

Running Head: EFFECTING A CHANGE IN POLICY AND PRACTICE

EFFECTING A CHANGE IN POLICY AND PRACTICE ON A BONE  
MARROW TRANSPLANT UNIT (BMTU) USING ROSSWURM AND  
LARRABEE'S EVIDENCE-BASED PRACTICE MODEL

By

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A project submitted in partial fulfillment of the requirements for the degree of

MASTER OF NURSING

In the School of Nursing, Faculty of Human and Social Development,  
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## Abstract

Nurses caring for blood and bone marrow transplant recipients need to understand the effects that respiratory syncytial virus (RSV) infection can have on patients, family members, and health care providers. The current treatment, using aerosolized ribavirin (AR), creates an occupational health hazard for both health care professionals and family members because of the lack of available information and lack of clarity in policy and procedure surrounding the use of the drug on the bone marrow transplant unit (BMTU). Although nurses are knowledgeable about the transmission, virulence, and treatment of RSV, they need to be able to practice safe, competent nursing care and provide education for patients and family members regarding the use of AR. It is a professional responsibility of nurses to participate in practice change and ensure a safe working environment. One resource that nurses can use to guide practice is from policy.

The purpose of this project is to provide a descriptive analysis of the current practices surrounding the administration of AR on the BMTU and to provide evidence to support the need for a change in practice based on the guidelines developed by the National Institute for Occupational Safety and Health (NIOSH). The outcome of this project was to develop a policy to guide professional nursing practice and ensure a safe working environment.

The framework and model that I used to assist in the process of changing practice was developed by Rosswurm and Larrabee (1999) entitled “A Model for Change to Evidence-Based Practice” which offers an exceptional systematic process to integrate evidence into practice at the individual nurse level.

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Historically, when pediatric bone marrow transplant recipients became infected with respiratory syncytial virus (RSV), the treatment of choice was aerosolized ribavirin (AR). AR is known to cause side effects such as eye irritation and bronchospasm, and has potential teratogenicity (“Virazole® Prescribing Information,” 2002). Nurses in the bone marrow transplant unit (BMTU) at a large pediatric teaching hospital in Toronto, Ontario, Canada have been practicing in an unsafe manner that has put them at risk of these potential side effects due to policy and procedures that lack clarity for practice (see Appendix A). The National Institute for Occupational Health and Safety (NIOSH) has made recommendations for the use of AR that can protect nurses from these risks, but the recommendations are not being followed at this hospital. In this project, I present the rationale for changing practice to be aligned with the NIOSH recommendations and to better protect the nurses on the BMTU. Specifically, I use Rosswurm and Larrabee’s Model for Change to Evidence-Based Practice (1999) to assess the need for a change in practice; identify the problem and links to potential interventions; review the literature; and design a case for practice change with future considerations.

Concept of Safe Practice

The idea of “safe practice” encompasses a number of different processes and practices; The Occupational Health and Safety Administration (OSHA), along with the National Institute for Occupational Safety and Health (NIOSH) play an important role in developing, promoting, and regulating safe practices and safe workplaces both in the United States and internationally.

In Canada, occupational health and safety is legislated both federally and provincially under various laws. In Ontario, the Ministry of Labour is responsible for enforcing the

Occupational Health and Safety Act (OH&S), conducting workplace inspections, disseminating information, promoting education, training and research, and resolving labour disputes between a worker and employer (CCOHS website, section “OH&S legislation in Canada”, n.d, p. 1 & 2). Under the OH&S act, the employee has the responsibility to work in compliance with OH&S acts and regulations, use personal protective equipment as directed by the employer, and report workplace hazards. Employees have three basic rights; the right to refuse unsafe work, the right to be informed about actual and potential dangers in the workplace, and the right to participate in workplace health and safety activities/committees (Ministry of Labour website, section “About the Act”, n.d., p. 2, 3, & 4). In regards to toxic/hazardous substances the OH&S act is very broad and in 1988 it was amended to include Canada-wide implementation of the Workplace Hazardous Materials Information System (WHMIS) (Ministry of Labour website, section “Toxic Substances”, n.d., p. 1). WHMIS legislation ensures that toxic substances are properly labeled, that workers are properly trained before handling the substance, and that the Material Safety Data Sheet (MSDS) covers proper handling, protection against exposure, health effects, and emergency procedures and is available to the employees (Ministry of Labour website, section “Toxic Substances”, n.d., p. 4). An occupational hygienist is available for consultation at this hospital, and when they were contacted they were not able to provide clear evidence or guidelines for the safe use of AR nor were they able to provide an MSDS at the time. However, in my personal search for an MSDS on AR, I was unsuccessful but did find an MSDS for RSV infection. On the Health Canada website, I was able to locate the product monograph for AR on the Drug Product Database Online Query (Health Canada website, section “Drugs and Health Products”, n.d.). After further investigating, I was also able to locate the product monograph for AR on the Canadian Centre for Occupational Health and Safety (CCOHS) website to which you

need a paid membership for<sup>1</sup>. In the future, there is a movement for international harmonization of MSDS's according to the CCOHS website.

However, there was very little information to be found on any of the Canadian websites regarding AR use, guidelines for practice or safe handling specific to AR. Due to the deficiencies and navigating of the multiple websites in regards to Canadian legislation and the lack of specific information regarding the use of AR in Ontario workplaces, and how workers can protect themselves, I have chosen to pursue the American governing bodies, OSHA and NIOSH since they have established guidelines for the safe use of this substance in practice. Thus, the OSHA and NIOSH will herein be referenced as the governing bodies for practice on the BMTU and will be the standards that are adopted into policy.

The Occupational Safety & Health Administration (OSHA) was created in 1970 as an agency to promote workplace safety by enforcing standards, providing training and education, and working with other agencies to promote continual workplace safety (United States Department of Labor website section "OSHA's role", n.d.). According to the OSHA, no specific standards govern reproductive hazards (except for ethylene oxide), and the agency is increasingly concerned with the potential reproductive effects of hazardous drugs (Worthington, 2001). The OSHA grants workers the right to be informed of all potential workplace hazards and encourages workers to request the material safety data sheets for these substances. The NIOSH was created by the OSHA to conduct research and provide recommendations about agents that can potentially cause harm (Centre for Disease Control website, section "About NIOSH", n.d.).

According to the NIOSH, AR should be considered potentially harmful, and the agency lists it as

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<sup>1</sup> The CCOHS was developed in 1978 and is a federal corporation that works with both the provincial and federal governments to promote workplace safety and strives to be the centre of excellence for work-related injury and prevention and for occupational health and safety information. The CCOHS also works with American agencies such as the NIOSH, ACGIH (American Conference of Governmental Industrial Hygienists), and NLM (National Library of Medicine) to provide information and databases of toxic effects of chemical substances (retrieved from [www.ccohs.org](http://www.ccohs.org) on June 29, 2009).

a hazardous drug (2004). The NIOSH determines what equipment, devices, control measures, personal protective equipment (PPE), and monitoring is necessary to ensure that work environments are safe. The criteria used by the NIOSH for classifying hazardous drugs includes drugs used for cancer chemotherapy, antiviral drugs, hormones, and some bio-engineered drugs that are known or suspected to cause adverse health effects from exposure in the workplace. The regulations and standards provided by the OSHA and the NIOSH, however, can only increase safety if institutions (and units like the BMTU) develop cultures of safety that follow them.

Within an institution, the culture dictates the behaviors, rules, norms, and expected behaviors (Phillips, 2005). A culture of safety considers the safety of patients, families, visitors, health care workers, etc., within the institution's environment. Phillips (2005) states that the characteristics of an institution that embrace a culture of safety include the acknowledgement of high-risk, error-prone environments, existence of a blame-free culture, interdisciplinary collaboration, and a willingness to commit resources to address safety concerns (p. 582). Errors occur with a lack of communication, inadequate flow of information, human error, patient-related issues, understaffing or heavy workloads, technical failures, inadequate policies and procedures, and a lack of the organizational transfer of knowledge (Phillips, 2005). An institution's ability to reduce such errors and create a culture of safety depends on the knowledge and skills of its staff; if nurses lack experience, as in the case of a teaching unit like the BMTU, the institution must work actively to help them gain knowledge and experience.

The majority of nurses hired in the past five years at this institution have been recent graduating nurses without prior nursing experience. These nurses are still in the process of developing their roles, their unique practices, and their personal relationships with nursing (Linder, 2009, p. 33). Linder (2009) points out that inexperienced nurses face many challenges,

such as adjusting to the demands of the workload, gaining awareness of learning needs, adjusting to shift work, coping with death and dying, and relating to the senior staff. Both Linder (2009) and Chang, Kicis, and Sangha (2007) purport that pediatric oncology nursing is stressful and less tolerated by inexperienced nurses. Therefore, due to their stressful work environment, lack of experience, and lack of knowledge about AR administration and safe handling methods, recently graduating nurses are possibly more at risk of occupational health hazards with AR use. Pediatric oncology nurses can be exposed to multiple hazardous drugs during the course of their work. When nurses administer AR, for example, they expect that proper policies and procedures are in place according to the governing bodies and that a culture of safety exists. Although such procedures have been developed by groups like the OSHA and the NIOSH, whether or not nurses properly followed them depends on the culture within the institution. Administering AR combined with the inexperience of many nurses on the BMTU makes creating a culture of safety all the more important.

### Background

RSV infection is a rare but potentially fatal complication for pediatric bone marrow transplant recipients and has a mortality rate of approximately 80% (Latchford & Shelton, 2003; Sparrelid et al., 1997). Traditionally, the universal treatment (in North America) for patients with RSV infections has been AR (or Virazole®, originally marketed by ICN Pharmaceuticals Inc.). AR was approved by the US Food and Drug Administration (FDA) in 1986 for treatment of infants and children with RSV.<sup>2</sup> AR is administered in an aerosol formation under an oxygen hood, mask, or tent for 8-20 hours a day, for 3-7 consecutive days, or it can be administered in larger doses for 2-4 hours a day, every 6-8 hours, for 3-7 consecutive days and prescribing rights

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<sup>2</sup> Virazole® has been marketed by Valeant Pharmaceuticals in North America since 2002 when ICN was bought by Valeant.

are limited to infectious disease physicians according to the product monograph (Virazole, 2002).

The spatial arrangements of the BMTU are such that individual patient rooms are positively pressured for high efficiency particulate air filtering, with more than six air exchanges a minute. Two patient rooms share an outer anteroom and a supply area where cross contamination can occur. Patients under the age of three use the hood system and patients over the age of three use an oxygen mask delivery system with a Small Particle Air Generator (SPAG-2) unit, which administers the drug. Patients are not required to wear any other protective gear. Parents wear protective gowns and gloves, but the use of masks and goggles has not been enforced and is left up to their discretion after they are advised of the potential side effects from inadvertently inhaling the drug particulate (e.g., bronchospasm, eye irritation, nausea, etc). However, the use of goggles for parents has been enforced if the parent is a contact lens wearer in order to prevent eye irritation and corneal damage. In my experience, most parents choose not to wear a mask. Health care professionals are advised to wear protective eyewear; N95 fitted respiratory masks, gowns, and gloves. All dirty linen and equipment is stored in regular laundry bins in the anteroom until the Personal Support Aide (PSA) has time to remove it to the central laundry area. No signage is used in the patient room to indicate that treatment is underway. As always, hand washing is a universal precaution and is a key for preventing contamination.

According to the current policy, nurses and other health care professionals who are providing direct care to patients are cautioned if they are wearing contact lenses, and advised to remove them or wear protective goggles when entering a patient's room during AR administration. Some precautions are given for those who may be pregnant, or of childbearing years. The nurses on the BMTU are typically young, recent graduates, of child bearing age, and

may be unaware of the potential occupational health hazard that this drug presents, due to their lack of experience with administering this drug.

Another risk factor is the fact that when administering therapy to pediatric patients, they can sometimes be uncooperative and prone to removing the oxygen mask from their face. The drug particulate can become dispersed into the environment and land on surfaces, or escape from the patient room and travel into the anteroom or outer hallway, an effect that can be enhanced by the positive pressure environment of the isolation rooms on the BMTU. If this occurs, both the drug particulate and the RSV itself can contaminate other patients, family members, and the staff on the BMTU.

Regardless of the above situational factors, AR is still prescribed for RSV positive patients on the BMTU. In fact, the decision-making that occurs between the BMT and the infectious disease teams does not directly involve the nurses, who may be the last to know that AR has been prescribed. The initiation, administration, and set-up of AR therapy are performed by a Respiratory Therapist (RT). When the initial call is placed to the RT, a search is initiated in their storage room for the SPAG-2 unit, since it is rarely used. The set-up, administration, and clean-up are both costly and time consuming (costing approximately \$1300 per 6 g vial) (Buck, 1997). Delays in treatment can occur if the RT is busy with another patient in the hospital since the BMTU does not employ its own RT. Nurses on the BMTU are responsible for all other aspects of care regarding RSV treatment, such as medication administration, patient monitoring, and equipment set-up. They are responsible for informing the child and the family about precautions for RSV and about the risks associated with AR administration. If nurses are not knowledgeable about RSV or AR, and the policy is unclear, or there is a lack of information to

support this practice, they may not be able to provide safe, competent care to the patient or to protect themselves from the potential occupational health hazards.

#### Advanced Practice Nurse (APN) Role

For staff nurses to engage in safe, competent, and ethical practice, they need the support and moral courage to enact ethics in practice, working within a shifting moral context, working between their own identities and values and those of the organization (Varcoe, et al., 2004). Having a resource person such as an advanced practice nurse (APN) can be a great support for the nurses on the BMTU in the described clinical situation. To be successful, the relationship between staff nurses and the APN must involve respect, trust, and an authentic presence. The APN can be the glue of the relational matrix, given her position of authority, autonomous decision-making, knowledge, and respect within the interdisciplinary team. The APN is well aware of facilitating co-operation and has the knowledge and ability to enact safe, competent, and ethical practice. APNs are clinical experts in their field and contribute to the understanding and development of nursing knowledge and implementation into practice through interdisciplinary consultation and collaboration within health care systems to affect practice at the policy level (Canadian Association of Nurses in Oncology, n.d. p.63). They contribute to advances in nursing knowledge by participating in research, reviewing evidence-based literature, and transferring the knowledge into practice. Thus, APNs can help change the practice norms and influence standards of practice within the profession.

Maloney & Volpe (2005) describe the APN role on the inpatient oncology unit within this institution in their paper. However, the BMTU does not employ an APN although the department does employ several and there are more than 60 APN defined roles within the institution. According to the institutional vision statement for advanced practice:

“APNs are expert practitioners within a specialty area of nursing practice, APNs work with children with complex health problems and with families with complex needs. They offer a broad-based nursing perspective that encompasses not only clinical practice but also professional leadership, nursing staff development, promotion of evidence-based practice and clinical application of research, and facilitation of quality improvement initiatives. APNs also provide consultation in their area of expertise to nursing colleagues, other members of the health care team, and individuals, groups, and organizations in the community.” (SickKids website (n.d). Section “Advanced Practice Nurses).

At the institution where the BMTU is situated, the Strong model of advanced practice is used to guide the APN role. This model was originally developed by Ackerman, Norsen, Martin, Weidrich, and Kitzman (1996) at the Strong Memorial Hospital in Rochester, NY, to guide nursing practice in an adult critical care setting (as cited in Maloney & Volpe, 2005, p. 255). The model is comprised of five domains of practice: direct comprehensive care, support of systems, education, research, and publication and professional leadership. The strands of collaboration, scholarship, and empowerment are elements of an APN’s attributes that envelop the five domains of practice.

Within the five domains of APN practice according to the Strong Model, direct comprehensive care is comprised from patient related activities including procedures, assessment, interpretation of data, and patient counseling; support of systems connotes nursing staff activities that represent professional contributions to optimize nursing practice; education relates to enhancement of patient, family, public, and

interprofessional learning related to health and illness; research supports a culture of practice that challenges the status quo and seeks improved patient care initiatives through scientific inquiry and; publication and professional leadership promotes dissemination of knowledge beyond the practice setting (Mick & Ackerman, 2000). The unifying strands of collaboration, scholarship, and empowerment describe the attributes, the approach to care, and the professional attitude that defines advanced nursing practice according to the Strong Model. The concept of collaboration represents the unique skills and abilities of various health care providers, and how in combination, contributes to the common goal of excellent patient care; scholarship is the constant inquiry that underlies the science and art of nursing practice and; empowerment is the authority and autonomy that nurses must have to identify problems in practice and develop, implement, and evaluate plans to overcome these problems (Mick & Ackerman, 2000).

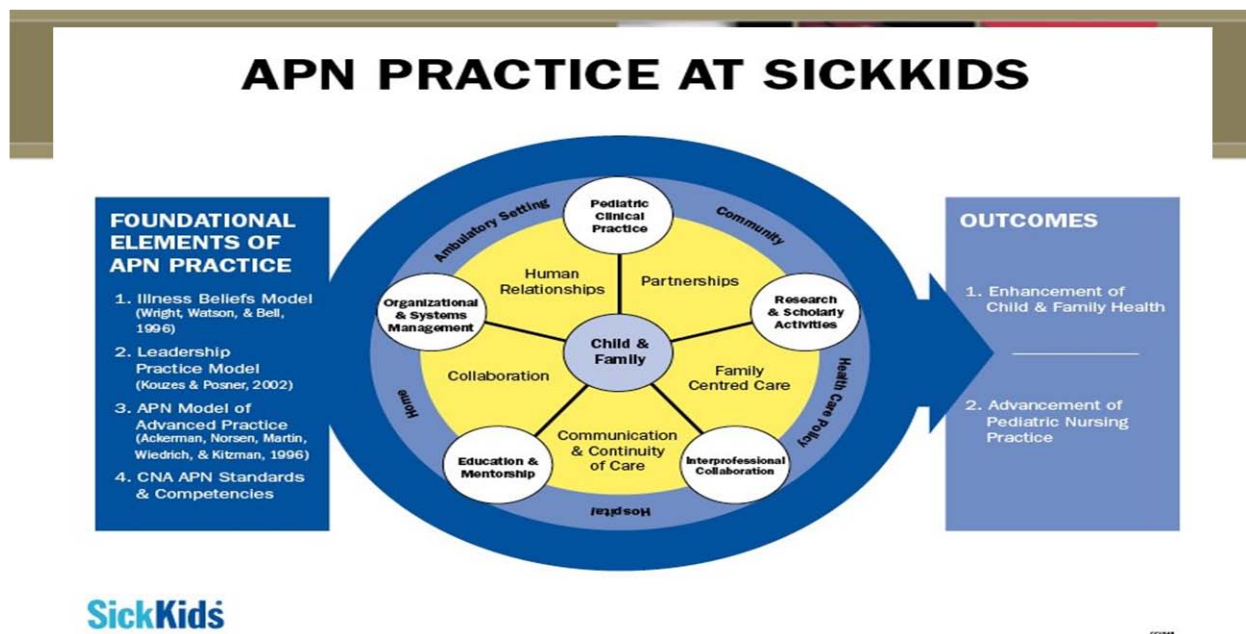


Figure1. Adapted Strong Model of Advanced Practice.<sup>3</sup>

<sup>3</sup> From APN Council at SickKids, by P. Hubley and K. LeGrow, 2005. Adapted with permission of the Chair of APN Council, Pam Hubley.

For the purposes of this project, an APN employed by the BMTU would have clinical expertise in pediatric oncology nursing; have expert skills in using research findings, and incorporating that knowledge to improve nursing practice and influencing health care policy by leading quality improvement initiatives in the organization (CANO, n.d., p. 64). The Strong Model would guide the practice of the APN and incorporate the five domains of practice and the intertwined conceptual strands to support the practice of administering AR on the BMTU in a safe manner. In order for an APN to assist in changing practice behavior or initiating policy change, a second framework is used. The Rosswurm and Larrabee Model for Change to Evidence-Based Practice are derived from literature on theory and research in relation to evidence-based practice, research use, and change theory. The model can guide individual practitioners through the process of changing to evidence-based practice, from the assessment of a need for change to the integration of an evidence-based protocol (Rosswurm & Larrabee, 1999). By following the framework of Rosswurm and Larrabee (1999), the APN would be the catalyst for change in practice and policy on the BMTU.

#### Rosswurm and Larrabee Model for Change to Evidence-Based Practice

Historically, practitioners relied heavily upon clinical experience, pathophysiologic rationale, and opinion-based processes to guide their practice (Ellrodt et al., 1997; Feinstein & Horowitz, 1997, as cited in Rosswurm & Larrabee, 1999, p. 317). In the new health care environment, practitioners need to question their current practices and seek improved, evidence-based alternatives. Practitioners need to be able to research and critically appraise the literature, synthesize the contextual, historical, and empirical evidence, and provide plans that clearly communicate critical thinking and evidence-based methodology for basing clinical decisions that

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will maximize the quality and cost effectiveness of care (Kessenich, Guyatt, & DiCenso, 1997; Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, as cited in Rosswurm & Larrabee, 1999, p. 317). The paradigm shift from tradition and intuition driven practice to one of evidence-based is a difficult path for most practitioners and is fraught with uncertainty. The Rosswurm and Larrabee model for Change to Evidence-Based Practice was developed to assist individual practitioners in making that paradigm shift to evidence-based practice. The model has six steps: 1) assessing a need for change in practice, 2) linking the problem with interventions and outcomes, 3) synthesizing best evidence in the form of a literature review, 4) designing practice change, 5) implementing and evaluating the change in practice, and 6) integrating and maintaining the change in practice.

#### *Use of the Model in this Setting*

For the purposes of this project, not all six steps were completed for achieving a change in practice. Steps 1 through 3 are discussed in detail, and then steps 4, 5 & 6, are discussed but not fulfilled due to dismemberment of the stakeholder committee by management.

#### *Step 1: Assessing the need for change in practice*

My interest in changing the practice for administering AR on the BMTU arose from my ten years of working on the unit without having a safe policy or procedure in place. I was always dissatisfied with the lack of information given to nurses who were managing the patient care of a child receiving AR, especially since an abundance of information was given to nurses regarding the use of other antineoplastic drugs (SickKids Safe Handling of Hazardous Drugs policy, n.d.). When I changed roles and became a Clinical Support Nurse, I felt responsible for providing accurate information to the nursing staff regarding AR administration and patient care. At the time, I began asking the Nurse Educators and Nursing Leaders (APNs) for support, but they were unsure and encouraged me to pursue more information. Thus began step one of the Rosswurm

and Larrabee model. The process began with a search for information from both the literature and from experts in the field, concerning policy, procedures, guidelines for practice, etc.

Using OVID, MEDLINE, CINAHL, PUBMED, and Google Scholar, I reviewed the literature using keywords such as: ribavirin, virazole, respiratory syncytial virus, bone marrow transplant, stem cell transplant, pediatrics, infectious diseases, occupational health hazard, and nursing. Although the searches found many hits, few were relevant to my search for “treatment of pediatric respiratory syncytial virus in a bone marrow transplant patient.” After reviewing 18 documents in the literature relating to my search and finding similar information regarding precautions with AR use, I halted the initial literature search as I felt there was sufficient evidence to present for discussion. Despite the lack of specific search results, I gathered sufficient evidence for supporting nursing practice when caring for pediatric patients receiving AR. Although the level of evidence for this literature review was weak, the content of the literature was consistent with regards to safety precautions and the most protective equipment. Few randomized control studies have been carried out because of the ethics of administering AR to someone for whom it is not indicated. Conflicting information exists in the literature in regards to prescribing AR and its indications for use, especially for pediatric bone marrow transplant recipients. In any case, the paucity of available information provided enough of an overview of the occupational health hazards associated with exposure to AR to warrant a stakeholder meeting and a change in practice on the BMTU.

When I completed my initial review of the literature I met with various stakeholders to discuss the issues and learned that at least one other nursing unit was also looking into this problem. Together, we assembled a meeting with other stakeholders to discuss the current situation and to see if a change in practice was warranted. The stakeholders who were invited to

the initial meeting included members from the pharmacy team, respiratory therapy, medical engineering, as well as hospital administrators, clinical leaders, nurse educators, staff nurses, and staff from infection control, infectious diseases, quality management, and occupational health departments. Physicians were not invited to participate in the stakeholder meeting. The physicians within this institution hold a significant amount of power and perpetuate hierarchical relationships that are not conducive to change. Moreover, the physician group is fuelled by the corporate ideology of working within world-renowned institutions that allow expenditures for expensive drugs without repercussion. Varcoe & Rodney (2002) define how this type of ideology justifies what is being done without question (p. 104). Varcoe and Rodney (2002) discuss how nurses participate in the corporate ideology by adjusting and organizing their work for efficiency (p. 105). After my discussions with the BMTU Director, and with the occupational hygienist and infectious disease physicians, it became apparent that the committee would not have the authority to initiate a full investigation into the use of AR in this setting. Thus, efforts were made to provide the safest environment possible for patients, families, and health care workers, especially nurses and RTs.

At the stakeholder meeting, I provided a summary of my findings from the literature review and provided a copy of the current policy for the AR procedure used by nurses. Everyone agreed that the current practice was a problem and a potential occupational health hazard. The Nursing-Pharmacy committee that had developed the original policy was comprised of pharmacists and RTs (no nurses), so we developed a new group to review the current practice and policy and to revise the policy according to evidence-based guidelines and current information in the literature.

*Step 2: Linking the problem with interventions and outcomes*

The standard classification for providing a safe working environment falls within the NIOSH and the OSHA divisions of the Centre for Disease Control (CDC). Many types of chemotherapeutic agents are used to treat a variety of malignancies in children and adolescents. Some of these agents are considered hazardous to the individuals who handle them. Hazardous drugs are those that require special precautions because of the potential risk to health. The NIOSH (2004) reports that health risk has been demonstrated in studies and “safe” levels of exposure to cytotoxic agents have not been determined by a reliable method. Bio-therapeutic agents also have potential risks but the data is limited and even though these agents do not affect the DNA, the NIOSH lists these agents as having potential occupational risk (2004). Although ribavirin is not classified as a bio-therapeutic agent, it is still considered a hazardous drug according to the NIOSH (2004).

Studies have indicated that healthcare workers handling hazardous agents are at risk for occupational exposure to the toxins, and the long-term effects are unknown. Potential health risks include: carcinogenicity, genotoxicity, teratogenicity, adverse reproductive outcomes (e.g., spontaneous abortion or infertility) organ toxicity; and acute symptoms, such as headache, nausea, dizziness, and skin, eye, or throat irritation (Valanis, Vollmer, Labuhn, & Glass, 1997). The potential routes of exposure are injection through needle stick; direct ingestion, or through food or beverages; inhalation of drug aerosols; and absorption through mucous membranes after direct contact. Some agents are vesicants and can cause severe burns if splashed in the mucous membrane of the eye or accidentally injected into tissue. The hazardous release of cytotoxic agents into the environment can occur at any step or with any method of administration, including preparation or transfer of medications from vials or ampoules; spiking, priming, or changing intravenous (IV) equipment; expelling air; and transferring medications using needles

or syringes. Other avenues of exposure include contact with leaking tubing or connection sites, cytotoxic spills, disposal of cytotoxic agents and mixing materials, and handling of body fluids of patients within 48 hours after they receive the hazardous agent.

In this hospital, AR is initially mixed from its original powder formation to a liquid and transferred into a bag under a special hood in the pharmacy. Thus, the pharmacist is the first person in the possible chain of exposure if safe handling measures are not followed. The drug is then transported to the BMTU or the RT physically picks it up from the pharmacy. The RT then transfers the medication into a reservoir in the SPAG-2® unit in the patient room and assembles the equipment. Thus, the second person who might be potentially exposed to AR is the RT. The nurse then dons a gown, mask, and gloves and prepares the patient and the oxygen hood or mask, depending on the patient's age, and initiates treatment. The nurse may have to re-enter the patient room several times during the treatment to provide direct patient care, which furthers the exposure risk. Based on first-hand experience, the use of PPE is inconsistent among nurses in this setting. Parents and other health care workers are often exposed to AR due to a lack of awareness and poor enforcement of the PPE use. The environment is not cleaned immediately after treatment and the hood or mask used to deliver AR and its tubing are left in the patient room for the next treatment. White particulate can be seen in the tubing and sometimes even on the linen and surfaces in the patient room. Both the actual and potential risk of exposure to AR is evident for anyone who comes into contact with the immediate environment of the patient.

The occupational exposure literature suggests that these medications and their toxic effects are detectable in healthcare workers (especially nurses and RTs) who do not take precautions to prevent exposure. Chronic low-level exposure to hazardous medications can lead to absorption and may cause significant long-term side effects (Blecher, Glynn-Tucker,

McDiarmid, & Newton, 2003). Also, surface contamination studies demonstrate that engineering controls and handling practices do not prevent the release of hazardous drugs into the environment, which led to the development of closed-system devices (Polovitz, 2004). Studies have indicated that compliance with established safety guidelines offers adequate protection to healthcare workers involved in the handling and administration of hazardous agents and to the care of patients receiving them (Ritchie, McAdams, & Fritz, 2000). Individual healthcare institutions are required by the OSHA to develop and implement policies regarding the safe handling of hazardous agents. These policies must include exposure protection measures for employees, patients, and the environment. Furthermore, these protection measures must include, at a minimum: provision for the safe administration, storage, transport, and disposal of hazardous agents; mandatory training of employees regarding hazardous materials; monitoring of long-term occupational exposure; minimization of employee risk; hazardous drug spill management planning and execution; exposure prevention measures, such as the prohibition of eating, drinking, chewing gum, storing food, or applying cosmetics in areas where hazardous agents are prepared or administered; specific exposure protection measures for employees who are planning a pregnancy, or who are pregnant or breast-feeding, including an option not to be exposed to hazardous agents or to care for patients receiving them; policy and procedures for compliance monitoring; and documentation of quality improvement indicators and training.

Despite national guidelines, recommendations, and supporting literature, safe handling practices for hazardous agents are not used consistently (Blecher et al., 2003). Nurses who are working with these agents must adhere to the practice guidelines and institutional policies established to prevent exposure (Polovich, White, & Kelleher, 2005). The following guidelines are consistent with current scientific knowledge and apply to all pediatric care settings, such as

hospitals, outpatient clinics, physician offices, and home care. The principles relate to personnel protection, product control, and environmental protection through the use of protective equipment, apparel, and practice.

*Personal protective equipment (PPE).* PPE should be used whenever a possibility exists that hazardous agents will be released into the environment. PPE includes gloves, gowns, respirators and face masks, and face shields or goggles. This applies to all types of hazardous medications. Administration includes: preparing oral drugs that must be compounded or crushed, preparing or transferring medications from vials or ampoules; spiking, priming, or changing IV equipment; expelling air or transferring medications using needles or syringes; contact with leaking tubing or connection sites; managing spills; disposing of agents and mixing materials and body fluids from patients who had received hazardous agents within the past 48 hours (NIOSH, 2004). Nurses on the BMTU typically wear a yellow linen gown, gloves, mask, and goggles when entering a room where AR is being administered.

Gloves should be disposable, powder-free gloves that have been tested for use with hazardous drugs. Latex gloves are safe for hazardous drug exposure protection but can cause latex sensitivity or allergy. Double gloves are recommended for all hazardous drug handling. The inner glove cuff should be under the gown and the outer glove cuff covering the gown cuff (NIOSH, 2004). The gloves should be discarded after 30 minutes of wear or if they become contaminated, torn, or punctured. On the BMTU, nurses wear latex-free disposable gloves but do not double glove or discard after 30 minutes of use.

Gowns should be disposable and made of lint-free, low-permeability fabric. The front should be solid, the sleeves should be long and fitted with cuffs, and the back should have a closure. Gloves should extend over the cuffs. Gowns should not be reused (NIOSH, 2004). On

the BMTU, nurses wear disposable gowns when handling chemotherapy drugs but wear yellow linen gowns for RSV and AR precautions that are removed to regular linen bins after use.

A respirator or face mask, approved by the NIOSH, must be used when cleaning up hazardous spills (Polovich, et al., 2005). A face shield or goggles should be worn whenever splashing or eye exposure might occur, such as when a child might spit, vomit, or struggle with oral medication. On the BMTU, nurses wear masks with face shields and goggles when entering a room where AR is being administered. There was inconsistent use and availability of mask type in the past. However, mask fit testing was performed hospital wide in 2003 post Severe Acute Respiratory Syndrome (SARS) and has continued every 2-3years since.

*Labeling and storage guidelines.* Hazardous agents should be stored in compliance with safety regulations and at appropriate temperatures as set forth by OSHA. Material Safety Data Sheets (MSDS) must be available for all hazardous medications to provide instruction for care in the event of accidental exposure. MSDS sheets can be found on OSHA's website and should also be available from either pharmacy or occupational health departments within an institution. Medications must be labeled clearly for content and hazardous nature. Containers should be checked to see that they are intact before they are removed from storage. Sealable plastic bags must be used to transport medications for use or to the pharmacy for disposal. Any areas that contain hazardous materials must have locks and other devices to make them inaccessible to children. Facilities requiring mixing of hazardous drugs by healthcare personnel should provide a biological safety cabinet (BSC). The cabinet requires vertical laminar air flow and high efficiency particulate air (HEPA) filtration. Personnel should be trained in its use and maintenance (Polovich, et al., 2005). The pharmacy at this hospital employs these standards as

set forth by the OSHA. However, the MSDS sheet is not readily available to the nurses on the BMTU and there is no specific training for the use of AR.

*Biotherapy safe handling.* Indications for safe handling of hazardous drugs are to wear gloves when mixing agents that cause skin or other irritation and to use safe handling for any biotherapy agent labeled hazardous by the manufacturer or OSHA.

*Disposal guidelines.* Hazardous medical waste containers must be available in all areas where hazardous medications are prepared and administered (OSHA, 1995). The waste containers should be puncture-proof, have a secure lid, and be clearly labeled as hazardous waste. A general guideline is that any item that has contact with a hazardous medication should be disposed of in a hazardous waste container. Any unused medication should be returned to the pharmacy for disposal. Sealable plastic bags may be used to collect hazardous waste, but these bags must then be placed in a puncture-proof hazardous waste container (Blecher et al., 2003). IV tubing that has been flushed with a non-drug solution should be disposed of as an intact unit in designated containers. Needles used for withdrawal should be placed in a sharps container labeled with a biohazard sticker. Gloves and gowns should be disposed of after use or contamination in hazardous waste containers and gowns may not be reused. Hazardous waste is handled separately from non-hazardous waste. Only personnel who are trained in safe-handling procedures should remove hazardous waste containers. At this hospital, hazardous waste containers are currently being used for medication disposal but the oxygen equipment, tubing, linen, and used PPE are being disposed of in regular garbage and linen containers.

*Body fluid guidelines.* The NIOSH currently promotes the use of standard universal precautions (disposable gown and double gloves) when handling patients' body fluid or lines for 48 hours after administration of hazardous agents. Disposable items should be used for body

fluids whenever possible. Diapers should be disposed of in the same manner as other hazardous waste by placing them in appropriately labeled plastic hazardous waste bags, or according to institutional protocol. Bedpans, hats, urinals, and emesis basins that are washed carefully with soap and water may be reused but after use, they should be discarded in hazardous waste receptacles (Polovich, et al., 2005). Linens that are contaminated with body fluids should be placed in a plastic bag and labeled as contaminated before they are placed with other hospital laundry. Some hospitals treat all laundry as contaminated with hazardous or contaminated waste and in these situations; the linens are placed in leak-proof laundry bags (Blecher et al., 2003). Plastic mattresses and pillow covers are recommended to prevent contamination of non-disposable items. Universal precautions are employed on the BMTU, but individual patient rooms share an outer anteroom where diapers, linen, and equipment such as emesis basins, bedpans, hats, and urinals are kept. The patient rooms have no toilets, requiring transport of contaminated body fluids by the nurse to a shared dirty utility room. The potential for contaminating the environment is a real and present danger on the BMTU.

Toilets should be flushed twice with the lid down after disposing of excreta from patients for 48 hours after chemotherapy. Patients may use regular toilet facilities. A hopper in the dirty utility room may also be used for disposal of body fluids and should be flushed twice. The BMTU has a dirty utility room with a hopper and lid but the nurses do not usually flush it twice.

When these standards were compared to our current policy regarding AR administration, the present information was found to be inadequate and referred to the Respiratory Therapy Policy and Procedure Manual within the AR policy. I was not able to locate this manual on the BMTU and when I called the RT she had to do some searching to find it. Nursing workload on the BMTU is heavy enough, let alone further increasing nursing workload by searching for

missing documents and manuals. Many of the statements from the above guidelines were not present in the original AR policy and some nurses are unaware that AR is a potentially hazardous drug with occupational health hazards. The current practice combined with the experience level of the nurses and lack of effective policy or support promoted a culture of unsafe practice. Nurses believed that the policy protected them adequately without having full knowledge or information pertaining to the safe use of AR in practice.

In the contemporary evidence-based health care climate, discourse on the use of research in practice has been given primacy over the discourse of knowledge that nurses generally use in practice. According to Estabrooks, et al. (2005), nurses obtain practice knowledge through social interactions, experience, documents, and a priori knowledge. This is because nurses seek knowledge for specific problems that are of immediate practical use to them. It is more convenient to inquire about practice issues by asking your colleagues rather than looking up a policy, because of the immediacy of the situation. Nurses also seek to validate their own experiences with those of their colleagues (Estabrooks, et al., 2005), which can lead to a mentality where nurses continue to validate their experiences with one another, regardless of support from the literature or from current policy. Thus, they may actually be rejecting evidence-based practice in favor of practices considered to be effective, on the basis of experience. Nurses also tend to not seek information from formal sources such as books or journals (Estabrooks, et al., 2005). This may be due to a lack of time or financial resources allotted for nurses' professional development. Many studies point to a lack of time and support within the organization as being the main barriers to enacting evidence-based practice (Brown, Wickline, Ecoff, & Glaser, 2008; Hutchinson & Johnston, 2004; Kajermo, Nordsrom, Krusebrant, & Bjorvell, 1998; McLeary & Brown, 2003; Retsas, 2000; Storch, Rodney, Pauly, Brown, &

Starzomski, 2002). Also, nurses may be socialized to maintain the unit cultural norm and therefore are less motivated to seek formal resources. Peer censorship, combined with minimal influence to potentiate a change in practice, decreases the likelihood that nurses will seek evidence-based resources. Towards better understanding how the factors evident in the literature resonated on the BMTU, I engaged staff nurses and a nurse educator in conversations. From these conversations I learned that the factors mentioned above resonated with these nurses. Further my colleagues pointed out that a key contributing factor to the issue related to lack of time for professional development due to high patient acuity. APNs are in the position to support nurses with their clinical decision-making and practice inquiries, and therefore, should be knowledgeable about practice and have the ability to ensure a safe practice environment.

*Step 3: Synthesize Best Evidence*

For this step, the information from Step 2 is refined and the major variables for reviewing the research literature are identified to assist in gathering evidence to support best practice. A worksheet can be used to synthesize the data and structure a framework that systematically critiques and provides the level of evidence so that the researcher can evaluate the strengths, weaknesses, and gaps in knowledge that exist in the literature (Rosswurm & Larrabee, 1999). The best research is then synthesized and combined with clinical judgment and any contextual data to either support or reject a change in practice.

The original research review that incorporated keywords (aerosolized ribavirin, pediatrics, bone marrow transplant recipient, RSV, treatment of RSV, etc.) yielded information that was extensive but not specific to the needs of the nurses on the BMTU. The search results mainly focused on the treatment management of RSV with pediatric patients and offered alternative interventions. In this project; however, I was more interested in obtaining information about the occupational health hazard that AR poses to nurses on the BMTU. After refining the

evidence and performing more research into current policies, a second literature review was performed with such keywords as: aerosolized ribavirin and occupational health hazards, aerosolized ribavirin and safe practices, nursing and AR, treatment of pediatric RSV post BMT. The information that was obtained from this review was far more specific than that of the original search and was more specific to nursing practices, safe handling, and occupational health hazard and AR administration for those on the BMTU. Although the numbers of articles were few, they were consistent in their message about preventing exposure to AR.

Adams (1994a,b) conducted an integrative literature review to identify the risk of environmental exposure to nurses and to determine what recommendations were available for nursing practice based on scientific findings or research conducted to date. Twelve studies were reviewed in total and were conducted from 1983 to 1993 in the United States. The variables that were scrutinized included method of administration, type of PPE, room ventilation, time of exposure, concentration of AR in room air, and self-reported symptoms from nurses. The major findings suggest recommendations for nursing practice to reduce occupational health hazards for nurses when administering AR and highlighted protection measures such as: turning off the SPAG-2 unit (or other scavenging system) at least 5 minutes before providing patient care, administering AR in a negative pressure room, administering AR under a hood or tent system, using respiratory fitted masks for nurses, and having a supportive policy in place for nurses' practice.

Krilov (2002), Loveless, Demers, and Linn (1995), Latchford and Shelton (2003), and Shults, Baron, Decker, Deitchman, Scott, and Connor (1996) supported the findings of Adams (1994) and added more information about protecting health care professionals; for example: using tight fitting goggles, especially for those who wear contact lenses; avoiding exposure if

you are pregnant or breast feeding; having more than six air exchanges per minute of the air flow in the patient's room; and using an alternate dosing schedule. The information provided by the first three articles was articulated through an editorial, symposium highlights from a pediatric nursing conference, and a review of the literature, respectively. Shults et al., (1996) actually conducted an evaluation study. In this evaluation, both urinary ribavirin and airborne ribavirin concentrations were measured in nurses and RTs post shift. Results indicated that nurses' levels of urinary ribavirin concentration were higher than those of RTs and that lower AR exposure correlated with the use of containment tents. However, there are several limitations in this study including; small sample size (n=40), lack of compliance with study participants (only 48 urine samples collected in total out of 120 possible), and differences in practice between participants.

Cohen and Brady (1992) surveyed 50 major pediatric centers, specifically addressing the safety precautions and practices surrounding AR administration, and found a variety of practices among the different centers. The authors posed a number of questions related to type of isolation, type of system used (i.e., SPAG-2 or not), use of PPE, existence of policy and procedures, number of air exchanges per hour, prescribing rights, visiting policy, and precautions taken with pregnant women. The reason for their study was to assist in policy and procedure formulation in community hospitals with pediatric departments. For my purposes, this study depicts the differences in practice that exist with AR.

Linn, Gong, Anderson, Clark, and Shamoo (1995) conducted an experimental study where volunteers (n=7) were exposed to AR, and their urine and plasma samples were compared to those of health care workers (n=7) who were exposed to AR through occupation. The results indicated that even in ideal conditions with all of the protective measures in place, the levels of the drug in subjects were undetectable and insignificant, and did not correlate to physiological

changes associated with AR exposure. However, the high exposure group did report more symptoms than the low exposure group in terms of changes to taste, smell, and sputum production. The outcome of this study supports the use of scavenging systems and adequate ventilation rates to reduce exposure.

Shults, Baron, Decker, Deitchman, Scott, and Connor (1996) also performed a study that looked at the urinary ribavirin concentration of exposed health care workers and found that nurses had higher concentrations of the drug than did RTs. Urine samples were collected at three times and by the third sample, the amount of detectable ribavirin had declined from 100% to 33%, which the authors attributed to the hospital's efforts to strengthen compliance with the ribavirin administration policy. The hospital has continued to provide information to their workers regarding safety precautions and has reinforced the ribavirin administration policy.

Jost et al., (1993) were part of a working group of the International Section on the Prevention of Occupational Risks in Health Services through the ISSA. This group was formed to develop a consensus statement regarding the administration of aerosols produced by nebulizers (which includes AR). Their recommendations include: use of a double containment system (i.e., SPAG-2® and tent/Demistifier®); administration in individual rooms; a ventilation system which allows for 20 air exchanges per hour (as recommended by the British Occupational Hygiene System); air to be exhausted to the outside or filtered through a HEPA filter; turning the nebulizer off from outside the treatment room before taking action with the patient; room surfaces should be cleaned and disinfected easily; pregnant women, those planning to conceive, or breastfeeding women should avoid exposure; goggles and fit-tested respirator to be worn when treatment is being delivered; only those instructed to use the equipment should do so; and removal of all contaminated clothing.

The hazard evaluations and technical assistance branch of the NIOSH conducts field investigations of possible health hazards in the workplace. Health Hazard Evaluation Reports from the San Francisco Bay area, Florida, and Pennsylvania suggest that levels of ribavirin collected in both urine and blood samples were negligible and did not cause significant occupational risk (Centre for Disease Control, 1988, 1992, 1993). Nevertheless, because the Florida group specifically had an increase in miscarriages during the study period, recommendations for controlling occupational exposure to ribavirin were implemented with adherence to NIOSH guidelines. These recommendations include:

- “1. Training programs should be developed to educate health care workers about potential risks of ribavirin exposure. Education should not be limited to direct care personnel, but should include ancillary personnel such as.....those who enter the room during treatment or who must clean contaminated rooms, waste, and bedding. ... Female HCW’s who are pregnant, lactating, or who may become pregnant, and male HCWs whose sexual partner is not actively avoiding pregnancy should be counseled about risk reduction strategies, such as alternate job assignments. Family members and visitors, who may stay in the room for long periods of time during treatment, should be notified of potential health effects to ribavirin.
2. Various ribavirin administration and scavenging systems result in different levels of environmental contamination. It is the responsibility of the hospital management to implement more effective control measures as they become available. The equipment should be inspected by RTs on a regular basis.

3. Rooms where AR is administered should provide a minimum of six total air changes per hour, and should be under negative pressure. Room air should be exhausted to the outside.
4. Air pressure in the rooms where AR is being administered should be evaluated before therapy begins and daily thereafter. Ideally, AR should begin only if the room air pressure is negative with respect to the hallway.
5. The aerosol generator should be turned off for a minimum of five minutes prior to the HCW entering the room to provide routine care.
6. During AR therapy, ribavirin precipitate is deposited on the patient and on the surrounding area. To prevent the dust from becoming airborne, care should be taken when ribavirin-contaminated clothing, bedding, or equipment is handled. Although dermal absorption is not thought to be significant, dermal exposure should be avoided to prevent unintentional oral ingestion or ocular contact. The use of PPE, including gloves, gowns, and air-tight goggles should be considered.
7. HCWs should be discouraged from wearing contact lenses when working with AR. If contacts are worn, air-tight goggles should be used.
8. Individual hospitals may choose to use respirators to further reduce HCW exposure to ribavirin. NIOSH-/OSHA-approved high efficiency particulate half-mask respirators, assigned to HCWs, based on the results of quantitative fit tests, were found... to reduce exposure to aerosolized ribavirin... OSHA standard (29 CFR 1910.134) requires that all occupational respirator use must take place within the context of a respiratory protection program that includes evaluation of worker fitness to use a respirator, training, fit testing,

and maintenance. Surgical masks should not be relied upon to provide personal protection from occupational exposure to AR.

9. To reduce exposure of HCWs to AR, medically unnecessary use of it should be avoided..." (Deitchman & Wall, 1993).

Another field study was conducted by the NIOSH in Denver, CO, to evaluate the use of an N95 mask for protection against AR. They specifically looked at air samples and personal breathing zones of both nurses and RTs and found that a leak was present in the system despite engineering controls and hospital policies (Decker, 1998). Recommendations to reduce potential exposures include: ensuring proper set-up is maintained during AR administration to prevent leaks or disconnections; ensuring adequate pressure is maintained to improve the integrity of the containment system: wearing respirators approved by the OSHA when administering AR; and, following all precautions when disassembling the equipment (Decker, 1998, p. 10). The report also indicated that multiple administrations throughout the day and spending more time in the room when caring for difficult patients can result in higher cumulative exposures (Decker, 1998).

Bradley, Connor, Compogiannis, and Eiger (1990) analyzed air samples and personal breathing zones of health care workers exposed to AR. The authors found that delivery of AR via ventilator or a vacuum exhaust hood system was superior to delivery by oxygen hood in rooms with adequate ventilation.

In a side note, Dimich-Ward, Wymer, and Chan-Yeung (2004) reported an increased risk for asthma-like symptoms and diagnoses of asthma among RTs being likely related to occupational exposure to glutaraldehyde and AR.

In a personal communication with Lucy Nicholls, Director of Nursing, BMTU, at United Bristol Healthcare, she provided me with specific information pertaining to the suspension of AR

use on their BMTU. AR use was suspended while the BMTU staff worked with an equipment manufacturer and Occupational Health to develop ways to minimize the risk of exposure. This resulted in the introduction of plastic tents, use of a scavenger system, and a protocol for nurses to use. She also provided me with a copy of their newly developed protocol (Appendix B).

From the above lines of evidence, and in combination with previous information about PPE and current practices on the BMTU, a change in practice on the BMTU (and hospital-wide) is warranted to ensure safety for all.

*Step 4: Design a Change in Practice*

In the Rosswurm and Larrabee model (1999), after synthesizing the best evidence, the stakeholders defined the proposed changes and identified resources to assist in designing a practice change (i.e., in the form of a protocol or policy). In this project, after the evidence was synthesized by the stakeholders, the group was disassembled by management and the project was turned over to the RTs for developing a new policy that would reflect current practice and the information from the stakeholder group. The proposed changes would maintain the corporate ideology and hierarchical nature of the organization with a top-down mentality. After the policy was written, select members of the stakeholder group and I were privileged to review the policy (Appendix C). An APN in the department and me then provided feedback regarding the needs of the nurses and spatial arrangements of the BMTU, though these suggestions were not used in the final version of the policy. According to Storch et al., (2002) “Nurses need to feel safe and secure in their work environments, and to feel a sense of appreciation and belonging in their workplaces in order to give to others that sense of feeling safe...” (p.13), thus creating a culture of safety. Nurses also need encouragement to speak about conflict and to voice their ideas for solutions and advancing practice. Nurses’ voices need to be heard and regarded as equally credible to those of physicians and other health care workers (Storch, et al., 2002).

Unfortunately, the power imbalances in many organizations prevent voices from being heard and nurses who are in leadership positions, such as APNs, need to role model the negotiation of conflict and respect during interdisciplinary dialogue (Storch, et al., 2002). Perhaps an experienced BMTU APN would have been able to represent the BMTU nurses to ensure a safe practice environment by articulating the safety issues in AR administration. Through interprofessional collaborations and expert knowledge of the issues, an APN would be able to navigate the organizational system and develop partnerships to advance safe nursing practice.

*Step 5 & 6: Implementing and Evaluating, and Integrating and Maintaining a Change in Practice*

In the final two steps of the model, a pilot study for the practice change is implemented and evaluated after a predetermined time, and additional adjustments and revisions are made which are either accepted or rejected in the practice change. If the results of the pilot study support a change in practice, the change is implemented hospital-wide with roll-out dates and education for the staff. Rosswurm and Larrabee (1999) suggest that their model encourages participation of the stakeholders throughout the various steps and that ongoing communication with stakeholders is vital to the acceptance of the change. They also say that “Informal leaders need to participate in the diffusion process. Continuing education and staff in-service education facilitate changes in practitioners’ behavior and reinforce implementation of the new evidence-based practice.” (Rosswurm & Larrabee, 1999, p. 321)

At this hospital, the implementation phase did not include a pilot project and the stakeholders were not completely involved in the change process. When the final version of the policy was written, the policy was immediately available online, and it replaced the old policy. No further education or discussion of the practice change took place. Even though the departmental APN and I offered to provide in-service education to our division with the roll-out

of the new policy and equipment, we did not receive a response from management. In any case, as we were the first unit in the hospital to practice under the new policy, we were able to do our own pilot testing of the equipment. For instance, a patient developed RSV and required AR therapy over the course of five days with intermittent scheduling. Because the APN and I were both aware that the practice change had been implemented, we were able to guide the BMTU nurses in the protocol for providing safe care to the patient, with the implementation of PPE, and in providing education for all health care workers who may come into contact with the patient or the surrounding area that might be contaminated with AR particulate. Signage was hung, and the parents were advised about the personal risk.

These activities are in keeping with the role of an APN with respect to education, direct comprehensive care, collaboration, and professional leadership. The BMTU nurses were supported in their practice of AR administration, set-up of new equipment, use of appropriate PPE, and new protection measures that allowed them to choose their assignments based on their personal situation. Because of the use of a new tent and ventilation system, parents and children were provided with more education and encouraged to participate in the protection measures using PPE. The BMTU nurses provided us with feedback about the change in practice and the use of the tent system. The nurses were effective in trouble-shooting the equipment and making adjustments to enhance safe practice. The communication and collaboration between the BMTU nurses and the APN enhanced their mutual respect and created a culture of safety that contributed to the common goal of safe, competent practice.

#### Future Considerations

Although the new policy changed the practice and provided increased protection for the exposed health care workers, a few remaining weaknesses should still be addressed. For example:

- no written information is given to the parents,
- Physicians are still prescribing AR despite other treatment options,
- AR is still being administered in positive pressure rooms on the BMTU,
- mask fit tests were not implemented until 2003 post SARS,
- disposal and storage of the new tent and filtration system has not yet been determined,
- equipment such as goggles are not easily found,
- respiratory masks are not well stocked in various sizes or models,
- the disposal of contaminated equipment, linen, etc. is not being considered as bio-hazardous, and
- the frequency of monitoring and testing of the air quality is not specified.

To address these issues, the APN and I have provided feedback to the original policy writers and have developed a checklist of necessary equipment for AR administration that is available for the nurses on the BMTU when needed. All of the above issues have also been brought to the attention of the BMT Director and the management of the BMTU for their consideration.

To improve practice, nurses must become actively involved in researching the problem and advocating for, in this case, exposure limits to AR, based on scientific studies. The lack of available research on this subject indicates the need for further studies. Until more information is available, efforts to minimize occupational risk should follow current evidence. Written educational materials for parents can be provided by the APN who has experience in AR administration and knowledge of safe practices. Likely, the BMTU nurses will want to participate in developing informative materials since they will be providing education to the families. As the nurses participate in patient and family education, they can gain a sense of empowerment while also contributing to a safe practice environment. Air quality testing can be

requested through plant operations and occupational health, requiring further research and interprofessional collaboration within the organization. The APN can be the driving force on the committee to ensure safe, evidence-based clinical practice. Moreover, the outcome would promote professional leadership and role modeling to encourage the BMTU nurses to voice their concerns about the issues. For nurses, 'speaking out' is considered an essential aspect of nursing leadership, according to Buresh and Gordon (2002; as cited in Storch et al., 2002, p. 13). At the level of management, the APN can impress upon others the need for an infrastructure that supports evidence-based practice and provides leadership for commitment and culture change at the organizational level.

### Conclusion

Nurses on the BMTU are now able to provide safe, competent care to children receiving AR due to changes in practice and policy that reflect current evidence-based recommendations and which follow the NIOSH guidelines. Nurses are more aware of the risks associated with exposure to AR and are less likely to engage in unsafe practice. The development of the new policy thus enhances clinical judgment and improves patient care.

The use of Rosswurm and Larrabee's model for Change to Evidence-Based Practice (1999) is a helpful framework from which nurses can implement change in their workplace. In this project, even though not all of the steps of the model were used, the framework was helpful in assisting with practice change at the level of individual nurses. The shift to evidence-based practice is time-consuming, as it involves collaboration among numerous health care professionals. Further discussions need to follow between nursing, management and physicians regarding the treatment options for pediatric bone marrow transplant patients who develop RSV while on the BMTU. Effective strategies to engage physicians in developing guidelines can be

prompted by providing evidence from the literature and promoting a culture of safety that improves patient outcomes and does not pose an occupational health hazard to nurses on the BMTU. The success of such change may be measured in small steps, and the implementation of change is most effective when it receives full support from management. The development of infrastructure to support evidence-based practice is necessary to ensure that current best evidence is used when providing patient care, and administrators must provide the infrastructure so that evidence-based practice can diffuse throughout the organization (Rosswurm & Larrabee, 1999). The APN also serves as an important link in moving research knowledge into practice and for ensuring that a culture of safety exists in which nurses can practice. A change in practice involves a major organizational commitment and a change in culture, along with the education of all those concerned. Future endeavors for both the nurses and APN are to educate themselves with occupational health and safety regulations, advocate for safe practice within the BMTU and hospital, and engage management in creating a culture of safety.

## Appendix A

### **Ribavirin Inhalation Therapy Policy**

Due for Review!

Not reviewed for 4 years and 11 months!

Hospital-wide patient care policy

3.29-Apr 91

#### **Ribavirin Inhalation Therapy**

Issuing Department: Pharmacy

Category: Pharmacy

Section Name: Policies & Drug Information for Nurses

Written By: Nursing-Pharmacy Committee

Converted Document!

Not revised since 1991-04 by Nursing-Pharmacy Committee

Original date written: 1990-12

#### **Preparation of Ribavirin Inhalation Solution**

A solution containing 6g of ribavirin in 300ml of sterile water for injection is used for inhalation. This solution is prepared in a sterile manner by the pharmacy and is dispensed in a 500ml viaflex bag. Keep refrigerated until use; administration must be completed before the expiry time on the bag.

#### **Administration of Ribavirin Inhalation Solution**

A small particle aerosol generator (SPAG-II®) is used for delivery of the ribavirin inhalation solution. Please refer to the Respiratory Therapy Policy and Procedure Manual, Policy W009 (p.75).

The administration of ribavirin by Registered Nurses is restricted to Infectious Disease, Hematology/Oncology, PICU, and NICU.

#### **Nursing Implications**

Women in the first trimester of pregnancy or those attempting to conceive should avoid prolonged or excessive exposure to ribavirin. Such exposure may occur while:

1. Opening the tent or hood while the SPAG-II unit is operating
2. Several SPAG-II units are in operation in one room or in a room with poor ventilation.

3. Ribavirin is administered by trach collar or without a hood box or tent.

In order to minimize exposure, the SPAG-II unit should be turned off whenever the hood is entered. If this is not possible (e.g., patients on concurrent oxygen) then a high-efficiency respirator mask should be used.

Hospital staff should wear gloves when cleaning ribavirin-contaminated equipment (i.e., hoods, tank, respirator tubing), due to high concentrations of the drug on the equipment.

Contact lenses should not be worn in a room where ribavirin therapy is in use. Goggles must be worn in the event that anyone wearing contact lenses needs to be in the room during treatment. Appropriate signs should be placed on the doors of all rooms where ribavirin is in use to warn contact lens wearers of this.

## Appendix B

### Stem Cell Transplant Programme Standard Operating Procedure

#### 1. INDICATIONS FOR PRACTICE

Nebulized Ribavirin is the current treatment of choice for Respiratory Syncytial Virus in Bone Marrow Transplant patients, but may also be prescribed for other respiratory viral infections.

It is necessary to minimize environmental exposure of staff and visitors to Ribavirin due to recognized and suspected side effects: Crystallization on contact lenses, nausea and teratogenicity.

Ventilation in isolation cubicles is provided by Positive pressure HEPA filtration which vents into the main ward area.

Patients with RSV must be strictly isolated to prevent cross infection.

#### 2. AUTHORISED PERSONNEL/TRAINING REQUIRED

All qualified nursing staff can administer Ribavirin: **Pregnant staff is advised to avoid entering the designated area during and immediately after administration of the drug.** Staff who wears contact lenses should be prepared to make alternative arrangements in the event that they are required to care for patients receiving this drug.

#### 3. PROCEDURE

A designated area is established on the BMT unit where Ribavirin can be given safely: cubicles 11 and 12. Patients requiring Ribavirin will be moved to these rooms and remain there for the whole course of the treatment.

Only patients who can be left safely with minimal contact for a minimum of two hours at a time and can tolerate the treatment with full precautions should be treated with nebulized Ribavirin.

No more than 2 patients can be treated with Nebulized Ribavirin on the BMT unit at one time.

If one of these rooms is used for this purpose, the occupant of the other room can only be a patient who also needs this treatment.

The standard dose of Nebulized Ribavirin is 6g dissolved in 100ml water suitable for inhalation given over six hours. The six hours will be organized in a way which can be best tolerated by the patient (e.g.: 1 x 6hrs, 2 x 3hrs or 3 x 2hrs) and at times to suit personal and clinical needs.

#### **Preparation and administration:**

When preparing the drug for administration, full protective clothing should be worn: gloves, mask, apron and goggles, avoiding splashes and spills. Other staff should be advised when preparation is taking place in order that they can choose to leave the room.

This drug is administered via a Small Particle Aerosol Generator (SPAG) machine, which is attached to the wall air supply and set up as per manufacturer's instructions. A special set of bottles is required. These are changed daily and returned to CSSD for cleaning and sterilization.

Once the SPAG machine has been set up correctly, it should not be necessary to adjust the controls, although regular checks should be made. Simply start and stop by attaching to and disconnecting from the air supply.

The drug will be administered to the patient via a "bucket mask" placed on or close to their face. This will allow the continued delivery of oxygen therapy, if required.

### **Preparing the patient:**

Ensure the patient is fully informed of the procedure, what to expect and what to do if they need to stop or leave the tent for any reason.

Assess need for prophylactic anti-emetics.

Ensure the patient has had a chance to use the toilet and has everything they may need at hand, within the tent: call button, drink, emesis basin etc...

### **Preparing the environment:**

A plastic tent is suspended over the bed, using 'drip strands', which can be attached at the four corners of the bed frame. This is tucked in securely all the way around the bed. The tent can be folded up behind the bed for re-use if the daily dose is to be given over more than one episode, and replaced daily.

A scavenger unit with filter is placed by the side of the bed with a length of elephant tubing passed into the tent. This is used to reduce the amount of Ribavirin being released into the room. This should be switched on prior to commencing the nebulizer. Filters should be labeled with time and date and changed daily.

At the rear of the tent are a number of plastic discs which can be removed to allow IV lines, nebulizer and extractor tubing etc. to be passed through the wall of the tent.

When everything is set up and the patient is comfortable, attach the SPAG to the air supply and leave the room.

### **During treatment:**

Entry to the cubicle, and the designated area should be kept to a minimum, with signs put up to alert staff and visitors who would otherwise enter.

Visitors should be advised of the risks of exposure to Ribavirin in order that they can make an informed decision whether to stay in the cubicle or leave. Precautions should be taken by contact lens wearers and pregnant women should not remain in the room.

If the patient needs to stop treatment for any reason, the SPAG machine should be switched off (by disconnecting and particles allowed to settle for 15-20 minutes before staff attend the patient when the tent is open).

**At the end of treatment:**

Disconnect SPAG from the air supply and leave scavenger running for 15-20 minutes. After rest period, wearing protective clothing, remove tent or fold it over the back of the bed, carefully folding it on itself, to prevent contact with inner surfaces.

Recommend that the patient has a wash and change of clothes. Change the bed linen.

When the SPAG has been switched off for 15-20 minutes it is no longer necessary to restrict traffic in the area outside the cubicle.

When the tent is dismantled and all contaminated linen has been removed from the room it should be considered safe for all staff to enter.

## Appendix C

### Revised Ribavirin Inhalation Therapy Policy

#### 1.0 Introduction

This policy, procedure and guidelines, applies to all spontaneously breathing patients who receive Ribavirin inhalation therapy at the hospital. Only individuals who have been trained on the safe handling and administration of Ribavirin may perform this procedure.

#### 2.0 Policy

A medical order is required for the administration of inhaled Ribavirin.

Ribavirin can cause bronchospasm. As a result, an order for a one time dose of Salbutamol must be obtained with all Ribavirin orders.

Contact lenses should not be worn in a room where Ribavirin therapy is in use.

Personal Protective Equipment (PPE) including gloves, gowns, goggles, and N95 respirator (for which you have passed a fit test) must be worn when entering the room where Ribavirin delivery is taking place or when handling the drug itself.

The administration of Ribavirin must be done by using a Small Particle Aerosol Generator (SPAG-2®) and a Negative Pressure Containment Unit (Demistifier®) and canopy.

The SPAG-2® internal components (drying chamber, reservoir and nebulizer tubing) as well as personal protective equipment (PPE) including gloves, gowns, goggles, and N95 respirator must be changed between every treatment.

#### 3.0 Guidelines

##### 3.1 Hospital Staff and Family Exposure Precautions

Please contact Occupational Health if you have any concerns about Ribavirin exposure.

The following precautions are recommended to minimize exposure risks:

- Women in the first trimester of pregnancy should avoid exposure.
- Men and Women attempting to conceive should avoid prolonged or excessive exposure.
- At the end of the treatment, the SPAG-2® unit should be turned off for 5-10 minutes prior to unprotected patient handling.

It is recommended that visitors be restricted to immediate family only, in order to minimize exposure risk (insert link to visitor policy)

Ensure “Ribavirin Therapy in Use” signage is on the anteroom door as well as the door to the patient room.

##### 3.2 Patient Placement

It is recommended that patients receiving Ribavirin inhalation therapy, be in a negative pressure room, in addition to the use of the Demistifier® and canopy if one is available. It is recommended that the patient be double gowned and an additional bed sheet be placed on top of the existing sheet for the treatment.

##### 3.3 Safety

In the event of an acute patient emergency, turn off the flow to the SPAG-2® unit, remove patient mask or oxyhood and apply oxygen as required. Page the Registered

Respiratory Therapist STAT and continue procedure as with any other medical emergency. (Call code blue, page CCRT, page physician, etc...) as required. In case of accidental contact with the medication, or in the event of a medication spill, please see to the Safe Handling of Hazardous Drugs policy for instructions on immediate action (insert link to policy).

### **3.4 Demistifier Canopy Change**

Manufacturer guidelines indicate the canopy can be used multiple times on the same patient. If the Demistifier® is to be used on multiple patients, the canopy must be changed before being used on another patient. It is recommended that the canopy be placed in a cytotoxic bag following the removal from the Demistifier® and stored in a place that is out of the way of caregivers and health care personnel until the next use.

### **3.5 Disposal of Ribavirin**

Remaining medication should be disposed of into the cytotoxic waste system. Patient's outer gown and linens should be placed in a red cytotoxic linen hamper with lid. The RRT will dispose of excess medication and send contaminated SPAG-2® components for cleaning.

## **4.0 Procedure**

### **4.1 Preparation of Ribavirin Inhalation Solution**

Ribavirin is provided by pharmacy in one of two ways:

- a) A solution containing 6g of Ribavirin in 300ml (20mg/ml) of sterile water for injection is used for inhalation. This solution is prepared in a sterile manner by the pharmacy and is dispensed in a 500ml viaflex bag. Keep refrigerated until use; administration must be completed before the expiry time on the bag. Administration of this solution is once daily over 12-18 hours.
- b) A solution containing 2g of Ribavirin in 33ml (60mg/ml) of sterile water for injection is used for inhalation. This solution is prepared in a sterile manner by the pharmacy and is dispensed in unit dose syringes. Keep refrigerated until use; administration must be completed before the expiry time on the syringes. Administration of this solution is usually over 2 hours (may be ordered 2g over 2 hours tid).

### **4.2 Administration of Ribavirin Inhalation Solution**

A SPAG-2® in coordination with Demistifier® and canopy is used for delivery of the Ribavirin inhalation solution.

### **4.3 Equipment**

- Personal Protective Equipment
- Room signage "Ribavirin in Use"
- SPAG-2®
- Sterile parts from Central Processing Department (Drying chamber, reservoir and nebulizer tubing)
- Demistifier® and canopy
- Blue corrugated tubing
- Aerosol mask (age appropriate size) or oxyhood

- Ribavirin
- 50psi oxygen and air outlets
- Oxygen triple bar
- Patient gowns
- Extra bed sheet
- Cytotoxic waste bag
- Cytotoxic waste container with lid
- Cytotoxic linen hamper with lid
- Salbutamol and nebulizer

#### 4.4 Preparation and Medication Administration

	<b>Important Steps</b>	<b>Key Points</b>
1.	Obtain a doctor's order for Ribavirin inhalation treatment and an order for a PRN dose of salbutamol post-Ribavirin inhalation	Please see medication orders
2.	Place "Ribavirin in Use" signage on the door to the patient room and anteroom	
3.	Page Respiratory Therapist and arrange for a negative pressure room if available	Please see 3.2 for patient preparation and placement
4.	Collect equipment	RT will collect and assemble medication delivery equipment
5.	Review patient's history	
6.	Wash hands Put on PPE: an N95 respirator, chemical splash goggles, gown, and gloves	Please see Hand Hygiene and Hand care policy Please see the N95 Respiratory Protection Policy Please refer to policy statement 3.0 Please see Eye and Face Protection Policy
7.	Enter room	Ensure all other individuals in the room are wearing PPE
8.	Identify patient and explain procedure to patient and family	Please see patient identification policy Ribavirin should be administered under close supervision
9.	Prepare the Ribavirin according to pharmacy directions	
10.	Assemble Demistifier® with a canopy as indicated in the user manual: <ul style="list-style-type: none"> <li>• Assemble the SPAG-2® unit as indicated in the user manual</li> <li>• Connect all high pressure hoses to the wall outlet</li> <li>• Assemble the user interface and attach it to the SPAG-2®</li> <li>• Add Ribavirin to the medication reservoir</li> </ul>	
11.	Position the Demistifier® canopy: <ul style="list-style-type: none"> <li>• Turn on the Demistifier®</li> <li>• Apply the aerosol mask on the patient, or if using an oxyhood, place patient under the hood</li> <li>• Close the ports of the canopy</li> <li>• Turn on the flow to the SPAG-2® and ensure dime-sized particles are seen in the medication reservoir and that there is misting of medication in the drying chamber</li> <li>• Drying chamber flow rate should be set at 2-9</li> </ul>	<ul style="list-style-type: none"> <li>• The Demistifier® and canopy is used to minimize employee and caregiver exposure to aerosolized Ribavirin.</li> <li>• Please cover the child's eyes during treatment, whenever possible</li> <li>• Ensure side ports on oxyhood are closed for those patients receiving Ribavirin via an oxyhood.</li> </ul>

	<p>Lpm and the nebulizer flow rate should be set at 6-10Lpm</p> <ul style="list-style-type: none"> <li>Encourage patient to breathe normally</li> </ul>	
12.	Frequently observe and assess respiratory rate (RR), heart rate (HR), blood pressure (BP) and signs of increase work of breathing (WOB).	<ul style="list-style-type: none"> <li>Ribavirin can cause bronchospasm.</li> <li>Watch for indications for salbutamol treatment</li> <li>It is recommended that vital signs (RR, HR, BP and signs of increased WOB or respiratory distress) be assessed q1/2 hour while the treatment is running.</li> </ul>
13.	<p>The RRT will discontinue the Ribavirin treatment at the end of the allotted time. If an RRT is unavailable or is delayed then the RN will discontinue the treatment.</p> <ul style="list-style-type: none"> <li>Turn the flow to the SPAG-2® off and remove the patient's mask or oxyhood</li> <li>Continue to run the Demistifier® over patient for 5-10 minutes following treatment.</li> <li>Encourage other health care professionals to wait 5-10 minutes prior to doing any routine patient care.</li> <li>At the conclusion of the treatment, enter room using PPE.</li> </ul>	<ul style="list-style-type: none"> <li>Treatment time is dependent on solution ordered (see 4.1)</li> <li>If you have to attend to another patient you can leave the Demistifier® and canopy running longer than the 5-10 minutes.</li> </ul>
14.	Assess and record the patient's respiratory rate, HR, BP and WOB.	
15.	Wash hands and remove PPE.	
16.	Document treatment and observations in the patient's flow sheet and chart.	
17.	<p>Dispose of Demistifier® canopy using PPE: Place canopy in a red cytotoxic bag.</p> <ul style="list-style-type: none"> <li>Dispose of leftover medication in the reservoir as recommended by pharmacy.</li> <li>Wipe down exterior of the Demistifier® with Virox</li> <li>Place Demistifier® in an area of the room that will not obstruct access to the patient or be hazardous to people in the room.</li> </ul>	<ul style="list-style-type: none"> <li>RRT will dispose of canopy and excess medication as per Safe Handling of Hazardous Drugs Policy</li> </ul>
18.	<p>Disassemble the SPAG-2®.</p> <ul style="list-style-type: none"> <li>Place drying chamber, reservoir and nebulizer and capillary tubing in a red cytotoxic bag to take to CPD for processing.</li> </ul>	<ul style="list-style-type: none"> <li>RRT to take equipment to CPD</li> </ul>
19.	Wash hands and remove PPE	

#### 4.5 Cleaning Guidelines and Procedure

	Important Steps	Key Points
1.	Wash hands. Put on PPE: an N95 respirator for which you have been fit tested, chemical splash goggles, gown and gloves.	<ul style="list-style-type: none"> <li>See Hand Hygiene and Hand Care policy</li> <li>See the N95 Respiratory Protection Policy</li> <li>Please refer to policy statement 3.0</li> <li>See Eye and Face Protection Policy</li> </ul>
2.	<ul style="list-style-type: none"> <li>Place Demistifier® canopy in a red cytotoxic bag and place the bag with the Demistifier®</li> <li>Dispose of the leftover medication in the reservoir as recommended by Pharmacy</li> <li>Wipe down the exterior of the Demistifier® with</li> </ul>	<ul style="list-style-type: none"> <li>RRT will dispose of canopy and excess medication</li> <li>Please see Safe Handling of Hazardous Drugs Policy</li> </ul>

	<p>Virox</p> <ul style="list-style-type: none"> <li>Place Demistifier® and canopy in an area of the room that will not obstruct access to the patient or be hazardous to people in the room</li> </ul>	
3.	Disassemble the SPAG-2®. Place drying chamber, reservoir, and nebulizer and capillary tubing in a cytotoxic bag to take to CSD for processing	<ul style="list-style-type: none"> <li>RRT to take contaminated equipment to CSD</li> </ul>
4.	Remove patient's outer gown and the top bed sheet and place in a cytotoxic linen hamper.	
5.	Wipe down the surface of the crib/bed and any other surface areas medication may have come in contact with using Virox.	<ul style="list-style-type: none"> <li>PPE should be used</li> </ul>
6.	Wash patient's face to remove Ribavirin particulate.	<ul style="list-style-type: none"> <li>PPE should be used</li> </ul>
7.	Wash hands and remove PPE	

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