Two Approaches to Incorporating Remote Monitoring into Disease Management Programs

Based on data from the University of South Alabama Health System
Emerging Health Technologies from a study effort performed in 2002 and reported by Susan G. Malone at the ATA Forum 2003

1. Introduction

Five chronic diseases (CHF, COPD, Diabetes, Hypertension, Asthma) account for more than two-thirds of all deaths in the United States. The costs of health care for people with chronic diseases account for 75% of the nation's total health care costs. The average daily cost of hospitalization in Alabama (based on Medicare statistics[1]) was $996.76 in 2001. This represents $1,542,851,140 in total Medicare reimbursement for chronic illness related hospitalizations in Alabama (also 2001).

In Alabama, where this study was done, the state is second in diagnosed adult diabetes (2002), third in obesity (2001), fourth in overall number of deaths (1999), sixth in heart disease (1999), and seventh in strokes (1999). These dismal statistics drove us to consider cost-effective disease management, which included the biometrics program.

2. Goals of the Biometrics Program

Our motivating goal was to improve patient outcomes and improve the patient's overall health status. We would accomplish this through early intervention, decreasing necessary hospital visits, and hopefully demonstrate savings in healthcare costs.

3. Biometrics Technology – How it works

We chose to work with Cybernet Medical's MedStar products[2] and web-based EMR[3] technology because it met our primary criteria:

- Low cost (less than $2 per day for long term use)
- Scalability to large populations under management
- Support of POTS Lines[4]
- Portability so that patients can collect data even when they are not home
- User Friendliness – many elderly are not computer of data terminal literate
- Ability to monitor data from anywhere there is internet access via an ordinary PC

The most critical part of the system is the home-based data collection devices. In our system, the patient simply uses home medical devices (scale, blood pressure cuff, personal glucometer, etc.) as they normally would. The difference is that these devices are connected to the Cybernet EMR via a MedStar data hub that reads data from each home medical device, tags and codes it, and

[1] Research, Statistics, Data & Systems, CMS, http://www.cms.hhs.gov/home/rsds.asp.
[2] www.cybernetmedical.com
[3] Electronic Medical Record
[4] Plain Ordinary Telephone System

sends it through the patient's POTS phone line to the secure Cybernet Medical web site for access by our case workers.

The home unit must be very easy to operate (in this system, the data acquisition process is completely transparent and required no computer literacy), it must be low in cost (the 5 year lease cost of a MedStar CHR kit is nominally $2.10 per day), and the it must be durable (the FDA MedStar equipment has been tested to stand up to virtually any home situation). Figure 1 shows one of our patients using the home unit, which includes blood pressure, weight scale, and glucometer).

Figure 1. Home use of the MedStar monitoring kit for CHF

4. Biomonitoring Study Protocol

Our studies were conducted in two adjacent Alabama rural areas served by the University of South Alabama Health System, the Pine Apple area and the Geneva area (Figure 2).
In the Pine Apple area, patients were assigned to one physician. The patients enrolled, were provided instruction at the local clinic, and were then sent home with their telemedical equipment. They were asked to set-up the kits, but were also supported by part-time nurses that provided patient monitoring from their homes.

The part-time home-based nurses accessed the patient electronic record and telemetry via a secure, login authenticated, web accessible database. The patient oversight procedures integrated in the telemetry processing included immediate physician notification of out-of-bounds data as well as nurse monitor reports, analysis of trends, and a daily written report.

In the Geneva area, patients were referred by multiple physicians. Home care nurses took care of patient enrollment, instruction, and monitoring equipment delivery and installation. The home health care nurses responded to patient data generated alerts which were programmed to hit the nurses' pagers, and provided physicians immediate notification of out-of-bounds data. They also provided nurse monitors and monitoring reports that identified data trends. These included periodic written reports and graphs that were reviewed with the physicians.

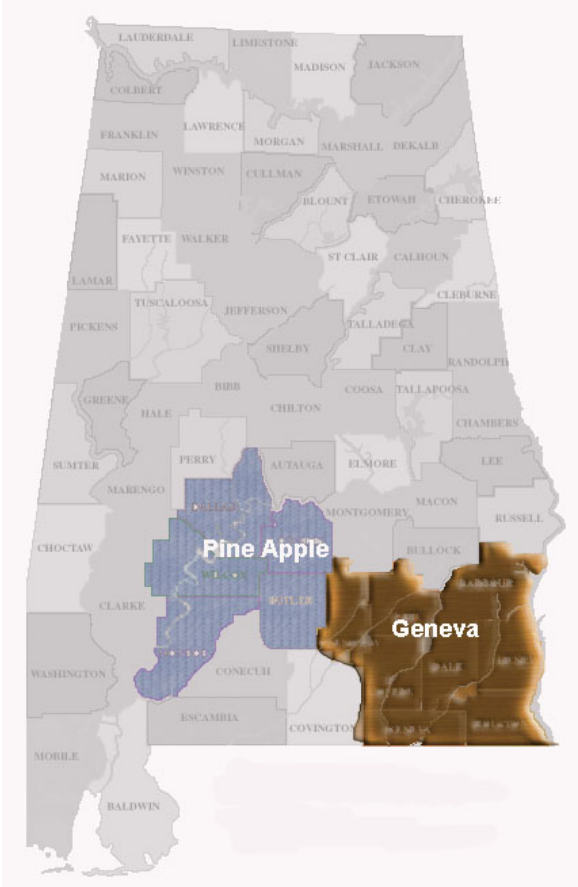

Figure 2. Pine Apple and Geneva Areas

Pine Apple

Geneva

5. Study Criteria

Pine Apple patients were selected from the population of patients suffering from Hypertension and/or CHF. The Geneva patients were selected from the population of patients suffering from disease states including Hypertension, CHF, and Diabetics. All patients had been hospitalized at least one time in the last 12 months due to their chronic illness, and were entered into the program based on physician referral. The patient's supervising physician set individualized parameters that triggered notification of abnormal values.

Pine Apple patients were African-American and numbered 27, all 27 with hypertension and 7 with CHF as well. During the study period, the test population dropped to 17 due to individualized reasons unrelated to the monitoring process. This population was supported by the study grant (otherwise unfunded, 9 patients), private insurance (8 patients), Medicare (6 patients) and Medicaid (7 patients).

Geneva patients were multiracial, 16 in total with 14 suffering from hypertension, 14 also suffering from CHF, and 7 suffering Diabetes. This group dropped to 10 during the study period and illustrated some of the barriers that must be considered to maximize compliance with monitoring. These included education (higher levels increased compliance), self-motivation (the more motivated the person was the higher their compliance to treatment), family and community support (those with a better personal support network were more compliant), ethnic differences,

and finally provider acceptance of the status quo (i.e. those whose provider was motivated more strongly to improve the patient's health status were more compliant).

6. Study Results

The study provided information in several areas. It brought quantitative data pertaining to compliance, accuracy, and patient acceptance issues (these are reported in the companion paper "MedStar System Consumer Study Report," October 2002[5]), it identified some specific operation issues which must be considered when developing a program, it determined patient responses to the monitoring program, and it identified short term outcome improvement effects. These will be discussed further in this section.

We used the MedStar system in part because it worked over POTS phone lines, which were prevalent in both study areas. However, this brings an operational issue, which is how to determine where responsibility for communication faults lie. The preliminary diagnosis is that the patient is not compliant with measurement prescriptions. However, this can occur due to:

(1) Telehealth hardware failure
(2) Phone line performing below operating ratings
(3) Patient noncompliance
(4) Server side database failure

Practically speaking, there are almost never any server side database system failures due to 24/7 support and multiple-redundant back-up systems incorporated into the system. Similarly, the basic patient side data hub is very simple and highly reliable. Therefore the common forms of noncompliance are due to:

(1) Cable disconnects between the patient data hub and measuring device (scale, blood pressure, glucometer).
(2) Battery exhaustion (if the unit has been in service beyond 6 months without a battery refresh).
(3) Poor quality phone service, which is often common in rural areas served by small telephone companies – also due to line problems resulting from rain or lightning strikes.
(4) Patient noncompliance due to lack of motivation or poor training in how to use the equipment.

Because the study was to determine cost savings as well as outcome improvement, any fault that must be diagnosed at the patient's premises is a costly set-back due to travel time and distance-related expenses required for such troubleshooting. This emphasizes the need for a good structure supporting initial enrollment and patient instruction.

The best approach to battery faults is to replace batteries at the manufacturer's suggested interval – approximately every six months.[6] The best approach to determining if cables have been pulled is to try pushing them back in – each is a small bayonet connector that is out of place if any contact metal is exposed. We also now acquire weight scales with strain relief enhancement so that if the patient pulls on the scale cable to move the scale, the connector stays firmly in place.

[5] Eric Lichtenstein, Joe Long, MedStar System Consumer Study Report, Cybernet Medical October 2002, www.cybernetmedical.com/media/papers/medstar%20white%20paper.pdf.
[6] A new MedStar unit that also allows battery elimination is in the product.

To differentiate between patient unit hardware failure and phone line failure is important so that we do not waste nurse's labor time acting as a phone repair technician. The MedStar provides a phone line diagnostic function that lets the patient or the visiting nurse determine that the data hub can connect through to the data servers (i.e. that the phone line is good). If this diagnostic fails, the phone line repair service should be called to repair the phone line.

Other roadblocks to successful data collection are (1) poor procedures to document all nurse's visits – reduced and efficient visit policies are critical to achieve reduced patient support cost through telemonitoring, (2) difficulty of obtaining hospital records, especially when the patients are served by multiple facilities – ultimately a comprehensive patient EMR system may fix this problem, but at the present time a comprehensive fix is not available, (3) adherence to the participant enrollment criteria that is set for patient inclusion (presently we require that the patient be mentally capable, and have been hospitalized in the last 12 months for their chronic illness), and other operational issues like family members using the patient's equipment (and therefore generating false readings that must be ignored after examination).

Outcome results were determined in two ways. The first was an assessment questionnaire to determine the participant's perception of success. The second was a survey of referring physicians and supporting medical staffs to determine their assessment of the approach, and third was a quantitative assessment of health status improvement and reduced cost of re-hospitalization.

Patient questionnaire surveys indicated that 92% of patients reported an increased knowledge about their disease and increased discipline in areas such as diet, exercise and activity level. 100% of patients reported an increased awareness of things they do in everyday life that can or do affect their disease. These results mean that the process does engender patient engagement and compliance to a significant degree.

100% of patients reported an increased willingness to follow physician advice regarding their disease, and had increased comfort knowing their data is being monitored and reported to the physician. This resulted in 83% reporting that they decreased the number of visits to the doctor, ER or hospital admissions.

Physicians reported a positive impact on patient outcomes, which are confirmed by quantitative data shown in Figures 3 and 4. Nurse Monitors expressed positive views as well. Patients stated that the monitoring program has contributed to an improvement in their overall health status and related very positive benefits received from program.

Figure 3 shows weight and blood pressure improvement in a same patient selected as typical of the group. The patient's BP was reduced by about 2% and their weight by about the same amount pre- and post-study. While this change is small, it reflects a greater consciousness that health factors can be controlled. This shows more dramatically in Figure 4.

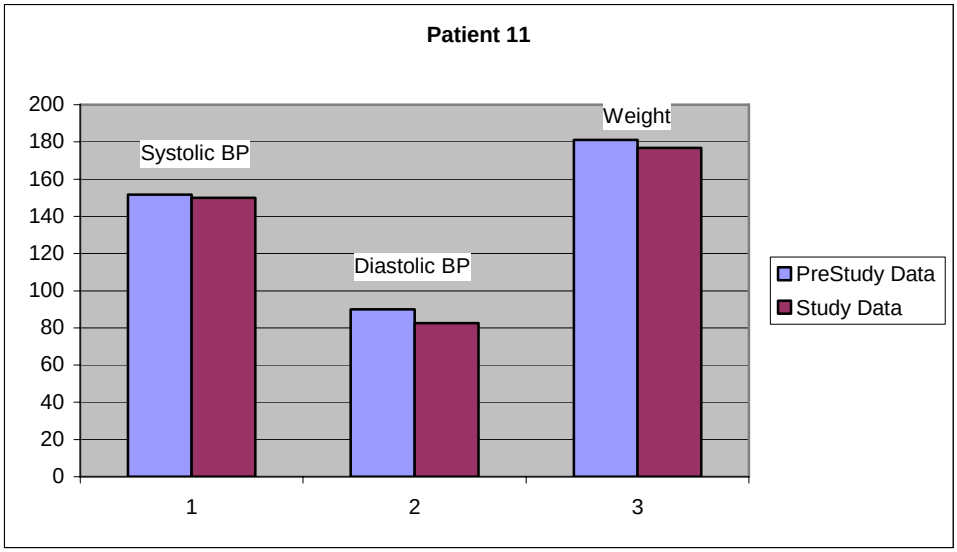

Figure 3. A Typical Patient Sample BP and Weight Data Set

Figure 4 shows how this patient also substantially reduced their usage of health services: physician visits, hospitalizations, or ER visits. This patient showed a 76 % reduction of health services expenses year of over year as a result of the monitoring-based management approach. This reduction has proven out over the larger group and in several other subsequent studies in other parts of the country, as well as across ethnic and economic group variations.[7]

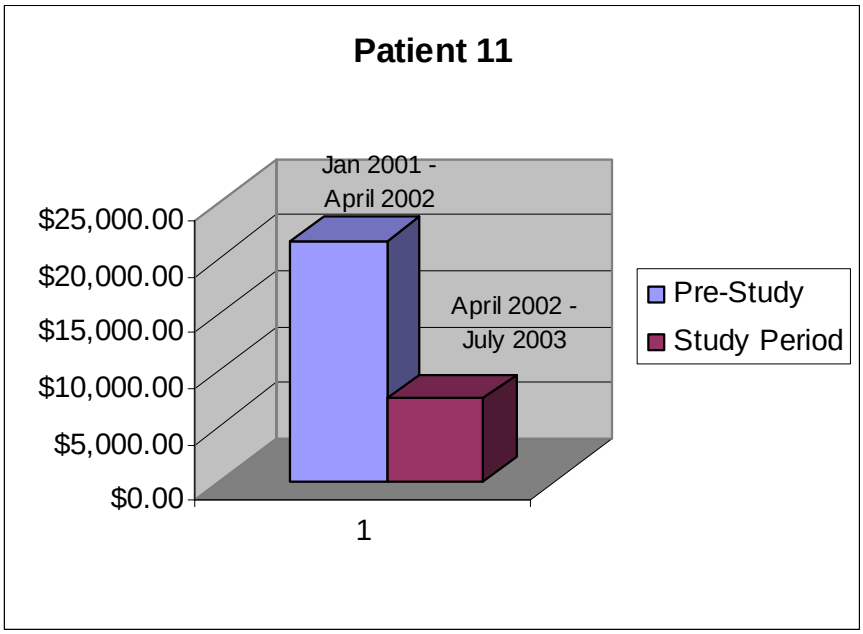

Figure 4. A Typical Patient Sample Hospital Visit Analysis

[7] Jacobus, Charles, Telehealth Outcomes, Conducted at a Major Midwest Health System, Study Completed October 31, 2005, First summarized January 23, 2005, June 26, 2006, shows a reduction in a similar but larger study of reduction of better than 86%, www.cybernetmedical.com/media/papers/TeleHealth%20Outcomes%2010.19.06.pdf.

7. Conclusions and Needs

This study showed that adding monitoring to the tools used to manage the chronically ill has the potential for substantial return on investment (in the 70 to 80% range). To further apply these lessons, it is necessary to overcome the barriers of physicians' busy schedules, rejecting acceptance that the chronically ill patient's status quo is the norm (i.e. that they cannot improve with proper care), and motivating patients to take an active role in their own well-being.

Monitoring is an assistive tool that is part of the solution to chronic disease management. It supports more efficient use of the physician's time and resources by keeping the controlled patients out of the office, and actively directing patients needing help into the office where the physician can take effective treatment actions. This is reinforced by our study enrollment criteria, which selected demonstrably sick patients for the extra help.

Monitoring assists physicians to better individualize patient expectations, and supports improved patient education regarding disease states and contributing factors. Consistent collection and transmission of data reinforces proper patient behavior by providing timely and active feedback.

For the future, we suggest further joint projects that incorporate more expertise in providing patient motivation – i.e. integration of monitoring with other disease management approaches in an integrated system. Also, while present ease of use is very good, making the system easier to use still will benefit some users. This can be done both by how the system is deployed, trained, and used, and by improvements in vital signs measurement peripherals.