Home Dialysis Toolkit

Developed by the Forum of ESRD Networks' Medical Advisory Council (MAC)

This toolkit for health providers and practitioners is a reference tool that gives information about overcoming barriers to starting or growing a home dialysis program.

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Introduction: Why aren't more people in the Unites States on home dialysis?

The thesis of this toolkit is that fewer of the people who require dialysis in the United States are dialyzing at home than should be the case. We propose to try to understand and rectify this situation by examination of some of the systemic and conceptual barriers that, in our view, restrain what would otherwise be the more widespread and appropriate use of home dialysis. In order to begin this process, we will briefly review the history of treatment of end stage renal disease (ESRD) by chronic dialysis. We will see that home dialysis has been part of this history almost since the beginning. Guidance for writing this introduction was obtained in large part from a useful article by Blagg (2007), from which more complete references to original source materials may be obtained by interested readers.

Hemodialysis was first successfully used in a human case of acute kidney injury by Kolff in Holland during World War II, but consistent technical success with his original apparatus and its successors was achieved only after he emigrated to the U.S. after the war. The technical aspects of hemodialysis were developed further under the pressure of another war, the Korean conflict, during which Teschan and colleagues used the new technique in the 1950s to treat combat injuries that would previously have been inevitably fatal.

The concept of maintenance hemodialysis for chronic kidney disease was first implemented on a substantial scale by Scribner and colleagues at the University of Washington in the 1960s. More than that of any other individual, Scribner's work contributed to saving hundreds of thousands of Americans otherwise doomed to die of uremia, not only because of his scientific contributions (including the concept of long-term vascular access), but because of the riveting testimony of Scribner and his patients before the U.S. Congress that led to the extension of Medicare to nearly all Americans with ESRD in 1973.

Prior to the funding of the ESRD program by Medicare, however, many of Scribner's patients were treated at home, starting as early as 1963-4. Shaldon introduced home hemodialysis in Great Britain in 1964 and in Germany in the late 1960s. After 1973, Medicare funding allowed the development of free-standing dialysis facilities in the U.S., but prior to that date, as many as 40% of all dialysis patients in the U.S. were dialyzing at home. It is apparent, therefore, that technical obstacles to home hemodialysis have not been insuperable, at least for some patients, for some 50 years. Despite all of the subsequent advances in technology and outcomes, however, less than 2% of ESRD patients in the U.S. were performing hemodialysis at home in 2013 (USRDS, 2015).

The initial successful use of peritoneal dialysis (PD) to treat acute renal failure was reported in 1951; however, its adaptation to support patients with ESRD, like that of hemodialysis, awaited the solution to the problem of chronic indwelling dialysis access. The first recorded patient with chronic uremia supported on home PD was treated by Palmer in Vancouver, Canada, starting in 1964, using a peritoneal catheter conceived by Palmer and fabricated by Wayne Quinton, an engineer who worked with Scribner's group in Seattle, Washington. The PD catheter was subsequently improved by Tenckhoff, again in the Seattle group, and the first report of a multi-patient home continuous ambulatory peritoneal dialysis (CAPD) program, by Popovich and Moncrief in Austin, Texas, followed in 1976. The subsequent introduction of premixed dialysate in plastic bags by Oreopoulos et al., the titanium

connector by Nolph et al., and the automated cycler by Diaz-Buxo et al. increased the technical ease, safety, and convenience of home PD to the point that it became, and has remained, far easier to learn and sustain than home hemodialysis.

Home PD experienced rapid gains in popularity soon after its introduction in the U.S., and its use as a percentage of all ESRD treatment reached its peak in the U.S. in the early 1990s. A subsequent long decline in the relative prevalence of PD use in the U.S. has started to reverse only since 2009. Despite the marked growth in the overall dialysis population since the early 1990s, the number of prevalent patients treated with PD in the U.S. (just over 30,000) was approximately equal in 2012 and in 1993, nineteen years earlier (USRDS, 2015). At the time of this writing, recent growth in PD has been further restrained by a shortage of PD solution from a major manufacturer, a hopefully temporary issue.

In recent years, home hemodialysis and continuous cycling peritoneal dialysis (CCPD) have made substantial relative gains in utilization in the U.S. Nevertheless, of patients starting dialysis in 2013, only about 10% started any form of home dialysis. This presumably represents a substantial failure of patient education and choice, since studies of predialysis modality education reveal that 30-50% of informed patients choose home modalities (Lacson et al., 2011). Polls of nephrologists consistently show that the vast majority would choose a home dialysis modality for themselves in the event of ESRD, and they estimate that a home modality would be the optimal choice for approximately one-third of their ESRD patients (Merighi, Schatell, Bragg-Gresham, Witten, & Mehrotra, 2012). Experience from numerous other countries around the globe, in fully developed and developing economies, supports the contention that a far larger number of patients in the U.S. could successfully dialyze at home.

As we will elaborate further in the later sections of this toolkit, recent dialysis funding decisions by the Centers for Medicare & Medicaid Services (CMS) have intentionally produced a relatively more favorable financial climate for home dialysis than for in-center dialysis, with the disparity likely to widen in the future (Golper, 2013). Thus, within the overall current context of constrained dialysis reimbursement, the financial climate is relatively more favorable for starting or growing a home dialysis program in the U.S. than it has been for many years. Nevertheless, the penetrance of PD is probably still less than 10%, and home hemodialysis less than 2%, of all U.S. dialysis patients at the time of this writing. What are the factors, then, that contribute to the huge ongoing disparity between the therapy that patients and their physicians think would be best and the therapy that they actually receive?

The purpose of this toolkit is to provide information and links to other resources to enable dialysis professionals to start or grow local home dialysis programs. It has been produced by volunteers recruited by the MAC of the Forum of ESRD Networks and is intended for distribution by the ESRD Network program. The Networks support informed patient decision making in the choice of dialysis modality, as well as the mandate from the CMS Conditions for Coverage (CfC) that Medicare beneficiaries be made aware of, and offered access to, all modalities of ESRD treatment. It is our contention, as it has been the contention of numerous authors of previous publications in the field, that the promotion of home dialysis as the treatment of first choice for individuals for whom it is medically appropriate has the potential to increase quality of life, decrease costs, and improve clinical outcomes—areas that all would agree are in need of substantial improvement in the ESRD program.

Chapter 1: Overcoming the barriers to starting or growing a home dialysis program: Administrative aspects

What are the requirements for a successful home dialysis program? Of course, the three required elements are patients, staffing, and a facility. Detailed recommendations for finding patients and staff are provided in later chapters in this toolkit. However, it is self-evident that without a financial and administrative structure, these elements cannot be assembled or maintained.

Naturally, the administrative infrastructure for a new home dialysis program is much easier to put together if there is an existing in-center program and, in particular, if the in-center program is part of a larger dialysis organization that has performed home dialysis elsewhere. A few independent home dialysis providers, including some intended to provide a place for local in-center programs in underserved areas to outsource their home dialysis needs, have been started in the past; however, it is our impression that such separate startups are less likely to prosper in the future. With the advent of CMS' prospective payment system (i.e., PPS or the "bundle") in 2011, there are few dialysis organizations of any size that can afford to refer home dialysis patients out. In addition, recall that the CfC require a qualified interdisciplinary team for any dialysis unit, with training and certification requirements for each member of the team. Clearly, a new, relatively small home dialysis unit is much more likely to break even sooner if it can share the services of renal dietitians, social workers, and technical staff with an existing program. As we will detail in the later chapter devoted to staffing, however, the provision of at least two nurses whose efforts are mainly or entirely dedicated to the home unit is desirable from the start in most cases.

In general, the economics of home dialysis should be relatively favorable, since patients are trained to perform their own treatments. Staff support for training and troubleshooting is required, but the staff is generally not required to be present during treatments after patient training is complete. Many of the costs of a home program are relatively fixed, however. Therefore, to an extent highly dependent on local factors, economies of scale are usually necessary to reach the financial break-even point. In areas where individual dialysis units are small and dispersed, it may make the most sense to have a regional home dialysis program. It is much less troublesome for patients to travel some distance to a regional unit twice a month than it would be to attend in-center hemodialysis three times weekly, even at a closer unit. While local factors may vary, a home dialysis population of about 20 patients seems to strike many authors as a viable minimum to sustain a dedicated facility and full-time nursing presence. Smaller numbers may work for a new program if home dialysis staff also work in the in-center program, if space for the home program is available from the start, or if a substantial proportion of prospective patients is commercially insured.

Administrative requirements at start-up

New facilities must become certified by CMS to offer home dialysis. After the initial application (form CMS-855A) is submitted to the regional Medicare administrative contractor, a state survey will be required and must be requested. In many states, there is also a Certificate of Need (CON) process required for approval of any new facility, even rededication of space within an existing structure. Provision of an agreement with the administrative contractor to allow the facility to bill Medicare will be contingent on passing the state survey and any other state requirements; at that point application can also be made to bill Medicaid.

A governing body is required for a home dialysis unit, just as it is for an in-center unit (Dept. of Health and Human Services, 2008). A robust quality assurance and improvement (QAI) program, supervised by the Medical Director, will ensure compliance with the CfC and help to produce good patient care outcomes, but obviously several of the parameters subject to QAI in a home program will need to differ from those followed in the in-center unit. For example, the measurement of dialysis adequacy differs greatly between in-center hemodialysis, home CCPD, and frequent home hemodialysis, and appropriate individual targets will need to be established for each modality. On the other hand, anemia management targets generally need not differ. In general, one should plan a dedicated monthly QAI meeting with individually maintained minutes, even in a home therapies unit that is administratively attached to, and shares a Medical Director with, an in-center hemodialysis facility.

Physical plant

A home dialysis facility requires dedicated space. Because of the needs for patient privacy, maintenance of sterile technique, and a distraction-free teaching environment, training for home dialysis is done in individual rooms. Attempting to train patients in a typical in-center hemodialysis space would predictably result in high complication and technique failure rates, as well as the loss of staff and patient buy-in. Training rooms can also be used for clinic visits with physicians and unit staff once patients are dialyzing at home, but at the minimum, there must be enough capacity to train new patients and sustain clinic visits simultaneously. This must include provision for urgent, unscheduled clinic visits and treatments, particularly if accommodation is to be made for "urgent start" PD (see Chapter 4), which we would recommend as a substantial source of patient recruitment for programs affiliated with sizable hospitals. Patient training/treatment and clinic space must obviously be secure and access available only to authorized individuals.

Some new home dialysis units might initially be accommodated within currently unused space in buildings that already house in-center units. For example, advance planning might have resulted in the construction of an in-center unit with suitable extra space for a home dialysis start-up in the future. However, in most cases, a building addition or a separate building will probably need to be constructed or acquired. Experience with new construction for existing programs has suggested that making the environment of a new facility as home-like as possible will markedly enhance patient training success and recruitment. Indeed, it might seem attractive to acquire and remodel an existing residence as a home training facility, rather than starting commercial construction from scratch. However, commercial construction may make it easier to comply with construction codes and life safety regulations, particularly when one factors in the needs for parking, access and safety of potentially handicapped patients, and the requirement to pass periodic inspections by the various regulatory agencies.

Optimally, a home dialysis facility will also contain or have access to space separate from training and examination rooms for patient waiting areas, nursing offices, storage, conferencing, and staff breaks. Home dialysis supplies are surprisingly bulky, so storage space is a significant consideration, which is best addressed prospectively. A pleasant conference space is useful not only for staff meetings, but also for group chronic kidney disease (CKD) patient education concerning ESRD treatment options, an activity which is potentially reimbursed by Medicare and of documented effectiveness for patient recruitment. Needs for larger programs might include offices for other staff (e.g., physicians and administrative support).

The majority of patients in most home programs will likely be doing PD. The training hurdle for patients to start dialyzing at home is much lower for PD than for hemodialysis, and the equipment less elaborate.

While a significantly different skill set is required for PD nursing compared with in-center hemodialysis, most new programs will probably choose to offer PD first. However, recall that the CfC require all modalities to be offered to patients. Therefore, if one wishes to retain home hemodialysis patients, then space, equipment, and technical expertise will have to be provided for their needs. In at least some CON states, the maximum number of hemodialysis stations in each region is specified, and any hemodialysis stations in the home training unit will therefore need to be subtracted from the capacity of local incenter units. Depending on the hemodialysis equipment chosen, the electrical or plumbing capacity of the home dialysis unit might also require upgrading.

Reimbursement issues specific to home dialysis

New ESRD patients not previously enrolled in Medicare and who start home dialysis immediately become eligible for Medicare; in fact, their Medicare coverage will be back-dated to the first day of the month in which they start. Under the CMS PPS, which most dialysis clinics elected to start using in 2011, the current per-treatment reimbursement rate is 151% of the standard rate for the first 120 days of dialysis. This adjustment should be applied automatically by the facility's regional Medicare administrative contractor. Thus, the home training facility can be reimbursed at this more generous rate for the entire 120-day period, known as the "onset of dialysis adjustment." While co-morbidity and training adjustments do not apply during this period, it is clear that the onset of dialysis adjustment more than makes up any deficit.

The first 60 to 90 days of in-center hemodialysis, in contrast, are not covered by Medicare, thereby shortening the period during which the onset of dialysis adjustment (and, indeed, any reimbursement at all) applies. For programs that see a high proportion of otherwise unfunded patients, this built-in Medicare encouragement for home dialysis can make an enormous difference to overall viability. This is particularly true if one recognizes that a patient switching from in-center hemodialysis to a home modality within the first 90 days restores his Medicare eligibility to the first day of the month in which chronic dialysis commenced.

For patients covered by commercial insurance, the coverage varies, but is often present from the start of dialysis, covers training, and usually covers the monthly billing of supplies and support, including the nephrologist billing, at a higher rate than Medicare. The number of patients required for financial viability of the program is, in general, substantially decreased by having even a few patients who are covered by commercial insurance. In areas with substantial penetration of commercial insurance among ESRD patients, it may be possible to start a program with a relatively small number of commercial patients while awaiting Medicare certification.

Patients already enrolled in Medicare who start home dialysis, or those returning to Medicare after renal transplant failure, are not eligible for the onset of dialysis adjustment. Such patients, as well as those training for home dialysis after a longer period of in-center hemodialysis, are eligible instead for a (relatively modest) training adjustment for treatments done in the home dialysis unit. This adjustment is currently limited to 15 treatments for PD (i.e., three weeks of five-day-per-week in-center cycler runs). In our experience, most patients can complete training and start home PD in a considerably shorter period than that.

Home hemodialysis training is covered by the training adjustment for up to two months, though this is usually reimbursed on a three-treatments-per-week basis, even for patients who are doing a daily dialysis regimen. When one factors in staff time and equipment complexity, most home training units

may not recoup expenses on home hemodialysis training itself. Legislative solutions to resolve this issue and thereby promote home hemodialysis penetration have been proposed, but at the time of this writing, no passage or implementation appears to be imminent. Training expenses for patients who switch home dialysis modalities are reimbursed in a similar fashion to those switching to home dialysis from in-center.

Certain medications are currently included in the reimbursement "bundle" for both home dialysis and in-center dialysis, including erythropoiesis stimulating agents (ESAs), intravenous iron, and vitamin D analogues. In our experience, home dialysis patients, particularly PD patients, tend to use lower doses of ESAs per capita, at least in part due to subcutaneous administration; therefore, there should be no financial disincentive to expanding the use of home dialysis from the medication expense standpoint. At the time of this writing, phosphate binders and cinacalcet, which are used by home dialysis patients and in-center hemodialysis patients alike, are not included in the bundle, and their inclusion appears to be unlikely for several years at least.

Chapter summary

- Home dialysis is generally less expensive to provide than in-center hemodialysis, mostly due to the fact that much of the labor is provided by the patient. Since it is reimbursed by CMS at a similar rate to in-center dialysis, the potential operating margin for the facility is greater, at least once some economies of scale are realized.
- New home dialysis facilities must be certified by CMS and pass inspection by the state agency in order to bill Medicare (and Medicaid) for home training and treatment. The CON process also provides a significant hurdle in many states. The requirements for a governing body, Medical Director, quality assurance process, and interdisciplinary patient care team, as specified in the CfC, are similar for home and in-center dialysis facilities.
- Dedicated space for patient treatment, education, and clinic visits is required for a viable home therapies program. Desirable attributes of the facility include adequate space for conferences, room for staff offices and breaks, and a homelike environment to facilitate the patient's transition to treatment in his or her own home.
- The human resources aspects of a home training program are covered in more detail in a later chapter. Nursing staff time dedicated to the home program is mandatory, and specific nursing qualification requirements are also discussed later. On the other hand, many successful programs share the services of the renal dietitian, social worker, and facility administrator (as well as the Medical Director) with in-center hemodialysis facilities.
- CMS provides some financial incentive to patients, physicians, and dialysis facilities to use home modalities, particularly at ESRD onset. The facility incentive has increased with the advent of the PPS (the "bundle"). If facility reimbursement by CMS decreases in the future, a development that seems likely at the time of this writing, the financial position of home therapies relative to in-center treatment will become still more favorable.

Chapter 2: Overcoming the barriers to starting or growing a home dialysis program: For clinicians and potential Medical Directors

Shortcomings of U.S. nephrology fellowship training in home therapies

Why aren't more people on home dialysis? Part of the answer to this question may lie in the comfort level of nephrologists with home techniques, particularly at the time when they complete their fellowships and enter clinical practice.

Nephrology has traditionally been a conceptually divided specialty, since nephrologists are trained in renal physiology and pathophysiology, but spend much of their time caring for patients who have no meaningful renal function at all. Nephrology is also a relatively young specialty. Some senior nephrologists still in practice today were trained by some of the founders of the field. Nearly all of the first and second generation of senior academic leaders in nephrology achieved their prominence through bench research in renal physiology or, later, renal cell and molecular biology, and, consequently, many training programs emphasized these areas. Few of the top-ranked programs aspired to train expert dialysis clinicians, hoping instead to generate bench researchers in the mold of their own successful senior faculty. Clinical fellowship in many traditional programs was limited to the one year required for board eligibility, and the services of clinical fellows were required most of the time in the hospital, with most of the leftover outpatient training time consumed in transplant or CKD clinics. Dialysis programs in many renal divisions, including some of the most elite academic divisions, were afterthoughts, where junior faculty made rounds, unaccompanied by trainees, often resenting the time that was spent there because it did not contribute to advancing their careers.

Mehrotra, Blake, Berman, and Nolph (2002) published a survey of fellowship training in the U.S., specifically focusing on dialysis experiences. At that time, 29% of nephrology fellows reported caring for less than five PD patients during their fellowship, and 14% reported spending less than 5% of clinical training time on PD. Nissenson et al. (2004) reported on the results of a small survey of attendees of a brief preceptorship in dialysis offered for second-year nephrology fellows. At that time, polling the (admittedly self-selected) attendees revealed that 25% had no exposure to PD, and 25% had never made dialysis rounds with an attending physician at all.

One might think that the training environment for dialysis has improved in recent years. At present, it is our perception that many nephrology training programs have a much larger dialysis component than they previously did, because of the growth of the ESRD patient population, the recognition of the dominant role of dialysis in the clinical practice of nephrologists, and the increasing dependence of most academic medical centers on clinical revenue. Despite this trend, relative utilization of PD has declined in the U.S. over the past 20 years (USRDS, 2015), and many academic centers continue to care for few PD patients. A survey of fellowship training directors published by Wadwha, Messina, and Hebah (2013) revealed persistent, systematic deficiencies in PD experience. Factors cited included not only the lack of patients, but also the lack of qualified faculty. Given the current rarity of home hemodialysis patients in the U.S., no publications were found that specifically addressed fellowship training in this area, but we suspect that most nephrology training programs offer very limited exposure to such patients and that faculty members with special interest or expertise in home hemodialysis are few and far between. Thus, a survey of U.S. nephrologists in clinical practice done in 2010 revealed that 80% felt well prepared to care for hemodialysis patients when they entered practice, but only 55% felt that way about PD (Merighi et al., 2012). Another question in the survey confirmed the results of many previous surveys: only 6% of

the responding nephrologists would have chosen thrice weekly in-center hemodialysis for themselves if they had developed ESRD. Nephrologists in the survey who received more fellowship training in dialysis, or who sought out additional training during or after the time they achieved board eligibility, were more likely to offer home therapies.

One persistent factor in the lack of penetration of home dialysis in the U.S., therefore, appears to be the lack of training in, and exposure to, home dialysis in many nephrology fellowship programs. While attempting to directly address the deficiency in knowledge of home dialysis is beyond the scope of this toolkit, a number of continuing medical education programs and other resources have been developed for the practicing clinician. A list of links, current at the time of publication, to some of these is provided in Appendix I. In particular, the large dialysis organizations, which have a vested interest in increasing the penetration of home therapies, are generally eager to offer education and programmatic expertise for those nephrologists who hold admitting privileges or medical directorships at their facilities.

Potential programmatic and personnel considerations

Within medical practice, dialysis is among the best examples of a "team sport." It is universally recognized that professionals from several other disciplines aside from nephrology are required for dialysis patients to successfully receive treatment, and minimum training and certification requirements for individuals in these professional roles are specified in the CfC. Nephrologists who wish to start home dialysis programs may encounter resistance from some of these individuals.

Another chapter in this toolkit is devoted to a more detailed description of features of a home program from the standpoint of nurses and other members of the interdisciplinary team. This discussion will therefore focus on the potential role of a prospective Medical Director of a home dialysis operation, as a team leader engaged in consensus building. The nephrologist who intends to be successful in starting or growing a home dialysis program should enter the process with an understanding of the potential demands on himself and the other members of the team, and the purpose of this section is to describe these demands.

Administrative issues

Among the first questions that needs to be answered in starting a home dialysis program is the potential independence of the program; that is, should the program be started within an existing in-center hemodialysis operation, or will it be separate? The majority of dialysis units in the U.S. are now owned and operated by one of two large corporations, and most of the remainder belongs to smaller chains. In theory, a multi-unit dialysis operation of any size should be willing to host a home program, since the financial margin on home treatment is favorable, compared with in-center treatment, and likely to become more so in the future. If the prospective home training unit is not part of a national or regional chain, the nephrologist may need to overcome a lack of local expertise in home therapies, a fear of risk taking, or concerns that the patient base will not support a home operation. Further issues may involve potential diversion of the effort of already oversubscribed local staffing or potential diversion of the patient base of an in-center unit whose margins are already thin.

In the case of practices located in CON states, opening a home dialysis facility requires state approval, with associated delays and costs, and could result in the loss of approved dialysis stations from the incenter unit. In all states, acquisition of suitable space for patient education, treatment, and training, separate from the in-center dialysis treatment space, is absolutely required from the practical

standpoint. If patients are to be attracted to home therapies and trained to succeed at home, making the training environment as homelike as possible is an important consideration.

In dealing with these concerns (and the inevitable associated start-up costs), the nephrologist should recall that patients must, according to the CfC, be informed of, and offered a choice among, all modalities of ESRD therapy, including home therapies. If the program cannot offer home therapies, it is obliged to refer patients who want them out to centers that do offer them.

In the case of a dialysis company that runs multiple in-center units in the same geographical area, starting a home dialysis program in a central location has often proven successful. Stable home dialysis patients generally need to be seen by their dialysis team only once or twice a month, so the overall travel burden is potentially much less than that experienced by in-center patients, even if the distance from home to the dialysis unit is significantly greater.

If a home dialysis operation that is administratively separate from local in-center facilities appears to be the best solution, the nephrologist must recognize that PD patients, and even home hemodialysis patients, may periodically require in-center hemodialysis for any of a number of changes in medical or social circumstances. Therefore, a home dialysis program cannot be safely and successfully operated unless there is a provision for back-up in-center treatment for its patients. Another consideration is the availability of PD in local hospitals. All dialysis units, whether home units or in-center units, are required by the CfC to have an agreement with a hospital to provide inpatient dialysis when required. While it is clearly suboptimal to offer only hemodialysis to inpatients who were doing home PD before admission, many smaller hospitals will not have any nurses with PD expertise. In such cases, an agreement from the hospital may be required to allow the outpatient home dialysis staff to do CCPD for patients who are too ill to dialyze themselves in the hospital, and the hospital will need to acquire PD apparatus and supplies compatible with the patient's catheter extension set or arrange to obtain them through the outpatient home program.

Staffing issues

From the professional perspective, nursing in a home dialysis program can be intensely satisfying, but it is self-evident that the skill set for home dialysis requires significant extension of that required for incenter hemodialysis. The foundation of any successful home dialysis program is the nursing staff, who have by far the largest role in interfacing with patients of any of the interdisciplinary team, including the nephrologist. Thus, a home dialysis program requires nurses who have made the extra effort to acquire additional skills in PD, who enjoy teaching, and who are willing to go on patient home visits and to be available to patients both inside and outside of regular working hours. Unless such individuals can be identified and appropriately compensated for their extra effort and expertise, no home dialysis program can be a success. On the other hand, it has been our experience that, once nurses are recruited, the professional satisfaction associated with home dialysis leads to greater retention of the nursing staff in home units than in-center.

Dietary management differs significantly for patients who dialyze daily at home than for patients on standard three-times-per-week in-center regimens. The ideal home dialysis dietitian recognizes and incorporates into his or her practice the additional flexibility that home dialysis offers. Indeed, it is this very flexibility that is one of the major advantages of home dialysis from the patient standpoint, and one should take care not to lose this significant advantage in quality of life by reflex prescription of a "renal diet." For example, no dietary potassium restriction at all may be required of many patients who dialyze

daily, whether on PD or hemodialysis. On certain intensive home hemodialysis regimens, phosphorus supplementation rather than phosphorus binders may be indicated. These situations may require significant conceptual adjustment on the part of both the nephrologist and dietitian.

At the same time, dietary prescription for PD in particular poses significant challenges, since protein loss through the peritoneal membrane represents a significant source of negative nitrogen balance that is not present in hemodialysis patients. Unless the PD patient can maintain protein anabolism outside the peritoneum, protein wasting will result in technique failure—or worse.

In summary, there is a far greater need for creativity in dietary prescription—"thinking outside the box"—in a home dialysis program than in an in-center program. The Medical Director who wishes to retain home dialysis patients should recruit a dietitian with this ability and encourage the required creativity. The dietitian may well need to become accustomed to generating different approaches to fulfill individual dietary recommendations for each patient.

Likewise, the challenges faced by the social worker in a home dialysis program differ in several respects from those seen in-center. The average age of home dialysis patients is likely to be lower than that of the in-center patients, and many individuals elect to do home dialysis so they can stay in the work force or do child care. The social worker should be prepared to interact more with employers and vocational rehabilitation counselors. It is the practice of the authors of this toolkit to make every possible effort to accommodate the time and lifestyle requirements of those patients who continue to work or attend school, and the social worker is obviously an integral part of these efforts.

Resources from the community may also need to be mobilized to alter a patient's home physical environment to allow for home dialysis. Many home dialysis patients should also be suitable candidates for renal transplantation, and the social worker may be involved in helping patients overcome personal or social obstacles to achieving placement on the waiting list. In general, most dialysis social workers should enjoy working with home dialysis programs, in which patients are (by definition) more independent and generally face fewer physical challenges.

Colleagues

Like other physicians in acute care specialties, nephrologists have tended to aggregate into groups, and relatively few are in solo practice any longer. Most large group practices will already have active home dialysis programs, but in smaller practices, inside or outside an academic setting, a nephrologist who develops an active interest in home dialysis may acquire a level of commitment and expertise not shared by his partners. Development of a "local expert" is undoubtedly a favorable influence on a home dialysis program and, in fact, is recommended, but that individual may face demands on his or her time that are not shared equally among partners.

Other perceived inequities may develop. Patients who want home dialysis will (and should) tend to gravitate toward the local expert. Practice revenue patterns may change; those practices that see their in-center hemodialysis patients four times monthly will not be able to bill home dialysis patients for quite the same level of reimbursement. A partner of the local expert might be asked to admit a PD patient with peritonitis during the night, and make decisions about antibiotic treatment and cycler orders that he or she might not have thought about for quite some time.

If such issues are anticipated, their exploration in advance should enable straightforward solutions in most cases. Well-trained PD nurses will be able to handle most nighttime patient calls, and pre-prepared protocols for peritonitis treatment and other anticipated technical problems should reliably facilitate management after hours. While physician monthly capitation payment (MCP) reimbursement for home dialysis patients is somewhat less than for the four-visit monthly in-center patients, the average face-to-face management time is less also, and the physician may be able to make up the monetary difference by spending the time difference on other reimbursable activities. Furthermore, the difference in long-term revenue will, in many cases, be partly offset by immediate Medicare eligibility for home patients, and a home training charge that can be billed by the physician who personally supervises patient training.

Regulatory requirements of the Medical Director

In general, the CfC do not make many distinctions between home and in-center dialysis programs with regard to regulatory requirements. The role of the Medical Director in the two settings is therefore quite similar. The Medical Director of a home dialysis program, like his or her in-center counterpart, is responsible for quality assurance and performance improvement (QAPI) activities and staff education, as well as for making sure that patients are seen by their attending nephrologists and other members of the interdisciplinary team and that care plans are completed for those patients. A home program, like an in-center facility, must have a governing body to which the Medical Director reports, and of which the Medical Director is usually a member. In the frequent case in which a single dialysis unit hosts in-center and home programs, the same individuals may serve on the governing bodies of both, but it is recommended that separate governing body and QAI committee meeting minutes be maintained. Some appropriate subjects for performance improvement projects in home dialysis do not apply to in-center programs, and vice versa.

Peritoneal dialysis access

In some areas, lack of local surgical experience with PD catheter placement may represent an obstacle to establishing a home dialysis program (Crabtree, 2010). While Tenckhoff and other PD catheters can be placed blindly into the pelvic peritoneal cavity, it is our belief that laparoscopic placement is responsible for the much higher success rate we have observed in recent years. Omental adherence is a relatively common cause of drain failure of blindly placed catheters; this can be minimized by laparoscopically visualized placement of the catheter tip in a paracolic gutter, away from the omentum. Some interventional radiologists and nephrologists have recently reported high success rates with percutaneous placement under ultrasound and fluoroscopic guidance, and dissemination of this skill set among training programs may decrease the need for laparoscopic placement in the future, at least in uncomplicated clinical scenarios.

A few nephrologists have sought training and achieved competence in laparoscopic PD catheter placement. However, most nephrologists in the U.S. currently rely on surgeons trained in laparoscopic abdominal surgery for catheter placement. While the operation is not technically difficult (by the standards of an experienced laparoscopic surgeon) in most patients, a learning curve may be anticipated, with an initially high rate of exit site leaks, drain problems, cuff extrusion, etc. A survey of surgical training programs in the U.S. found that most programs offered the procedure, but that most residents finished their training having performed less than five catheter placements (Wong, Liebman, Wakefield, & Messing, 2010).

Occasional patients may benefit from a more advanced technical armamentarium that includes omentopexy, alternate (e.g., parasternal) exit site placement, or takedown of intraperitoneal adhesions. Occasionally, a malfunctioning catheter can be salvaged by stylet placement and repositioning by an interventional radiologist, nephrologist, or other appropriately trained physician.

If appropriate local expertise in PD catheter placement is not available and cannot readily be developed, it may be worthwhile establishing a referral relationship with a center that supports an established program. A useful webinar with video illustrating some of the finer points in laparoscopic catheter placement, featuring surgeon John Crabtree, MD, is available to interested parties on the Internet.

Chapter summary

• The nephrologist interested in starting or expanding a home dialysis program may face several obstacles. Among the most prevalent of these is lack of training and experience in home dialysis patient care, which many nephrology fellowships still do not offer to a suitable extent, but which can be overcome with continuing medical education (CME) offerings, published materials, and Internet resources. A facility that can provide space and time for patient care and training will be needed. Professionals in other dialysis disciplines will need to be recruited, and among these the nursing staff is the most crucial, though buy-in will also be required from a facility administrator, dietitian, and social worker. Though the interested nephrologist may intend, through self-directed learning and accumulated experience, to assume the "local expert" role in home therapies, support from nephrology colleagues, as well as local hospitals, hemodialysis facilities, and a surgeon or interventionalist will also be required.

Chapter 3: Overcoming the barriers to starting or growing a home dialysis program: Staffing considerations

The CfC (2008) require the training of home dialysis patients to be provided by a registered nurse who meets the practice requirement of the state in which he or she is employed. The nurse must also have at least 12 months experience in providing nursing care and an additional three months of experience in the modality (hemodialysis or PD) for which he or she will provide training. In home dialysis, the CfC do not specify maximum patient-to-nurse ratios, though state regulations may apply in this regard.

For established programs, staffing ratios of registered nurses to patients vary, generally falling into the range of one registered nurse per 15-25 patients. This can include both PD and hemodialysis patients. Programs that include pediatric patients or a large proportion of home hemodialysis patients may be able to justify one full-time registered nurse position per 10 patients. Many states require one full-time nurse for every 20 or 25 PD patients (Saxena, 2011). A <u>fact sheet of best practices</u> discussing these ratios and delineating broad roles within the PD program is available online.

For new programs, the minimum staffing is two nurses. One nurse is dedicated to home training and the other nurse to fill in as a backup as required (Counts [Ed.], 2008). Although it may seem efficient for smaller programs to divide a nurse between in-center hemodialysis and home dialysis responsibilities, this does not provide the flexibility needed for training, follow-up, and recruitment of new patients into the home program. Furthermore, home dialysis nurses need to be available to patients at night and on weekends, and it would clearly be difficult to recruit and retain a nurse to work full-time during the day and be on-call all or most nights and weekends, as well. Recruitment from the in-center hemodialysis staff may be optimum for at least three reasons: 1) patients will ask where the nurse has gone and ask to see him or her about the new therapy; 2) the nurse may well be looking for a program with less stress than the long hours of the in-center unit; and 3) the nurse already has experience with renal disease, dialysis, and medications used in dialysis. The opportunity to work with patients who are very interested in their own care and well-being is an added bonus for the nursing staff.

Characteristics of successful home dialysis nurses

The primary role of the nurse in the home program is to provide patients and caregivers with complete, accurate, and understandable information, which will allow them to perform dialysis safely and independently in the home setting. However, in viable and growing programs, nurses go far beyond this primary role. They are the primary interface between patients and the program, and since they usually know the patients and their home environments best, they are in the best position to direct the efforts of dietitians, social workers, and technical staff where they are most needed. As the public face of the program, they are often the decisive factor in the recruitment of new patients and new staff.

Given these considerations, several authors (Counts [Ed.], 2008; Diaz-Buxo, Crawford-Bonadio, St. Pierre, & Ingram, 2006; Kong et al., 2003) have sought to define the attributes of successful home dialysis nurses. A survey of this literature suggests that these attributes include:

- Enthusiasm and motivation to inspire staff and patients to do their best
- Knowledge of learning styles to enable effective teaching to each individual

- Advocacy for self-care, combined with flexibility to adjust training and follow-up to accommodate differences in patient/caregiver capabilities
- Self-direction, with ability to multi-task
- Comfort with evaluating, troubleshooting, and counseling patients/caregivers personally and by phone
- Confidence in the professional nursing role and sphere of expertise in working with physicians and midlevel providers, combined with recognition of the appropriate time to contact them when the limits of nursing practice are reached

Excellent home dialysis nurses are avid supporters of home therapies and develop close bonds with their patients. Perusal of the list above makes it clear that not all dialysis nurses, no matter how experienced in in-center dialysis, are equipped to do well in the home setting.

Professional development

Many excellent resources are available for nurses to begin and continue their education regarding home therapies. Conferences are offered by several organizations and special interest groups, and listservs organized by such groups are available online. Links to some of these resources are provided in Appendix I; we will refer to a few useful examples here.

Journals with timely information are available both in print and online. The <u>American Nephrology Nurses Association</u> is for nurses working with patients and families with kidney disease and publishes the <u>Nephrology Nursing Journal</u>. For members of ANNA, a discussion site called "Home Therapies SPN" offers information from practicing nephrology nurses on a variety of home dialysis issues including managing calls, staffing, and inpatient issues. Certification in nephrology nursing is available through the Nephrology Nursing Certification Commission (NNCC).

The International Society of Peritoneal Dialysis has a training segment titled <u>"Teaching Nurses to Teach: Peritoneal Dialysis Training."</u> The series was developed in 2006 by the University of Pittsburgh. The lessons include videos, written material, and a post test. The purpose is to help home nurses organize and present training materials using principles of learning. All aspects of training are included.

A smartphone app that is useful to both nephrologists and nurses working with PD is <u>QxMD</u>. A segment devoted to nephrology includes access care and complications of PD catheters and management of peritonitis.

Training for nurses new to PD is available through a number of avenues. The large dialysis organizations, and some smaller organizations, as well, have found it advisable to assume responsibility for training nurses who are transitioning to PD, as well as for the start of new home programs within their facilities. Baxter, a large manufacturer of home dialysis equipment and supplies, offers TeamPD, an education program for nurses learning PD. It combines online materials, live workshops, and clinic training visits from a clinical educator. Training includes all aspects of PD, troubleshooting, equipment use, and supply management. For new PD programs, this course and support can be part of the development of the entire program.

However, online or classroom training will not suffice for staff being hired by a new home dialysis program. Because of the CMS guideline requiring three months of experience, nurses new to PD will need to be mentored by an experienced nurse before being allowed to train home dialysis patients on their own. Therefore, a new program must either hire an experienced staff member from an existing program or make arrangements for newly hired staff to spend at least three months working in such a program.

Other staff

A home program must have a dietitian registered with the Commission on Dietetic Registration with a minimum of one year of experience in clinical nutrition as a registered dietitian (Dept. of Health and Human Services, 2008). These are the same requirements as in-center hemodialysis. Dietitian responsibilities include initial and ongoing nutritional assessments, the provision of tools and education for diet management, and the active participation in the patient's plan of care (Diaz-Buxo et al., 2006). In practice, the dietitian role is often shared with in-center programs. Experienced renal dietitians recognize that dietary prescriptions and restrictions may be quite different for home patients than they are for in-center patients, since most home patients dialyze more frequently.

The home program must have a social worker who has a master's degree in social work from a school accredited by the Council on Social Work Education. As in the in-center dialysis unit, social workers are responsible for the evaluation and documentation of a patient's psychosocial status and assessing patient satisfaction with the program. The special expertise of the social worker in both in-center and home dialysis is the identification and mobilization of family and community resources needed to achieve and maintain the best possible patient functional status and quality of life. Clearly, the need for, and availability of, such resources may differ substantially between in-center and home dialysis patients, even in the same geographic area, so there is not complete overlap in the knowledge base required to serve these potentially disparate groups. The home program social worker must be prepared to incorporate the patient's employment, school, or child care responsibilities into individually customized financial, psychological, and modality choice counseling. The social worker in the home program is also the key to early identification of potential changes in the home that may lead to patient (or caregiver/dialysis partner) burnout or dropout (Luongo & Prowant, 2009).

After hour availability

It is essential that patients know how to contact the correct person for questions or problems at all times. Though programs may use on call dialysis nurses, nephrologists, advance practice nurses, physician assistants, renal fellows, and corporate technical help lines, in our experience most successful programs utilize the nursing staff as the initial point of contact for patients, whether the contact occurs during or after working hours. Continuous and prompt on-call support improves patient outcomes through rapid response, preventing waste of resources, and maximizes the patient's confidence and satisfaction (Counts [Ed.], 2008). If emergency care is required, emergency departments need protocols for managing dialysis-related problems, such as peritonitis or catheter malfunction, and this information is best provided in advance by the home dialysis nursing department, in concert with the Medical Director. The means to provide PD in the hospital, including technical assistance for the hospital nurses and the management of EMR, cycler, and connector compatibility issues, is also far better planned for by the home dialysis nursing staff, in detail, in advance, and during normal working hours, than on an urgent basis in the middle of the night.

Patients who are normally highly capable of self-care may be temporarily too ill to dialyze themselves in the hospital. In order to avoid the potential for technique failure or other complications resulting from the hospitalization, it may well be better for the home dialysis nursing staff to be credentialed to provide this care in the hospital, than for hospital staff nurses to attempt cycled PD on the basis of occasional exposure to the technique and equipment. Well-trained patients who are well enough to dialyze themselves in the hospital should be permitted and encouraged to do so. We have occasionally encountered hospitals that consider patient self-dialysis in the facility to be some sort of liability risk, but typical home CCPD patients are likely to have a much higher level of expertise, including meticulous infection control technique, than the nursing staff of a general medical-surgical ward.

Chapter summary

- The nursing staff is the key to success for a home dialysis program. Interpersonal skills, flexibility, professional dedication, and an interest in teaching and learning are among the characteristics of successful home dialysis nurses. While fulfilling the responsibilities of a home dialysis nurse is professionally rewarding, it is also demanding, and staff-to-patient ratios that recognize this reality must be maintained. Many in-person and web-based training resources are available for nurses who wish to acquire the home dialysis skill set and enter the field.
- The CfC requirements for staff other than nurses are as stringent, and for nursing staff somewhat more stringent, than those for in-center dialysis personnel. While responsibility for patient training falls on the Medical Director, the teaching itself must be done by a nurse who has at least three months of home dialysis experience. The home program dietitian and social worker, as well as the nursing staff, should be advocates for home dialysis and patient self-care and must recognize the special and often individualized requirements of home dialysis patients and incorporate them in their professional spheres of expertise.
- Since most home dialysis patients are dialyzing outside of normal working hours, nursing and technical support must be available to patients 24 hours a day, seven days a week. For PD patients, their chosen modality should be available in the hospital, meaning that compatible cycling equipment and supplies must be available at all times. Hospital nurses may need to be trained in cycling PD, or the home dialysis staff may need to come in to the hospital.

Chapter 4: Overcoming barriers to patient success with home dialysis

This chapter is about patients, but since it is directed at an audience of dialysis professionals, the body of the chapter was also prepared by dialysis professionals. Nevertheless, the writing committee for the toolkit benefitted greatly from patient input, as have all of the activities of the Forum of ESRD Networks in general. For a first-person patient perspective on the issues covered in this chapter, please see the sidebar.

Home PD regimens may be entirely cycler-driven, entirely ambulatory with manual exchanges, or hybrids of the two; assuming that the home environment is suitable for PD in general, individualizing prescriptions among these choices is not likely to run into technical constraints. The options for home hemodialysis equipment and regimens are somewhat wider, and both the physical and social aspects of the patient's home situation might constrain some of these choices. In earlier eras, patients who were in Veterans Affairs (VA) home dialysis programs, for example, might have had their homes renovated by the VA to install electrical and plumbing systems capable of accommodating standard hemodialysis machines and water treatment devices. In some cases, professional dialysis staff were hired to travel to the patient's home and perform dialysis there, as well. The availability of such resources is rather unusual at present, as Medicare does not pay for assistants for dialysis (though one may occasionally encounter a commercial insurance policy, or patients with private means, that enable the hiring of a dialysis assistant). By way of compensation, however, the technical state of the field has advanced. The advent of hemodialysis machines specifically engineered for home use has greatly lowered the potential technical obstacles to doing hemodialysis in many patients' homes.

Assessment of potential home dialysis patients

Clearly, home dialysis is not for everyone. Growth in a home dialysis program depends on retention of patients as well as recruitment, and the ideal shared decision-making process

regarding modality choice may well lead to the realization on the part of the patient, as well as the dialysis team, that home dialysis is likely to fail or is not in accordance with patient goals to start with. The assessment by the dialysis team should include the following:

"My hope is that this home dialysis toolkit will increase home dialysis patients in the next year so more patients can experience the benefits of home dialysis."—Lana Schmidt

Patient Success with Home Dialysis

Medicare's ESRD program is a federal health insurance program for people with ESRD. The program is designed to encourage "self-care dialysis" and kidney transplantation and clarify reimbursement procedures to achieve effective

There are Medicare benefits of choosing home dialysis "first" if the patient is not already on Medicare. Medicare coverage can start as early as the first month of dialysis if the patient takes part in a home dialysis training program offered by a Medicare-approved training facility to teach patients how to administer dialysis treatments by themselves at home. Patients will be able to do their own dialysis treatments once they finish the training. Otherwise Medicare benefits will not start until the fourth month the patient is on incenter dialysis.

- Evaluate the home environment: safety, living arrangements, clean water, adequate space, and electricity.
- Evaluate the potential need for a partner: memory deficit, mental challenges, uncontrolled mental illness, or alcohol and drug abuse in the case of PD. Safe home hemodialysis almost universally requires a trained partner.
- Complete an individualized patient assessment: literacy, language fluency, age, weight, physical health, eyesight, mobility, manual dexterity and strength, employment status, and transportation.

Many potential barriers can be adequately addressed and managed during the training sessions if they are planned for before training begins (Czajkowski, Pienkos, Schiller, & Doss-McQuitty, 2013; Koester, 2013). Monthly clinic visits offer the opportunity to address new or potential changes before they become problems. Both patients and partners need to feel safe about discussing concerns and asking for help. Having clear written expectations of both the patient/caregiver and the staff is useful for avoiding potential miscommunications.

Incident patient recruitment

Potential candidates for home dialysis must obviously be recruited from one of two groups: those patients new to the ESRD program and established ESRD patients who desire or require a change in modality. Mechanisms for identifying and recruiting patients from the two groups must differ, and successful programs are likely to have strong pathways for patient intake from each group, recognizing the need to tailor patient education programs to local needs and conditions.

This being said, it has been universally observed that patients are more likely to choose a home modality if that choice occurs prior to starting in-center hemodialysis. Even with very intensive and enthusiastic home education days both in groups and with individual sessions, many patients already performing in-center dialysis are reluctant to change (Schiller, Munroe, & Neitzer, 2011). Reasons include comfort with their current therapy, disruption of family life, concerns about ability or benefits of changing therapy, and loss of socialization with a group of people with the same modality.

FREEDOM Study by NxStage

The latest interim findings from Nxstage's FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study show that daily home hemodialysis treatments with the NxStage System Oneare associated with long-term improvements in various physical and mental quality of life measures. Some of the areas of improvement were: post dialysis recovery time, depressive symptoms, anti-hypertension medications, sleep quality, restless legs, and mortality.

"ESRD patients struggle on a daily basis with maintaining their overall health while trying to better manage their chronic condition. This data shows that more frequent home hemodialysis can have a positive impact on a patient's perception of his quality of life," says Frederic Finkelstein, MD, Chief of Nephrology at the Hospital of St. Raphael in New Haven, Connecticut, and Clinical Professor of Medicine at Yale University Medical School, the study's primary author

"This recent data builds upon an already robust mountain of clinical evidence pointing to the benefits of more frequent home hemodialysis," says Jeffrey H. Burbank, Chief Executive Officer of NxStage Medical, Inc. "FREEDOM continues to show that more frequent home therapy with the NxStage System One transforms patient lives for the better, resulting in healthier, happier patients who are empowered in their own health care "

Most patients first hear about home therapies through their doctors. While predialysis modality education has recently become reimbursable to physicians by Medicare, physicians are more likely to discuss home options if structured education classes led by home dialysis nurses are readily available (Czajkowski et al., 2013). Nurses presenting the information should be knowledgeable and enthusiastic about all modalities (home, in-center, transplantation, and conservative management) yet respectful of

patient and family choices. Biasing a talk towards the "best" therapy can be counterproductive if a patient needs to have a different type of therapy. Attendees expect accurate information and can plan more realistically if detailed information is available. Examples could include dialysis access surgery site, limitations, and time to full recovery; available training dates and anticipated length of training; and potential barriers to successful home therapy.

A focus group of PD and home hemodialysis patients found five themes important in establishing and maintaining successful independent programs: 1) patients need to know that the team hears their fears and concerns; 2) their own treatment choices will be supported; 3) training and education materials will be comprehensive and realistic; 4) 24-hour support for clinical or technical problems will be available; and 5) peer support is available (Sondrup, Copland, Black, & Trask, 2011).

Well-organized patient education material is available through the large dialysis organizations; multiple patient and dialysis non-profit advocacy organizations have also freely disseminated such materials online, and the selection is wide (links are provided in Appendix I). Therefore, there should be a very limited need for individual facilities to develop their own material. As with all medical coding and billing, compliance with certain CMS guidelines and conditions for predialysis education must be met in order to bill Medicare for the activity, and the use of structured materials provided by public organizations should assist with compliance.

Recruitment of established ESRD patients

In some areas, access to nephrology care prior to the onset of

ESRD is limited, and many patients therefore present to the facility with irreversible uremia, no previous CKD care, and a more or less immediate need to start renal replacement therapy. If there is no urgent start PD program in place, such patients seem to inevitably start in-center hemodialysis through what has been referred to as the "two phone call" process (J. Bargman, personal communication, 2013). That is, the nephrologist makes one phone call to get the patient enrolled in the ESRD program and another to the dialysis unit to communicate orders. A well-oiled machine slides a tunneled catheter into the patient and the patient into an in-center hemodialysis slot, and the nephrologist goes on with his day.

Statistics

Currently, according to Renal Network statistics, only 2% of kidney patients are on home hemodialysis, while 8% are on PD, totaling only 10% of patients on home dialysis with 90% on incenter dialysis.

In a recent survey, more than 90% of nephrologists said they would choose a home therapy for themselves if faced with dialysis, with home hemodialysis as the preferred option (Schiller, Neitzer, & Doss, 2010). Yet, more than 90% of patients undergoing dialysis in the U.S. are doing thrice-weekly incenter hemodialysis therapy.

Among the reasons cited for choosing home dialysis by nephrology professionals were more treatment flexibility, control over their own therapy, and, most importantly, better results. Many physicians believe that between 25-35% of patients would do better if they were on a home dialysis therapy.

Patient Demand and Predialysis **Education**

Medicare standard V458 states all Medicare beneficiaries are required to be informed about all treatment modalities and settings, including but not limited to, transplantation, home dialysis modalities (home hemodialysis, intermittent PD, CAPD, CCPD), and in-facility hemodialysis.

The patient has the right to receive resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients. Furthermore, if the patient requests a transfer to another facility that offers a treatment they desire, it must be facilitated

Documentation in patient records must demonstrate that the facility staff provided unbiased education to patients/designees about transplantation and all dialysis treatment options (modalities and settings) offered for ESRD

Patients must also, upon entry to the facility, be informed about transplantation as an option of treatment for ESRD (V544). The care plan must include: a statement concerning renal transplantation; that the patient is considered unsuitable for a transplantation; that the patient refuses transplantation; that the patient has or will be referred for a transplant evaluation.

The CfC mandate education for all new entrants into the ESRD program, including education about all modalities of treatment, including home dialysis and transplantation. Unfortunately, many or most patients still face the need for dialysis without the opportunity for adequate preparation. Given the epic changes in lifestyle, information overload, and general atmosphere of fear and uncertainty that is likely to prevail under the circumstances, such patients are not in a good position to make an informed choice about treatment modality. Handing the patient another thick stack of paper and checking the box that says he has received modality choice information may fulfill the requirements of the CfC, but is not likely to result in the decision to learn to do his own dialysis, even by a patient who is otherwise fully qualified to do so.

If this scenario often prevails locally, patients may ultimately be able to make a better choice if they are personally visited in the dialysis unit by home training staff, perhaps after some initial adjustment period, and offered the opportunity to visit the home training facility and participate in the same educational program offered to predialysis patients. Identification by, and positive reinforcement from, the nephrologist for patients who would be good home dialysis candidates is undoubtedly helpful, as well. A home training facility that is itself homelike may be an excellent recruiting tool, in that it may provide a striking contrast to a seemingly chaotic in-center hemodialysis environment to the new patient's eyes, if only he or she gets to see it.

Dialysis patient support groups are also a tremendous potential source of support for the modality decision-making process. The ESRD Network program scope of work includes the promotion of patient involvement in the education of other patients at the local facility level through identification of patient navigators and subject matter experts. Certainly the home dialysis program should encourage the involvement of committed and successful patients in such activities, which are increasingly required of all facilities by the Networks (see the sidebar). Numerous online home dialysis resources are also available to the increasing

proportion of patients who are in the position to take advantage of them.

Even though this is a requirement by Medicare, many patients report not being informed of all the treatment options, not having had a choice in the matter, and automatically being put on incenter dialysis. A dialysis method decision is made for them before being provided with proper information and understanding of all the treatment options. There seems to be a mindset within the kidney community that in-center dialysis is the "first" choice for patients and home dialysis is looked at later. It would be good if the mindset would change to home dialysis as a "first" choice and then in-center later, if home dialysis is not feasible.

Once patients are fully aware of all the treatment options available, many choose home dialysis because of the benefits it offers them. Many patients who are on home dialysis have reported great success along with feeling better, greater energy, and an improved quality of life.

The non-profit Medical Education Institute, Inc. developed the Method to Assess Treatment Choices for Home Dialysis (MATCH-D) for Home Dialysis Central to help nephrologists and dialysis staff identify and assess candidates for home dialysis therapies (PD and home hemodialysis). It is designed to sensitize clinicians to key issues about who can use home dialysis.

Unfortunately, one of the more rapidly growing sources of new dialysis patients in the U.S. is failure of a renal transplant. Previously transplanted patients clearly are likely to be much more sophisticated about dialysis and modality choices than those with new onset ESRD. This potential source of patients should certainly not be overlooked by home training programs. Even if the transplant patient never dialyzed at home previously, he or she is likely to place a high value on the freedom from in-center dialysis schedules that he or she enjoyed when the transplant was functioning. Cultivation of a good relationship with local transplant programs is therefore important for the home dialysis program, in order to make it easier for patients to transition from transplant to home dialysis, as well as the reverse.

Urgent start

"Urgent start" PD refers to the use of PD as a first modality choice in patients newly dependent on chronic dialysis, most often in the hospital setting, in spite of the lack of time or opportunity for predialysis education and planning. Urgent start PD avoids the need for a central tunneled hemodialysis catheter, ensures the patient leaves the hospital with a permanent access, and allows patients without other resources immediate coverage by Medicare. Immediate use of a skillfully placed Tenckhoff catheter is possible without leaks, as long as reasonable precautions are taken. Patients are generally initially dialyzed with low volumes, 500ml to 1000ml every 1-2 hours, in the supine position. Gradual increase to full volume and postural freedom is usually achieved within two weeks (Ghaffari, Kumar, & Guest, 2013). PD can be done with a cycler or by manual exchanges. Because of the low volume of dialysis, patients need to have at least 500ml urine/day and a residual urea clearance of 5ml/min.

If PD is urgently started in the hospital, the patient is immediately referred to the home training program upon discharge; initial outpatient PD "runs," usually

cycler driven, are performed during working hours in the home training center, and the patient can be simultaneously or intermittently instructed in the performance of his own dialysis. Planning for an urgent start program requires nursing input for staff training and protocol/procedure development (Ghaffari et al., 2013). The accepting program needs to have sufficient staff, as well as a fully reclining

chair or bed, along with the room to offer PD and training with little advance notice, while meeting the needs of previously scheduled patients for training and outpatient visits.

Casaretto et al. (2011) describe their experience in detail. They recommend at least two registered nurses to ensure that any other planned training is not disrupted. They also suggest the need to hire a nurse before the program grows since "urgent start" is a new nursing responsibility. As long as the patient can be monitored (e.g., via a window, multi-site training room, or intercom) the nurses can continue to work with other patients. The fresh urgent start patient may dialyze in a supine position for six hours three days a week (e.g., Monday, Wednesday, and Friday) with 1000ml dwell, with exchanges occurring up to hourly. Patients are drained completely before sitting or standing for any reason.

Billing can only be done for either PD treatment or home training on any given day. Therefore, training programs could consider, for example, continuously dialyzing patients with significant residual renal function three days a week, with some dialysis interruption for training on the other two days. This is not to say that patient education cannot occur on the dialysis-billed days. Patients certainly can watch instructional videos and review written information on non-training days.

Impact of unexpected events, complications, and technique failure among home dialysis patients

A major component of a successful home program is the flexibility to deal with the unexpected. Patients may need temporary in-center dialysis, either hemodialysis or peritoneal, for reasons such as acute illness, respites for caregivers, peritonitis, or access problems. Therefore, home dialysis nurses need to have working relationships with the local in-center hemodialysis units and hospital-based dialysis staff. Patients need to be able to transfer back and forth between therapies with ease to continue their care. Factors to consider when establishing procedures to provide respite or urgent care plans include billing mechanisms, the location of respite dialysis, and the authorization to proceed with this care with a minimum of difficulty.

Failure to achieve or maintain acceptable clinical outcomes with home PD is reported in up to 50% of cases at one year. Proximate causes for technique failure are often medical in nature (e.g., recurrent peritonitis or transdiaphragmatic hernia), but social and demographic factors are known to increase the risk (Shen, Mitani, Saxena, Goldstein, & Winkelmayer, 2013). In our experience, one factor that may not be appreciated in advance is the potential for patient or caregiver burnout, particularly as dialysis regimens are intensified in response to ongoing loss of residual renal function.

The dialysis clinician may recognize factors at the initiation of chronic dialysis support that would make success with home dialysis difficult or unlikely. It is our belief, however, that motivated patients deserve a chance to do home dialysis if the factors that mitigate against success are not overwhelming (see the sidebar). Experienced clinicians will recognize that technique failure cannot always be predicted with accuracy. PD and in-center hemodialysis are not modalities forever slated to mutually exclusive for a given patient; patients may benefit from their consecutive use. If one never prescribes PD for patients considered at some risk for technique failure, many candidates who would do well for a long period of time would be excluded, and the growth of the home program unnecessarily constrained as a result.

If the home program Medical Director recognizes and accepts the possibility of PD technique failure, a corollary question that frequently arises is whether all PD patients should ideally have an arteriovenous

(AV) fistula. The need for a technique switch, or respite from PD, often comes up rather suddenly, and one would like to avoid the necessity of placing hemodialysis catheters; yet routine AV fistula surgery creates morbidity and expense for patients who might never require the fistula to be used. We are aware of successful home programs that have good results with or without a near-universal fistula policy; the best answer probably varies depending on local conditions, including the philosophies and preferences of patients and surgical consultants. Shared decision making with patients/families allows for the development of a "life plan" that addresses many of these issues upfront and provides guidance for the patient's care team in these circumstances. A link to Michael J. Schreiber's article "The ESRD Patient's Life Plan: Extending Survival by Managing Health" is provided in the Appendix. Additionally, Chapter 7 of the Forum's Transitions of Care Toolkit expands on many of the concerns that prevalent patients have about changing modalities and suggests ways to address them. A link to this toolkit is provided in the Appendix.

Chapter summary

- Potential candidates for home dialysis must be identified and recruited in order to maintain a
 strong program. Both patients with new onset ESRD and those previously treated with in-center
 hemodialysis are required to receive education about modality choice; making a good, informed
 choice may require more than the simple provision of printed information. Depending on local
 resources, programs to promote exposure of all potential home dialysis candidates to
 committed home dialysis staff and patients should be considered.
- Urgent start PD may provide a meaningful source of patients to programs that serve sizable
 hospitals, populations with previously limited access to care, or both. A defined urgent start
 pathway, supported by adequate reserve capacity of staffing and space within the home training
 unit, is required.
- Patient retention is as important as recruitment for program success, and realistic assessment of
 patient functional capacity, social support, and home environment is a crucial component of the
 optimal shared decision-making process regarding modality choice, as well as the process of
 overcoming barriers to home dialysis success once the decision to do it is made.
- Having arrangements in place for respite in-center care or the possibility of technique failure is
 highly recommended as an important contribution to patient accrual and informed mutual
 decision-making. Prospective placement of an AV fistula may be prudent for some proportion of
 patients who plan to do PD. A program that never experiences technique failure is probably not
 accepting many potentially available patients who would succeed.

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Appendix I: Annotated links

Baxter International

This site is obviously commercially sponsored, but the "Home Therapies Institute" tab links to a large number of educational videos and webinars that cover numerous topics in home dialysis, presented by experts and intended for physicians and nurses, without necessarily referencing to the company's products. The intention appears to be the promotion of home dialysis in general. There is also a link to "Team PD," an online and potentially face-to-face program developed by Baxter nurse clinical educators to train PD nurses; some of this material is specific to the company's products and services.

Home Dialysis Central

A website created by the Medical Education Institute (MEI), a non-profit whose purpose, as expressed on the site, is to improve the lives of patients with CKD and ESRD. Much of the website (and other sites sponsored by MEI) is directed at patients, but it does have a "Professional Tools" tab that incorporates some useful and practical information about starting a home dialysis program, as well as resource links and FAQs. Also, please see Match-D, an online tool for dialysis professionals to help assess the suitability of patient candidates for home therapies.

RenalWeb Nocturnal and Home Hemodialysis

RenalWeb is described on its website as a "neutral, non-affiliated" site that aggregates links to dialysis companies, products, and services; many of the links are commercial advertising, but there are also links to recent journal articles and non-commercial websites of interest. The site as a whole appears to rather aggressively promote the opinion that conventional thrice-weekly in-center hemodialysis is "inadequate" therapy of uremia, which continued use is sustained mostly by inertia and financial conflicts of interest among payors and providers. PD is not covered.

Finances of Home Dialysis

A useful slide deck generated by Thomas Golper, MD, for a talk at the International Society of Peritoneal Dialysis.

Advanced Renal Education Program

A website created and maintained by Fresenius Medical Care (FMC) that covers numerous topics of interest in home dialysis—founded in part by cycling PD pioneer Jose Diaz-Buxo, MD. The site offers "elearning" modules for nephrology nursing continuing education credit. It also links to the ongoing live symposium series "Current Best Practices in Home Therapies," sponsored by FMC several times each year in locations across the country, which can be attended by any medical professional without registration fees.

QxMD Calculate

A decision support tool for mobile devices that includes a number of modules of interest in PD, such as access care and peritonitis treatment, as well as a mobile version of the Match-D tool described above.

American Nephrology Nurses Association

The association website offers much material relevant to home dialysis therapies, including a specialty package of continuing nursing education (CNE) credits related to home therapies, an online library that includes webinars and archived meeting presentations, and modules from the Core Curriculum for

Nephrology Nursing. Some resources are limited to members or provided to members (or local professional groups) at a discount.

Implementing Hemodialysis in the Home: a Practical Manual

The International Society for Hemodialysis has sponsored the formation of a committee (The Global Forum for Home Hemodialysis) in order to generate and disseminate this manual. It can be read online or downloaded in PDF format in its entirety, at no charge.

The committee is international in composition. It includes many leading experts from various disciplines in the field and includes at least one patient; the U.S. is well represented. Though the initiative was funded by a grant from Baxter International, care was evidently taken to keep the material free of commercial considerations. The manual includes references up through 2014; in fact, new modules were still being posted at the time of publication of this document.

"New Concepts in PD Catheters and Placement"

This YouTube video features John Crabtree, MD, and includes video taken through the laparoscope, demonstrating some basic and advanced techniques. The material is presented at a level intended for trainee and experienced physicians and surgeons. The video is approximately 90 minutes in length. Its production was sponsored by DaVita Kidney Care. Several other, briefer videos demonstrating basic Tenckhoff catheter placement, as well as material intended for PD nursing and patient training, are also available on YouTube.

United States Renal Data System (USRDS)

The USRDS produces the Annual Data Report on ESRD and CKD, providing yearly updated information on trends in dialysis patient demographics, modality use, costs, regional disparities, etc.

The International Society for Peritoneal Dialysis

This website has a number of links to online educational material for physicians and nurses, as well as links to meetings offered by the Society and others. A three-day meeting for nephrologists known as "Home Dialysis University" was sponsored by the Society and Wake Forest University, through a grant from Baxter International, at three locations in the US in 2015; future meetings, as well as sessions for fellows, surgeons, and interventionalists, are evidently in the planning stage, but the website does not contain information about future meetings at the time of this writing.

The Society's journal is <u>Peritoneal Dialysis International</u>. Most articles are limited to subscribers or purchasers, but some useful articles are free; see, for example, the article <u>"Infrastructure requirements for an Urgent Start Peritoneal Dialysis Program"</u> by Ghaffari et al. (2013).

"The ESRD Patient's Life Plan: Extending Survival by Managing Health" by Martin J. Schreiber, Jr., MD

Transitions of Care Toolkit

The Transitions of Care Toolkit was developed by the Forum of ESRD Network's Medical Advisory Council (MAC). This Toolkit for health providers and practitioners is a reference tool that gives information about challenges in transitions of care and suggestions to help create solutions.

Appendix II: Home dialysis checklist

	Yes	Not yet	No	N/A
Certificate of need in hand?				
Appropriate space for unit constructed or obtained? Is it				
compliant with ADA and local life safety code?				
Application to Medicare fiscal intermediary submitted? (Form				
CMS-855A)				
State agency notified? (Certification for PD, HHD, or both may be requested) (Form CMS-3427)				
be requested) (Form eivis 5427)				
Governing body appointed?				
Medical director appointed?				
Nurse manager appointed?				
Nursing staff in place?				
Dietitian appointed?				
Social worker appointed?				
Technical staff available? (HHD)				
Quality assurance committee and program in place?				
Agreements with equipment/supply vendors in place?				
Agreement with hospital(s) in place?				
Nursing and technical call support available for patients 24/7?				
Nephrologist available 24/7?				
State agency inspection completed?				
Agreement signed by CMS regional office? Contact made with ESRD Network?				
Medicaid payments authorized? (Not necessary to start training patients, but advisable)				
Hospital staff capable of performing PD? Or home PD staff credentialed in the hospital?				
Compatible CCPD equipment/connectors in hospital?				
In-center hemodialysis unit available for respite/backup care?				
At least 2 qualified nurses on staff?				
At least 1 RN per 20 patients?				
(Optional) Space/staffing for urgent start program in place?				
At least 20 potential home dialysis patients? Referral				
sources/growth potential assessed?				

Attending physicians credentialed and appointed?		
Advanced practitioners credentialed and appointed?		
Qualified surgeon or interventionalist for Tenckhoff catheters available?		
Predialysis education/modality choice program in place?		
Modality choice education program for local in-center patients in place?		
Inpatient and outpatient protocols for infections, inflow/outflow issues, leaks, other urgent issues in place?		