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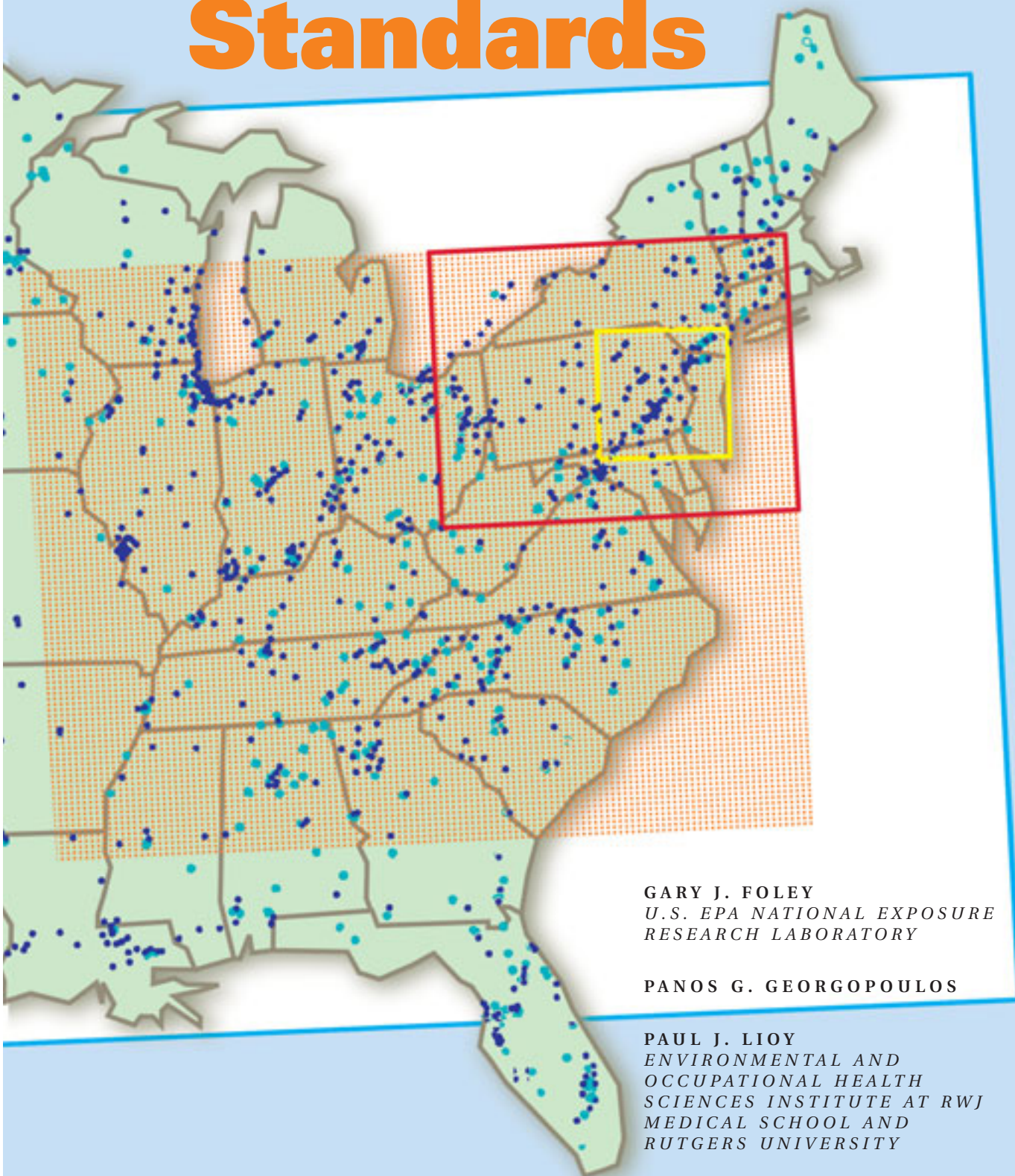
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Accountability Within **New OZONE** **Standards**



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**Congress and
the public are
holding the U.S. EPA
to higher standards,
which are being
implemented in new
air quality
standards.**

Over the past two decades, as part of the effort to develop the National Ambient Air Quality Standards (NAAQS), researchers have been using real human exposure data to help analyze the magnitude and extent of the risks from specific or multiple pollutants. Surrogates for exposure have also been used, such as the ambient air quality measured at fixed monitoring sites. These approaches are based on available science. Meanwhile, during the past decade, researchers at the U.S. EPA, universities, and institutes have been developing better scientific approaches for measuring and modeling real or potential human exposures that explain hazardous exposure situations.

In parallel, the President, Congress, and the public have set higher expectations for government programs, such as NAAQS. These expectations were first defined through the evolution of the “risk assessment–risk management paradigm” and then by the requirements of the Government Performance and Results Act (GPRA), which defines accountability for government programs.

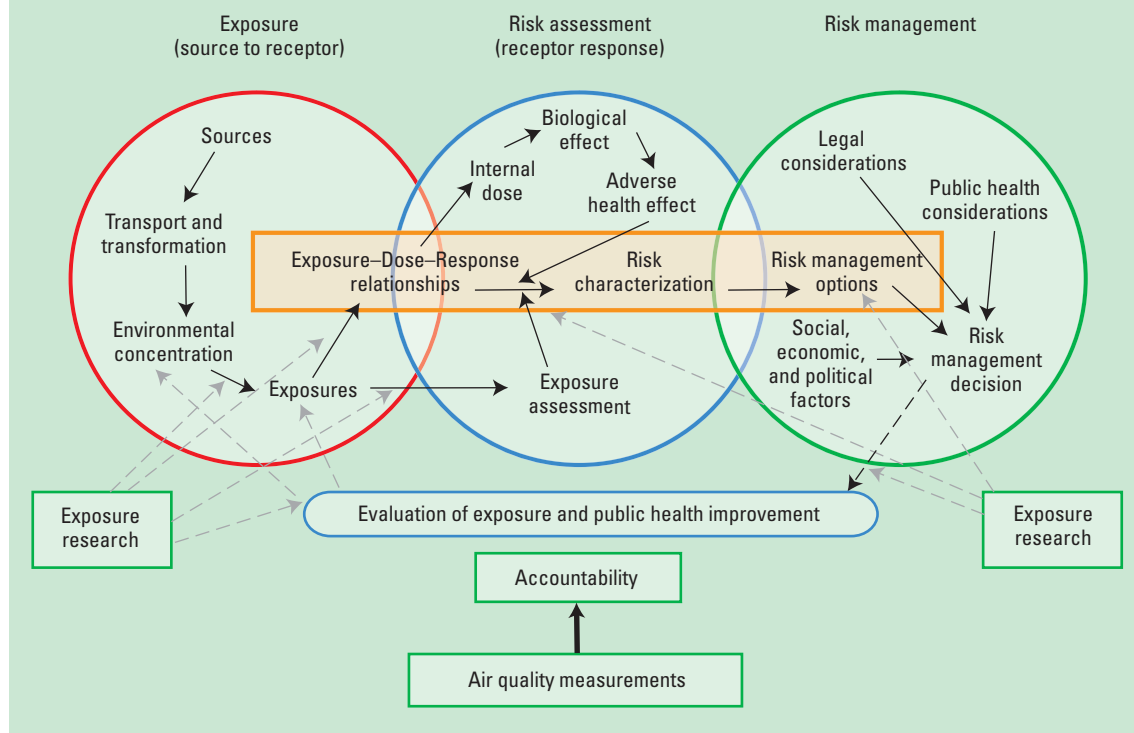
In this article we examine the challenges that EPA faces in its NAAQS program and

how the scientific results of its National Exposure Research program, conducted by the National Exposure Research Laboratory (NERL) within EPA's Office of Research and Development, and its partners, such as the Exposure Measurement & Assessment Program at the Environmental and Occupational Health Sciences Institute (EOHSI), can be used to achieve these higher expectations. Specifically, we will show the implications that accountability brings to the risk assessment–risk management paradigm. This will be done by stressing the importance of understanding human exposure and the linkages across the continuum from the emission of the causal agents or their precursors to effects and population risk. We will also present advances in air quality and exposure modeling tools that can assist in defining population exposure patterns. To address each of these issues, estimates of potential population exposures for the new standard for 8-hour (h) ozone standard will be used to demonstrate the implications of various control strategy scenarios on achieving exposure reductions that can meaningfully reduce population risk and provide benchmarks for accountability.

FIGURE 1

Applying exposure analysis to risk assessment—risk management and accountability

This diagram illustrates how an approach that uses measurements and exposure analysis can help decision makers, as long as it also takes background contributions into account.



Why is human exposure important?

Human exposure can be expressed as an event that leads to contact with a concentration of a chemical, physical, or biological agent at a route of entry into the body (e.g., inhalation). It is quantified on the basis of the contact time with the agent (*1*). Thus, exposure is the only element that can link risk assessment to risk management to accountability when the objective is to protect human populations—including susceptible and highly exposed populations—from environmental contaminants. Therefore, exposure helps focus on the effects of human contact with a toxic agent before and after the implementation of control strategies.

In 1983, the National Academy of Sciences published a landmark report that was the first to illustrate and describe the risk assessment–risk management paradigm (*1*). The paradigm evolved over the next decade and was often described by decision makers and researchers as a continuum from sources to human health response, which Lioy labeled an “integrative framework” (*2*).

Yet, knowledge of real or potential human exposures—both for the current conditions and in the future when ambient air quality standards are achieved—is the least understood element across the continuum of the risk assessment–risk management paradigm, a point that was discussed in the National Research Council’s (NRC) Human Exposure Assessment for Airborne Pollutants report in 1991 (*3*).

For potential exposures, our approach will focus

on using modeling to estimate the intensity and duration of contact with air pollutants by individuals or populations. Total exposure includes all sources, and ambient exposures means only outdoor sources. Actual exposures are the results obtained from field studies that measure the exposures of representative populations or populations at high risk. With these definitions in mind, we explore the implications that accountability brings to the risk assessment–risk management paradigm and its exposure component as the new health standard for ozone is implemented.

In 1993, framers of the GPRA challenged federal agencies to be accountable for achieving program results (*4*). For a major program, such as the Clean Air Act Amendments (CAAA), EPA was required to set program goals, measure program performance against these goals, and report publicly on their progress. The CAAA has NAAQS as one benchmark and can use successes in reducing population exposure to the pollutants as a major goal. In the 1999 GPRA Annual Plan Request to Congress, the Clean Air Strategic Goal included the following words: “The air in every American community will be safe and healthy to breathe. In particular, children, the elderly, and people with respiratory ailments will be protected from health risks of breathing polluted air.” Thus, policy makers have set a measure of program performance, referred to as accountability, for the NAAQS program.

What are the implications of accountability within the CAAA program? Principally, EPA needs to

demonstrate that, as a result of setting NAAQS and implementing strategies to reduce or eliminate a contaminant, the air is continually becoming safer to breathe. The expectation is that measurements or benchmarks will quantify the current health risks and show whether they are changing as a result of any action or inaction by federal, state, or local governments. As intended by those who framed the GPRA, any measurements would provide the required feedback on the performance resulting from the many federal and state decisions being made to achieve NAAQS. As a result, in the near future, EPA will need to supplement its current air quality measurement programs with a program that determines or estimates current exposures for general and sensitive groups in the population. In addition, the program will need to show how the implementation of control strategies to achieve NAAQS has changed exposure and reduced risk. Thus, measurements and modeling should also focus on exposure—not just compliance at fixed monitoring sites—and include planning-based model estimates of population exposures before and after implementation of control strategies. Measurements to test the performance among the populations considered at risk could supplement the models. In summary, the previous statements mean linking future exposure measurements and modeling results to implementation of controls that are designed to meet the standards, but at the same time providing metrics that can be used to demonstrate accountability.

Because the performance of the NAAQS portion of the CAAA program will be based on measured or estimated exposures, these analyses will begin to play a more significant role in the initial stages of making NAAQS implementation decisions. For example, states may use many combinations of control programs to meet the standard. However, if a state had more comprehensive modeling tools available that could also predict changes in potential or actual exposures to the general and susceptible populations, then those regulators would be in a position to pick the most effective combination of control programs to comply with the standard. Ultimately, EPA will achieve a level of accountability for the activities completed to achieve NAAQS.

Figure 1 shows that exposure has a much more direct link to potential health effects than air quality.

Traditionally, air quality measurements provide information on the status and trends of pollution in the ambient air. However, for portions of the population at highest risk from the effects of pollutants, these measurements are not the best surrogates for human exposure. Exposure is a closer measure of the dose delivered to the respiratory system or any target organ system. Research is under way to link the current air quality simulation models with available exposure and dose models to provide the comprehensive modeling tools needed for more effective decision making.

In addition, the risk paradigm must be integrated in two ways. First, to address accountability, the relationship between the human health effects studies that provided the basis for the ambient standard and the actual or potential exposures experienced by a population in these studies must be established. For the new ozone standard, individual exposures were well characterized in clinical and field health studies. However, the hospital admissions and visits for acute health effects used only central monitoring results (5). To quantify improvements in health in the future, these two approaches must be strongly coupled, which will allow similar measurements of exposure to serve as the metric of GPRA performance.

Second, to bring estimates of the potential changes in exposure or risk into the decision-making process, researchers need to assemble the methodologies for combining measurements and modeling tools and evaluate their use in demonstrating accountability. These measurement/modeling tools will be used initially in decision making and later in interpreting the performance measurements that show that these decisions have resulted in the desired end—making the air safer to breathe. This approach is illustrated in Figure 1, but it must also take into account background contributions to ensure that there is proper attribution of the controlled portion of any regulation or control strategy.

New standards for ozone and PM_{2.5}

The development of ambient air quality standards has followed the principles of the risk assessment–risk management paradigm for more than two decades. In 1997, major changes were proposed for the ozone and particulate matter (PM) portions of the standards, and these were recently upheld by the U.S. Supreme Court (6).

EPA promulgated a revision to NAAQS for ozone in 1997 (7), effectively changing the 1-h standard of 120 parts per billion (ppb) to a form that considers exposure. According to the revision, attainment of the standard for an area will be achieved when the 3-year average of the 4th-highest daily maximum 8-h ozone concentrations is ≤ 80 ppb. EPA is proposing to revoke the 1-h standard 1 year after the effective date of the attainment and non-attainment designations under the 8-h standard. These designations will be published on April 15, 2004.

The standard for PM was revised in 1987 (8). Since then, the scientific community has continued to publish significant community health studies on adverse effects of PM in general population subgroups. These studies, which are summarized in the 1996 PM criteria document (9), indicate that breathing PM at concentrations allowed by the 1987 standard likely causes significant health effects, including respiratory and cardiovascular problems, and, with long-term exposure, possibly reduced life span (10). Thus, EPA promulgated a revision to NAAQS for PM in 1997 (11). In

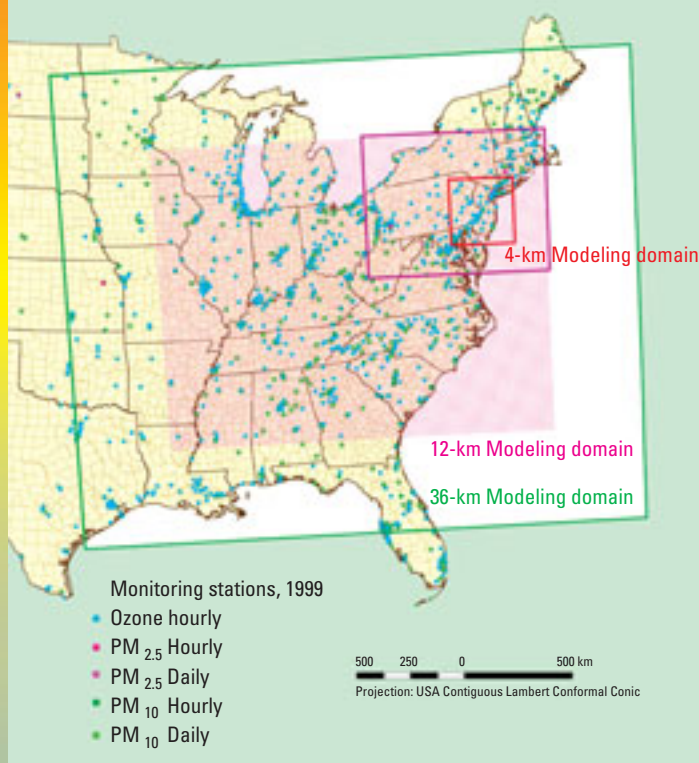
EPA needs to demonstrate that, as a result of setting NAAQS and implementing strategies to reduce or eliminate a contaminant, the air is continually becoming safer to breathe.

a similar manner, the promulgation revised the 24-h standard for PM_{10} to concentration-based forms. However, because of the results of epidemiological studies, the proposal also included the additional standards for annual and 24-h ambient exposures to $PM_{2.5}$ using ambient exposure-response relationships.

FIGURE 2

Multiscale photochemical modeling

Ozone and particulate matter over the eastern United States were simulated for July 11–24, 1999, using the Community Multi-Scale Air Quality model. The nested grids represent resolutions of 36, 12, and 4 km (from outermost to innermost grid). Our analyses for the 12-km grid focus only on the northeast region.



By shifting to an 8-h averaging time for ozone and adding $PM_{2.5}$ standards, regulators have moved toward exposure-based considerations for both pollutants. These changes reflect a greater recognition of the exposures that sensitive groups of people are experiencing in the ambient environment. It is possible now to evaluate these changes by looking at the attributes of the potential population exposures using recent advances in modeling tools (12, 13). In the remainder of this article, we will focus on ozone.

Advances in modeling tools

During the past decade, air quality modeling has advanced from single-pollutant models to multipollutant “one-atmosphere” models and from single-scale models to nested, multiscale models that cover coarse grids with sides of approximately 100 kilometers (km) down to fine grids of 4 km or less.

Recognizing the potential benefit of using multipollutant, multiscale models in environmental deci-

sion making, EPA initiated the Models-3 program a decade ago to develop a modeling framework that would make complex and advanced models more available to state and local governments, industry, and academia (14). Within this user-friendly framework, the Community Multi-Scale Air Quality (CMAQ) model was developed. Its purpose was to improve the environmental management community’s ability to evaluate the impact of air quality management practices on ozone, PM, acid deposition, visibility, and some air toxics at multiple scales and to enable the scientific community to better probe, understand, and simulate chemical and physical interactions in the atmosphere.

Scientists and engineers also realized that a generalized system—models, databases, and numerical and analytic tools for probabilistically assessing exposures and doses to individuals, populations, and susceptible subpopulations—was needed for diagnosing the complex relationships between sources and dose and for conducting the “what-if” analyses associated with decisions relevant to NAAQS implementation. Thus, the Modeling Environmental for Total Risk Studies Project (MENTOR), currently part of an EPA–University Partnership Program, set out to develop, apply, and evaluate state-of-the-art computational tools (15). These tools support multiscale source-to-dose studies and exposure assessments for a wide range of environmental contaminants. They include both mechanistic (emissions-based) air quality simulation models and phenomenological aerometric observation-based models, which are both linked with novel microenvironmental and exposure-dose models that aim to enhance understanding of exposures and health risk from fine airborne PM and photochemical pollution (16).

The overall effort to use better models and more realistic levels of exposure to assist in examining the effectiveness of regulatory strategies was recently discussed in an NRC document (17). The document states that such results assist in planning and determining what can be beneficial exposure reductions and that measurements are necessary to evaluate the performance of a program. This is essential for showing that NAAQS is protecting the population at risk. Note that a key element of the modeling approach in MENTOR is the explicit requirement of maintaining mechanistic compatibility across different spatial and temporal scales (corresponding to regional, urban, local, microenvironmental, and physiological processes) by treating the underlying physics and chemistry in a consistent manner.

To move beyond potential exposures, a seven-step process is now available for assessing actual exposure to air pollutants over multiple scales that use Models-3/CMAQ and MENTOR in conjunction with measurements (see “Seven steps of assessment” on p 399A).

This process provides an opportunity to integrate and use both measurements and models to understand and quantify general and individual exposures for populations at risk. Clearly, the measurements have distinct value for testing the performance of the model estimates used in designing control strategies

and for helping to determine whether adjustments are required to achieve the goals of GRPA.

Ozone metrics

One of the most significant recent advances in air quality management has resulted from the work of the Ozone Transport Assessment Group (OTAG). OTAG came to represent a new way of developing environmental policy. Its analyses included extensive regional modeling and provided excellent case studies for examining the attributes of the potential population exposures associated with the new and old standards for ozone.

OTAG functioned from 1995 to 1997 as a partnership between EPA and the Environmental Council of the States (a national organization of environmental commissioners from 50 states and some additional U.S. territories) as well as various industry and environmental groups. The partnership successfully developed a thoughtful assessment and a consensus for reducing ground-level ozone and the pollutants that cause ground-level ozone (18).

OTAG ultimately included more than 700 individuals representing state and federal government, industry, and environmental groups. The OTAG modeling domain included 37 states and the District of Columbia, all of which participated in OTAG's technical analyses and policy debates.

Through its modeling efforts, OTAG was able to demonstrate three important policy-relevant findings. First, urban nonattainment areas were shown to contribute significantly to their own ozone problems as well as to downwind areas 150–500 miles away. Second, the examination of urban volatile organic

carbon (VOC) controls indicated that they were effective for peak shaving, or reducing daily maximums, near metropolitan areas. Third, after completing a combination of several types of analyses, OTAG members agreed that the results suggested that NO_x controls may be more effective for regional ozone reductions. Other regional modeling efforts have supported the same NO_x control approach.

The multiscale modeling domain used in this article is shown in Figure 2. The purpose is to simulate the spatial and temporal attributes of potential population exposures to the ozone within this domain and then demonstrate a flexible metric of this exposure that can be used for comparative evaluation of changes associated with different control strategies.

CMAQ was used to simulate the ozone patterns for the inner OTAG domain in the eastern United States. Figure

3a shows a simulation using exposure estimating, or the nonmonitoring component of the seven-step process, and illustrates the daily maximum of the 8-h running average ozone concentrations calculated for July 16, 1999. The results are depicted as a gradient of 8-h average ozone values.

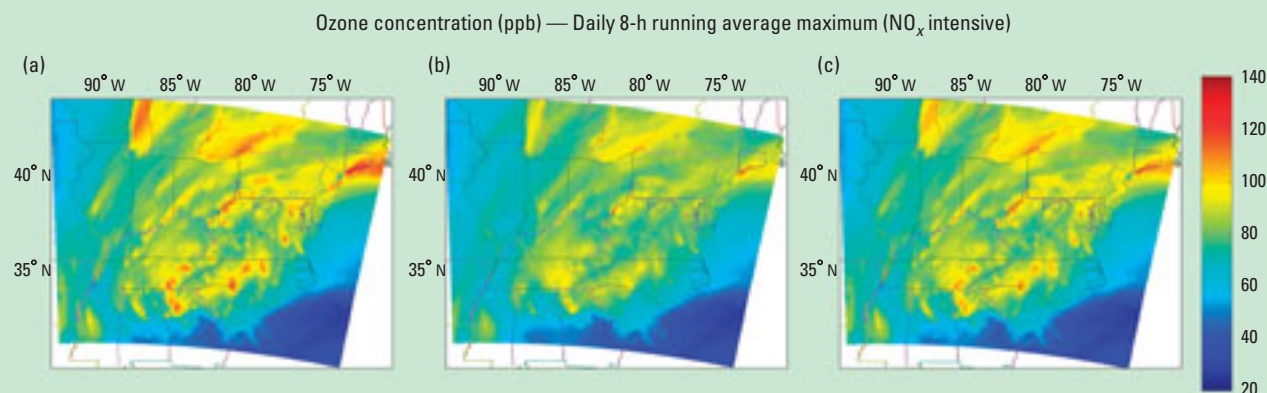
Because the standard calls for the 3-year average of the 4th-highest daily maximum 8-h ozone concentrations to be ≤ 80 ppb, the evaluation of potential control strategies would require simulations of many ozone-forming events. However, we will focus only on how the 8-h maximum could change for different hydrocarbon and NO_x control strategies on a high-pollution day, which should be expanded to include the entire ozone season in applications for the GPRA and accountability.

To move beyond potential exposures, a seven-step process is now available for assessing actual exposure to air pollutants over multiple scales.

FIGURE 3

Daily 8-h average ozone concentrations and effectiveness of NO_x and VOC controls

The Community Multi-Scale Air Quality model was used to create (a) a plot that represents the base case, an 8-h ozone concentration for July 16, 1999, for a portion of the eastern United States. Other plots created from the same software demonstrate that in a simulation of the base case where (b) nitric oxides (NO_x) and (c) volatile organic compounds (VOCs) are reduced by 75%, the NO_x controls are more effective at reducing ozone levels than the VOC controls.



In addition, OTAG compared the effectiveness of VOC versus NO_x intensive controls in several model simulations. A similar process was used to simulate the effect of intensive NO_x and VOC controls on reducing the ozone levels in the base case day. Results are presented in Figures 3b and 3c. A comparison with Figure 3a demonstrates the OTAG conclusion that NO_x controls appear to be more effective for regional ozone reductions. This is illustrated by the decrease in spatial extent of 8-hour ozone values above 80 ppb and is denoted by a decrease in regions of red, orange, and yellow.

Examining potential population exposure

The availability of comprehensive modeling tools is important because the results can be directly related to accountability, by indicating, potentially, the most effective combination of control programs that can eliminate exposure. Figure 4 provides an example of how this can be done using simulations obtained

Exposure-based metrics provide an information-rich tool in assessing relative effectiveness of alternative control strategies.

As a point of reference, the old 1-h standard of 120 ppb is examined in Figure 4. Starting on the x-axis at 120 ppb and moving up to the purple curve provides the estimate of the number of people exposed above 120 ppb on the y-axis: ~5 million. Both types of intensive control strategies bring the population below the 1-h standard. In fact, the impact of any strategy is indistinguishable at a level of 120 ppb but becomes very significant at levels below 100 ppb.

For EPA's new standard, the statistics for the 8-h ozone standard call for a 3-year average of the 4th-highest daily maximum 8-h

ozone concentrations to be ≤ 80 ppb, which translates to ~90 million people exposed at or above the standard level of 84 ppb for the analysis in Figure 4. In contrast to the old standard, the VOC control strategy has little or no effect on reducing the number of people exposed to ozone levels above the 8-h standard. However, the NO_x control strategy is predicted to be the most effective because it would reduce the number of people above the standard by 20 million.

Unfortunately, the simulations still project that ~70 million people in the inner OTAG domain remain potentially exposed to ozone at or above the standard on this highly polluted day of July 16, 1999. Thus, further efforts would be required to achieve clean air and meet the goals of accountability for the vast number of people living in this area. In addition, true accountability can be achieved only when the population exposure maps focus on reducing the number of people at risk in the most vulnerable or sensitive subgroups. Under this paradigm, personal exposure measurements would need to be made after implementation of the appropriate control strategies to determine if exposures of the most sensitive subgroups actually dropped, along with reductions at fixed ambient monitoring sites.

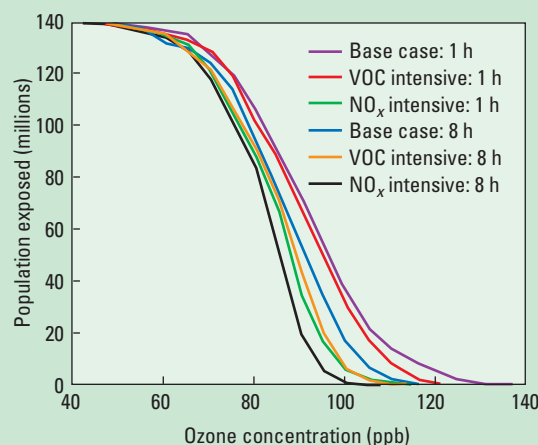
According to the Models-3/CMAQ/MENTOR system, the next steps would be to determine the details of spatial and temporal attributes of potential population exposures to ozone, including general and specialized populations. To continue achieving the goals of accountability, subregions or states will need to identify and evaluate additional source and precursor reduction strategies that can be tested within this modeling system. The objective would be to determine the most effective way to bring the number of people exposed to levels above the standard close to zero.

Thus, the approach presented here provides an example of a new metric based on population exposure that can be used in comparative evaluations required for achieving the public health objectives of NAAQS. By augmenting the indicators of environmental quality with a metric that actually evaluates the spatial and temporal relationships of ambient exposures of concern to health, we can then provide information that will improve our ability to demon-

FIGURE 4

Relative effectiveness of VOCs versus NO_x controls for reducing potential outdoor ozone exposures in 1- and 8-h cases

On the basis of the simulations done using Models-3/CMAQ/MENTOR system for the eastern United States on July 16, 1999, NO_x controls appear to be more effective than VOCs for both cases.



from the Models-3/CMAQ/MENTOR system. The exposure metric is the number of people potentially exposed on a particular day at or above an ambient level of concern for a specific averaging time within the eastern United States. The base cases and the intensive control strategy cases considered above only from an ozone ambient air quality point of view were re-examined in terms of their relative effectiveness in reducing the outdoor population exposures to ambient ozone.

Seven steps of assessment

These steps help assess real exposures using measurements and different models.

1. Estimate background levels of air pollutants by using appropriate air quality monitoring databases or emissions-based regional air quality modeling, such as Models-3 or CMAQ.
2. Estimate local outdoor pollutant levels that characterize the ambient air for groups of individuals (populations) within appropriate units (e.g., census tract in the location of the study).
3. In parallel with steps 1 and 2, use appropriate local-scale databases and models to estimate levels and temporal profiles of pollutants in various microenvironments (streets, residences, offices, restaurants, vehicles, etc.), and then develop and complete actual measurements of exposure.
4. Identify relevant attributes of the selected populations (geographic density, age, gender, race, income, etc.) to produce a sample population that represents each administrative unit in the domain of interest.
5. Develop activity event or exposure event sequences for each member of the sample population.
6. Calculate appropriate inhalation rates for the members of the sample population by combining the physiological attributes of the study subjects or sample populations and the activities pursued during the individual exposure events.
7. Combine intake rates and physiological attributes with microenvironmental or personal sample concentrations for each activity event to assess exposures and doses for the sample population.

strate the effectiveness of the NAAQS component of the CAAA program.

Exposure-based metrics provide an information-rich tool in assessing relative effectiveness of alternative control strategies and introduce a higher degree of accountability in meeting NAAQS by augmenting air quality metrics with ones more closely associated with morbidity and mortality caused by air pollution exposure. The Models-3/CMAQ/MENTOR system demonstrated that outdoor general population exposures to 8-hour ozone concentrations are most effectively reduced by NO_x control strategies. At smaller grid scales, subgroups of the population will be needed to examine population exposure reductions within an overall control program.

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Gary J. Foley is the director of EPA's NERL. Paul J. Liroy is department director and Panos G. Georgopoulos is the director of computational chemodynamics at EOHSI.

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