.

TSANZ

Thoracic Society of Australia and New Zealand. http://www.thoracic.org.au

Validation

The demonstration and documentation that an instrument produces the correct result. This is usually achieved through the use of syringes and trained subjects. This is required in addition to calibration.

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