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REVIEW OF RESPIRATOR PERFORMANCE TESTING IN THE WORKPLACE: ISSUES AND CONCERNS

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Performance capability of respirators has traditionally been evaluated by testing components of the respirator (e.g., filter efficiency), facepiece fit, total inward leakage, or some other measure of performance evaluated under laboratory conditions. In recent years, increased emphasis has been placed on development of test methods suitable for evaluating respirator performance in the workplace. The goal of such testing is to evaluate the level of protection provided by respirators in the work environment. The AIHA Respiratory Protection Committee believes that workplace testing of respirators has the potential to be an excellent tool for increasing knowledge about the effectiveness of respiratory protection. However, a number of technical issues remain to be addressed before optimal test protocols and data analysis methods can be defined. The progress made to date in workplace testing will be reviewed, and broader discussion about key elements that must be considered when developing guidelines for testing respirators in the workplace will be initiated.

In situations where respirators are used to control worker exposure to hazardous airborne contaminants, the respirator program should include means for ensuring the quality and effectiveness of the respirators. A common starting point for this process is selection of respirators approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH/MSHA). NIOSH/MSHA certification criteria include laboratory methods for testing filter efficiency, cartridge service life, breathing resistance, and other properties of respirator performance.[1]

Researchers evaluating respirator performance frequently use results from these or similar laboratory tests as performance benchmarks to provide some indication of the respirator's workplace performance. However, the ability of laboratory performance data to predict workplace performance of respirator ensembles remains unclear. No research studies have been reported or found in the literature that have identified such correlations. Those that have attempted to identify such correlations have been unsuccessful.[2–5] This has led to increased interest in evaluating the performance of respirators in the workplace. In fact, NIOSH has proposed that workplace testing or simulated workplace testing be incorporated into respirator certification tests.[6]

The AIHA Respiratory Protection Committee believes that workplace testing of respirators holds promise for increasing knowledge about the effectiveness of respiratory protection. The committee reviewed published workplace studies and other sources of information to evaluate test methodologies and data analyses that have been used to date. On the basis of that review, the committee has identified a number of technical issues that it believes need to be resolved before standardized test protocols and data analysis methods can be defined. Issues not yet completely resolved were classified for this review into several general categories. These include concerns about (1) study objectives, (2) site selection, (3) subject selection and preparation, (4) sampling procedures and analytical methods, and (5) data analysis procedures.

This review focuses on each of these areas for the purpose of referencing work that has been reported or published. Methodology that appears to make sense is cited. Potential sources of variability that may not yet be controllable to the extent necessary for standardizing test methods are listed.

PROTECTION FACTOR

The U.S. Bureau of Mines, in its Approval Schedule 21B issued in 1965, made reference to the term *decontamination factor* and defined it to be "the ratio of the concentration of dust, fume, or mist present in the ambient atmosphere to the concentration of dust, fume, or mist within the facepiece while the respirator is being worn."[7] This term is no longer used in the respirator literature, but an analogous term, *protection factor* (PF), has taken its place.

The protection factor, like the decontamination factor, represents an expression of the performance of a respirator based upon the ratio of two generalized concentration variables, C_o and C_i. The variable C_o is defined as the measured concentration of a contaminant outside the facepiece of the respirator, and the variable C_i is defined as the measured concentration of a contaminant inside the facepiece of the respirator. These concentration variables, in addition to being used to define a protection factor, can be used to express the penetration (P) or efficiency (E) of the respirator.[8] An equality exists between protection factors, penetration, and efficiency as follows:

$$P = C_i/C_o$$

$$E = (C_o - C_i)/C_o$$

$$PF = C_o/C_i = 1/P = 1/(1 - E)$$

Therefore, the protection factor is simply another way of expressing the penetration or efficiency of a respiratory protection ensemble.

Protection factors serve as criteria used by regulatory agencies and occupational safety and health professionals to determine, for different classes of respirators, the limiting concentration of contaminant(s) in the ambient environment against which the respirators would afford adequate protection to the user. For example, if a respirator has a protection factor of 10, it would be considered suitable (assuming it was properly selected, fitted, and used) to protect workers at exposure concentrations up to 10 times the Occupational Safety and Health Administration's (OSHA's) permissible exposure limit (PEL) or the American Conference of Governmental Industrial Hygienists' (ACGIH) threshold limit value (TLV).

The NIOSH *Respirator Decision Logic*,[9] the 1980 American National Standards Institute (ANSI) *Practices for Respiratory Protection*,[10] and several OSHA health standards, such as the lead standard,[11] assign protection factors to different classes of respirators. Assignment of protection factor values was initially based solely on data produced by quantitative facepiece fit tests (QNFTs). More recent protection factor reviews have also considered data generated by protection factor studies conducted in the workplace.

Protection Factor Terminology

When reviewing the literature on respirator performance testing, a reader often encounters ambiguity in use of the term protection factor. Historically, estimates of respirator fit originating from quantitative fit testing were routinely referred to as protection factors.[12–17] In these classical determinations, fit was expressed as a ratio of C_o/C_i. The concentration outside the facepiece, C_o, represented the concentration of aerosol inside the test chamber. The concentration inside the facepiece, C_i, represented the leakage through the face seal area that entered the respirator during certain head and face movements, speaking, and normal and deep breathing patterns.

When results of workplace testing began appearing in the literature, protection factor was also used to express the respirator performance data measured from those studies.[18–22] In addition, these early workplace studies often differed because the protection factors being measured and reported were not necessarily comparable. By the late 1970s, protection factor was appearing in the literature with several different meanings and interpretations. The term was being used to refer to respirator performance in the laboratory and the workplace. Unfortunately, the ambiguity in using protection factor continued for some time without the terminology problem being resolved.

In the early 1980s, two respirator research laboratories put forward a number of respirator performance definitions in an attempt to clarify different measures of respirator performance.[8,23] Working with those definitions, the AIHA Respiratory Protection Committee published a series of performance definitions to help reduce confusion about protection factor terminology.[24] The performance definitions proposed by the committee included the following: assigned protection factor (APF), workplace protection factor (WPF), effective protection factor (EPF), program protection factor (PPF), and simulated workplace protection factor (SPF), as well as qualitative fit factor (QLFF), quantitative fit factor (QNFF), and filter efficiency factor (FEF). Each term, while still constituting a protection factor ratio, has been distinctly defined depending on the conditions around which the measurements of C_o and C_i are made.

For example, respirator performance results obtained from quantitative fit tests (QNFTs) are now generally referred to as fit factors, and as such are considered to be different than workplace protection factors.

The objective of any given study of respirator performance will determine the type of protection factor that will be measured. Use of proper respirator performance terminology by the respirator community is necessary for meaningful categorization of respirator performance and comparison of study results.

SUMMARY OF LITERATURE REVIEW

Respirator performance terminology used in early workplace studies[18–22] is usually not consistent with current respirator performance terminology. However, descriptions of the methodology used in these early studies are generally complete enough to retroactively categorize the studies by the type of protection factor actually measured.

The first workplace protection factor (WPF) study was conducted on powered air-purifying respirators.[25] This study was followed by studies that evaluated a variety of half- and full-facepiece respirators and other powered air-purifying respirators.[2,5,26–32]

In general, the goal of these WPF studies was to measure protection provided by a respirator that was properly selected, fitted, and conscientiously worn and used. Attempts were made to measure in-facepiece concentrations only while the respirator was properly donned. Where this goal was achieved, resulting

WPFs might reasonably be considered estimates of performance capabilities of respirators in a well-run respirator program.

Some of these WPF studies were better controlled than others and, therefore, better able to generate results that meet the definition of a WPF. Critical review of the test protocols followed in individual studies may explain some of the differences in results obtained.

Many more WPF studies have been reported at a variety of professional and scientific meetings but not yet published in the literature.[3,4,33–42] These studies provide additional information of value for conducting critical review of WPF studies conducted in the workplace.

Effective protection factor (EPF) studies have been conducted on half-mask air-purifying respirators and powered air-purifying respirators.[18–20,43–45] These studies evaluated the performance of respirators that were properly selected, fitted, and conscientiously worn and used. In contrast to WPF studies, in-facepiece sampling was done during periods of respirator use as well as during periods of nonuse. Thus, results from these studies might be considered estimates of the effectiveness of respirator use policies, rather than estimates of respirator performance capability. As was the case for WPF studies, there are also a number of unpublished EPF studies worth referencing.[46,47]

Program protection factor (PPF) studies have been conducted on a number of half-mask air-purifying respirators and supplied-air respirators.[21,22,48,49] These studies involved evaluation of respirators that may or may not have been properly fit tested, worn, stored, or otherwise used in accordance with the manufacturer's selection and use guidelines. Results from these studies might be considered estimates of how well the respirator program is set up or functioning, as opposed to measures of respirator performance capability or respirator use practices alone. Once again, a number of unpublished PPF studies may be useful references.[50,51]

A review of the literature shows that studies conducted in the workplace to evaluate respirator performance, regardless of their objective, have more logistical problems and variability than laboratory testing. Simulated workplace protection factor (SPF) studies have been suggested as a possible way to merge the beneficial aspects of laboratory and workplace testing. Large chambers with variable but controlled environmental conditions have been used on a limited basis for these types of studies.[52–54] SPF study results have so far confirmed, not contradicted, results from workplace (WPF, EPF, and PPF) studies. Future SPF studies may prove to be particularly useful for addressing many of the variability issues and other questions raised by workplace studies.

When protection factor studies are undertaken, whether in the workplace or under simulated workplace conditions, the test protocol needed will vary significantly depending on the type of protection factor information desired.

Before deciding to conduct a protection factor study, another significant outcome of workplace testing should first be considered. In-facepiece sampling may be a very valuable exposure assessment tool.[55,56] From a practical and professional standpoint, many industrial hygienists may find it more straightforward and more useful to use in-facepiece sampling to evaluate worker exposures rather than to determine protection factors provided by a respirator. In-facepiece sampling offers the potential of providing the industrial hygienist with data critical for evaluating health risk. On at least one occasion, an OSHA citation of alleged violations was challenged because OSHA did not show that an employee was actually exposed to excessive levels of silica dust inside his respirator. The employer claimed that OSHA failed to meet the burden of proof because readings were taken outside the employee's respirator.[57]

A literature review also has indicated that sampling inside a respirator facepiece presents some difficulties not encountered with standard personal (lapel) sampling techniques. Review of a number of literature references will provide useful background information on this issue. Articles describing basic physics of aerosol entry into holes the size of small respirator leaks should be consulted.[58–63] Other useful articles describe findings and experiences related to measuring respirator performance through quantitative fit testing,[12,13,15–17,64] define factors that may bias air contaminant concentration measurements inside of respirator facepieces,[65–71] and discuss probe design.[72]

OBJECTIVES

The objective of testing respirators in the workplace must be clearly defined before a suitable test protocol can be developed. The goal may or may not be to quantify performance of a respirator by conducting a workplace protection factor study. One goal may be to use in-facepiece sampling techniques to obtain more accurate estimates of the actual airborne exposures workers receive while using respirators. Another goal might be to develop a program protection factor estimate, which would be specific for a given respirator type, respirator program, and work environment. Such estimates could be used as a means of providing respirator program audit data. Alternatively, the data might be useful for developing charts on respirator performance, such as R-bar charts, commonly used in quality assurance programs.

In any case, clear and consistent terminology must be used for study results to be meaningful. It is not sufficient to state that the objective of a study is to define the protection factor provided by a respirator worn in the workplace.

Site Selection

In-facepiece sampling techniques might reasonably be used in virtually any workplace if the goal is to estimate actual air contaminant exposures of workers wearing respirators. The same is not true if the intention of such sampling is to generate protection factors for respirators in use. Valid or meaningful protection factors depend on the researcher's ability to control, or at least identify and understand, the impact of several variables.

Important site-selection considerations include type of operation, size of work force wearing respirators, physical layout and accessibility to work areas, distance between work areas, availability of "clean" areas for sample setup and changing, variability of work processes, duration of respirator use, work rates and movements, amount of interruption of work tasks that can be tolerated, impact of interference with workers, safety rules, type of respirators being used, other protective equipment in use, air contaminants present, available air-sampling data, completeness of respirator program, compliance with fit testing and training program elements, management interest and commitment to a study, and clearance to take photographs for study documentation.

The goal of the protection factor study will determine how important these and other site-related variables are to the study protocol. For example, completeness of the respirator program may not be an important factor for site selection in a program protection factor (PPF) study, but it is critical to site selection for workplace protection factor (WPF) and effective protection factor (EPF) studies.

Subject Selection and Preparation

If the goal of in-facepiece sampling is to generate exposure data as part of an industrial hygiene evaluation, virtually any worker could be a suitable test subject. The situation is considerably different if the purpose of the sampling is to generate protection factor information.

The most critical needs for good subject selection in a protection factor study appear to be the subject's willingness to participate in the study, level of training and understanding of that training, experience with the respirator to be tested, fit capability, exposure level, and job task. WPF and EPF studies in particular require that test subjects be familiar with the respirator, perform a job for which the respirator is appropriate, be trained in proper fitting and use, be capable of getting a good fit, and be willing to follow established respirator use policies.

The worker's level of experience should be identified because it may have a significant impact on test results. Other criteria, such as age, work rate, facial size, facial hair, eyeglass requirements, medical or job restrictions, and work location should be controlled or recorded as necessary to meet the study objective.

In some cases, it may be necessary to conduct education and training programs or perform fit tests prior to sampling. Fit tests must be suitable for the type of respirator involved. At least one published study used a fit testing method unsuitable for the respirator involved.[31] Where qualitative fit tests are used, those with established protocols and a full regimen of exercises should be used.[11] Where quantitative fit tests are used, manufacturers' recommendations, recent work on variability and test design,[60-68] and recent OSHA and American National Standards Institute (ANSI) guidelines should be referenced.[10,73]

Sampling Procedures

The biggest concern with in-facepiece sampling procedures is the ability to obtain reproducible results. Respirators must be fitted with a probe for this type of testing. Various probe locations have been evaluated with different face seal leak sites and different breathing patterns.[65-67] A sampling bias related to probe location, probe depth into the facepiece, and sampling method (continuous flow versus pulsed flow) has been identified. A problem with unaccountable variability (sometimes called random error) has also been noted.

Laboratory research on sampling bias has concentrated on vaporous test agents. More work is needed to evaluate sampling bias with particulate test agents, better define sources of random error, determine how the laboratory research relates to workplace testing, and identify and validate improved sampling methods that can be incorporated into workplace studies.

Although optimal sampling methods have not yet been defined, several key elements of importance can be identified. Probe location is critical. The best current advice is to locate the probe opposite the mouth. If that is not possible, then a location approximately midway between the nose and the mouth should be chosen. In no case should the probe be located above the nose. Probe depth is also important. If possible, the probe inlet should be inset about 1–1.5 cm from the inner surface of the respirator, rather than mounted flush against it, as illustrated in Figure 1. Other concerns related to the probe include design (should minimize particle entry losses), integrity and tightness of the seal with the respirator (must not leak), integrity of the connection to the sampling train, and cleanliness.

Commonly available personal sampling pumps are appropriate for in-facepiece sampling. Airflow rates of 1–2 L/min have been used in most workplace sampling to avoid significant pressure changes inside respirator facepieces. Moisture buildup from exhaled breath has been a concern in some studies. Moisture traps downstream from sampling devices have been used in some studies.[3,38,40,42] Heated coils around particulate filters connected to respirators have been successfully used in others.[41] Pump calibration should be done before and after each sample, preferably with an in-line calibration technique. Other methods are acceptable as long as sample contamination is avoided.

The type of sampling device will vary depending on the contaminants present. Careful handling of samples is critical. Air contaminant levels inside respirators are often at or near detection limits. Thus, any contamination caused by sample handling can greatly affect results. Clean hands and a clean work area are needed for hooking up and removing samples. The integrity of the sampling train and respirator probe must be checked, and for WPF studies, verification that the respirator is being properly

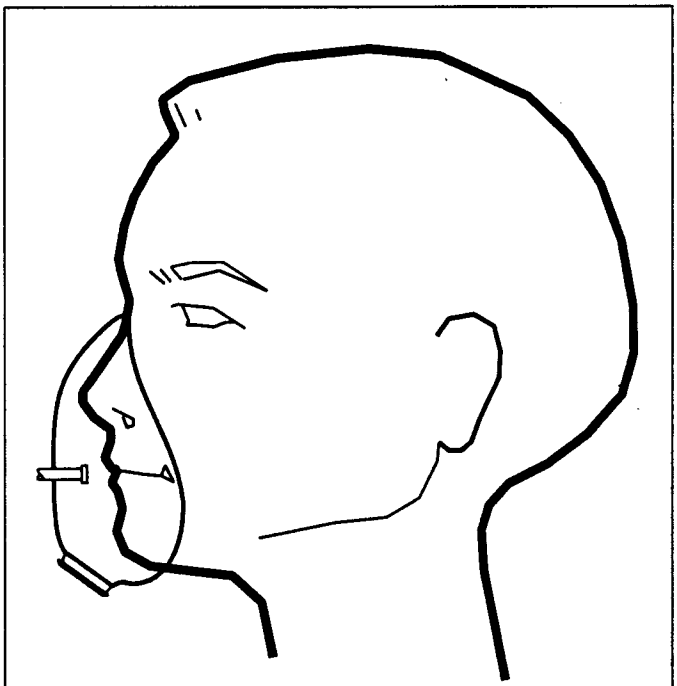

FIGURE 1. Probe location currently recommended for in-facepiece sampling

worn before sampling pumps are started must be made. Sampling pumps must be turned off prior to sample removal and prior to removing the respirator in the case of WPF studies. In addition to taking these precautions, a sufficient number of field blanks must be collected to estimate how much sample contamination might be attributable to handling procedures. The field blanks should be handled in the same manner as the inside and outside samples, with the exception that no air is run through them.

Sampling strategy should also be considered. In-facepiece sampling procedures recommended in Europe for determining total inward leakage into respirators involve sampling during the inhalation portion of the breathing cycle only.[74] This has been suggested as a way to more accurately measure contaminant concentrations leaking into respirators. The theory is that the dilution effect from exhaled breath will be minimized; however, this may not hold true in practice. Air contaminants do not appear to mix well within respirator cavities during inhalation.[60,65-68,70] Thus, inhalation-only sampling may significantly increase sampling bias.[69] Exhalation-only sampling has shown better results in the laboratory, but these studies have involved vapors only, have not been done on people, and have not been confirmed in the workplace.[69] Sampling during inhalation and exhalation is likely to continue for most studies until this issue is further resolved.

Another important requirement is collection of a sufficient number of samples to allow meaningful statistical analysis. If plans are to complete all sampling prior to initiating laboratory analyses, extra samples (perhaps two times the minimum thought necessary for statistical purposes) should be collected in case some samples must later be invalidated. This can occur if analytical acceptance criteria (discussed below) defined before the study are not met.

The validity of samples collected on test subjects may depend on whether an appropriate level of observation of test subjects was provided. This is especially true for WPF studies where collection of valid data is likely to require one observer for each test subject.

Consideration should also be given to collecting a certain number of samples for the purpose of characterizing air contaminants present. For example, where the contaminants are particulate matter, sampling to estimate particle-size distribution is recommended.

ANALYTICAL METHODS

The selection of an analytical method for in-facepiece sampling is complicated by a need for extremely good sensitivity for samples collected inside respirators, while at the same time being able to handle sample loadings orders of magnitude higher outside the respirators. Other potential complicating factors include the high moisture content of exhaled breath that passes through inside samples; limited sampling times because of duration of job tasks; and presence of gases, vapors (from previous exposures), or particles—such as cigarette smoke—in exhaled breath.

The best analytical methods will be very specific. Methods such as gravimetric analysis are easy to perform but have poor sensitivity and cannot identify workplace contaminants that leaked into a respirator from other contaminants not related to the workplace (e.g., cigarette smoke, saliva, sputum, or sweat). This is especially critical where the intent is to generate WPF numbers.

The benefits and limitations of analytical methods need to be carefully considered. A number of methods have been evaluated for particulate contaminants. Microscopy methods sometimes have good sensitivity and specificity, sometimes have neither, and always present a filter overloading concern. Proton-induced x-ray emission (PIXE) analysis, inductively coupled plasma (ICP) analysis, graphite furnace atomic absorption, and radioimmunoassay have good-to-excellent sensitivity and specificity but also have inherent limitations.[75]

Potential analytical methods for in-facepiece sampling of gases and vapors in the workplace are not as well defined. Thermal desorption shows good promise, but more work is needed in this area. More work is also needed to address the potential for problems, such as deposition of particles on the walls of filter cassettes used for sampling inside facepieces.[41,42]

Some general rules for the sensitivity of an analytical method for WPF studies have been suggested.[3,36-38] The goal of these studies is often to determine if a respirator has the capability to achieve the assigned protection factor for a specific class (e.g., an APF of 10 for a half-mask respirator). In order to make this determination, the detection limit must be low enough to ensure that outside (lapel) samples collect sufficient material, in a reasonable sampling time, to be able to show if a WPF is equal to or greater than the APF. In other words, at an absolute minimum, the following criteria must be met:

Outside Sample
Analyte Weight = APF × Mean Field Blank Analyte Mass
(e.g., ng)

Because analytical confidence is generally poor at or near the detection limit, it would be better to apply more stringent acceptance criteria. For example:

Outside Sample
Analyte Weight = 10 × APF × Mean Field Blank Analyte Mass
(e.g., ng)

If the analytical detection limit is not low enough to meet these criteria, sampling times should be increased, an alternate analytical method selected, or the study objectives redefined.

Analytical precision is another concern. Results of personal samples collected for industrial hygiene evaluations are generally considered acceptable if the precision is ±25% or better. Because samples collected inside respirators are frequently at or near detection limits, this may not be a reasonable limitation for in-facepiece sampling. Levels of ±35% or ±50% may be the best achievable. Sample acceptance criteria should be established based on sampling and analytical limitations.

Data Analysis Procedures

With all the variability inherent in sampling strategies, sampling methods, analytical methods, and overall study designs, a variety of opinions on analyzing and interpreting data from workplace tests is not surprising. A considerable amount of research has been done to identify and control sources of variability associated with in-facepiece sampling, but a number of

unknown or incompletely defined variables cannot be accounted for at this time. This does not mean that in-facepiece sampling data generated in the workplace are invalid; however, it does mean that they must be interpreted carefully.

Individual data points from in-facepiece sampling continue to be highly subject to what has been classified as random error. This means that very little confidence can be placed in fit factors or protection factors as stand-alone numbers. The impact of random error can be minimized and more meaningful information generated when the data are analyzed as a part of a population. Rules for data handling should be established immediately to help with study design and facilitate evaluation of resulting data.

RECOMMENDATIONS AND CONCLUSIONS

In-facepiece sampling techniques may be a useful tool for evaluating exposures workers receive while wearing respirators. They also show good potential for estimating protection factors provided by respirators in the workplace. The degree of difficulty associated with conducting protection factor studies in the workplace depends on the type of protection factor to be measured, workplace, workers, contaminants involved, sampling and analytical methods available, and ability of the researcher to resolve or control problems such as sampling bias and random error.

Many good protection factor studies have been conducted, but a stage where test protocols, data analysis, and data interpretation can be standardized has not yet been reached. More disciplined use of protection factor terminology will help pave the way for standard protocols. In conjunction with proper terminology, further research on how sampling bias and other variables affect in-facepiece sampling results in the workplace appears necessary before validated methods for determining and interpreting protection factors can be agreed upon.

The following basic rules may be a good starting point for WPF studies.

1. Prior to sample analyses, invalidate sample sets affected by sampling problems, such as leaky probes, loose sampling devices, loose hoses, malfunctioning pumps, removal of the respirator while pumps were running, or other observations that indicate the protocol was not met.
2. After sample analyses, reject sample sets with insufficient inside or outside sample loading or unacceptable analytical precision.
3. Use the mean value of field blanks to correct inside and outside sample loadings.
4. Use corrected sample loadings to calculate concentrations and protection factors. Be sure proper terminology is used (i.e., WPF as opposed to EPF, PPF, and so forth).
5. Consider whether corrections are desirable for lung retention. Determining factors may include sampling strategy used and type of contaminant.
6. Calculate appropriate measures of distribution, such as geometric means, geometric standard deviations, and fifth percentiles.
7. Identify potential outliers. Investigate reasons. Retain or reject data points in question.
8. Examine data to determine if protection factors generated are independent of outside sample loading. If not, re-evaluate amount of mass collected.
9. Test for differences among respirators, test subjects, observers, operations, and days as appropriate for the study design.
10. Define any problems encountered with data analysis that may make the results unsuitable for defining protection factors. Be sure to describe clearly conditions for which the study may be relevant. Avoid overinterpretation of results.

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