CENTERS FOR DISEASE CONTROL AND PREVENTION

convenes the

WORKSHOP ON RESPIRATORY PROTECTION FOR AIRBORNE INFECTIOUS AGENTS

Atlanta, Georgia
November 30-December 1, 2004

RECORD OF THE PROCEEDINGS

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Workshop Report

The Centers for Disease Control and Prevention (CDC) convened a Workshop on Respiratory Protection for Airborne Infectious Agents (AIAs) on November 30-December 1, 2004 at the Westin Buckhead Hotel in Atlanta, Georgia. The meeting was convened for CDC to obtain input and participants to exchange information in four major areas: (1) current scientific knowledge on the transmission of certain AIAs with an emphasis on the scientific basis for respiratory protection of workers and patients; (2) current scientific knowledge on respiratory protection of droplet nuclei and certain aerosol-transmitted agents; (3) strategies to improve the quality and effectiveness of respiratory protection; and (4) research needs to fill current knowledge gaps. The list of workshop participants is appended to the report as Attachment 1.

OPENING SESSION

Dr. Dixie Snider, Jr., the CDC Chief of Science, welcomed the participants to the workshop and thanked the planning committee members for their tremendous efforts in convening the meeting. He reviewed the four objectives and outlined the two overarching goals of the workshop. A forum would be provided for relevant stakeholders to review the current state of science regarding respiratory protection against infectious agents. Major areas where increased knowledge is needed on bioaerosols and controls would be identified. To guide the presentations and discussions, Dr. Snider provided information on several opportunities in respiratory protection.

CDC is currently being reorganized under the Futures Initiative with a stronger focus on health impact, customers, public health research, leadership, performance improvement and global health impact. CDC will implement several activities under its new organizational structure. Strategies will be aligned, health impact goals will be developed and tracked, and performance in achieving goals will be determined. Components that persons need and desire to select health will be marketed to CDC's

entire range of customers, including state and local health departments, healthcare providers, community-based organizations, businesses and the general public. CDC will continue its leadership role in applied public health research to ensure that research is relevant to persons, programs are based on sound science and research has a health impact. CDC will leverage its unique capabilities to improve the health system and global health impact. Performance will be improved in terms of accountability, effectiveness and efficiency.

Challenges related to global infectious diseases over the past decade include airborne transmission of influenza, severe acute respiratory syndrome (SARS) and more traditional diseases. CDC learned several lessons about the key epidemiologic features of SARS. A fairly high proportion of cases occurred in healthcare workers (HCWs). In the majority of countries, most cases were spread person-to-person. The disease rapidly spread around the world, but healthcare facilities played a central role in the epidemic. The vast majority of febrile respiratory infections in the United States were not SARS. The epidemic emphasized the critical importance of preparedness planning and strong partnerships at national and international levels. CDC's concern for respiratory protection extends to patients, visitors and other persons in healthcare settings in addition to HCWs.

The potential for pandemic influenza is a tremendous concern due to the persistence of and extreme difficulty in controlling the H5N1 Epizootic strain in Asia. H5N1 is established as enzootic and is unprecedented in its scope and complexity. H5N1 has an extremely high case fatality rate, but the majority of cases have occurred in young and healthy persons with no sustained person-to-person transmission. A seasonal pattern for avian influenza in Asia has been detected with increased activity expected during winter months.

The U.S. Department of Health and Human Services has taken several actions to address these challenges. Influenza surveillance capacity was strengthened in Asia with funding of $5.5 million. Bilateral funding was allocated to China, India, Indonesia, South Korea, Philippines, Mongolia, Malaysia, Pakistan and Thailand in conjunction with World Health Organization (WHO) National Influenza Centers. Support was provided to WHO's Geneva and Manila offices for pandemic preparedness, country assessments, training, biosafety initiatives, staff, supplies and equipment.

Tuberculosis (TB) has declined in the United States, but a resurgence was seen in the mid-1980s and early 1990s when investments in TB control decreased. The current decline in TB is not as significant as originally expected based on initiatives that were implemented. CDC is concerned about capacity to continue the TB decline in the United States; TB disparities at both domestic and global levels; the disproportionate TB burden among foreign-born persons and minority populations in the United States; and

increased TB rates in other countries, particularly those in which HIV/AIDS and socioeconomic conditions facilitate transmission.

CDC is currently attempting to link rather than conduct activities in isolation. These efforts include public health research, surveillance and evaluation, Epi-Aid initiatives, and the development of policy, programs and other public health projects. For example, research practice and surveillance will be connected to determine the size, type and target area of CDC programs; improve and measure surveillance; and identify gaps in research practice gaps. Public health research findings will continue to be translated into practice and disseminated. CDC will continue to engage and collaborate with partners that are critical to its success. In this effort, CDC convened the workshop to obtain input from participants on the state of knowledge of respiratory protection, data gaps in this area and research needs. CDC plans to use this guidance and collaborate with partners to develop a research agenda and practice guidelines on respiratory protection of AIAs.

PLENARY SESSION 1: BASICS OF AIA CONTROL

Drs. Kenneth Castro and Charles Schable of CDC co-moderated the presentations and discussion period for Plenary Session 1.

Aerobiology and Physics of Infectious Agents. Dr. Eugene Cole, of Brigham Young University, discussed the aerobiology and physics of infectious agents. A bioaerosol is an assembly of particles with variable biological origins suspended in a gaseous medium within a sufficient period of time to allow for observation and measurement. An aerosol of bacterial, viral or fungal origin is typically capable of initiating an infectious process in a susceptible host. These aerosols generally consist of a mixture of mono-dispersed and aggregate cells, spores or viruses carried by respiratory secretions, inert particles or other materials.

The discrete size range for most bacterial cells and spores is ~0.3-10 µm; ~2.0-5.0 µm for fungal spores; and ~0.02-0.30 µm for viruses. However, the size of infectious agents changes in conjunction with the carrier matrix upon generation from a source during aerosolization and exposure to relative humidity (RH), temperature and other environmental factors that favor desiccation or hygroscopicity. Resultant smaller aerosols can remain airborne for a longer period of time with rapid desiccation, while larger aerosols may initially fall out and then resuspend after desiccation. Respiratory disease agents are expelled from the respiratory tract within a matrix of mucus and other secretions typically begin to desiccate upon expulsion by coughing, sneezing, talking or singing. Dried residuals of these large aerosols are droplet nuclei with a size range of 0.5-12 µm. Clear definitions are needed for “droplet nuclei,” “larger droplets”

with a potentially infectious outcome, and “other” droplets that are much larger than fallout and subject to potential resuspension.

Infectious agents generated from HVAC, cooling tower water with *Legionella* and other wet environmental sources can also result in droplet nuclei. Construction dusts with *Aspergillus fumigatus* spores, indoor dusts with Hantavirus or other infectious aerosol carriers generated from dry sources may absorb water in the airborne state, but still measure in the droplet nuclei size range. Particle size and shape determine the behavior of the agent suspended in air. An airborne particle is referred to its equivalent or aerodynamic diameter regardless of size or shape. The aerodynamic diameter is equivalent to the diameter of a sphere with the same value of physical property as the actual particle.

A particle may be agglomerate or otherwise extremely complex in shape in which a significant part of the internal volume is comprised of voids. Agglomerate particles can be referred to as a mass-equivalent diameter because the particle is compressed into a spherical particle without voids. The particle bulk density is important to the gravitational setting velocity. Particles up to 100 µm in diameter are generally considered to be capable of remaining airborne for a sufficient period of time to be observed or measured as aerosols or droplets that are able to transmit infectious agents. Although laden with moisture from respiratory secretions, particles expelled from humans during coughing, sneezing or even talking begin to immediately dry upon expulsion to air.

Particle drying is dependent on atmospheric RH and temperature, typically proceeds rapidly, and changes aerodynamic diameters to the droplet nuclei range. A sneeze can generate as many as 40,000 droplets, but most will evaporate to particles or droplet nuclei in the range of 0.5-12 µm. Studies of aerosolized pure water droplets have shown very brief drying times. Water droplets with diameters of 100 µm and 50 µm that fell in 50% RH air had drying times of 1.3 and 0.3 seconds, respectively. Another study showed that water droplets with diameters of $\leq$20 µm evaporated in less than one second. Respiratory droplets contain dissolved substances and microorganisms and dry less quickly. A droplet in air settles due to the gravitational field at a velocity that is dependent upon its mass. The drag or viscous frictional force acting on the particle increases along with the rate of fall. The droplet attains its final terminal velocity when the two forces are equal.

Droplet aerosols <100 µm can remain suspended for prolonged periods of time because typical room air velocities exceed the terminal settling velocities of particles. Aerosols >100 µm are typically very large, rapidly fall out of the air, and are usually described as “splash” or “splatter” as opposed to aerosols. Diffusional, thermal and electrostatic field effects, temperature, RH and other physical parameters also affect the fate of droplets.

Infectious microbes within droplets must survive radiation, oxygen, other pollutants and additional stressors following aerosolization, transport, desiccation and landing or deposition. The capacity of an infectious microbe to initiate and spread disease depends on its ability to survive or reproduce and maintain infectivity or cause infection. The infectious disease process is a function of microorganism concentration or infective dose and virulence or disease-promoting factors that enable an agent to overcome physical and immunological defenses of the host. The susceptibility of hosts can significantly vary.

The initiation of some diseases requires only small infective doses for humans because the agents have an affinity for specific tissue and possess one or more potent virulence factors that facilitate resistance to inactivation. Infection with *Francisella tularensis* is reported to result from a single organism in which virulence is associated with a cellular capsule. Only a few cells of *M. tuberculosis* (*M.tb*) are required to overcome normal lung clearance and inactivation mechanisms in a susceptible host. Deposition within the respiratory tract is inherent in the infection process that is initiated by the inhalation of infectious droplet nuclei. Deposition is influenced by hygroscopicity that causes an increase in the size of the inhaled particles through moisture take-up during movement within airways.

Transmission of infectious disease by the airborne route is dependent upon the interplay of several critical aerosol factors. First, particle size and shape or aerodynamic diameter is an issue due to generation from primary source or resuspension; desiccation dependent on RH, temperature, air flow velocity and the formation of droplet nuclei; effective aerial transport subject to gravitational, diffusional, thermal and electrostatic forces; and contact with or deposition in a new host. Second, the survival of microbes or an infective dose is an issue because sufficient numbers must survive effects of aerosol age, RH, temperature, oxygen toxicity, ultraviolet (UV) and other radiation, and other pollutants to constitute an appropriate infective dose.

Third, microbe virulence is a concern because genetically-based and disease-promoting factors enable an agent to overcome normal physical and immunologic defenses, such as SARS and the smallpox virus. Fourth, host susceptibility is an issue due to a slow, weak or non-existent immune function from immunodeficiency disease or immunosuppression as a result of chemotherapy, transplantation, pregnancy or lack of appropriate and available vaccine.

Several environmental management and control strategies can be applied to infectious agents. For source management, each infectious agent is derived from a human, animal, surface, material or process source. Sources can be managed by removing mold-contaminated building materials or modified by purging hot water systems to eliminate *Legionella* species. Active TB patients can be housed in negative-pressure

rooms, required to wear respiratory protection or placed in laminar-flow beds until confirmed as non-infectious. Sources can also be managed through a program of building maintenance, cleaning and disinfection that ensures routine inspection of HVAC components and other potential sources.

For activity management, this process ensures that a building or a particular section is used for activities it was designed to accommodate. The process also assures proper renovations were completed within a framework of operational infection control practices. For example, if a section of an existing hospital will be used for immunocompromised patients, renovations must include a dedicated HVAC system with high-efficiency air filtration and patient rooms operated under positive pressure. The use of a facility in its original intent also facilitates and promotes a routine program of inspection, maintenance, cleaning and disinfection.

For design intervention, a building and its furnishings need to be designed to be effectively inspected, cleaned and maintained. This type of intervention is important when designing new facilities and renovating or remodeling an old structure for new use. Design interventions may include special exhaust ventilation, other air flow requirements, or the removal of certain building or furnishing materials that are particularly susceptible to microbial contamination, such as ceiling tile and carpet.

For ventilation and filtration, dilution is a process to lessen the concentration of airborne pollutants by replacing contaminated air with clean air. The capture of infectious particles is typically combined with controlled air flow and high-efficiency filtration, but can also be integrated with UV treatment. A study investigating airborne TB control showed that ventilation plus recirculating air filtration could reduce droplet nuclei concentrations with 30%-90% efficacy. This intervention may significantly lower the potential for transmission in high-risk settings, particularly in combination with treatment booths, respirators and other source management controls. High air exchange rates have been shown to be effective in controlling nosocomial aspergillosis, particularly in combination with filtration.

Respiratory Protection: An Important Part of the Hierarchy of Controls. Ms. Teresa Seitz, of the CDC National Center for Occupational Safety and Health (NIOSH), presented the hierarchy of controls in respiratory protection. Preventive measures should be taken to control hazardous exposures when work activities are anticipated, recognized or found to involve risks to the health of workers. The traditional hierarchy has been recognized and accepted for a long period of time due to its basis in broad practical experience and scientific and technical logic. NIOSH published specific characteristics of control measures that can be followed in an ordered approach to assess controls. These principles include reliable, consistent and adequate levels of protection; determination of the efficacy of protection for each individual worker; minimal

dependence on human intervention; consideration of all routes of entry; and ability of the solution to not exacerbate or create health or safety problems.

Application of the hierarchy of principles has led to a traditional occupational health approach of eliminating hazards, minimizing risks with engineering controls, implementing administrative controls, and providing personal protective equipment (PPE). The hierarchy in healthcare settings is outlined as follows. Administrative controls are first because the source must be rapidly identified and known and suspect cases must be isolated. Engineering or environmental controls are second and include airborne infection rooms (AIIRs) with specific ventilation criteria, anterooms, general and local exhaust ventilation, and air cleaning technologies. PPE is third and provides skin, mucous membrane and respiratory protection as needed. The N95 filtering face-piece (FFP) respirator is recommended as the minimum protection against infectious aerosols.

Isolation precautions include standard precautions that are recommended for the care of all patients. Standard precautions contain three transmission-based precautions depending on the specific agent of concern. Contact precautions are applied when direct or indirect contact can result in transmission. Droplet precautions are applied when contact with large-particle droplets >5 µm in size requires close contact of $\leq$3 feet or a mask within three feet. Airborne precautions with respiratory protection and ventilation controls are applied when airborne droplet nuclei $\leq$5 µm in size are transmitted and remain suspended in air. Respirators are recommended in healthcare settings when entering AIIRs with infectious patients; transporting patients in an enclosed vehicle; or attending aerosol-generating procedures, such as an autopsy, aerosol medication administration, bronchoscopy, wound irrigation, intubation or airway suctioning.

Recommendations for respirator use in healthcare settings are generally based on TB outbreak investigations that resulted in transmission and excess risk to HCWs. The Occupational Safety and Health Administration (OSHA) incorporated the same guidance into its enforcement strategies for TB. Similar actions were recommended for the use of respirators with SARS. Three primary methods have been established to select respirators. The hazard ratio method is quantitative, viewed as the traditional industrial hygiene approach, and uses air concentrations and occupational exposure limits. However, the application of this method is limited with infectious agents because occupational exposure limits have not been collected and air concentration estimates of agents are frequently unknown.

The risk analysis method is a quantitative modeling approach, but complete information is seldom available. However, the advantage with this strategy is that assumptions and data are identified and an acceptable level of risk is specified. The expert opinion

method is qualitative and can include categorical risk estimates. This strategy is applied when important data for quantitative methods are not available. Characteristics of work activities are considered, such as the agent, assigned protection factors (APFs), and the advantages and disadvantages of respirators. This method is most commonly used to select respirators for infectious aerosols.

OSHA's recently proposed definition of APFs is "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program" (RPP). The most common APFs for respirators in healthcare settings are the FFP or disposable N95 respirator with an APF of 10; elastomeric half-mask with an APF of 10; full face-piece respirator with an APF of 50; loose-fitting powered air-purifying respirator (PAPR) with an APF of 25; and tight-fitting PAPR with an APF of 50. For ranking purposes, for example, the N95 respirator has an estimated particle penetration of ~10% compared to 4% for a loose-fitting PAPR. The overall effectiveness of respiratory protection for an individual will depend on the level of protection selected, fit characteristics of the respirator, care in donning the respiratory, and accuracy of the fit-testing program.

The relative efficacy of respirators is difficult to independently assess due to the implementation of multiple controls at the same time, variations in exposure, small numbers of employees in most healthcare facilities, and tuberculin skin test (TST) conversions. Modeling studies have been published for TB focusing on the relative efficacy of respirators in ventilation. In two studies, data were used from the Riley experiments with guinea pigs to calculate the lifetime exposure risk. Respirators were found to offer benefits to further reducing risks even in the presence of other controls. Respirators were also found to be more efficacious with decreased ventilation and increased concentration of infectious aerosol.

Several research opportunities for respiratory protection have been identified. First, environmental assessment tools can be refined with a number of strategies. Environmental sampling methods that are specific to AIAs can be developed and validated. Sampling methods can be validated in the field during outbreak investigations of TB, varicella and respiratory syncytial virus (RSV). Generic protocols can be developed and used during emerging infectious disease and bioterrorism (BT) events. CDC is currently making efforts to enhance environmental microbiology capacity. Second, agreement can be reached on definitions of "aerosols," "droplets" and "airborne transmission." Evidence for definitions can be reexamined, such as droplets as particles >5 µm in size or propelled only three or six feet from the source. The uncertainty of whether the "true airborne transmission" concept is too restrictive can be resolved.

Third, more definitive routes of exposure in outbreak situations can be established. Additional relevant information can be collected on exposure duration, distance from the source, environmental conditions, and type of and compliance with PPE. Novel approaches can be developed to evaluate outbreak situations, such as computational fluid dynamics in conjunction with epidemiologic analysis. Fourth, control measure can be evaluated in terms of efficacy and PPE levels.

Additional quantitative data would be helpful in determining whether higher levels of respiratory protection for aerosol-generating procedures are needed in certain situations or if controls are sufficient to discontinue respiratory protection. These data would also be useful in deciding the order of donning and doffing respirators and clarifying reuse issues. Despite the data gaps, uncertainties and disagreements in respiratory protection, engineering and administrative controls should continue to be applied whenever possible and respirators should remain as the last strategy in the hierarchy of controls.

Translating Aerobiology and the Hierarchy of Controls into a Hospital Infection Control Program. Dr. David Henderson, of the National Institutes of Health, outlined the process to translate basic science findings into infection control practice in healthcare settings. The application of basic aerobiology results from the laboratory to the clinical setting is extremely difficult due to fewer controls in clinical settings, unclear dynamics of transmission, and the tremendously complex relationship between the host and pathogen. Clinical management strategies must be driven by the best possible risk assessment and a risk-benefit analysis. The evaluation requires accurate and precise scientific data and translational clinical research findings to confirm laboratory data. Optimally, clinical experience will be available as final confirmation.

Laboratory data, clinical research and relevant clinical data are needed to accurately assess risk, but several issues must be addressed to translate basic aerobiology findings into clinical science or practice. Minimal data have been collected in controlled clinical studies or actual practice to demonstrate the efficacy of particulate respirators in preventing transmission of infectious diseases. Limited data have been gathered to demonstrate the superiority of particulate respirators over well-fitting surgical masks in preventing transmission of infectious diseases. The relevance of the General Industry Respiratory Protection Standard to clinical science or medicine has not been established to date. Fit testing is a science in evolution that is not standardized, reliable or reproducible. Fit-testing circumstances typically are not similar to clinical settings where respirators would be used.

Costs associated with both the use of particulate respirators and fit testing need to be carefully modeled. Minimal data have been collected to demonstrate the superiority of required and periodic fit-test training over other approaches. Creativity from basic

scientists, insights from regulators, and experiences and contributions from clinicians are all needed in a joint effort to answer important and complex questions and provide solid guidance for clinical settings. First, what clinical data have been generated that demonstrate the efficacy of particulate respirators in preventing the transmission of infectious diseases? How should studies be designed to address this critical question if existing data are limited? Second, what studies are needed to provide an opportunity to align basic aerobiological data with epidemiological and clinical data?

Third, what clinical data have been generated that demonstrate the superiority of particulate respirators over surgical masks in preventing the transmission of infectious diseases? How should this issue be retrospectively assessed or how should studies be designed to address this critical question if data are limited? Fourth, what characteristics of various types of respirators contribute to efficacy in clinical use as compared to industrial use? How should studies be designed to address this issue if comparative data are limited? What is the role of industry in assuring respirator fit? Fifth, is the use of particulate respirators for the protection of HCWs cost-effective?

The broad public health and healthcare communities are interested in providing a safe environment for HCWs and patients by balancing safety, practicality and cost-effectiveness. However, the safety of patients cannot be ignored. Collaborative efforts that represent available basic science, epidemiological data and clinical information must be developed to identify the most effective strategies to increase patient and worker safety in the healthcare environment. Several translational questions must be answered to make the most sentient, reliable and practical recommendations. Science-driven, practicable and cost-effective guidelines must be developed and implemented in existing healthcare settings throughout the country.

Discussion. The co-moderators opened the floor for the workshop participants to provide input, make recommendations and pose questions to the Plenary Session 1 panel of presenters. The deliberations are outlined below.

- Caution should be taken in stating that the N95 respirator provides 95% of protection against aerosols. All filters are velocity-dependent, the 95% rate is irrelevant when respirators are worn, and 10% leakage occurs around the side of the face.
- Experiences in other industries should be considered and reviewed. The asbestos, lead, nuclear and biotechnology industries have already faced the same issues as the healthcare industry in terms of the cost, implementation and other realities of an RPP.
- Additional research on reaerosolization should be conducted because the issue of resuspension or the release of particles from filters has not been addressed in detail to date. A study by the University of California-Los

Angeles was recently published that showed a significant number of particles were released and resuspended from filters.

- Implementation of an RPP in the healthcare setting should not be compared to other industries due to unique operational issues, variables and other fundamental differences. For example, language skills, communication between patients and staff, interpersonal contact as the primary mode of activity, and safety culture and awareness all play an important role in the healthcare setting. Data that will be useful in and can be applied to actual practice are a critical research need. However, field trials to validate the efficacy of respirators will be extremely challenging because proven effectiveness in a controlled study may not translate to the healthcare setting.
- Future research efforts should focus on components that are truly necessary to interrupt transmission of respiratory-spread pathogens.
- Solid data should be collected to compare the efficacy of fit testing versus training in daily use of respirators.
- Research should be performed with a cohort of persons with several different facial sizes and shapes to identify respirators that fit the widest range of individuals.

The Plenary Session 1 panel of presenters made follow-up remarks to the discussion.

- The N, P and R series of respirators have no distinction in terms of APFs, but “95% efficiency” refers to the worst-case scenario. The N95 respirator has been recommended as the minimum for most infectious aerosols due to its high efficiency in removing particles that are both greater and smaller than 3 μm in size.
- Effective implementation of solid RPPs is similarly difficult in non-healthcare settings due to employee dislike of wearing respirators, cost issues, the complexity of selecting a respirator and fit-testing problems. However, the most significant difference is that control of the environment is much easier in other industries than in the healthcare setting. Nevertheless, experiences in non-healthcare industries can still be reviewed and benchmarked to identify best practices and lessons learned in developing, implementing and maintaining successful RPPs. Consideration must now be given to whether other controls can provide protection in a better and more cost-effective manner.
- Respiratory protection must be viewed from scientific, clinical and public health perspectives in order to take conservative prevention and control actions.

- More emphasis is placed on resuspension in CDC's revised TB guidelines; the draft document will soon be published in the *Federal Register*.
- Two studies were conducted to evaluate HCW compliance with and adherence to respiratory protection. The findings showed that behavior and performance continued to decrease as the difficulty in the level of protection increased.
- The traditional practice of polarizing regulators, industrial hygienists and clinicians must be discontinued. Relevant disciplines must engage in collaborative efforts to reach agreement and develop solid recommendations to address complex respiratory protection issues.
- The workshop participants and other groups can propose that the complexities associated with donning and doffing respirators be addressed. Authorities have not reached agreement on this issue to date due to different procedures being implemented by different countries on the order of removing PPE. UV fluorescent agents and other surrogates can be used to model different approaches.
- The extensive aerobiology literature contains a wealth of solid scientific studies that have been published since the 1940s on particle measurement and detection methods, such as light scattering, impaction and impingement of collected particles, and microscopic examination of collected particles on glass slides treated with oil or another substance.

PLENARY SESSION 2: CURRENT STATE OF KNOWLEDGE ABOUT AIAs

Drs. Denise Cardo and David Weissman of CDC co-moderated the presentations and discussion period for Plenary Session 1.

What Do We Know About TB Transmission? Dr. Kent Sepkowitz, of the Memorial Sloan-Kettering Cancer Center, presented data on the current knowledge of and strategies to interrupt TB transmission. Riley performed a series of studies on guinea pigs and research has been conducted on the dispersal of other bacteria in non-clinical settings. However, minimal studies have been performed in the clinical context. TB outbreaks that occurred in submarines, classrooms, school buses, hospitals and communities have been analyzed after the fact to identify common factors. The premise of the Riley studies in the 1950s and 1960s was to place treated and untreated TB patients in one of six rooms. All air was carried into nearby chambers with 120 guinea pigs that received regular purified protein derivative (PPD). The Riley studies proved that UV light is effective as a germicidal agent.

Of 61 untreated patients, 53 did not spread TB to guinea pigs and eight infected 29 guinea pigs. No obvious differences were seen among the 53 patients by smear, cough or other status with the exception of one patient with laryngeal disease. Minimal treatment resulted in marked diminution of spread with one guinea pig being infected by 29 patients. Although the Riley studies represent old data, lessons can still be learned from this research. Most notably, TB is a relatively non-transmissible disease and even minimal treatment can play a significant role in protection. In terms of accidents, TB transmission in submarines in the 1950s and 1960s demonstrated the airborne nature of the disease. Schoolroom reports demonstrated the concept of an "infectious room" after the infectious individual exited. Transmission on school buses demonstrated the effect of duration of exposure.

For hospital settings, an emergency room outbreak showed that a very infectious person or situation could result in widespread transmission in a brief period of time. No outbreak has ever been linked to using the wrong PPE. The "super-spreader" concept has never been proven and is believed by several groups to be misguided. Data have been collected from several sources on interrupting TB transmission. In the deliberate experimental study, emphasis was placed on the mask, UV light and air handling. The droplet nucleus size and PPE pore size were known. PPE fit was found to be measurable by standards established for other groups. UV light was found to be effective in the guinea pig study, but operational limits were detected. Numerous studies have examined the speed in which bacteria can be evacuated from a room.

In hospital reports, several cases documented decreases in PPD conversions after implementation of numerous interventions. However, obtaining knowledge on successful interventions other than patient isolation is difficult. Community versus hospital transmission was difficult to distinguish, but the current perspective is that community transmission rather than occupational exposure accounts for much of the risk of tuberculin conversion in HCWs. In healthcare system reports, 17 Canadian hospitals were stratified by air exchanges in general rooms rather than respiratory isolation rooms. Increased risk of PPD conversion was associated with fewer air exchanges and a greater effect was seen in higher risk employees. Because this effect was not seen in isolation rooms, undiagnosed patients were found to pose the greatest risk.

Data are now needed to determine the generation of infectious particles from the host; TB transmission and dissemination through the environment; infection of susceptible individuals; and organism-specific data. Overall, knowledge about TB transmission has not been greatly enhanced over the past 50 years. An effective package of interventions has been developed to interrupt TB transmission, but specific components that are effective have still not been identified.

SARS. Dr. Mark Loeb, of McMaster University in Canada, reviewed descriptive epidemiologic data, preplanned studies, mock experiments and mathematical modeling related to SARS transmission and evidence for PPE effectiveness. The SARS coronavirus is 100 nm in size, enveloped and has the ability to survive outside the host for up to six days on hard surfaces. Peiris, *et al.* published a 2003 study on increased viral load from 5-10 days after 14 individuals became infected. However, a decrease was seen in the viral load from 10-15 days. The WHO epidemiology report analyzed the transmission efficiency of SARS. The study showed that the number of secondary cases was low between the time of onset of symptoms and isolation within five days, but the rate of secondary transmission was high after five days.

Shen, *et al.* published a 2004 study on the super-spreading of SARS within one Beijing hospital. Of 74 contacts of the index case, 33 developed SARS. "Super-spreaders" were more likely to be ill and old with a mean age of 64 years. To date, no studies have used the viral load in regression models of SARS transmission. The key message from the first SARS outbreak in Toronto, Canada was that unrecognized cases and the absence of a highly-accurate diagnostic test played the most significant roles in transmission.

Loeb, *et al.* published a 2004 retrospective study on the relative risk of SARS. The cohort of 32 nurses was analyzed by both PPE and ten patient care activities in which each nurse had spent at least one shift in the intensive care unit (ICU) or critical care unit (CC) with a SARS patient. The study showed that of ten patient care activities, intubation, suctioning and nebulizers presented the top three risks for nurses developing SARS. Nurses who wore a mask had an 80% risk reduction of developing SARS. A trend toward a better effect was seen in nurses who wore an N95 respirator versus a surgical mask. The Kaplan-Meier curve showed that nurses working in the ICU or CCU had an extraordinarily high risk of 6% of developing SARS per shift.

Somogyi, *et al.* published a 2004 study demonstrating a subject exhaling previously inhaled saline aerosol mist of 3% while wearing a non-rebreathing oxygen mask and Venturi-type oxygen mask. The study emphasized the importance of analyzing devices of source patients. Seto, *et al*. published a 2004 cross-sectional study of 11 index patients with SARS in five Hong Kong hospitals. Surveys were distributed to persons who provided care to these patients. The results showed that individuals using masks were more likely to be protected with a risk reduction of nearly 90%. This effect was seen with both paper and surgical masks. Significant effects were not seen with gloves; a small effect was seen with gowns; and an 80% risk reduction was seen with hand washing.

Teleman published a 2004 case-control study of a multi-variable analysis of factors associated with transmission of SARS to HCWs in Singapore. A list of source patients

was distributed to HCWs to determine if care had been provided. The results showed that hand washing after each patient had an important protective effective with a relative risk reduction of ~90%. An N95 mask was found to be strongly protective with an odds ratio of 0.1. Contact with respiratory secretions was found to be an extremely strong effect with an odds ratio of ~22. Several of the studies are problematic due to the small number of cases.

Research was performed to identify probable and suspect SARS cases in Ontario by date of onset. Between April 15-24, a report of 11 HCWs was well publicized because nine of these individuals met WHO's SARS criteria. However, all nine persons reported using full PPE with the exception of face masks. A retrospective cohort study was conducted among 630 HCWs who were involved in the intubation of 56 source patients. Shigayeva, *et al.* published a 2004 study of an initial multi-variable analysis of risk factors for SARS among Toronto HCWs exposed to patients prior to intubation. The results showed that splash secretions in eyes was an extremely strong risk with an odds ratio of ~17. Completion of an N95 fit test was found to have a borderline protective effect. Exposure to high-frequency ventilation was also found to be important.

Lau, *et al.* published a 2004 case-control study in an effort to explain the development of SARS among HCWs in Hong Kong despite their use of PPE. The multi-variable analysis was designed with a 2:1 match of 72 cases compared to 144 controls. The results showed that the perceived inadequacy of PPE was associated with transmission. SARS infection control training of <2 hours and inconsistent use of PPE with direct patient contact were found to be important risk factors. Park, *et al.* published a 2004 study of HCWs in U.S. hospitals who reported exposure to SARS. Transmission of SARS in the United States was minimal due to very few exposures to aerosolization, resuscitation or bronchoscopy.

Wong published a 2004 report of medical students exposed to SARS by a single unrecognized patient in Hong Kong. The report was unable to determine whether the outbreak was due to fomite or airborne transmission. Olsen, *et al.* published a 2003 study of a SARS outbreak on a three-hour flight from Hong Kong to Beijing with 112 passengers. Of all cases, 90% were >3 feet from the index case. Several conclusions have been reached in reviewing data from the SARS studies. Transmission in hospitals appears to be primarily due to large droplets traveling short distances. Droplet nuclei of airborne transmission do not play a major role in hospital transmission. The importance of environmental spread or fomite transmission is unclear, but the patient source was found to play an important role. Use of a mask and hand hygiene reduces transmission in hospitals and overall risk.

Influenza. Dr. Carolyn Bridges of CDC presented an epidemiologic perspective of influenza transmission. Influenza is a single strand RNA virus that has the ability to

continuously change through antigenic drift, but rarely through antigenic shift resulting in the emergence of a pandemic. Annual winter epidemics in the United States can lead to infection in 5%-20% of the population, >200,000 hospitalizations and 36,000 deaths with >90% of mortality among persons ≥65 years of age. The typical two-day incubation period of influenza can range from one to four days. Infection of the respiratory columnar epithelium causes sloughing and may result in a prolonged cough that lasts two to six weeks.

Viral shedding can begin one day before the onset of symptoms with peak shedding occurring the first three days of illness. Shedding generally correlates with a temperature and usually subsides by day 5-7 in adults. However, shedding can continue for ≥10 days in children or even longer in severely immunocompromised persons. The clinical syndrome of influenza is characterized with an abrupt onset; fever and constitutional symptoms of body aches, headaches and fatigue; respiratory symptoms of a cough, rhinitis and sore throat; gastrointestinal symptoms and myositis more commonly in young children; and complications of viral and bacterial pneumonia, febrile seizures, cardiomyopathy, encephalopathy, encephalitis and deterioration of underlying chronic conditions.

Infection rates of influenza are greatest in young children, while complication rates are primarily in older persons and individuals with chronic underlying conditions. The rates of influenza hospitalizations are ~472/100,000 in persons ≥65 years of age and 115/100,000 in children <5 years of age. Persons ≥65 years of age also have the greatest impact from influenza-associated deaths. Most HCWs are categorized into the low-risk group in terms of complications, but influenza acquired in healthcare facilities has been reported from multiple settings. Outbreaks in nursing homes, adult and pediatric wards, neonatal ICUs and bone marrow transplant units generally occur during community outbreaks. The simultaneous healthcare facility/community outbreaks increase the difficulty of identifying the source of infection in hospitals.

HCWs are often implicated as vectors due to working while ill or unvaccinated and transmitting infection to patients and other personnel. Three major strategies have been established to prevent influenza. Vaccination is a primary prevention measure, but coverage is sub-optimal with only 48% of HCWs and 69% of persons ≥65 years of age being immunized. The influenza vaccine may only be 70%-90% effective in healthy young adults with a good match between the vaccine and circulating strains. The vaccine is less effective in elderly individuals, immune-suppressed persons and when a match is sub-optimal. Antiviral medication prophylaxis is a prevention measure that requires a daily prescription for one to several weeks depending on circumstances. Many studies have shown that prophylaxis is as effective as vaccination, but the medication has the potential for side effects. Infection control recommendations advise droplet plus standard precautions as a prevention measure.

Limited studies that have been conducted to demonstrate influenza transmission have varying interpretations. The evidence supports contact, droplet and droplet nuclei or airborne transmission, but the relative contribution of each mode is unclear. However, droplet transmission is considered to be the most important mode due to the production of particles through coughing, sneezing and talking. Most studies are either animal or human experiments under artificial conditions and are based on outbreak investigations or observational data. Sneezing generates particles of varying sizes, but a much smaller infectious dose is needed with influenza if the smallest particles are introduced into lower airways.

The current influenza isolation precautions for healthcare settings are standard plus droplet isolation in which an infected patient is placed in a private room or an area with other influenza patients. A mask should be worn when entering the patient's room and standing within three feet of the patient. A surgical mask should be placed on patients who are moved out of the room. The use of negative pressure rooms remains an unresolved issue at this point. Influenza studies in various settings are summarized as follows. Bean, *et al.* published a 1982 study on the survival of influenza viruses on surfaces. Viruses were recoverable for >24 hours from plastic or stainless steel and could be transferred to hands up to 24 hours. Viruses were recoverable for 8-12 hours from cloth or tissue and could be transferred to hands in 15 minutes.

Viruses were extremely difficult to recover after five minutes when hands were inoculated with influenza viruses. Viruses on hands <5 minutes were only viable at high viral titers. The study indicated a potential for influenza transmission through indirect contact. Ryan published a 2001 study on the benefits of hand washing among military recruits. Doctor visits for acute respiratory illness were reduced 45% among recruits who engaged in compulsory hand washing versus those who engaged in standard hand washing. However, the study did not specifically focus on influenza and hand hygiene.

Loosli, *et al.* published a 1943 animal study in which influenza was sprayed with an atomizer into an 8 x 10 x 10 room. The air was constantly agitated with a ceiling fan and humidity varied, but the air exchange rate was not reported. Groups of mice were placed in the room for 20-minute intervals to identify evidence of infection. Mice became infected up to 22 hours at the lowest humidity levels after the virus was aerosolized into the room. Vigorous sweeping of the room resulted in increased infection. Infectivity of the mice was much more limited at higher humidity levels. The study showed prolonged viral infectivity for $\geq$24 hours at lower humidity levels and raised the possibility of contact transmission. Increased infectivity after sweeping indicated possible airborne transmission. The ability to extrapolate the Loosli animal study to humans is unclear.

Schulman, *et al.* published a 1967 animal study in which mice were exposed for a 24-hour time period in the same cage with infected mice and mice separated by two wire screens. The groups of mice developed infection at the same rate. The study provided evidence for direct, droplet spread and airborne transmission because infected mice produced influenza infectious particles <10 µm. The ventilation rate was found to be inversely related to transmission. The relevance of the Schulman animal study to human experience is unclear. Blumenfeld, *et al.* published a 1959 observational study on an intra-hospital epidemic with a new subtype of influenza in a highly susceptible population. An acutely ill patient 40 years of age with rheumatic heart disease was admitted to a four-person room with no isolation precautions. Of the 62 patients and staff, 19 were vaccinated and 48% developed influenza-like illness (ILI); 70% of 30 persons tested had serologic evidence of influenza. The outbreak resulted in increased influenza in the community 11 days later.

Moser, *et al.* published a 1979 study of an influenza outbreak on a commercial airplane with five crew and 49 passengers. The plane was detained for 4.5 hours in Alaska with no ventilation for two to three hours. Of all crew and passengers, 30 remained on the plane. An acutely ill passenger 21 years of age also remained on the plane with severe coughing and fever. The individual was later found to be infected with the drifted H3N2 strain that was not included in the vaccine. The epidemic curve showed that 72% developed ILI and 20 of 22 persons tested had laboratory-confirmed influenza. The study indicated a point-source outbreak and efficient spread of influenza, but no increased risk of infection among passengers who completed the last leg of the trip with the index case. The 72% infection rate was found to be much higher than the secondary household attack rate of 20%.

The study showed a point-source outbreak with a new variant and transmission of influenza in a small enclosed space with low or no air exchange. Most passengers were likely to have come within 3 feet of the index case. Transmission was consistent with either droplet or airborne. Salgado, *et al.* published a 2002 study of influenza in an acute hospital. Influenza surveillance among inpatients showed rare nosocomial cases even with the use of positive pressure private rooms. The explosive nature of the nosocomial outbreaks may have been due to an ill HCW or another common mobile source.

Bridges published a 2003 study of previously unpublished data on influenza hospital transmission. Infants were cultured for RSV and influenza every two to three days. RSV patients were isolated and influenza cases were placed in one- to three-crib rooms. All doors remained opened, but no infections were detected in infants across halls or in adjacent rooms. Most nosocomial infections were in infants in adjacent cribs rather than in infants at the furthest distance in three-crib rooms. The study concluded that most spread was by large droplet and possibly contact.

Several infection control measures are recommended when an influenza outbreak occurs, such as cohorting, droplet precautions, vaccinations, antiviral medications, and limited movement of ill HCWs and visitors. However, multiple interventions increase the difficulty of evaluating and comparing the effectiveness of different strategies. During an influenza outbreak in a long-term care facility in California in 1998-1999, eight of ten residents tested positive for influenza. Illness was detected among staff one week prior to the outbreak; the vaccination rate was only 17% among personnel. Of 192 residents, 25 developed ILI and three were hospitalized. Of the two deaths, one resident was not vaccinated. The health department was notified and quickly stopped the outbreak by initiating control measures of droplet precautions, cohorting and antiviral medications.

An influenza outbreak among children and adults at a summer camp occurred when staff became ill first. Because cohorting was found to be ineffective as the initial control measure, antiviral medications were administered and resulted in a rapid decline of cases. The influenza studies and outbreaks show that contact, droplet and airborne transmission are all potential routes. The virus is transmissible after drying and some infectious particles <10 µm can be transmitted through the airborne route. Ventilation rates play an important role in transmission, but droplet and contract transmission are most observed in clinical settings. HCWs are critical in spreading influenza in healthcare facilities. Data have not been collected on the benefits of negative pressure rooms. Airborne transmission may occur, but clinical data suggest droplet transmission is most important. Additional studies are needed to assess the benefit of various control measures, including increased air exchange rates, surgical versus N95 masks, gowns and other barrier precautions, the role of contact transmission, and the benefit of negative pressure rooms.

Nosocomial Smallpox. Dr. Michael Lane, of the Emory University School of Medicine, presented an overview of nosocomial smallpox. Solid clinical, virologic and epidemiologic data have been collected to demonstrate that variola is spread by the respiratory route. Patients are non-infectious until the end of the prodrome when an enanthem forms in the back of the throat. Copious amounts of virus are present in the throat and respiratory secretions. Virus isolation in settling plates >6 feet from the patient is rare. Gauze masks were found to greatly reduce virus landing on plates of viral culture media near the bed.

No data of any sort have been gathered to compare rates of attack or transmission in persons with and without masks. Rare and well-documented instances of droplet nuclei aerosolization have been observed. For example, outbreaks in Great Britain were well-documented in which laundry workers who handled bed linens were presumably infected by aerosols from fomites. Of all patients in 48 European post-World War II outbreaks, ~50% acquired smallpox in the hospital. Of all spread cases, approximately

twice as many occurred from every hospitalized case than from every community case. Although the data are limited, these studies can be used to reach several conclusions.

Transmission immediately ceases after smallpox is recognized, patients are isolated and staff are vaccinated. Well-experienced vaccinators should have capacity to obtain a 100% take-rate, but reliance should not be placed on vaccination to protect HCWs who enter rooms of smallpox patients. As a result, some type of respiratory protection is needed. Fitting a smallpox patient with a modern N95 or another mask of a higher level is difficult due to tremendous edema and illness. However, masks on HCWs are useful and greatly effective in reducing large droplet transmission. Although additional research is needed to identify the types of masks that are necessary if any, vaccination is the first line of defense against smallpox.

Discussion. The co-moderators opened the floor for the workshop participants to provide input, make recommendations and pose questions to the Plenary Session 2 panel of presenters. The deliberations are outlined below.

- Stronger emphasis should be placed on the benefits of hand washing since this strategy is not well understood or used. Respirators and surgical masks will not be effective if individuals do not successfully implement easier control methods.
- Efforts to discontinue fit testing should cease. Fit testing and training must be continued because these interventions produce evidence on the effectiveness of respirators in preventing transmission of diseases. Fit testing is a critical component of respiratory protection that must continue to be conducted on an annual basis.
- The importance of the hierarchy of controls should be emphasized before a stronger focus is placed on respiratory protection. Previous studies have demonstrated the limitations of several interventions.
- Smallpox vaccination and other respiratory protection measures should be balanced.
- Patients should be immediately placed in respiratory, contact or droplet isolation before questions are asked and diagnostic test results are obtained as a general rule across all diseases. The sensitivity and specificity of tests should also be considered in isolation precautions.
- Goggles should be more strongly emphasized, made available and optimized from a product development perspective. Placement of surgical masks on patients is under-utilized to reduce large droplets.
- More attention should be given to higher rates of air exchange in hospitals outside of negative pressure isolation rooms. General dilution ventilation should not be used as the sole strategy to prevent disease transmission.

- Efforts should be made to identify the most important environmental controls. Minimal attention has been given to identifying and properly treating or placing patients in environmentally-appropriate rooms. For example, TB can be controlled or eliminated in healthcare facilities by recognizing the disease, isolating and maintaining patients in rooms, and administering treatment.
- Stronger attention should be given to behavioral research to increase proper use of respirators and promote hand washing and other environmental or hygiene interventions.

The Plenary Session 2 panel of presenters made follow-up remarks to the discussion.

- Problems with respiratory protection will decrease if the vaccination rate of HCWs and high-risk patients increases.
- Smallpox vaccination is 100% effective in the presence of a take of at least five years, but no studies have been conducted to prove this theory.
- Re-aerosolization is not a significant factor in the epidemiology of smallpox and TB, but may serve as an important component in SARS.
- Negative pressure isolation rooms for many viral respiratory illnesses that occur in the winter are not practical. However, clinical judgments must be made based on the patient's chest x-ray, presentation and context of the illness. More aggressive actions must be taken to implement hand hygiene programs.
- Training and education should be provided to HCWs to enhance understanding and knowledge of disease transmission and preventive measures. A study by the University of Geneva demonstrated a reduction in methicillin-resistant *Staphylococcus Aureus* and nosocomial infection rates with improved adherence to hand hygiene. Antiseptic hand gels are now widely available on cruise ships to decrease the incidence of transmission.

PLENARY SESSION 3: CURRENT STATE OF SCIENCE ABOUT RESPIRATORY PROTECTION

Drs. Paul Jensen and Douglas Trout of CDC co-moderated the presentations and discussion period for Plenary Session 3.

Respirator Performance with Infectious Agents. Dr. Sergey Grinshpun, of the University of Cincinnati Center for Health-Related Aerosol Studies, described several studies that have been conducted with simulants to demonstrate the performance of respirators with infectious agents. Respiratory protection devices are widely used

worldwide to reduce human exposure to aerosol particles. Extremely efficient respiratory protection devices are required for an outbreak of a highly infectious respiratory disease or deliberate use of a BT agent. Several indoor test chambers were designed with manikin-based protocols. The size of chambers ranged from 1-30 cubic meters and sodium chloride, potassium chloride and other non-biological particles were aerosolized.

A perfectly faced sealed mask was glued on the face of a manikin. An aerosol monitor was used to analyze the concentration and particle size distribution of microorganisms or particles in the breathing zone outside and inside the mask. Different inhalation flow rates and breathing patterns with breathing simulators were applied. The aerosol monitor targeted particle size distribution in addition to total particle concentrations within a given particle size range. A personal sampling system was recently developed to evaluate the respirator in the field. The device includes two optical particle counters, filters for microbial analyses and direct reading instruments.

Several microorganisms with diverse particle sizes were used in the respirator studies. The aerodynamic size combined physical size characteristics and the shape and density of particles, but most microorganisms are rod-shaped. The performance and efficiency of the N95 respirator and surgical mask were expected to be dependent on the microbial size, but respirator performance was actually found to rely on the aspect ratio. Because the similarities among respirators included penetration through filtered materials and leak, experimental studies were designed and conducted under controlled conditions to introduce a well-characterized leak under different situations, sizes and locations. The studies were also designed to distinguish the portion of the fraction of particles and microorganisms penetrating through the leak versus those directly penetrating through the filter.

The manikin-based protocol was standardized to perform aerodynamic modeling. The penetration efficiency was dependent on the number of physical characteristics. Re-entrainment of particles collected on the outer surface of the mask into the air during exhalation was analyzed, but the literature contains controversial evidence about the efficiency of resuspension. Efforts to introduce exhaled air with respirators on the manikin showed that actual resuspension was dependent on the type of microorganisms. Single particle counters did not measure aerosolization when the velocity of air in the opposite direction during exhalation was $\leq$3 m/second, but aerosolization can be expected when the velocity of >3 m/second represents coughing and sneezing.

In analyzing the survival of viable microorganisms on respirator filters and multiplication during single use, repeated use and storage, minimal growth was seen in four microorganisms. However, this effect was found to be statistically negligible in contrast

to the re-entrainment of particles. The surgical mask has a collection efficiency of at least 80% with 20% penetration. The N95 respirator has a collection efficiency of at least 95% with 5% penetration. Although the collection efficiency should be increased >95% with penetration of few particles, the pressure drop and discomfort of the respirator will increase with this method. Small particles are primarily collected by diffusion and large particles are collected by impaction and interception with maximum penetration of ~0.3 µm.

Several attempts have been made to introduce additional mechanisms, particularly pre-treated surfaces that utilize electrostatic deposition, diffusion, impaction and interception. Because the efficiency decreases over time with these strategies, efforts are being made to drastically increase the efficiency of existing respirators. Unipolar ion emission is a mechanism that has been incorporated into several commercial air cleaning devices. Viruses, bacteria and other fine and ultra-fine particles are unipolarly charged by air ions, repel and migrate toward surfaces. Several experiments have been performed showing the quantitative characteristics of this method. A hypothesis was developed indicating that continuous unipolar emission of air ions in the vicinity of an FFP enhances the protection efficiency of the respirator without decreasing the comfort level. The hypothesis was based on the theory that charged particles are collected on the outer surface of an FFP. A barrier would then be created near the respirator to ensure that air rather than particles penetrate.

The hypothesis was tested by face sealing the respirator on a manikin and conducting a leak test. N95 and R95 respirators, dust and mist masks and the surgical mask were tested at two breathing flow rates to reflect normal working conditions and a high workload. The penetration efficiency was calculated as the ratio of the particle concentration inside and outside the mask. The average penetration efficiency of the N95 respirator was 2% without ion emission, but decreased as the time of ionization increased. Similar results were seen with the dust and mist mask, but the initial penetration efficiency was more dependent on size and higher than the N95 respirator. The surgical mask had an initial penetration efficiency of 18% for sub-micron particles and ~12% for super-micron particles.

An enhancement factor resulting from continuous unipolar ion emission was introduced to quantify this effect. The enhancement factor was calculated as the ratio of penetration efficiency with and without ionization. Enhancement factors of 48.4 for the N95 respirator and 194 for the surgical mask were at 30 L/minute measurements. Similar results were seen for 85 L/minute measurements. The ion emission rate was found to depend on the enhancement factor, but polarity had no effect. Several conclusions were reached after testing the hypothesis with the manikin-based protocol. Continuous emission of air ions in the vicinity of a face-sealed filter respirator drastically enhanced its performance against fine and ultra-fine particles. The protection efficiency

of a face-sealed respirator improved 20- to >1,000-fold compared to conventional masks. The enhancement effect was found to be applicable to various protection devices, such as the N95 and R95 respirators, dust and mist masks, and surgical masks.

The hypothesis was also tested with a human subject using a standard PortaCount device for fit testing. The fit factor was calculated as the ratio of the total particle concentration outside and inside the mask. The overall fit factor without ionization was an order of magnitude higher than the fit factor with ionization. Pilot tests involving a human subject confirmed that the face-piece respirator protection efficiency could be considerably enhanced due to air ionization. The leakage effect between the mask and human reduced the enhancement factor, but was still significant. To determine the importance of the enhancement from the human exposure viewpoint, calculations were performed based on the experimental study. Ions were introduced at a level of 10^6 cm^3 in the vicinity of the respirator. The air velocity was compared, inhalation was applied to a particle size of 0.1 µm, and migration velocity was compared due to repelling.

The calculation showed that the ratio of these factors was 75 with migration being much more significant. Enhancement of the respirator performance by the unipolar ion emission was governed by the electrostatic shield mechanism. Experimental data were used to apply the calculation to different situations and translate results to exposure, inhalation dose and risk. Assumptions were made for influenza virus concentrations in air of 10^4 cm^3, an inhalation rate of 30 L/minute, and an inhalation time of 15 minutes. The conventional surgical mask would provide 18% penetration efficiency for 0.1 µm particles. With no ion emission, 810 viruses would be inhaled. The actual number of viruses that would be inhaled during the same time would be ~1 due to migration and electrostatic shield effects. The ion emission effect would make an important difference in health risks with an infectious influenza A2 dose of 790 viruses.

Respirator Selection for AIAs. Dr. Mark Nicas, of the University of California-Berkeley, described the process to select respirators for AIA. The SARS virus, *M.tb*, smallpox and the pneumonic plague are pathogens that are transmitted person-to-person via air. Infection is often due to droplet transmission or spraying of non-inspirable particles onto mucous membranes. Close contact is required for infection because droplets do not travel far. Close contact is also required with inhalational exposure because the infection risk is inherently low. Based on these views, an N95 FFP respirator is judged to be sufficient as a barrier to prevent droplet contact and also as a means to prevent inhalation exposure.

Inhalation transmission can occur with droplet transmission because droplets up to 100 µm in size can be inhaled, but close contact is required. The variola virus, *M.tb* and certain other pathogens have an infectious dose as low as one organism and can be

carried on respirable particles. However, close contact is not required for infection in these situations. A low pathogen concentration in air can impart a high risk of infection if one organism has the ability to infect. N95 masks permit 10% total inward leakage (TIL) of contamination around the face seal. As a result, the residual risk with an N95 respirator may still be substantial. With smallpox, for example, the infectious dose appears to be a single virus and airborne infection is via droplet transmission and inhalation. A recommendation has been made for HCWs to use N95 masks when attending smallpox patients related to a BT incident.

The expected inhaled dose depends on the airborne concentration of the pathogen, breathing rate of the individual, exposure duration and fraction of inhaled particles deposited. Calculations were performed with an expected dose of 3% and an infection risk of 26% for smallpox at a fairly low virus concentration in air. Because a respirator permits penetration due to face seal leakage, the risk equation was modified to include a penetration factor. If the expected dose was 3% without a respirator, an N95 mask would reduce the expected dose by 90% and decrease the infection risk to 3%. However, a determination would need to be made on whether 3% is an acceptable infection risk because federal and state agencies have not yet addressed this issue for HCWs to make informed choices.

High-quality hooded PAPRs used in the pharmaceutical industry are better respirators and show a typical penetration factor of <0.1% leakage based on the Cohen, *et al.* 2001 published study. When a hooded PAPR with a HEPA filter was input into the smallpox equation, the new risk of infection was 0.03% and reflected a 100-fold lower risk than 3%. The equation showed that a respirator of higher quality than an N95 FFP would reduce infection risk. A risk-based approach can be applied to select an appropriate respirator, but certain parameters must be specified, including the airborne pathogen concentration, exposure duration of frequency, infectious dose model, model parameters, respirator penetration value, and acceptable risk of infection.

The risk-based approach contains several uncertainties, particularly the pathogen concentration in air, model parameters, and a threshold versus probabilistic infectious dose model. To address uncertainties in the infectious dose model, alternatives can be applied. The infection risk can be calculated by identifying a certain number of microbes each individual must receive to become infected. The infection risk can also be estimated by determining the probability of success of each microbe in infecting an individual. Minimal data have been published about the infectious dose of airborne pathogens or the best infectious dose model. However, the overall evidence is consistent with an infectious dose of one bacillus or one virus for *M.tb* bacilli or the variola virus, respectively.

For a single short emission event, the expected dose of respirable pathogens due to a single release can be estimated by the number of microbes released into the air and carried by respirable particles, room volume, a ratio of the room supply and exhaust air rate, and exposure duration. If the exposed individual was near the emission point within three feet, the estimated expected dose would be multiplied by 2 or 3. For ongoing emission, the emission rate can be estimated by the number of pathogens released into the air per hour and carried by respirable particles, room volume, a ratio of the room supply and exhaust air rate, and exposure duration. If the exposed individual was near the emission point within three feet, the expected dose would be multiplied by 2 or 3. The respirable pathogen emission rate is a product of the cough rate per hour, respirable volume per cough, and pathogen concentration in respiratory fluid.

Several published studies were used to identify parameters, including the Loudon and Roberts 1967 study for the cough rate; the Nicas, *et al.* 2004 study for the respirable and inspirable particle volume; and the Yeager, *et al.* 1967 study for *M.tb* values. The median cough rate and mean concentration from these studies were input into the equation with the respirable volume. The estimated emission of 1.5 respirable bacilli/hour is extremely close to the average emission rate of respirable *M.tb* bacilli of 1.2/hour found in the classic Riley, *et al.* study. Super-spreaders and dangerous disseminators are highly infectious source cases that are likely to have high values for cough frequency, pathogen concentration in respiratory fluid and aerosol volume per cough. Source cases appear infrequently, but generally cannot be identified beforehand and are certain to present eventually.

Estimating the particle size distribution or volume of culture fluid that would be aerosolized is difficult in a laboratory setting. Other than for *M.tb*, data on pathogen concentrations in respiratory fluid are not published and tremendous variability can exist among patients. As a result of these uncertainties, a conservative approach should be taken in which the infectious dose is assumed to be one microbe and the expected dose without respirator use over the duration of exposure is assumed to equal to one microbe. These assumptions should be made unless solid evidence supports contrary beliefs. Based on these default assumptions, the risk of infection would be 63% without a respirator, 9.5% with an N95 FFP respirator, and 0.1% with a hooded PAPR with a HEPA filter. Regardless of the final selection, the decision process should be documented with assumptions identified, a numerical risk estimate offered and an acceptable risk level specified. Reliance should not be placed on expert opinion if the assumptions and acceptable risk values are not defined.

Respiratory Protection in Health Care: Opportunities for Risk Reduction. Dr. Donald Wright of OSHA described several opportunities to reduce risk in healthcare settings with respiratory protection. The U.S. healthcare industry employs ~10 million workers with HCWs comprising 8% of the total workforce. The 2002 Bureau of Labor

Statistics (BLS) Survey showed that illness and injury rates of all types in the healthcare industry are two times higher than those in private industry. Occupational hazards in healthcare settings include chemical hazards from solvents and antineoplastic drugs; biological hazards from TB, HIV, SARS and the hepatitis B virus; physical hazards from ionizing radiation and noise; musculoskeletal hazards from patient handling; and work organizational hazards from shift work, stress and workplace violence.

Respiratory hazards in healthcare settings can be categorized by source. TB, SARS, pertussis, varicella, anthrax, plague and smallpox are hazards from individual patients. Radiation, pharmaceuticals, disinfectants, chemical reagents, anesthetic gases and formalin are hazards from patient diagnosis or treatment. Chemical, nerve or blister agents from sarin and mustard; biological agents from anthrax, smallpox and plague; and radioactive agents from a "dirty bomb" are emerging hazards from BT events. In addition to hazards, hospital employees may also be exposed to chemical, infectious or BT agents and other airborne contaminants. Engineering controls are extremely valuable, but may not be adequate or feasible to protect HCWs. All of these hazards and exposures demonstrate the critical need for respiratory protection in healthcare settings.

OSHA determined that the Dartmouth-Hitchcock Medical Center (DHMC) serves as an exceptional model of hospital respiratory protection. DHMC contains a hospital with 396 inpatient beds and a tertiary care center; a clinic with physicians throughout New Hampshire and Vermont; and a 16-department medical school with 600 students. Of DHMC's 6,300 employees, 4,300 are involved in direct patient care. The DHMC Safety and Environmental Program (SEP) manager serves as the program administrator of the RPP. The RPP is divided into an industrial RPP for hazards with no direct patient care and a clinical RPP for biological hazards.

DHMC's written and comprehensive RPP features several components, such as a thorough hazard assessment, appropriate respirator selection, records maintenance, annual program evaluation, modification and improvements, department program champions for annual fit testing and training, and medical certification. The industrial RPP is comprised of 75 workers certified for industrial respirator use in the areas of chemical spill response; engineering to change HEPA filters; the laboratory for use of formalin, Xylene and biologic agents; the pharmacy for use of antineoplastic drugs; and the SEP. The hazard assessment component of the industrial RPP was designed by selecting a respirator, identifying a filter and describing an activity for each hazard.

The clinical RPP is comprised of 19 departments at "higher risk" of exposure to infectious aerosol patients, including the emergency, occupational medicine, radiology, transportation and infectious disease departments, the IV team, ICU, housekeeping, General Medicine Clinic and Fast Track. The hazard assessment component of the

clinical RPP was designed by selecting a respirator and describing an activity for each infectious agent. The N95 FFP respirator was selected for routine care of TB and SARS patients, but a PAPR was selected for aerosol generating procedures of TB and SARS patients.

Departmental program champions manage and serve as the hallmark of DHMC's RPP. Each shift in all 19 high-risk departments has a champion. Workers must undergo a comprehensive train-the-trainer program to become champions and are then qualified to perform fit testing and provide annual training and education to staff who need a respirator in the department. Champions are responsible for tracking and updating the respirator certification process and ensuring 24-hour/day, seven-day/week coverage of infectious aerosol patients. The SEP performs periodic and unannounced audits of each department. Of DHMC's 4,300 employees in direct patient care, only 8% or ~350 are enrolled in the RPP for infectious agents. The remaining 92% of staff continue to provide coverage for DHMC. Although DHMC treats pertussis and other AIAs, the facility only treats ~4 TB cases per year.

DHMC's terrorism and respiratory response is comprised of an ambulatory decontamination team with PPE of a PAPR and protective clothing as well as a trauma decontamination team with PPE of supplied air respirators. However, use of the supplied air respirator is being reevaluated due to the hazard of tripping over hoses. DHMC has taken several actions to prepare for an infectious crisis. Program champions can rapidly certify additional users if demanded by a certain situation. An infectious disease readiness committee was established. A contingency plan was developed to convert one wing to a respiratory isolation unit if needed and a nearby off-site location was identified to serve as a field hospital if DHMC becomes overwhelmed during a crisis.

DHMC recently developed a protective code blue to respond to real-time incidents. Large numbers of staff respond to a regular code blue, but the "protective" component limits the number of responders to six employees enrolled in the RPP, including a physician, nurse, respiratory technician and CPR team members. A respiratory response cart that is prepared and positioned prior to a protective code blue includes 2 PAPRs on the top of the cart, six additional tagged PAPRs in a locked drawer of the cart, and all CPR supplies. DHMC periodically performs tabletop exercises to test the infectious disease crisis plan and learned several lessons from a SARS tabletop exercise.

An infectious disease disaster workgroup should be developed and maintained. A general audit system should be created to evaluate supplies and training. The Public Affairs Office should take more proactive measures in preparing for an event by developing literature that can be rapidly released to the media. Methods to notify staff

should be improved and facilities within DHMC that are covered by a lock-down should be clarified. A color system should be adopted to restrict access. Drills should be performed to enhance operations and the decision-making tree.

DHMC has identified several programmatic challenges in developing and maintaining its RPP, such as employee turnover, education and communication among SEP units and individual departments, availability of clinical staff for fit testing and training, endorsement of the RPP by management, decontamination of PAPRs, and the audit process. Overall, all facilities must consider several issues in using respiratory protection to reduce risk in healthcare settings. Hospitals have high illness and injury rates, are challenged by numerous and diverse respiratory hazards, and need a comprehensive RPP. A comprehensive RPP can be developed and designed to preserve valuable financial resources.

Discussion. The co-moderators opened the floor for the workshop participants to provide input, make recommendations and pose questions to the Plenary Session 3 panel of presenters. The deliberations are outlined below.

- A study should be conducted to compare hospital costs between developing an RPP and defending an allegation that appropriate respiratory protection was not provided.
- Clear messages should be delivered to avoid inaccurate perceptions that implementation of an RPP in non-healthcare settings is relatively simple. For example, development and maintenance of an RPP in a steel mill and asbestos or lead abatement project are as complex as the healthcare industry.
- Data should be gathered on actual injury and illness rates specifically from respiratory transmission in healthcare facilities. This information will be extremely important to guide the decision-making process of hospitals in selecting an appropriate RPP.
- Caution should be taken in stating that the risk of TB infection is 63% without a respirator. For example, many HCWs who have treated TB suspects and active TB patients over a long period of time have never developed infection. Moreover, the infection risk is <33% for household contacts of TB patients.
- Efforts should be made to reconcile theoretical models with the realities in healthcare. Based on the default assumption, for example, transmission of a variety of respiratory-spread infectious agents from emergency rooms and patient floors to HCWs would be more widespread.
- A healthcare facility's rate of treating AIAs should be acknowledged as a critical factor in the workforce that will be needed to maintain an RPP. For example, DHMC only needs 8% of its direct patient care staff to implement

the RPP because ~4 TB cases are treated per year. However, Grady Memorial Hospital in Atlanta is an inner-city facility that would need a larger proportion of its staff to maintain an RPP because 150 active TB cases are treated and 1,500 patients are isolated each year.

The Plenary Session 3 panel of presenters made follow-up remarks to the discussion.

- Endorsement of an RPP by management is generally strengthened over time and with education.
- OSHA's July 23, 2004 letter of interpretation states that an RPP for TB is not necessary if a facility does not admit TB patients and is located in an area with no TB cases over the last one or two years. The letter is posted on OSHA's web site.
- An antimicrobial coating could be placed on respirator filters to destroy viable pathogens that remain on the surface of the respirator and are then available to be touched by hands and transferred to mucous membranes.

PLENARY SESSION 4: RESEARCH ON RESPIRATORY PERFORMANCE

Drs. Michael Iademarco and Ronald Shaffer of CDC co-moderated the presentations and discussion period for Plenary Session 4.

Evaluation of Respirator Fit-Test Methods. Dr. Roy McKay, of the University of Cincinnati Medical Center, assessed several respirator fit-test methods. Engel and Waters published a 2004 editorial to examine whether the benefits of OSHA's new TB respiratory protection standard are justified by its cost. The letter stated that fit-testing requirements are complicated and include placing banana oil and other liquids in front of the respirator wearer to determine whether odors can be detected. Because banana oil is not used to test FFP respirators, the letter demonstrates that confusion exists about fit testing. OSHA's 1998 accepted fit-test methods are categorized into two groups. Qualitative methods include saccharin solution aerosol, Bitrex solution aerosol, isoamyl acetate and irritant smoke. Quantitative methods include generated aerosol, ambient aerosol or the TSI PortaCount Plus with the N95 Companion, and controlled negative pressure or the Fit Tester 3000.

The only acceptable methods to test N95 FFPs are saccharin solution aerosol, Bitrex solution aerosol, and ambient aerosol or the TSI PortaCount Plus with the N95 Companion. Accepted and reliable fit-test protocols that are appropriately followed and conducted will be effective and provide a high level of confidence on the fit of the respirator. However, pass/fail criteria are still an area of debate among fit testers. The OSHA standard requires several test exercises to simulate whether a respirator will

continue to fit after an employee wears the device in actual practice. These exercises include breathing normally and deeply; moving the head side-to-side and up and down; talking and grimacing; and bending over or jogging in place.

As a result of management opposition to all of the one-minute exercises in the required protocol, some tests may be shortened or not administered at all. This practice may lead to decreased confidence about the effectiveness of the fit-test methodology, particularly the pass/fail criteria. To address this issue, respirator fit testers must be appropriately trained, knowledgeable of the fit-testing method and not alter the protocol. The purposes of fit testing are to identify a specific make, model, style and size of a face piece that provides an acceptable level of fit to the individual; provide an opportunity to evaluate whether additional hands-on training is needed; and assess the ability of the individual to appropriately don the respirator.

The best frequency for respirator fit testing has not yet been determined, but frequency in using the respirator as well as problems and advantages of the fit test can be examined to increase confidence. Infrequent respirator use is problematic because the user is less familiar with donning and user seal check procedures. Donning the respirator and assessing user seal check procedures are more difficult with FFPs. The advantage of the fit test with infrequent respirator use is that a qualified individual can provide independent evaluation and guidance. Frequent respirator use is problematic because opportunities for exposure and damage are greater. The advantage of the fit test with frequent respirator use is a greater need to evaluate fit, donning due to wear and tear, and changes in fit.

The most important fit-testing component has not been specified to date, such as more, less or different exercises, repeat donning and frequency. However, one opinion is that repeating the fit test a short time after the initial test may provide the best opportunity to evaluate problems with donning, selecting and using the respirator. All workers do not correctly wear respirators even after training, but industrial evidence has been collected to show that fit testing is necessary and beneficial with FFP respirators. Data have also been gathered to demonstrate that fit factors correlate with workplace factor studies. Earlier studies did not show a strong relationship, but these results were most likely related to study designs.

Decker and Crutchfield performed a laboratory evaluation in 1993 and found a significant correlation between fit factors and workplace protection factors (WPFs). Coffey, *et al.* conducted a 1998 study that showed a significant relationship between simulated WPFs and fit factors based on three quantitative fit-test methods. However, this research demonstrated minimal correlation when poorly fitting face pieces were excluded. The results provide a possible explanation for no or limited correlation in

previous studies. Workers must pass a fit test to participate in a WPF study, but prior research attempted to link only passing fit factors.

Fit tests were initially conducted in the majority of previous WPF studies, but WPF samples were obtained at a later date. As a result, these studies did not consider re-donning. A single measure of fit factor may not fully take into account variability associated with re-donning. The Coffey data showed that laboratory performance of N95 respirators was greatly enhanced when quantitative fit-testing was performed to screen out poorly fitting respirators. Zhuang, *et al.* reached several conclusions in a 2003 study to investigate the effect of good and poorly fitting elastomeric half-mask respirators at a steel foundry. WPFs are significantly correlated with fit factors. Fit factors are a meaningful indicator of respirator performance in actual workplace environments. The use of quantitative fit testing as part of an RPP is supported. Inclusion of poorly fitting face pieces in WPF studies is an important component.

Nicas and Neuhaus conducted a 2004 study on APFs of half-mask respirators. The authors concluded that the wide discrepancy among WPF studies was due in large part to the physical nature of measured contaminants. Studies involving gas-phase and small-particle contaminants tend to yield relatively low WPFs, while those with large-particle contaminants typically generate relatively high WPFs. This research shows that fit factors correlate with WPF studies. Recent and well-designed studies provide solid support for fit testing of respirators.

Recent NIOSH Fit-Testing Research. Dr. Christopher Coffey of CDC presented several fit-testing studies conducted by NIOSH. The purposes of the research were to determine the performance of surgical masks; ascertain the performance of N95 respirators without training or fit testing; investigate the efficacy of current fit-test methods; and verify the value of fit testing in general. The studies were designed with 54 respiratory devices, including 33 N95 FFP respirators, 15 N95 elastomeric half face-piece (HFP) respirators and six surgical masks. Of the N95 FFPs selected from 14 manufacturers, 20 were of the cup design and 13 were of the “duck bill” design. The N95 elastomeric HFPs were selected from 11 manufacturers and the surgical masks were selected from five manufacturers with various configurations for ear loops, face shields and cup shape.

The models were randomly selected from devices that were commercially available when the studies were initiated, but may not represent products currently on the market. The 25 subjects had a variety of facial sizes ranging from small to large, but the cohort was not selected to fit a particular face-piece test panel. The Bitrex, saccharin and TSI PortaCount Plus with the N95 Companion were the three fit-test methods used in the studies. All methods were conducted in accordance with Title 29 CFR 1910.134. A reference test was also performed to compare the fit test results and determine

performance of various devices. The simulated WPF (SWPF) test included six donnings and seven one-minute exercises to obtain filter penetration and face seal leakage measurements. SWPF values were equivalent to the PortaCount fit factor and used to calculate the fifth percentile value of the geometric mean (GM) and geometric standard deviation (GSD).

In terms of the performance of the six surgical masks combined, the GM was 2.6, the GSD was 1.6, and the fifth percentile value was 1.2. For individual surgical masks, the GM ranged from 1.6-4.0, the GSD ranged from 1.4-1.6, and the fifth percentile value ranged from 1.0-1.9. The GMs and fifth percentile values were statistically significant for several masks. Of the 600 simulated WPF tests NIOSH performed, only three surgical masks were found to provide an adequate level of protection.

To determine the performance of the 33 N95 FFPs, H-values were calculated to identify the percentage of users who received an adequate level of protection without training or fit testing. Research in the early 1970s specified an H-value of 0.9 for an HFP respirator. Of the 600 simulated WPF tests NIOSH performed, adequate levels of protection were provided by 74% of the 33 N95 FFPs and 92% of the 15 N95 elastomeric HFPs. Seven models of each type had good fitting characteristics without fit testing or user training. The fifth percentile value was 2.9 for N95 FFPs and 7.3 for N95 elastomeric HFPs, but an acceptable level of performance is $\geq$10. Of the 33 N95 FFPs, 18% had a fifth percentile value of at least 10. Of the 15 N95 elastomeric HFPs, 40% had a fifth percentile value of at least 10.

The worst performing N95 elastomeric HFP was nearly three times better than the worst performing N95 FFP. Less than 5% of N95 FFPs had an SWPF fifth percentile value <10, but the most poorly performing respirator had an SWPF fifth percentile value of nearly 80%. The range of SWPF values for N95 elastomeric HFPs was not as wide as those for N95 FFPs. The GMs and fifth percentile values of the N95 elastomeric HFP, N95 FFP and surgical mask were statistically different.

To determine the efficacy of fit-test methods, two statistical analyses were applied. The alpha error determined the probability of rejecting adequately fitting respirators, while the beta error identified the probability of accepting poorly fitting respirators. Each SWPF value was matched with fit-test results. False conclusions of an adequate protection level were the same overall for each of the three fit-test methods for all 48 models combined, but the N95 Companion method generated a lower rate of false conclusions. The beta error was much lower for N95 elastomeric HFPs than N95 FFPs.

To verify the value of fit testing, the cumulative distribution of SWPF values was compared between subjects with no fit testing and those who passed three fit-test methods. The results showed that passing any fit test increased the level of protection

provided by any type of respirator. No subjects passed the three fit-test methods for several N95 FFPs, but subjects passed fit-test methods in all N95 elastomeric HFPs. For N95 FFPs, passing the Bitrex method resulted in fifth percentile values ranging from 2.8-39.2. Without fit testing, only 25% of respirators met the expected level of protection. Percentages of respirators meeting the expected level of protection increased to 76% after passing the Bitrex test, 67% after passing the saccharin test, and 97% after passing the N95 Companion test.

In terms of the effect of fit testing on fitting characteristics of the respirator, passing a fit test did not result in a substantial gain in protection. However, passing a fit test with poorly fitting respirators provided a tremendous increase compared to no fit testing. The results of 18 N95 FFPs showed a fifth percentile value of 2.3 or nearly no protection when failing the N95 Companion test, but this number increased to 74.5 when passing the test.

Several conclusions were reached based on the results of the NIOSH studies. The level of protection is statistically difference among N95 FFPs, N95 elastomeric HFPs and surgical masks. The strongest to weakest levels of protection were provided by N95 elastomeric HFPs first, N95 FFPs second, and surgical masks third. Protection was found to vary among models in each category with N95 elastomeric HFPs having the smallest distribution of values. No fit-test method met the American National Standards Institute (ANSI) Z88 recommended criteria for accuracy, but the data demonstrated that fit testing is an important element of an RPP. The highest level of protection is provided by passing a fit test with a respirator that has inherently good fitting characteristics.

Respirator Fit and Anthropometrics. Dr. Ziqing Zhuang of CDC presented anthropometrics research that has been conducted to support fit-test panels. Anthropometrics panels of facial dimensions are relied upon to provide sizing references for respirators in several applications, such as establishing APFs, designing and developing respirators, creating TIL performance standards and testing, and developing research standards. The Los Alamos National Laboratory (LANL) established current panels based on U.S. Air Force (USAF) survey data from 1967-1968. The facial anthropometry was assumed to be representative of U.S. adults with LANL panels expected to accommodate 90%-95% of the U.S. population.

The 25-member LANL panel was selected with the following criteria. To test full face-piece respirators, face length ranged from 93.5-133.5 mm and face width ranged from 117.5-153.5 mm. To test half-mask respirators, face length ranged from 93.5-133.5 mm and lip length ranged from 34.5-61.5 mm. However, concerns were raised about the LANL panel because demographics of the U.S. population have changed over the last 30 years and military data may not fairly represent the diversity of face sizes in the

civilian population. In 1975, 1,467 employees were measured and >10% were found to be outside the boundary of the LANL panel.

The U.S. Bureau of Mines (USBM) 1978 survey of 48 male mine rescue workers also showed that the LANL panel was not representative of the U.S. population. As a result, a large-scale survey of civilian workers was recommended. In 2002, NIOSH determined that 16% of subjects enrolled in the Civilian American and European Surface Anthropometry Resources were outside the limits of the LANL panel for full face-piece respirators because facial dimensions were not measured. NIOSH initiated a research project to address these issues. An anthropometrics database was developed specifying the face size distributions of respirator users. The applicability of the LANL respirator fit-test panel was evaluated. The correlation between facial dimensions and respirator fit was investigated. New respirator fit-test panels were developed.

NIOSH's stratified sampling plan for the anthropometrics database included both genders; four racial/ethnic groups of whites, blacks, Hispanics and others; and three age groups of 18-29, 30-44 and 45-66. The "other" group included Pacific Islanders and Native Americans. The 3,997 subjects were recruited from eight states, represented 2,543 males and 1,454 females, and included various industries of manufacturing, construction, healthcare, law enforcement and firefighters. Traditional measurements included an anthropometer and both sliding and spreading calipers. The USAF subjects were extremely well matched with the U.S. population by age and race based on 2000 census data.

However, the NIOSH and USAF surveys were significantly different in terms of face length, face width and lip length. Only 84.7% of subjects were included when NIOSH data were incorporated into the LANL panel for full face-piece respirators. NIOSH reached several conclusions based on these results. The LANL panel for full face-piece respirators excluded >15% of the current U.S. population. Subjects in the 2003 NIOSH survey had larger key facial dimensions than USAF subjects. The recent NIOSH survey is more representative of the current civilian population and the LANL panel should be revised. NIOSH applied two-dimensional and principal component analysis approaches to develop the new panels. The dimensions were selected based on a literature review and correlation analysis among 18 facial dimensions, body weight, body height and neck circumference.

The literature contains evidence to demonstrate the correlation between facial dimensions and the fit of half-mask respirators. The eight studies included in the literature review were conducted from 1982-2003 with both males and females and focused on face length and face width. The research showed that lip length is not an appropriate factor to define a test panel for half-mask respirators. Face length and face

width were selected to define panels for both half-mask and full face-piece respirators. In the new 25-member NIOSH panel, face length ranges from 98.5-138.5 mm and face width ranges from 120.5-158.5 mm. The panel includes >97% of the population because subjects were weighted to match the national population.

Ten facial dimensions were selected for the principal component analysis (PCA), including minimum frontal breadth, face width, bigonial breadth, face length, inter-pupillary breadth, head breadth, nose protrusion, nose breadth, nasal root breadth, and Menton-Subnasale length. The PCA defines a new coordinate system using linear combinations of original variables to describe trends in data. Of NIOSH's two new panels, the face length/face width panel is recommended for selecting subjects for TIL testing of both half-masks and full face-piece respirators. Additional research is needed before recommendations can be made on the PCA panel.

Respirator Disinfection, Disposal, Reuse and Storage for Infectious Aerosols. Mr. Craig Colton, of the 3M Company, outlined several actions that should be taken when respirators are used for infectious aerosols. Guidance on respirator disinfection has been issued since 1963, but several concerns have been raised about the recommendations. Users of shared respirators can spread disease if the device is not cleaned and treated on a regular basis or before being worn by different persons. Infectious hazards from handling respirators have not traditionally been a concern. The ANSI Z88.2 standards recommend sanitization of respirators by removing contaminants and inhibiting actions of agents that cause infection of disease. The disinfection guidance recommends destroying and removing pathogenic organisms, particularly with chemical substances.

Cleaner sanitizers containing quaternary ammonium or another bactericidal agent should be sanitized in hypochlorite, aqueous iodine or quaternary ammonium solutions. With infectious aerosols, concerns have shifted from spreading disease to handling a contaminated respirator. These issues have emphasized the need to develop infectious aerosol recommendations. Low-level disinfection is the process that eliminates some bacteria, viruses and fungi, but may not kill resistant microorganisms. Low-level disinfection is generally recommended for non-critical items in which a respirator rather than a patient is touched. Non-critical items do not normally touch a patient or only touch intact skin.

The Association for Professionals in Infection Control and Epidemiology developed guidelines in 1990 that recommended some materials for respirator use, but handling precautions have been added since that time to infectious aerosol requirements for cleaning, disinfecting, inspecting, maintaining, repairing and storing respirators. Handling precautions recommend that respirators be handled for disposal in the same manner as contaminated waste. Autoclaving should only be applied when the respirator

or filter will not be reused. Because some materials may off-gas or damage respirator components, a disinfectant may need to be tested on the respirator or the respirator manufacturer should be consulted.

The disposal guidance recommends disposing of FFP respirators or replaceable filters, but specific requirements to dispose of a respirator are minimal. Respirators used in asbestos activities are treated as asbestos waste and respirators used in infection control should be treated as contaminated waste. Reuse guidelines in NIOSH Publication 96-101 recommends reuse based on loading of the filter and functioning of the respirator. The guidance also clarifies that the respirator is limited by hygiene, damage and breathing resistance if no oil mist is present. Studies have shown that properly fitted FFP respirators may be reused several times during a day and reuse may be more dependent upon infection control procedures. Key outcomes from this research are summarized below.

Four separate situations in WPF studies did not indicate significant differences in performance over the course of a shift. Significant effects were not seen from re-donning the respirator, slippage, change in fit, filter efficiency degradation, or increased face seal leakage from loading. The studies did not demonstrate that time of day or duration of use of the respirator was associated with a difference in performance. Brosseau, *et al.* conducted a study in 1997 that demonstrated experimental concentrations were probably higher than those in work settings. The results indicated that bacteria could remain viable on filters for several days. The implications for reusing, handling and disposing of respirators showed that training might be needed to recognize when exposures require immediate disposal of respirators.

Reponen, *et al.* conducted a study in 1999 with N95 respirators using *Mycobacterium smegmatis* as a surrogate for *M.tb*. Bacteria were tested for survival one to nine days after loading, but were unable to grow on filters. However, bacteria survived up to three days even under ideal growth conditions. Wang, *et al.* conducted a study in 1999 to test bacteria on NIOSH-certified polypropylene respirator filters. Bacteria were unable to grow, but the *Pseudomonas fluorescens* bacteria survived <3 days and the *Bacillus subtilis* survived >13 days. The findings suggested that spore forming bacteria may have greater viability than vegetative bacteria and careful consideration is required for filter reuse.

Johnson, *et al.* conducted a study in 1998 with a TB simulant to test six FFP respirator models that were stored at room temperature in a plastic bag for 28 days. No additional viable organisms were recovered after day 7. Internal contamination from environmental bacteria was believed to be a result of handling by removing the sample from the bag. The results showed that respirators might be reused with minimal risk of internal contamination over a one-week period if the respirator is carefully handled with

non-filter components and stored. Pasanen, *et al*. conducted a study in 1993 in which two high-efficiency filters of fiberglass and cellulose were loaded. Microorganisms were loaded in a cow barn for an eight-hour day over a two-week period and continuously in a wastewater treatment plant for a one-week period. The filters were stored at 98% RH for 35 days and growth of microorganisms was attributed to storage in a humid environment.

Pasanen, *et al.* conducted a similar study in 1994 in which two high-efficiency filters of fiberglass and cellulose were loaded, inoculated with *Stachybotrys atra*, and stored at three RH ranges of 78%-100% for 86 days. The bacteria grew and produced toxins on cellulose filters at high RH conditions, but these conditions probably would not occur during normal respirator use and storage. The reaerosolization of microorganisms is the process by which aerially deposited materials can be resuspended by high air flow through the filter with a cough, sneeze or handling. The size of resuspended particles may be different from deposited particles.

Quian, *et al.* conducted a study to measure reaerosolization of *M.tb* surrogates and other test particles using three N95 respirators. No reaerosolization was found at RH levels >35%. The results showed that reaerosolization of collected TB bacteria and other particles less than a few microns in size is insignificant at conditions encountered in respirator wear. These conclusions may also be valid for other fibrous filters. Kennedy and Hinds conducted a study in 2004 in which polystyrene latex particles 1 µm in size were used to simulate anthrax spores. Particles from two brands of N95 disposable respirators were dropped three feet onto a hard surface to be measured. The study showed that a small and consistent fraction of 1 µm particles captured by a disposable respirator can be released into air. The fraction release ranged from 0%-0.5%. The findings suggested caution in handling and disposing of respirators contaminated with anthrax spores.

All of the studies can be used to reach several conclusions on reusing respirators. Some bacteria and fungi can survive on respirator filters, but may be dependent on the organism, filter material and storage conditions. The implications on reuse and storage are unclear, but the guidance at this time is to dispose of filters or respirators on a daily basis and apply knowledge of disease transmission for agents of interest. Disposal of respirators after exposure to high levels of organisms may be warranted. Recommendations for storage are to protect respirators from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. Deformation of the face piece and exhalation valve should be prevented. Plastic bags may not be the best option for infectious aerosols.

Discussion. The co-moderators opened the floor for the workshop participants to provide input, make recommendations and pose questions to the Plenary Session 4 panel of presenters. The deliberations are outlined below.

- Research should be performed to adequately characterize the features of respirators that were found to be effective without fit testing in the NIOSH studies. Annual fit testing is an imposition, particularly since epidemiological data have not been gathered to demonstrate more disease transmission in hospitals without this requirement.
- The critical need for respiratory protection in healthcare facilities should be strongly emphasized. Institutions can take advantage of ongoing fit-testing training that is being implemented in major hospitals in large cities throughout the country. Some of these efforts are using train-the-trainer models to train HCWs to perform fit testing and then apply this knowledge to train coworkers. This strategy has demonstrated a minimal burden to employers. HCWs should not be treated differently than workers in other industries in terms of respiratory protection.
- Concrete recommendations should be made on training fit testers because neither OSHA nor ANSI standards currently contain these requirements.
- NIOSH should post information about respirators on a web site to provide the public with guidance on the comfort, proper fit and cost-effectiveness of various devices.
- Important lessons on emergency preparedness and response should be learned from the 9/11 terrorist attacks. Emphasis should be placed on the design of respirators to minimize fit-testing requirements and achieve the desired goals of devices. This objective could be accomplished by combining the NIOSH studies, anthropometrics data and other relevant data sets.
- The strengths and limitations of the NIOSH studies should be acknowledged. On the one hand, the research validates the need for fit testing. On the other hand, H-values are a new methodology that questions the need for fit testing or training. Significant variability has been identified between SWPF values and fit testing with the ambient aerosol method since the NIOSH studies were conducted. More recent papers will soon be published in the peer-reviewed literature to show that some variability can be eliminated if an aerosol is generated with a known concentration.
- Consideration should be given to changing “annual fit testing” to “annual respirator training” that includes fit testing.

The Plenary Session 4 panel of presenters made follow-up remarks to the discussion.

- Additional exercises can be incorporated into the fit-test protocol to reflect certain activities workers perform on a routine or repetitive basis. The ANSI Z88.10 guideline on respirator fit testing contains a list of additional exercises to consider.
- The NIOSH studies cannot be used to support discontinuation of fit testing with respirators that have good characteristics. Fit tests are still needed to identify individuals who do not achieve an adequate level of protection on the best performing devices.
- Fit testers must have solid moral and ethical values in addition to strong knowledge and training. The ANSI Z88.10 committee will be reconvened to develop fit-testing guidelines. The committee will be advised to list specific characteristics for an appropriate fit tester and strengthen language on developing train-the-trainer programs.
- NIOSH's TIL program is an initial step in ensuring that certified respirators meet certain standards.
- Training for an N95 elastomeric HFP typically requires two hours and fit testing can generally be completed in 20-30 minutes. However, the length of time to conduct fit testing will significantly vary based on the quality of training provided, fit characteristics of the respirator and number of fit testers available. The cost of fit testing can range from $28-$39, but pricing can also differ based on local, regional or other factors.
- The percentage of persons who are given a different respirator during annual fit testing depends on the type of respirator, interpretation of pass/fail criteria and quality of training. Research is currently being conducted to address these issues.
- NIOSH's anthropometrics studies included 3-D head scans of ~1,500 subjects. These data are currently being analyzed and will hopefully lead to the development of better RPPs.
- Fit testing should be used as an opportunity to provide additional training and more effectively communicate procedures to don the respirator. However, fit testing and training are much more difficult if management, the group of trainees or the individual user shows little interest.

PLENARY SESSION 5: REGULATORY AND STANDARDS PERSPECTIVES AND OUTLOOK

Mr. Heinz Ahlers and Dr. Rima Khabbaz of CDC co-moderated the presentations and discussion period for Plenary Session 5.

NIOSH Respirator Certification Regulations and TIL Testing. Mr. Roland Berry Ann of CDC described TIL tests NIOSH is currently developing for respirator certification regulations. USBM initiated respirator certification in the United States in the early 1900s. This process included a 30-minute fit test in a room filled with coal dust to assess the fit of a respirator based on intrusion of coal dust among workers. The coal dust test was retained in 1965, but the exercises were eliminated and an isoamyl acetate test (IAT) for chemical cartridge respirators was added. The IAT test was retained and expanded for use with particular respirators in 1972, but the coal dust test was abolished and certain respirators were modified to meet these requirements.

NIOSH eliminated the IAT in 1995 due to concerns that the efficacy of the test had not been validated and modified rather than actual respirators were being tested. For consistency with OSHA's individual fit-testing requirements, NIOSH recommended that an RPP with individual fit testing be established any time respirators are used. NIOSH and BLS jointly administered a survey in 2001 to obtain input on private respirator usage. The results showed that only 53% of respondents conducted fit tests. During OSHA's public hearings on its proposed revisions to the APF table and maximum-use concentrations, several concerns were raised about half-mask respirators, APFs for these devices, and the level of protection from PAPRs and hooded or helmeted supplied air respirators.

Flaws in previous research and concerns raised at OSHA's public hearings led to NIOSH's commitment to collaborate with the National Personal Protective Technology Laboratory (NPPTL) to develop a TIL test. The TIL program has been designed with several guiding principles. Respirators with face-seal leakage are a major contributor, but TIL is important to the wearer regardless of the means of entry. The NIOSH TIL program will be expanded to cover all PPE, including encapsulated suits, protective garments and chemical protective suits. The ANSI standard for respiratory protection and the OSHA proposed APF schedule are the two areas most heavily debated by experts in terms of actual protection and associated APFs.

To address this dilemma, NIOSH took a modular approach to developing standards for the TIL program. Half-mask respirators were established as the first priority and PAPRs and supplied air respirators were identified as the second focus area. NIOSH is conducting the TIL program in three phases. In Phase I, existing TIL respirator data were gathered and reviewed. Existing TIL test equipment capabilities and technical specifications were analyzed. A peer review team of manufacturers, users, academia and government representatives was formed. An initial TIL concept was developed to address the test protocol and performance requirements. Technical specifications for the TIL test facility were established.

In Phase 2, the NPPTL TIL test facility will be established and benchmark testing will be performed to assess state-of-the-art respirator performance. The TIL concept requirements and protocols will continue to be developed and the implementation plan will be drafted. In Phase 3, validation testing for the TIL facility will be performed and the implementation plan, concept requirements and protocols will be finalized. At this point, NIOSH has completed the Phase I activities and is now focusing on the Phase II objectives. The TIL program will be based on state-of-the-art capabilities and not associated with APFs. Standards will be established at an achievable and challenging level. The TIL program will not serve as a substitute for individual fit testing mandated by OSHA because no respirator can be certified to fit and fit testing is the only method to assess individual fit.

Certification performance criteria of the TIL program will be based on actual fit factor results of the device rather than OSHA's APFs. NIOSH's position is that the use of previously obtained fit-test data is inappropriate because a new fit panel and test procedures are being developed. Benchmark testing will be conducted on state-of-the-art respirators in each class and reliance will be placed on manufacturer instructions for users. The entire panel will be used for assessments in the TIL program rather than specific guidance. For the half-mask project, several test method characteristics were compared in the TIL program. These factors included the ability to conduct, reproduce and replicate the fit test in different locations; accuracy of readings and equipment cost; the need for a test chamber; and ease in preparing, using and cleaning the device.

Based on these parameters, the PortaCount Plus with the N95 Companion was found to be the best device for measuring the half-mask respirator in the TIL program in a direct reading mode. Moreover, the OSHA fit-test protocol was found to be the most reproducible exercise method. However, NIOSH realizes that a standardized workplace and movements do not exist. The TIL program will be peer-reviewed from programmatic and scientific perspectives. In 2005, NIOSH will hold a second public meeting on the half-mask project, initiate benchmark testing and complete the final concept. NIOSH welcomes input from all stakeholders and has opened a docket for the public to submit comments on the TIL program. The concept papers are available for viewing on the NIOSH web site.

OSHA's Respiratory Protection Standard (RPS). Ms. Caroline Freeman of OSHA outlined the history of and evidence to support the development of the RPS. In 1971, OSHA adopted the ANSI 1969 consensus standard and codified the guidance into law as 29 CFR 1910.134. In 1994, OSHA published a proposal to update §1910.134 and initiated a TB rule-making process. OSHA took these actions because the ANSI RPS was significantly modified to include the APF concept and standardized fit-testing protocols to evaluate the fit of a respirator to the face. OSHA also published the 1994 proposal due to its development of 16 vertical standards that included all provisions

needed to reduce hazards and exposures and provide medical coverage and benefits. TB, asbestos, benzene, lead and blood-borne pathogens are five of the 16 vertical standards.

OSHA mandated the use of respirators for several of the vertical standards because engineering controls were not economically possible or technologically feasible to reduce risks from aerosol hazards. Some vertical standards also require annual fit testing and APFs. NIOSH re-certified filter media and developed the N, P and R series of respirators. These actions were a major achievement because the healthcare community could rely on the inexpensive, disposable and efficient N series of respirators. In the published 1994 proposal, OSHA stated its intent to supersede all RPSs with one robust, complex and complete RPP under §1910.134. OSHA promulgated the final RPS in 1998 and definitively proved that all elements included in §1910.134 were required to increase the probability of the successful function of a respirator.

OSHA also demonstrated an increase in the potential for a respirator to fail to function if one or more elements were absent. OSHA further stated that the absence of an airborne risk was the only situation in which a poor respirator outside of §1910.134 and a proper respirator within the program could reduce risk to the same extent. The major provisions of the 1998 revised RPS are outlined as follows. First, the scope of the RPS was retained and still applied to respirator use for biological agents, all other airborne contaminants and all industries with the exception of agriculture.

Second, guidance was provided on all necessary elements for a full RPP. Employers must develop and implement a written RPP with procedures that are specific to the particular work site. The RPP must be updated annually or as needed to reflect workplace changes that affect respirator use. A suitably trained program administrator must administer the RPP. OSHA would provide information to employers on factors that should be considered in evaluating workplace risks and determining whether respirator use is required. Third, a nine-question medical evaluation must be administered prior to use or fit testing to assess the ability of employees in wearing a respirator. The medical evaluation should serve as an initial assessment only and can be performed by a physician or other licensed healthcare professional.

Fourth, employees wearing a tight-fitting face-piece respirator must be fit tested with the same make, model, style and size of the device prior to use. Employees must pass an appropriate qualitative or quantitative fit test prior to initial use, whenever a different respirator face piece is used, and at least annually thereafter. Evidence showed that annual fit testing of the face piece detects poorly fitting respirators and a higher percentage of employees may rely on poorly fitting respirators if respirators are retested longer than one year. Fifth, initial and annual training and information must be provided

for employees to demonstrate knowledge of the need for the respirator; the potential for improper fit, use or maintenance to compromise protection of the device; limitations and capabilities of the respirator; procedures for inspecting, donning, doffing, using and checking seals; and general requirements of the RPS. Sixth, the language in the RPS was changed from "should" to "shall" to legally enforce the standard.

The annual fit-testing requirement of the RPS was challenged in court by the American Iron and Steel Institute, but the court found that the provision was supported by substantial evidence and upheld the RPS. In terms of the 16 vertical standards, OSHA published the proposed TB standard in 1998 and published the final revised RPS in 1998. The original §1910.134 was re-codified as "Respiratory Protection for *M.tb*" under §1910.139 pending completion of TB rule-making. OSHA withdrew the proposed TB standard and revoked §1910.139 on December 31, 2003 because the outdated and legally unenforceable language was based on the 1969 ANSI standard. OSHA then applied the revised RPS under §1910.134 to the use of respirators for TB. At this point, all respiratory hazards that must be addressed with respiratory protection are covered under §1910.134.

OSHA withdrew the proposed TB standard due to the decline in TB rates and increased implementation of CDC's TB guidelines among hospitals. OSHA concluded that a final TB standard is unlikely to reduce exposure risks among workers and decrease the number of persons with undiagnosed and unsuspected TB. OSHA's RPS has always covered the healthcare industry. All elements of an RPP are needed to ensure that respirators will function as designed and employees are adequately protected.

ANSI Z88 Consensus Standards for an RPP. Dr. James Johnson, of the Lawrence Livermore National Laboratory, described the background of the ANSI standards process. Proper protection of respirator users is the overall goal of an RPP and respirator fit is a long-standing foundational component of an RPP. Implementation of a minimum RPP is both an art and science. The healthcare industry should follow the normal industrial RPP. The ANSI Z88 Secretariat and predecessor organization have been involved with RPPs since the 1930s with the development of the American Standard Safety Code for the Protection of Heads, Eyes and Respiratory Organs in 1938 and revision of this language in 1959. The American National Standard Practices for Respiratory Protection was developed in 1969 as ANSI Z88.2 and revised in 1980 and 1992. The most recent revision is currently under appeal, but is expected to be issued in 2005.

ASA-Z2 of 1938 recognized that good respirator fit is needed to avoid leakage of air; individual fit is important; high efficiency is needed to filter foreign material out of the air; and low resistance to air flow is required to avoid impeding breathing. ASA Z2 of 1938 referred to the USBM "man test" to measure respirator performance in the laboratory.

ASA Z2.1 of 1959 provided more details on properly selecting and using respirators by outlining the nature and severity of the hazard; type and concentration of the contaminant; period for which respiratory protection must be afforded; location of containment area with respect to a source of respirable air; expected activity of the wearer; and operational characteristics and limitations of available respirators.

ASA Z2.1 of 1959 relied on USBM's approved schedules and publications to describe the characteristics and limitations of available respirators. Gas-tight and dust-tight fits were identified for testing of a satisfactory face-piece fit by introducing positive and negative pressure checks. Qualitative man tests were recommended for self-contained breathing apparatus with test agents of formaldehyde and isoamyl acetate. ANSI Z88.2 of 1959 introduced the minimal acceptable respirator program (MARP) with written standard operating procedures on the selection and use of respirators. The language contained several conditions. Respirators shall be selected on the basis of hazards to which the worker is exposed and users shall be instructed and trained in the proper use and limitations of respirators.

Respirators should be assigned to individual workers. Respirators shall be regularly cleaned and disinfected; stored in a convenient, clean and sanitary location; and routinely inspected and maintained during clean. Surveillance should be performed of work area conditions; the degree of employee exposure or stress shall be maintained; regular inspection shall be established to determine continued effectiveness of the RPP; and responsibility for the RPP shall be vested in one individual. Persons should be medically qualified to wear respirators and the medical status of these individuals should be periodically reviewed. Approved or accepted respirators shall be used when available.

ANSI Z88-2 of 1969 also recognized the importance of facepiece-to-face seal with language that stated every respirator wearer shall receive fitting instructions, including demonstrations and practice in wearing, adjusting and determining the proper fit of the device. The face-piece fit shall be checked by the wearer each time the respirator is donned to assure proper protection. The positive and negative pressure tests were specified as two simple field tests and isoamyl acetate and irritant smoke tube were recommended as qualitative test methods. The 1963 *Respiratory Devices Manual* was used as the basis for recognizing several methods to determine face-piece fit.

ANSI Z88-2 of 1980 expanded the MARP by including a specific section on respirator fit. The language stated that each respirator wearer shall be provided with a respirator fitted by a qualitative or quantitative method. Each respirator shall be required to check the seal of the respirator by appropriate means prior to entering a harmful atmosphere. Respirator protection factors were assigned on the fit test that was performed. Fit testing shall be performed while wearing the same PPE that will be worn during work

activities and may interfere with fit of the respirator. PPE was specified as spectacles, goggles, face shield, hard hat or welding helmet. A detailed eight-point training outline was provided.

ANSI Z88-2 of 1992 continued to refine the MARP with additional language. Each individual shall be fit tested before being assigned a tight-fitting respirator. Each individual using a tight-fitting respirator shall conduct a fit check of the respirator by appropriate means each time the respirator is donned or adjusted. The OSHA asbestos standard was referenced for qualitative and quantitative respirator fit-test requirements until ANSI Z88.10 on fit-test methods was published. A fit factor that is at least 10 times greater than the APF of a negative pressure respirator shall be obtained before the respirator is assigned to an individual. Fit tests shall be conducted every 12 months. The language continued to emphasize detailed respirator training.

The current revision of ANSI Z88.2 maintains the focus on the MARP by requiring respirator fit testing and a user seal check. Requirements for acceptable qualitative and quantitative fit tests are referenced in ANSI Z88.10. The language continues to emphasize detailed respirator training. Respirator sealing surfaces significantly differ, but respirator fit and performance are directly related to the performance of the sealing surface. Respirator fit testing is intended to measure the quality of the respirator seal to the face of the wearer and assess other components of performance. Respirator fit checks measure the functionality of the facepiece-to-face sealing surface and assure proper respirator performance with positive and negative fit checks.

The overall success of an MARP depends on providing the user with the correct respirator; ensuring the user understands the hazard, function, proper use and maintenance of the respirator; and giving the worker information on the time to replace or obtain a new device. Medical and respirator program elements and workplace surveillance are also required. Fit testing is necessary for correctly selecting a respirator, training the worker in wearing the device, and understanding the limitations of the respirator. All elements of an MARP are necessary to assure proper protection of the respirator user. The healthcare industry should follow the normal industrial RPP. Airborne hazards in the healthcare industry include particulates, aerosols, vapors or gases. Respirators can provide appropriate protection from airborne hazards when engineering controls are not practical or available in maintenance activities or emergencies.

Respiratory Protective Equipment (RPE) for AIAs: U.K. Regulatory Perspective. Dr. Michael Clayton, of the U.K. Health and Safety Laboratory, described respiratory protection practices in the United Kingdom. All regulations that have been established for the use of PPE contain general duties for employers to conduct a thorough risk assessment, prevent exposure to risk whenever possible, and control risks to

acceptable levels if exposures cannot be prevented. PPE should be used as a last resort in the hierarchy of controls. The Control of Substances Hazardous to Health (COSHH) regulations of 2002 specifically apply to healthcare and all other industries. This law states that PPE used at work must be adequate and suitable for intended use of the device; provide the wearer with effective protection; "CE" marked to the PPE directive; correctly selected, used, maintained, examined and tested by properly trained persons; and stored with appropriate records.

The RPE Programme features several components to meet these requirements, including hazard identification, risk assessment, selection of adequate and suitable RPE, training, cleaning, maintenance, record keeping, review, and management systems to implement the programme. European directives were established to eliminate barriers to trade while safeguarding the health and safety of PPE users. Essential health and safety and requirements (EHSRs) were developed for different types of PPE. Compliance with EHSRs can be demonstrated by conforming to a European standard or applying technical specifications that a notified body has assessed as meeting the EHSRs.

Exemptions to the PPE directive include equipment solely used by the armed forces; equipment used to maintain law and order; equipment used to escape from ships and aircraft that is not worn at all times; and medical devices or other equipment covered under another directive. Because the medical devices directive does not apply to equipment covered under the PPE directive, the directive that applies to devices used in health care settings needs to be clearly identified. Equipment should comply with the directive that covers the principle intended purpose of the device. For example, the medical devices directive protects the patient, while the PPE directive protects the wearer. PPE should not be used or placed on the European market without conforming to the PPE directive.

The Tecnol PFR95 is a NIOSH N95 class respirator that is commonly used in the United Kingdom for infection control. However, the respirator is CE marked to the medical devices rather than the PPE directive and cannot be used as PPE in Europe. The PPE directive was designed with three categories. Category 1 devices are PPE of a simple design that is self-certified by the manufacturer. Category 2 devices are PPE of an intermediate design that is type-tested by an accredited testing laboratory and assessed by a notified body. Category 3 devices are PPE of a complex design that is type-tested by an accredited testing laboratory, assessed by a notified body for compliance to the European standard, and evaluated for ongoing quality control production. All respirators are classified as Category 3 devices.

The medical devices directive was designed with three classes. Class I devices are non-invasive and self-certified by the manufacturer. Class II devices are surgically

invasive and self-certified by the manufacturer with limited quality assurance. Class III devices are medicinal products that are type-tested by an accredited testing laboratory and assessed by a notified body for full quality assurance. Multiple tests are performed to evaluate FFPs in several areas, including filtering efficiency with solid and liquid aerosols, TIL measurements, breathing resistance, re-breathed oxygen, strength, vision, flammability and clogging. However, the tests are not designed to assess bacterial filtration efficiency or fluid penetration.

Surgical masks are tested in several areas as well, including bacterial filtration efficiency, biocompatibility, fluid penetration, bioburden, breathing resistance, and eye protection against fluid splash. However, the tests are not designed to consider inhalation protection. A study was recently conducted in the United Kingdom to determine the quality and level of protection of surgical masks. The TIL of three different types of surgical masks ranged from 19%-36% compared to the TIL of 2%-8% of three different types of respirators. In a journal article, a mask containing an enzyme claimed to kill the SARS virus, but the mask is most likely poor. The U.K. Department of Health issued TB guidance in 1998 that recommended the N95 respirator as the most appropriate device for use in healthcare settings and also mentioned surgical masks as providing sufficient protection. However, the guidelines did not consider the COSHH regulations and European directives and are currently being revised.

The Health Protection Agency issued guidance during the SARS outbreak that advised use of a device with 98% efficiency. The guidelines were revised to follow the WHO recommendations to wear N95 respirators, but were again modified to recommend the highest class of respiratory protection for FFPs. Current guidance for AIAs among HCWs recommends conducting a thorough risk assessment, reducing exposure as low as reasonably practical, wearing the best filtering mask on the market if this device is necessary, fit testing respirators, adequately training users, and using CE marked devices to the PPE directive.

Fit testing is required by U.K. regulations, but the requirement is often questioned because respirators are tested for TIL on a panel of ten test subjects. Certification tests do not guarantee that the face piece is suitable for actual wearers, but fit testing determines the suitability of the device by the actual user. Fit testing is performed in the United Kingdom when the RPE is initially selected, the face piece has not been previously tested, the RPE or facial characteristics change, or the employer has a health and safety policy that requires fit testing. The United Kingdom currently has no requirement for general repeat fit testing, but this practice will be reviewed in 2005. Decisions will be based on whether sufficient evidence is available to justify the need for repeat fit testing or if the frequency of testing should be based on a risk assessment. However, training and the competence of fit testers are major issues in the United Kingdom that need to improved before decisions are made on repeat fit testing.

The United Kingdom plans to take several actions in the future. The healthcare community will review the current guidance and use of PPE, including masks, protective clothing and gloves. The primary intended purpose of the device will be assessed and education will be evaluated. Fit testing will most likely be expanded and repeat fit testing will be considered. Guidance will be developed for testing and parameters will be recommended for the safe use of specific RPE items in potential terrorist events. A British standard is currently being developed for CBRN respirators.

Current Status of Respiratory Protection Against Infectious Diseases in Japan. Dr. Yoshimi Matsumura, of the Technology Institution of Industrial Safety in Japan, described respiratory protection practices in Japan. The health protection of medical staff was regulated by the Ministry of Health and Welfare rather than the Ministry of Labor prior to 2001. As a result, occupational safety and health (OSH) laws in Japan did not cover health problems of medical staff. The two ministries were combined in 2001, but the registration systems have not been changed to date. As a result, industrial workers continue to be regulated, but respiratory protection of medical staff is still not covered. The only exception to the law is notification to the government of staff working on TB wards.

SARS was spread in Asian countries in 2003 and led to the formation of a committee of infectious disease specialists that took actions and provided guidance in several areas. WHO's urgent information on SARS was communicated and SARS diagnostic criteria were identified. The government was notified about the need to establish medical systems to measure SARS. Development of a stockpile of N95 respirators in medical facilities was recommended. Notification was given related to SARS examination standards and reporting systems. Government controls were suggested to quarantine passengers, imported animal meat, pets, hotels and medical facilities. The use of N95 respirators was strongly recommended. The infectious disease surveillance system reported two SARS cases and 48 suspected cases in Japan, but all 48 suspects were diagnosed as negative.

Based on recommendations from the committee, the government issued guidance for respiratory protection of medical staff and patients. Suspicious patients should be separated from others and wear N95 respirators or surgical masks if the N95 is not available. Sick rooms should be isolated with doors and maintained at negative pressures or established in large rooms with independent ventilation. Medical staff and visitors who were in contact with patients or handled bodily fluids or secretions should wear N95 respirators, water-resistant gowns, head caps, goggles and face shields. The government guidance did not include recommendations on fit checking respirators.

The Japanese health agency provided television stations with information on SARS. The broadcasts covered the N95 respirator, advantages of this device in respiratory protection and fit, the effectiveness of respiratory protection devices against fine particles, the efficacy of face masks against SARS, and face mask labeling. The 1999 guidance for respiratory protection on TB wards contained several recommendations. Medical staff should use "so-called" N95 respirators; users should periodically perform the determined fit test; and medical staff should be trained in using N95 respirators. Patients out of sick rooms should wear cotton gauze face masks. N95 respirators should be used only when necessary. However, these guidelines were not sufficient to fully protect against the spread of TB.

OSH laws in Japan have required respirator standards and certification systems for >45 years. Standards for particulate respirators were revised in 2000 and are now close to NIOSH standards. Two test particles of sodium chloride and DOP were adopted. Japan's particle sizes and distribution are nearly identical to NIOSH, but airborne concentrations and loading limits are lower than NIOSH standards. The test air flow rate is 85 L/minute and Japan's filtration efficiency criteria are also different than NIOSH standards. Particulate respirators are categorized into two groups of replaceable devices and two groups of disposable devices. Filtration efficiency criteria were defined by loading tests and have been established at 99.9%, 95% and 80%. Two of the four particulate respirators closely correspond to the N95 respirator.

Devices currently on the market are in compliance with Japanese standards for particulate respirators and gas masks. The majority of respirators are from Japanese manufacturers, but some products are imported. Although the government advised medical staff to use N95 respirators, citizens could not purchase these devices or DS2 respirators. Infectious disease specialists made television appearances to publicly advise citizens to use face masks to protect against splash from large particles, but no evidence was available to support this guidance. The Japanese health agency measured the filtration efficiency of face masks with sodium chloride particles. The flat- and pleated-type face masks were not found to fit as well as cup-type masks.

Due to these problems, the Japanese health agency examined the filtration efficiency of 50 types of face masks using sodium chloride, ragweed pollen and other agents on the package. The flat-type face mask is labeled for 99.9% filtration efficiency against viruses and pollen, but the package does not describe test methods. A three-dimensional face mask is labeled as effective against pollen. The device has a better fit to the face than the flat-type face mask, but has gaps on both sides of the nose. A face mask with an electric filter is labeled for 99.9% effectiveness against the influenza virus. Overall, the package descriptions of the face masks were not found to be reliable.

The Japanese health agency examined the filtration efficiency of face masks with pollen and sodium chloride particles. Ragweed pollen could not be dispersed in air at stable conditions, but the air flow rate changed to 85 L/minute when ragweed pollen was sprayed on downstream air and the face piece was placed at the bottom of the cylinder. No penetration and no loss of pollen were observed when the filter of the face mask was loaded with 50 mg of ragweed pollen. Pollen was collected at the center portion of the filter of the flat-type respirator.

Sodium chloride was dispersed at a range of 2%-81%, but pollen showed a higher filtration efficiency of 99%. The test results showed that pollen is not a solid agent to evaluate or classify face masks. Sodium chloride is useful to distinguish between filter materials, but test conditions may not be suitable to assess face masks for daily use. At this time, a determination needs to be made on proper test agents for face masks. The Japanese health agency recently analyzed face masks with sodium chloride or pollen based on requests from manufacturers. The SARS outbreak resulted in improvements in filter materials, but face seals are still problematic. The types of respiratory devices that are suitable for citizens are still unclear.

Discussion. The co-moderators opened the floor for the workshop participants to provide input, make recommendations and pose questions to the Plenary Session 5 panel of presenters. The deliberations are outlined below.

- OSHA standards and the unpublished revision to ANSI Z88.2 should be reviewed to clarify the confusion between “fit checks” and “fit tests.”
- Progress should be made on ANSI Z88.6. The standard focuses on the physical qualifications of respirator wearers and the guidance is needed for the occupational medicine community to develop appropriate medical clearance for respirators.
- Extensive consideration should be given to the cost impact of annual fit testing and training on affected institutions. OSHA’s economic analysis of ~6,500 hospitals throughout the country showed that $10.7 million will be needed to implement annual fit testing and training requirements nationally. However, an individual facility may need to allocate an additional $3.5 million to hire more industrial hygienists and other staff to comply with annual fit-testing requirements. As a result, calculations from OSHA’s economic analysis may be naive because the national estimate could actually range from $150-$300 million per year based on the cost of individual facilities.
- A process should be developed to apply OSHA’s RPS to billing staff, receptionists, technicians and all other healthcare personnel who encounter patients prior to diagnosis, admission and placement in a room.

- Inconsistencies and other problems with current respiratory protection guidance should be acknowledged. For example, physicians, nurses, janitors, firefighters, paramedics and emergency medical technicians are informed that a lesser protective device up to and including a surgical mask can be used to protect against infectious diseases in the workplace.
- The importance and benefits of fit testing should be more strongly emphasized. Workers are provided basic and fundamental training on using respirators. Fit tests have a relationship to the failure of respirators. Opposition to annual fit testing should be clarified.
- Efforts should be made to resolve the disaster with and political implications of respiratory protection guidance. For example, OSHA is unable to release regulations, issue citations and provide recommendations on TB and respiratory protection until CDC completes and issues the updated TB guidelines.
- A forum should be provided to obtain passionate input from persons representing all industries who are affected by respiratory protection guidelines and regulations.
- OSHA should review other data sets to establish a sound scientific basis for the annual fit-testing requirement of N95 respirators for TB, such as operational research, outcome data, epidemiology, experiences of hospitals and bioaerosol data. For example, Grady Memorial Hospital in Atlanta is an inner-city healthcare facility that treats a large number of TB cases per year compared to other institutions throughout the country. The TST conversion rate among Grady HCWs is extremely low at <2/1,000 per year. The risk of TST conversions is not related to contact with or care of TB patients, but is associated with annual salaries, residence in areas with incredibly high TB rates and community transmission. Moreover, nosocomial transmission of TB has been reduced to an absolute minimum without annual fit testing. Initial diagnosis and suspicion of cases rather than respirators are the most important measures to protect HCWs. The NIOSH studies demonstrate that inherently well-fitting and well-designed respirators out of the box without fit testing are better than efforts to improve poorly-fitting respirators with fit testing.
- Inaccurate perceptions should be clarified about the role of respirators in SARS transmission. For example, a Vietnamese hospital with no respirators in its infection control program had absolutely no transmission of SARS to HCWs, other patients or family members. The outbreak emphasizes the need to learn more about the transmission of SARS. Extreme caution should be taken in issuing guidance about the use of respirators and fit testing because data are currently limited.

The Plenary Session 5 panel of presenters made follow-up remarks to the discussion.

- ANSI Z88.6 is currently in the final comment resolution stage and will hopefully be released by June 2005.
- OSHA's economic analysis demonstrated that the healthcare industry will not be faced with an unbearable burden to implement annual fit testing and training requirements.
- Healthcare facilities should pre-plan, assess hazards and develop an emergency plan to address uncertainties, replace a workforce or resolve other potential problems to protect HCWs during a crisis. For example, the entire medical staff of an institution could be unable to work during a pandemic due to infection or exposure.
- OSHA has collected data that show healthcare facilities can implement a PAPR program and other strategies to address cost issues related to compliance with annual fit testing and training requirements. An industrial hygiene evaluation was performed of high-risk exposures by job task during the SARS outbreak that demonstrated a reduction in the number of persons who needed respirators.
- Respirator use does not negate the need to perform fit testing to assure respirators fit individual workers. NIOSH's TIL program is designed to ensure a minimum level of performance of all NIOSH-approved respirators.
- OSHA relied on solid industry evidence to mandate the annual fit-testing requirement. The data showed that ~1 of the population needed a new mask after one year, while ~7% of the population needed a new mask after two years. OSHA took a conservative approach to require annual fit testing based on the best available evidence at that time.
- Annual fit testing is an important and state-of-the-art component of an effective RPP and represents current available knowledge.

BREAKOUT GROUP REPORTS

The workshop participants were assigned to three breakout groups to discuss the overarching issues of the five plenary sessions in more detail. Key points raised during discussions of each plenary session issue are highlighted below.

Plenary Sessions 1 and 2 Report. Dr. David Weissman of CDC presented the breakout group report for Plenary Sessions 1 and 2. Questions by CDC and recommendations by the workgroup participants in each breakout group are summarized below.

Question: What considerations differentiate infectious from non-infectious aerosols?

- Organisms must remain viable and competent to transmit infection in order for an aerosol to remain infectious. Exposure to particles that are incompetent to transmit infection is irrelevant for transmission of infectious diseases.
- Microorganisms replicate and can amplify.
- Current terminology on “airborne,” “droplet” and “contact” transmission are not intuitive. More intuitive and better defined terms would be useful, such as “respirable,” “spray” and “contact.”
- Size-specific distribution of infectious particles should be determined for sick and healthy populations.
- Research is needed to determine the distance at which specific organisms can be sprayed and remain viable and infectious. The three-foot guideline for droplet transmission may or may not be correct. Research should include field sampling from infectious patients, microbiological characteristics and epidemiology.
- Studies are needed about the ability of organisms to become re-aerosolized from filters and other surfaces.
- Individual susceptibility factors are important and can greatly differ among individuals in a population.

Question 2: How can a determination be made on when respiratory protection is needed and the selection of appropriate respiratory protection without an exposure limit?

- The most important research needed is to better assess exposure and develop information about exposure-response and infectious doses. Research should include animal modeling to assist in determining rational exposure limits. Calculations of survival rates for exposures are an example of an “exposure limit.”
- Infectious doses are the foundation for meaningful standards.
- Modeling results should be validated by consistent epidemiological observations. Assumptions underlying models should be adjusted to incorporate observations where data are available.
- The healthcare industry needs clear-cut and clinically relevant endpoints to monitor the effectiveness of interventions similar to other industries. For example, TST conversion is a difficult endpoint.
- Respirators as a part of a system and the application of a systems approach in determining respirator use should be remembered. Environmental controls, administrative controls and other PPE should be

considered. An individual facility should consider its environmental control capacity in conducting a risk assessment because different APFs may be appropriate for different institutions.

- Epidemiology, clinical experience and modeling should all be considered in performing a risk assessment, guiding operational research, and translating data into evidence-based rules and regulations.
- Research is needed that identifies the individual contributions of preventive interventions, including respirators and other PPE as well as environmental, source and administrative controls.
- Animal and other biological models are needed to assess the relative efficacy of preventive interventions.
- Control banding approaches in which agents are categorized according to risk and recommendations are made based on results may be quite useful.
- Generic and unified decisions that are relevant to all infectious agents should be developed. This logic should include guidance on assessing risk, identifying hazards and determining the necessary level of respiratory protection.

Question: Which are the most and least appropriate rules and regulations governing the use of respirators in healthcare settings? What research should be conducted?

- Respiratory protection should be separately considered from other elements in the prevention hierarchy. Respiratory protection is a back-up method to other interventions and should serve as the last line of defense.
- Risk assessments would be easier to conduct with more knowledge of relevant exposures and risks. The information could then be applied to perform risk assessments in a similar manner the U.S. Environmental Protection Agency (EPA) uses for non-viable agents.
- An RPP is required if a risk assessment indicates the need for respirators. More knowledge should be applied in the decision-making process to determine when respirators are actually needed.
- Research is needed to identify the individual protective contribution of respirators.
- Situations when to voluntarily use FFP respirators should be identified.
- Options other than FFP respirators that do not require fit testing should be reviewed, such as better PAPRs or approved use of hospital air to drive supplied air respirators.
- Recommendations should be evidence- and outcome-based.

Question: What was learned about respiratory protection in hospitals from the foreign experience on SARS, particularly in Toronto and Taiwan?

- Contact and droplet precautions were found to be highly effective. Episodes of airborne transmission were the exception rather than the rule.
- A total approach that considers mucosal, upper airway, respirable and contact exposures was found to be important.
- An effective RPP will address new and unknown threats.

Question: How can current approaches be improved to identify contagious persons and infectious environments in the era of BioWatch devices and monitoring of the mail by polymerase chain reaction (PCR) techniques? Are improved methods needed to assess the competence of microorganisms for airborne transmission of disease?

- Real-time detection of infectious disease agents is debatable due to the questionable cost-effectiveness and minimal ability of PCR or antibody techniques to distinguish between viable and infectious microorganisms versus those that are non-viable and non-infectious. Real-time detection techniques are probably better suited for focused rapid identification of cases or research than for monitoring emergency rooms, clinics and other settings.
- The ability of organisms to survive, remain infectious in aerosols and transmit disease via an airborne or respirable route should be better defined.
- Consideration should be given to making latent TB infection a reportable disease to improve tracking of the impact of interventions.

The importance of emergency preparedness for BT and outbreaks of new, emerging and re-emerging diseases should always be remembered. These catastrophic events may need a different paradigm than management of routine daily hazards. The supply and distribution of vaccines, respirators and drugs are extremely important issues in catastrophic situations, but the availability of respirators with a good fit out of the box would be highly desirable in these situations as well.

Plenary Sessions 3 and 4 Report. Dr. Paul Jensen of CDC presented the breakout group report for Plenary Sessions 3 and 4. Questions by CDC and recommendations by the workgroup participants in each breakout group are summarized below.

Question: What scientific or anecdotal evidence has been collected on the effectiveness of respirators or surgical masks to filter AIAs and reduce infection? Do respirators perform any differently with viable aerosols compared to toxic

dusts and chemicals? Are concerns about the face-to-respirator seal different with infectious aerosols?

- WPFs and health outcomes of workers exposed to infectious aerosols should be investigated in a field study.
- Research should be performed to determine the significance of hand, mouth or face contamination in relationship to respirators and surgical masks. The study should also focus on the extent to which secondary infection can be prevented by wearing a surgical mask or respirator.
- The extent to which surgical masks prevent dissemination of viable organisms into the environment should be determined.

Question: What research or data are available to guide decisions on the necessary periodicity for fit testing? Under what conditions can respirators be used without requiring fit testing? What are the benefits of respirator fit testing, such as impacts on appropriate use, exposure prevention or infection prevention? Does fit testing ensure proper fit during use?

- Guidelines for trainers and fit testers should be developed.
- An algorithm should be designed to use in emergency situations or other settings when fit testing is not possible.
- Workplace surveillance and assessment should be conducted both pre- and post-fit testing. The findings can be used to determine the predictive value of fit testing in continuing a good fit. The information can also be used to identify factors that impact changes in fit test results, such as changes in the respirator or fit-test process and anthropometrics.
- The incremental benefit of various components of an RPP or a combination of these factors should be quantified, including the fit test, training and user seal checks.

Question: What are the considerations or parameters to guide the design of good fitting respirators? Have data been gathered to determine the effectiveness of NIOSH-certified FFP respirators? How well do current respirators certified by NIOSH, CEN or other organizations fit the general population? What is the possibility of designing a respirator to fit the general population without fit testing?

- New technologies should be developed or integrated into respirators to improve performance, including smart seals, sensors, and new elements, filters, face pieces or other materials.
- “Working population” should be better defined, such as a national or regional workforce, special population or industry-specific group.

- The BLS Survey published by CDC in 2003 should be expanded to validate data and determine the rationale for the limited number of companies that conduct fit testing.

Question: Does disinfection and reuse affect the performance of respirator face-seal fit or filtration efficiency? If respirators can be safely disinfected and reused, what are the circumstances, such as method of disinfection, organism of interest and application or procedure? What research has been performed in this area?

- Guidance should be developed on the disinfection of respirators, including disposable versus elastomeric devices, contact time needed with different disinfectants, and the effect of various disinfectants on the respirator and fit.
- Performance guidelines that emphasize disinfection should be created for the manufacture of respirators.

All research opportunities should be viewed as tripartite efforts in which CDC, other governmental entities, labor and all industries are engaged.

Plenary Session 5 Report. Dr. Michael Iademarco presented the breakout group report for Plenary Session 5. Questions by CDC and recommendations by the workgroup participants in each breakout group are summarized below.

Question: What are the research issues with respect to implementing RPPs?

- Risks that are relative to personnel should be identified and quantified.
- Research endpoints should be clinically linked to transmission-measured events.
- Research should be performed on behavior and training.
- Studies should be conducted on the frequency of fit testing.
- Protocols and models should be developed to assess engineering controls.
- Research designs should address situational contexts that include visitors, emergency use and routine use.

Question: Can non-NIOSH certified respirators be used in the United States?

- Regulatory and performance perspectives of non-NIOSH certified respirators should be considered and addressed separately.
- An analysis should be conducted to compare performance tests among different regulatory perspectives.

- A mechanism to evaluate a broader set of respirators for emergency use should be prospectively considered.
- International standards should be harmonized.
- Communications related to the decision logic of selecting a respirator should be enhanced.

Question: What is the scientific basis of the duration for using and reusing the N95 respirator?

- Research is needed on the viability of agents on respirators, biocidal treatment of FFPs, and the structural integrity of respirators for reuse.
- Lessons can still be learned from the solid TB infrastructure that has been built in the United States, but preparations must also be made for the next unknown agent.

Question: What is the value of RPPs?

- The value of RPPs should be viewed in the context of the hierarchy of controls and based on a hazard analysis and need for the RPP.
- Projections of the credible value of an RPP to respiratory protection users are critical.
- Research should be conducted on motivating users to effectively utilize respirators.

OPEN DISCUSSION

Mr. Fred Robinson of Cambridge Communications facilitated an open discussion for the workshop participants to revisit previous agenda items or explore new topics to assist CDC in developing a research agenda on respiratory protection for AIAs. Key points raised during the open discussion are outlined below.

- Research should be performed that focuses more on dynamic testing of respirators rather than static testing. This goal could be achieved by harnessing mechanical behaviors of fibers and the overall fibrous structure. The structure should be reasonably elastic in nature and have the ability to quickly assume the shape required in dynamic situations. This strategy could minimize problems associated with respirator fit.
- The need for solid research using health outcomes as objective endpoints should be balanced with public health and occupational health needs to prevent infections from initially occurring.

- Guidance should be provided on properly conducting a hazard assessment to allow organizations to make better decisions on when respirators are actually needed. These actions should be placed as a higher priority in the existing process to facilitate compliance.
- Respirator users should be aware that manufacturers will have little incentive to develop better products if the desire is to maintain a cost per use of $0.1. Economic analyses should include life-cycle costs of devices in addition to perceived and actual purchase costs.
- A determination should be made on an "acceptable" level of risk for hospitals. This decision will be important in terms of allocating healthcare dollars to efforts that will reduce risks to less than those in the broader community. The information will also play a role in identifying standards for the healthcare industry that are different than those in other occupational settings.

CLOSING SESSION

Dr. Snider noted that the dialogue on respiratory protection of AIAs must continue because the current knowledge base in this area has not significantly expanded over the past 15 years. He summarized the common themes, key issues and recommendations raised during the workshop. The importance of conducting rapid risk assessments was strongly emphasized. Current initiatives on rapid diagnostics for terrorism are critically important to respiratory protection. The need to quickly identify agents when patients present to healthcare institutions is a research issue of high priority. CDC is currently drafting an environmental microbiology research plan in partnership with EPA. The initiative is relevant to and should strengthen the knowledge base on respiratory protection. Efforts will be made to establish facilities where transmission studies are conducted and animal models are used to analyze health outcomes.

The efficacy of RPPs and interventions to prevent transmission continue to be challenging issues. The contributions of each individual component in reducing transmission in healthcare settings are still unknown. Both natural and designed experiments are needed to fill this data gap as well as to determine the appropriate time and use of individual respiratory protection interventions. The need for training across the entire spectrum of respiratory protection was repeatedly underscored. Skills should be enhanced in recognizing and conducting risk assessments, ensuring the proper function of environmental controls, and assuring appropriate use of PPE. A behavioral science component should be incorporated into CDC's research agenda to strengthen respiratory protection training as well.

Respirators and other PPE continue to be problematic. CDC should follow up on research projects suggested during the workshop. Studies on reuse, disinfection and static versus dynamic testing will provide a stronger evidence base and more knowledge of respirators and other PPE. Populations within healthcare institutions that need to be protected must be considered, but patients and other persons in these environments should be equally protected. Perspectives must be broadly applied because RPPs should not be designed for TB, SARS or another specific disease. Instead, RPPs should be developed to address agents that are airborne, aerosolized, droplet-spread or contact-spread until a specific diagnosis is made. RPPs should broadly cover the agent, host and available interventions. Repeat fit testing continues to be a source of debate, but the need for respirators to fit well cannot be ignored. Consideration must be given to whether a well-fitting respirator can be designed and quickly donned, particularly for terrorism events.

The overall goal of the workshop will be to engage in collaborative efforts in which governmental entities allocate resources and develop regulations; healthcare institutions and the private sector provide valuable input on health protection requirements; and manufacturers design new technologies and cost-effective interventions that are needed and desired. These joint efforts should be designed to develop solutions to critical and complex issues. At this point, CDC will consider all input provided by the workshop participants and initiate a process to prioritize issues for the research agenda. Internal CDC staff and external partners in both public and private sectors will be actively engaged in this effort. CDC will develop guidance documents based on the best available evidence and clinical data, but investments in research will continue to be made to strengthen the existing knowledge base. This approach will be used to improve guidelines, interventions and health outcomes in the future.

Dr. Snider reiterated his tremendous appreciation to the attendees for actively participating in the workshop and providing CDC with creative ideas to consider. He also expressed his gratitude to the meeting organizers for their diligent efforts in identifying speakers to present valuable information and providing opportunities for the participants to hear different perspectives during the breakout groups. Overall, the workshop served as an extremely valuable and important forum of persons with diverse backgrounds who all care about respiratory protection of AIAs.

ATTACHMENT 1

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