

Value of Quality Improvement Reporting

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Mortality among patients who are on dialysis in the United States is high, especially within the first 90 d after initiation of dialysis (1). How can this problem be addressed? A typical model for solving such clinical dilemmas begins with intensive clinical research to identify causes and correlates of mortality as well as strategies to improve outcomes. This is often followed by the development of evidence-based clinical practice guidelines or recommendations by expert advisory panels. Although such evidence-based clinical practice guidelines often provide recommended clinical targets (e.g., glycosylated hemoglobin <7% for patients with diabetes), specific strategies for achievement of these targets (beyond choice of medications in some cases) are usually not offered. Because of the lack of specific implementation recommendations within practice guidelines, quality improvement programs are often initiated within medical practices or institutions to translate the results of clinical research and the recommendations of experts into effective practice in their unique environments. Such programs usually have as their goals standardization of care and improvement of processes with the ultimate aim of improving patient outcomes.

Within nephrology, particularly within the realm of ESRD, all of these steps are being carried out. Unfortunately, there are problems and controversies at each level. First, clinical research in the dialysis arena has been largely observational with few randomized control trials to guide clinical decision making and development of guidelines (2). Second, the process of guideline development has been tainted by the specter of pharmaceutical influence (3–5). Finally, although quality improvement programs are widespread in ESRD, facilitated by the concentration of dialysis care within a few large providers with attendant centralized clinical databases, their results have not been widely disseminated to the nephrology community, and it has been difficult to determine whether they are actually improving care (6). There is a need for evaluation of quality improvement activities so that we may critically review what others have tried and whether it has been successful (6).

What is quality improvement, and how does it differ from clinical research? Quality improvement activities share some of the characteristics of clinical research. Both study processes and

outcomes for groups of patients and apply the results to improve the care of other patients (7); however, there are several differences. Quality improvement endeavors are generally applied to all patients within a practice or institution rather than selected patients, as in clinical research. Informed consent is generally not sought from patients before participation in quality improvement programs. Because quality improvement activities are usually implemented as across-the-board changes in practices or procedures, they are generally reviewed and approved by local practice organizations rather than institutional review boards (8). Perhaps the most important distinguishing feature of quality improvement activities is their underlying goal. Whereas clinical research aims to develop or contribute to generalizable knowledge, quality improvement uses existing evidence-based knowledge to improve immediately health care delivery in particular settings (6–8).

These differences between quality improvement programs and clinical research are partly responsible for the difficulty in systematically evaluating and disseminating the results of quality improvement programs. Because they have not been designed as clinical trials, it is more difficult to evaluate rigorously quality improvement programs. For example, ideally, reports of quality improvement activities should have a comparable, concurrent control group to allow direct comparison of outcomes with and without the intervention; however, because practices for all patients are usually changed simultaneously, such a comparison group is usually not available. In addition, because informed consent is usually not sought and formal research is not the initial goal, individual patient-level data from before and after an intervention may not be available.

What are the characteristics of a “high-quality” quality improvement activity? It should target an important clinical problem for which performance is currently poor and for which considerable practice variability exists so that standardization is likely to affect outcomes. Changes in practice should be based on evidence so that they could lead to improvement, and such interventions should be clearly defined and reproducible. Finally, the program should include measurable targets for performance improvement and should incorporate regular review of its impact with refinement as necessary.

In this issue of the *Clinical Journal of the American Society of Nephrology*, Wingard *et al.* (9) report on the results of the Right-Start Program, designed to improve outcomes within the first 90 d of maintenance hemodialysis. The program was a 3-mo intervention that included intensive patient education coupled

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with interventions that focused on anemia management, adequate dialysis dosage, nutrition, reduction of catheter use, review of medications, logistical support, and psychosocial assessment with appropriate referral to social services, as well as encouragement to participate in self-care and rehabilitation services. The program was approved by the medical director of each facility as a standard of care for all incident patients. A case manager implemented the program and met with the patients on average one to two times per week during the first month and every 1 to 2 wk for the remaining 2 mo. Outcomes measured were laboratory parameters, vascular access type, hospitalization, mortality within the first year of dialysis, and quality of life using the Kidney Disease Quality of Life Short Form, and a 23-item dialysis knowledge test. Outcomes among the 918 RightStart patients from 39 participating units were compared with those of 1020 concurrent control patients from 31 nonparticipating units. Three months after initiation of dialysis, some of the target process measures were improved. Specifically, RightStart patients had higher albumin and hematocrit values, but urea reduction ratio and proportion with permanent vascular access were not different between the groups. In addition, within the RightStart group, the mental composite score improved significantly from baseline to 3 mo, although comparison with the control group was not possible. Finally, mean hospitalization days and mortality rates were lower in the RightStart group compared with the control group at all time points (3, 4.5, 6, and 12 mo).

The RightStart Program fulfills the criteria for a quality improvement program because the interventions, for the most part, were based on clinical practice guidelines, and the focus was on a structure within which best practices could be implemented for patients who initiated dialysis, rather than on generating new targets for anemia management or other aspects of dialysis care. A strength of this report is the inclusion of a concurrent control group, available because not all clinics implemented the RightStart Program. Nevertheless, it is possible that there were some systematic differences between the RightStart patients and the control patients, particularly because it was necessary to exclude cognitively impaired individuals from this largely educational intervention; however, this is an inherent problem with reports on quality improvement that cannot be overcome unless formal clinical trials are undertaken

at the outset and should not lead us to disregard the potentially valuable information that can be gained from these activities.

As with any successful quality improvement activity, it will be important to confirm the success of the RightStart Program in other settings. A more detailed description of the program would facilitate such replication and could also allow others to consider partial implementation if resources are scarce. It is fortunate that the results of this quality improvement activity are now available to the nephrology community; they provide a glimmer of hope that perhaps it will be possible to improve survival in early ESRD.

Disclosures

None.

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See the related article, "Early Intervention Improves Mortality and Hospitalization Rates in Incident Hemodialysis Patients," on pages 1170–1175.