

Cancer Survivorship

Lymphoma Survivor Turns Entrepreneur

Cari Ugent is a good example of the old adage, "When life hands you lemons, make lemonade." Diagnosed with non-Hodgkin's lymphoma at the age of 21 just before her

senior year in college, she was in and out of the hospital for 9 years before receiving an allogeneic stem cell transplant at the age of 30. "I celebrated my 30th birthday in the hospital," she recalls. During the

time between relapses, Cari started a career as a journalist and was awaiting publication of her third book when she received the transplant.

Cari received her transplant at

Northwestern Memorial Hospital in Chicago. Her doctors and nurses encouraged her to take daily laps around the hospital, which helped her avoid complications like blood clots and pneumonia that often result from prolonged bed rest. But she found her mobility and independence were limited by the cumbersome intravenous (IV) pole that was her constant companion. "It is there from the moment you step in to the moment you leave," and she found it "was counterproductive to many of the things that I was being encouraged to do that I knew were beneficial for my health."

During her long weeks of recovery, Cari talked to her doctors and nurses about the drawbacks of the standard IV pole, and they shared ideas about how it could be improved for greater patient safety and convenience. "It became a nice pastime to brainstorm how the pole should look," she says, and it gave her a sense of purpose. "The process kept me going."

After her recovery, Cari worked with industrial designers to develop a safer, more convenient IV pole, known as Safepole. The new pole has features that make it attractive to both patients and caregivers, such as a tip-resistant design, an integrated power strip, and a covered dome to prevent tripping and tangling of tubes. Because the pole's design allows patients greater mobility and independence, nurses have more time to attend to other matters. "What is good for the patient, is good for the nurse," Cari says.

Grateful to those who helped her during her illness and recovery and wanting to give back to patients, doctors and nurses, and charities, Cari now shares her story with other survivors and works with organizations such as the Lymphoma Research Foundation of America and the Bone Marrow Transplant Information Network (www.bmtinfonet.org). Safepole is sold directly to hospitals, but individuals can also purchase a pole to be donated to a hospital or clinic, customized with a plaque engraved with the donor's name and inspirational messages or words of wisdom if they wish.

Cari is a healthy cancer survivor and a successful entrepreneur. One key to her success is her own positive attitude. Another is open communication with her doctors, nurses, and other caregivers. They listened to her complaints about the standard IV pole and worked with her to design an improved model. Cari's story shows how important it is for patients to take a proactive role in

drugs affecting hemostasis such as NSAIDs (see boxed WARNING and ADVERSE REACTIONS, Ongoing Safety Surveillance). As with other anticoagulants, bleeding can occur at any site during therapy with FRAGMIN. An unexpected drop in hematocrit or blood pressure should lead to a search for a bleeding site.

Thrombocytopenia: In FRAGMIN clinical trials supporting non-cancer indications, platelet counts of <100,000/mm³ and <50,000/mm³ occurred in <1% and <1% of patients, respectively. In the clinical trial of patients with cancer and acute symptomatic venous thromboembolism treated for up to 6 months in the FRAGMIN treatment arm, platelet counts of <100,000/mm³ occurred in 13.6% of patients, including 6.5% who also had platelet counts less than 50,000/mm³. In the same clinical trial, thrombocytopenia was reported as an adverse event in 10.9% of patients in the FRAGMIN arm and 8.1% of patients in the OAC arm. FRAGMIN dose was decreased or interrupted in patients whose platelet counts fell below 100,000/mm³. Thrombocytopenia of any degree should be monitored closely. Heparin-induced thrombocytopenia can occur with the administration of FRAGMIN. The incidence of this complication is unknown at present. In clinical practice, rare cases of thrombocytopenia with thrombosis have also been observed.

Miscellaneous: Each multiple-dose vial of FRAGMIN contains benzyl alcohol as a preservative. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants. Because benzyl alcohol may cross the placenta, FRAGMIN preserved with benzyl alcohol should be used with caution in pregnant women and only if clearly needed. If anticoagulation with FRAGMIN is needed during pregnancy, preservative-free formulations should be used, where possible (see PRECAUTIONS, Pregnancy Category B, Nonteratogenic Effects).

PRECAUTIONS
General: FRAGMIN Injection should not be mixed with other injections or infusions unless specific compatibility data are available that support such mixing. FRAGMIN should be used with caution in patients with bleeding diathesis, thrombocytopenia or platelet defects; severe liver or kidney insufficiency, hypertensive or diabetic retinopathy, and recent gastrointestinal bleeding. If a thromboembolic event should occur despite dalteparin prophylaxis, FRAGMIN should be discontinued and appropriate therapy initiated.

Drug Interactions: FRAGMIN should be used with care in patients receiving oral anticoagulants, platelet inhibitors, and thrombolytic agents because of increased risk of bleeding (see PRECAUTIONS, Laboratory Tests). Aspirin, unless contraindicated, is recommended in patients treated for unstable angina or non-Q-wave myocardial infarction (see DOSAGE AND ADMINISTRATION).

Laboratory Tests: Periodic routine complete blood counts, including platelet count, blood chemistry, and stool occult blood tests are recommended during the course of treatment with FRAGMIN. No special monitoring of blood clotting times (i.e., APTT) is needed. When administered at recommended prophylaxis doses, routine coagulation tests such as Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) are relatively insensitive measures of FRAGMIN activity and, therefore, unsuitable for monitoring the anticoagulant effect of FRAGMIN. Anti-Factor Xa may be used to monitor the anticoagulant effect of FRAGMIN, such as in patients with severe renal impairment or if abnormal coagulation parameters or bleeding should occur during FRAGMIN therapy.

Drug/Laboratory Test Interactions: Elevations of Serum Transaminases: In FRAGMIN clinical trials supporting non-cancer indications where hepatic transaminases were measured, asymptomatic increases in transaminase levels (SGOT/AST and SGPT/ALT) greater than three times the upper limit of normal of the laboratory reference range were seen in 4.7% and 4.2%, respectively, of patients during treatment with FRAGMIN. In the FRAGMIN clinical trial of patients with cancer and acute symptomatic venous thromboembolism treated with FRAGMIN for up to 6 months, asymptomatic increases in transaminase levels, AST and ALT, greater than three times the upper limit of normal of the laboratory reference range were reported in 8.9% and 9.5% of patients, respectively. The frequencies of Grades 3 and 4 increases in AST and ALT, as classified by the National Cancer Institute, Common Toxicity Criteria (NCI-CTC) Scoring System, were 3% and 3.8%, respectively. Grades 2, 3 and 4 combined have been reported in 12% and 14% of patients, respectively.

Carcinogenicity, Mutagenesis, Impairment of Fertility: Dalteparin sodium has not been tested for its carcinogenic potential in long-term animal studies. It was not mutagenic in the *in vitro* Ames Test, mouse lymphoma cell forward mutation test and human lymphocyte chromosomal aberration test and in the *in vivo* mouse micronucleus test. Dalteparin sodium at subcutaneous doses up to 1200 IU/kg (7080 IU/m²) did not affect the fertility or reproductive performance of male and female rats.

Pregnancy: Pregnancy Category B. Teratogenic Effects: Reproduction studies with dalteparin sodium at intravenous doses up to 2400 IU/kg (14,160 IU/m²) in pregnant rats and 4800 IU/kg (40,800 IU/m²) in pregnant rabbits did not produce any evidence of impaired fertility or harm to the fetuses. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nonteratogenic Effects: Cases of "Gasping Syndrome" have occurred when large amounts of benzyl alcohol have been administered (99–404 mg/kg/day). The 9.5 mL and the 3.8 mL multiple-dose vials of FRAGMIN contain 14 mg/mL of benzyl alcohol.

Nursing Mothers: Limited data are available for excretion of dalteparin in human milk. One study in 15 lactating women receiving prophylactic doses of dalteparin detected small amounts of anti-Xa activity in breast milk, equivalent to a milk/plasma ratio of <0.025–0.224. As oral absorption of LMWH is extremely low, the clinical implications, if any, of this small amount of anticoagulant activity on the nursing infant are unknown. Caution should be exercised when FRAGMIN is administered to nursing women.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.
Geriatric Use: Of the total number of patients in clinical studies of FRAGMIN, 5516 patients were 65 years of age or older and 2237 were 75 or older. No overall differences in effectiveness were observed between these subjects and younger subjects. Some studies suggest that the risk of bleeding increases with age. Postmarketing surveillance and literature reports have not revealed additional differences in the safety of FRAGMIN between elderly and younger patients. Careful attention to dosing intervals and concomitant medications (especially antiplatelet medications) is advised, particularly in geriatric patients with low body weight (<45 kg) and those predisposed to decreased renal function (see also CLINICAL PHARMACOLOGY and General and Drug Interactions subsections of PRECAUTIONS).

ADVERSE REACTIONS
Hemorrhage: The incidence of hemorrhagic complications during treatment with FRAGMIN Injection has been low. The most commonly reported side effect is hematoma at the injection site. The incidence of bleeding may increase with higher doses; however, in abdominal surgery patients with malignancy, no significant increase in bleeding was observed when comparing FRAGMIN 5000 IU to either FRAGMIN 2500 IU or low dose heparin. In a trial comparing FRAGMIN 5000 IU once daily to FRAGMIN 2500 IU once daily in patients undergoing surgery for malignancy, the incidence of bleeding events was 4.6% and 3.6%, respectively (n.s.). In a trial comparing FRAGMIN 5000 IU once daily to heparin 5000 U twice daily, the incidence of bleeding events was 3.2% and 2.7%, respectively (n.s.) in the malignancy subgroup.
Unstable Angina and Non-Q-Wave Myocardial Infarction: Table 8 summarizes major bleeding events that occurred with FRAGMIN, heparin, and placebo in clinical trials of unstable angina and non-Q-wave myocardial infarction.

Table 8: Major Bleeding Events in Unstable Angina and Non-Q-Wave Myocardial Infarction

Indication	Dosing Regimen		
	FRAGMIN 120 IU/kg/12 hr. s.c. ¹ n(%)	Heparin i.v. and s.c. ² n(%)	Placebo every 12 hr s.c. n(%)
Major Bleeding Events ^{3,4}	15/1497 (1.0)	7/731 (1.0)	4/760 (0.5)

¹Treatment was administered for 5 to 8 days.
²Heparin i.v. infusion for at least 48 hours, APTT 1.5 to 2 times control, then 12,500 U s.c. every 12 hours for 5 to 8 days.
³Aspirin (75 to 165 mg per day) and beta blocker therapies were administered concurrently.
⁴Bleeding events were considered major if: 1) accompanied by a decrease in hemoglobin of ≥ 2 g/dL in connection with clinical symptoms; 2) a transfusion was required; 3) bleeding led to interruption of treatment or death; or 4) intracranial bleeding.

Hip Replacement Surgery: Table 9 summarizes: 1) all major bleeding events and, 2) other bleeding events possibly or probably related to treatment with FRAGMIN (preoperative dosing regimen), warfarin sodium, or heparin in two hip replacement surgery clinical trials.

Table 9: Bleeding Events Following Hip Replacement Surgery

Indication	FRAGMIN vs Warfarin Sodium Dosing Regimen		FRAGMIN vs Heparin Dosing Regimen	
	FRAGMIN ² 5000 IU once daily s.c. n(%)	Warfarin Sodium ¹ oral n(%)	FRAGMIN ⁴ 5000 IU once daily s.c. n(%)	Heparin 5000 U three times a day s.c. n(%)
Major Bleeding Events ³	7/274 (2.6)	1/279 (0.4)	0	3/69 (4.3)
Other Bleeding Events ⁵				
Hematuria	8/274 (2.9)	5/279 (1.8)	0	0
Wound Hematoma	6/274 (2.2)	0	0	0
Injection Site Hematoma	3/274 (1.1)	NA	2/69 (2.9)	7/69 (10.1)

¹Warfarin sodium dosage was adjusted to maintain a prothrombin time index of 1.4 to 1.5, corresponding to an International Normalized Ratio (INR) of approximately 2.5.

²Includes three treated patients who did not undergo a surgical procedure.

³A bleeding event was considered major if: 1) hemorrhage caused a significant clinical event, 2) it was associated with a hemoglobin decrease of ≥ 2 g/dL or transfusion of 2 or more units of blood products, 3) it resulted in reoperation due to bleeding, or 4) it involved retroperitoneal or intracranial hemorrhage.

⁴Includes two treated patients who did not undergo a surgical procedure.

⁵Occurred at a rate of at least 2% in the group treated with FRAGMIN 5000 IU once daily.

Six of the patients treated with FRAGMIN experienced seven major bleeding events. Two of the events were wound hematoma (one requiring reoperation), three were bleeding from the operative site, one was intraoperative bleeding due to vessel damage, and one was gastrointestinal bleeding. None of the patients experienced retroperitoneal or intracranial hemorrhage nor died of bleeding complications. In the third hip replacement surgery clinical trial, the incidence of major bleeding events was similar in all three treatment groups: 3.6% (18/496) for patients who started FRAGMIN before surgery; 2.5% (12/487) for patients who started FRAGMIN after surgery; and 3.1% (15/489) for patients treated with warfarin sodium.

Abdominal Surgery: Table 10 summarizes bleeding events that occurred in clinical trials which studied FRAGMIN 2500 and 5000 IU administered once daily to abdominal surgery patients.

Table 10: Bleeding Events Following Abdominal Surgery

Indication	FRAGMIN vs Heparin Dosing Regimen				FRAGMIN vs Placebo Dosing Regimen		FRAGMIN vs FRAGMIN Dosing Regimen	
	FRAGMIN 2500 IU once daily s.c. n(%)	Heparin 5000 U twice daily s.c. n(%)	FRAGMIN 5000 IU once daily s.c. n(%)	Heparin 5000 U twice daily s.c. n(%)	FRAGMIN 2500 IU once daily s.c. n(%)	Placebo once daily s.c. n(%)	FRAGMIN 2500 IU once daily s.c. n(%)	FRAGMIN 5000 IU once daily s.c. n(%)
	Postoperative Transfusions	26/459 (5.7)	36/454 (7.9)	81/508 (15.9)	63/498 (12.7)	14/182 (7.7)	13/182 (7.1)	89/1025 (8.7)
Wound Hematoma	16/467 (3.4)	18/467 (3.9)	12/508 (2.4)	6/498 (1.2)	2/79 (2.5)	2/77 (2.6)	1/1030 (0.1)	4/1039 (0.4)
Reoperation Due to Bleeding	2/392 (0.5)	3/392 (0.8)	4/508 (0.8)	2/498 (0.4)	1/79 (1.3)	1/78 (1.3)	2/1030 (0.2)	13/1038 (1.3)
Injection Site Hematoma	1/466 (0.2)	5/464 (1.1)	36/506 (7.1)	47/493 (9.5)	8/172 (4.7)	2/174 (1.1)	36/1026 (3.5)	57/1035 (5.5)

Medical Patients with Severely Restricted Mobility During Acute Illness: Table 11 summarizes major bleeding events that occurred in a clinical trial of medical patients with severely restricted mobility during acute illness.

Table 11: Bleeding Events in Medical Patients with Severely Restricted Mobility During Acute Illness

Indication	Dosing Regimen	
	FRAGMIN 5000 IU once daily s.c. n(%)	Placebo once daily s.c. n(%)
Medical Patients with Severely Restricted Mobility		
Major Bleeding Events ¹ at Day 14	8/1848 (0.4)	0/1833 (0)
Major Bleeding Events ¹ at Day 21	9/1848 (0.5)	3/1833 (0.2)

¹A bleeding event was considered major if: 1) it was accompanied by a decrease in hemoglobin of ≥ 2 g/dL in connection with clinical symptoms; 2) intraocular, spinal/epidural, intracranial, or retroperitoneal bleeding; 3) required transfusion of ≥ 2 units of blood products; 4) required significant medical or surgical intervention; or 5) led to death.

Three of the major bleeding events that occurred by Day 21 were fatal, all due to gastrointestinal hemorrhage (two patients in the group treated with FRAGMIN and one in the group receiving placebo). Two deaths occurred after Day 21: one patient in the placebo group died from a subarachnoid hemorrhage that started on Day 55, and one patient died on day 71 (two months after receiving the last dose of FRAGMIN) from a subdural hematoma.

Patients with Cancer and Acute Symptomatic Venous Thromboembolism

Table 12 summarizes the number of patients with bleeding events that occurred in the clinical trial of patients with cancer and acute symptomatic venous thromboembolism. A bleeding event was considered major if: 1) it was accompanied by a decrease in hemoglobin of ≥ 2 g/dL in connection with clinical symptoms; 2) occurred at a critical site (intraocular, spinal/epidural, intracranial, retroperitoneal, or pericardial bleeding); 3) required transfusion of ≥ 2 units of blood products; or 4) led to death. Minor bleeding was classified as clinically overt bleeding that did not meet criteria for major bleeding. At the end of the six-month study, a total of 46 (13.6%) patients in the FRAGMIN arm and 62 (18.5%) patients in the OAC arm experienced any bleeding event. One bleeding event (hemoptysis in a patient in the FRAGMIN arm at Day 71) was fatal.

Table 12: Bleeding Events (Major and Any) (As treated population)¹

Study period	FRAGMIN 200 IU/kg (max 18,000 IU) s.c. once daily x 1 month, then 150 IU/kg (max 18,000 IU) s.c. once daily x 5 months			OAC FRAGMIN 200 IU/kg (max 18,000 IU) s.c. once daily x 5-7 days and OAC for 6 months (target INR 2-3)		
	Number at risk	Patients with Major Bleeding n(%)	Patients with Any Bleeding n(%)	Number at Risk	Patients with Major Bleeding n(%)	Patients with Any Bleeding n(%)
Total during study	338	19 (5.6)	46 (13.6)	335	12 (3.6)	62 (18.5)
Week 1	338	4 (1.2)	15 (4.4)	335	4 (1.2)	12 (3.6)
Weeks 2-4	332	9 (2.7)	17 (5.1)	321	1 (0.3)	12 (3.7)
Weeks 5-28	297	9 (3.0)	26 (8.8)	267	8 (3.0)	40 (15.0)

¹Patients with multiple bleeding episodes within any time interval were counted only once in that interval. However, patients with multiple bleeding episodes that occurred at different time intervals were counted once in each interval in which the event occurred.

Thrombocytopenia: See WARNINGS: Thrombocytopenia.

Other Allergic Reactions: Allergic reactions (i.e., pruritus, rash, fever, injection site reaction, bullous eruption) have occurred rarely. A few cases of anaphylactoid reactions have been reported. Local Reactions: Pain at the injection site, the only non-bleeding event determined to be possibly or probably related to treatment with FRAGMIN and reported at a rate of at least 2% in the group treated with FRAGMIN, was reported in 4.5% of patients treated with FRAGMIN 5000 IU once daily vs 11.8% of patients treated with heparin 5000 U twice daily in the abdominal surgery trials. In the hip replacement trials, pain at injection site was reported in 12% of patients treated with FRAGMIN 5000 IU once daily vs 13% of patients treated with heparin 5000 U three times a day.

Ongoing Safety Surveillance: Since first international market introduction in 1985, there have been more than 15 reports of epidural or spinal hematoma formation with concurrent use of dalteparin sodium and spinal/epidural anesthesia or spinal puncture. The majority of patients had postoperative indwelling epidural catheters placed for analgesia or received additional drugs affecting hemostasis. In some cases the hematoma resulted in long-term or permanent paralysis (partial or complete). Because these events were reported voluntarily from a population of unknown size, estimates of frequency cannot be made. Post-Marketing Experience: Skin necrosis has occurred rarely. There have been isolated cases of alopecia reported that improved on drug discontinuation.

OVERDOSAGE

Symptoms/Treatment: An excessive dosage of FRAGMIN Injection may lead to hemorrhagic complications. These may generally be stopped by the slow intravenous injection of protamine sulfate (1% solution), at a dose of 1 mg protamine for every 100 anti-Xa IU of FRAGMIN given. A second infusion of 0.5 mg protamine sulfate per 100 anti-Xa IU of FRAGMIN may be administered if the APTT measured 2 to 4 hours after the first infusion remains prolonged. Even with these additional doses of protamine, the APTT may remain more prolonged than would usually be found following administration of conventional heparin. In all cases, the anti-Factor Xa activity is never completely neutralized (maximum about 60 to 75%). Particular care should be taken to avoid overdosage with protamine sulfate. Administration of protamine sulfate can cause severe hypotensive and anaphylactoid reactions. Because fatal reactions, often resembling anaphylaxis, have been reported with protamine sulfate, it should be given only when resuscitation techniques and treatment of anaphylactic shock are readily available. For additional information, consult the labeling of Protamine Sulfate Injection, USP, products. A single subcutaneous dose of 100,000 IU/kg of FRAGMIN to mice caused a mortality of 8% (1/12) whereas 50,000 IU/kg was a non-lethal dose. The observed sign was hematoma at the site of injection.

Rx only

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Lymphoma Survivor

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get people to stop thinking that way," Cramer said, because early intervention is key to preserving function.

Primary tumors account for 1% to 3% of cases, with the rest from metastatic disease. Metastases seem to show a preference for the spinal level affected depending on the tissue of origin: cervical for breast; thoracic for breast, lung, prostate, and renal tumors; and lumbosacral for gastrointestinal tumors. Cancer treatments themselves can lead to lytic lesions of vertebrae.

Spinal cord compression presence and extent is diagnosed by spinal radiographs, computed tomograph, magnetic resonance image, bone scan, and myelograms. The strongest indicator for a good prognosis is detection and intervention within 24 hours. Even then, most patients do not regain lost function.

Up to 95% of patients first present with pain, ranging from dull or aching to severe, burning, or shooting. Most have central back pain, which may or may not radiate. Lying down provides no relief. Other early signs and symptoms are weakness; affecting mobility and coordination; and sensory loss to pain, temperature, and light touch. Later, muscle atrophy, paralysis, and bowel and bladder incontinence may ensue. Spinal shock, an extreme outcome with lesions at T6 and above, manifests as autonomic dysreflexia with hypertension, heart rate changes, and respiratory distress.

Caregivers have to decide between palliative care and treatment. Depending on the cause of the spinal cord compression, interventions may include radiation, surgery, and medication, such as high-dose steroids, analgesics, low-molecular-weight heparin, chemotherapy, bisphosphonates, and a bowel regimen. Whereas laminectomy or spinal fusion are not generally used to treat vertebral compression fractures, "kyphoplasty is a big player," Cramer said. Patients "can have immediate relief" of pain. It involves inserting a balloon into one or more collapsed vertebrae and expanding the balloon with a quick-hardening cement to approximate the normal anatomy of the vertebra.

Patients should be immobilized and log-rolled. Monitoring and assessment should focus on sensory (pinprick) and motor function (ataxia), pain, airway maintenance, good circulation to avoid deep-vein thrombosis, and bowel and bladder function. Cramer recommends maintaining urine pH < 7.0 and voiding every 2 to 3 hours or catheterizing as needed. Spinal rehabilitation may be appropriate for some patients.

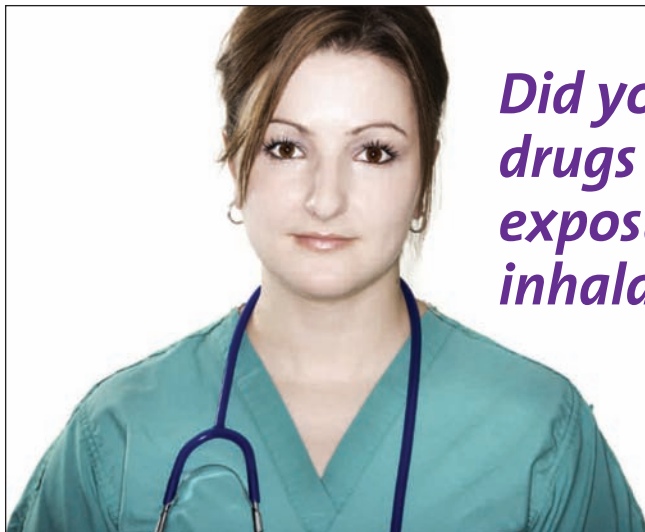
"Any patient with cancer who complains of new back pain, suspect something is going on," Cramer warned, since early intervention can provide "time with quality" of life. ●

their own care and for their healthcare providers to listen to their ideas and treat them as partners in their treatment. Commenting on Cari's experience, Karen Haller, vice president, Nursing and Patient Care Services, Johns

Hopkins Hospital and associate dean for clinical affairs at the School of Nursing, recommended considering including patient representatives on hospital committees. She wrote, "Patients, especially those who stay in hospitals for long peri-

ods, are motivated to solve safety problems. Whenever possible, we should harness their wisdom" (*Johns Hopkins Magazine*, Summer 2006).

For more information on Safepole, visit their Web site www.safepole.net. ●



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