



1725 I Street NW • Suite 510 • Washington, DC 20006
Tel 202-659-0599 • Fax 202-659-0709 • www.asn-online.org

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Contact: Shari Leventhal 202-416-0658, sleventhal@asn-online.org

EARLY INTERVENTION DRAMATICALLY IMPROVES OUTCOMES FOR NEW DIALYSIS PATIENTS

RightStart Program Reduces Risk of Death Up to One Year after Starting Dialysis

Washington, DC (October 16, 2007) — A program of education, close medical follow-up, and self-empowerment for patients with end-stage renal disease (ESRD) newly starting dialysis, reduces complications and improves outcomes—including significant reductions in mortality and hospitalization rates, reports a study in the November *Clinical Journal of the American Society of Nephrology*.

The researchers initiated a structured quality improvement program, called RightStart, for ESRD patients within their first two weeks and continuing for up to three months of starting dialysis. "This program for new patients has shown itself to dramatically improve outcomes, when compared to a control group that did not receive the intervention," comments Dr. Raymond Hakim of Fresenius Medical Care in Brentwood, Tenn.

"The goal of this research was to implement a patient care strategy that focused on improving clinical outcomes in the first 90 days of hemodialysis, through intensified medical, nursing, and dietary focus and empowerment of patients to influence their own health," Dr. Hakim explains. The program included one-on-one time with nurses, who provided an educational program focusing on patient self-management.

Because new patients are often malnourished, a key emphasis was nutrition teaching, especially the need for adequate amounts of protein and calories. Dietary restrictions were introduced only as needed for the individual patient. Each patient was assigned to a case manager, who actively identified and addressed any medical problems developing in the first weeks and months on dialysis, along with the multidisciplinary team.

The study tracked survival, hospitalization rates, and other outcomes for 918 patients participating in RightStart. Outcomes were compared with those of 1,020 new dialysis patients at clinics not using the RightStart program. "It is important to note that the ESRD community provides excellent care to dialysis patients overall," says Dr. Hakim. "However, because new dialysis patients have special needs, they require intense and focused care to improve their outcomes further."

After three months, patients who went through the RightStart program had better nutrition, as reflected by levels of albumin in the blood; and less anemia, as indicated by the hematocrit level. RightStart patients also improved their scores on tests of knowledge regarding ESRD and its treatment and on quality of life and

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mental health scores. "This result may be an indication that the program had a positive impact on the depression that is common among dialysis patients, as they experience a life changing event," says Dr Hakim.

In the year after starting dialysis, RightStart patients spent fewer days in the hospital: an average of 7.2 days, compared to 10.5 days for patients not receiving RightStart.

RightStart was also associated with nearly a one-half reduction in mortality rate: 17 per 100 patient-years, compared to 30 per 100 patient-years in the comparison group. For individual patients, RightStart reduced the risk of death in the year after starting dialysis by about 40 percent. "Such results speak for themselves," Dr. Hakim says. "We are actively expanding the program, and making program changes to best meet the patients' needs, based on feedback from the patients and the outcomes data."

For patients starting dialysis, the mortality rate is "alarmingly high"—about double the rate in patients who have been on dialysis longer than 90 days, according to Dr. Hakim. In designing the RightStart program, the researchers hoped to address some of the reversible risk factors contributing to this early mortality, such as nutrition, anemia, dialysis dose, and patient empowerment. "These new patients have special needs and require more intense focus during the early period of treatment," says Rebecca Wingard, RN, MSN, CNN, Vice-President of Quality Initiatives of Fresenius Medical Services and coordinator of the RightStart program.

Dr. Hakim also calls for expanded efforts to detect, educate, and treat patients in the earlier stages of kidney disease, before dialysis is required. "The lack of payment coverage by Medicare for patients less than 65 years old is a major impediment to providing such patients with timely education and preventive measures."

This study was partially supported by Amgen, Inc. Dr. Raymond Hakim and Ms. Rebecca Wingard are employees of Fresenius Medical Care and Drs. Lara Pupim and Mahesh Krishnan are employees of Amgen, Inc.

The study entitled, "Early Intervention Improves Mortality and Hospitalization Rates in Incident Hemodialysis Patients: RightStart Program" will be available online at www.asn-online.org under Media, 2007, beginning on Wednesday, October 17 and in print in the November issue of the *Clinical Journal of the American Society of Nephrology* (CJASN).

The ASN is a not-for-profit organization of 10,000 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases.

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