
ORIGINAL ARTICLES

Remote Monitoring of Daily Nocturnal Hemodialysis

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*D*aily nocturnal hemodialysis (DNHD) is a new variant of home hemodialysis that allows patients to dialyze at home, at night, while they sleep, providing longer duration and greater frequency of treatments. This paper describes a 3-year experience with remote monitoring of DNHD patients over the Internet, and we review the remote monitoring experience of the Toronto program, which pioneered DNHD. Technology, structure, and costs are reviewed. Remote monitoring enhanced safety, accuracy of data collection, patient catchment area, and the overall comfort of patients, providers, and regulators.

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Key words

Daily nocturnal hemodialysis, remote monitoring, Internet

Initial rationale for remote monitoring

In 1994, Dr. Uldall and his collaborators established the first daily nocturnal hemodialysis program (DNHD) in Toronto [1]. Integral to the program was the ability to monitor patients remotely from the center while they dialyzed at home, at night, asleep. The rationale for remote monitoring at the time was safety, accurate data collection, and reassurance to patients, providers, and regulators [2]. Today, the justification for remote monitoring of DNHD patients remains fundamentally unchanged, despite more than 50,000 uneventful treatments in at least 6 centers in Canada and the United States.

The Rubin Dialysis Center is a not-for-profit independent provider of dialysis services with 2 dialysis centers in upstate New York. In March 1998, a DNHD program was started at the Saratoga Springs facility. This step came after a year of investigation into an old modality (home hemodialysis) with a new variation: a dialysis prescription that is longer, slower, and more frequent.

The investigation included a visit to Toronto, discussions with Dr. Andreas Pierratos, nurses, technicians, and adminis-

trators; meetings with patients; nighttime visits to the monitoring station; and a visit to a patient's home. The Board of Directors and the medical staff then met and discussed at length the potential benefits of such a program for our patients, as well as the potential financial risk to our well-run but small program. We were also aware of the program in Lynchburg, Virginia, the first in the United States, which had decided not to use remote monitoring [3]. The decision of our board was to commit to a DNHD program with remote monitoring despite the additional cost.

So far, we have trained 15 patients, 12 of whom remain in the program, all using remote monitoring.

Protocol for remote monitoring

The protocol for remote monitoring is straightforward. Our observer monitors patients from 9 PM to 7 AM, 6 nights per week. Data from each patient's dialysis machine is downloaded in real time over the Internet. All alarms are detected and recorded. If a patient does not successfully reset an alarm within 2 minutes, our observer calls on a second telephone line and assists.

Structure and technology for remote monitoring

Remote monitoring has four technical components:

- the central station software and hardware,
- the central observer,
- the communications carrier, and
- the patient's dialysis machine.

Central station software and hardware

At the present time, only one tested software program exists for centrally monitoring DNHD: the software program developed by Cybernius Medical Ltd. (Edmonton, Alberta, Canada) for the Toronto program. The software is UNIX-based. It allows for real-time collection of data from patients' dialysis machines over telephone lines by modem, or over the Internet. The software can download data directly to the CyberREN (Cybernius Medical Ltd.) database, and it has control capability designed in. The system can be purchased, or service can be provided by the company at a monthly fee per patient. The company provides 24-hour customer service.

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The system has visual and audio alarms that alert the observer to problems simultaneously with the alarms in the patient's home. The observer can then click on the patient's name to show an icon of the patient's dialysis machine with all of its data and the alarms. If the patient does not successfully reset the alarm within 2 minutes, the observer calls to awaken the patient or to assist with the alarm. Our center does not monitor blood pressure during the night, although pre and post blood pressures are recorded. Pierratos *et al.* [2] have already demonstrated the stability of blood pressure during DNHD, and our experience supports the lack of any need to monitor blood pressures directly.

Most of the monitoring in Toronto has used telephone modems. This approach is feasible as long as the patients are local, but is prohibitively expensive if patients require long-distance service. Direct telephone connections also require multiple telephone modems and lines centrally, one for each patient. Use of the Internet obviates this need, allowing many patients to be followed using a single line. We currently follow all of our patients over the Internet using the Cybernius program.

Fresenius Medical Care North America (Lexington, MA, U.S.A.), Aksys Ltd. (Lincolnshire, IL, U.S.A.), Baxter International (Deerfield, IL, U.S.A.), and other manufacturers are reportedly considering the development of proprietary systems.

The hardware required for central monitoring is off-the-shelf computer equipment: an Internet server and a monitor. We have a continuous connection to the Internet as an Internet node.

Central observer

The Cybernius program allows 30 patients to be followed by 1 observer. Pierratos *et al.* [2] reported an average of 1.7 alarms per patient per night, 90% arterial. Our program has experienced 1.1 alarms per patient per night, 70% arterial. A higher incidence of alarms is seen in the first month after training, with a fall thereafter.

The observer monitors patients for 10 hours nightly, 6 nights per week. Even if the observer were monitoring 30 patients, the demand on the observer's time would not be excessive. We believe that 1 observer may be able to monitor up to 50 patients safely.

The Toronto program uses observers without dialysis or health care experience. We prefer to use trained dialysis technicians because, using established protocols, they are able to assist patients.

Communications carrier

The options regarding communications carriers are increasing. Our experience is that the Internet is the least expensive for patients and provider. It has also been generally reliable, especially given that we are monitoring at night. Downtime has been minimal, and Cybernius customer service has been immediately available.

Locally, the reliability of telephone carriers varies widely; a few patients have had to switch carriers. Also, the Cybernius program is not currently compatible with some of the more structured Internet providers, such as The Microsoft Network (MSN: Microsoft Corporation, Redmond, WA, U.S.A.). Road Runner (Time Warner Cable, Herndon, VA, U.S.A.) also did not work for one of our patients. America Online (AOL Time Warner, Atlanta, GA, U.S.A.) has worked well.

Dialysis machine

Each patient requires an interface in the home for the dialysis machine. When local telephone lines are used, only a modem is required. With the Internet, a basic computer with a hard drive programmed by Cybernius is required. This computer is dedicated to DNHD. Each patient must have a second telephone line, so that the observer can call during monitoring, if necessary.

Costs of remote monitoring

With DNHD, expenses are increased: a dialysis machine for each patient, disposables and dialyzers for 6 or 7 treatments weekly, provision of water treatment, and extended training. These expenses alone have deterred most providers from offering a DNHD program to patients. The additional cost of a remote monitoring program would seem to create an insurmountable obstacle. In fact, the program's losses have been predictable and acceptable (even to a small independent provider), and have diminished over time as the number of patients in the program increases. Our losses decreased from \$67,000 in 1998 to \$25,000 in 2000, while the number of patients on treatment rose from 2 to 10.

Remote monitoring incurs ongoing maintenance costs in addition to one-time capital investments. The one-time cost associated with the central monitoring station was approximately \$40,000 for hardware and software. For each patient, a one-time cost of \$1,300 was incurred for the computer necessary for Internet monitoring. Installation of a second telephone line in homes with only one line represents another one-time cost (\$150) that our program currently absorbs.

Ongoing central costs include software and hardware maintenance, and Internet and telephone expenses, which are budgeted at \$10,000 annually. Observers' salaries and benefits are another ongoing central cost. For 60 hours per week of monitoring, the total cost is \$50,000 annually. Finally, ongoing costs to the patients include the cost of basic service for the additional telephone line, and a monthly Internet access fee (\$400 – \$500 annually).

Over the last three years, we have carried out cost analyses of our program. Cost per administered treatment (6 per week) and cost per billed treatment (3 per week) fall to \$90 and \$166 respectively when we have 15 patients. With the current patient profile and reimbursements, we estimate that we could break even at 16 – 18 patients.

Monitoring has been included in all of our cost analyses. Our estimate is that, with 16 patients, the cost of monitoring

is \$1.25 per hour per patient, or just under \$4,000 annually per patient. Obviously the more patients in the program, the lower the per-patient cost of monitoring.

The initial losses sustained while building a DNHD program without monitoring are already a significant deterrent to many providers interested in DNHD. The costs of remote monitoring increase that disincentive; however, in our experience, those costs have not been prohibitive provided one looks beyond short-term return on investment.

Current rationale for remote monitoring

What is the current rationale for remote monitoring in DNHD?

Patient safety remains central to our considerations. Daily nocturnal hemodialysis is a new way of dialyzing patients. Fewer than 125 patients have used this modality [Lockridge RS Jr. Personal communication based on data collected for the 7th Hemodialysis Symposium of the 21st Annual Dialysis Conference; New Orleans, LA; February 19 – 21, 2001]. Fewer than 2500 patient-months of experience have been accumulated.

Would anyone argue that the first 125 patients on conventional hemodialysis or peritoneal dialysis got us over the steep part of the learning curve? Can we honestly say that our 7 years of experience with DNHD compares to the experience of even 1 year of conventional dialysis?

In the year 2000 alone, 250,000 patients were hemodialyzed in the United States, representing more than 3,000,000 patient-months of experience. Too many examples of techno-hubris in medicine, engineering, and science already exist; we don't need to add to them. However, we believe that remote monitoring enhances the safety of this new modality, DNHD—although by no means renders it foolproof. At this formative time in the development of this new modality, enhanced safety counts.

Remote monitoring also allows more accurate data collection. Data is downloaded in real time from patients' dialysis machines. We know whether the machines run, exactly how long they run, what alarms occur, and how quickly the patients respond. We know blood flow rates and dialysate flow rates. We review each patient's data each month at our DNHD clinic. We believe that accurate data collection is essential to monitoring patients individually and, ultimately, to justifying to the payors the need for enhanced reimbursement.

Further, remote monitoring allows us to offer DNHD to patients who are less comfortable with technology. The single absolute criterion for selecting patients has been motivation. Those who select this modality are more adventurous than most of our patients—more comfortable in cutting the umbilical cord to the hemodialysis unit. To make the technique viable for more people, we will need simpler technology, but the patients will still need technical support. When our patients need assistance, our technicians help them troubleshoot problems in real time, allowing dialysis to proceed where it otherwise might have been discontinued.

Remote monitoring has allowed us to increase our patient catchment area. We now dialyze patients across upstate New York and Vermont, with our most distant patient being 200 miles away. Although the benefit for rural areas is obvious, our reach has had the additional, unexpected advantage of attracting more patients with private insurances and, therefore, enhanced reimbursements. This factor has reduced our overall losses significantly during the start-up phase.

Finally, remote monitoring offers a reassuring connection between patients and providers. Dr. Pierratos has stated that he is not sure that a definite need exists for remote monitoring [Personal communication. 6th Annual Hemodialysis Symposium of the 20th Dialysis Conference; San Francisco, CA; February 27 – 29, 2000]. However, when we talked with some of his patients, and when we talk with our own patients now, we hear that they definitely feel better knowing the monitor is there while they sleep, even knowing the limitations of what the monitor can do. One third of our patients have said that they would not have opted for the modality without the remote monitoring.

Daily nocturnal hemodialysis is technically more complex than continuous cyclic peritoneal dialysis. Until much more experience with this modality has accumulated, patients deserve the additional technical and emotional support that remote monitoring provides. Expanding the population of patients attracted to this modality requires this support.

This reassurance extends to physicians and nursing staff, and also to regulators. After the Board decided that we would have a DNHD program with remote monitoring, we met with the New York State Department of Health (DOH), to be sure that they would not veto the program. They informed us that, by regulation, every home hemodialysis patient must have a trained partner. We do not require our patients to have partners, nor do we usually train partners. However, the DOH felt comfortable that our remote observer constituted a "virtual" partner, thus fulfilling their regulations. Whether this reassurance was technically justified or not, it allowed us to start the program. The comfort of patients, staff, payors, and regulators will be essential to the ultimate success of DNHD in the United States.

Future potential of remote monitoring

The DNHD program has been an incredible stimulus for us to think differently and positively about what we could be doing for all our patients. Similarly, remote monitoring has been less a burden and more an additional stimulus to think more imaginatively about how we might better provide dialysis services.

For example, one of the major criticisms of remote monitoring has been that, if something catastrophic happens to a patient, a remote observer cannot help. But it is equally true that we can do little for any home patient who has a catastrophic event, whether on peritoneal dialysis or hemodialysis. Remote monitoring does allow for more rapid intervention, as we have a protocol for our observer to call the patient's

local 911 in the event that the patient fails to respond to an alarm and to the monitor's telephone call.

This situation raises the idea of a more interactive system of monitoring. Are there interactions that we would like to be able to have directly with the machine?

We have started discussions with Cybernius and others about the feasibility of a less passive monitor. The Cybernius system already has a control function designed into its software. With the cooperation of the machine manufacturers and regulators, and with two months of software development, we could have a system that allows us to intervene in the nocturnal dialysis patient's treatment from a distance, if necessary.

Another area we would like to explore is the use of the Internet for telephone communication, avoiding the expense of a second telephone line. We would also like to expand what we monitor. We already install inexpensive moisture detectors under the dialysis machine and the water treatment system. These alarms warn the patient of a leak, but we would like to monitor these sensors remotely in real time as well.

We have considered and discarded (for obvious reasons) the idea of video monitoring of DNHD. Nevertheless, circumstances occur in which video monitoring might be interesting. For example, our monitoring system could easily be adapted with video to allow us to remotely monitor a satellite dialysis unit in a nursing home or at a distance from nephrologists.

We also have an opportunity to provide remote monitoring for other DNHD programs. We can remotely monitor anyone, anywhere, over the Internet. We estimate our marginal cost of adding new patients to our system at \$1.00 per hour per patient (about \$3000 annually). The only issue from our perspective is the time zones involved.

Finally, software and hardware providers have an opportunity to bring competition to DNHD. Currently, only the Fresenius 2008H machines can download through the Cybernius system. Baxter International has had a Cybernius system driver designed for the Baxter Meridian; that driver is currently in beta testing. Other dialysis machine companies need to invest in the software so that we can use their machines as well.

Could dialysis machines contain the hardware and software for a direct Internet connection, allowing us to discard the in-home computer? Does wireless technology have a place here? Other software companies need to invest in monitoring programs and new technology.

As those of us with established programs know, DNHD works. Our program continues to grow.

The best day of my month is the day I see my nocturnal dialysis patients in clinic. These patients feel better and do better than any of our other patients, perhaps even better than many of our transplant patients. They function better in society and in their families [4,5]. They are hospitalized less, take fewer medications, need less erythropoietin, sleep bet-

ter [6], and have fewer cardiovascular complications, showing improved left ventricular hypertrophy on echocardiogram. Although we know that the costs to dialysis providers are higher, we believe that the total annual medical costs for these patients are lower.

Unfortunately, experience is limited to fewer than 125 patients. Now, we have to prove our results to others with more patients. And we need to do it safely and with accurate data collection, if these programs are going to be appropriately reimbursed.

Will we always need remote monitoring? Perhaps not, but we don't have enough experience yet to prove that.

Daily nocturnal hemodialysis is a win-win proposition for patients and payors. Unfortunately, this intensive home therapy currently costs about \$500 per week for each patient. Remote monitoring constitutes only about \$60 of that cost. The ultimate survival of current programs, as well as the growth of new programs, will depend on payors agreeing to a formula that partially shares their savings with the providers.

We are all too aware that, in dialysis units, finding and keeping competent, compassionate staff while providing high-quality care to an increasing number of older and sicker patients is becoming more and more difficult. We are going to have to find more cost-efficient ways to provide this care with fewer staff. Conventional home hemodialysis has failed primarily because of the burnout of partners. Peritoneal dialysis fails to grow beyond 10% – 15% of patients. With remote monitoring, DNHD offers a safe, cost-effective way for fewer staff to provide more dialysis to a larger group of patients than is possible for DNHD without remote monitoring.

Past discussions about remote monitoring have tended to focus solely on the additional cost of this service. Our experience at the Rubin Dialysis Center with remote monitoring suggests that cost is a red herring. Our real dilemma is that resources for health care in general are becoming more limited while demand for services is rising. If we are going to justify this program to payors, regulators, and legislators increasingly skeptical of new and always-more-expensive medical technology, we can't afford to cut corners. We need to create the safest program now, with the best data collection now, to demonstrate that DNHD is a win-win proposition for patients, providers, payors, and society. In our opinion, that program is DNHD with remote monitoring.

Our commitment to DNHD with remote monitoring continues.

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