

Diabetes and Telemedicine

Is the technology sound, effective, cost-effective, and practical?

In this issue of *Diabetes Care*, Chase et al. (1) have very nicely demonstrated how modem technology can be a useful tool for providing effective management of type 1 diabetes when used in lieu of a clinic visit. This study represents an example of telemedicine, a technology that can be defined as the use of telecommunications to support health care. Was their Colorado program sufficiently successful in becoming a model for other programs that will provide modem transmission of glucose values? I believe it was. An analysis of the technology utilized by this telematic program for type 1 diabetes demonstrates that the method appears to provide effective tools for health care providers to deliver a valuable experience for patients, with decreased costs for payers.

The value of a new application of technology to medicine can be judged by four criteria, each of which may be expressed as a question. First, is the technology sound? That is, did the technology fulfill its purpose? Second, was the program effective? That is, was the new program successful compared with base care? Third was the program cost-effective? That is, did it provide sufficient benefit for the cost to be economically viable? Fourth is the program practical? That is, did the program create new significant problems that we do not currently have to deal with in the absence of the program? Applying these criteria, the Colorado program can be evaluated as to whether it was successful.

A set of criteria for assessing whether a telemedicine program is technologically sound was proposed recently by Ronald C. Merrell, MD, director of the NASA Telemedicine program. He stated that the elements of a successful telemedicine program include: 1) accurate collection of data in digital format; 2) incorporation of those data into an electronic record that may be transmitted with fidelity; 3) protocols for distant analysis; and 4) communication tools to permit effective dialogue among primary managers, patients, and consultants (2). I would add that the analysis and communications system

must specifically establish a system for automatic flagging and provision of feedback to the patient for outlier data, also known as "panic values."

An argument can be made that handheld data-capture technology, which contains electronic time stamps, can actually be more accurate than traditional paper-based recording of blood glucose values into a logbook. Paper-based recording methods are susceptible to back-filling (i.e., recording entries late, just before the doctor visit). Most clinicians have observed back-filling in neatly written, clean (free of dried blood spots) white paper logbooks in which a single color of ink and the same handwriting was used throughout. Paper-based recording is also susceptible to forward-filling (recording entries before the corresponding date and time) (3). A system for daily downloading of electronically time-stamped data, through a modem, has the potential to be very accurate and helpful for patient monitoring by the caregiver. I have worked with such a system that recorded, downloaded, and displayed (on a website) blood glucose data for a research trial of an investigational drug (4), and I found it very useful in that setting. I conclude that Chase et al. did create a program with sound technology.

Ultimately, the success of a program must be judged on its clinical outcomes. For type 1 diabetes, the surrogate marker for long-term complications is HbA_{1c}. A new program that can consistently lower (or at least not raise) the HbA_{1c} level is considered by most diabetes experts to be better (or no worse) than existing care in terms of the risks of long-term microvascular complications of diabetes. Patients with type 1 diabetes can also develop acute complications related to hypoglycemia, and it is much easier to quantify the success of new program over the short term (i.e., 6–12 months) based on the incidence of symptoms of hypoglycemia, or emergency room visits for hypoglycemia, than it is to judge a program associated with improvement of a surrogate marker

that predicts decreased end organ disease after many years. Many short-term programs for type 1 diabetes (especially when the patients are not blinded) look better during the first year than base case treatment because of initial patient enthusiasm, which may or may not be able to be sustained beyond the study period or because of maldistribution of prognostic variables (5).

Chase et al. specifically pointed out that their study cannot necessarily be generalized beyond the 6-month time frame studied. This is an important point. I feel that if any clinic attempts to duplicate the Colorado program based on the results of Chase et al., then that clinic should not go beyond the substitution of a single clinic visit (with modem technology) over a 6-month time frame. There is no data at this time to demonstrate that the similar outcomes from program and base case care achieved at 6 months can be maintained beyond the time frame of the study. One question I would raise is whether patients would go less often to consultants, such as ophthalmologists or podiatrists, or check their urine for microalbumin if additional telemedicine contact were to be gradually substituted for direct contact. I conclude that Chase et al. created a program in which the outcomes were no less successful than base care, but there is a risk that their data could be inappropriately extrapolated in an attempt to justify (as proven when it is not) even greater use of telemedicine compared with base care.

Currently, as a result of budget deficits and unemployment problems in the U.S., there is great pressure for new treatments to not only be more effective but also more cost-effective. Cost-effectiveness is usually defined as the amount of benefit achieved for the money spent. A treatment that costs less and provides equal or greater benefit is referred to as cost saving. Benefits from all disease management programs for all diseases can be converted to a common unit of improved health known as quality-adjusted life

years (QALYs). If a new treatment provides one QALY for a certain cost, and it is no more expensive to provide that QALY than it is to provide a similar amount of benefit through existing public health measures that are accepted by society as worthwhile, then the new intervention is defined as cost-effective (6).

The costs of the Colorado program were less than base case and the outcomes were similar, which would make the program cost saving. Costs are assigned on the basis of assumptions, and I am not sure whether every health economist would agree with Chase et al. that a physician's salary should be budgeted as low as \$50/h or a diabetes nurse specialist's salary as low as \$25/h, and without overhead figures added for worker benefits or for managing these providers. Assuming that these Colorado salaries can be extrapolated to other parts of the country, I would add at least 25% to these figures for indirect costs (benefits) and an additional 40% for "overhead" to maintain their infrastructure. Such figures are commonly added to salary estimates when researchers apply for grants, and I believe that indirect costs and "overhead" figures should not be omitted from an economic analysis of any experimental program. A 65% increase in the cost of paying the program staff would result in less cost savings for the study program than the base case program. I also believe that many patients do not incur such high indirect expenses for a clinic visit as those estimated by the authors and that the estimated savings in indirect costs associated with the experimental program may not be as high for many patients as the authors predict, especially if the patient lives near the clinic and does not have to spend a night in a hotel before the visit. Finally, the estimated costs of the computer system are optimistically projected to be held down by sharing arrangements that are not guaranteed. To the extent that experimental case expenses are underestimated, the potential savings associated with an experimental program will be correspondingly inflated.

Modem technology will solve some problems and raise new ones. Physicians, as compared with other science professionals, have been slow to adopt computerized storage of data in their daily activities. There is no mechanism for most physicians to be paid for time spent on data analysis unless the patient is present.

Modem technology is designed to facilitate communication between caregivers and patients who are remotely separated. Until physicians, who are already experiencing many demands on their time, can be paid for telemedicine care, they will be reluctant to embrace this method of interacting with their patients (7). Telemedicine is more suited to be part of managed care programs, where health care providers are receiving a fixed salary, than fee-for-service programs. There are medical-legal issues that will need to be considered for cyber encounters with patients, relative to how much patient history and data the physician is expected to store in the physician's hospital or health plan computer system and how easy it is to access this information in an emergency. Each disease management tool must communicate with the entire hospital's database and other disease management programs. There is absolutely no interest at any hospital or health plan for simultaneously implementing multiple telemedicine systems using multiple types of hardware and software tools. The diabetes telemedicine program would need to be developed simultaneously with disease management programs for other diseases to become established outside of a research setting. Telemedicine technology will require excellent encryption for patients to entrust their medical data to be transmitted online, where it could be illicitly downloaded (8). The potential loss of privacy with online telemedicine data must be addressed, but I believe that this problem can be solved (9). The Colorado project does not appear to create any special problems other than those that would be present in any telemedicine program. I believe the Colorado program would be practical for other hospitals to also initiate, providing these hospitals' other telemedicine programs can be seamlessly linked to the type 1 diabetes program.

The time has come for greater use of telematic care of diabetes. As many aspects of our lives become automated and handled online, so will routine medical care of chronic diseases (10). Data on clinical outcomes and costs for telematic care of patients with type 1 diabetes is currently scarce. The Colorado study is the first such report from the U.S. In Germany, Biermann et al. (11) established a telemedicine program for patients with type 1 diabetes and compared the costs and outcomes of a randomized group re-

ceiving monthly visits with a group receiving telematic care. The telemedicine group cost was 650 Euros (~650 dollars) per year per patient less than the base case group, and metabolic control in both groups was comparable. In Poland, Wojcicki et al. (12) administered telematic care, as a supplement to base care, in a population of 15 pregnant type 1 diabetic patients and found improvements in the control group; however, they did not present economic data.

In the U.S., telematic care of children with type 1 diabetes has been studied by a team from Harvard Medical School, Joslin Diabetes Center, and Massachusetts Institute of Technology using a telemedicine system called DiaBetNet. Telematic care of both type 1 and type 2 diabetes is being studied at many medical centers in the U.S. One of the largest of these projects is being directed by the Columbia University College of Physicians and Surgeons, which has received a \$28 million grant from the Health Care Financing Administration to study how telemedicine can improve diabetes care. The study will randomly select 1,500 diabetes patients from impoverished, medically underserved areas (half in New York City and half in other areas of New York state). The goal of the study is to evaluate the feasibility, acceptability, effectiveness, and cost-effectiveness of telemedicine. The focal point of the intervention is the home telemedicine unit, which provides four functions: synchronous videoconferencing over standard telephone lines, electronic transmission for fingerstick glucose and blood pressure readings, secure Web-based messaging and clinical data review, and access to Web-based educational materials (13,14). Georgetown University recently tested a telemedicine program called MyCareTeam (15). The article by Chase et al. is an announcement that telemedicine is rapidly maturing and that this technology is indeed sound, effective, cost-effective, and practical.

DAVID C. KLONOFF, MD

From the Dorothy L. and James E. Frank Diabetes Research Institute of Mills-Peninsula Health Services, San Mateo, California.

Address correspondence to David C. Klonoff, MD, Editor, Diabetes Technology & Therapeutics, Dorothy L. and James E. Frank Diabetes Research Institute, Mills-Peninsula Health Services, 100 South San Mateo Dr., Room 3128, San Mateo, CA 94401. E-mail: klonoff@compuserve.com.

© 2003 by the American Diabetes Association.



References

1. Chase, HP, Pearson JA, Wightman C, Roberts MD, Oderberg AD, Garg SK: Modem transmission of glucose values reduces the costs and need for clinic visits. *Diabetes Care* 26:1475–1479, 2003
2. Merrell RC: Current status of telemedicine technology: potential applications to the management of diabetes. *Diabetes Technol Ther*. In press
3. Stone AA, Shiffman S, Schwartz JE, Broderick JE, Hufford MR: Patient non-compliance with paper diaries. *BMJ* 324: 1193–1194, 2002
4. Hufford MR, Kolterman O: Helping patients to succeed: applying handheld technology to a clinical trial in type 1 diabetes. *Diabetes Technol Ther*. In press
5. Chalmers TC, Celano P, Sacks HS, Smith H Jr: Bias in treatment assignment in controlled clinical trials. *N Engl J Med* 309: 1358–1361, 1983
6. Klonoff DC, Schwartz DM: An economic analysis of interventions for diabetes. *Diabetes Care* 23:390–404, 2000
7. Smith SP: Internet visits: a new approach to chronic disease management. *J Med Pract Manage* 17:330–332, 2002
8. Starren J, Sengupta S, Hripcsak G, Ring G, Klerer R, Shea S: Making grandma's data secure: a security architecture for home telemedicine. *Proc AMIA Symp* 657–61, 2001
9. Lahtela JT, Lamminen H: Telemedical devices in diabetes management. *Ann Med* 34:241–247, 2002
10. Wilson M: The future of telemedicine. *Stud Health Technol Inform* 80:129–136, 2002
11. Biermann E, Dietrich W, Rihl J, Standl E: Are there time and cost savings by using telemanagement for patients on intensified insulin therapy? A randomized, controlled trial. *Comput Methods Programs Biomed* 69:137–146, 2002
12. Wojcicki JM, Ladyzynski P, Krzymien J, Jozwicka E, Blachowicz J, Janczewska E, Czajkowski K, Karnafel W: What we can really expect from telemedicine in intensive diabetes treatment: results from 3-year study on type 1 pregnant diabetic women. *Diabetes Technol Ther* 3:581–589, 2001
13. Starren J, Hripcsak G, Sengupta S, Abbruscato CR, Knudson PE, Weinstock RS, Shea S: Columbia University's Informatics for Diabetes Education and Telemedicine (IDEATel) project: technical implementation. *J Am Med Inform Assoc* 9:25–36, 2002
14. Shea S, Starren J, Weinstock RS, Knudson PE, Teresi J, Holmes D, Palmas W, Field L, Goland R, Tuck C, Hripcsak G, Capps L, Liss D: Columbia University's Informatics for Diabetes Education and Telemedicine (IDEATel) Project: rationale and design. *J Am Med Inform Assoc* 9:49–62, 2002
15. Hu M-JT, Levine BA, Smith KE, Alaoui A, Clement S, Mun SK: MyCareTeam: an internet tool for better glucose control. *Diabetes Technol Ther*. In press