Reducing Pressure Injuries Using InSPiRE

Monitoring Gastric pH

Patient Hand Hygiene to Reduce HAIs

Intracerebral Hemorrhage and Nosocomial Infections

Negotiating Transitions at the End-of-Life

Patients Transferred to an Oncologic ICU

Screening for Risk of Ethical Conflicts

Feasibility of Holding or Continuing Enteral Feedings

Thyrotoxic Periodic Paralysis With Respiratory Failure
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Oil on canvas
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An Official Publication of the American Association of Critical-Care Nurses
Important Risk Information

NEXTERONE (amiodarone HCl) Premixed Injection is contraindicated in patients with:

- Known hypersensitivity to any of the components of NEXTERONE, including iodine
- Cardiogenic shock
- Marked sinus bradycardia
- Second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available

- NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

- Hypotension is the most common adverse reaction seen with intravenous amiodarone. In clinical trials, treatment-emergent, drug-related hypotension was reported in 16% (288/1836) of patients treated with intravenous amiodarone. Clinically significant hypotension during infusions was seen most often in the first several hours of treatment and appeared to be related to the rate of infusion. Monitor the initial rate of infusion closely and do not exceed the recommended rate. In some cases, hypotension may be refractory and result in a fatal outcome. Treat hypotension initially by slowing the infusion; additional standard therapy may be needed, including: vasopressors, positive inotropic agents and volume expansion.

- In 4.9% (90/1836) of patients in clinical trials, drug-related bradycardia that was not dose-related occurred while patients were receiving intravenous amiodarone for life-threatening VT/VF. Treat bradycardia by slowing the infusion rate or discontinuing NEXTERONE. Treat patients with a known predisposition to bradycardia or AV block with NEXTERONE in a setting where a temporary pacemaker is available.

- Elevations of blood hepatic enzyme values ALT, AST, GGT are commonly seen in patients with immediately life-threatening VT/VF. In patients with life-threatening arrhythmias, the potential risk of hepatic injury should be weighed against the potential benefit of NEXTERONE therapy. Carefully monitor patients receiving NEXTERONE for evidence of progressive hepatic injury. In such cases, consider reducing the rate of administration or withdrawing NEXTERONE.

- Like all antiarrhythmics, NEXTERONE may cause worsening of existing arrhythmias or precipitate a new arrhythmia. Monitor patients for QTc prolongation during infusion with NEXTERONE. Reserve the combination of amiodarone with other antiarrhythmic therapies that prolong the QTc to patients with life-threatening ventricular arrhythmias who are incompletely responsive to a single agent.

- There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with intravenous amiodarone. Findings included pulmonary infiltrates and masses on X-ray, bronchospasm, wheezing, fever, dyspnea, cough, hemoptyis, and hypoxia. Some cases have progressed to respiratory failure or death. Two percent (2%) of patients were reported to have acute respiratory distress syndrome (ARDS) during clinical studies involving 48 hours of therapy. Pulmonary toxicity including pulmonary fibrosis is a well-recognized complication of long-term amiodarone use.

- Amiodarone inhibits peripheral conversion of thyroxine (T4) to triiodothyronine (T3) and may cause increased T4 levels, decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone can cause either hypothyroidism or hyperthyroidism. Evaluate thyroid function prior to treatment and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter, or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function, and abnormal thyroid function tests may persist for several weeks or even months following NEXTERONE withdrawal.

- The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block. The most common adverse reactions leading to discontinuation of intravenous amiodarone therapy were hypotension (1.6%), asystole/cardiac arrest/PEA (1.2%), VT (1.1%), and cardiogenic shock (1%).

- Drug Interactions
  - Since amiodarone is a substrate for CYP3A and CYP2C8, drugs/substances that inhibit these isoenzymes may decrease the metabolism and increase serum concentration of amiodarone.
  - Amiodarone inhibits p-glycoprotein and certain CYP450 enzymes, including CYP1A2, CYP2C9, CYP2D6, and CYP3A. This inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by those CYP450 enzymes or are substrates for p-glycoprotein. HMG-CoA reductase inhibitors that are CYP3A4 substrates in combination with amiodarone have been associated with reports of myopathy/rhabdomyolysis. Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Limit the daily dose of lovastatin to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required.
  - Some drugs/substances are known to accelerate the metabolism of amiodarone by stimulating the synthesis of CYP3A (enzyme induction). This may lead to low amiodarone serum levels and potential decrease in efficacy. Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly.

Please see Brief Summary of Full Prescribing Information on the following pages.
Waiting in the ICU: Not an option.

Nexterone is ready when every second counts.

<table>
<thead>
<tr>
<th>PRODUCT CODE</th>
<th>STRENGTH/VOLUME</th>
<th>CONCENTRATION</th>
<th>NDC #</th>
<th>PACK FACTOR (cartons/case)</th>
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Indications

NEXTERONE (amiodarone HCl) Premixed Injection is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. NEXTERONE also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication. During or after treatment with NEXTERONE, patients may be transferred to oral amiodarone therapy.

Use NEXTERONE for acute treatment until the patient’s ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but NEXTERONE may be safely administered for longer periods if necessary.

NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

Nexterone (amiodarone HCl) Premixed Injection

Please see Important Risk Information and Brief Summary of Full Prescribing Information on adjacent pages. Store in carton to protect from light until ready to use.

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NEXTERONE (amiodarone HCl) Premixed Injection for intravenous use

Brief Summary of Prescribing Information. See PI for Full Prescribing Information.

1 INDICATIONS AND USAGE

NEXTERONE is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular fibrillation (VF) and hemodynamically unstable ventricular tachycardia (VT) in patients refractory to other therapy. NEXTERONE also can be used to treat patients with VT/VF for whom oral amiodarone is indicated, but who are unable to take oral medication.

During or after treatment with NEXTERONE, patients may be transferred to oral amiodarone therapy [see Dosage and Administration (2) in full prescribing information].

Use NEXTERONE for acute treatment until the patient’s ventricular arrhythmias are stabilized. Most patients will require this therapy for 48 to 96 hours, but NEXTERONE may be safely administered for longer periods if necessary.

4 CONTRAINDICATIONS

NEXTERONE is contraindicated in patients with:

- Known hypersensitivity to any of the components of NEXTERONE Premixed injection, including iodine. Hypersensitivity reactions may involve rash, angioedema, cutaneous/mucosal hemorrhage (bleeding), fever, arthralgias (joint pains), eosinophilia (abnormal blood counts), urticaria (hives), thrombotic thrombocytopenic purpura, or severe periarthritis (inflammation around blood vessels).
- Cardiogenic shock.
- Marked sinus bradycardia.
- Second- or third-degree atrio-ventricular (AV) block unless a functioning pacemaker is available.

5 WARNINGS AND PRECAUTIONS

NEXTERONE should be administered only by physicians who are experienced in the treatment of life-threatening arrhythmias, who are thoroughly familiar with the risks and benefits of amiodarone therapy, and who have access to facilities adequate for monitoring the effectiveness and side effects of treatment.

5.1 Hypotension

Hypotension is the most common adverse reaction seen with intravenous amiodarone. In clinical trials, treatment-emergent, drug-related hypotension was reported as an adverse effect in 18% (9/50) of 186 patients treated with NEXTERONE. Clinically significant hypotension during infusions was seen most often in the first several hours of treatment and was not dose related, but appeared to be related to the rate of infusion. Hypotension necessitating alterations in intravenous amiodarone therapy was reported in 3% of patients, with permanent discontinuation required in less than 2% of patients.

Treat hypotension initially by slowing the infusion; additional standard therapy may be needed, including the following: vasopressor drugs, positive inotropic agents, and volume expansion. Reduce the initial rate of infusion closely and do not exceed the recommended rate [see Dosage and Administration (2) in full prescribing information].

In some cases, hypotension may be refractory and result in a fatal outcome [see Adverse Reactions (6.2) in full prescribing information].

5.2 Bradycardia and Atio-ventricular Block

In 90 (4.9%) of 1836 patients in clinical trials, drug-related bradycardia that was not dose-related occurred while they were receiving intravenous amiodarone for life-threatening VT/VF. Treat bradycardia by slowing the infusion rate or discontinuing NEXTERONE. In some patients, inserting a pacemaker is required. Despite such measures, bradycardia was progressive and terminal in 1 patient during the controlled trials. Treat patients with a known predisposition to bradycardia or AV block with NEXTERONE in a setting where a temporary pacemaker is available.

5.3 Liver Enzyme Elevations

Elevations of blood hepatic enzyme values (alanine aminotransferase (ALT), aspartate aminotransferase (AST), and gamma-glutamyl transferase (GGT)) are commonly seen in patients with immediately life-threatening arrhythmias treated with intravenous amiodarone. Clinically significant elevation during infusions was seen most often in the first several hours of treatment and was not dose related, but appeared to be related to the rate of infusion. Hypotension necessitating alterations in intravenous amiodarone therapy was reported in 3% of patients, with permanent discontinuation required in less than 2% of patients.

If liver enzyme (ALT, AST, GGT) levels exceed 3 times the upper limit of normal, NEXTERONE should be discontinued and treatment withheld if the patient is asymptomatic. If symptoms of hepatitis occur, NEXTERONE should be discontinued and liver function tests monitored. If liver enzyme (ALT, AST, GGT) levels exceed 5 times the upper limit of normal, or if the patient has evidence of hepatitis (e.g., jaundice), NEXTERONE should be discontinued and the patient removed from the treatment setting. In the absence of inflammatory signs and symptoms, liver enzyme elevations can be managed clinically with no further drug discontinuation or treatment withholding required. Clinical monitoring of the patient’s hepatic function should be continued until resolution occurs.

5.4 Proarrhythmia

Like all antiarrhythmic agents, NEXTERONE may cause a worsening of existing arrhythmias or precipitate a new arrhythmia. Proarrhythmia, primarily torsade de pointes (TdP), has been noted to occur at any time following initiation of therapy. A causal relationship to the drug has not been clearly established. Perform an ophthalmic examination if symptoms of visual impairment appear, such as changes in visual acuity and decreases in peripheral vision. Re-evaluate the necessity of amiodarone therapy if optic neuropathy or neuritis is suspected. Perform routine ophthalmic examination, including fundoscopy and slit-lamp examination, during administration of NEXTERONE.

5.5 Pulmonary Disorders

There have been postmarketing reports of acute-onset (days to weeks) pulmonary injury in patients treated with intravenous amiodarone. Findings have included pulmonary infiltrates and masses on X-ray, bronchospasm, wheezing, fever, dyspnea, cough, hemoptysis, and hypoxia. Some cases have progressed to respiratory failure or death.

ARDS

Two percent (2%) of patients were reported to have adult respiratory distress syndrome (ARDS) during clinical studies involving 48 hours of therapy. Pulmonary Fibrosis

There have been reports of chronic interstitial lung disease associated with amiodarone use. In patients with pre-existing lung disease, prophylactic corticosteroids have been used. For patients with pulmonary disease, the decision to use NEXTERONE should be made only after careful consideration of the risks and benefits of this therapy.

5.6 Loss of Vision

Cases of optic neuropathy and optic neuritis, usually resulting in visual impairment, have been reported in patients treated with oral amiodarone. In some cases, visual impairment has progressed to permanent blindness. Optic neuropathy and neuritis may occur at any time following initiation of therapy. A causal relationship to the drug has not been clearly established. Perform an ophthalmic examination if symptoms of visual impairment appear, such as changes in visual acuity and decreases in peripheral vision. Re-evaluate the necessity of amiodarone therapy if optic neuropathy or neuritis is suspected. Perform prompt ophthalmic examination, including fundoscopy and slit-lamp examination, during administration of NEXTERONE.

5.7 Long-Term Use

There has been limited experience in patients receiving intravenous amiodarone for longer than 3 weeks. See package insert for oral amiodarone.

5.8 Thyroid Abnormalities

Amiodarone inhibits peripheral conversion of thyroxine (T4) to triiodothyronine (T3) and may cause increased T4 levels, decreased T3 levels, and increased levels of inactive reverse T3 (rT3) in clinically euthyroid patients. Amiodarone is also a potential source of large amounts of inorganic iodine and can cause either hypothyroidism or hyperthyroidism. Evaluate thyroid function prior to therapy and periodically thereafter, particularly in elderly patients, and in any patient with a history of thyroid nodules, goiter, or other thyroid dysfunction. Because of the slow elimination of amiodarone and its metabolites, high plasma iodide levels, altered thyroid function, and abnormal thyroid function tests may persist for several weeks or even months following NEXTERONE withdrawal.

There have been postmarketing reports of thyroid nodules/thyroid cancer in patients treated with amiodarone. In some instances hyperthyroidism was also present [see Adverse Reactions (6.2) in full prescribing information].

Hyperthyroidism and Thyrotoxicosis

Hyperthyroidism occurs in about 2% of patients receiving amiodarone, but the incidence may be higher among patients with prior inadequate dietary iodine intake. Amiodarone-induced hyperthyroidism usually poses a greater hazard to the patient than hyperthyroidism because of the possibility of thyrototoxicosis and arrhythmia breakthrough or aggravation, all of which may result in death. There have been reports of deaths associated with amiodarone-induced thyrotoxicosis. Consider the possibility of hyperthyroidism if any new signs of arrhythmia appear.

Identify hyperthyroidism by relevant clinical signs and symptoms, subnormal serum levels of thyroid stimulating hormone (TSH), abnormally elevated serum free T4, and elevated or normal serum T3. Since arrhythmia breakthroughs may accompany amiodarone-induced hyperthyroidism, aggressive medical treatment is indicated, including, if possible, dose reduction or withdrawal of amiodarone. Amiodarone hyperthyroidism may be followed by a long period of hyperthyroidism.

The institution of antithyroid drugs, β-adrenergic blockers or temporary corticosteroid therapy may be necessary. The action of antithyroid drugs may be especially delayed in amiodarone-induced thyrotoxicosis because of substantial quantities of preformed thyroid hormones stored in the gland. Radioactive iodine therapy is contraindicated because of the low radioisotope uptake associated with amiodarone-induced hyperthyroidism.

When aggressive treatment of amiodarone-induced thyrotoxicosis has failed or amiodarone cannot be discontinued because it is the only drug effective against the resistant arrhythmia, some management may be an option. Experience as a treatment for amiodarone-induced thyrotoxicosis is limited, and this form of therapy could induce thyroid storm. Therefore, surgical and anesthetic management require careful planning.

Neonatal Hypo- or Hyperthyroidism

Amiodarone can cause fetal harm when administered to a pregnant woman. Although amiodarone use during pregnancy is uncommon, there have been a small number of published reports of congenital goiter/hyothyroidism and hyperthyroidism associated with oral administration. Inform the patient of the potential hazard to the fetus if NEXTERONE is administered during pregnancy or if the patient becomes pregnant while taking NEXTERONE.
Hypothyroidism

Hypothyroidism has been reported in 2% to 4% of patients in most series, but in 8% to 10% in some series. This condition may be identified by relevant clinical symptoms and particularly by elevated serum TSH levels. In some clinically hypothyroid amiodarone-treated patients, free thyroid index values may be normal. Manage hypothyroidism by reducing the NEXTERONE dose and considering the need for thyroid hormone supplement. However, therapy must be individualized, and it may be necessary to discontinue oral amiodarone in some patients.

5.9 Surgery

Perform close perioperative monitoring in patients undergoing general anesthesia who are on amiodarone therapy as they may be more sensitive to the myocardial depressant and conduction defects of halogenated inhalational anesthetics.

5.10 Corneal Refractive Laser Surgery

Advise patients that most manufacturers of corneal refractive laser surgery devices contraindicate corneal refractive laser surgery in patients taking amiodarone.

5.11 Electrolyte Disturbances

Correct hypokalemia or hypomagnesemia whenever possible before initiating treatment with NEXTERONE, as these disorders can exaggerate the degree of QTc prolongation and increase the potential for TdP. Give special attention to electrolyte and acid-base balance in patients experiencing severe or prolonged diarrhea or in patients receiving concomitant diuretics.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. In a total of 1836 patients in controlled and uncontrolled clinical trials, 14% of patients receiving intravenous amiodarone for at least one week, 5% received it for at least 2 weeks, 2% received it for at least 3 weeks, and 1% received it for more than 3 weeks, without an increased incidence of severe adverse reactions. The mean duration of therapy in these studies was 5.6 days; median exposure was 3.7 days.

The most important adverse reactions were hypotension, asystole/cardiac arrest/pulseless electrical activity (PEA), cardiogenic shock, congestive heart failure, bradycardia, liver function test abnormalities, VT, and AV block. Overall, treatment was discontinued for about 9% of the patients because of adverse reactions. The most common adverse reactions leading to discontinuation of intravenous amiodarone therapy were hypotension (1.6%), asystole/cardiac arrest/PEA (1.2%), VT (1.1%), and cardiogenic shock (1%).

Table 4 lists the most common (incidence ≥2%) adverse reactions during intravenous amiodarone therapy considered at least possibly drug-related. These data were collected in clinical trials involving 1836 patients with life-threatening VT/VF. Data from randomized treatment groups are pooled because none of the adverse reactions appeared to be dose-related.

| Table 4: ADVERSE REACTIONS IN PATIENTS RECEIVING INTRAVENOUS AMIODARONE IN CONTROLLED AND OPEN-LABEL STUDIES (≥2% INCIDENCE) |
|-------------------------------------------------|----------------|----------------|----------------|
| Study Event                                      | Controlled Studies (n=814) | Open-Label Studies (n=1022) | Total (n=1836) |
| Body as a whole                                 | Body as a whole |
| Fever                                           | 24 (2.9%)                | 13 (1.2%)                | 37 (2.0%) |
| Cardiovascular System                           | Cardiovascular System   |
| Bradycardia                                     | 49 (6.0%)                | 41 (4.0%)                | 90 (4.9%) |
| Congestive heart failure                        | 18 (2.2%)                | 21 (2.0%)                | 39 (2.1%) |
| Heart arrest                                    | 29 (3.5%)                | 26 (2.5%)                | 55 (2.9%) |
| Hypertension                                    | 165 (20.2%)              | 123 (12.0%)              | 288 (15.6%) |
| Ventricular tachycardia                         | 15 (1.8%)                | 30 (2.9%)                | 45 (2.4%) |
| Digestive System                                | Digestive System         |
| Liver function tests normal                     | 35 (4.2%)                | 29 (2.8%)                | 64 (3.4%) |
| Nausea                                          | 29 (3.5%)                | 43 (4.2%)                | 72 (3.9%) |

Other adverse reactions reported in less than 2% of patients receiving intravenous amiodarone in controlled and uncontrolled studies included the following: abnormal kidney function, atrial fibrillation, diarrhea, increased ALT, increased AST, lung edema, nodal arrhythmia, prolonged QT interval, respiratory disorder, shock, sinus bradycardia, Stevens-Johnson syndrome, thrombocytopenia, VF, and vomiting.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of amiodarone. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Body as a Whole: anaphylactic/anaphylactoid reaction (including shock), fever

Cardiovascular: hypotension (sometimes fatal), sinus arrest

Dermatologic: toxic epidermal necrolysis (sometimes fatal), exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, skin cancer, pruritus, angioedema

Endocrine: syndrome of inappropriate antidiuretic hormone secretion (SIADH)

Hematologic: pancytopenia, neutropenia, hemolytic anemia, aplastic anemia, thrombocytopenia, agranulocytosis, granuloma

Hepatic: hepatitis, cholestatic hepatitis, cirrhosis

Injection Site Reactions: pain, erythema, edema, pigment changes, venous thrombosis, phlebitis, thrombophlebitis, cellulitis, necrosis, and skin sloughing

Musculoskeletal: myopathy, muscle weakness, rhabdomyolysis

Nervous System: hallucination, confusional state, disorientation, and delirium, pseudotumor cerebri

Pancreatic: pancreatitis

Renal: renal impairment, renal insufficiency, acute renal failure

Respiratory: bronchospasm, possibly fatal respiratory disorders (including distress, failure, arrest and ARDS), bronchiolitis obliterans organizing pneumonia (possibly fatal), dyspnea, cough, hemoptysis, wheezing, hypoxia, pulmonary infiltrates and/or mass, pleuritis

Thyroid: thyroid nodules/thyroid cancer

Vascular: vasculitis

7 DRUG INTERACTIONS

Since amiodarone is a substrate for CYP3A and CYP2C8, drugs/substances that inhibit these isoenzymes may decrease the metabolism and increase serum concentration of amiodarone.

Amiodarone inhibits p-glycoprotein and certain CYP450 enzymes, including CYP1A2, CYP2C9, CYP2D6, and CYP2A6. This inhibition can result in unexpectedly high plasma levels of other drugs which are metabolized by these CYP450 enzymes or are substrates for p-glycoprotein.

HMCo-reductase inhibitors that are CYP3A4 substrates in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Limit the daily dose of lovastatin to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required.

Some drugs/substances are known to accelerate the metabolism of amiodarone by stimulating the synthesis of CYP3A (enzyme induction). This may lead to low amiodarone serum levels and potential decrease in efficacy.

Fluoroquinolones, macrolide antibiotics, and azoles are known to cause QTc prolongation. There have been reports of QTc prolongation, with or without TdP, in patients taking amiodarone when fluoroquinolones, macrolide antibiotics, or azoles were administered concomitantly.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Category D

Reproductive and teratology studies performed in rabbits and rats at doses of up to 100 mg/kg/day (about 1.4 times the maximum recommended human dose on a body surface area basis) revealed no evidence of embryo/fetal toxicity at 5 mg/kg and no teratogenicity was observed at any dosage in rabbits. Maternal toxicity and embryotoxicity were observed in rats in the 100 mg/kg group.

Use NEXTERONE during pregnancy only if the potential benefit to the mother justifies the risk to the fetus.

8.2 Labor and Delivery

It is not known whether the use of amiodarone during labor or delivery has any immediate or delayed adverse effects.

8.3 Nursing Mothers

Amiodarone and one of its major metabolites, desethylamiodarone (DEA), are excreted in human milk, suggesting that breast-feeding could expose the nursing infant to a significant dose of the drug.

8.4 Pediatric Use

The safety and effectiveness of amiodarone in pediatric patients have not been established; therefore, the use of amiodarone in pediatric patients is not recommended.

8.5 Geriatric Use

Clinical studies of amiodarone did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Carefully consider dose selection in an elderly patient.

10 OVERDOSAGE

There have been cases, some fatal, of amiodarone overdose. Effects of an inadvertent overdose of intravenous amiodarone include hypotension, cardiogenic shock, bradycardia, AV block, and hepatotoxicity. Treat hypotension and cardiogenic shock by slowing the infusion rate or with standard therapy: vasopressor drugs, positive inotropic agents, and volume expansion. Bradycardia and AV block may require temporary pacing. Monitor hepatic enzyme concentrations closely. Amiodarone is not dialyzable.

Baxter Healthcare Corporation
Deerfield, IL 60015

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Editorial

MEASLES 2015: WHY PUBLIC HEALTH MATTERS TO CRITICAL CARE

By Cindy L. Munro, RN, PhD, ANP, and Richard H. Savel, MD

The elimination of endemic measles from the United States in 20001 demonstrated the power of vaccination and public health to improve lives. However, recent outbreaks of measles in the United States illustrate how important it is to continue vigilance against pathogens we thought were controlled, and to encourage vaccination to prevent disease and its spread.

These outbreaks also illustrate that health care outcomes are dependent not only on high quality research, but also on the willingness of the public to accept research findings and the advice of health care providers. Measles is an exemplar of a public health issue that matters to critical care.

Measles is a highly contagious virus and a significant cause of mortality and morbidity.1 It is spread to others through respiratory secretions, including by coughing or sneezing. Because it can live for up to 2 hours in the air or on surfaces, it can infect others even after the infected person has left an area. Infected people can spread the disease for 4 days before the characteristic rash appears, and continue to be infective for 4 days following the appearance of the rash. After contact with an infected person (or with that person’s secretions in the air or on surfaces), 90 of every 100 people who are not already immune to measles will be infected.

The Measles Vaccine Track Record

Before vaccination for measles was available, an estimated 3 to 4 million cases occurred in the United States each year. Recovery from measles did convey immunity, but having the disease was a risky way to become immune. Measles accounted for about 500 deaths, 48,000 hospitalizations, and 4,000 cases of measles encephalitis annually.

Two effective vaccines for measles were developed in the late 1960s. Both used a weakened viral strain that gave the immune system an opportunity to learn to fight the virus without resulting in disease. Today, a live-attenuated measles vaccination is administered in combination with vaccination for mumps and rubella in the MMR vaccine.

The vaccine has an excellent safety record.2,3 Multiple high quality research studies have failed to find any relationship between MMR vaccine and autism spectrum disorder, despite ongoing myths based on a retracted 1998 *Lancet* paper that was later found to include misrepresented or altered data.3 The vaccine is also highly effective.1 After contact with a person who has measles (or with their secretions
To break the chain of infection for a highly communicable disease like measles, nearly all individuals must be vaccinated.

in the air or on surfaces), only 3 of every 100 people who have received 2 doses of the vaccine will contract measles, and they will tend to have milder symptoms and fewer complications.

The Value of Community Immunity

If a sufficient number of people in a population are immune to measles, the spread of disease from person to person is reduced, resulting in better levels of community immunity (also known as herd immunity). Vaccine compliance enhances community immunity and can provide some protection to those who cannot be vaccinated because they are too young to receive the vaccine or have contraindications to vaccination. Community immunity varies at a local level, and pockets of unvaccinated people can occur within states that have overall high vaccination coverage.

Unvaccinated people pose the greatest threat for the spread of measles in the United States. In today's highly mobile society, we are interconnected to local and global neighbors. Areas outside the United States (including Europe, Asia, the Pacific, and Africa) continue to have endemic measles, annually accounting for 20 million cases and 146,000 deaths worldwide. Susceptible US residents may come in contact with measles through international travelers coming to the United States, or through international travel to destinations with endemic measles. However, it is the spread among unvaccinated US residents that fuels US outbreaks, and most outbreaks occur in groups of people with suboptimal levels of vaccination.

In 2004, measles in the United States reached an all-time low of only 37 cases, but only 10 years later we had the largest reported number (644) of annual cases of measles since eradication; the 23 outbreaks that occurred in 2014 were centered in groups with low vaccination compliance. In the first 2 months of 2015, four measles outbreaks were active and 170 cases had been reported, including a large multistate outbreak linked to an amusement park in California (a state with pockets of low compliance with vaccination recommendations). Outbreaks take advantage of venues where large numbers of people convene (for example, amusement parks, airport terminals, and schools and colleges), and where there are unvaccinated individuals to support disease transmission.

Why Not Vaccinate?

In an era when we have a highly effective, safe, and inexpensive means to prevent a disease that has substantial mortality and morbidity, why do we still have measles outbreaks? To break the chain of infection for a highly communicable disease like measles, nearly all individuals must be vaccinated. Thus, vaccination benefits not only vaccinated individuals but their community. Preventing the spread of measles through participating in and advocating for vaccination is important community service.

There are many reasons for pockets of low vaccination rates, but one that has received considerable attention is vaccine hesitancy—a degree of indecision about specific vaccines or vaccination in general that interferes with people agreeing to vaccine recommendations for themselves or their children. A recent systematic review identified 3 components that may contribute to vaccine hesitancy: issues of confidence (related to trust in the provider, vaccines, or research), complacency (a perception that the vaccine is not needed or valued), and convenience (problems with access or cost). Framing the problem as vaccine hesitancy avoids a dichotomous view of people as “pro-vaccine” or “anti-vaccine” and acknowledges that multiple factors influence vaccination choices. Scientific studies and facts are not the only information weighed in vaccine decisions: personal risk appraisal, relationships with health care providers, and beliefs matter as well.

Overcoming Vaccination Hesitancy

Why do measles outbreaks—and the vulnerability of unvaccinated people—matter to critical care providers? First, measles outbreaks result in critical care admissions that are preventable. These preventable admissions increase overall costs to the health care system, but the most devastating impact is on those who suffer from the complications and sequelae of measles. Some of these patients may have chosen to
remain unvaccinated, whereas other patients may have had contraindications to vaccination and are the victims of a lack of community immunity. Clearly, prevention of measles-related encephalitis is preferable to costly critical care supportive treatment, which nonetheless may result in lasting neurological consequences.

Second, research about vaccine hesitancy provides a model for understanding resistance to research-based best practices and for dealing with hesitancy about care decisions. Domachowske and Suryadevara suggest using a CASE framework to guide discussions with vaccine hesitant patients (Corroborate with patients, About you as an expert, what Science has to say, and Explain and advise); this framework may be applicable to discussions about care decisions in critical care as well. The discussion begins with corroboration, during which providers inquire about patient and family concerns, acknowledge the stated concerns, and set a tone for a respectful discussion beginning with areas of agreement (for example, optimal outcomes for the patient).

Next, the provider needs to give the patient and family a reason to trust the provider as a knowledgeable expert who will provide complete and accurate information. This sets the stage to provide the patient and family with scientifically relevant information, to explain and discuss the information, and to advise them of available options and evidence to support care decisions.

It is important to be ready to counter myths and inaccuracies patients may discover as they independently seek information, particularly from Web-based sources. In an examination of 84 websites related to vaccine information, Ruiz and Bell found that only 18% recommended vaccination; further, they found that more websites perpetuated vaccine myths and recommended against vaccination than conveyed the benefits of vaccination. Patients and families need help in identifying high quality, accurate, trustworthy information about vaccines and other health care decisions.

**We Can Make a Difference**

Critical care providers are viewed as credible sources of health advice in their communities, and can positively influence local vaccination rates. Larson and colleagues found that encouragement from health professionals and others, as well as belief that immunization should be a social, familial, or workplace norm, promoted immunization.

Modeling compliance with vaccination recommendations for ourselves and our families, sharing accurate information, and countering vaccine hesitancy will contribute to higher levels of vaccination, better community immunity, and avoidance of unnecessary critical care hospitalizations. Public health issues are important to critical care, and our support of public health advances better health outcomes for all.

The statements and opinions contained in this editorial are solely those of the coeditors in chief.

**FINANCIAL DISCLOSURES**

None reported.

**REFERENCES**

Research at the bedside makes a difference for our patients—and also for our nurses. However, it is now time to broaden our focus from research on interventions or events at a narrow point in time to research that addresses care across the continuum.

This continuum may start at a point of injury, such as the battlefield, through en route care delivered during the 8000 mile journey home for our wounded warriors; or for critically ill patients as they move between the emergency department, operating room, and the intensive care unit. This focus also requires researchers to consider “care within context,” that is, research and evidence-based practice tailored to the unique conditions of the care environment. Beyond conducting research and developing new knowledge, is the challenge of translating evidence into practice. A culture of inquiry is a critical element to the successful translation of evidence into practice. In a culture of inquiry, nurses are empowered to question and evaluate their practice, provide evidence-based care, and actively participate in and lead clinical inquiry.

This article will draw from a program of applied clinical research that reflects care across the continuum, within both military and civilian health care settings, and will discuss how the application of these research findings and the advancement of a culture of inquiry make a difference for both patients and nurses.
Clinical Pearls

Using a Screening Tool to Prevent Ethical Conflicts

Ethical conflicts in intensive care units (ICUs) often reflect a tension between patients’ expectations and providers’ autonomy regarding medically appropriate care. These conflicts can cause moral distress for patients, families, and health care providers. Pavlish and colleagues developed an ethics screening tool for nurses to assess early indicators of ethical dilemmas and to analyze the level of risk likely to develop in specific situations. Use of the tool helped nurses to do the following:

- Proactively screen specific patient situations
- Clarify complicated clinical issues for better understanding and communication with the health care team
- Initiate difficult conversations with team members, patients, and families.

The authors advocate early screening for all patients and recommend that interventions such as family care conferences, ethical consultations, and palliative care services become more prominent and routine in the care of critically ill patients.

—Rhonda Board, RN, PhD, CCRN

See Article, pp 248-257

Preventing Pressure Injuries

Critically ill patients experience the highest prevalence of skin integrity issues. This contributes to increased lengths of stay, costs, morbidity, and mortality. Many pressure injuries (PIs) are preventable, but hypoxia, hemodynamic instability, or use of vasopressors place patients at risk. Coyer and colleagues compared patients who received standard skin care practices with patients who received a protocol that targets key areas of assessment, hygiene, repositioning, and prevention strategies. Their findings include the following:

- Cumulative incidence of PIs was significantly lower in the intervention group.
- Intervention patients had fewer skin injuries.

These results indicate that this new protocol warrants examination in other intensive care populations.

—Rochelle Armola, RN, MSN, CCRN

See Article, pp 199-210

Nosocomial Infections and Intracerebral Hemorrhage

What is the most common nosocomial infection in patients with intracerebral hemorrhage? Hinduja and colleagues did an analysis of 202 patients with intracerebral hemorrhage and found the following:

- The most common infection was pneumonia (18%), then urinary tract infection (12%), and meningitis or ventriculitis (3%).
- Patients with infection had more intraventricular hemorrhage, hydrocephalus, hyperglycemia, and required mechanical ventilation.
- They were more likely to have a low Glasgow Coma Scale at admission, require a central catheter, and a nasogastric tube.
- Those with infection were more likely to have a longer length of ICU stay and a poor outcome at discharge.
- Brain ischemia may cause a state of relative immunosuppression which increases the risk of infection.

—Janet F. Mulroy, RN, MSN, ACNP, CCNS, CCRN

See Article, pp 227-231

Critical Care Outreach Teams

Assessment by critical care outreach teams (CCOTs) prevents deterioration of acutely ill patients or facilitates admission to the critical care unit. With continued difficulty discussing end-of-life care (EOLC) decisions, the appropriateness of escalating care to a CCOT is not broached early enough. This retrospective study in a United Kingdom cancer center determined how much time CCOTs spend with EOLC patients and their influence in those situations. Pattison and colleagues found the following:

- 66.7% of referrals were made by nurses, 32.4% by residents/fellows.
- 87.9% of these patients already receive palliative treatment.
- Time spent with these patients was longer, but 51.9% had a clear EOLC plan after intervention.
- CCOTs are viewed as experienced critical-care experts with notable influence over EOLC.

—Alethea Sment, RN, BSN, CCRN-CSC

See Article, pp 232-240

Hand Hygiene Includes Patients, Too!

Elimination of hospital-acquired infections (HAIIs) is a priority in health care and requires multimodal approaches. A common intervention to eliminate HAIIs is adequate hand hygiene. Fox and colleagues added patient hand hygiene to their hospital’s hygiene protocol. This resulted in positive trends over a 12-month period. The authors noted the following:

- A protocol to wash patients’ hands with a 2% chlorhexidine gluconate (CHG) cloth 3 times daily may increase nurse awareness of the need for hand hygiene, thus increasing nurse hand hygiene compliance.
- Hand washing with CHG may affect fingerstick glucose readings. Be sure to thoroughly clean the finger with an alcohol wipe prior to obtaining blood.
- Patients should be instructed not to touch their face or mucous membranes until the CHG dries.

—Kimberly Whitman, RN, DNP

See Article, pp 216-224
 Provider to Patient Ratios for Nurse Practitioners and Physician Assistants in Critical Care Units

By Ruth Kleinpell, RN, PhD, Nicholas S. Ward, MD, Lynn A. Kelso, RN, MS, Fred P. Mollenkopf, Jr, PA-C, and Douglas Houghton, MSN, ARNP, CCRN

Background Nurse practitioners and physician assistants are being increasingly integrated into intensive care unit and hospital-based care teams, yet limited information is available on provider to patient ratios.

Objective To determine current provider to patient ratios for nurse practitioners and physician assistants working in intensive and acute care units and to assess factors that affect the ratios.

Methods A descriptive study design was used with a web-based survey of members of the American Association of Nurse Practitioners, American Academy of Physician Assistants, and the Society of Critical Care Medicine.

Results Responses were received from 222 nurse practitioners and 211 physician assistants from all but 8 of the 50 United States and from Canada. Mean provider to patient ratios in intensive care were 1 to 5 (range, 1 to 3 - 1 to 8). In pediatric intensive care, the mean ratio of nurse practitioners to patients was 1 to 4 (range, 1 to 3 - 1 to 8). Factors that affected nurse practitioner and physician assistant provider to patient ratios included patients’ severity of illness, number of patients in the unit, number of providers in the unit, patient diagnosis, number of physicians in the unit, time of day, and number of fellows and medical residents on service.

Conclusions Additional information on factors influencing provider to patient ratios and specific components of the roles of nurse practitioners and physician assistants will be important to ensure the best utilization of these providers to enable optimal patient care outcomes. (American Journal of Critical Care. 2015;24:e16-e21)

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Secondary Ventricular Fibrillation or Pulseless Ventricular Tachycardia During Cardiac Arrest and Epinephrine Dosing

By Andrew D. Straznitskas, PharmD, BCPS, Sylvia Wong, PharmD, Nicole Kupchik, RN, MN, CCNS, CCRN, and David Carlbom, MD

Background Development of ventricular fibrillation or pulseless ventricular tachycardia after an initial rhythm of pulseless electrical activity or asystole is associated with significantly increased cardiac arrest mortality.

Objective To examine differences in epinephrine administration during cardiac arrest between patients who had a secondary ventricular fibrillation or ventricular tachycardia develop and patients who did not.

Methods Data were collected for 2 groups of patients with in-hospital cardiac arrest and an initial rhythm of pulseless electrical activity or asystole: those who had a secondary ventricular fibrillation or ventricular tachycardia develop (cases) and those who did not (controls). Dosing of epinephrine during cardiac arrest and other variables were compared between cases and controls.
Results Of the 215 patients identified with an initial rhythm of pulseless electrical activity or asystole, 51 (23.7%) had a secondary ventricular fibrillation or ventricular tachycardia develop. Throughout the total duration of arrest, including periods of return of spontaneous circulation, the dosing interval for epinephrine in patients who had a secondary ventricular fibrillation or ventricular tachycardia develop was 1 mg every 3.4 minutes compared with 1 mg every 5 minutes in controls ($P= .001$). For the total duration of pulselessness, excluding periods of return of spontaneous circulation during the arrest, the dosing interval for epinephrine in patients who had a secondary ventricular fibrillation or ventricular tachycardia develop was 1 mg every 3.1 minutes versus 1 mg every 4.3 minutes in controls ($P= .001$).

Conclusion More frequent administration of epinephrine during cardiac arrest is associated with development of secondary ventricular fibrillation or ventricular tachycardia. (*American Journal of Critical Care.* 2015;24:e22-e27)

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REDUCING PRESSURE INJURIES IN CRITICALLY ILL PATIENTS BY USING A PATIENT SKIN INTEGRITY CARE BUNDLE (InSPIRE)

By Fiona Coyer, RN, PhD, CritCareCert, PGCEA, Anne Gardner, RN, MPH, PhD, CritCareCert, Anna Doubrovsky, BSc(Hons), MPH, Rae Cole, RN, GradCertNsg (IntCareNsg), Frances Mary Ryan, RN, BN, BAppSc(Hons), GradCertNsg (IntCareNsg), Craig Allen, RN, BN, GradCertNsg (IntCareNsg), and Greg McNamara, RN, BN, GradCertNsg (IntCareNsg), GradDip(MentalHlthNsg)

Purpose To test an interventional patient skin integrity bundle, the InSPIRE protocol, for reducing pressure injuries in critically ill patients in an Australian adult intensive care unit.

Methods Before and after design: patients receiving the intervention (InSPIRE protocol) were compared with a similar control group who received standard care. Data collected included demographic and clinical variables, skin assessment, presence and stage of pressure injuries, and score on the Sequential Organ Failure Assessment (SOFA).

Results Overall, 207 patients were enrolled, 105 in the intervention group and 102 in the control group. Most patients were men (mean age, 55 years). The groups were similar on major demographic variables (age, SOFA scores, intensive care unit stay). Cumulative incidence of pressure injuries was significantly lower in the intervention group (18.1%) than in the control group (30.4%) for skin injuries ($\chi^2 = 4.3, P = .04$) and mucous injuries ($t = 3.27, P \leq .001$). Significantly fewer pressure injuries developed over time in the intervention group ($log \text{rank} = 11.842, df=1, P \leq .001$) and intervention patients had fewer skin injuries (>3 pressure injuries/patient = 1/105) than did control patients (>3 pressure injuries/patient = 10/102; $P = .02$).

Conclusion The intervention group, receiving the InSPIRE protocol, had a lower cumulative incidence of pressure injuries, and fewer and less severe pressure injuries that developed over time. Systematic and ongoing assessment of the patient’s skin and risk for pressure injuries as well as implementation of tailored prevention measures are central to preventing pressure injuries. (American Journal of Critical Care. 2015;24:199-210)
A pressure injury is a “localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear.”1(7) The term pressure injury is used in this study, in line with the contemporaneous position that the word injury refers to a preventable event.1 Skin and mucosal pressure injuries are now differentiated; mucosal pressure injuries are found on mucous membranes with a history of a medical device in use at the location of the injury.5 Both mucosal and skin pressure injuries are due to prolonged compression of tissue that causes reduction or occlusion of microcirculation to the localized area, resulting in tissue hypoxia, edema, consequent ischemia, and (when the compression is relieved) reperfusion injury.2,3

Pressure injuries cause considerable harm to patients, hindering recovery, frequently causing pain, development of serious infections,4,5 other morbid conditions, and increased mortality.5 Patients with pressure injuries have hospital stays a mean of 4.31 days longer than other patients.7 Intensive care units (ICUs) have the highest prevalence and incidence of pressure injuries in the hospital setting.8,9 Annual costs to treat pressure injuries in Australia are as high as A$285 million7 and in the United States as much as $11 billion annually,10 contributing significantly to patients’ disease burden and ongoing health care costs.

Critical illness and admission to an ICU are significant contributors to the development of acknowledged risk factors for pressure injuries: increased pressure, shear, and altered skin microclimate.1,2,4,11 These risk factors are particularly evident in immobile critically ill patients receiving mechanical ventilation; such patients are commonly unable to bathe, toilet, change position, or feel increased pressure from prolonged periods in 1 position because of the continuous administration of intravenous sedation and analgesia.12 A combination of additional threats in critical illness increases risk of pressure injuries, including pathophysiological (hypoxia), biophysical (hemodynamic instability, reduced/poor tissue perfusion, and diaphoresis), and pharmacological (agents such as vasopressors and inotropes causing peripheral vasoconstriction) threats. Thus, critically ill patients in ICUs are a unique, vulnerable population at high risk for disruption of skin integrity, particularly development of pressure injuries.

Most pressure injuries are preventable,1,2 yet the prevalence of such injuries in critical care facilities is usually higher than the prevalence in general care areas.6 The prevalence of pressure injuries internationally in acute care areas is estimated at 15%,13 whereas the prevalence in critical care areas is considerably higher: 49% across Western European countries,12,14,15 22% in North America,8,16 and up to 50% in Australia.6 These alarming figures indicate an imperative to change skin management practices in these vulnerable patients and this high-risk practice environment. Quality of care is directly related to the number of pressure injuries that occur during hospitalization.15,17,18 Thus, we developed and tested a skin care protocol, InSPiRE, to address the incidence of pressure injuries in ICUs.

**Purpose of the Study**

The purpose of this study was to test the effect of implementation of an interventional patient skin integrity protocol, the InSPiRE protocol, on the cumulative incidence of pressure injuries in ICU patients.
Study Hypotheses
When compared with those patients who receive standard skin care practices, intensive care patients who receive the InSPIRE protocol will have:
1. a lower cumulative incidence of pressure injuries,
2. pressure injuries develop later in their ICU stay,
3. fewer pressure injuries per patient, and
4. processes of care for pressure injuries delivered more often.

Methods
Design
This study used a before and after design in which the group of patients receiving the intervention (InSPIRE protocol) was compared with a similar group of patients who received standard care before the InSPIRE protocol began being used.

Setting and Sample
The study was conducted during 12 months in a 36-bed general adult ICU in an Australian metropolitan tertiary referral hospital, the Royal Brisbane and Women’s Hospital. The ICU admits general medical, surgical, and trauma patients. The ICU is staffed by specialist intensive care medical practitioners responsible for admission and management of all patients. Registered nurses provide all care for patients with a ratio of 1 nurse per patient for patients requiring mechanical ventilation and 1 nurse per 2 patients for other patients. Approximately 60% of nurses working in the ICU had completed postgraduate critical care qualifications. Enrolled nurses (equivalent to licensed practical nurses in the United States) do not provide direct patient care in this Australian ICU.

Patients were included in the study if they were admitted to the ICU, were expected to remain there for more than 24 hours, and were older than 18 years. Excluded patients were those who had (1) a community-acquired loss of skin integrity on admission, (2) pressure injuries diagnosed within 24 hours of ICU admission, or (3) medical orders contraindicating any part of the InSPIRE protocol.

The sample size was calculated on the basis of the control group’s cumulative incidence rate of 0.1154 per day, assuming that events were independent of one another. Thus, 408 days of observation time per group (ie, 102 persons per group, with mean stay of 4 days) was required to detect a 50% reduction in this rate with 80% power and significance (P) less than .05.19,20

Measures
A data collection form, developed by the researchers, included demographic and clinical variables, a skin assessment tool, established tools for staging pressure injuries,2 score on the Sequential Organ Failure Assessment (SOFA),21 and process of care measures for pressure injuries.

Demographic and Clinical Data. Demographic variables were sex, age, diagnosis on admission, comorbid conditions, preadmission trajectory (eg, elective or emergency admission), length of ICU admission, and discharge to general care area or death. Clinical variables were number of days of mechanical ventilation, highest and lowest recorded mean arterial pressure in 24 hours, highest and lowest recorded core temperature in degrees Celsius in 24 hours, vasopressor and steroid medications, serum albumin levels, and serum white cell count.

Skin Assessment Tool. A standardized skin assessment tool based on assessment via physical examination and common sites for development of pressure injuries1-3,5,6,8-10,12-17,22-28 was used to standardize clinical examination among the research nurses.

Pressure Injuries. Pressure injuries were divided into skin and mucous injuries. At the time of the study, we used current international guidelines for staging pressure injuries1 to measure skin injury depth: stage I to IV. Mucous injuries were recoded, where applicable, by the device causing the injury. Location for both injuries was recorded by using a body figure. For patients who had pressure injuries develop, 2 digital images of the pressure injuries (close-up and midway) were taken by a medical photographer.

SOFA Score. The SOFA score is a scoring system to determine the extent of a person’s organ function or failure in the ICU.21 The score is based on 6 body systems of organ dysfunction/failure: the respiratory, cardiovascular, hepatic, coagulation, renal, and neurological systems. Each organ is graded from 0 (normal) to 4 (the most abnormal), providing a daily score of 0 to 24 points. The SOFA provides a mechanism to score severity of illness on a daily basis after ICU admission.21

Process of Care Measures. Process of care measures for pressure injuries were defined as part of the InSPIRE protocol and standard skin care (Table 1).

Intervention
The intervention, InSPIRE, is a bundle of processes for preventing pressure injuries by targeting key areas of nursing clinical assessment and documentation, hygiene measures, repositioning, and strategies for preventing pressure injuries in

The intervention was a bundle of pressure ulcer prevention processes based on best evidence.
1. Skin assessment on admission: All patients admitted to intensive care units (ICUs) are considered to be at risk of development of pressure injury. Within 4 hours of admission to the ICU, a full physical assessment of the patient’s skin integrity is performed and documented on the clinical information system; allocation to a pressure-relieving mattress or specialty device bed is based on risk (clinical judgment).

2. Ongoing assessment: Physical assessment of patient’s skin integrity is performed and documented every 12 hours. Full documentation in clinical information system comprises drop-down menu of descriptors of skin color, moisture, texture, edema, and turgor. Loss or alteration of skin integrity is documented along with management plans. The ICU nursing team leader is notified of any pressure injuries. Identified pressure injuries are staged by using an international pressure injury staging system. Digital images of the skin integrity loss will be taken. Images uploaded and attached to the patient’s record in clinical information system noting the wound location, size, and depth; description of the wound bed and periwound; the amount and type of exudates; and the presence of tunneling and degree of undermining.

### B. Strategies to prevent pressure injuries

1. Skin hygiene: Patients bed-bathed once per day, unless otherwise clinically indicated, using a pH-balanced cleansing agent (prepackaged cloth containing 2% chlorhexidine and 1% dimethicone). Dry flaky skin treated with a topical moisturizer.

2. Turning schedule: A 3-hourly minimum turning schedule using a “turn team” and according to a “turn clock.” Where possible, patients are repositioned left lateral-supine-right lateral. Where clinically tolerated, lateral positioning is a full lateral turn. Foam wedges are used to maintain the patient’s position. Where clinically indicated, patients are repositioned more frequently than every 2 hours.

3. Elimination of pressure and friction related to mucosal pressure injury development: On admission, patients are placed on either a nonpowered pressure-redistribution support surface, a dynamic powered alternating pressure support surface, or another support surface (eg, spinal support surface) based on nurse’s clinical judgment. Support surface changed as required depending on patient’s need. Clinical examination of the nares, lips, and mouth for loss of skin integrity is performed and documented on the clinical information system; allocation to pressure-relieving mattress or specialty device is based on risk score.

### C. Protection against forces of pressure and friction

1. Maintenance of stable skin temperature: Skin contact with plastic surfaces is avoided. Patient is repositioned per section B, item 2.

2. Optimize nutritional status: Nutritional status assessment is undertaken by a dietician.

3. Promotion of mobility: Where clinically possible, patients are mobilized daily to sit out of bed. Bedside nurses liaise with the ICU physiotherapy team.

<table>
<thead>
<tr>
<th>Intervention group–InSPiRE bundle8,10,11</th>
<th>Control group: standard skin care</th>
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<tr>
<td><strong>A. Assessment of skin integrity</strong></td>
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<td>1. Skin assessment on admission: Waterlow score tool (site modified for ICU patients with no reported reliability or validity testing) completed in first 24 hours and documented on the clinical information system; allocation to pressure-relieving mattress or specialty device is based on risk score.</td>
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<tr>
<td>2. Ongoing assessment: Physical assessment of patient’s skin integrity is performed and documented every 12 hours. Full documentation in clinical information system comprises drop-down menu of descriptors of skin color, moisture, texture, edema, and turgor. Loss or alteration of skin integrity is documented along with management plans. The ICU nursing team leader is notified of any pressure injuries. Identified pressure injuries are staged by using an international pressure injury staging system. Digital images of the skin integrity loss will be taken. Images uploaded and attached to the patient’s record in clinical information system noting the wound location, size, and depth; description of the wound bed and periwound; the amount and type of exudates; and the presence of tunneling and degree of undermining.</td>
<td>2. Ongoing assessment: Patient’s skin assessment is completed daily. Documented in clinical information system as intact or not intact; the only recording option available.</td>
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**B. Strategies to prevent pressure injuries**

1. Skin hygiene: Patients bed-bathed between 4 AM and 6 AM and again in early evening. Cleansing agent is basin bowl of water and pH-balanced soap-free skin cleanser or surgical sponges. There is no policy for application of topical moisturizer.

2. Turning schedule: Patient repositioning turning regimen is every 2 to 4 hours as determined by the bedside nurse’s clinical judgment of patients’ repositioning needs.

3. Elimination of pressure and friction related to development of mucosal pressure injury: On admission, patients are placed on either a non-powered pressure-redistribution support surface, a dynamic powered alternating pressure support surface, or another support surface (eg, spinal support surface) based on nurse’s clinical judgment. Support surface changed as required depending on patient’s need. Skin surrounding the nasogastric and endotracheal tubes is assessed every 12 hours. There is no policy for repositioning nasogastric or endotracheal tubes.

**C. Protection against forces of pressure and friction**

1. Maintenance of stable skin temperature: Skin contact with plastic surfaces is avoided.

2. Optimize nutritional status: Nutritional status assessment is undertaken by a dietician.

3. Promotion of mobility: There is no policy to mobilize patients to sit out of bed.
10% of data were cross-checked for accuracy. Descriptive statistics were calculated for all variables (means and standard deviations for continuous variables; frequencies and percentages for categorical variables). The cumulative incidence of pressure injuries was calculated by dividing the total number of new cases of pressure injuries, multiplied by 100, by the total number of participants in the time period.\(^3\)\(^1\)\(^-\)\(^3\)\(^2\)\(^3\)

Kaplan-Meier survival analysis was used to compare time to new pressure injury events between the 2 groups. A \(\chi^2\) test of independence was used to determine differences in stages of pressure injuries and to determine differences in process of care practices delivered between the groups. Logistic regression analysis was used to adjust for confounders.\(^3\)\(^3\)

**Results**

**Sample**

Of the total sample of 207 participants recruited, 102 with 843 days of observation were in the control group and 105 with 855 days of observation were in the intervention group. Table 2 provides an overview of the patient and process characteristics of the 2 groups. Most patients in both the intervention group and the control group were men. Groups were similar in all demographic characteristics.
<table>
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<th>Characteristic</th>
<th>Control (n = 102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%) of patients</td>
<td>62 (60.8)</td>
</tr>
<tr>
<td>Age, mean (SD, IQR), y</td>
<td>54 (18.0, 38-66)</td>
</tr>
<tr>
<td>Body mass index, mean (SD, IQR)</td>
<td>26.5 (5.34, 23.6-28.1)</td>
</tr>
<tr>
<td>Admission via emergency department</td>
<td>54</td>
</tr>
<tr>
<td>Transfer from general care area or other hospital</td>
<td>41</td>
</tr>
<tr>
<td>Hours in operating room, mean (SD, IQR)</td>
<td>4.4 (2.01, 3-5.5)</td>
</tr>
<tr>
<td>Hours in emergency department, mean (SD, IQR)</td>
<td>2.6 (1.53, 1.5-4)</td>
</tr>
<tr>
<td>Comorbid conditions, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>15 (14.7)</td>
</tr>
<tr>
<td>Non–insulin-dependent diabetes</td>
<td>18 (17.6)</td>
</tr>
<tr>
<td>Smoking</td>
<td>2 (2.0)</td>
</tr>
<tr>
<td>Insulin-dependent diabetes</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (11.8)</td>
</tr>
<tr>
<td>Nil</td>
<td>53 (52.0)</td>
</tr>
<tr>
<td>Missing</td>
<td>10 (9.8)</td>
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<tr>
<td>Diagnosis, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Neurological trauma/bleeding</td>
<td>29 (28.4)</td>
</tr>
<tr>
<td>Neurological disorders (tumor, seizures, meningitis, stroke, Guillain Barré syndrome)</td>
<td>9 (7.5)</td>
</tr>
<tr>
<td>Respiratory failure (pneumonia, chronic obstructive pulmonary disease, pulmonary embolism, pulmonary edema)</td>
<td>17 (16.7)</td>
</tr>
<tr>
<td>Trauma</td>
<td>13 (12.7)</td>
</tr>
<tr>
<td>Sepsis</td>
<td>12 (11.8)</td>
</tr>
<tr>
<td>Cardiovascular disorders (cardiac arrest)</td>
<td>2 (2.0)</td>
</tr>
<tr>
<td>Renal and metabolic disorders (failure, drug overdose/toxicity)</td>
<td>5 (4.9)</td>
</tr>
<tr>
<td>Abdominal disorders (trauma, hemorrhage, pancreatitis, abdominal aortic aneurysm)</td>
<td>15 (14.7)</td>
</tr>
<tr>
<td>Days in intensive care unit, mean (SD, IQR)</td>
<td>9.9 (9.60, 4-13)</td>
</tr>
<tr>
<td>Daily SOFA score, mean (SD, IQR)</td>
<td>4.1 (2.97, 2-6)</td>
</tr>
<tr>
<td>Discharged to general care area</td>
<td>93</td>
</tr>
<tr>
<td>Death</td>
<td>9</td>
</tr>
<tr>
<td>Number of days observed</td>
<td>843</td>
</tr>
<tr>
<td>Mechanical ventilation, mean (SD, IQR), % of observed days</td>
<td>47.7 (38.8, 0-83)</td>
</tr>
<tr>
<td>Highest daily temperature, mean (SD, IQR), °C</td>
<td>37.3 (0.6, 37.3-38.2)</td>
</tr>
<tr>
<td>Lowest daily temperature, mean (SD, IQR), °C</td>
<td>36.2 (0.6, 36.2-37.0)</td>
</tr>
<tr>
<td>Daily serum albumin, mean (SD, IQR), g/L</td>
<td>27.1 (5.0, 24.8-31.1)</td>
</tr>
<tr>
<td>Daily white blood cell count, mean (SD, IQR), $\times 10^9$/L</td>
<td>12.3 (4.6, 8.8-14.1)</td>
</tr>
<tr>
<td>Steroid administration, mean (SD, IQR), % of observed days</td>
<td>25.1 (39.4, 0-50)</td>
</tr>
<tr>
<td>Vasoactive drug administration, mean (SD, IQR), % of observed days</td>
<td>17 (27.7, 0-25)</td>
</tr>
<tr>
<td>Type of support surface used, No. (%) of patients</td>
<td></td>
</tr>
<tr>
<td>Nonpowered pressure redistribution</td>
<td>55 (53.9)</td>
</tr>
<tr>
<td>Dynamic powered alternating pressure</td>
<td>31 (30.4)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (13.7)</td>
</tr>
<tr>
<td>Patient bed-bathed once per 24 hours, mean (SD, IQR), % of observed days</td>
<td>92.7 (15.8, 95-100)</td>
</tr>
<tr>
<td>Patient repositioned every 3 hours, mean (SD, IQR), % of observed days</td>
<td>57.5 (30.8, 0-80)</td>
</tr>
<tr>
<td>Heel protectors used, mean (SD, IQR), % of observed days</td>
<td>27.2 (35.5, 0-63)</td>
</tr>
<tr>
<td>Exposed skin protected, mean (SD, IQR), % of observed days</td>
<td>2.4 (14.4, 0-0)</td>
</tr>
<tr>
<td>Mobilized to sit out of bed, mean (SD, IQR), % of observed days</td>
<td>22.5 (31.3, 0-34)</td>
</tr>
</tbody>
</table>

Abbreviation: IQR, interquartile range; SOFA, Sequential Organ Failure Assessment.

* Calculated as weight in kilograms divided by height in meters squared.
* Data were missing for 6 patients.
* Total of 19 patients, but data were missing for 3 patients.
* Data were missing for 2 patients.
* Total of 19 patients, but data were missing for 2 patients.
* Total of 38 patients, but data were missing for 4 patients.
* Data were missing for 2 patients.
except body mass index and number of comorbid conditions and in all clinical characteristics except for serum albumin level. Further, patients in the intervention group were more frequently placed on nonpowered pressure redistribution support surfaces ($P < .001$).

**Hypothesis 1**

The cumulative incidence of pressure injuries was significantly different ($\chi^2 = 4.3, P = .04$) between the intervention group (18.1%, 19/105 patients) and the control group (30.4%, 31/102 patients).

**Hypothesis 2**

Table 3 provides an overview of the demographic and clinical characteristics of patients with pressure injuries. Nineteen patients in the intervention group had 24 pressure injuries develop, compared with 31 patients with 64 pressure injuries in the control group. The intervention group had significantly fewer pressure injury events develop over time (log rank [Mantel-Cox] = 11.842, $df = 1$, $P \leq .001$; Figure 2).

**Hypothesis 3**

Table 3 presents descriptions of the pressure injuries that developed. Most patients in the intervention group had only 1 pressure injury and fewer skin injuries (stage II-IV; 4/105) than patients in the control group (17/102). Pressure injuries located on the heel were significantly more common in the control group ($P = .02$). For both groups, skin pressure injuries were located most commonly on the sacrum (Table 3). Mucous injuries occurred significantly less often in the intervention group (15 injuries in 19 patients) than the control group (39 injuries in 31 patients; $P < .001$). In both groups, mucous injuries on the lip and nare were respectively related to the presence of an endotracheal tube or a nasogastric tube. These injuries were classified as medical device-related injuries.

**Hypothesis 4**

Processes of care for assessment of skin integrity did not differ between groups. Both groups completed 98% of admission skin assessments and documentation within required time frames (control group within 24 hours; intervention group within 4 hours) and ongoing assessment and documentation (control group, every 24 hours; intervention group, every 12 hours). Documentation of nare, lip, and mouth examination every 12 hours occurred on 91% of days observed for both groups. In the intervention group, patients’ devices (nasogastric and endotracheal tubes) were repositioned every 12 hours for 76% of days observed and in the
### Table 3: Demographic and clinical characteristics of patients with pressure ulcers

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n = 31)</th>
<th>Intervention (n = 19)</th>
<th>Statistic</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex, No. (%) of patients</td>
<td>20 (65)</td>
<td>10 (53)</td>
<td>$\chi^2 = 0.7$</td>
<td>.30</td>
</tr>
<tr>
<td>Age, mean (SD, IQR), y</td>
<td>50 (17.99, 36-62)</td>
<td>53.5 (19.5, 19-80)</td>
<td>$t = -0.63$</td>
<td>.54</td>
</tr>
<tr>
<td>Body mass index,$^a$ mean (SD, IQR)</td>
<td>22.6 (7.01, 23.7-27.8)</td>
<td>27 (6.7, 22.3-28.4)</td>
<td>$U = 275$</td>
<td>.84</td>
</tr>
<tr>
<td>Days in intensive care unit, mean (SD, IQR)</td>
<td>19.2 (12.2, 12-25.5)</td>
<td>17.4 (7.6, 13.5-22)</td>
<td>$U = 292.5$</td>
<td>.97</td>
</tr>
<tr>
<td>Daily SOFA score, mean (SD, IQR)</td>
<td>4.2 (2.4, 2-6)</td>
<td>4.5 (2.5, 2-6)</td>
<td>$\chi^2 = 0.7$</td>
<td>.30</td>
</tr>
<tr>
<td>Admission via emergency department</td>
<td>20</td>
<td>11</td>
<td>$\chi^2 = 0.0$</td>
<td>.88</td>
</tr>
<tr>
<td>Transfer from general care area or other hospital</td>
<td>14</td>
<td>10</td>
<td>$\chi^2 = 0.3$</td>
<td>.61</td>
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<tr>
<td>Comorbid conditions, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>6 (19)</td>
<td>6 (32)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non–insulin-dependent diabetes</td>
<td>9 (29)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>1 (3)</td>
<td>4 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>15 (48)</td>
<td>9 (47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological trauma/bleeding</td>
<td>10 (32)</td>
<td>8 (42)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neurological disorders (tumor, seizures, meningitis, stroke, Guillian Barré syndrome)</td>
<td>5 (16)</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory failure (pneumonia, chronic obstructive pulmonary disease, pulmonary embolism, pulmonary edema)</td>
<td>6 (19)</td>
<td>4 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trauma</td>
<td>5 (16)</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sepsis</td>
<td>2 (6)</td>
<td>1 (5)</td>
<td></td>
<td></td>
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<tr>
<td>Cardiovascular disorders (cardiac arrest)</td>
<td>0 (0)</td>
<td>2 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal and metabolic disorders (failure, drug overdose/toxicity)</td>
<td>3 (10)</td>
<td>2 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharged to general care area</td>
<td>26</td>
<td>17</td>
<td>$\chi^2 = 0.3$</td>
<td>.46</td>
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<tr>
<td>Death</td>
<td>5</td>
<td>2</td>
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<td></td>
</tr>
<tr>
<td>Number of days observed</td>
<td>843</td>
<td>855</td>
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<tr>
<td>Type of support surface used, No. (%) of patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Nonpowered pressure redistribution</td>
<td>15 (48)</td>
<td>13 (68)</td>
<td>$\chi^2 = 1.9$</td>
<td>.39</td>
</tr>
<tr>
<td>Dynamic powered alternating pressure</td>
<td>10 (32)</td>
<td>3 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4 (13)</td>
<td>2 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of pressure injuries</td>
<td>64</td>
<td>24</td>
<td>$t = 3.27$</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Number of pressure injuries per patient, No. (%) of patients</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>11 (35)</td>
<td>15 (79)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>10 (32)</td>
<td>3 (16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>7 (23)</td>
<td>1 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>3 (10)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. (%) of patients with skin ulcers</td>
<td>24 (77)$^b$</td>
<td>9 (47)$^b$</td>
<td></td>
<td></td>
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<tr>
<td>Skin ulcer stage, No. (%) of pressure injuries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>8 (12)</td>
<td>5 (21)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>16 (25)</td>
<td>4 (17)</td>
<td>$\chi^2 = 0.3$</td>
<td>.42</td>
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<tr>
<td>Ill and IV</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
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<tr>
<td>Skin ulcer location, No. (%) of pressure injuries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Occiput</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
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<tr>
<td>Wrist</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elbow</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
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</tr>
<tr>
<td>Ischium</td>
<td>0 (0)</td>
<td>1 (4)</td>
<td></td>
<td></td>
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<tr>
<td>Sacrum</td>
<td>8 (12)</td>
<td>8 (33)</td>
<td></td>
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<tr>
<td>Buttock</td>
<td>1 (2)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heel</td>
<td>11 (17)</td>
<td>0 (0)</td>
<td>$\chi^2 = 4.7$</td>
<td>.02</td>
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<tr>
<td>No. (%) of patients with mucosal injuries</td>
<td>31 (100)$^b$</td>
<td>15 (79)$^b$</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucosal injuries, No. (%) of pressure injuries</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nare</td>
<td>22 (34)</td>
<td>4 (17)</td>
<td>$\chi^2 = 2.6$</td>
<td>.08</td>
</tr>
<tr>
<td>Lip</td>
<td>14 (22)</td>
<td>9 (38)</td>
<td>$\chi^2 = 2.2$</td>
<td>.11</td>
</tr>
<tr>
<td>Tongue</td>
<td>2 (3)</td>
<td>0 (0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ear</td>
<td>1 (2)</td>
<td>2 (8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: IQR, interquartile range; SOFA, Sequential Organ Failure Assessment.

$^a$ Calculated as weight in kilograms divided by height in meters squared.

$^b$ Some patients had both skin ulcers and mucosal injuries develop.
collection through databases, and surveys. Also importantly, intensive care workload organizational practices (eg, staff to patient ratio) vary from country to country, and patient skin care practices vary from ICU to ICU, further confounding the issue.\(^8,31\)

Pressure Injury Type, Severity, and Development

Implementation of the InSPiRE protocol resulted in the intervention group having significant reduction in the severity of skin pressure injuries and taking a longer time for pressure injuries to develop. This study is the first to report a successful intervention to reduce medical device–related injuries, an underreported phenomenon. Coyer and colleagues\(^37\) recently conducted a comparative audit of medical device–related injuries in critically ill patients in ICUs in Australia and the United States. Their results showed a 3.1% prevalence of medical device–related injuries (15/483) with 6.1% (8/132) in the Australian sample and 2.0% (7/351) in the US sample.\(^37\) The incidence of medical device–related injuries was higher in our study (control group, 39 injuries in 31 patients); however, our study was conducted before the Coyer comparative audit.

Discussion

This study presents compelling results to demonstrate that the InSPiRE protocol, an evidence-based bundle of strategies for preventing pressure injuries, resulted in the intervention group showing reduced cumulative incidence of ICU-acquired pressure injuries, fewer pressure injuries per patient, and development of pressure injuries later in the ICU stay. Cumulative incidence was lower regardless of whether we examined skin injuries, mucous injuries, or a combination of skin and mucous injuries. Most research on pressure injuries has examined only skin injuries, and our results for skin injury only (8.6%; 9/105) were similar to results of other international studies, which reported rates of hospital-acquired pressure injuries of 10.4% (2003),\(^34\) 1.8% (2010),\(^34\) 7.5% to 14.3% (2012),\(^35\) and 12% (2012).\(^36\)

This study is also the first Australian study to show that assessment of both traditional skin pressure injuries and mucous injuries, combined with a bundle (InSPiRE protocol), is successful in reducing device-related mucous injuries. Further, our results show a marked reduction in the incidence of pressure injuries from 30% to 18%, with this rate now comparable to recent data from the National Pressure Ulcer Advisory Panel.\(^8,34\) Estimates of rates of pressure injury development in various ICUs and countries differ widely for a number of reasons. For example, studies have employed different methods including direct clinical examination of patients, use of retrospective data control group for 28% of days observed (\(P<.001\)). There was no difference between groups in frequency of bed baths (intervention group, 1.49 bed baths/day; control group, 1.46 bed baths/day) or the application of moisturizer to dry skin (11.7% of days for both the intervention group and the control group). However, patients were more likely to be bathed only once per day in the intervention group (96.2% of days vs 72.5% of days in the control group; \(\chi^2_1 = 22.1, P<.001\)). Positioning care practices, frequency and type of position, were significantly different between groups. Intervention group patients were repositioned every 3 hours for 83% of days observed versus 51% of days observed for patients in the control group (\(\chi^2_1 = 171.5, P<.001\)). In the intervention group, patients were positioned at least once in a full lateral turn for 23% of days observed versus 2% of days observed for patients in the control group (\(P<.001\)). Mobilizing the patient to sit out of bed did not differ between groups. Use of heel protectors was significantly different between groups (intervention group for 41% of days; control group for 27% of days; \(\chi^2_1 = 5.9, P = .02\)).

This study is the first to report a successful intervention to reduce medical device–related injuries.
study. Systematic and regular assessment of the patient’s skin and mucous membranes where devices are situated combined with regular repositioning of devices is fundamental to reducing the incidence of medical device–related injuries.

**Process of Care Measures**

Our study provides valuable insight into the operational implementation of the intervention, the InSPiRE protocol. Soban and colleagues\(^3\) conducted a systematic review of studies from 1990 to 2009 reporting nurse-focused quality improvement interventions to reduce pressure injuries in hospitals. They noted failure of implementation studies to measure and report process of care (only 6 of 39 studies reported this).\(^3\) The process of care measures reported for the InSPiRE protocol showed that patients were repositioned more frequently, had their devices checked and repositioned more often, and had their heels elevated more often than patients in the control group, thus verifying our protocol implementation. Interestingly, although skin assessment processes did not differ between groups, the time frames for clinical assessment of patients on admission and for the remainder of the patient’s stay were reduced for those patients who received the intervention protocol (4 vs 12 hours). It is accepted that all patients should have an admission risk assessment to determine potential risk of pressure injuries developing as well as regular comprehensive skin assessment to detect existing or potential pressure injuries.\(^1\,\,^3\,\,^5\,\,^8\)

Waterlow is the risk assessment tool most commonly used for pressure injuries in Queensland, Australia. Webster et al\(^3\) completed a single-center blind randomized controlled trial, enrolling 1231 patients admitted to internal medicine or oncology services to 3 groups for assessment of risk of pressure injuries: Waterlow (n = 410), Ramstadius (n = 411), or clinical judgment (n = 410). The authors found that group allocation had no effect on subsequent management of those patients in whom pressure injuries developed or who were at risk of a pressure ulcer developing. Subsequently, the research site in our study implemented nurses’ clinical judgment to determine the risk for pressure injuries as a facility-wide policy,\(^5\) and that was included in the InSPiRE protocol.

Chaboyer et al\(^5\) reported that improvements in ICU safety culture (eg, prevention of pressure injuries) require high uniformity and reliability of process implementation. Our study shows that use of a protocol directly targeted at critically ill patients and containing multiple strategies to reduce development of pressure injuries was successfully translated into nurses’ bedside care practices. Use of a protocol, supported by education and ongoing support, raises clinicians’ awareness of the problem. Two other recent studies\(^10,\,\,^11\) support this, reporting reduction in the prevalence of pressure injuries when structured themed education and feedback are used. Ongoing feedback on performance and incidence rates further draws the problem of development of pressure injuries to the forefront of clinicians’ thinking.

**Limitations**

Replication is needed to confirm our findings in other studies and preferably in other contexts. The InSPiRE protocol, developed specifically for critically ill patients, is context specific to the ICU where it was implemented. We acknowledge that the lack of data on pressure injury risk assessment scores for the intervention group is a limitation. Formal risk assessment is a recommendation in current pressure injury prevention guidelines to ensure that all patients are assessed with reliable valid criteria. The potential benefit and applicability of this protocol warrants adaptation and testing in other intensive care populations. We recommend testing the protocol in a large multicenter cluster randomized controlled trial.

**Conclusion**

This study tested a protocol, InSPiRE, to reduce development of pressure injuries in critically ill ICU patients. Overall, InSPiRE was successful in reducing the cumulative incidence, severity, and type of pressure injuries in the intervention group. Further, this study measured and reported processes of care, thus assisting in understanding the mechanisms of the intervention. This is the first study to use a protocol to prevent medical device–related injuries, showing a significant reduction in these iatrogenic injuries. We suggest that the InSPiRE protocol is effective in reducing pressure injuries; however, further investigation is warranted to explore the protocol in different ICU organizational contexts and specific populations of critically ill patients.

**ACKNOWLEDGMENTS**

The authors gratefully acknowledge the work of the registered nurses who assisted with data collection (Robyn Strachan, Rachael Dunlop, Simona Asomah-Hartl, Lorraine Walker, Stephanie Deller, and Lorraine Dyer). We thank the patients who participated in this study and the nurses who implemented the protocol. Sincere thanks are extended to Emeritus Professor Nancy Stotts, University of Cali-
REFERENCES


To purchase electronic or print reprints, contact the American Association of Critical-Care Nurses, 101 Columbia, Aliso Viejo, CA 92656. Phone, (800) 899-1712 or (949) 362-2050 (ext 532); fax, (949) 362-2049; e-mail, reprints@aacn.org.
1. According to the study, which of the following is the mean increase in the length of stay for patients with pressure injuries compared with patients without pressure injuries?
   a. 4.3
   b. 2.5
   c. 3.6
   d. 4.0

2. Which of the following is the estimated annual cost to treat pressure injuries in the United States?
   a. $11 million
   b. $14 billion
   c. $11 billion
   d. $14 million

3. Which of the following was the length of this study?
   a. 24 months
   b. 6 months
   c. 18 months
   d. 12 months

4. According to the study, which of the following disciplines provided all the patient care?
   a. Certified Nurse Assistants
   b. Registered Nurses
   c. Licensed Practical Nurses
   d. Physicians

5. The Sequential Organ Failure Assessment (SOFA) score is a tool to determine the extent of a patient’s organ function or failure in the intensive care unit (ICU). The SOFA score can range from 0 to which of the following total points?
   a. 12
   b. 20
   c. 15
   d. 24

6. According to the InSPIRE bundle, how many times a day was the intervention group bathed?
   a. Three times daily
   b. As needed
   c. Twice daily
   d. Once daily

7. Which of the following is the number of participants in the control group?
   a. 105
   b. 102
   c. 108
   d. 110

8. Which of the following was the control group’s most common area of pressure injury?
   a. Sacrum
   b. Ankle
   c. Trochanter
   d. Heel

9. How often did the documentation of nares, lip, and mouth by registered nurses occur in both groups?
   a. Every 6 hours
   b. Every 12 hours
   c. Every 4 hours
   d. Every 2 hours

10. Which of the following mobilization therapies was done daily for both study groups?
    a. Dangle at the side of bed
    b. Active range of motion
    c. Ambulate in the halls
    d. Sit out of bed

11. According to Table 2, which of the following was the most prevalent diagnosis?
    a. Cardiovascular disorder
    b. Respiratory failure
    c. Sepsis
    d. Neurological trauma

12. Which of the following is directly related to the number of pressure injuries that occur during hospitalization?
    a. Mechanical ventilation
    b. Quality of care
    c. Hypertension
    d. Transfer of care from a general care area

---

**Program evaluation**

<table>
<thead>
<tr>
<th>Objective 1 was met</th>
<th>Objective 2 was met</th>
<th>Objective 3 was met</th>
<th>Content was relevant to my nursing practice</th>
<th>My expectations were met</th>
<th>This method of CE is effective for this content</th>
<th>The level of difficulty of this test was:</th>
<th>To complete this program, it took me _____ hours/minutes.</th>
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**Test: CE Test A1524033: Reducing Pressure Injuries in Critically Ill Patients by Using a Patient Skin Integrity Care Bundle (InSPIRE)***

**Learning objectives:*** 1. Identify the need for clinical assessment of patients’ skin on admission. 2. Discern strategies to prevent pressure injuries. 3. Discuss successful implementation of protocols to prevent pressure injuries.

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**Fee: AACN members, $0; nonmembers, $10  Passing score: 9 correct (75%)  Category: CERP A  Test writer: Darlene Pileski, CRNP, ACNP-BC**

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**The American Association of Critical-Care Nurses is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation. AACN has been approved as a provider of continuing education in nursing by the State Boards of Nursing of Alabama (#ABNP0062), California (#CEP1036), and Louisiana (#LSBN12). AACN programming meets the standards for most other states requiring mandatory continuing education credit for relicensure.**
VALIDATION OF THE RIGHTLEVELPH DETECTOR FOR MONITORING GASTRIC pH

By Charles R. Lambert, MD, PhD, MBA, David Varlotta, DO, Marjorie Posey, BSN, Jadie L. Heberlein, BSN, MPH, and Janice M. Shirley, MPH, MBA

**Background** The RightLevelpH indicator is a new device designed to measure the pH of gastric aspirate obtained via a nasogastric tube while minimizing exposure of the operator.

**Objective** To validate the RightLevelpH indicator in vivo and in vitro.

**Methods** With general anesthesia, 20 patients had placement of a nasogastric tube and a gastric pH electrode catheter after endotracheal intubation. Direct intragastric pH was recorded simultaneously with gastric aspirate pH by using the RightLevelpH indicator and by using an external pH electrode. Measurements were made every 30 minutes until removal of the nasogastric tube as indicated clinically. In vitro validation of the RightLevelpH indicator was performed by using standard buffer solutions.

**Results** The pH of clear buffer solutions was linearly related to pH determined by the RightLevelpH indicator ($R^2 = 0.99; P < .001$). The pH of gastric aspirate determined with an external pH electrode was linearly related to the gastric aspirate pH determined by using the RightLevelpH indicator ($R^2 = 0.92; P < .001$). Intragastric pH determined with the catheter electrode was also linearly related but more loosely correlated with gastric aspirate pH determined by using an external pH electrode ($R^2 = 0.52; P < .001$) and by the RightLevelpH indicator ($R^2 = 0.55; P < .001$).

**Conclusions** The RightLevelpH indicator provides accurate measurements of the pH of gastric aspirate in patients. (American Journal of Critical Care. 2015;24:211-215)
Monitoring gastric pH may be useful in preventing stress ulcers and gastrointestinal bleeding, especially in critically ill patients.\(^1,2\) In an intensive care unit, gastric pH can be determined by using either an electrode or indicator paper. The RightLevelpH detector is a new device with indicator paper technology that attaches to the proximal end of a standard nasogastric tube for measuring aspirate pH while minimizing potential exposure to body fluids (Figures 1 and 2). This device provides a closed system for aspiration of fluid (1 mL) that flows over the indicator paper visualized in the window of the detector. The color change of the indicator paper is compared with a color scale next to the window on the device (Figure 1). The device is discarded after use.

In this study, we compared pH measurements obtained by using an intragastric catheter pH electrode with pH measurements of gastric aspirate determined by using an external pH electrode and the RightLevelpH detector in patients. This study is the first in vivo human validation study for this device.

**Methods**

The study was approved by the institutional review board at Florida Hospital Tampa. From January to July 2012, patients were included in the study if they were 21 years or older, were scheduled for a planned elective procedure requiring general anesthesia with endotracheal intubation and placement of a nasogastric tube, and were able to give informed consent. The only exclusion criterion was the presence of grossly bloody aspirate.

A standard nasogastric tube was secured by suture to a pH electrode catheter (Versaflex, Given Imaging) and introduced orally by the attending anesthesiologist after endotracheal intubation. Before placement, the pH catheter was calibrated by using buffer solutions per the manufacturer’s direction. Auscultation was also routinely done after tube placement.

When a set of measurements were obtained, pH was determined first by using the intragastric pH electrode catheter and recorded and then by aspirating gastric contents via the nasogastric tube through the RightLevelpH indicator into a syringe. The RightLevelpH indicator measurement was recorded, and then gastric aspirate remaining in the syringe was placed into a container for pH determination via the external electrode. This electrode (Model 1112000, Thermo Scientific Environmental Instruments) was calibrated by using buffer solution before each measurement.

All operators were previously tested for color blindness (Ishihara color vision test). Measurements of pH were then repeated at 30-minute intervals until the nasogastric tube was removed.

Linear regression was used to compare direct intragastric pH measurements with pH values obtained by using the RightLevelpH indicator and the external laboratory pH electrode. Similarly, the RightLevelpH indicator value was compared with the aspirate pH measurement obtained by using the external laboratory pH electrode. An in vitro validation study was done by using standard clear buffer solutions of pH 2 to pH 7. A total of 83

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**Figure 1** The RightLevelpH indicator connects to the proximal end of a standard nasogastric tube, allowing aspiration of fluid into a chamber containing pH-indicating paper. The pH-indicating paper is visualized through a clear window and the color is compared with a color pH scale. The device allows aspiration of fluid in a closed system that can be easily discarded.

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**About the Authors**

Charles R. Lambert is the medical director of Florida Hospital Tampa Pepin Heart Institute and the Dr Kiran C. Patel Research Institute, Tampa, Florida, and professor of medicine, Division of Cardiovascular Medicine, University of Florida, Gainesville, Florida. David Varlotta is a staff anesthesiologist, Marjorie Posey and Jadie L. Heberlein are clinical research nurses, and Janice M. Shirley is administrative director of research, Florida Hospital Tampa Pepin Heart Institute and the Dr Kiran C. Patel Research Institute.

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measurements of buffer solution pH were made in blinded fashion with the RightLevelpH indicator, and data were analyzed in the same manner as data for the in vivo comparisons.

Values for pH measured by using electrodes were recorded to 0.01 unit, whereas values for pH measured by using the RightLevelpH indicator were recorded as 1, 2, 3, 4, 5, or 6 or more.

Results

A total of 28 patients consented to participate in the study. The patients were sequential and were approached for participation during the preoperative visit. Patients were not given proton pump inhibitors or antacids and had nothing by mouth after midnight before their procedure as standard clinical practice. Data were collected from 20 patients; the other patients were excluded because of no aspirate, bloody aspirate, or the surgeon’s request. No complications occurred during the study.

As noted earlier, measurements were made until use of the nasogastric tube was discontinued as indicated clinically. In total, 154 measurement periods were recorded in 20 patients. The number of measurement periods for a given patient ranged from 2 to 10 (mean, 14; SE, 7). Thus, the duration of use of a nasogastric tube in these elective surgical patients ranged from 1 hour to 20 hours. Intragastric electrode measurements were recorded for all 154 periods, RightLevelpH measurements were made for 130 periods, and external pH measurements were made for 120 periods. These differences were due to the volume of available gastric aspirate.

Results for the in vitro validation revealed a significant linear relationship between RightLevelpH indicator determinations (n=83) and actual pH of clear buffer solutions \( (P = .001) \), where the best-fit line was RightLevelpH = 1.01 (actual pH) - 0.02 with \( R^2 = 0.99 \).

The relationship between the pH of 120 gastric aspirate samples determined by using an external pH electrode and by using the RightLevelpH indicator is illustrated in Figure 3. The gastric aspirate was placed into a small sampling beaker into which the pH electrode was placed after calibration of the electrode according to standard laboratory technique. A highly significant linear relationship is apparent between the 2 methods, validating pH determination of gastric aspirate by the RightLevelpH indicator compared with determination via a standard laboratory pH electrode.

Figure 4 shows the relationship between intragastric pH determined by using a catheter electrode and the pH of gastric aspirate determined with the

![Figure 2](image_url) Use of the RightLevelpH indicator as described in the text.

![Figure 3](image_url) Relationship between measurements of pH of gastric aspirate obtained with a laboratory pH electrode and with the RightLevelpH indicator. Dotted lines indicate the 95% CIs for the linear regression. Best-fit line: \( \text{pH by external pH electrode} = 1.29 \times \text{pH by RightLevelpH indicator} - 0.61 \).
RightLevelpH indicator. Figure 5 depicts the relationship between intragastric pH determined by using a catheter electrode and measurements obtained with both external determination methods.

**Discussion**

Determining the pH of gastric aspirate has been of interest primarily in the context of preventing stress ulcers and placing nasogastric tubes. Methods for determining the pH of gastric aspirate have most commonly entailed use of either indicator paper or a pH electrode. In direct measurement of intragastric pH, a catheter or capsule-based method is used. Use of pH indicator paper or a pH electrode at the bedside requires aspiration of gastric contents and subsequent handling of the sample to directly touch the indicator paper or pH electrode. After measurement, disposal of the sample and associated hardware as well as cleaning and storage of the pH electrode and meter are required.

The RightLevelpH was designed to offer a quick, inexpensive solution for determining pH without the use of complicated electrode-based pH equipment and for avoiding contact with gastric aspirate. We validated the RightLevelpH system in vitro by using buffers and by comparing measurements of gastric aspirate pH with simultaneous pH measurements obtained with a pH electrode on the same samples. In addition, measurements obtained with the RightLevelpH system correlated with direct measurements of intragastric pH via a catheter electrode.

The correlation between intragastric pH determined by using a catheter electrode and values of gastric aspirate pH measured externally by using either an electrode or the RightLevelpH indicator was less than the correlation between pH measurements obtained by using an external pH electrode and measurements obtained via the RightLevelpH indicator. This finding is not surprising when the observations of others are considered and may be due to regional differences in gastric pH and contact of the electrode catheter with the mucosa. The RightLevelpH indicator offers accurate determination of gastric aspirate pH equivalent to that of pH electrode determinations in patients.

**FINANCIAL DISCLOSURES**

This work was supported by a grant from RightBio Metrics, Scottsdale, Arizona.
REFERENCES


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12. Gunnarsdóttir A, Stenström P, Arnbjörnsson E. Wireless and click “Responses” in the second column of either the online discussion on this topic. Visit www.ajcconline.org and click “Responses” in the second column of either the online discussion on this topic. Visit


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USE OF A PATIENT HAND HYGIENE PROTOCOL TO REDUCE HOSPITAL-ACQUIRED INFECTIONS AND IMPROVE NURSES’ HAND WASHING

By Cherie Fox, RN, MSN, CCRN-CSC, Teresa Wavra, RN, MSN, CNS, CCRN, Diane Ash Drake, RN, PhD, Debbie Mulligan, RN, MSN, PHN, CIC, Yvonne Pacheco Bennett, RN, BSN, JD, CCRN, Carla Nelson, BSN, CIC, Peggy Kirkwood, RN, MSN, ACNPC, CHFN, AACC, Louise Jones, RN, MSN, CCRN, and Mary Kay Bader RN, MSN, CCNS

**Background** Critically ill patients are at marked risk of hospital-acquired infections, which increase patients’ morbidity and mortality. Registered nurses are the main health care providers of physical care, including hygiene to reduce and prevent hospital-acquired infections, for hospitalized critically ill patients.

**Objective** To investigate a new patient hand hygiene protocol designed to reduce hospital-acquired infection rates and improve nurses’ hand-washing compliance in an intensive care unit.

**Methods** A preexperimental study design was used to compare 12-month rates of 2 common hospital-acquired infections, central catheter–associated bloodstream infection and catheter-associated urinary tract infection, and nurses’ hand-washing compliance measured before and during use of the protocol.

**Results** Reductions in 12-month infection rates were reported for both types of infections, but neither reduction was statistically significant. Mean 12-month nurse hand-washing compliance also improved, but not significantly.

**Conclusions** A hand hygiene protocol for patients in the intensive care unit was associated with reductions in hospital-acquired infections and improvements in nurses’ hand-washing compliance. Prevention of such infections requires continuous quality improvement efforts to monitor lasting effectiveness as well as investigation of strategies to eliminate these infections. (American Journal of Critical Care. 2015;24:216-224)
Improving HCWs’ hand-washing practices is an effective method to reduce the prevalence of HAIs, and such improvement is identified by the California Department of Public Health as the first intervention to prevent HAIs. Many creative strategies have been investigated to monitor and improve HCWs’ hand-washing compliance, including the use of chlorhexidine gluconate (CHG) disinfectant. Baths with CHG were recommended by the Centers for Disease Control and Prevention to reduce the occurrence of HAIs and have been used as the primary bathing method in many hospitals for ICU patients since 2009. Adoption of CHG baths has not been established in all ICUs.

ICU patients experience many barriers to adequate hand hygiene for themselves, including immobility related to being connected to monitor cables and devices, lack of access to needed supplies, critical illness, confusion and delirium, and inconsistent hand hygiene practices by providers. In a study conducted in a mixed medical surgical unit, researchers reported that patients unable to wash their hands had their hands washed by nurses only 14% of the time. Many factors and beliefs influence why HCWs do not wash their hands or a patient’s hands: attitude, lack of awareness of outcomes, social pressure, control, and prior life experiences.

**Intended Improvement:**

**Patient Hand Hygiene Protocol**

The hospital in the present study (Mission Hospital) had not adopted the use of daily bathing with CHG because of concerns associated with the deactivation of skin care products used in the prevention and treatment of pressure ulcers. This concern was not supported by published reports, but was a concern raised by our skin care team. Because CHG baths were not adopted, the ICU’s shared governance council decided to continue soap and water baths and evaluate the use of 2% CHG wipes applied to patients’ hands 3 times a day as a method of reducing HAIs. The intervention was identified as the “patient hand hygiene protocol (PHHP).” CHG was chosen because it provides continuous microbial killing for up to 6 hours by disrupting the bacterial cells and causing cytoplasmic leak and cell death.
they enter and leave ICU patients’ rooms, and (4) conduct a study to evaluate rates of HAI (CLABSI and catheter-associated urinary tract infection [CAUTI]) and nurses’ hand-washing compliance rates before and after implementation of the PHHP.

The purpose of this quality improvement study was to answer 2 research questions.

1. Is the PHHP associated with decreased CLABSI and CAUTI rates in the ICU?
2. Is the PHHP associated with increased hand-washing compliance among ICU nurses?

**Methods**

The study was approved by the hospital’s institutional review board. Informed consent was waived because the study met the criteria for a quality improvement program.

**Setting**

The study was conducted in a 27-bed adult cardiovascular medical ICU at Mission Hospital in Mission Viejo, California, a 498-bed community hospital. The diagnoses of patients admitted to this unit included medical diagnoses (50%), cardiac diagnoses including open heart surgery (34%-39%), and surgical diagnoses (12%-14%). The mean annual ICU daily census was 22.2 patients, with seasonal fluctuations ranging from 12 to 27 patients. Staffing was based on ratios and acuity with a ratio of 1 nurse to 2 patients in most cases.

**Protocol Training**

A 10-week protocol phase-in period was scheduled by the study team for protocol training of ICU staff. All members of the nursing staff received verbal instructions from a study team member and were monitored for proper return demonstration of the protocol to improve consistency of their technique for hand hygiene. An electronic medical record “intervention” was created to trigger a timely reminder to perform the PHHP 3 times a day. The prompt in the electronic medical record also required nurses to document hand hygiene with a “yes” or “no” and to provide a comment response. If the nurse documented “no” (meaning the patient did not receive hand hygiene), the nurse was required to enter a comment explaining the rationale. Implementation and adherence were achieved through the 10-week training process, where study team members were present for each scheduled hand hygiene time (8 AM, 2 PM, and 8 PM). After the training period, auditing and observation were used to assess compliance. Resistance was met, as with any change, and was addressed on a 1-to-1 basis.

Figure 1 Hand hygiene protocol from the hand hygiene study.

A 2% CHG cloth (500 mg of CHG per cloth) was used for ICU patients’ hand hygiene 3 times a day (Figure 1). A quality improvement strategy was proposed to (1) train every nurse to demonstrate the PHHP competently, (2) monitor nurses’ use of the PHHP, (3) monitor nurses’ hand washing before
Implementation
The primary ICU nurse introduced the protocol to each patient and/or patient’s family, and a document explaining the protocol was added to each ICU patient’s admission packet. All patients admitted to the ICU were included in the study. Contraindications for CHG use included allergy to CHG, open wounds on hands, and/or other indications such as fissures or scales on hands. If CHG was contraindicated, a substitute nonrinse soap and wipes were used and a sign was posted outside the patient’s room indicating "no CHG."

Monitoring Protocol Adherence and Documentation of Skin Reactions
Two documents were created and maintained throughout the study period to assess and report nurses’ adherence to the PHHP.
1. Nurse documentation of protocol adherence: a daily report in the electronic medical record of the frequency of nurse documentation of yes, no, and provided comments to the PHHP.
2. Nurse adherence audit: a biweekly audit completed by a nurse on the study team observing frequency and timeliness of nurses’ completion of the PHHP. Report results were compared biweekly to measure nurses’ adherence to the protocol (Figure 2).

Protocol adherence was defined as washing the patient’s hands at 8 AM, 2 PM, and 8 PM. A 1-hour grace period for the nurse to wash the patient’s hands was established. Nurses were prompted with a time-sensitive reminder in the electronic medical record to document all 3 patient hand hygiene episodes, as well as assess the patient’s hands for cracking, fissures, scales, redness, and dryness during hand hygiene. The repeated use of CHG had the potential to remove protective substances on the surface of the hands, making the hands more pliable with greater risk for cracks and fissures. Skin assessment criteria originally developed by Frosch and Kligman to study skin reactions to soaps were adapted for the study to evaluate skin reactions to CHG use (Table 1). If skin

![Figure 2](https://example.com/image2.png)
Figure 2. Nurses’ adherence with the patient hand hygiene protocol (documentation audit) and biweekly observational audit for compliance.

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<th>Observational audit</th>
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![Table 1](https://example.com/image1.png)
Table 1. Criteria for assessment of skin reactions in a biweekly skin audit

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<td>1 Slight redness (spotty or diffuse)</td>
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<tr>
<td>2 Moderate redness (uniform redness)</td>
</tr>
<tr>
<td>3 Intense redness</td>
</tr>
<tr>
<td>4 Fiery red (with edema)</td>
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<td>2 Moderate</td>
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<tr>
<td>3 Severe</td>
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<table>
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<td>1 Fine cracks</td>
</tr>
<tr>
<td>2 Single or multiple cracks and/or broad fissures</td>
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<tr>
<td>3 Wide cracks with hemorrhage or exudate</td>
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<td>1 Yes</td>
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Reprinted from Frosch and Kligman, with permission from Elsevier.
and during implementation of the PHHP were compared from two 12-month periods. A $\chi^2$ test was used to compare changes in HAI rates and also changes in nurses’ hand-washing compliance rates. Significance was defined as a $P$ less than .05.

Results

In the year before protocol implementation, 2183 patients were admitted to the ICU compared with 2326 admitted during the protocol (Table 2). All patients admitted to the ICU were included in the study. However, 3 patients did not receive hand hygiene with CHG because of blisters, dry cracked skin, and a known CHG allergy. The mean daily census was 22.7 before the PHHP and 22.3 during the PHHP. More males than females were admitted to the ICU, comprising 57% of patients before and 59% of patients during the PHHP.

HAI Rates

CAUTIs were measured and reported by using the Centers for Disease Control and Prevention’s definition: incidence per 1000 indwelling urine catheter days. CAUTI results were summarized by comparing monthly means before and during implementation of the PHHP (Figure 3). The mean monthly CAUTI rate decreased from 9.1 to 5.6 per 1000 catheter days. The decrease in CAUTI rates was not statistically significant, $\chi^2_{110} (N=12)=120, P=.24$. Device utilization days decreased from 5190 days to 4992 days; could the reduction in device days have contributed to the reduction in CAUTIs? Differences in device days during the 2 study periods were analyzed to evaluate their contribution to improved outcomes, but no significant difference was found between urinary catheter days before the PHHP (mean, 399.23; SD, 106.26) and during the PHHP (mean, 384; SD, 111.81), $\chi^2_{132} (N=13)=143, P=.24$.

CLABSIs were measured and reported by using the Centers for Disease Control and Prevention’s definition: incidence per 1000 central catheter days. CLABSI results were summarized by comparing monthly means before and during the PHHP (Figure 3). The mean monthly CLABSI rate decreased from 1.1 to 0.50 per 1000 catheter days. The differences in CLABSI rates were not statistically significant, $\chi^2_8 (N=12)=6.08, P=.64$. During the study protocol, there were 0 CLABSIs for 9 months, which unfortunately ended with 1 CLABSI 2 weeks before the end of the study. Device utilization days decreased from 6447 days to 5620 days; could the reduction in device days have contributed to the reduced CLABSI rate? No significant difference was

Study Design

A preexperimental (posttest only with a comparison group) study design was conducted. All study data were collected from a single ICU beginning in December 2009 and ending February 22, 2012. The investigation included 3 consecutive phases: (1) a comparison 12-month period before protocol implementation, (2) a 10-week protocol training period, and (3) a 12-month period during the protocol implementation. Patient-related variables including age, sex, hospital length of stay, severity of illness, and daily census were collected to compare variables that might contribute to differences in HAI rates (Table 2).

Analysis

Statistical analyses were conducted by using SPSS version 21. Rates of HAI s (both CAUTIs and CLABSIs) and nurses’ hand-washing compliance before

<table>
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<th>During protocol</th>
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<td>Days in hospital, mean</td>
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<td></td>
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<td>9</td>
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<td>32</td>
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<td>Extreme</td>
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<td>37</td>
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<td>Age in years, No. of patients</td>
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<td>≥ 91</td>
<td>94</td>
<td>64</td>
</tr>
<tr>
<td>Population, No. (%) of patients</td>
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<td>n = 2326</td>
</tr>
<tr>
<td>Cardiac</td>
<td>773 (35)</td>
<td>900 (39)</td>
</tr>
<tr>
<td>Medical</td>
<td>1108 (51)</td>
<td>1091 (47)</td>
</tr>
<tr>
<td>Surgical</td>
<td>302 (14)</td>
<td>335 (14)</td>
</tr>
<tr>
<td>Sex, No. (%) of patients</td>
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<td></td>
</tr>
<tr>
<td>Male</td>
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<td>1361 (59)</td>
</tr>
<tr>
<td>Female</td>
<td>934 (43)</td>
<td>965 (41)</td>
</tr>
<tr>
<td>Mean daily census</td>
<td>22.7</td>
<td>22.3</td>
</tr>
</tbody>
</table>
found between central catheter days before the PHHP (mean, 495.92; SD, 112.68) and during the PHHP (mean, 432.31; SD, 115.75), $\chi^2_{144} (N=13) = 156, P=.23$.

In the 2326 patients in the study during the 12-month protocol, only 1 case of CHG irritation was observed (~0.0004%). Raised red blotches were observed on the dorsal surface of both hands in 1 patient after 2 days of CHG use. CHG skin irritation rates in other studies have been as high as 5.9%.21

Nurses’ Hand-Washing Compliance

Results of the surveillance of nurses’ hand-washing compliance were summarized in monthly percentage reports (Figure 4). Hand-washing compliance rates were measured and compared between
groups and also by time of hand washing: before entering the patient’s room and exiting the patient’s room. Hand-washing compliance rates in the 12-month period before the protocol was implemented were from 0% to 86% with a mean of 35% when entering a patient’s room. The hand hygiene compliance rate before the PHHP was implemented was from 41% to 87% with a mean of 66% when exiting a patient’s room. The difference in hand hygiene compliance when exiting a patient’s room compared with when entering a patient’s room was not statistically significant: $\chi^2_{38} (N=12)=96, P=.26$.

During protocol implementation, hand-washing compliance rate was 51% to 71% when entering a patient’s room with a mean of 66%. When exiting a patient’s room during the protocol implementation, the range was from 65% to 87% with a mean of 79%. The difference in hand hygiene compliance when exiting a patient’s room compared with entering a patient’s room was not statistically significant $\chi^2_{63} (N=12)=67, P=.34$.

The protocol appears to have shifted nurses’ focus from self-protection to protection of patients. Although nurses’ hand-washing compliance when exiting the patient’s room also improved, the results were not as remarkable, with an increase from 66% to 79%. Before the protocol was implemented, the nursing focus was on washing hands as the nurses left the patient’s room, protecting themselves, not the patient. The PHHP appears to have shifted the nurses’ focus from self-protection to protection of patients.

During the study period, overall hand hygiene compliance improved gradually from 48% to 75%. The PHHP was an effective quality improvement strategy in the ICU and was associated with reductions in HAIs and improved hand-washing compliance by nurses. Patients and their families were eager to participate and have their hands washed 3 times daily. Many patients commented on this being the first time their hands were washed in a hospital. Simply stated, “if a patient cannot reach the sink, the sink must be brought to them.” Patients’ hand hygiene is simple, potentially lifesaving, and often overlooked by HCWs.

The adoption of a PHHP was structured to include adequate preparation, training, and validated competency by the ICU nurses. The 10-week protocol phase-in period required return demonstration training of all nursing staff. Compliance auditing showed that 96.5% of 2326 patients’ hand hygiene was sustained for 12 months. With the direct observation and 1-on-1 training, compliance with the protocol was 100% during the training period. A decision was made to observe nurses during the study protocol period biweekly in order to validate adherence to the protocol.

The use of CHG as part of a PHHP had not been reported before and therefore required vigilance to observe concerns and side effects. Patients’ hands were assessed before each application by the primary ICU nurse as well as twice a week by a member of the study team. CHG exposure to mucous membranes may cause tissues to become red and irritated.19 Two cases of mucous membrane irritation due to patients touching their eyes before their hands were dry that resulted in mild eye irritation were observed by an ICU nurse. Following these 2 episodes, the entire ICU team was reeducated on the need for CHG to dry before touching the face. Another CHG concern was reported by an ICU nurse, who observed an elevated glucose result after performing a bedside glucose test on a patient who had just had his hands cleansed with CHG. The patient’s glucose level was checked again after the finger was cleaned with alcohol and revealed a value near the patient’s...
baseline, which was confirmed with laboratory results on a venipuncture sample. The incorrect glucose result associated with CHG cleansing was communicated to the entire ICU team through immediate educational training. Resistance to CHG was not examined in the study but should be considered in future investigations.

Limitations

Protocol results were compared with preintervention results instead of a randomized control group, limiting confidence in the effect of the protocol. The demographics of the 2 groups were not evaluated with respect to number of isolation patients or type of isolation. Because many factors affect infection rates, the study results cannot be solely attributed to the intervention. In addition, physician training and site of catheter insertion were not evaluated.

Although nurses were aware that their hand-washing rates were being observed, they did not know who was doing the observations. Knowing their practice was being observed may have resulted in a Hawthorne effect, resulting in higher than normal hand-washing rates for the nurses. Because of the nature of the intervention, participants were not blinded to the hand hygiene procedure. The study was completed in only 1 ICU at a single institution during a 1-year period; therefore, the results have limited generalizability to other institutions or units.

Conclusions

Reduced rates of HAIs (CAUTI and CLABSI) were observed following implementation of the PHHP and nurses’ hand-washing compliance rates improved both for entering and exiting a patient’s room. The PHHP was quickly adopted in the clinical setting. Future studies that use an experimental design are recommended in the investigation of an ICU PHHP and the use of 2% CHG to prevent HAIs.

FINANCIAL DISCLOSURES

This clinical investigation was supported by the Mission Hospital Center for Nursing Excellence.

REFERENCES


SEE ALSO

For more about preventing hospital-acquired infections, visit the Critical Care Nurse Web site, www.connonline.org and read the article by Zurawski, “Carbapenem-Resistant Enterobacteriaceae: Occult Threat in the Intensive Care Unit” (October 2014).


* eLetters must be approved by the journal’s coeditors for publication online, in the print edition, or both.
Evidence-Based Review and Discussion Points

By Ronald L. Hickman, RN, PhD, ACNP-BC

Evidence-Based Review (EBR) is the journal club feature in the American Journal of Critical Care. In a journal club, attendees review and critique published research articles: an important first step toward integrating evidence-based practice into patient care. General and specific questions such as those outlined in the "Discussion Points" box aid journal club participants in probing the quality of the research study, the appropriateness of the study design and methods, the validity of the conclusions, and the implications of the article for clinical practice. When critically appraising this issue's EBR article, found on pp 216-224, consider the questions and discussion points outlined in the "Discussion Points" box. Visit www.ajconline.org to discuss the article online.

Hospitals-acquired infections (HAIs) affect millions of Americans each year. Critically ill patients are highly susceptible to HAIs because of their need for central intravenous access, indwelling urinary catheters, acute delirium, and inability to perform hand washing independently. Nationwide, health care organizations continue to implement quality improvement strategies to address HAIs but primarily focus on enhancing the hand-washing practices of health care workers.

Few studies have investigated the effects of a patient-centered hand hygiene protocol on HAI rates. To address this, the authors implemented a quality improvement project that consisted of a patient hand hygiene protocol using chlorhexidine gluconate impregnated wipes to deter 2 commonly occurring HAIs, central line-associated bloodstream infections (CLABSIs) and catheter associated urinary tract infections (CAUTIs), among critically ill adult patients.

Prior to data collection, the authors conducted orientation sessions for critical care nurses that consisted of training on electronic medical record documentation and demonstration of proper patient hand-washing technique. After the training period, participants, critical care nurses, and patients, were observed while in a cardiovascular medical intensive care unit (ICU). Data on the patients' lengths of stay, severity of illness, and occurrence of CLABSIs and CAUTIs were collected through hospital discharge. Compliance with the patient hand hygiene protocol was evaluated by review of electronic medical record documentation and direct observations of critical care nurses by trained research nurses.

Across the 12-month observational period, the authors report reductions in CLABSIs and CAUTIs, as well as improvements in nurse hand-washing compliance; however, none of these results achieved statistical significance.

Investigator Spotlight

This feature briefly describes the personal journey and background story of the EBR article's lead investigators, discussing the circumstances that led them to undertake the line of inquiry represented in the research article featured in this issue.

Cherie Fox, RN, MSN, CCRN-CSC, is currently a nurse manager at Mission Hospital, Mission Viejo, California. Fox has 18 years of experience managing the complex care of critically ill adults and their families.

She notes, "Every nurse has that one aspect of nursing care she or he feels is essential. Patient hygiene was that aspect of my nursing care I have always valued."

Investigator Spotlight

Taking the lead on this quality improvement initiative seemed natural because of her focus on patient hygiene and reputation for getting things done, says Fox in explaining how she assumed the role of project leader.

With no prior research experience, Fox was supported by clinical nurse specialists and a nurse scientist. Fox took steps to ensure the success of the project. "At first it was difficult to convince the team that we needed to go through the institutional review board, and there was a debate as to whether this was a research study or a quality improvement initiative," she says.

Fox and the research scientist collaboratively reached out to other nurse scientists and statisticians. Although she met some institutional resistance, she says she had immense administrative support that enabled her to successfully conduct the project and gather the resources needed to publish the results.

Information From the Authors

Cherie Fox, RN, MSN, CCRN-CSC, lead author on this article provides additional information about the study. A former charge nurse in the cardiac intensive care unit, Fox considers herself a novice researcher and active contributor to her institution's council on nursing practice. A commitment to quality patient care, evidence-based
nursing practice, and a hospital initiative to reduce HAIs served as the impetus for conducting this project focused on a patient hand hygiene protocol.

According to Fox, the project was an opportunity to engage bedside nurses in an evidence-based practice initiative. She says, “It brought about remarkable discussions about the difference between research and quality improvement.” For Fox, leading this quality improvement initiative was an invaluable learning opportunity that challenged her to deal with the institutional review board (IRB) and become the first baccalaureate-prepared nurse to serve as the responsible investigator for an IRB approved project at her institution.

Fox highlights several unexpected successes, “Because the project stemmed from the practice council, we had numerous registered nurses interested in serving as research nurses for data collection, which was unanticipated.” She adds, “To our surprise, patients loved washing their hands and wanted to continue to use the chlorhexidine wipes after their ICU discharge.” Fox said this was an unexpected patient-centered success. Although Fox and her coauthors suspected that their patient hygiene protocol would lower CLABSI rates, they were pleasantly surprised when the CAUTI rates were also decreased.

**Implications for Practice**

The project findings confirm the promise of a patient hand hygiene protocol as an evidence-based strategy to reduce HAIs. Critically ill patients are known to come in contact with contaminated surfaces and equipment. Furthermore, states of acute delirium and agitation can promote the inadvertent transference of bacterial to central lines and indwelling urinary catheters, which can contribute to genesis of a CLABSI or CAUTI. Although the results of this project hold promise to reduce HAIs, “More research is needed to assess the frequency of hand-washing, the effectiveness of chlorhexidine impregnated wipes compared liquid chlorhexidine baths, and the risk of bacterial resistance,” she adds.

Fox encourages the readers of the American Journal of Critical Care to practice judicious hand-washing for themselves and incorporate frequent patient hand washing with chlorhexidine gluconate into their nursing care.

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**About the Author**

Ronald L. Hickman is an assistant professor, Case Western Reserve University, and an acute care nurse practitioner at University Hospitals Case Medical Center, Cleveland, Ohio.

Fox concludes, “Patient’s hands are not frequently washed and, at best, are washed only during a daily bath.” She says hand-washing is a well-established strategy to prevent infections in healthy adults and holds the potential to significantly lower HAI rates among critically ill patients.

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**Discussion Points**

A. **Description of the Study**

- How do hospital-acquired infections affect patient outcomes?
- Describe the focus of cited quality improvement initiatives to reduce hospital-acquired infections.

B. **Literature Evaluation**

- What factors enhance the susceptibility of critically ill patients to hospital-acquired infections?
- What strategy does the Centers for Disease Control and Prevention recommend to prevent hospital-acquired infections?

C. **Sample**

- What patients were eligible to participate in this study?
- How did the investigators train the critical care nurses who participated in this study?

D. **Methods and Design**

- How did the investigators assess the hospital-acquired infection rates and the nurses’ hand-washing compliance?
- Describe how the patient hygiene protocol was integrated into the electronic medical record.

E. **Results**

- What were the major findings of this study?
- How can you use the findings of this project to improve the quality of your nursing care?

F. **Clinical Significance**

- What are the implications of this study for clinical practice?
Nosocomial Infections in Patients With Spontaneous Intracerebral Hemorrhage

By Archana Hinduja, MD, Jamil Dibu, MD, Eugene Achi, MD, Anand Patel, MD, Rohan Samant, MD, and Shadi Yaghi, MD

**Background** Nosocomial infections are frequent complications in patients with intracerebral hemorrhage.

**Objectives** To determine the prevalence, risk factors, and outcomes of nosocomial infections in patients with intracerebral hemorrhage.

**Methods** Prospectively collected data on patients with spontaneous intracerebral hemorrhage between January 2009 and June 2012 were retrospectively reviewed. Patients who had nosocomial infection during the hospital stay were compared with patients who did not. Poor outcome was defined as death or discharge to a long-term nursing facility.

**Results** At least 1 nosocomial infection developed in 26% of 202 patients with intracerebral hemorrhage. The most common infections were pneumonia (18%), urinary tract infection (12%), meningitis or ventriculitis (3%), and bacteremia (1%). On univariate analysis, independent predictors of nosocomial infection were intraventricular hemorrhage, hydrocephalus, low score on the Glasgow Coma Scale at admission, hyperglycemia at admission, and treatment with mechanical ventilation. On multivariate regression analysis, the only significant predictor of nosocomial infection was intraventricular hemorrhage (odds ratio, 5.4; 95% CI, 1.2-11.4; P = .02). Patients with nosocomial infection were more likely than those without to require a percutaneous gastrostomy tube (odds ratio, 33.1, 95% CI, 23.3-604.4; P < .001) and to have a longer stay in the intensive care unit or hospital without a significant increase in mortality. Patients with nosocomial pneumonia were also more likely to have a poor outcome (P < .001).

**Conclusion** Pneumonia was the most common infection among patients with intracerebral hemorrhage. (American Journal of Critical Care. 2015;24:227-231)
The aim of our study was to identify the risk factors associated with nosocomial infections in patients with spontaneous intracerebral hemorrhage (sICH) and the impact of these infections on the patients’ outcomes at discharge from the hospital.

**Methods**

**Study Design and Selection of Patients**

The study was approved by the appropriate institutional review board. Data collected prospectively on patients admitted to the University of Arkansas for Medical Sciences, Little Rock, Arkansas, a tertiary medical center, with a diagnosis of sICH between January 2009 and June 2012 were reviewed retrospectively. All consecutive patients admitted with a diagnosis of sICH were included in the sample. Patients were excluded if they had infection at the time of admission; were hospitalized less than 48 hours; or had ICH due to arteriovenous malformation, trauma, tumor, infarction, cerebral venous sinus thrombosis, or infective endocarditis (as indicated by results of computed tomographic angiography, digital subtraction angiography, or magnetic resonance imaging).

**Definitions**

Infections were defined by using the criteria of the Centers for Disease Control and Prevention. Diagnosis of pneumonia included (1) new or worsening pulmonary infiltrate, (2) fever, leukopenia or leukocytosis, altered mental status without other cause in patients more than 70 years old, coupled with new or worsening character of sputum, worsening gas exchange, and (3) laboratory evidence of the causative organism.

**UTI** was defined as an infection associated with a single sign or symptom, which included fever (>38°C), urgency, frequency, dysuria, suprapubic tenderness, and cultured urine samples with 10⁵ or more colony-forming units per milliliter with no more than 2 microorganisms. Alternatively, criteria for UTI were also met if a patient had 2 signs and symptoms and 1 of the following: dipstick test positive for leukocyte esterase or nitrate; pyuria of 10 or more white blood cells per microliter or 3 or more white blood cells per high-power field for unspun urine; or positive Gram stain.

**Diagnosis of meningitis or ventriculitis** was based on cultures of cerebrospinal fluid positive for microorganisms. Alternatively, fever (>38°C), meningeal signs and symptoms, with either increased cerebrospinal fluid pleocytosis, elevated protein level, and low glucose level or a positive Gram stain of cerebrospinal fluid.

**Bloodstream infection** (bacteremia) was diagnosed on the basis of 1 or more cultures of blood positive for a pathogen not related to infection at another site. In addition to laboratory results positive for microorganisms, patients might also have fever...
(> 38°C), chills, or hypotension. For common skin contaminants, detection of the microorganisms in 2 more cultures of samples obtained on separate occasions was required to meet the criteria for bacteremia.

Data Collection

Patients’ data were dichotomized into 2 groups on the basis of whether any of the infections just described developed during the patients’ hospital course. The 2 groups were compared for baseline demographics, risk factors, imaging findings (location of hemorrhage, hematoma volume, intraventricular hemorrhage [IVH], hydrocephalus), score on the Glasgow Coma Scale at admission, intubation, blood glucose level and blood pressure upon admission, complications (need for percutaneous gastrostomy tube, tracheostomy, lengths of stay in the intensive care unit and the hospital, in-hospital mortality), and outcomes. A staff neuroradiologist calculated the hematoma volume from the admission computed tomography scans by using thin volumetric cuts and Extended Brilliance Workspace software (Philips Healthcare). The IVH score was calculated by using the LeRoux score.

Outcome

Survival and functional outcome at the time of discharge from the hospital were assessed for all patients. Poor outcome was defined by using the modified Rankin Scale as death or severe disability (score, 4-6).

Statistical Analysis

The 2 groups were compared by using the Fisher exact test for categorical variables and t tests for continuous variables. Multivariate regression analysis was performed to identify predictors of nosocomial infection. For all statistical analysis, SPSS, version 18.0, software (IBM SPSS) was used, and a P value of .05 or less was considered significant.

Results

Of the 204 patients who had sICH between January 2009 and June 2012, 2 were excluded because of incomplete data, and 202 were included in the primary analysis. At least 1 nosocomial infection developed in 26% of the 202 patients during their hospital course. The most common infections, in order, were pneumonia (18%; hospital-acquired pneumonia in 6% and ventilator-associated pneumonia in 12%), UTI (12%), meningitis or ventriculitis (3%), and bacteremia (1%). According to univariate analysis, patients with nosocomial infections were more likely than those without infection to have IVH (with infection, 75% vs without infection, 42%; \( P < .001 \)), hydrocephalus (40% vs 20%; \( P = .005 \)), hyperglycemia at the time of admission (56% vs 39%;

<table>
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<th>Table 1</th>
<th>Predictors of nosocomial infections in patients with spontaneous intracerebral hemorrhage</th>
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<td>Variable</td>
<td>Infection (n = 52)</td>
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<tr>
<td>Use of cocaine, %</td>
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<td>Coumadin (%)</td>
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<td>Location of hemorrhage (capsuloganglionic), %</td>
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<tr>
<td>Volume of hematoma, mL</td>
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<td>Intraventricular hemorrhage, %</td>
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<tr>
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<tr>
<td>Hydrocephalus, %</td>
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<td>Admission score on Glasgow Coma Scale≥8, %</td>
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<td>Blood glucose &gt; 144 mg/dL, %</td>
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<td>Systolic blood pressure, mean (SD), mm Hg</td>
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<tr>
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<tr>
<td>Urinary catheter, %</td>
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<tr>
<td>Tracheostomy, %</td>
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<tr>
<td>Percutaneous gastrostomy tube, %</td>
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<td>Mortality, %</td>
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<td>Days in intensive care unit, mean (SD)</td>
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<td>Days in hospital, mean (SD)</td>
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www.ajcconline.org
Intraventricular hemorrhage at admission was the only independent predictor of infectious complications.

In our study, despite similar rates of nosocomial infections and prolonged length of hospital stay, overall mortality did not increase. When all infections were analyzed individually, patients with nosocomial pneumonia were more likely than patients without this infection to have a poor outcome at discharge.

The major predictor of infectious complications in our study was IVH at the time of admission; IVH has also been identified as a risk factor for nosocomial infections among patients with subarachnoid hemorrhage. In fact, IVH at admission was the only independent predictor of infectious complications in our study. The relationship between IVH and infectious complications is not well understood. Evidence suggests that brain ischemia may cause a relatively immunosuppressed state, increasing the risk for infection. The immunosuppression most likely is related to activation of the sympathetic nervous system, which modulates the immune system via the hypothalamic-pituitary-adrenal axis, the sympathetic-adrenal-medullary axis, and the parasympathetic nervous system (vagus nerve). In another study, a decrease in the baroreceptor reflex, which is a measurement of the sympathetic surge after intracerebral hemorrhage, was independently correlated with infectious complications. This sympathetic activation was more pronounced in patients with IVH, in whom the inflammatory response and activation of the hypothalamic-pituitary-adrenal axis may be more potent.

Another potential mechanism for poor clinical outcome with IVH could be the increased risk for hydrocephalus leading to a prolonged stay in the intensive care unit and thereby predisposing patients to nosocomial infections. However in our study, the relationship between IVH and nosocomial infections was independent of the presence of hydrocephalus, and thus could not be fully explained by the aforementioned relationship. Although infarct volume and involvement of insular and right frontal-parietal regions may play a role in immunomodulation and susceptibility to infections in patients with ischemic stroke, in our patients, neither the volume nor the location of the ICH increased the susceptibility to infectious complications. In our patients,

and occurred in 26% of the patients in our sample. The rates of infection in our study are consistent with results from studies of mixed populations of patients admitted to a neurological intensive care unit: pneumonia, 18% in our study versus 5.6% to 47% in other studies; UTI, 12% versus 7% to 26.9%; meningitis or ventriculitis, 3% versus 1% to 20%;5,12, and bacteremia, 1% versus 1% to 2%. In our study, despite similar rates of nosocomial infections and prolonged length of hospital stay, overall mortality did not increase. When all infections were analyzed individually, patients with nosocomial pneumonia were more likely than patients without this infection to have a poor outcome at discharge.
the results of previous studies. Despite these limitations, including the retrospective data collection, which may introduce bias; however, the use of standardized definitions of the various infections might limit the effect of this bias. Other limitations include relatively few patients in the sample, the lack of data on aspiration or device-associated infection rates, the absence of inflammatory markers such as C-reactive protein, and no long-term outcome data. Also, the cause-and-effect relationship between infection and prolonged hospitalization was unclear.

**Conclusion**

We found that development of nosocomial infections in patients with sICH increases the length of stay in the intensive care unit and the overall hospital length of stay, a finding consistent with the results of previous studies. Despite these increases, we found no significant increase in mortality, a variable that has not been evaluated in other studies. Major preventive measures need to be undertaken to reduce the rates of hospital-acquired infection, especially in patients with IVH, to reduce the length of stay and overall cost of health care. Larger prospective studies to evaluate the risk of infections and locations of ICH, especially in patients with IVH, and to correlate the findings with measurable biomarkers are needed for earlier identification of these patients and prompt therapeutic interventions.

**FINANCIAL DISCLOSURES**

None reported.

**REFERENCES**

NEGOTIATING TRANSITIONS:
INVOLVEMENT OF
CRITICAL CARE OUTREACH
TEAMS IN END-OF-LIFE
DECISION MAKING

By Natalie Pattison, RN, DNSc, Geraldine O’Gara, RN, BSc, and Timothy Wigmore, MA, FRCA

**Background**  Little research has examined the involvement of critical care outreach teams in end-of-life decision making.
**Objective**  To establish how much time critical care outreach teams spend with patients who are subsequently subject to limitation of medical treatment and end-of-life decisions and how much influence the teams have on those decisions.
**Methods**  A single-center retrospective review, with qualitative analysis, in a large cancer center. Data from all patients referred emergently for critical care outreach from October 2010 to October 2011 who later had limitation of medical treatment or end-of-life care were retrieved. Findings were analyzed by using SPSS 19 and qualitative free-text analysis.
**Results**  Of 890 patients referred for critical care outreach from October 2010 to October 2011, 377 were referred as an emergency; 108 of those had limitation of medical treatment and were included in the review. Thirty-five patients (32.4%) died while hospitalized. As a result of outreach intervention and a decision to limit medical treatment, 56 (51.9%) of the 108 patients received a formal end-of-life care plan (including care pathways, referral to palliative care team, hospice). About a fifth (21.5%) of clinical contact time is being spent on patients who subsequently are subject to limitation of medical treatment. Qualitative document analysis showed 5 emerging themes: difficulty of discussions about not attempting cardiopulmonary resuscitation, complexities in coordinating multiple teams, delays in referral and decision making, decision reversals and opaque decision making, and technical versus ethical imperatives.
**Conclusion**  A considerable amount of time is being spent on these emergency referrals, and decisions to limit medical treatment are common. The appropriateness of escalation of levels of care is often not questioned until patients become critically or acutely unwell, and outreach teams subsequently intervene. ([American Journal of Critical Care. 2015;24:232-240](http://dx.doi.org/10.4037/ajcc2015715))
Medical emergency teams (METs) and critical care outreach teams (CCOTs) have a prominent role in handling triage of patients who are acutely ill or whose condition is deteriorating and in determining courses of treatment. This role often involves facilitating admission to a critical care unit or a decision about limitation of medical treatment (LOMT). Research has shown that CCOTs initiated a LOMT (subsequently leading to end-of-life [EOL] decision making) in 25% of all CCOT referrals and were involved in around a third of MET calls.\(^3\) The role of MET teams in EOL decision making has been explored in very few studies.\(^5\) Qualitative investigation has revealed the usefulness of CCOT in facilitating timely EOL decisions and LOMTs.\(^6\)

The primary goal of CCOT/MET intervention is to prevent deterioration in an acutely ill patient's condition or to facilitate a timely, appropriate admission to a critical care unit. However, the course of patients who are acutely unwell and then transferred to an EOL model is difficult to map. A relatively new phenomenon has arisen of patients receiving EOL care in the hospital but outside the intensive care unit.\(^7\) In the Australian studies\(^3-5\) that have explored this issue, the MET teams studied comprised doctors who could make LOMT decisions. Models of CCOTs and METs differ worldwide, with some METs being mandated in certain states to see all palliative care patients with acute deteriorations in condition (even at EOL, eg, breathlessness triggering on a warning score). These teams have to make explicit exemption orders.\(^3,5\) This approach differs from practice in the United Kingdom, where CCOTs rarely make overriding decisions about patients transferring to an EOL model, but do see EOL patients with reversible intercurrent critical illness (eg, cardiac arrhythmias). Moreover, nurse-led teams predominate in the United Kingdom, which limits the prospect of this model developing.

No studies exploring the time that CCOTs spend on EOL or LOMT decision making or the characteristics of that time have been published. However, anecdotal comment suggests that referrals to a MET/CCOT and subsequent consultation time associated with a LOMT often take considerably longer than referrals without those features.\(^4\) Dealing with such issues is an important and necessary part of the role, but the US Institute for Healthcare Improvement's scope of practice for rapid response teams and METs\(^6\) does not currently refer to this aspect of work within their delineation of the role. The UK national competency documents for critical care outreach services\(^7\) also offer limited discussion of the topic. Data on what happens to patients after they are discharged from these teams' care appear to be collected ad hoc. Furthermore, although there are national minimum datasets specifically for CCOTs being developed in the United Kingdom and elsewhere (rather than for critical care or emergency care\(^9\)), these are not yet mandatory.

Quantifying CCOT/MET involvement in EOL care and managing transitions to EOL care in acute illness are important in order to map service provision, recognize and develop skills in EOL decision making and management, and qualify time spent on different aspects of their work, including LOMT. Previous data showed that 30% of emergency critical care referrals result in the patient being admitted to a critical care unit, with the remainder of the patients either achieving stable condition in a general care area, improving in condition, or being transferred to EOL care.\(^4\) In this study, we also planned to assess long-term mortality outcomes of these EOL patients, as previous data have indicated that EOL patients who are sick enough to be referred to outreach do poorly in 100-day and 6-month outcome data, even if they survived the hospital and/or critical care episode.\(^7\)

**Objectives**

The primary aim was to establish how much time (in minutes) CCOTs spend with patients who

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**About the Authors**

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are subsequently subject to EOL and/or LOMT decisions and how much subsequent influence CCOTs have on those decisions. The secondary objectives were (1) to assess the level of involvement of CCOTs in EOL decision making (by using qualitative free-text analysis); (2) to determine the mortality rates of CCOT patients who are subject to EOL decisions and LOMTs while in the hospital, at 30 days, at 100 days, at 6 months, and at 1 year after CCOT referral (including admission to critical care unit); and (4) to explore characteristics of patients who were subject to an LOMT (including treatment intent, performance status, diagnosis, resuscitation status).

**Sampling**

The study center was a tertiary referral cancer center. Sample size estimates of around 100 to 200 patients were used, assuming 15% to 20% of all referrals received EOL decisions and limitations of treatment (based on previously published data) and a service seeing approximately 1000 patients a year. Table 1 outlines inclusion/exclusion criteria.

**Methods**

A retrospective review of patients’ records with additional qualitative text analysis was undertaken in order to explore the degree of influence of CCOTs and illuminate the decisions made. This review included data held on the IntelliVue Clinical Information Portfolio system (a real-time electronic care record in intensive care and for critical care outreach that holds all critical care data) and patients’ electronic medical records, which hold all the hospital records and medical notes. Data on CCOT patients referred during a 1-year period (October 2010-October 2011) were extracted and followed forward for 1 year. Where there was more than 1 hospital admission, with more than 1 EOL decision in the 12-month period (rarely, decisions have been reversed and thus CCOTs have been involved in reinitiating decisions at a later admission), only the last hospital admission in that period was analyzed. Long-term mortality data were collected from the patient’s electronic medical record. Data entered into the IntelliVue Clinical Information Portfolio system as part of routine care records by the CCOT include medical history, time spent with patient, presenting problems, bodily systems assessment (including physiological variables, observations, and case history), interventions undertaken, recommendations for care, summaries of care episodes, EOL decisions, and outcomes of care.

**Analysis and Statistics**

Descriptive statistics were used for quantitative data (frequency and percentages, mean, standard deviation, median, ranges) and are presented to describe the study population. Cancer diagnoses were grouped into 10 categories: hemato-oncology, bowel cancer, skin, other, gynecological, lower gastrointestinal, upper gastrointestinal, genitourinary, lung, head and neck.

Overall mortality data were calculated from the date of referral to CCOT until death and from referral to LOMT. The Kaplan-Meier method was used to estimate survival time from inpatient admission to death or time of censoring (time of withdrawal from the study, eg, follow-up/date last seen). The 95% confidence intervals for percentages were calculated with maximum width plus or minus 7%. Furthermore, qualitative free-text analysis was used to analyze free text written in medical records about level of involvement at EOL, transfer decisions to EOL care, decision reversals, and LOMTs. Data (Table 2) were collected to establish characteristics and outcomes.

The study was conducted in accordance with the Research Governance Framework and the ethical...
principles of the Helsinki Declaration. Data protection was applied according to the UK Data Protection Act. Approval to access records was obtained via the trust’s Clinical Audit and Service Evaluation Committee and the institutional research and development department.

**Results**

In the study period, 890 patients were seen overall, comprising 4693 reviews (number of times those 890 patients were reviewed by CCOT during those admissions) including re-referrals. Out of those, 377 patients were referred as an emergency. Of all patients referred emergently, 108 (28.6%) underwent transition to EOL care and LOMT and were included in the study.

**Patient Characteristics**

At least 31 patients (28.7%) were known to have metastases. Treating medical teams, based on diagnosis and presenting problem, fell into 3 overall categories: hemato-oncology: \( n = 15 \) (13.9%); medical oncology: \( n = 90 \) (83.3%); and surgical oncology: \( n = 3 \) (2.8%).

Performance status scales were used including standard Eastern Cooperative Oncology Group/World Health Organization scales of 0 to 4 (with 4 being death and 0 being optimal health), alongside the Karnofsky scale (where 100 indicates the best performance status and standard intervals of 10 are used to mark degrees of performance status). Table 3 outlines how the performance status, presenting problem, and treatment intent compared with the subsequent outcome of the CCOT review (categories were collapsed because of the small numbers into 2 categories of Karnofsky scores 60%-100% and 0%-50%).

**Referral Characteristics**

Eleven referrals (10.2%) were re-referrals to CCOT within 1 hospital admission, of which data from the last referral were analyzed. Predominantly nurses (\( n = 72, 66.7\% \)) referred patients to the CCOT; however, 35 referrals (32.4%) were by junior physicians and fellows and 1 referral (0.9%) was by a consultant (attending physician).

Treatment intent was categorized as follows: aiming for curative intent (\( n = 12, 11.1\% \)); palliative/ noncurative (\( n = 95, 87.9\% \)); defined as no further active treatment available, but could be on phase 1 trials; this does not mean receiving EOL care, and patients could still be receiving treatment to control or maintain disease stability but without curative intent; patients might not have a do not attempt cardiopulmonary resuscitation [DNACPR] order or other LOMT at this point, despite being regarded as palliative; and missing (unable to ascertain from notes; \( n = 1, 0.9\% \)). No patients in the study had a treatment intent of EOL (“actively dying,” made DNACPR, transition to EOL plan or pathway) because such patients did not meet the eligibility criteria for participating in the study.

Few details regarding LOMT, before the CCOT, were present in the records. It was a gray area because many patients were receiving palliative or noncurative treatment; 21 (19.4%) had some form of LOMT in place (19 patients [17.6%] had a DNACPR in place). Two patients (1.8%) had LOMTs for levels of care; 84 (77.8%) had no LOMT; for 3 patients (2.8%), the documentation was unclear (using electronic care record systems, notes).

**Episode Outcome**

The time spent with patients (in minutes) who have an LOMT or EOL transition was substantially longer than the mean time for the 890 patients referred to outreach (mean, 45 min; SD, 84.4 min). The mean duration for all CCOT episodes (times during which the CCOT was intervening) for these 108 patients was 135 minutes (SD, 99.1 min; median,
of review by critical care outreach team

<table>
<thead>
<tr>
<th>Performance status (Eastern Cooperative Oncology Group/World Health Organization)</th>
<th>Karnofsky performance status, %</th>
<th>No. (%) of patients</th>
<th>Continued with outreach care</th>
<th>Discharge from outreach (to palliative care)</th>
<th>Died</th>
<th>Transferred to level 2 or 3 care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic: 0</td>
<td>100</td>
<td>5 (4.6)</td>
<td>11</td>
<td>70</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Symptomatic, independent: 1</td>
<td>80-90</td>
<td>25 (23.1)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic, in bed &lt; 50% day: 2</td>
<td>60-70</td>
<td>33 (30.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic, in bed &gt; 50% day: 3</td>
<td>40-50</td>
<td>25 (23.1)</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Bed-bound: 4</td>
<td>10-30</td>
<td>6 (5.6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>108 (100.0)</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Table 3**

Influence of patients’ characteristics on decision making

<table>
<thead>
<tr>
<th>Presenting problem</th>
<th>No. (%) of patients</th>
<th>Continued with outreach care</th>
<th>Discharge from outreach (to palliative care)</th>
<th>Died</th>
<th>Transferred to level 2 or 3 care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory failure</td>
<td>27 (25.2)</td>
<td>5</td>
<td>18</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Cardiovascular compromise (including sepsis)</td>
<td>20 (18.7)</td>
<td>3</td>
<td>15</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Neurological issue</td>
<td>4 (3.7)</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Acute kidney injury/renal/fluid imbalance</td>
<td>10 (9.3)</td>
<td>2</td>
<td>9</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Abdominal/gastrointestinal emergency</td>
<td>12 (11.2)</td>
<td>0</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other (referrer “worried”; MEWS &gt; 3; oncological emergency)</td>
<td>34 (31.8)</td>
<td>4</td>
<td>30</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>108 (100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment intent</th>
<th>No. (%) of patients</th>
<th>Continued with outreach care</th>
<th>Discharge from outreach (to palliative care)</th>
<th>Died</th>
<th>Transferred to level 2 or 3 care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Curative treatment</td>
<td>12 (11.1)</td>
<td>1</td>
<td>7</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Palliative (including maintenance treatment and phase 1 trials)</td>
<td>94 (87)</td>
<td>13</td>
<td>76</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Missing/unable to ascertain</td>
<td>2 (1.8)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>108 (100)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: MEWS, Modified Early Warning Score.

90 min; interquartile range, 165-250 min), with a total time expenditure of 848 hours (50 880 min) out of a total time for all 890 referrals of 236 295 minutes, or 21.5% of all clinical contact time. This analysis included patients who were referred for higher levels of care as well as an LOMT (eg, admitted to critical care unit but care limited to level 2).

In relation to LOMT outcome, a large proportion of patients (56/108, 51.9%) had a clear EOL plan made by the CCOT and the treating team following a CCOT referral. For a third of patients, a transfer to a specific national EOL pathway was made. Of the 56 patients with an EOL plan, 8 were transferred to our Hospital2Home service, 12 to the national EOL pathway, 28 to palliative care services (domicile/hospices), 5 to another (local) hospital. Five patients were either transferred to other places or it was unclear where they were transferred. Of 12 patients (11.1%) admitted to critical care for higher levels of care, 1 (0.9%) died during the CCOT episode and a further 6 (0.55%) did not survive to hospital discharge, 3 had “not for intubation” documented, and 4 were subsequently documented as having a DNACPR decision although it was unclear at which exact point (during CCOT intervention or admission to the critical care unit) that decision was made.

Figure 1 outlines Kaplan-Meier curves for median survival from referral to outreach in relation to LOMT, and Figure 2 shows time from a new LOMT to the
patient’s death (excluding patients with an LOMT in place on referral and missing data).

Regarding time from referral to CCOT to a new LOMT being made, only 74 patients (69%) had a clearly documented date of new LOMT; therefore, only these data were used in survival analyses. For these patients, the mean time to LOMT was 0.7 days (SD, 1.24 days). The median time to LOMT was 0 days (interquartile range, 0-1 day). Median overall survival from CCOT referral was 27.0 days (95% CI, 18.5-35.5 days). The proportion of patients surviving to 100 days from referral date was 17.8% (95% CI, 10.6%-25.1%) (Figure 1). For time from LMOT to death (subgroup of 74 for whom data were available), the median overall survival from LMOT to death was 21.0 days (95% CI, 11.7-30.3 days). A total of 13.8% (95% CI, 5.8%-21.8%) survived to 100 days from the LMOT date (Figure 2).

**Patient Outcome**

During the whole hospital episode for the 108 patients, 35 patients (32.4%) died. During the CCOT episode (the time during which the CCOT was intervening, within that hospital episode), 1 patient (0.9%) died; 73 patients (67.6%) were discharged alive. Most patients died within 1 month; some discharged to palliative care services (as described previously), and the long-term outcomes for all patients (not just the subgroup of 74 for whom we had data on LOMT dates) were as follows: 45 (41.7%) were alive at 30 days, 6 (5.6%) were alive at 6 months, and 1 (0.9%) was alive at 12 months.

**Qualitative Free-Text Data Analysis**

In scoping the level of involvement, several themes emerged from free-text data from each of the 108 patients’ records. These themes were difficulty of DNACPR discussions, coordinating multiple teams, dealing with delays, revocation and uncertainty of decisions, and technical versus ethical implications. Negotiating transitions was the main, underlying theme; the negotiating transitions theme related to how the CCOT negotiated between teams to facilitate a smooth transition to EOL care.

The theme difficulty of DNACPR discussions recurred many times in patients’ notes and involved difficulties with communicating DNACPR decisions to patients, as well as difficulties with raising the DNACPR discussion with members of the primary medical team, who were reluctant to approach patients’ families or patients. This theme is reflected in the verbatim comments below.

Patient found DNAR discussion difficult, unable to make decisions, therefore not signed. 18.30 Discussion with consultant, patient not for resus[citation]. (R84)
Not for ventilation in the event of deterioration but hope that he will recover from
elevated troponin level, and chest pain) because she was transferred to another hospital for possible cardiac intervention. She was transferred back with no intervention and the CCOT initiated a new DNACPR decision 10 days later and her care was fully transferred to palliative care with an EOL care plan made. She died 9 days after that care plan was initiated. Her case also exemplifies the theme of dealing with delays.

Another LOMT decision was revoked because a junior doctor perceived an improvement in a patient’s condition, but after CCOT intervention to escalate to the consultants and discussion with the patient’s family, who outlined that the patient would not wish to be intubated and ventilated, a decision for DNACPR and to commence an EOL pathway was subsequently made. This, and another excerpt given below, demonstrate the theme technical versus ethical implications, where the CCOT found it difficult to reconcile the parent teams’ desire for further technical intervention for the critical illness, when they felt that the ethical imperative to facilitate a good death should prevail.

She was initially being considered for further active treatment, but unfortunately, her performance status continued to worsen, hence she was deemed unsuitable for further treatment. (R58, notes in patient’s electronic medical record)

Discuss with palliative care team if patient for draining of R [right] pleural effusion and or stenting; if not, Hospital2Home [palliative care home discharge package]. (R42)

The excerpts from the notes provide some detail around the complexities involved in negotiating transitions to EOL care for patients referred to the CCOT.

Discussion

This retrospective review and qualitative analysis study has shown that the CCOT has considerable input in EOL decisions. More than half of all patients had a clear EOL plan after CCOT intervention. Survival analysis shows that the time elapsed from time of referral to death is relatively short (< 1 month, and the time from LOMT to death was 21 days), and very few patients were alive long term. These findings echo published findings; Jones et al also reported that 1 in 3 referrals were associated with an LOMT.

The study’s strengths are that it was an enhanced retrospective review, spanning a year, with additional data sources analyzed by using qualitative methods to augment the quantitative data, providing substantially more information, which helped us to under-
stand certain courses of action. To our knowledge, this review is one of the first in this area to have combined these approaches and yielded such rich data.

However, the study did have several limitations; it was done at a single center and was a retrospective review, thus limiting the generalizability of the conclusions. These findings highlight the issues encountered in the paucity of documentation of patients' care and treatment decisions. It was difficult to determine who influenced the decision making, and how, for every case. The data collection form outlined if the CCOT had initiated discussions, and we used this as a proxy indicator.

Significant endeavor was required to collate the qualitative data, and these data reflect only the written texts and not the in-depth discussions that would have been had in practice but that were not documented. There is no formal Utstein-style recording of MET/CCOT calls; however, a national and international critical care outreach/MET minimum database has been called for.9 Furthermore, the study relies on subjective estimates of CCOT time. We have not reported exactly what kind of LOMT was made, other than DNACPR; doing so would have enhanced the study's reporting. We also cannot comment on the nature of the staff involved, and therefore we cannot understand why decisions were made about LOMT.

Also, this population of patients was unique. However, having cancer or even metastatic cancer does not necessarily mean that decisions to move to EOL care in acute and critical illness are well managed, as indicated in the report from the National Confidential Enquiry into Patient Outcome and Death,14 where a large proportion of patients did not receive timely EOL care, experienced poor decision making, and were still receiving anticancer therapies. Doctors found it hard to present options to patients, focusing on future treatment instead of appropriate palliation or EOL care and discontinuing treatment.15 This result has implications for the findings in this study, as indicated in Figure 1, because many patients were actively undergoing treatment. Cancer patients are now increasingly perceived as chronic health patients, with a projection of 22 million new cases each year by 2030,15 meaning that many of the world's population will experience cancer in their lifetime, reflecting other long-term conditions. Therefore, we have to address advance care planning in a different way in this population, including earlier discussions about treatment preferences.16-17 Furthermore, these issues about receiving treatment inappropriately at the EOL are not limited to people with cancer and pervade many other chronic illness populations such as patients with pulmonary, cardiac, or kidney disease.16-20

This study has shown how much time is spent with patients who subsequently are subject to EOL decisions and LOMT and emphasizes that, although not a widely recognized part of the CCOT/MET role or competencies,9 dealing with EOL care constitutes a significant aspect of the work of CCOTs. The teams appear to have notable influence over decisions and are seen as experienced critical care experts and thus are perceived as able to give an informed opinion of patients' likely outcome following critical illness. However, sometimes LOMTs are not facilitated in a timely manner owing to communication breakdowns between teams. Future work could be focused on collaborative team communication at transition points21 and between critical care teams and referring medical teams in patients with critical illness in particular.

What did not emerge in this study, probably by virtue of the study design, which did not qualitatively seek to explore experiences, was how patients and their families influence these decisions. Their influence could be poorly documented or they may simply not be involved. We know that involving patients’ families and patients in decisions can place burdens,22-28 but well-facilitated involvement can ease patients’ transitions to EOL care.29 Future studies should be focused on understanding how these LOMTs are made in an acute/critical care situation, outlining how these processes occur and why.

**Conclusion**

A sizable proportion of outreach time is being spent on patients who subsequently are subject to an LOMT. EOL decisions or LOMTs are frequently made, equating to a considerable proportion of all clinical contact for outreach. Mortality data also reflect our population of cancer patients. This study builds on previous work we have published in this area and informs an ethnographic study we are undertaking to explore why these difficulties in timely and appropriate transitions are occurring. The appropriateness of escalation of levels of care is often not considered until patients become critically or acutely unwell and outreach teams subsequently intervene.

**ACKNOWLEDGMENTS**
The authors would like to thank Kabir Mohammed and Karen Thomas for assistance with statistics, Andrew Dimoch, and the CCOT members.
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This study was unfunded but research time and research and development support were provided via the Biomedical Research Centre and Royal Marsden NHS Foundation Trust charity.

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AN ANALYSIS OF PATIENTS TRANSFERRED TO A TERTIARY ONCOLOGICAL INTENSIVE CARE UNIT FOR DEFINED PROCEDURES

By Sunil Kamat, MD, Sanjay Chawla, MD, Prabalini Rajendram, MD, Stephen M. Pastores, MD, Natalie Kostelecky, RN, and Neil A. Halpern, MD

Background  Up to 50,000 intensive care unit interhospital transfers occur annually in the United States.

Objective To determine the prevalence, characteristics, and outcomes of cancer patients transferred from an intensive care unit in one hospital to another intensive care unit at an oncological center and to evaluate whether interventions planned before transfer were performed.

Methods Data on transfers for planned interventions from January 2008 through December 2012 were identified retrospectively. Demographic and clinical variables, receipt of planned interventions, and outcome data were analyzed.

Results Of 4625 admissions to an intensive care unit at the oncological center, 143 (3%) were transfers from intensive care units of other hospitals. Of these, 47 (33%) were transfers for planned interventions. Patients’ mean age was 57 years, and 68% were men. At the time of intensive care unit transfer, 20 (43%) were receiving mechanical ventilation. Interventions included management of airway (n=19) or gastrointestinal (n=2) obstruction, treatment of tumor bleeding (n=12), chemotherapy (n=10), and other (n=4). A total of 37 patients (79%) received the planned interventions within 48 hours of intensive care unit arrival; 10 (21%) did not because their signs and symptoms abated. Median intensive care unit and hospital lengths of stay at the oncological center were 4 and 13 days, respectively. Intensive care unit and hospital mortality rates were 11% and 19%, respectively. Deaths occurred only in patients who received interventions.

Conclusions Interhospital transfers of cancer patients to an intensive care unit at an oncological center are infrequent but are most commonly done for direct interventional care. Most patients received planned interventions soon after transfer. (American Journal of Critical Care. 2015;24:241-247)
Transfer of critically ill patients from an intensive care unit (ICU) in one hospital to another ICU in another hospital occurs with a frequency 4.5% to 22% and may account for up to 50,000 ICU transfers per year in the United States.\(^1\)\(^2\) Reasons for such transfers may include a request for transfer by a patient or the patient’s surrogates, a request by a hospital that has previously cared for the patient, or inability of the current ICU and hospital to deliver requisite interventional services.\(^6\) Interhospital ICU to ICU transfers have been well described for regional centers for treatment of infants and children\(^7\) and for specialized interventions such as extracorporeal membrane oxygenation (ECMO),\(^11\) neurointerventional procedures,\(^11\) and percutaneous coronary interventions\(^12\) at medical centers that treat large numbers of patients. Studies of interhospital ICU to ICU transfers have focused mainly on the methods of transport, the obligatory preparations, frequency of transport-related adverse events,\(^13\)\(^17\) and outcome and resource comparisons among transfer sources (ICU, emergency department, and general care unit).\(^3\)\(^5\)\(^18\)\(^21\)

Since the early 2000s, earlier diagnoses and therapeutic advances have increased the longevity of patients with cancer. These advances have resulted in the development of defined oncological related problems that require specialized interventions.\(^22\)\(^24\) Many studies have indicated that outcomes are enhanced when patients with cancer undergo major oncological surgeries and interventional procedures at regional centers or at facilities that treat large numbers of patients\(^25\)\(^33\) and the procedures are performed by experienced surgeons and interventionalists.\(^25\)\(^26\)\(^33\)\(^34\) However, interhospital transfer of critically ill cancer patients for specialized oncological interventions has not been previously described. Moreover, these transfers are generally perceived as resource intensive, and the newly scheduled interventions at the receiving center are an important issue because they may preclude other uses of the interventionalists and the interventional suites. The objectives of this study were to retrospectively describe the prevalence, characteristics, and outcomes of critically ill patients transferred to the adult ICU at Memorial Sloan Kettering Cancer Center (MSKCC) for oncological interventions and to determine whether the planned interventions were actually provided.

**Methods**

**Data Source and Study Setting**

Data on all adult (>18 years old) critically ill patients transferred from ICUs in other hospitals to the 20-bed closed medical-surgical adult oncological ICU at MSKCC specifically for oncological interventions during a 5-year period (January 1, 2008, through December 31, 2012) were analyzed retrospectively. The study was granted a limited waiver of informed consent by the facility’s institutional review board/privacy board (WA0283-12).

MSKCC is a 470-bed academic, tertiary care cancer center. The ICU is staffed by full-time intensivists, fellows in critical care medicine, acute care nurse practitioners, physician assistants, and anesthesiology residents. The center’s general policy is to facilitate transfer of previously registered MSKCC patients from other hospitals; however, it also accepts transfer of patients never previously seen or admitted at MSKCC. Policy additionally mandates that any patient already hospitalized in an outside ICU must be transferred directly to the MSKCC ICU. All ICU transfers must be approved by the critical care medicine attending physician of record in collaboration with the primary admitting service attending physician. The transfer approach complies with the Society of Critical Care Medicine guidelines\(^35\) for the interhospital transfer of critically ill patients, which mandate ongoing discussion between critical care medicine physician and nursing teams at the...
receiving hospital with the equivalent groups in the
transferring hospital to determine the optimal time for
transfer and the requisite transfer method.

MSKCC is contractually associated with a nearby
large teaching hospital (New York Presbyterian Hos-
[5%]](h[0x0]), located directly across the street, for
procedural care not offered at the center (eg, invasive
cardi and neurointerventional procedures). Thus,
patients from the urgent care center (the MSKCC
emergency department equivalent), the ICU, and
general units are routinely transferred back and forth
between MSKCC and NYPH.

**Study Population**

The MSKCC ICU database, medical records, and
correspondence from the referring hospitals were used
to identify all interhospital ICU transfers. The transfers
were categorized into 3 groups according to the pur-
pose of the transfer: specialty care (for oncological or
related procedures or therapies), general care (for rou-
tine critical care support), and nearby transfers (for
transfer back to MSKCC from NYPH after an invasive
cardi procedures or neurointervention). For the pur-
poses of this study, the specialty care group was the
only one whose data were analyzed.

Data abstracted from the medical records included
age; sex; admitting hospital service (medical or surgical);
and day, time, and date of previous hospital and ICU
admissions. Clinical data included the score on the
Mortality Probability Model, version 2 (MPM[0,II]), and
serum lactate level on arrival at the cancer center ICU;
resuscitation status; and use of mechanical ventilation,
avasopressors, or renal replacement therapy at the time
of transfer or during the ICU stay at MSKCC. Outcome
data included previous hospital and MSKCC hospital
length of stay, previous ICU and MSKCC ICU length of
stay, ICU and in-hospital mortality, and mortality at 3
months after discharge from MSKCC. Electronic records
were analyzed to determine whether the patients were
current or new to MSKCC.

**Cancer History and Interventions**

Oncological data included cancer type (thoracic,
gastrointestinal, genitourinary, hematologic, hematopoi-
etic stem cell transplant, head and neck, or other) and
history of previous cancer care at MSKCC or at an outside
hospital. Occasionally, MSKCC provides care for patients
without cancer but with cancer-related illnesses; thus,
these patients were also included in the analysis. The
intervention planned for each patient (interventional
radiology; pulmonary support; endoscopic or surgical
treatment of tumor-related bleeding or gastrointestinal
or airway obstruction; or chemotherapy), the indication
for the intervention, whether the intervention was actu-
ally performed at MSKCC, any associated complica-
tion, and the timing of the intervention in relation
to the transfer were determined. If a planned interven-
tion was not performed, medical records were con-
sulted to determine the reason for deferral.

**Hospital Transfer Data**

Transferring hospitals were identified by name
and location. Transfers were characterized by day
of week and time of transfer. Emergency medical
services data were analyzed to determine if compli-
cations occurred during interhospital transport, and
if complications did occur, what actions were taken,
if any.

**Statistical Analysis**

Descriptive data are summarized as mean and
standard deviation (SD), median and interquartile
range (IQR), or number and percentage.

**Results**

During the 5-year period, 143 of 4625 patients
(3%) admitted to the MSKCC ICU were transferred
from an ICU at another hospital. Of these, 47
patients (33%) were transferred specifically for

![Diagram](https://via.placeholder.com/150)

**Figure** Of the 4625 admissions to the Memorial Sloan Kettering Cancer Center intensive care unit (ICU) during the study, 47 were patients transferred from outside hospitals to receive specialty oncological care. Most of these patients (78%) received the planned intervention within 48 hours of transfer. Overall ICU mortality was 11% for the entire study group.
specialty interventions, thus representing 1% of total ICU admissions (see Figure).

Demographic and Clinical Data

The mean age was 57 (SD, 17) years, and 32 patients (68%) were men (Table 1). A total of 25 patients (53%) were admitted by surgical services. Scores on the MPM0II, and serum lactate levels on admission to the cancer center ICU were 28% (SD, 16%) and 1.3 (SD, 0.7) mmol/L, respectively. At the time of transfer, 20 patients (43%) were receiving mechanical ventilation, and none were receiving vasopressors or renal replacement therapies. An additional 4 patients required mechanical ventilation during their ICU stay, increasing the total number to 24 (51%). One patient (2%) required vasopressors in the ICU; none of the patients required continuous renal replacement therapy. None of the patients had do-not-resuscitate orders on admission to the cancer center ICU; however, do-not-resuscitate orders were placed for 6 patients (13%) during the patients’ ICU stay. Overall, the median ICU length of stay was approximately 8 days (4 days in the outside ICU and 4 days in the MSKCC ICU). The median total hospital stay was 13 days at MSKCC. ICU and hospital mortality at MSKCC were 11% and 19%, respectively (Table 1). Of the 37 patients who received planned interventions, 28 (76%) were discharged home alive. Among these 28 patients, mortality 3 months after discharge from the hospital was 43% (n = 12). The 10 patients who did not receive planned interventions were discharged home alive; their mortality 3 months after discharge from the hospital was 30% (n = 3).

Cancer Diagnoses and Interventions

The predominant cancers were neoplasms of the gastrointestinal tract, head and neck, hematologic system, and thorax; 3 patients did not have active cancer (Table 1). Among the study group, 30 patients (64%) were current patients at MSKCC; all 30 had had previous cancer therapies (surgery, chemotherapy, radiation therapy, stem cell transplant, or a combination of these therapies). Among the 17 patients new to MSKCC, 9 (53%) had received prior cancer treatment. A total of 37 patients (79%) received their planned interventions (Figure and Table 2) within 48 hours of ICU transfer. Because of an extensive tumor burden, the initial intervention of endobronchial stent placement was delayed for 1 of these 37 patients in order to provide high-dose radiotherapy. The patient subsequently underwent stent placement after 2 weeks in the ICU. Of the 10 patients transferred for chemotherapy, 5 patients (50%) had large mediastinal tumors causing airway or vascular compression, 2 (20%) had been treated previously at MSKCC, and 3 (30%) were transferred to receive therapeutic regimens that were not available at the transferring hospital.

Complications related to the performed interventions occurred in 3 patients (8%); 1 patient progressed to airway obstruction and respiratory failure within 96 hours of insertion of a tracheal stent, and 2 patients did not respond to chemotherapy and experienced multiorgan failure within 72 hours of receiving the chemotherapy. The signs and symptoms of the 10 patients who did not receive planned interventions (endoscopic stent for airway obstruction in 6 patients and interventional radiology embolization for tumor bleeding in 4 patients) were controlled with conservative measures.

### Table 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Study groupa (n = 47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>57 (17)</td>
</tr>
<tr>
<td>Sex, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>32 (68)</td>
</tr>
<tr>
<td>Female</td>
<td>15 (32)</td>
</tr>
<tr>
<td>Cancer type, No. (%)</td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>11 (23)</td>
</tr>
<tr>
<td>Thoracic</td>
<td>10 (21)</td>
</tr>
<tr>
<td>Hematologic</td>
<td>9 (19)</td>
</tr>
<tr>
<td>Head and neck</td>
<td>8 (17)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (6)</td>
</tr>
<tr>
<td>Hematopoietic stem cell transplant</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Genitourinary</td>
<td>1 (2)</td>
</tr>
<tr>
<td>No cancer</td>
<td>3 (6)</td>
</tr>
<tr>
<td>MPM0II, mean (SD), %</td>
<td>28 (16)</td>
</tr>
<tr>
<td>Lactate level, mean (SD), mmol/L</td>
<td>1.3 (0.7)</td>
</tr>
<tr>
<td>Mechanical ventilation, No. (%)</td>
<td>24 (51)</td>
</tr>
<tr>
<td>Continuous renal replacement therapy, No. (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Vasopressors, No. (%)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Length of stay, median (IQR), days</td>
<td></td>
</tr>
<tr>
<td>In outside hospital</td>
<td>4 (2.4-5)</td>
</tr>
<tr>
<td>In ICU at outside hospital</td>
<td>4 (2-4)</td>
</tr>
<tr>
<td>In MSKCC ICU</td>
<td>4 (2-6.5)</td>
</tr>
<tr>
<td>In MSKCC after ICU (n = 32)</td>
<td>6 (2-15.5)</td>
</tr>
<tr>
<td>Total in MSKCC</td>
<td>13 (8-21.5)</td>
</tr>
<tr>
<td>ICU mortality, No. (%)</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Hospital mortality, No. (%)</td>
<td>9 (19)</td>
</tr>
</tbody>
</table>

Abbreviations: ICU, intensive care unit; IQR, interquartile range; MPM0II, Mortality Probability Model, version 2, score on ICU admission; MSKCC, Memorial Sloan Kettering Cancer Center.

aBecause of rounding, not all percentages total 100.
10 patients did not undergo their planned interventions after transfer, and interestingly, their signs and symptoms resolved. The procedural cancellations “saved” the patients from potentially unnecessary procedures and highlighted the necessity, benefit, and value of the interhospital transfers with the associated on-site review by oncological intensivists, proceduralists, and oncologists. A similar scenario has been previously described in patients with respiratory failure who were transferred to ECMO centers and whose clinical conditions improved without ever receiving ECMO.10

Interhospital ICU to ICU transfers commonly are associated with longer lengths of stay and higher mortality rates than are direct ICU admissions from the standard sources (emergency department, general units, operating rooms, and postanesthesia care units).17-19 However, in our study we found the opposite. Compared with our usual ICU patients, patients in the study group had shorter ICU length of stay (4 vs 6.5 days) and lower ICU mortality rates (11% vs 18%). These findings may be due to our interhospital ICU triage policy that mandates direct ICU admission for all patients transferred from outside hospital ICUs. Although difficult to discern retrospectively, many of these patients may not have been transferred to the ICU if they were already on the medical or surgical units at MSKCC. The inter-

### Transfer Data

The majority of the patients (n = 42; 89%) were transferred on weekdays. Approximately half of the patients (24) arrived after 5 PM. Patients were transferred from 38 different hospitals, mostly hospitals in urban areas of New York and New Jersey. Only 2 patients (4%) experienced adverse events during the transfer process (hypoxia due to airway obstruction treated with supplemental oxygen).

### Discussion

In this study, we found a low overall rate (3%) of interhospital ICU transfer of cancer patients to the ICU at MSKCC and an even lower rate (1%) for the purpose of receiving specialty interventions. Our rate of interhospital ICU transfer of adult critically ill cancer patients was lower than the rates (4.5%-22%) described previously for transfers of adult ICU patients to ICUs of full-service medical centers.14-1 The proposed reasons for this finding. First, our cancer center may not be comparable to a large medical center in the range of services offered because we focus primarily on defined oncological interventions. Second, oncological interventions, similar to the ones we studied, may also be available in many community hospitals, theoretically limiting the need for such transfers.

To our knowledge, we are the first to report on the outcomes of planned specialized interventions for critically ill patients transferred to a tertiary cancer center. We found that the planned interventions were performed in the majority (79%) of cases. Most of these patients (92%) did not experience any complications related to the interventions. However, 10 patients did not undergo their planned interventions after transfer, and interestingly, their signs and symptoms resolved. The procedural cancellations “saved” the patients from potentially unnecessary procedures and highlighted the necessity, benefit, and value of the interhospital transfers with the associated on-site review by oncological intensivists, proceduralists, and oncologists.

### Table 2

<table>
<thead>
<tr>
<th>Reason for transfer (n = 47)</th>
<th>Planned interventions</th>
<th>Performed interventions</th>
<th>Performed but complications</th>
<th>Not performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway obstruction (n = 19, 40%)</td>
<td>Endoscopic stent (n = 17)</td>
<td>11a</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Gastrointestinal obstruction (n = 2, 4%)</td>
<td>Endoscopic stent (n = 2)</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tumor bleeding (n = 12, 26%)</td>
<td>Interventional radiology, embolization (n = 10)</td>
<td>6</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Mediastinal mass (n = 5, 11%)</td>
<td>Chemotherapy (n = 5)</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Regimen unavailable at outside hospital (n = 3, 6%)</td>
<td>Chemotherapy (n = 3)</td>
<td>3</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Prior MSKCC patients (n = 2, 4%)</td>
<td>Chemotherapy (n = 2)</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Specialized procedures (n = 4, 9%)</td>
<td>Denver shunt (n = 1)</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Empyema drainage (n = 3)b</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

a Includes 3 patients without cancer who received tracheal stents for benign airway obstruction (tracheomalacia, connective tissue disease, and postoperative fibrosis).
b Empyema drainage was done for patients who had infections develop in the chest wall and pleural space at previous surgical resection sites.
ventions may then have been performed without an associated ICU admission.

Our study has several limitations, including the retrospective design and the relatively small number of patients at a single tertiary cancer center. However, we think that the results are generalizable both to large medical centers and to the increasing number of specialty hospitals that accept patients for interventional care. The concomitant collection of data on interhospital ICU transfers only accounted for a small percentage of ICU admissions at MSKCC. Transferring physicians may have deferred transfer for extremely sick patients; alternatively, MSKCC might have deferred accepting such transfers because of safety considerations. Unfortunately, such information was not available to us. Finally, beyond specialized chemotherapy regimens, we could not ascertain if interventions offered at MSKCC were also available at transferring institutions.

Conclusion

In summary, interhospital ICU to ICU transfers are a small percentage of ICU admissions at MSKCC. The interventions planned before interhospital transfer, when deemed clinically appropriate, were implemented soon after arrival at MSKCC. Additional studies on the reasons for transfer, characteristics, resource use, and outcomes of interhospital ICU transfers of critically ill cancer patients could provide additional information about which patients are most likely to benefit from interhospital ICU transfer for specialized care.

FINANCIAL DISCLOSURES

None reported.

eLetters

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SCREENING SITUATIONS FOR RISK OF ETHICAL CONFLICTS: A PILOT STUDY

By Carol L. Pavlish, RN, PhD, Joan Henriksen Hellyer, RN, PhD, Katherine Brown-Saltzman, RN, MA, Anne G. Miers, RN, MSN, ACNS, CNRN, and Karina Squire, RN, MPH, CCRN

Background  Ethical conflicts, often leading to poor teamwork and moral distress, are very challenging to patients, patients’ families, and health care providers. A proactive approach to ethical conflicts may improve patient care outcomes.

Objectives  To examine acceptability and feasibility of an ethics screening and early intervention tool for use by nurses caring for critically ill patients.

Methods  Twenty-eight nurses in 2 medical centers applied the ethics screening tool to 55 patient situations. Nurses assessed situations for risk factors and early indicators of ethical conflicts and analyzed level of risk. At study completion, nurses participated in focus group discussions about the tool’s benefits and challenges. Frequency counts were performed on risk factors and early indicators of ethical conflicts. Content analysis was used on written explanations regarding high-, medium-, and low-risk situations and on focus group data.

Results  Older patients with multiple comorbid conditions and aggressive treatments were frequently assessed to be at risk for ethical conflicts. Nurses who witnessed patients’ suffering and deterioration were likely to initiate the screening process. The most prominent family risk factors included unrealistic expectations and adamancy about treatment. The most prominent early indicators were signs of patients’ suffering, unrealistic expectations, and providers’ own moral distress. High-risk situations averaged a greater number of risk factors and early indicators than did medium- and low-risk situations. Certain risk factors featured prominently in high-risk situations.

Conclusions  A phenomenon of shared suffering emerged from the study and signifies the importance of relational strategies such as routine family conferences and ethics consultation.

(American Journal of Critical Care. 2015;24:248-257)
Background

Current ethical conflicts reflect advanced medical technology, consumers’ expectations of medical care, tension between patient autonomy and medically appropriate treatment, shifts in health care financing, and limited economic and workforce resources. Providers’ expectations of medical care, tension between patient autonomy and medically appropriate treatment, shifts in health care financing, and limited economic and workforce resources.5,9 Sources of ethical conflict include poor communication, competing values and interests, divergent goals, and disruptive behavior.9-11 Whether they occur between providers and patients’ families or among health care teams themselves, ethical conflicts in intensive care units (ICUs) are prevalent.2,5,12-15 In the Conflicus Study, 71.6% of 7498 ICU nurses and physicians in 24 countries reported a perceived ethical conflict in the week before the survey.2 Swetz et al16 reviewed 255 ethics consultations and reported that most cases involved multiple ethical conflicts including staff disagreement with the plan of care (76%), end-of-life issues (60%), and futility concerns (54%); 40% involved ICU situations.

Ethical conflicts are among the most challenging situations faced by patients with life-threatening conditions, their families, health care providers, and the health care system.1-5 In complex clinical situations, different moral perspectives are expected and can improve the plan of care. However, if health care providers avoid discussion about ethical concerns or systems fail to provide opportunities to resolve disagreements, ethical conflicts often result in suffering of patients. Ethical conflicts represent divergent values and are usually accompanied by strong and sometimes troubling emotions.6 Furthermore, ethical conflicts can lead to providers’ moral distress, which the American Association of Critical-Care Nurses identifies as critically important.7 In a consensus statement, the American College of Critical Care Medicine asserted that effective team communication plays a crucial role in preventing and managing ethical conflicts during end-of-life care.8 In this article, we describe a research project that pilot tested a new ethics screening and early intervention tool to improve communication and prevent potentially harmful conflicts and moral distress.

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Ethical conflicts often result in moral distress among providers and suffering of patients.
Nurses’ moral distress is associated with absenteeism, burnout, and leaving the profession.

The negative effects of ethical conflicts are widespread for patients, patients’ families, and health care providers. Quality care and patient safety are threatened when health care providers are burdened by stressful ethical conflicts that erode interpersonal trust, compromise working relationships, and fragment care. Furthermore, these compromised relationships increase patients’ mortality and morbidity and organizational costs. Ethical conflicts can also delay treatment decisions and increase the risk for family conflict.

Ethical conflicts contribute to moral distress, Jameton introduced the concept of moral distress as an experience in which a person is constrained from taking an action he or she believes to be right. Moral distress not only affects individual behavior but also the workplace environment. For example, distressed health care providers can experience decreased job satisfaction, unsettling physical symptoms such as insomnia and headaches, and disruptive psychological symptoms such as loss of confidence and self-worth. Moreover, nurses’ moral distress has been associated with absenteeism, burnout, intentions to quit, and leaving the profession. These consequences can lead to inadequate staffing, which in turn, is linked to unfavorable patient outcomes such as hospital-acquired infections. Lingering effects of providers’ moral distress can lead to moral desensitization, harmful workplace climates, and suffering of patients and their families. The health system itself is financially affected when moral distress drives nurses and other providers to decrease their work engagement and productivity.

**Method**

This feasibility study was conducted at Mayo Clinic in Rochester, Minnesota and the University of California Los Angeles Medical Center. Two institutional review boards approved the study. The aim was to assess utility and acceptability of an ethics screening tool for clinical practice.

**Development of the Ethics Screening and Early Intervention Tool**

We used the results of a critical incident study to construct the tool. Pavlish et al asked nurses to identify risk factors for and early indicators of ethical dilemmas and conflicts. We selected the most prevalent responses and constructed the tool accordingly. Five critical care, oncology, and ethics experts assessed the tool for content clarity and relevance. The tool’s first section required nurses to assess clinical situations for which risk factors and early indicators were evident and to analyze the level of risk (low, medium, high) that the situation was likely to develop into an ethical conflict. Next, nurses identified appropriate follow-up actions. Finally, nurses were asked to appraise the risk of negative consequences for themselves if they initiated action to address the potential conflict.

**Participants**

We recruited oncology and ICU nurses via flyers; 28 bedside nurses participated, 14 from each site. Most (n = 25) worked in ICUs. Five men and 23 women participated; they had a mean of 9.65 years of clinical experience. Educational preparation included 1 diploma, 4 associate’s degrees, 21 baccalaureate degrees, and 2 master’s degrees. Half of the participants reported ethics education as part of their nursing curriculum, 5 reported attending ethics conferences, and 9 reported little or no ethics training. Most nurses were white; 1 nurse was African American, 1 was Asian American, and 1 was a Pacific Islander.

**Study Procedures and Data Collection**

Before ethics screening started, participants attended a 4-hour ethics workshop where researchers reviewed ethical responsibilities, a case study with guidelines on raising concerns, and orientation to the ethics tool and study procedures. Researchers in both sites used the same training materials and discussion outline. Because the workshop was interactive, active, many participants raised their own questions and provided their own examples. The result was a structured, interactive dialogue about ethical responsibilities and concerns. After the workshop, we asked participants to apply the screening tool in clinical practice for 3 months. All but one nurse initiated the tool when an ethics-related issue seemed pertinent. One ICU nurse chose to change his use of the tool to 6 weeks of the study and applied the tool on every patient he cared for. Because his use of the tool varied from that of other participants, we analyzed and reported his data separately.

When applying the tool, nurses also responded to a brief questionnaire with 2 major sections: (1) ethics situation such as patients’ diagnoses, general condition, and time required for screening, and (2)
tool’s usefulness for that particular situation. After study completion, nurses evaluated the tool’s overall usefulness and acceptability and also attended a 1-hour focus group session to describe their experiences. All focus groups were digitally recorded and transcribed. For this article, we reported quantitative data about the clinical situations, including pertinent risk factors and early indicators and qualitative data on how nurses analyzed whether situations were very likely (high risk), somewhat likely (medium risk), or not likely (low risk) to develop at least one ethical conflict. Interventions deemed appropriate for the situation and nurses’ own perceived risks in implementing the intervention are reported elsewhere.70

Data Analysis

We calculated frequency of risk factors and early indicators with descriptive statistics. Content analysis was used on the written explanations about high, medium, and low risk levels for each situation and the focus group data. All qualitative data were initially detail-coded with subsequent collating of codes into specific insights about the data.71 Specific quotes correlating with the study findings were highlighted.

Results

Situational Factors

Nurses initiated the ethics screening tool most often on older patients who had multiple comorbid conditions and were currently hospitalized for life-threatening sepsis or organ injury and/or organ failure (Table 1). In both sites, nurses who witnessed patients’ suffering and deterioration were most likely to initiate the screening process. During the focus groups, when asked what triggered ethics screening, nurses identified responding to an “uncomfortable feeling” that something was “out of the ordinary” or “wasn’t running smoothly.” One nurse stated, “Something was wrong and at the time I didn’t know what. Then looking at my choices [on the screening tool], it was a whole lot easier for me to understand and communicate what I was thinking to my co-workers.” As previously mentioned, one ICU nurse after approximately 6 weeks, decided that ethics screening should be “standard care” and therefore, screened all patients he admitted during the remaining test period. The time required for ethics screening was usually less than 10 minutes.

When applying the screening tool to specific patient situations, nurses identified patient and family risk factors for ethical conflicts more often than health care team and system factors (Table 2). Life-threatening illness and patients’ vulnerabilities such as advanced age, diminished capacity, and inability to speak English were the risk factors most prevalently identified at both sites. Nurses across both settings also identified “family adamancy about aspects of patient care” and “unrealistic expectations” as prominent risk factors. The most prominent early indicators of ethical conflicts were the same in both settings and included “signs of patient suffering” and “signs of unrealistic expectations” followed closely by indicators of nurses’ own moral distress.

Risk Level Assessment

The screening tool asked nurses to analyze whether situations were high, medium, or low risk for ethical conflicts and briefly explain their reasoning. High-risk situations averaged more risk factors and early indicators than medium- and low-risk situations (10.17 vs 7.46 and 1.9, respectively). A few risk factors were especially prevalent in the high-risk versus medium- and low-risk categories: (1) patients who were imminently dying (50% vs 16.7% and 3%, respectively) and (2) situations that involved family disagreements with care (50% vs 10.7% and 3.4%, respectively). Signs of moral distress among caregivers occurred in both high-risk and medium-risk situations, but were more likely to occur in high-risk situations (67.8%) than in medium-risk situations (58.3%). Nurses never indicated signs of moral distress in low-risk situations. Signs of conflict were also more prevalent in high-risk situations (57%) than in medium-risk (41.6%) and low-risk (12.9%) situations. Signs of patients’ suffering were also prevalent in both high-risk and medium-risk situations, but rare in low-risk situations.

Nurses’ narrated rationale for assigning risk revealed some patterns. For example, nurses consistently reasoned that high-risk situations included decidedly aggressive treatments in patients with advanced illness or poor prognosis; violation of patients’ advance directives; distressed family members, especially if accompanied by disagreement with the plan of care; and health care providers’ own moral distress. Some nurses also reasoned that seriously ill patients without family or other supports were high risk. Situations that included uncertainty with plan of care or delays in making difficult decisions tended to be reasoned as medium risk and worth monitoring.
Screening Tool Benefits and Limitations

At the conclusion of the 3-month data collection period, we held focus groups and distributed a final survey. Nurses indicated that the screening tool’s primary benefit was its capacity to clarify “murky” issues in complicated clinical situations. For example, one nurse commented that the tool validated the participant’s concerns and proved “it wasn’t just some crazy nurse thinking a gut feeling.” Other nurses suggested that the tool “brings the conversation to the table” so everyone is “on the same page.” Some nurses commented that the tool empowered them to “push for an ethical plan of care” and also promoted teamwork, which relieved their moral distress. Other benefits included “the tool promotes nurses’ confidence,” and “starts conversations early enough

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<tr>
<td>Heart failure</td>
<td>6</td>
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<tr>
<td>Liver failure</td>
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<td>Brain injury (trauma, vascular)</td>
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<tr>
<td>Respiratory failure</td>
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<td>Complications after surgery</td>
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<td>Otherb</td>
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| **Patients’ health condition**           |                 |
| Deteriorating                            | 14              |
| Suffering distressing symptom            | 3               |
| Cognitively impaired                     | 5               |
| New diagnosis                            | 8               |
| Imminently dying                         | 6               |
| Other (prolonged illnesses)              | 2               |
| **Events that prompted screening**       |                 |
| Patient suffering                        | 9               |
| Vulnerable patient                       | 6               |
| Family statement                         | 8               |
| Code status                              | 7               |
| Admission to unit                        | 11              |
| Change in patient’s condition            | 8               |
| Health care provider’s statement         | 10              |
| Concern for patient’s autonomy           | 6               |
| Patient’s statement                      | 6               |
| Other                                    | 2               |

| Minutes required for screening           |                 |
| ≤ 5                                      | 12              |
| 6-10                                     | 9               |
| 11-15                                    | 3               |
| ≥ 16                                     | 3               |
| None listed                              | 3               |

---

a Nurse screened all patients he cared for instead of only when an ethical issue seemed likely.

b Cocaine overdose, cerebral palsy, systemic inflammatory response syndrome.

c Multiple responses in each situation.

d Daily assessment.

---

Table 1
Frequency of situational factors

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<thead>
<tr>
<th>Situational factors</th>
<th>Site A (30 patients)</th>
<th>Site B (25 patients)</th>
<th>Totals (55 patients)</th>
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<td>2</td>
<td>5</td>
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to prevent demoralizing crisis situations.” Nurses also believed that the tool was convenient, easy to use, and would be acceptable to complete on a daily basis.

Nurses also provided suggestions for improving the screening tool. For example, nurses suggested that ethics screening should be multidisciplinary and include the whole team in discussing different perspectives about care. Several nurses stated that the tool should be applied soon after a patient’s admission and regularly thereafter. Nurses frequently compared the ethics tool to skin and fall risk assessments; they suggested that the tool should be computerized, easily accessible, and expected as a standard of care. Others encouraged development of more objective measures for distinguishing between low-, medium-, and high-risk situations. Some nurses also indicated that the tool needed to provide more guidance for follow-up action. A few believed that the tool should include some automatic triggers. For example, one nurse stated, “If you were to create something that would automatically [trigger] a consult or some other action, it would decrease the possibility for interpersonal conflict.”

**Discussion**

Results indicate that nurses are aware of certain risk factors and early signs that potentiate ethical conflicts. Given the time that nurses spend at patients’ bedsides, it is not surprising that these nurses were especially sensitized to risk factors related to patients and patients’ families. Peter and Liaschenko” claimed that proximity to patients helps nurses understand their moral responsibilities but does not necessarily provide the resources and power to formulate a response. Participants in our study verified this assertion when describing their

<table>
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<td><strong>Frequency of risk factors and early indicators</strong></td>
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<tr>
<td>Failed treatments</td>
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<tr>
<td>Unnecessary suffering</td>
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<tr>
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<tr>
<td>Family risk factors</td>
</tr>
<tr>
<td>Adamancy about aspects of care or unrealistic expectations</td>
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<td>Uncertainty about plan of care</td>
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<tr>
<td>Disagreement with plan of care</td>
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<tr>
<td>Conflict between family members about plan of care</td>
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<tr>
<td>Other (no family present; family underpressure)</td>
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<tr>
<td>Multilevel risk factors</td>
</tr>
<tr>
<td>Need for cohesive plan of care</td>
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<td>Conflict among health care team about plan of care</td>
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<td>Divergence of views regarding prognosis</td>
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<td>Standard of care concern</td>
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<td>Other (false hope; uncertainty about capacity)</td>
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<td>Health care system risk factors</td>
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<td>Unclear or absent ethics policies</td>
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<td>Lack of clear, specific communication</td>
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<td>Other</td>
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<td>Total</td>
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<tr>
<td>Early indicators (checked all that apply)</td>
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<tr>
<td>Signs of patient suffering (prolonged, unrelieved pain)</td>
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<tr>
<td>Signs of unrealistic expectations (unwavering belief in patient recovery)</td>
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<tr>
<td>Signs of nurses’ moral distress (believe treatment is not helpful, causes suffering)</td>
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<tr>
<td>Signs of conflict (disagreements, different opinions)</td>
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<td>Signs of poor communication (avoid end-of-life and other difficult discussions)</td>
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<tr>
<td>Signs of ethics violation (disrespect autonomy, right to information/standard care)</td>
</tr>
<tr>
<td>Other (surrogate decision maker has diminished capacity, patient has no support)</td>
</tr>
<tr>
<td>Total</td>
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distress with difficult situations. For example, a particularly surprising finding was that despite nurses’ comments about the empowering benefits of the screening tool, several nurses still remained silent about their concerns. Nurses described power structures and unit norms that often dictate who gets to say what in these complex situations. From this, we reasoned that the screening tool strengthened nurses’ internal voices but did not necessarily encourage them to voice their concerns to others. We believe that this finding also explains why nurses suggested objective measures for determining risk level, more guidance for follow-up action, and automatic triggers for certain actions such as ethics consultation.

Nurses identified multiple risk factors and early indicators of ethical conflicts in all high- and medium-risk situations. Furthermore, they had little trouble distinguishing low-risk from medium-risk and high-risk situations, although some indicated that they had difficulty distinguishing between medium- and high-risk situations. This may indicate that these complex situations are very fluid and have multiple, influencing variables with uncertain outcomes. Additionally, not much is known about the characteristics of ethically difficult situations or the effectiveness of follow-up actions. A few studies exist. For example, Schneiderman and colleagues found in a multi-center randomized trial that ethics consultations were effective in decreasing conflicts. Browning found that nurses who reported being involved in patient care conferences were less likely to experience moral distress, which is often associated with ethical conflicts. In an intervention led by ICU nurses, researchers found improved surrogate decision making and urged nurses to become more involved in collaborative discussions about ethical issues.

In our research, the top 3 indicators of high risk for ethical conflicts in both settings pertained to patients’ suffering, providers’ distress, and unrealistic expectations among patients’ families. When families are distressed and adamant and providers believe that treatments are harmful and increase needless suffering, patients ultimately endure the consequences. This triangle of suffering may reflect a phenomenon of shared suffering. If suffering is seen as an individual experience, as it often is, feelings of isolation and being trapped in silence can result. In contrast, if suffering is viewed as a shared experience, then easing suffering could also include relational treatments such as timely and periodic family care conferences that not only provide information but also create an atmosphere of trust by being present to one another, listening, and acknowledging grief. In addition, the team might benefit from collaborative work with clinical ethics and palliative care. Relational interventions that decrease the emotional suffering of critically ill patients and their families as they confront important treatment decisions need to be researched.

Limitations

Results are limited by the small, nonrepresentative sample. Participants who volunteered might be more interested and sensitive to ethical issues in clinical practice, which could skew the results. The 3-month time period also limits any conclusions about sustainability of the benefits of using the tool. Our deciding not to require nurses to implement follow-up actions that were included on the tool limits our findings on the tool’s usefulness and acceptability. Future research should determine the effectiveness of the tool by measuring outcomes such as stress and perceptions of care among patients and their families, providers’ moral distress, and team collaboration.

Conclusion

Four key results from our study seem particularly relevant to critical care nurses. First, we learned that seriously ill patients are at risk for ethical conflicts and that all patients may benefit from being initially and periodically evaluated for that risk. Screening all critically ill patients would lead to early identification of particular medium- and high-risk situations and prompt early action that could modify risk and mitigate suffering for both patients and caregivers. Second, we learned that using an ethics screening and early intervention tool is feasible but needs to include a team-based approach, objective indicators, and clear guidelines for follow-up actions. More research on specific actions such as relational support that mitigates or prevents ethical conflict is needed. Third, we learned that nurses should be involved in ethics-related discussions, but ethical concerns are sometimes perceived by critical care nurses as too risky to voice. To address this risk, we need to create systems that set a high standard for collaboration in ethics conversations for all ICU patients. Critical care researchers indicate that nurses are well positioned to initiate and strengthen teamwork in ethically complex situations. Specific approaches for early nursing assessment that leads

The top 3 indicators for ethical conflicts are patients’ suffering, providers’ distress, and families’ unrealistic expectations.
to collaborative action need to be developed and tested. Finally, we learned that suffering is a complex, shared experience that has significant consequences for patient, family, and the care team. Responding to shared suffering through early recognition of moral disagreements and implementing relational approaches to address differences could mitigate conflict and mounting distrust, providing an opportunity for authentic dialogue, deeper understandings, and good outcomes.

FINANCIAL DISCLOSURES

This work was funded by a Sigma Theta Tau International Research Grant.

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REFERENCES


1. Which of the following statements reflects an ethical conflict?
   a. A patient with stage IV lung cancer has determined his code status as "do not resuscitate and do not intubate (DNR/DNI)."
   b. A patient with stage IV lung cancer has agreed to palliative radiation therapy.
   c. A patient with stage IV lung cancer has become unable to make his own decisions and the surrogate decision maker wishes to reverse the DNR/DNI status that was decided previously by the patient.
   d. A patient with stage IV lung cancer understands that chemotherapy will not be curative.

2. Which of the following strategies is considered to be the most effective and manage ethical conflicts in the intensive care unit (ICU)?
   a. Ethical consultations to override decisions for aggressive treatment
   b. Authentic leadership and appropriate staffing
   c. Effective team communication
   d. Palliative care consults

3. Ted, a longtime ICU night nurse, has asked to work day shift after he was involved in a difficult situation where he disagreed with the aggressive plan of care for a patient with end-stage liver disease who required weeks of treatment and an ethics consult. Which of the following reflects that Ted may be experiencing moral distress?
   a. Ted has developed insomnia and recurrent headaches after this situation.
   b. Ted has expressed the professional goal to become involved in the hospital’s ethics committee.
   c. Ted has collegial relationships with the nurses and physicians on the night shift and wants to expand this to the day-shift colleagues.
   d. Ted has had several difficult conversations with the attending physician regarding end-of-life care for patients.

4. What is the basis for “prognostic conflict”? 
   a. There are differing opinions between providers about the diagnosis.
   b. There are 2 different treatment regimens for the diagnosis.
   c. There is a poor prognosis and palliative care is initiated.
   d. There are different perspectives regarding anticipated benefit from aggressive treatment.

5. Which of the following statements most accurately reflects the relationship between low-, medium-, and high-risk ethical conflicts as perceived by the nurses in the study?
   a. It was often difficult for nurses to distinguish between medium- and high-risk patient situations.
   c. Unit norms and power structures had significant influence on which risk level was scored.
   d. Low-risk situations were screened as such due to the presence of structured family meetings.

6. Application of the ethics screening tool was found to identify which of the following risk factor categories as the most prevalent?
   a. Health care team
   b. Health care system
   c. Family
   d. Individual

7. Which of the following statements most accurately reflects the identification of patients that prompted the use of the ethics screening tool in this study?
   a. Young patients with terminal disease processes
   b. Elderly patients with life-threatening sepsis or organ failure
   c. Elderly patients without family support
   d. Middle-aged patients with traumatic brain injury

8. Which of the following statements reflects most accurately the analysis of risk factors by the nurses in the study?
   a. Nurses indicated moral distress among caregivers in low-, medium-, and high-risk situations.
   b. Signs of patient suffering were prevalent in high- and medium-risk situations.
   c. Family disagreements regarding care were prevalent in high- and medium-risk situations.
   d. Seriously ill patients without family were considered low risk for ethical conflict.

9. The nurses in the study found which of the following to be the primary benefit of an ethics screening tool?
   a. Promotes nursing confidence to relieve moral distress
   b. Identifies what needs to be done for ethical issues
   c. Promotes teamwork surrounding identification of ethical issues
   d. Empowers nurses by clarifying issues in complicated clinical situations

10. The authors concluded which of the following key results regarding ethics screening?
    a. A nurse-driven screening tool is sufficient to guide early interventions.
    b. Routine screening of all critically ill patients could lead to earlier ethical action.
    c. Team-based collaboration for screening is only helpful for seriously ill patients.
    d. Moral distress is eliminated by ethics screenings.

11. Which of the following were identified by the authors as the top 3 indicators of high risk for ethical conflicts?
    a. Providers’ distress, violation of patients’ advance directives, concern for patients’ autonomy
    b. Unrealistic expectations from patients’ families, violation of patients’ advance directives, patients’ advanced illness
    c. Unrealistic expectations from patients’ families, providers’ distress, and patients’ suffering.
    d. Providers’ distress, patients’ suffering, patients’ advanced illness.

12. Which of the following statements most accurately reflects the authors’ view of suffering in ethical conflicts?
    a. Easing shared suffering may be accomplished through family care conferences and grief acknowledgement.
    b. Relational interventions to relieve suffering are well studied.
    c. An atmosphere of trust is violated in shared suffering.
    d. Clinical ethics and palliative care are the only avenues by which to alleviate shared suffering.

Test ID: A152403  Test Answers: Mark only one box for your answer to each question.

1. ☐ a  2. ☐ a  3. ☐ a  4. ☐ a  5. ☐ a  6. ☐ a  7. ☐ a  8. ☐ a  9. ☐ a  10. ☐ a  11. ☐ a  12. ☐ a

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Objective 1 was met ☐ ☐
Objective 2 was met ☐ ☐
Objective 3 was met ☐ ☐
Content was relevant to my nursing practice ☐ ☐
My expectations were met ☐ ☐
This method of CE is effective for this content ☐ ☐
The level of difficulty of this test was: easy ☐ medium ☐ difficult ☐
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A closed-book, multiple-choice examination following this article tests your understanding of the following objectives:

1. Describe the methods of the study.
2. Identify the incidence of aspiration during repositioning of patients.
3. Discuss the results of the study.

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Background  Withholding enteral feedings during repositioning is based on tradition, but available evidence does not support this practice. Although research indicates that withholding of enteral feedings during repositioning contributes to undernourishment, the relationship between continuing enteral feedings during repositioning and the incidence of aspiration has not been determined.

Objective  To determine the feasibility of a study designed to explore differences in the incidence of aspiration when enteral feedings are withheld or continued during repositioning.

Methods  A crossover design with a convenience sample from 3 medical and 3 surgical intensive care units was used. Two sample sets of subglottal secretions were collected from each patient, once when enteral feedings were withheld during repositioning and once when feedings were continued during the change in position. The incidence of aspiration was assessed by testing specimens for the presence of pepsin.

Results  Subglottal secretions were collected from 23 patients (n=46 with crossover design). Aspiration during repositioning occurred in 2 patients when enteral feedings were withheld and in 2 patients when feedings were continued during repositioning. According to the McNemar test, the incidence of aspiration when enteral feedings were withheld did not differ significantly from the incidence when the feedings were continued during repositioning (P=.88).

Conclusions  A research protocol to directly explore the relationship between the incidence of aspiration and withholding or continuing enteral feedings during repositioning is feasible. (American Journal of Critical Care. 2015;24:258-262)
The purpose of our study was to obtain preliminary data and explore the feasibility of the study design. The ultimate goal is to develop evidence-based clinical policies and procedures to standardize care and reflect best practice.

**Methods**

Because currently both continuing and withholding enteral feedings occur in routine practice, a crossover design was used. This design made any deviation from standard practice unnecessary and allowed each patient to serve as his or her own control, optimizing both patient safety and the strength of the study.4 Patients were included in the study if they were 18 years or older, admitted to a medical or surgical intensive care unit, endotracheally intubated and treated with mechanical ventilation, and receiving enteral feedings at ordered goal volumes or at a rate of at least 50 mL/h. Patients were excluded if routine subglottal suctioning was contraindicated, backrest elevation was less than 30°, gastric residual volumes were greater than 200 mL, or enteral feedings were delivered via postpyloric or surgical jejunostomy tube. The study was approved by the appropriate institutional review board.

Patients were screened by review of the daily census. Data were collected from all patients who met the inclusion criteria. Randomization in a crossover design is achieved by counterbalancing the treatment effects such that their order is systematically varied.7 In this study, patients were randomly assigned to the withhold-continue or the continue-withhold sequence by using a random number table. Specimens were collected by 3 of the study investigators (J.D., M.L., S.O.). Before data collection, interrater reliability between all data collectors was verified. At the time of data collection, the angle of the head-of-bed elevation was measured by using protractors and was recorded. After this measurement, gastric residual volume was determined. Subglottal specimens were obtained with a 14F suction catheter attached to a sputum trap. Two samples were obtained during each collection. The first sample was obtained before repositioning; the second sample, after repositioning. The first sample was used as a control for baseline aspiration. The second set of specimens was collected at the next position change. All specimens were pipetted into tubes, placed on ice, and immediately transported for storage in a -80°C freezer until data collection was completed. All specimens were then transported together on dry ice to a research laboratory for analysis.

Specimens were tested for pepsin by using an enzyme-linked immunoassay and were analyzed for differences in the incidence of aspiration between times when enteral feedings were withheld during repositioning and times when enteral feedings were continued during repositioning. The data were analyzed by using the McNemar test.

**Results**

A total of 23 patients (n = 46 with the crossover design) were enrolled in the study, and samples were collected between July 20, 2012, and September 10, 2012. Of the 23 patients, 13 were admitted to medical intensive care units and 10 were admitted to surgical intensive care units. Patients were 31 years to 91 years old (median, 64 years).

Enteral feeding rates were 30 mL/h to 75 mL/h (mean; 52 mL/h; SD, 12.3 mL/h). Feeding rates did not change between the time of collection of the first and second set of subglottal specimens. Gastric residual volumes were 0 mL to 180 mL (mean, 17.4 mL; SD, 40.2 mL). Gastric residual volumes were less
than 100 mL in all detected instances of aspiration that occurred during repositioning. The head of the bed was lowered for 3 to 10 minutes (mean, 5.4 min; SD, 1.9 min) when enteral feedings were withheld and 3 to 12 minutes (mean, 6.1 min; SD, 2.4 min) when enteral feedings were continued.

Pepsin results were reported in picograms per milliliter. The reported criterion threshold\(^6\) for determining pepsin levels indicative of aspiration is 70 to 108.1 pg/mL. This threshold was validated in our study, and the lower value of 70 pg/mL was used as the criterion threshold. Aspiration during repositioning occurred in 4 patients, 2 when enteral feedings were withheld and 2 when enteral feedings were continued. However, in 1 of these patients, although aspiration occurred when enteral feedings were continued during repositioning, it could not be determined whether or not aspiration occurred when enteral feedings were withheld during repositioning. Therefore, data on this patient were excluded from primary analysis.

The McNemar test revealed no significant difference between the incidence of aspiration during repositioning when enteral feedings were withheld and the incidence when the feedings were continued (\(P=.88\)). Because of the possibility of aspiration during repositioning in instances when the specimens obtained both before and after repositioning were positive for pepsin, the specimens that were positive at both times were included as specimens indicative of aspiration in a secondary analysis. When these specimens were included as results indicative of aspiration, the McNemar test still revealed no significant difference between the incidence of aspiration during repositioning when enteral feedings were withheld and the incidence when the feedings were continued (\(P=.61\)).

**Discussion**

Precautionary withholding of enteral feedings during repositioning of patients has been a longstanding practice. Despite recent evidence suggesting that such withholding should be avoided, the lack of direct research findings has contributed to marked variations in practice.\(^7\) Our results indicate the feasibility of a research protocol designed to directly explore the relationship between the withholding or continuing of enteral feedings during repositioning and the occurrence of aspiration. The ability of the research team to enroll the target sample of 23 patients within the study period suggests that obtaining a larger sample for future studies should not be difficult. Further, our findings show that the data collection procedures and instruments we used are appropriate and that a larger-scale study can be safely implemented.

The frequency of baseline aspiration has been reported to be as high as 70% to 88% in critically ill patients.\(^3\) Therefore, baseline aspiration must be accounted for in assessment of the occurrence of aspiration during repositioning. Collecting a sample before repositioning is an ideal method to control for baseline aspiration.

**Conclusion**

Precautionary withholding of enteral feedings during repositioning does not reduce the incidence of aspiration in critically ill patients. Our results show the logistic feasibility of conducting a larger scale study and indicate the minimal risk associated with this study design. The study findings will be used to support implementation of a larger-scale study. Other variables that were not fully described in our study, including how long the head of the bed was lowered at each point of data collection and level of sedation, should be further explored in larger, subsequent studies. Further research is needed to provide the definitive evidence necessary to support the development of policy and practice that will optimize the delivery of enteral feedings and minimize morbidity and mortality related both to undernourishment and aspiration in critically ill patients.

**FINANCIAL DISCLOSURES**

This research was supported by internal funding provided by the Louis E. Silverman Department of Nursing, Beth Israel Deaconess Medical Center, and by Clinical Translational Science Award UL1RR025758 to Harvard University, Cambridge, Massachusetts, and Beth Israel Deaconess Medical Center from the National Center for Research Resources. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

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For more about withholding nutrition, visit the Critical Care Nurse Web site, [www.ccnonline.org](http://www.ccnonline.org) and read the article by Stewart, “Interruptions in Enteral Nutrition Delivery in Critically Ill Patients and Recommendations for Clinical Practice” (August 2014).
REFERENCES


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1. The nursing practice of continuing or withholding enteral feeding during reposition of patients receiving mechanical ventilation is based on which of the following?
   a. Research
   b. Tradition
   c. Experience
   d. Evidence

2. Which of the following types of study design was used?
   a. Cross-sectional survey
   b. Randomized controlled trial
   c. Crossover design
   d. Quasi-experiment

3. Which of the following patients were not included in the study?
   a. Patients 18 years of age or older
   b. Patients admitted to a medical or surgical intensive care unit
   c. Patients who were intubated and receiving mechanical ventilation
   d. Patients with gastric residual volumes greater than 200 mL

4. Which of the following was the purpose of this study?
   a. Obtain preliminary data and explore the feasibility of the study design
   b. Standardize care
   c. Develop new policies
   d. Establish a tube-feeding algorithm

5. Subglottic specimens were tested for which of the following?
   a. Hydrochloric acid
   b. Amylase
   c. Pepsinogen
   d. Pepsin

6. Which of the following was used to analyze the data?
   a. Fisher exact test
   b. McNemar test
   c. Paired-t test
   d. Mann-Whitney test

7. How many subglottic specimen samples were obtained during each collection?
   a. One
   b. Two
   c. Three
   d. Four

8. Gastric residual volumes were less than which of the following in all detected incidences of aspiration that occurred during repositioning?
   a. 100 mL
   b. 150 mL
   c. 200 mL
   d. 250 mL

9. The frequency of baseline aspiration in critically ill patients has been reported to be as high as which of the following?
   a. 50% to 60%
   b. 65% to 75%
   c. 70% to 88%
   d. 75% to 85%

10. Which of the following levels of pepsin was used as the criterion threshold?
    a. 50 pg/mL
    b. 60 pg/mL
    c. 70 pg/mL
    d. 80 pg/mL

11. Aspiration during repositioning occurred in how many patients?
    a. One
    b. Two
    c. Three
    d. Four

12. Which of the following was measured and recorded at the time of data collection?
    a. Height
    b. Weight
    c. Head-of-bed elevation
    d. Pepsin

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CARING FOR PATIENTS WITH ENTERAL FEEDINGS

By Linda Bell, RN, MSN

The withholding of enteral feedings during repositioning of critically ill patients receiving mechanical ventilation is based on tradition. However, DiLibero et al.¹ remind us that there is no consistent standard for managing continuous enteral feedings while repositioning patients. This matter weighs the risk of aspiration against the potential interruption of nutrition that will negatively impact the patient. It is important that all patients receiving enteral feedings, whether continuously or in intermittent bolus feedings, are assessed for feeding tube positioning and feeding tolerance before making any repositioning practice a standard for the unit. It should not be assumed that one standard protects all patients equally.

Here’s what you can do:

• Survey the staff on your unit for their understanding of safety practices during enteral feedings including assessment for feeding tube positioning and feeding tolerance.
• Collaborate with an interprofessional team of nurses, physicians, respiratory therapists, speech therapists and nutritional support to determine needs of your patients.
• Consider the needs of patients who are receiving mechanical ventilation and those who aren’t.
• Include your medical librarian in a literature search to find current practice recommendations.
• Evaluate the literature based on your patient population.
• Develop process standards based on recommendations established in the literature.
• Establish processes for patients who are receiving mechanical ventilation and those who aren’t.
• Organize an inservice for the interprofessional staff on the process developed for your patients.

Other helpful resources:

• American Society for Parenteral and Enteral Nutrition (ASPEN), www.nutritioncare.org

REFERENCES


Based on material from and published as a supplement to the article by DiLibero et al. “Withholding or Continuing Enteral Feedings During Repositioning and the Incidence of Aspiration” (American Journal of Critical Care. 2015;24:258-262).
A Case of Thyrotoxic Periodic Paralysis With Respiratory Failure in an African American Woman

By Denise L. Shields, MSN, ACNP-BC, CRNP

Abstract
Thyrotoxic periodic paralysis is an acute endocrine emergency characterized by hyperthyroidism, profound muscle weakness and/or paralysis, and hypokalemia that is not due to potassium deficiency. Typically described in young males of Asian descent, it is becoming increasingly recognized outside of this demographic group and is believed to be an underrecognized cause of symptomatic hypokalemia. Thyrotoxic periodic paralysis usually manifests as acute onset of symmetrical distal extremity weakness and is treated with careful potassium replacement and nonselective β-blockers. In this case, a 43-year-old African American woman with thyrotoxic periodic paralysis had recurrent lower extremity myopathy and acute respiratory failure precipitated by noncompliance with treatment for Graves disease. (American Journal of Critical Care. 2015;24:264-267)

Thyrotoxic periodic paralysis (TPP) is an acute endocrine emergency characterized by hyperthyroidism, profound muscle weakness and/or paralysis, and hypokalemia that is not due to potassium deficiency. Typically described in young males of Asian descent, it is becoming increasingly recognized outside of this demographic and is believed to be an underrecognized cause of symptomatic hypokalemia with its ensuing sequelae. Here we describe the case of a 43-year-old African American woman with TPP who had recurrent lower extremity myopathy and acute respiratory failure precipitated by noncompliance with treatment for Graves disease.

Case Report
A 43-year-old African American woman came to a community hospital for complaints of recurrent bilateral lower extremity weakness and dyspnea. The patient reported being admitted twice in the past 2 months to a tertiary facility for similar complaints where she had Graves disease diagnosed and was discharged with propylthiouracil and propranolol. Review of systems was otherwise...
negative. She denied any other past medical history but admitted to being noncompliant with the prescribed medication regimen for her Graves disease. The patient was obese with a body mass index (calculated as weight in kilograms divided by height in meters squared) of approximately 35. Radiography and computed tomography of the chest were negative for pulmonary embolism or other acute pulmonary processes. Laboratory tests revealed a thyrotropin level less than 0.005 mIU/L, free thyroxine level of 8.0 ng/dL, a potassium level of 2.8 mEq/L, and a phosphorus level of 2.4 mg/dL; remaining levels were normal and the complete blood cell count was unremarkable. Uncontrolled hyperthyroidism with hypokalemia was diagnosed, and treatment with potassium supplementation, propranolol, and methimazole was started and she was transferred to the general care area.

Upon arrival in the step-down unit, the patient became nauseous with persistent complaints of lower extremity weakness and dyspnea. Neurological examination was notable for bilateral lower extremity weakness. Lungs were clear to auscultation. Telemetry showed sinus tachycardia with short bursts of nonsustained ventricular tachycardia. Her blood pressure was within normal range, pulse oximetry showed 97% saturation on 2 L oxygen, and she was afebrile. Results of arterial blood gas analysis were unremarkable. Albuterol/ipratropium nebulization was administered without improvement in her respiratory complaints.

Approximately 1 hour later, the patient went into acute respiratory arrest and was intubated. Repeat testing showed a potassium level of 3.0 mEq/L; further potassium supplementation was administered. After 48 hours, the patient’s thyrotoxic state came under control with propranolol and methimazole, potassium levels normalized, and she was successfully weaned off of mechanical ventilation. She was ultimately discharged with propranolol and methimazole with instructions to follow up with an endocrinologist for possible surgical ablation of the thyroid gland as an outpatient.

Discussion

Demographic Features

TPP is an acute endocrine emergency that can result in severe neuromuscular dysfunction, includ

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Pathophysiology

Although hypokalemic periodic paralysis can be a familial variant that is more common in white males and has a similar clinical presentation to the nonfamilial variant, there is no thyroid involvement and genetic mutations are well documented. In contrast, nonfamilial hypokalemic TPP will always have hyperthyroid abnormalities and is more prevalent in nonwhite populations. Genetic mutations have yet to be clearly identified in TPP, although some evidence indicates that it is a channelopathy defect in skeletal muscle that is partially regulated by thyroid hormones and may thus explain the correlation with an acute thyrotoxic state. This defect involves activity of the sodium-potassium adenosine triphosphatase (ATPase) pump that causes an acute intracellular influx of potassium ions with a subsequent decrease in extracellular potassium levels.

Provocative Factors

Although a hyperthyroid state is the driving cause of the hypokalemia seen in TPP, a number of other known triggers increase susceptibility. For example, androgens are a recognized stimulant of ATPase activity, which is believed to explain the prevalence of TPP in young adult males. For this same reason, TPP is uncommon in women, as estrogens have the opposite effect on ATPase activity. Although Graves disease is the most common hyperthyroid state to evoke TPP, any cause of thyrotoxicosis, including thyrotoxic medications and thyroid nodules, can be responsible because of thyroid-mediated ATPase activity. Such medications also include herbal and dietary supplements containing

With growing mobility and intermarriage, the prevalence of thyrotoxic periodic paralysis in Western medicine is increasing.

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Persistent signs and symptoms: Age in 40s, Female sex, muscle weakness and fatigue

Thyrotoxic myopathy
- Thyrotoxic periodic paralysis

Clinical profiles of thyrotoxic states

<table>
<thead>
<tr>
<th>Thyrotoxic myopathy</th>
<th>Thyrotoxic periodic paralysis</th>
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<tr>
<td>Female sex</td>
<td>Male sex</td>
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<tr>
<td>Age in 40s</td>
<td>Age in 20s</td>
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<tr>
<td>Persistent sign and symptoms: muscle weakness and fatigue</td>
<td>Neuromuscular weakness and decreased deep tendon reflexes</td>
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<td>Signs and symptoms resolve between attacks</td>
<td>Signs and symptoms resolve between attacks</td>
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Thyroxine, as cases of TPP due to thyroxine-based weight loss supplements have been reported. Additional TPP triggers include insulin and high carbohydrate intake, both of which drive potassium ions into cells and reduce serum levels of potassium. Researchers in several studies have noted TPP incidence to be higher in obese persons and persons with insulin resistance. Obesity as a provocative factor may have contributed in the case presented here; however, obesity is also associated with increased estrogen levels that would seemingly negate this effect.

Steroid use has also been implicated in the occurrence of TPP, most likely owing to mineralocorticoids promoting excretion of potassium and corticosteroids elevating serum levels of glucose with a parallel insulin response. Additionally, any number of stressors (injury, infection, emotional turmoil) as well as exercise activate an adrenergic response that is also known to cause hypokalemic TPP in susceptible persons. The albuterol nebulizer, a known β-agonist used in our female patient in attempts to alleviate her dyspnea, may have been an additional provocative factor and may even have been the final trigger of her TPP-induced respiratory failure.

Clinical Manifestations

Clinical manifestations include complaints of painless weakness, usually symmetrical and involving the distal parts of the extremities, but may involve proximal muscle groups and rarely the respiratory musculature (see Table). Although a thyrotoxic state is responsible for inducing hypokalemia in TPP, clinical indicators of hyperthyroidism are often absent or very subtle. Respiratory arrest due to TPP has been reported very infrequently; however, respiratory arrest was an unfortunate consequence in our case study. Importantly, extreme hypokalemia is not necessary to evoke a TPP episode and has been documented to occur with mild subtherapeutic or even normal potassium levels in susceptible persons.

Even so, it does appear that the degree of myopathy matches the severity of hypokalemia. Hypophosphatemia is also often present and appears to play a complementary role in respiratory muscle fatigue, leading to respiratory failure. Electrocardiographic abnormalities consistent with hypokalemia are common in addition to tachycardia due to a hyperthyroid state. Ventricular fibrillation is a rare occurrence although it has been documented.

Treatment and Goals of Care

Goals of treatment are to prevent recurrent attacks, achieve a euthyroid state, correct hypokalemia, and minimize provoking factors. Initial treatment for TPP is nonselective beta-blockade (propranolol) and potassium replacement. Beta-blockade serves to inhibit adrenergic activity (reducing sodium-potassium ATPase pump activity) as well as aid in the control of the thyrotoxic state. Careful supplementation with potassium is the rule. It is important to remember that aggressive replacement of potassium has been associated with rebound hyperkalemia once the myopathy begins to correct itself and is therefore avoided. Moreover, aggressive replacement is discouraged because TPP hypokalemia is merely reflective of intracellular potassium shifts due to a thyrotoxic state and is not a result of inherent depletion of potassium stores. Complete resolution and prevention requires strict control or abolition of the hyperthyroidism that drives this physiological response as well as the avoidance of provoking factors.

FINANCIAL DISCLOSURES
None reported.

REFERENCES


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POST-MYOCARDIAL INFARCTION ARRHYTHMIAS

By Mary G. Carey, RN, PhD, CNS, Salah S. Al-Zaiti, RN, PhD, CRNP, Teri M. Kozik, RN, PhD, CNS, CCRN, and Michele M. Pelter, RN, PhD

Scenario: This electrocardiogram (ECG) rhythm strip (leads II and V₁) is from a 56-year-old African American man, 11 hours after admission to the coronary care unit (CCU) with chest pain and a non–ST-elevation myocardial infarction (NSTEMI) per cardiac troponin levels (> 0.10 ng/mL); this is his first MI. He was treated with primary percutaneous coronary intervention (PCI), during which a stent was placed in the circumflex coronary artery. While reviewing the alarm history at the central monitor, his CCU nurse found this rhythm strip and wonders if he should notify the patient’s cardiologist.

Interpretation Questions:
1. Is the ECG properly calibrated (10 mm) and are leads properly placed? □ Yes □ No □ NA
   If no, interpret cautiously.
2. Is this a sinus rhythm (one P wave preceding every QRS complex)? □ Yes □ No □ NA
   If no, check for number of P waves in relation to QRS complexes.
3. Is the heart rate (R-R interval) normal (60-100 beats/min)? □ Yes □ No □ NA
   If no, check for supra-ventricular or ventricular arrhythmias.
4. Is the QRS complex narrow (duration < 110 milliseconds [ms] in V₁)? □ Yes □ No □ NA
   If no, check for bundle branch blocks (BBBs), pacing, or ventricular arrhythmia.
5. Is the ST segment deviated (> 2 mm in V₂-V₃, or > 1 mm in other leads)? □ Yes □ No □ NA
   If yes, check for similar deviations in contiguous cardiac territories.
6. Is the T wave inverted in relation to the QRS (> 0.5 mV)? □ Yes □ No □ NA
   If yes, check for ST deviation or conduction abnormalities.
7. Is the QT interval lengthened (> 450 ms [women] or > 470 ms [men])? □ Yes □ No □ NA
   If yes, check for ventricular arrhythmias or left ventricular hypertrophy.
8. Is R- or S-wave amplitude enlarged (S wave V₁ + R wave V₅ > 35 mm)? □ Yes □ No □ NA
   If yes, check for axis deviation or other chamber hypertrophy criteria.

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**Interpretation and Rationale**

Sinus tachycardia at 110 beats/min, with premature atrial contractions ([PAC] the letter “S” for supraventricular appears above them) and a 3-beat episode of paroxysmal supraventricular tachycardia (PSVT). It is important to differentiate ventricular tachycardia (VT) from SVT because the later responds well to an atrioventricular (AV) node blocking agent, but the same drug can compromise the hemodynamics of a patient with VT. A triphasic rSR’ pattern in lead V1 favors the diagnosis of SVT with aberrant ventricular conduction.

**Mechanism and Management**

SVT is not typically life threatening. However, frequent PACs in the presence of heart disease and acute MI may be a marker of early heart failure, to which African Americans are more susceptible, and possibly the start of atrial fibrillation, a rhythm associated with heart failure. In addition, persistent sinus tachycardia can also be an indication of marked left ventricular impairment and heart failure. Therefore, the CCU nurse should notify the cardiologist to ensure adequate revascularization and that optimal medical therapy has been prescribed. In NSTEMI patients treated with PCI, optimal pharmacological management is crucial and includes: a β-blocker, aspirin, P2Y12 receptor inhibitor, a statin, and either an angiotensin converting enzyme inhibitor or angiotensin receptor blocker.

The practice standards for in-hospital ECG monitoring recommend that patients in the early phase of acute coronary syndromes (ie, ST-elevation, NSTEMI, or unstable angina/rule-out MI) be continuously monitored from hospital presentation, and for at least 24 hours, when uncomplicated. For this patient, ECG monitoring longer than 24 hours would be indicated due to the tachycardia, PACs, and PSVT.

Notably, it has been reported that, among patients with a first-time MI, malignant reperfusion arrhythmias after PCI are more common in those who arrived with elevated troponin at admission as compared with those who had normal troponin levels that became positive after admission.
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