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**HCA WESLEY MEDICAL CENTER**
**WICHITA, KANSAS**

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## *SUMMARY*

A management request was received from the respiratory therapist educator of HCA Wesley Medical Center in Wichita, Kansas, for a Health Hazard Evaluation of the effectiveness of procedures used at the hospital to control exposures of respiratory therapists and nurses to aerosolized ribavirin. Ribavirin (1-beta-D-ribofuranosyl- 1,2,4-triazole-3-carboxamide) is a synthetic nucleoside analogue which is licensed in the United States for the short-term treatment of respiratory syncytial virus (RSV) infection.[1] Occupational exposure criteria have not been established for ribavirin. Because the drug has been found to be teratogenic and/or embryolethal in most animal species in which it has been tested,[1-3] there is concern about its potential reproductive effects in humans.

Twelve-inch cubical "Care Cube" disposable oxygen-delivery hoods and Viratek Small Particle Aerosol Generators are used for administration of Virazole® aerosol (ribavirin) at HCA Wesley Medical Center. In addition, each "Care Cube" hood is adapted with a scavenging system in an attempt to limit the amount of ribavirin released from the hood into a patient's room. As an extra precautionary measure, hospital management requires that a 3M 8710 dust/mist respirator (NIOSH/MSHA approval number TC-21C-132) be worn by every person who enters a room where ribavirin is being administered.

Three site visits were made in association with this Health Hazard Evaluation. The purposes of the first site visit were to evaluate exposures of respiratory therapists and nurses to ribavirin during aerosol administration with infant mannequins used to simulate patients and to conduct a pilot study to develop a sampling technique for evaluating in-mask exposures to ribavirin. Area samples were collected within the "Care Cube" disposable hoods used for administration of ribavirin, beside beds upon which the hoods were located, and at a location where no exposure to ribavirin was expected. Four respiratory therapists and two nurses agreed to participate in personal exposure monitoring, which consisted of the simultaneous collection of lapel and in-mask samples for ribavirin. While hospital management requires that a 3M 8710 respirator be worn by everyone entering a room where ribavirin is administered, 3M 9920 dust/fume/mist respirators (NIOSH/MSHA approval number TC-21C-202) were used during this site visit because they can better support a sampling probe and cassette without affecting the fit of the respirator. Quantitative fit testing was not conducted.

During the second site visit, area air samples were collected within "Care Cube" disposable hoods that were not adapted with scavenging systems and beside beds upon which the hoods were located. Quantitative fit testing using a Portacount™ Respirator Fit Tester was also conducted for respirator assignment to respiratory therapists and nurses. The purpose of the third site visit was to collect simultaneous in-mask and lapel samples to evaluate the level of protection received by respiratory therapists and nurses during ribavirin administration to a patient.

The results of simultaneous lapel and in-mask sampling during the first site visit produced 8-hour time-weighted average (TWA) lapel concentrations of ribavirin ranging from 87 to 323 micrograms per cubic meter ($\mu g/m^3$). Fifty-nine percent (10/17) of the in-mask samples had no detectable ribavirin, four others contained trace quantities, and the three remaining samples

contained quantifiable amounts of ribavirin. Respirators which were assigned based on the results of quantitative fit test conducted during the second site visit were worn by four respiratory therapists and three nurses during the third site visit. All of the respirators were high efficiency half-masks jointly approved by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration (NIOSH/MSHA). The results of lapel sampling produced 8-hour TWA lapel concentrations ranging from 40 to 120 $\mu g/m^3$. Seven of the eight in-mask samples obtained simultaneously with the lapel samples had no detectable ribavirin, and one sample was reported at the limit of detection.

The sampling results from this Health Hazard Evaluation suggest that notable concentrations of aerosolized ribavirin were present in the rooms where the drug was administered despite the addition of a scavenging system to the "Care Cube" disposable hood. High efficiency air-purifying respirators approved by NIOSH/MSHA and assigned to employees based on the results of quantitative fit tests were found by in-mask sampling to reduce exposures to aerosolized ribavirin to the limit of detection of the analytical method. Therefore, a recommendation was made to continue the use of respirators and initiate a complete respiratory protection program that would remain until technically feasible devices and/or procedures for the administration of ribavirin are developed and implemented that would alone reduce exposures of health care providers at HCA Wesley Medical Center to aerosolized ribavirin.

**Keywords:** SIC 8062 (General Medical and Surgical Hospitals), CAS number 36791-04-5, health care workers, respirators, ribavirin, workplace protection factors.

## *INTRODUCTION*

A management request was received from the respiratory therapist educator of HCA Wesley Medical Center in Wichita, Kansas, for a Health Hazard Evaluation of the effectiveness of procedures used at the hospital to control exposures of respiratory therapists and nurses to aerosolized ribavirin. Ribavirin (1-beta-D-ribofuranosyl- 1,2,4-triazole-3-carboxamide) is a synthetic nucleoside analogue which is licensed in the United States for the short-term treatment of respiratory syncytial virus (RSV) infection.[1] Ribavirin aerosol is indicated in the treatment of carefully selected hospitalized infants and young children with severe lower respiratory tract infections due to RSV.[2]

Occupational exposure criteria have not been established for ribavirin. Because the drug has been found to be teratogenic and/or embryolethal in most animal species in which it has been tested,[1-3] there is concern about its potential reproductive effects in humans. Health hazard assessment data available for ribavirin aerosol are currently insufficient to assess accurately the health risk to exposed health care workers.[3] Ribavirin has not been linked to fetal abnormalities in humans; however, given the wide spectrum of teratogenic potential in most animal species, avoidance of ribavirin prior to pregnancy, during pregnancy, and during lactation has been recommended by the author of a review of the toxicology of antimicrobial aerosols.[1]

HCA Wesley Medical Center is licensed for 760 beds, employs approximately 3,000 full-time and part-time employees, and has a 640 member medical staff. The hospital's Pediatric Intensive Care Unit (PICU) has 18 beds. To address the concerns of the respiratory therapists and nurses who worked on this unit regarding their potential exposures to aerosolized ribavirin, the management of the hospital implemented procedures in March 1987, in an attempt to limit environmental exposures to ribavirin for these health care providers.

The HCA Wesley Medical Center program for limiting environmental exposure to ribavirin consists of the following procedures:[4]

- A patient who will receive ribavirin is to be admitted to a private room. The door to the room is to be closed during ribavirin treatment.

- When entering a ribavirin patient's room, all employees and visitors are to wear a respirator with a capability of filtering particles with aerodynamic diameters ranging from 0.4 to 0.6 micrometer (3M model 8710).

- When ribavirin is administered via ventilator, a filter is to be used in the ventilator circuit to prevent the release of ribavirin aerosol into the room. When the ventilator is disconnected, a second filter is to be attached to the patient's connector to prevent release.

- When ribavirin is administered via an oxygen-delivery hood, a "Care Cube" is to be used. An air-entrainment adapter with filter is to be used to scavenge excess ribavirin from the outflow port of the "Care Cube."

- After the administration of ribavirin is completed, employees and visitors are to continue to wear their respirators for 30 minutes. After 30 minutes, the room's ventilation exchange system is expected to have cleared any escaped ribavirin aerosol. (The air exchange rate is estimated by the hospital's engineering staff to be twelve air changes per hour.)

Three site visits were made in association with this Health Hazard Evaluation: (1) July 17-18, 1990, (2) January 15-16, 1991, and (3) February 28-March 1, 1991. The purposes of the first site visit were to evaluate exposures of respiratory therapists and nurses to ribavirin during aerosol administration with infant mannequins used to simulate patients and to conduct a pilot study to develop a sampling technique for evaluating in-mask exposures to ribavirin. After the first site visit, an interim letter dated December 5, 1990, was mailed to the requestor. During the second site visit, samples were collected both inside and outside the hoods used to administer ribavirin to patients, and respirator quantitative fit tests were conducted using different air-purifying respirators. The purpose of the third site visit was to collect simultaneous in-mask and lapel samples to evaluate the level of protection received by respiratory therapists and nurses during ribavirin administration to a patient.

## *BACKGROUND*

Twelve-inch cubical "Care Cube" disposable hoods and Viratek Small Particle Aerosol Generators (model SPAG-2, 6000 series, ICN Pharmaceuticals, Inc., ICN Plaza, 3300 Hyland Avenue, Costa Mesa, California 92626) are used for administration of Virazole® aerosol (ribavirin) at HCA Wesley Medical Center. The drug manufacturer's recommended concentration of 20 milligrams of ribavirin per milliliter of sterile USP water (mg/ml) is used as the starting solution for the drug reservoir of the SPAG-2. This drug concentration is expected to produce an aerosol concentration of 190 mg per cubic meter ($mg/m^3$) inside a ribavirin administration hood for a 12-hour period.[2]

The operating parameters of the SPAG-2, as used at HCA Wesley Medical Center during this study, were a regulator pressure of 26 pounds per square inch gauge (psig), a nebulizer air flow rate of 6.5 liters per minute (l/min), and a drying air flow rate of 6.5 l/min. These values are within the ranges of the operating parameters recommended by the manufacturer.[2] (The aerosol delivery rate of 13 l/min is at least twice the minute volume of a typical patient.[5]) In addition, each "Care Cube" hood is adapted with a scavenging system in an attempt to limit the amount of ribavirin released from the hood into a patient's room. The scavenging system consists of a 24 percent venturi oxygen mask adapter operated at 2 l/min, corrugated plastic tubing, and a model BB-50T Pall breathing circuit filter (Pall Biomedical Products Corporation, East Hills, New York) placed on top of the hood. Air is exhausted from the filter into the room environment.

As an extra precautionary measure, a 3M 8710 dust/mist respirator (NIOSH/MSHA approval number TC-21C-132) is required by hospital management to be worn by every person who enters a room where ribavirin is being administered. An exposure limit has not been established or recommended for ribavirin, and industrial hygiene sampling had not been conducted previously at the PICU of HCA Wesley Medical Center to evaluate exposures of respiratory therapists and nurses to ribavirin. Therefore, it was not possible to calculate the minimum level of protection that a respirator would need to achieve in order to be selected for this application. The 3M 8710 respirator was selected by hospital management based upon a knowledge of the filter efficiency of the class of respirators to which the 3M 8710 belongs and of the reported particle size of the ribavirin aerosol generated by the Viratek SPAG-2.

Single-use dust and mist respirators must demonstrate 99 percent efficiency against silica dust particles with a geometric mean diameter of 0.4 to 0.6 micrometer and a geometric standard deviation not greater than 2 to be certified by the National Institute for Occupational Safety and Health (NIOSH).[6] Health professionals at HCA Wesley Medical Center believed that the 3M 8710 would

adequately protect a user against the ribavirin aerosol with a reported mass median diameter of approximately 1.3 micrometers.[2] Consideration was not given regarding the contribution of face to facepiece seal leakage to the overall performance of a respirator. In addition, the measures generally incorporated in an acceptable respiratory protection program (e.g. medical examinations, fit testing, and training) required by the Occupational Safety and Health Administration (described in 29 Code of Federal Regulations Part 1910.134), were not present at HCA Wesley Medical Center.

[APPENDIX A (page 14) contains a short discussion concerning protection factors for respirators which is provided as background information to assist the reader in understanding the methods and results of this study.]

## *METHODS*

### Site Visit #1 (July 17 and 18, 1990)

Twenty milligrams per milliliter (mg/ml) is the recommended concentration of ribavirin prepared as the starting solution for the drug reservoir of the Viratek small particle aerosol generator (SPAG) model SPAG-2 used at HCA Wesley Medical Center. Bulk samples of ribavirin solutions were collected on both days of sampling and were analyzed to confirm that the solutions contained the recommended concentration of ribavirin.

Area air samples were collected within the "Care Cube" disposable hoods used for administration of ribavirin, beside beds upon which the hoods were located, and at a location where no exposure to ribavirin was expected. Respiratory therapists and nurses were asked to participate in personal exposure monitoring, which consisted of the simultaneous collection of lapel and in-mask samples for ribavirin. The respiratory therapists and nurses simulated the activities that would normally have been necessary if a patient was actually receiving care, but did so with infant mannequins for the purposes of this site visit.

While a 3M 8710 respirator is required by hospital management to be worn by everyone entering a room where ribavirin is administered, 3M 9920 dust/fume/mist respirators (NIOSH/MSHA approval number TC-21C-202) were used for this evaluation because they can better support a sampling probe and cassette without affecting the fit of the respirator. Both respirators belong to the class of respirators described as disposable air-purifying half-mask respirators and are selected for protection against particulate exposures. This class of respiratory protection has an assigned protection factor of 5, but an assigned protection factor of 10 can be used if they have been properly fitted using a quantitative fit test.[7]

A plastic Liu probe for in-mask sampling was positioned at a location directly below the exhalation valve of each 3M 9920 respirator used during this evaluation.[8] Quantitative fit tests were not conducted during this site visit. Respirators were always donned and removed at a location designated as the "IH office," where no exposure to ribavirin was expected. Area air sampling was conducted at this location to determine whether ribavirin was present at concentrations that would influence the overall results of the pilot study. Sampling pumps were always started after respirators were in place and were stopped before respirators were removed to ensure the integrity of each in-mask sample. All study participants were observed to ensure that they wore their respirators properly during all periods of potential exposure to ribavirin. Each sampling probe was washed at the conclusion of each full-shift sampling period with 10 milliliters (ml) of purified water, and the resulting liquid was submitted for ribavirin analysis. This was done to ensure that all ribavirin entering a sampling probe was collected within a sampling cassette.

Equipment for each area, personal, or in-mask sample consisted of a three-piece, closed-face 37-millimeter (mm) cassette containing a glass fiber filter (type A/E, Product Number 61652, Gelman Sciences Inc., Ann Arbor, MI 48106-9990) and a cellulose backup pad. Each cassette was connected by flexible tubing to a personal sampling pump operated at 1.0 liter per minute (l/min) for samples collected inside the "Care Cube" hoods and at 2.0 l/min for all other samples. Field blanks were prepared and submitted for analysis along with the sample cassettes.

Samples were analyzed in accordance with NIOSH analytical method 5027 issued

May 15, 1989.[9] Each filter sample was removed from its cassette, folded in half, and inserted into a culture tube for extraction with 3 ml of deionized water with sulfuric acid added (90 ml/l, pH = 2.5) in an ultrasonic bath. Each sample was agitated for 15 minutes. After each filter sample solution or each bulk sample of ribavirin solution was filtered through a syringe filter, an injection volume of 30 microliters (µl) was analyzed using a high performance liquid chromatograph equipped with an ultraviolet detector.

**Site Visit #2 (January 15 and 16, 1991)**

Area air samples were collected within "Care Cube" disposable hoods that were not adapted with scavenging systems and beside beds upon which the hoods were located. Samples were collected in the same manner as for site visit #1, and each sample was likewise analyzed in the same manner according to NIOSH analytical method 5027. Bulk samples of ribavirin solutions were collected both before and after administration and analyzed for ribavirin.

Quantitative fit testing was also conducted for respirator assignment using a Portacount™ Respirator Fit Tester (TSI, Inc., P.O. Box 64394, St. Paul, MN 55164). Quantitative fit factors of respirator wearers measured with the Portacount™ have been reported on a group basis as being highly correlated to those obtained by a recognized photometer quantitative fit test system.[10] A Portacount™ was used during this study because it is less cumbersome than conventional quantitative fit test systems to transport to a study site. The group of respirators used for fit testing consisted of Moldex 2300 dust/mist disposable respirators (NIOSH/MSHA approval number TC-21C-350), Moldex 3400 dust/fume/mist disposable respirators (NIOSH/MSHA approval number TC-21C-418) (Moldex-Metric, Inc., 4671 Leahy Street, Culver City CA 90232), 3M 8710 dust/mist disposable respirators (NIOSH/MSHA approval number TC-21C-132), 3M 9920 dust/fume/mist disposable respirators (NIOSH/MSHA approval number TC-21C-202), medium and large 3M 9970 high efficiency dust/fume/mist disposable respirators (NIOSH/MSHA approval number TC-21C-437) (3M Occupational Health and Environmental Safety Division), and small, medium, and large MSA half-mask respirators with high efficiency dust/fume/mist cartridges (NIOSH/MSHA approval number TC-21C-135) (Mine Safety Appliances Company, P.O.Box 439, Pittsburgh, PA 15230).

Each employee's fit test started with a series of screening tests consisting generally of one of the Moldex respirators, one of the 3M low efficiency respirators, one of the 3M high efficiency respirators, and one of the MSA half-mask, high efficiency respirators. Each screening fit test was conducted while the employee breathed normally. The respirator with the highest screening fit factor was selected for a complete fit test during which the employee performed the following six exercises: normal breathing (NB1), deep breathing (DB), moving head side to side (SS), moving head up and down (UD), talking (TK), and normal breathing (NB2). An overall fit factor (FF) was then calculated using the following equation:[10]

$$\text{Overall FF} = 6/[(1/NB1_{FF}) + (1/DB_{FF}) + (1/SS_{FF}) + (1/UD_{FF}) + (1/TK_{FF}) + (1/NB2_{FF})]$$

**Site Visit #3 (February 28 and March 1, 1991)**

Area air samples were collected within a "Care Cube" disposable hood used for administration of ribavirin to an infant patient, beside the bed upon which the hood was located, and at locations where no exposure to ribavirin was expected. Bulk samples of ribavirin solutions were collected before administration at the beginning of each day of testing. Study participants were selected for

participation in the personal exposure monitoring phase of this site visit from among the nurses and respiratory therapists available during the work shifts when ribavirin was being administered.

Based upon the results of the quantitative fit tests conducted during site visit #2, the respiratory therapists or nurses scheduled to work on one of the days of sampling who had the highest overall fit factors were asked to participate in the personal exposure monitoring phase of the study, which consisted of the simultaneous collection of lapel and in-mask samples for ribavirin. Samples were collected in the same manner as for site visits #1 and #2, and each sample was likewise analyzed in the same manner according to NIOSH analytical method 5027.

## *RESULTS AND DISCUSSION*

### Site Visit #1 (July 17 and 18, 1990)

Two bulk samples collected on July 17, 1990, from different flasks containing starting solutions of ribavirin were analyzed, and both were reported to contain 30 mg/ml, which is greater than the recommended concentration of 20 mg/ml. A sample collected on July 18, 1990, was reported to contain 21 mg/ml.

The results of sampling with cassettes placed inside "Care Cube" hoods are presented in Table I. The results of the 21 short-term samples (10-18 minutes in duration) range from 1.3 to 123 $mg/m^3$. The five mean concentrations range from 3.6 to 93.2 $mg/m^3$. These concentrations are lower than the expected concentration of 190 $mg/m^3$, possibly because of decreased delivery pressures, obstructed delivery nozzles, or removal of excessive amounts of ribavirin by the scavenging system. Research has been conducted which demonstrates that fluctuations in delivery concentrations can occur as a function of nebulizer air flow rate.[5] Decreasing the nebulizer air flow rate resulted in a significant reduction of aerosol concentration. A concentration of 190 $mg/m^3$ at a nebulizer air flow rate of 7 l/min was reduced to only 7 $mg/m^3$ at a nebulizer air flow rate of 4 l/min. Based upon the results of this study,[5] a concentration of approximately 140 $mg/m^3$ would be predicted from the nebulizer air flow rate of 6.5 l/min used at HCA Wesley Medical Center.

The results of area air sampling conducted in room 512 and the intensive care unit of the pediatric ward are presented in Table II. There is no obvious or apparent explanation for the discrepancies between the ribavirin concentration estimate of 9 $\mu g/m^3$ achieved beside Bed #3 in room 512 and the concentration estimate of 59 $\mu g/m^3$ achieved approximately 25 feet away at the nurse's desk in room 512. Similarly, there is no explanation for the difference between the concentration estimates achieved beside Bed #3 on the first day of sampling (9 $\mu g/m^3$) and the second day (573 $\mu g/m^3$). Sampling at these locations was initiated on both days after ribavirin administration was started, and sampling was stopped after ribavirin administration was completed. Therefore, the differences are not associated with variabilities related to sampling methods, or to sampling during only certain phases of a ribavirin administration procedure. It is also unlikely that the administration techniques of the respiratory therapists and nurses were contributing factors, since the mean concentrations inside the delivery hoods used at Bed #3 were similar (62.4 and 93.2 $mg/m^3$). It is plausible that differences in the orientation of the sampling cassettes with respect to the delivery hoods might have been a contributing factor for the observed differences.

The sampling location identified in Table II as "IH office" was an area of the pediatric ward where respirators and personal and in-mask sampling cassettes were donned and removed. As anticipated,

there was essentially no ribavirin exposure at this location, and it is unlikely that the trace concentration present on July 18, 1990, affected the overall results of the pilot study.

The results of simultaneous lapel and in-mask sampling are presented in Table III. The 8-hour TWA lapel concentrations range from 87 to 323 µg/m$^3$. Fifty-nine percent (10/17) of the in-mask sampling results were reported as none detected; the analytical limit of detection was 1 microgram per sample (µg/sample). An additional four samples contained quantities of ribavirin between the limit of detection (1.0 µg/sample) and the limit of quantitation (4.0 µg/sample), and they should be considered trace amounts with limited confidence in their accuracy. Three samples contained quantities of ribavirin which exceeded the limit of quantitation.

To conservatively approximate the workplace protection factors achieved during this phase of the study, in-mask samples that were reported as none detected were replaced with the limit of detection (1 µg/sample), and 8-hour TWA concentrations were determined. Also, the amount of ribavirin found from the probe wash of one sample (RT/PICU on July 17, 1990) was included in the calculation of its associated in-mask concentration. Probe wash concentrations that were reported as none detected were assumed to contain no ribavirin. The workplace protection factors achieved are presented in Table IV. A workplace protection factor was not calculated for the registered nurse in room 512 on July 17, 1990, because the quantity of ribavirin reported for the probe wash associated with this set of samples was twice the amount reported for this individual's lapel sample. This situation suggests that the probe, or probe wash solution, was contaminated and that using this value would not reflect a true indication of respirator performance.

Disposable respirators like the 3M 8710 and the 3M 9920 have an assigned protection factor of 5.[7] While the respirators used at Wesley Medical Center were not quantitatively fit tested, the five calculated workplace protection factors exceed 5, and range from 15 to 29. Although the sample size is small, an assigned protection factor of 12 results from these five values using a calculation method described elsewhere.[11, 12]

**Site Visit #2 (January 15 and 16, 1991)**

The results of analysis of bulk samples taken from pre-administration and post-administration ribavirin solutions used during the two days of testing are presented in Table V. The solutions ranged from 22 to 38 mg/ml, and all exceeded the recommended concentration of 20 mg/ml.

Because the concentrations within the "Care Cube" hoods evaluated during site visit #1 were all less than the expected concentration of 190 mg/m$^3$, testing was conducted during site visit #2 to evaluate the concentrations of ribavirin inside hoods without scavenging systems. The results of testing are presented in Table VI. The 32 short-term samples (10-11 minutes in duration) range from 0.3 to 180 mg/m$^3$. The four mean concentrations range from 91.0 to 124 mg/m$^3$. While nurses and respiratory therapists simulated their normal activities during site visit #1, which included frequent opening of the hood, this was not done during site visit #2. Although all of the short-term sampling results were still less than 190 mg/m$^3$, seven equaled or exceeded the predicted concentration of 140 mg/m$^3$.

The results of area air sampling conducted in Room 512 and the intensive care unit of the pediatric ward are presented in Table VII. Overall, the 8-hour TWA ribavirin concentrations are slightly higher than those achieved during site visit #1.

The results of quantitative fit testing for 32 nurses and respiratory therapists are presented in Tables VIII and IX. The 35 fit factors achieved during normal breathing with low efficiency disposable respirators (Moldex 2300 and 3400, and 3M 8710 and 9920) range from 2 to 92 and have a geometric mean of 15 with a geometric standard deviation of 2.54. Generally, quantitative fit tests of negative pressure respirators are conducted using high efficiency filters, so as to achieve the test's primary purpose of evaluating face to facepiece seal leakage only. The fit factors reported here for low efficiency disposable respirators might be underestimates, since in-mask concentrations could have represented not only leakage of the challenge aerosol between the face to facepiece seal, but also an unknown amount of penetration of the aerosol through the filter material.

The 40 fit factors achieved with the high efficiency disposable respirator (3M 9970 medium and large) range from 2 to 25,000 and have a geometric mean of 142 with a geometric standard deviation of 17.9. The 34 fit factors achieved with the MSA half-mask with high efficiency cartridges range from 22 to 13,000 and have a geometric mean of 1,120 with a geometric standard deviation of 4.60. The high degree of variability associated with the fit factors achieved with the 3M 9970 respirator serves to emphasize the importance of conducting quantitative fit tests prior to providing respirators to employees.

As stated in APPENDIX A (page 14), the majority of assigned protection factors for the various classes of respirators have been based upon the results of quantitative fit testing. While the fit factors presented in Table VIII represent the values achieved during only the normal breathing exercise, it is of interest that the assigned protection factors achieved with these values are 3.2 for the low efficiency disposable respirators, 1.2 for the 3M 9970 high efficiency disposable respirator, and 92 for the MSA half mask respirator with high efficiency cartridges.

Overall fit factors ranked from highest to lowest according to job and work shift are presented in Table IX for the respirators with the highest screening fit factors achieved by the nurses and respiratory therapists who were tested. Assignment of a respirator to each nurse and respiratory therapist based upon the highest overall fit factor achieved during their fit tests resulted in seventy-two percent of the employees (23/32) being assigned a half mask respirator with high efficiency cartridges (MSA), and the remainder of the employees (9/32) being assigned a high efficiency disposable respirator (3M 9970).

**Site Visit #3 (February 28 and March 1, 1991)**

Testing during the administration of ribavirin to an infant patient occurred on the second and third days of a three-day treatment period. The analysis of bulk samples of both pre-administration ribavirin solutions were reported as 21 mg/ml.

The results of sampling with cassettes placed inside the "Care Cube" hood with a scavenging system used for ribavirin administration are presented in Table X. The results of 16 short-term samples (10-21 minutes in duration) range from 52.7 to 180 $mg/m^3$. The two mean concentrations are 85.2 and 148.6 $mg/m^3$. Interestingly, the mean concentration for the treatment given on February 28 is less than the predicted concentration of 140 $mg/m^3$. Two of the three short-term concentrations which exceeded 140 $mg/m^3$ occurred at the end of the study on March 1, 1991. Because the patient's activity within the "Care Cube" had made it difficult to keep the opening of the hood closed securely, a nurse used two of the "gator" clips from the NIOSH sampling equipment to effect a better seal. While the infant's movements were not restricted by this innovation, ribavirin concentrations inside the hood were apparently increased.

The results of area air sampling are presented in Table XI. The patient's parents were unable to visit their child on the days of testing, and therefore, only area samples were collected on a window curtain near a chair for visitors in the patient's room. The sampling locations identified as Room 511 (Bed #8) and Room 512 were areas where respirators, and personal and in-mask sampling cassettes were donned and removed. As anticipated, there was essentially no ribavirin exposure at these locations, and it is unlikely that the trace concentrations present on February 28, 1991, in Room 511 (Bed #8) affected the overall results of this phase of the study.

The results of simultaneous lapel and in-mask sampling are presented in Table XII. The 8-hour TWA lapel concentrations range from 40 to 120 µg/m$^3$. Seven of the eight in-mask sampling results were reported as none detected and the remaining sampling result was reported at the limit of detection of the analytical method (0.7 µg/sample). As with the personal sampling data of site visit #1, approximate workplace protection factors were calculated and are presented in Table XIII. They range from 50 to 133.

## *CONCLUSIONS/RECOMMENDATIONS*

The sampling results of this study demonstrate that notable concentrations of aerosolized ribavirin were present in the rooms where the drug was administered despite the addition of a scavenging system to the "Care Cube" disposable hood. Therefore, the policy established in 1987 by the management of HCA Wesley Medical Center regarding the wearing of respirators by health care workers in rooms where ribavirin is administered should continue. However, the use of respirators should involve all of the components of a complete respiratory protection program and should be developed in accordance with the requirements for an acceptable program established by the Occupational Safety and Health Administration as described in 29 Code of Federal Regulations Part 1910.134. The respiratory protection program should be considered an interim measure that will remain until technically feasible devices and/or procedures for the administration of ribavirin aerosol are developed and implemented that will alone reduce exposures of health care providers at HCA Wesley Medical Center to aerosolized ribavirin.

The respiratory protection program should include the performance of quantitative fit tests to assign the particular respirator that each individual should wear from a group of respirators that are approved jointly by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, and that represent a variety of manufacturers and facepiece sizes. Additionally, a minimum overall quantitative fit factor should be selected that must be achieved before a specific respirator is assigned to an individual. While no data have been reported to demonstrate a relationship between quantitative fit factors and the workplace performance of a respirator, safety factors have been used to establish minimum acceptable quantitative fit factors. A safety factor of 10 has been applied to half-mask respirators,[13-15] but other factors (e.g., 20[16] and 25[11]) have also been used. The minimum overall quantitative fit factor selected for use at HCA Wesley Medical Center should be determined with caution and with recognition of the uncertainty of its effectiveness.[7]

A sampling surveillance program should be developed to routinely monitor the effectiveness of the respiratory protection program. Such a program can consist of lapel sampling alone by determining whether or not 8-hour TWA concentrations experienced by nurses and respiratory therapists potentially exposed to aerosolized ribavirin remain similar to those levels reported here. However, if it is feasible to conduct simultaneous lapel and in-mask sampling for ribavirin, this approach is preferred for ensuring the continued effectiveness of the respiratory protection program.[7]

As mentioned previously, the engineering staff of HCA Wesley Medical Center estimated that the rooms used for ribavirin administration had twelve air changes per hour. The 1991 Aerosol Consensus Statement of the American Association for Respiratory Care contains guidance that patient rooms where ribavirin is administered should have a minimum of six air changes per hour.[17] The ventilation system of each room where ribavirin is administered at HCA Wesley Medical Center should continue to be monitored on a routine basis to ensure that optimal operation is maintained. The ventilation system of each room should also be maintained at a slight negative pressure to prevent aerosolized ribavirin from entering other occupied areas of the Pediatric Intensive Care Unit.

## *APPENDIX A: PROTECTION FACTORS FOR RESPIRATORS*

Because differences exist among the various classes of respirators with regard to their protective capabilities, respirators are assigned protection factors as guidance for their selection. A protection factor is the ratio of the concentration of a contaminant in the environment surrounding a respirator wearer to the concentration of the contaminant inside the respirator wearer's facepiece. The majority of assigned protection factors are based on quantitative fit factors rather than workplace protection factors. **Quantitative fit factors** are determined from tests in which a group of respirator wearers perform a specific regimen of head and body movements for a short period of time while in a laboratory test chamber containing a challenge aerosol. A **workplace protection factor** is a measure of the protection provided in a workplace under the actual conditions of that workplace by a properly functioning respirator which is correctly worn and used.[18] An **assigned protection factor** is the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator, or class of respirators, to a stated percentage of properly fitted and trained users.[18, 19] This proportion has usually been specified as 95 percent for test data derived from both quantitative fit factors[20] and workplace protection factors.[11, 12]

The maximum use concentration for a respirator is generally determined by multiplying the assigned protection factor of the respirator by a contaminant's lowest occupational exposure limit (i.e., the lowest value among a contaminant's Permissible Exposure Limit of the Occupational Safety and Health Administration, Recommended Exposure Limit of NIOSH, and Threshold Limit Value of the American Conference of Governmental Industrial Hygienists). Alternatively, the minimum level of protection necessary for a specific occupational application can be calculated after exposure estimates have been determined for environmental contaminants. This is usually done by dividing the highest 8-hour time-weighted average (TWA) exposure estimate of an airborne contaminant by the contaminant's lowest occupational exposure limit. Then, a class of respiratory protection is selected with an assigned protection factor equal to or exceeding the needed level of protection. For example, if a set of industrial hygiene samples collected during a particular operation produced 8-hour TWA exposure estimates ranging from 8 to 50 $mg/m^3$ for a contaminant with an occupational exposure limit of 10 $mg/m^3$, then a respirator with an assigned protection factor of at least 5 (50/10 = 5) would be selected. Such a respirator would reduce the highest exposure concentration to an in-mask concentration equal to, or less than, the contaminant's exposure limit for the majority of respirator wearers.

After implementation of a respiratory protection program, simultaneous lapel and in-mask sampling should be performed on a sample set of respirator wearers to ensure that the respirator selected is

indeed sufficient to protect its user during all conditions of use. Such sampling should be conducted periodically to further ensure that there have been no significant changes in the conditions of respirator usage that might reduce the effectiveness of the particular respirator in service.

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2. NIOSH Region VIII (Denver, CO)
3. OSHA Region VII (Kansas City, MO)

For the purpose of informing affected employees, copies of this report should be posted by the employer in a prominent place readily accessible to such employees for a period of 30 calendar days.

TABLE I

Concentrations of Ribavirin Inside "Care Cube" Disposable Hoods
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #1 (July 17 - 18, 1990)
HETA 90-155

| Sampling Location | Sample Number | Ribavirin Sampling Period | Mean (SD) Concentration ($mg/m^3$) | Concentration ($mg/m^3$) |
|---|---|---|---|---|
| | | July 17, 1990 | | |
| Room 512, Bed #3 | 7 | 0810 - 0820 | 4.1 | 62.4 (32.5) |
| | 15 | 0936 - 0948 | 82.5 | |
| | 18 | 1204 - 1215 | 45.5 | |
| | 20 | 1235 - 1246 | 74.5 | |
| | 24 | 1356 - 1406 | 76.0 | |
| | 26 | 1440 - 1450 | 92.0 | |
| Intensive Care | 13 | 0921 - 0931 | 48.0 | 41.2 (26.1) |
| | 6 | 1006 - 1016 | 64.0 | |
| | 5 | 1102 - 1112 | 47.0 | |
| | 19 | 1209 - 1219 | 69.0 | |
| | 22 | 1316 - 1326 | 6.4 | |
| | 25 | 1422 - 1433 | 12.7 | |
| | | July 18, 1990 | | |
| Room 512, Bed #1 | 40 | 0938 - 0951 | 76.9 | 71.6 (54.2) |
| | 47 | 1056 - 1106 | 15.0 | |
| | 53 | 1346 - 1359 | 123.0 | |
| Room 512, Bed #3 | 41 | 0938 - 0951 | 76.9 | 93.2 (16.6) |
| | 46 | 1056 - 1106 | 110.0 | |
| | 54 | 1346 - 1400 | 92.8 | |
| Intensive Care | 43 | 0954 - 1012 | 6.1 | 3.6 (2.4) |
| | 48 | 1059 - 1112 | 1.3 | |
| | 55 | 1348 - 1401 | 3.5 | |

Limit of Detection: 1.0 µg/sample
Limit of Quantitation: 4.0 µg/sample
SD: standard deviation
TWA: time-weighted average

TABLE II

Results of Area Air Sampling for Ribavirin
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #1 (July 17 - 18, 1990)
HETA 90-155

| Sampling Location | Sample Number | Ribavirin Sampling Period | 8-hr TWA Ribavirin Concentration ($\mu g/m^3$) | Concentration ($\mu g/m^3$) |
|---|---|---|---|---|
| | | July 17, 1990 | | |
| Rm. 512, beside bed #3 | 8 | 0816 - 1508 | 11 | 9 |
| Rm. 512, on desk | 9 | 0819 - 1458 | 71 | 59 |
| PICU, beside bed | 14 | 0923 - 1511 | 330 | 239 |
| "IH office" | 12 | 0848 - 1514 | ND | --- |
| | | July 18, 1990 | | |
| Rm. 512, beside bed #1 | 38 | 0802 - 1505 | 378 | 333 |
| Rm. 512, beside bed #3 | 37 | 0802 - 1504 | 652 | 573 |
| PICU, beside bed | 39 | 0809 - 1501 | 243 | 209 |
| "IH office" | 30 | 0729 - 1509 | (3) | (3) |

Note: Values in ( ) represent a quantity of ribavirin between the Limit of Detection [1.0 µg/sample] and the Limit of Quantitation [4.0 µg/sample], and should be considered trace concentrations with limited confidence in their accuracy.

PICU: pediatric intensive care unit
ND: none detected
TWA: time-weighted average

TABLE III

Results of Lapel and In-mask Air Sampling for Ribavirin
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #1 (July 17 - 18, 1990)
HETA 90-155

| Job/Location | Lapel Sample Number | Sampling Duration (min) | Actual/8-hr TWA Ribavirin Concentration ($\mu g/m^3$) | In-mask Sample Number | Sampling Duration (min) | Ribavirin Concentration ($\mu g/m^3$) |
|---|---|---|---|---|---|---|
| | | | July 17, 1990 | | | |
| RN/Room 512 | 3 | 285 | 147/ 87 | 4 | 178 | ND |
| | | | | 17 | 107 | ND |
| RT/Room 512 | 1 | 189 | 220/ 87 | 2 | 115 | ND |
| | | | | 16 | 51 | ND |
| | | | | 23 | 23 | ND |
| RT/PICU | 11 | 173 | 607/219 | 10 | 124 | (8) |
| | | | | 21 | 49 | ND |
| | | | July 18, 1990 | | | |
| RN/Room 512 | 33 | 371 | 418/323 | 36 | 138 | (7) |
| | | | | 44 | 17 | ND |
| | | | | 45 | 216 | 39 |
| RT/Room 512 | 31 | 302 | 447/281 | 34 | 82 | ND |
| | | | | 42 | 89 | (6) |
| | | | | 50 | 26 | ND |
| | | | | 52 | 105 | 38 |
| RT/PICU | 32 | 304 | 197/125 | 35 | 152 | 13 |
| | | | | 49 | 15 | ND |
| | | | | 51 | 137 | (11) |

Note: Values in ( ) represent quantities of ribavirin between the Limit of Detection [1.0 µg/sample] and the Limit of Quantitation [4.0 µg/sample], and should be considered trace concentrations with limited confidence in their accuracy.

PICU: pediatric intensive care unit
ND: none detected
RN: Registered Nurse
RT: Respiratory Therapist
TWA: time-weighted average

TABLE IV

Workplace Protection Factors for Registered Nurses (RNs) and Respiratory Therapists (RTs) during Ribavirin Administration
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #1 (July 17 - 18, 1990)
HETA 90-155

| Job/Location | (A) Ribavirin in Probe Wash (µg/10 ml) | 8-hr TWA Lapel Concentration ($\mu g/m^3$) | (B) Approximate 8-hr TWA In-mask Concentration ($\mu g/m^3$) | Workplace Protection Factor (A/B) |
|---|---|---|---|---|
| | | July 17, 1990 | | |
| RN/Room 512 | 160 | 87 | -- | -- |
| RT/Room 512 | ND | 87 | 3 | 29 |
| RT/PICU | (10) | 219 | 14 | 16 |
| | | July 18, 1990 | | |
| RN/Room 512 | ND | 323 | 21 | 15 |
| RT/Room 512 | ND | 281 | 11 | 26 |
| RT/PICU | ND | 125 | 8 | 16 |

Note: The value in ( ) represents a quantity of ribavirin between the limit of detection [6 µg/10 ml] and the limit of quantitation [19 µg/10 ml], and should be considered a trace amount with limited confidence in its accuracy.

PICU: pediatric intensive care unit
ND: none detected
TWA: time-weighted average

TABLE V

Concentrations of Ribavirin Solutions Prepared for Reservoirs of SPAGs
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #2 (January 15 - 16, 1991)
HETA 90-155

| SPAG Location | Sample Number | Ribavirin Concentration (mg/ml) Pre-administration | Post-administration |
|---|---|---|---|
| | | January 15, 1991 | |
| Room 512, Bed #1 | 63 | -- | 37 |
| Room 512, Bed #3 | 64 | -- | 38 |
| | | January 16, 1991 | |
| Room 512, Bed #3 | 65 & 67 | 31 | 38 |
| Room 511, Bed #8 | 66 & 68 | 22 | 36 |
| Purified Water | 69 | None Detected | |

Limit of Detection: 0.0003 mg/ml
Limit of Quantitation: 0.0009 mg/ml

TABLE VI

Concentrations of Ribavirin inside "Care Cube" Disposable Hoods
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #2 (January 15 - 16, 1991)
HETA 90-155

| Sampling Location | Sample Number | Sampling Period | Ribavirin Concentration ($mg/m^3$) | Mean (SD) Concentration ($mg/m^3$) |
|---|---|---|---|---|
| | | January 15, 1991 | | |
| Room 512, Bed #1 | 1 | 0945 - 0955 | 0.3 | 124 (65) |
| | 9 | 1025 - 1035 | 48.0 | |
| | 11 | 1110 - 1120 | 120 | |
| | 13 | 1235 - 1245 | 150 | |
| | 15 | 1325 - 1335 | 160 | |
| | 17 | 1420 - 1431 | 164 | |
| | 19 | 1525 - 1535 | 180 | |
| | 21 | 1650 - 1700 | 170 | |
| Room 512, Bed #3 | 2 | 0945 - 0955 | 0.4 | 91.0 (44) |
| | 8 | 1025 - 1035 | 87.0 | |
| | 10 | 1110 - 1120 | 110 | |
| | 12 | 1235 - 1245 | 110 | |
| | 14 | 1325 - 1335 | 110 | |
| | 16 | 1420 - 1431 | 118 | |
| | 18 | 1525 - 1535 | 140 | |
| | 20 | 1650 - 1700 | 53.0 | |
| | | January 16, 1991 | | |
| Room 512, Bed #3 | 31 | 0910 - 0920 | 58.0 | 92.2 (19) |
| | 33 | 1007 - 1017 | 77.0 | |
| | 35 | 1105 - 1115 | 95.0 | |
| | 37 | 1205 - 1215 | 84.0 | |
| | 39 | 1305 - 1315 | 98.0 | |
| | 41 | 1407 - 1417 | 110 | |
| | 43 | 1507 - 1517 | 120 | |
| | 45 | 1542 - 1552 | 96.0 | |
| Room 511, Bed #8 (Intensive Care) | 32 | 0855 - 0905 | 110 | 109 (27) |
| | 34 | 0950 - 1000 | 110 | |
| | 36 | 1050 - 1100 | 99.0 | |
| | 38 | 1152 - 1202 | 110 | |
| | 40 | 1250 - 1300 | 110 | |
| | 42 | 1355 - 1405 | 130 | |
| | 44 | 1455 - 1505 | 150 | |
| | 46 | 1558 - 1608 | 55.0 | |

Limit of Detection: 0.8 µg/sample
Limit of Quantitation: 2.0 µg/sample
SD: Standard Deviation

TABLE VII

Results of Area Air Sampling for Ribavirin
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #2 (January 15 - 16, 1991)
HETA 90-155

| Sampling Location | Sample Number | Sampling Period | Ribavirin Concentration ($\mu g/m^3$) | 8-hr TWA Ribavirin Concentration ($\mu g/m^3$) |
|---|---|---|---|---|
| | | Room 512 (January 15, 1991) | | |
| Bed #1, beside SPAG | 4 | 0919 - 1249 | 381 | 646 |
| | 24 | 1257 - 1722 | 868 | |
| Bed #1, opposite SPAG | 3 | 0919 - 1251 | 424 | 833 |
| | 23 | 1257 - 1725 | 1157 | |
| Bed #3, beside SPAG | 7 | 0920 - 1252 | 472 | 677 |
| | 22 | 1257 - 1721 | 852 | |
| Bed #3, opposite SPAG | 5 | 0920 - 1252 | 448 | 792 |
| | 25 | 1257 - 1721 | 1080 | |
| on nurse's desk | 6 | 0919 - 1251 | 354 | 666 |
| | 26 | 1257 - 1722 | 924 | |
| | | Rooms 512 & 511 (January 16, 1991) | | |
| Bed #3, beside SPAG (Room 512) | 50 | 0847 - 1247 | 875 | 667 |
| | 56 | 1247 - 1557 | 579 | |
| Bed #3, opposite SPAG (Room 512) | 51 | 0847 - 1247 | 1062 | 760 |
| | 57 | 1247 - 1557 | 579 | |
| on nurse's desk (Room 512) | 49 | 0847 - 1247 | 312 | 271 |
| | 55 | 1247 - 1557 | 290 | |
| Bed #8, beside SPAG (Room 511) | 47 | 0835 - 1235 | 292 | 313 |
| | 53 | 1236 - 1610 | 374 | |
| Bed #8, opposite SPAG (Room 511) | 48 | 0835 - 1235 | 542 | 584 |
| | 54 | 1236 - 1611 | 698 | |
| outside of Room 511 | 52 | 0853 - 1253 | (4) | (3) |
| | 58 | 1253 - 1613 | (2) | |

Note: Values in ( ) represent a quantity of ribavirin between the Limit of Detection [0.8 µg/sample] and the Limit of Quantitation [2.0 µg/sample], and should be considered trace concentrations with limited confidence in their accuracy.

TWA: time-weighted average

TABLE VIII

Screening Quantitative Fit Factors for Nurses and Respiratory Therapists
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #2 (January 15 - 16, 1991)
HETA 90-155

| | Moldex | | 3M | | | | MSA | | |
|---|---|---|---|---|---|---|---|---|---|
| Employee | 2300 | 3400 | 8710 | 9920 | 9970M | 9970L | Small | Medium | Large |
| | | | | | *Nurses* | | | | |
| A | 5 | -- | -- | -- | 3700 | 10 | -- | **9100** | -- |
| B | -- | 72 | -- | -- | -- | 2700 | -- | **8300** | 160 |
| C | -- | 4 | -- | -- | 2 | 2 | -- | **2800** | -- |
| D | 6 | -- | -- | -- | 480 | -- | -- | **4700** | -- |
| E | -- | -- | -- | 31 | -- | 32 | -- | **800** | -- |
| F | -- | 6 | -- | -- | -- | 28 | -- | -- | **430** |
| G | -- | -- | -- | 43 | 7 | 13 | **2400** | 22 | -- |
| H | -- | -- | 16 | -- | 2400 | -- | -- | **7700** | -- |
| I | -- | 30 | -- | -- | -- | **3600** | -- | -- | 1200 |
| J | -- | 4 | -- | -- | 450 | -- | -- | **13000** | -- |
| K | -- | -- | -- | 36 | **130** | 31 | -- | 100 | -- |
| L | -- | -- | 12 | -- | -- | 15 | -- | -- | **900** |
| M | 6 | -- | -- | -- | 18 | 3 | -- | **130** | -- |
| | | | | | *Respiratory Therapists* | | | | |
| N | -- | -- | 16 | -- | **2800** | -- | -- | 970 | -- |
| O | -- | 18 | -- | -- | 280 | 7 | -- | **9400** | -- |
| P | 8 | -- | -- | -- | -- | 810 | -- | -- | **1900** |
| Q | 8 | 49 | 17 | 76 | -- | **7900** | -- | -- | 1800 |
| R | -- | -- | 34 | -- | 580 | -- | -- | **670** | -- |
| S | 7 | -- | -- | -- | -- | 20 | -- | -- | **520** |
| T | -- | -- | -- | 10 | -- | 31 | -- | -- | **890** |
| U | 10 | -- | -- | -- | 4 | 5 | -- | **4700** | -- |
| V | -- | -- | -- | 57 | -- | **6400** | -- | -- | 1200 |
| W | 2 | -- | -- | -- | 3 | -- | -- | **370** | -- |
| X | -- | -- | 11 | -- | 3 | -- | -- | **130** | -- |
| Y | 8 | -- | -- | -- | -- | **11000** | -- | -- | 710 |
| Z | -- | -- | 17 | -- | 530 | -- | -- | **800** | -- |
| AA | -- | -- | -- | 92 | 50 | -- | -- | **7800** | -- |
| BB | -- | 22 | -- | -- | -- | **3300** | -- | -- | 1300 |
| CC | -- | 23 | -- | -- | 3700 | -- | -- | **5100** | -- |
| DD | 8 | -- | -- | -- | 290 | **25000** | -- | 150 | -- |
| EE | -- | -- | 13 | -- | -- | 650 | -- | -- | **1100** |
| FF | -- | -- | -- | 11 | **2500** | -- | -- | 1000 | -- |

TABLE IX

Overall Quantitative Fit Factors for Nurses and Respiratory Therapists
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #2 (January 15 - 16, 1991)
HETA 90-155

| *Nurses* | | | *Respiratory Therapists* | | |
|---|---|---|---|---|---|
| Employee | Respirator/Size | Overall Fit Factor | Employee | Respirator/Size | Overall Fit Factor |
| | | First Shift | | | |
| A | MSA/medium | 5734 | N | 3M 9970/medium | 7088 |
| B | MSA/medium | 3106 | O | MSA/medium | 6210 |
| C | MSA/medium | 2226 | P | MSA/large | 1948 |
| D | MSA/medium | 1594 | Q | 3M 9970/large | 1282 |
| E | MSA/medium | 1335 | R | MSA/medium | 636 |
| F | MSA/large | 226 | S | MSA/large | 467 |
| G | MSA/small | 88 | T | MSA/large | 374 |
| | | | U | MSA/medium | 210 |
| | | | V | 3M 9970/large | 149 |
| | | | W | MSA/medium | 58 |
| | | | X | MSA/medium | 29 |
| | | Second Shift | | | |
| H | MSA/medium | 8070 | Y | 3M 9970/large | 9339 |
| I | 3M 9970/large | 739 | Z | MSA/medium | 1476 |
| | | Third Shift | | | |
| J | MSA/medium | 8393 | AA | MSA/medium | 4298 |
| K | 3M 9970/medium | 2244 | BB | 3M 9970/large | 3881 |
| L | MSA/large | 610 | CC | MSA/medium | 3422 |
| M | MSA/medium | 386 | DD | 3M 9970/large | 1900 |
| | | | EE | MSA/large | 981 |
| | | | FF | 3M 9970 medium | 361 |

TABLE X

Concentrations of Ribavirin inside "Care Cube" Disposable Hood
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #3 (February 28 and March 1, 1991)
HETA 90-155

| Sampling Location | Sample Number | Sampling Period | Ribavirin Concentration ($mg/m^3$) | Mean (SD) Concentration ($mg/m^3$) |
|---|---|---|---|---|
| | | February 28, 1991 | | |
| Room 511, Bed #7 | 5 | 1110 - 1121 | 77.3 | 85.2 (21.8) |
| | 9 | 1150 - 1200 | 70.0 | (9 samples) |
| | 10 | 1241 - 1252 | 52.7 | |
| | 11 | 1405 - 1420 | 62.7 | |
| | 13 | 1517 - 1530 | 107.7 | |
| | 16 | 1635 - 1646 | 100.0 | |
| | 19 | 1809 - 1821 | 108.3 | |
| | 21 | 2046 - 2104 | 77.8 | |
| | 23 | 2216 - 2226 | 110.0 | |
| | | March 1, 1991 | | |
| Room 511, Bed #7 | 33 | 1032 - 1045 | 138.5 | 148.6 (22.0) |
| | 38 | 1136 - 1157 | 157.1 | (7 samples) |
| | 39 | 1235 - 1245 | 130.0 | |
| | 41 | 1424 - 1434 | 130.0 | |
| | 42* | 1434 - 1636 | ND | |
| | 50 | 1656 - 1706 | 130.0 | |
| | 51 | 2041 - 2051 | 180.0 | |
| | 53 | 2240 - 2252 | 175.0 | |

* Air was not drawn through sample 42 in order to evaluate the potential for migration.

Limit of Detection: 2 µg/sample
Limit of Quantitation: 5 µg/sample
SD: standard deviation

TABLE XI

Results of Area Sampling for Ribavirin
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #3 (February 28 and March 1, 1991)
HETA 90-155

| Sampling Location | Sample Number | Sampling Period | Ribavirin Concentration ($\mu g/m^3$) | 8-hr TWA Ribavirin Concentration ($\mu g/m^3$) |
|---|---|---|---|---|
| | | February 28, 1991 | | |
| Room 511, Bed #7 (on window curtain) | 8 | 0914 - 1317 | 181 | 170 |
| | 12 | 1317 - 1717 | 229 | |
| | 20 | 1717 - 2049 | 170 | |
| | 22 | 2049 - 2255 | 218 | |
| Room 511, Bed #8 (on privacy curtain) | 7 | 0912 - 1540 | (1.3) | (1.6) |
| | 17 | 1540 - 2230 | (2.4) | |
| Room 512 | 6 | 0916 - 1542 | ND | ND |
| | 18 | 1542 - 2248 | ND | |
| | | March 1, 1991 | | |
| Room 511, Bed #7 (on window curtain) | 36 | 0855 - 1220 | 366 | 279 |
| | 40 | 1220 - 1520 | 306 | |
| | 48 | 1522 - 1918 | 275 | |
| | 52 | 1918 - 2250 | 330 | |
| Room 511, Bed #8 (on privacy curtain) | 35 | 0856 - 1514 | (2.6) | (3.7) |
| | 47 | 1514 - 2240 | 5.6 | |
| Room 512 | 34 | 0847 - 1525 | ND | ND |
| | 49 | 1525 - 2233 | ND | |

Note: Values in ( ) represent quantities of ribavirin between the limit of detection [0.7 µg/sample] and the limit of quantitation [2 µg/sample], and should be considered trace concentrations with limited confidence in their accuracy.

ND: none detected
TWA: time-weighted average

TABLE XII

Results of Lapel and In-mask Sampling for Ribavirin
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #3 (February 28 and March 1, 1991)
HETA 90-155

| Job/Emp./Mask (Shift) | Lapel Sample Number | Sampling Duration (min) | Actual/8-hr TWA Ribavirin Concentration ($\mu g/m^3$) | In-mask Sample Number | Sampling Duration (min) | Ribavirin Concentration ($\mu g/m^3$) |
|---|---|---|---|---|---|---|
| | | | February 28, 1991 | | | |
| RN/E/MSA M (7 am - 7 pm) | 3 | 88 | 438/120 | 1 | 88 | ND |
| RT/U/MSA M (7 am - 3 pm) | 4 | 89 | 236/ 44 | 2 | 89 | ND |
| RT/S/MSA L (3 pm - 11 pm) | 15 | 46 | 413/ 40 | 14 | 46 | ND |
| | | | March 1, 1991 | | | |
| RN/F/MSA L (7 am - 3 pm) | 31 | 92 | 408/ 78 | 32* | 92 | (4) |
| RN/H/MSA M (3 pm - 11 pm) | 43 | 78 | 494/ 80 | 44 | 78 | ND |
| RT/Q/3M 9970 L (7 am - 3 pm) | 29 | 102 | 279/ 59 | 30<br>37 | 15<br>87 | ND<br>ND |
| RT/Y/3M 9970 L (3 pm - 11 pm) | 45 | 45 | 733/ 69 | 46 | 45 | ND |

* The cassette of sample 32 was disconnected accidentally from the respirator facepiece for approximately 2 seconds during sampling.

Note: The value in ( ) represents a quantity of ribavirin between the limit of detection [0.7 µg/sample] and the limit of quantitation [2 µg/sample], and should be considered a trace concentration with limited confidence in its accuracy.

Emp.: employee identification letter
L: large
M: medium
ND: none detected
RN: Registered Nurse
RT: Respiratory Therapist
TWA: time-weighted average

TABLE XIII

Workplace Protection Factors for Registered Nurses (RNs) and Respiratory Therapists (RTs) during Ribavirin Administration
HCA Wesley Medical Center
Wichita, Kansas
Site Visit #3 (February 28 and March 1, 1991)
HETA 90-155

| Job/Emp./Mask (Shift) | Ribavirin in Probe Wash (µg/10 ml) | (A) 8-hr TWA Lapel Concentration (µg/m$^3$) | (B) Approximate 8-hr TWA In-mask Concentration (µg/m$^3$) | Workplace Protection Factor (A/B) |
|---|---|---|---|---|
| | | February 28, 1991 | | |
| RN/E/MSA M (7 am - 7 pm) | ND | 120 | 1.1 | 109 |
| RT/U/MSA M (7 am - 3 pm) | ND | 44 | 0.7 | 63 |
| RT/S/MSA L (3 pm - 11 pm) | ND | 40 | 0.8 | 50 |
| | | March 1, 1991 | | |
| RN/F/MSA L (7 am - 3 pm) | ND | 78 | 0.8 | 98 |
| RN/H/MSA M (3 pm - 11 pm) | ND | 80 | 0.6 | 133 |
| RT/Q/3M 9970 L (7 am - 3 pm) | ND | 59 | 0.6 | 98 |
| RT/Y/3M 9970 L (3 pm - 11 pm) | ND | 69 | 0.8 | 86 |

Emp.: employee identification letter
L: large
M: medium
ND: none detected
TWA: time-weighted average