

**Remote Physiological Monitoring
Discussion Paper**

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Discussion Paper

Remote Physiological Monitoring (RPM)

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Purpose and Scope of Review

The Maine Quality Forum (MQF) contracted with the Muskie School of Public Service to review the viability and funding of remote physiological monitoring (RPM) devices. The MQF was particularly interested in the various applications of RPM, as well as the pros and cons of these devices and their effectiveness in reducing hospital costs and utilization and improving outcomes.

In order to better understand these issues, we reviewed current literature and spoke with several individuals involved in RPM demonstrations. This paper discusses RPM's application and appeal, as well as challenges to implementation and outstanding questions about RPM's effectiveness. Current literature and select demonstrations are reviewed and, finally, the paper speculates on the future of RPM and possible changes on the horizon.

Remote Physiological Monitoring (RPM) Defined

What is RPM?

Remote physiological monitoring (RPM), also called remote patient monitoring, is a form of telemedicine that uses computerized technology to track patients' vital signs and health status without face-to-face contact. Physiological parameters, such as weight, blood pressure, heart rate, oxygen saturation and/or glucose levels, are measured using small in-home electronic devices that are connected to specialized computer modems. Data are then transmitted to clinicians using store-and-forward technologies (essentially multimedia e-mail), and clinicians conduct further analysis and follow-up with patients as needed. By monitoring patients' parameters remotely, RPM allows clinicians to intervene before emergency room utilization or hospitalization is needed thereby preempting unnecessary costs. At its best, RPM has the potential to serve both patients and clinicians; allowing patients to stay in their homes and enabling doctors and nurses to use their time and resources more efficiently and effectively.

Application

RPM varies in terms of the clinical conditions being monitored, the frequency with which physiological variables are monitored, the data collection technique (e.g. glucose meter vs. spirometer, etc.) and whether or not data are monitored on a 'real-time' or periodic basis. There are several applications of RPM that are relevant to the work of the MQF.

- **Home Health Care:** In the home health arena, RPM can be used (1) as a substitute for home care visits, (2) as a means of maximizing limited nursing resources and (3) as a strategy for better managing high risk, high cost patients, such as those with congestive heart failure (CHF).
- **Disease Management:** Used as part of a disease management program, RPM has the potential to help limit patient costs by (1) equipping caregivers with the information they need to detect health management problems at the earliest possible stage, and (2) providing patients with the feedback needed for informed self-management.

Disease management programs may vary in the extent to which they pair RPM with other interventions such as patient education, attention to medication compliance and facilitated access to healthcare information through individual patient Web sites and links to healthcare providers.

Hospitals: In addition to the two applications mentioned above, pilot studies suggest that RPM can be used to provide continuous intensive care unit (ICU) patient management.¹ Also, hospitals may use RPM to automate the process of measuring vital signs.

Payment

In the past five years, Medicare's coverage of telemedicine has expanded to include a broader range of geographic regions and physicians services, including teleradiology (telemedicine for medical imaging), remote cardiac monitoring and live interactive patient services in select rural areas. Other avenues of coverage have opened as well. Distance Learning and Telemedicine grants are currently available through the United States Department of Agriculture to help rural health care agencies purchase remote monitoring equipment.² Additionally, in what might be the largest national rollout of such systems, the US Department of Veteran Affairs has spent over \$20 million and will be installing as many as 15,000 monitors across the country.³

Despite these advancements, full reimbursement of most RPM applications is limited. With the exception of several Medicare demonstration projects, there is currently no Medicare reimbursement for remote disease management services. Among home health agencies, telehealth services can be integrated into individualized plans of care without payment difficulties, but no specific Medicare funds may be used to offset the costs of RPM equipment or the related technology needed for service delivery.⁴

State and commercial insurance policies vary in the extent to which they reimburse telemedicine. The trend in Medicaid reimbursement is to cover all services provided via telemedicine if the services are a covered benefit when provided in person. Eighteen states have regulations of this type.⁵ With regards to RPM specifically, most states and third-party payers are looking to Medicare as the payer to follow.

Benefits

A number of catalysts and potential benefits have fueled recent interest in RPM:

- **Improved quality of care.** Using RPM, clinicians can identify worsening physiological profiles and take corrective measures before patients require emergency care or hospitalization.
- **Emphasis on patient self-management and care.** As individuals undergo daily self-monitoring, they are provided with feedback that can make them more aware of behaviors that contribute to fluctuations in vital signs and health. Once these behaviors are identified, patients can learn to restrict or monitor them to prevent symptoms from recurring and/or worsening in the future.

¹ Rosenfield BA, Dorman T, Breslow MJ, et al. Intensive care unit telemedicine: alternate paradigm for providing continuous intensivists care. *Crit Care Med.* 2000; 28: 3925-3931.

² Distance Learning and Telemedicine Program: USDA – Rural Development: <http://www.usda.gov/rus/telecom/dlt/2006-program/06dltgrantsappguide.pdf>; accessed August 24, 2006.

³ Heuser S. 'Telehealth' systems slowly gaining: devices help curb visits to hospital. *Boston Globe.* July 26, 2006.

⁴ American Telemedicine Association. Telemedicine and Federal Policy: <http://www.atmeda.org/news/libpriority.htm>; accessed August 24, 2006.

⁵ American Telemedicine Association. June 2006. Medicaid Handbook – Medical Assistance and Telehealth: An evolving partnership. Available at: http://www.atmeda.org/news/policy_issues/policy_issues.htm; accessed August 22, 2006. States include: AK, AR, CO, GA, IL, IN, KS, ME, MI, MN, MT, NE, NC, ND, SD, UT, VA, WI, and WV.

- ***Compelling value proposition.*** RPM has the potential both to (1) decrease health care costs by reducing unnecessary hospital and ER visits and (2) increase the efficiency of services provided by directing clinicians to the most serious cases that require immediate attention.
- ***Outreach to underserved areas.*** RPM creates opportunities for increased access to care in rural and remote locations and for patients living at home.
- ***Medical error reduction.*** RPM has the potential to automate many processes, particularly the measurement of vital signs that today are performed manually or not at all.
- ***Patient satisfaction.*** Anecdotal conversations suggest that patients who use RPM technology feel safe. Many of them are aware of how fragile they are, and remote monitoring gives them an increased sense of security.

Challenges

Conversely, several key factors have slowed the growth and acceptance of RPM.

- ***Limited reimbursement.*** The lack of full-scale reimbursement by Medicare and other insurers is perhaps the greatest barrier to more widespread adoption of RPM.
- ***Questionable return on investments.*** Despite the apparent promise of this technology, the clinical and cost effectiveness remains poorly documented. This lack of evaluation data can be attributed to a number of factors, including the difficulty and cost of conducting large-scale RPM evaluations using randomization and controls.
- ***Physician resistance.*** Without hard data, it is difficult to convince physicians to learn and use new technology.
- ***Restrictive licensing laws.*** Licensing laws complicate the use of RPM. Health care licensure laws regulated at a state level, and it is unclear what laws and regulations would govern telehealth services that are provided across state lines.
- ***Skepticism regarding patient acceptance and compliance.*** While early evidence suggests that patients with minimal computer experience can adapt to RPM, many people still question patients' ability to interact with and comply with these programs.

Review of the Literature

The literature on RPM is still developing. Recent studies suggest that RPM helps to reduce hospital utilization and improve clinical outcomes when used with CHF and diabetes patients. Many of these studies, however, are limited by small sample sizes, lack of randomization and the absence of long-term follow-up data. In addition, few take into account the actual expense of RPM equipment when calculating the cost savings that are brought on by decreased hospitalizations and service use.

Below, the current literature is summarized and organized by clinical condition.

Congestive Heart Failure

Congestive heart failure (CHF) is one of the most deadly and costly chronic diseases. CHF is a particularly appropriate target for a disease management intervention because the behaviors and symptoms that can signal the onset of crisis are known and can be readily monitored and detected. Some CHF disease management programs are trying to enhance their interventions by incorporating RPM into traditional disease management models. Findings from these programs are not conclusive, but suggest that RPM can help reduce hospital costs and rates of admissions and readmissions.

In a 2005 study, Hudson et al. examined the clinical, financial and behavioral outcomes of a CHF disease management program using RPM.⁶ Participants in the program received a scale, a blood pressure machine and an electronic 'hub' for transmitting weight and blood pressure data via their home telephone lines to trained clinicians. The study analyzed claims data, medical records, data transmissions and quality of life survey results for 91 individuals who successfully completed the RPM program. In order to evaluate the initial as well as the long-term impact of RPM intervention, data were analyzed before, during and after the program.

Study participants experienced a significant reduction in per member per month (PMPM) costs during the period on home monitoring (average \$629.79) when compared with PMPM costs during the pre-RPM period (average \$1,002.81). Participant claims for the post-monitoring period revealed a further decrease in PMPM costs (average \$508.54) when compared to the pre-RPM period. Cost savings were derived from decreased rates of emergency visits, hospital admissions and readmissions both during remote monitoring (decreases observable, but not significant) and after removal of the monitoring (all decreases significant). These patterns were consistent across gender and age groups. Additionally, results of the telephone survey indicated that most participants were satisfied with the RPM program; 97 percent of participants believed that the program made them better able to take care of themselves; and 81 percent of participants reported making positive dietary changes as a result of the program.

Other studies with similar design and equipment have shown reductions in hospitalizations, hospital costs and length of stays.

University of Illinois at Chicago (1999)⁷

N=60 CHF patients

- **Reduced hospital admissions:** Compared to pre-intervention values, participants exhibited an 81 percent decrease in hospital admissions at 3 months post intervention, a 77 percent decrease at 6 months post intervention and a 70 percent decrease at 12 months post intervention.
- **Reduced length of stay:** Compared to pre-program values, hospital lengths of stay were 90 percent shorter at 3 months post intervention, 86 percent shorter 6 months post intervention and 67 shorter 12 months post intervention.

⁶ Hudson LR, et al. Remote physiological monitoring: clinical, financial, and behavioral outcomes in a heart failure population. *Disease Management*. 2005; 8(6): 372-381.

⁷ Bondmass M, Bolger N, Castro G, and Avitall B. The effect of physiologic home monitoring and telemanagement of chronic heart failure outcomes. *The Internet Journal of Asthma, Allergy and Immunology*. 1999; 3(2).

- **Reduced hospital readmission charges:** Compared to pre-program values, hospital charges decreased by 91 percent at 3 months post-intervention, 88 percent at 6 months post intervention and 69 percent at 12 months post intervention.
- **Self-reports of quality of life also showed significant improvement.**

Department of Medicine and Cardiovascular Research Institute, University of California (1998 and 1999)^{8,9}

N=27 patients (utilization measures); N=68 patients (medical claims comparison)

- **Cardiovascular hospitalization rates declined by 66 percent** from 0.6 per patient per year before the study to 0.2 per patient per year during the monitoring.
- **Hospitalization rates for all causes declined by 50 percent** from 0.8 per patient per year before the study to 0.4 per patient per year during the monitoring.
- **Cardiovascular hospital days were reduced by 91 percent** from an average of 7.8 before the study to an average of 0.7 during the monitoring.
- **All hospitalization days were reduced by 92 percent** from an average of 9.5 before the study to an average of 0.8 during the monitoring.
- **Reduced medical claims for monitoring group.** Compared with the prior year, medical claims per year decreased from \$8,500 to \$7,400 for the monitoring group, whereas they increased in the control group from \$9,200 to \$18,800.

A reduction in hospitalization rates was not observed in one of the only large randomized trial of RPM in CHF disease management.¹⁰ In this 2003 study, Goldberg et al. studied 280 CHF patients. One hundred and forty-two patients were assigned to a standard care group and received regular heart failure program care, while the remaining 138 were assigned to an intervention group that received regular heart failure care plus an electronic scale linked to a database monitored by cardiac nurses. The study found no differences in hospitalization rates between the intervention and control groups. There were also no differences in time to death, time to first rehospitalization or time to first ER visit. The one difference observed was a 56 percent reduction in mortality for patients randomized to the intervention group.

This study had one notable design difference when compared with others that have reported reduced utilization with RPM. Throughout the study period, both the intervention and control group received aggressive medical management. Many earlier non-randomized studies examining the impact of RPM in disease management have measured the disease management intervention as a whole (including educational materials, nurse access, etc.) without specifically teasing out the impact of RPM technology. This study suggests that the introduction of the technology alone, in this case the presence of an electronic scale and data transmitting device, does not necessarily reduce hospital use rates.

⁸ Shah N, Der E, Ruggerio C, Heidenreich P, and Massie B. Prevention of hospitalizations for heart failure with an interactive home monitoring program. *American Heart Journal*. 1998; 135: 373-378.

⁹ Heidenreich P, Ruggerio C, and Massie B. Effect of a home monitoring system on hospitalization and resource use for patients with heart failure. *American Heart Journal*. 1999; 138: 633-640.

¹⁰ Goldberg L, Piette J, Walsh M, Frank T, Jaski B, Smith A, Rodriguez R, Mancini D, Hopton L, Orav J, and Loh E. Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: The weight monitoring in heart failure (WHARF) trial. *American Heart Journal*. 2003; 146(4): 705-712.

Diabetes

Diabetes disease management involves patient adherence to a strict schedule of blood glucose monitoring, insulin use, skin care, diet and exercise. RPM can be used to enhance diabetes management by facilitating the exchange of information between patients and physicians and by providing patients with feedback on their blood sugar levels and how these levels may be impacted by behavior. Two recent studies at the Department of Veterans Affairs (VA) Boston Healthcare System and Columbia University compared remote diabetes management with regular care alone and documented greater clinical improvements in the intervention group when compared to those receiving only usual services.^{11,12}

In the VA study (2005), researchers assessed the effects of web-based care management on glucose and blood pressure control. One hundred and four diabetes patients were recruited and randomly assigned to either a control group (regular PCP care) or intervention group (web-based care management plus regular PCP care). Patients in the intervention group received a notebook computer, a glucose meter and a blood pressure monitor. A program website accepted uploads from the monitoring devices and displayed data for intervention group participants and case managers to review. The program website also contained diabetes resources and email links to case managers. A nurse reviewed participants' data and provided recommendations to the participant and their physician.

Researchers measured Hemoglobin A1C (A1C) and systolic and diastolic blood pressure at 3, 6, 9 and 12 months after group assignment and found that participants receiving web-based care had lower A1C over the 12 month period when compared to the usual care group. Individuals who had greater adherence with the intervention had more improvement in A1C, and hypertensive participants in the web-based group had a greater reduction in systolic blood pressure when compared with the usual group. These effects were observed despite the fact that most study participants had no prior computer and/or internet access. The study did not include any measures of cost-effectiveness, but suggests that web-based care management can be a useful add-on to regular care in the management of patients with poorly controlled diabetes.

In the Columbia study (2006), Shea et al. compared diabetes telemedicine case management to usual care for 1,665 Medicare recipients living in medically underserved areas of New York State. The study is one of the largest randomized trials of RPM to date and is part of a larger 4-year CMS demonstration project intended to test the feasibility, acceptability, effectiveness and cost-effectiveness of telemedicine. Participants randomly assigned to the telemedicine case management group received a home telemedicine unit with capabilities for (1) videoconferencing, (2) electronic transmission of fingerstick glucose and blood pressure readings, (3) Web-based messaging and clinical data review and (4) accessing Web-based educational materials.

Researchers assessed Hemoglobin A1C, blood pressure and low-density lipoprotein (LDL) cholesterol levels at one year into the intervention and found that diabetes management delivered using telemedicine improved A1C, blood pressure and LDL cholesterol levels compared to usual care. Effects of about the same magnitude were observed in both urban and rural subgroups. Interestingly, at one-year of follow-up, Medicare claims were greater in the intervention group compared to the usual care group, indicating that the telemedicine intervention actually increased

¹¹ McMahon G, Gomes H, Hohne S, Hu T, Levine B and Conlin B. Web-based care management in patients with poorly controlled diabetes. *Diabetes Care*. 2005; 28(7): 1624-1629.

¹² Shea S, Weinstock R, Starren J, Teresi J, et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus. *Journal of the American Medical Informatics Association*. 2006; 13(1): 40-51.

use of health care services. While this study supports the role of RPM in diabetes management and demonstrates its application to a large numbers of patients with limited computer experience, it does not address the cost effectiveness of this method. A full report of patient Medicare claims and program costs is forthcoming and was not yet available at the time of this review.

Asthma

Less work has been done around RPM for asthma management, however, a number of RPM devices support pulse oximetry (measurement of blood oxygenation and pulse rate) and electronic spirometry (total lung volume and peak rate), two measures that are essential to the evaluation of asthma severity and asthma management. A 2000 study of internet-based home asthma telemonitoring, found that spirometry self-testing of asthma patients during telemonitoring is valid and comparable to those tests collected under the supervision of a trained medical professional.¹³ The study, which involved 31 low-income, inner city asthma patients, also concluded that internet-based home asthma telemonitoring can be successfully implemented in a group of patients regardless of computer background. By and large, study participants expressed a positive attitude towards the home monitoring system, even though the majority had very limited prior computer experience.

Review of Select Non-Published Demonstrations

In order to better understand RPM's application, we spoke with two New England organizations that are currently using RPM to provide home health services.

HealthReach Network of Maine

HealthReach Network is a private, not-for-profit health care organization which provides home health, substance abuse, mental health and outreach services to clients living in their homes and/or in rural/underserved areas of Maine. Beginning in February 2006, HealthReach began using RPM devices with a subset of its CHF patients. The agency now has twenty VitalNet units in the field; all purchased using funds from a United States Department of Agriculture Rural Utility Services matching grant. The VitalNet product offers video visits; monitors heart rate, respiratory, oxygen level and weight; and enables nurses to conduct an entire cardiopulmonary assessment over the telephone. It also can be used to test for oxygen saturation, glucose levels and temperature.

Like most RPM programs, HealthReach Network's uses nurses to monitor incoming data. Nurses are alerted to measurements that fall outside the expected parameters and are then responsible for calling the patient, running through a series of questions and determining what the problem might be. Follow-up actions may include: in-person visits, changes in medication, doctor's visit, etc.

Doctors in the area have bought into this intervention and have been very responsive. Doctors seem to understand the benefit of putting in work up front to reduce hospitalizations and emergency room use. Another positive outcome is that patients have become more aware of their diet and medication and more engaged in managing their health. Families report having greater peace of mind because they know that their relatives are being monitored closely and on a daily basis by trained nursing staff. Some families have even asked to rent/purchase RPM devices when it comes time to remove them from the patients' homes. While it is still too early to draw any firm conclusions about the program's impact, HeathReach staff and providers believe

¹³ Finkelstein J, Cabrera M, and Hripcsak G. Internet-based home asthma telemonitoring: Can patients handle the technology? *Chest*. 2000; 117:148-155.

that RPM has the potential to improve quality of care, while making the best use of limited RN time and resources.

The agency has, however, faced several challenges in its use of RPM, including the lack of reimbursement and the difficulties of adjusting to new technology. In the past six months, the program has encountered some technical difficulties, primarily related to data transmission. As a result, the project was forced to stop briefly in April and May 2006. Now operational again, HealthReach expects to have its first full quarter of RPM data in the fall, at which point the program will begin to assess cost and utilization measures, such as visits per episode and hospital/emergency room use, and clinical measures, such as shortness of breath.

Visiting Nurse Association of Southeastern Massachusetts

The Visiting Nurse Association (VNA) of Southeastern Massachusetts is a not-for-profit home health care organization that has been using RPM for more than four years to serve hundreds of patients, primarily with CHF. Currently, the VNA has eighty Honeywell HomMed Telemonitoring units out in the field.

The device is about the size of a clock radio and collects data on five key vital signs: weight, blood pressure, heart rate/pulse, oxygen saturation and temperature. It can also be programmed to ask subjective disease-specific questions. Data are transmitted to a central station where nurses are alerted if there are breaks in the parameters. Currently, the VNA is paying the full cost for these devices and their supporting technology.

The VNA has invested in this technology because of its potential for preemptive intervention. Used correctly, RPM can keep patients in their homes and reduce movement in and out of hospitals. In addition, the VNA's clients love it and feel safe.

From the VNA's perspective, RPM technology adds cost, particularly when doctors have not bought on and are not tightly managing their patients care. When parameters are broken and an intervention is required, doctors may not necessarily follow the intervention team's recommendations and may still advise patients to seek out ER care, thereby negating any possible cost savings from reduced hospitalizations. Some doctors may not respond at all and, again, patients end up in the hospital and the opportunity for a preemptive intervention is lost.

In the region served by the Southeastern Massachusetts VNA, only about half of the doctors involved are on board with the project's philosophies and therefore, the RPM technology is only about half as effective as it could be. It has not proven to be a major cost saver at this point, but some patients have grown accustomed to it and expect it. The VNA is hopeful that there will be greater application and reimbursement down the road.

What is on the Horizon?

With its potential to prevent unnecessary emergency room use and hospital utilization, the value of RPM is compelling. However, its return on investments is not yet well documented. RPM does not come cheap. A recent Spyglass report quoted the price per unit as ranging from between \$3,000 and \$5,000.¹⁴ The same study questioned whether there is enough value to justify RPM technology when there are cheaper alternatives available, specifically traditional blood pressure

¹⁴ Sarasohn-Kahn J. Mixed signals for remote monitoring. *iHealthBEAT*. Available at: <http://ihealthbeat.org/index.cfm?Action=dspItem&itemID=120704>; accessed August 17, 2006.

cuffs and weight scales. Researchers and others will need to continue exploring RPM's medical and cost-effectiveness as new applications are developed and familiar applications are evaluated on a larger scale.

Some major RPM studies that are currently in the works and are worth keeping on eye include the following:

- ***The Columbia University Informatics for Diabetes Education and Telemedicine (IDEATel) Project.*** The study is one of the largest randomized trials of RPM to date and is part of a larger 4-year CMS demonstration project intended to test the feasibility and effectiveness of using telemedicine to provide case management to Medicare recipients with diabetes. First year clinical outcomes are now available, and a full report of patient Medicare claims and program costs is forthcoming.^(See 12)
- ***The Department of Veterans Affairs Trial.*** The Department of Veteran Affairs currently is studying 6,000 patients using RPM for CHF, diabetes, depression, hypertension and/or chronic obstructive pulmonary disease. The VA has invested \$21 million in this program and is administering the program across 30 states. Thus far, the patients enrolled in the program have shown a 30 percent reduction in hospitalizations and emergency room visits.^(See 14)
- ***Medicare's Care Management for High-Cost Beneficiaries Demonstration Project.*** A number of these home care pilots, recently awarded by CMS, involve the use of RPM. CMS will be using some of the findings from the pilots to help determine the value of applying technology in the provision of home care to Medicare beneficiaries.¹⁵

Within the state of Maine, a handful of home health providers, including HealthReach Network, have begun to purchase and pilot RPM devices. Additionally, the Telehealth Workgroup, sponsored by the Maine Health Access Foundation and the Governor's Office of Health Policy and Finance, has begun exploring ways to remove barriers to the use of telemedicine, including how to streamline the licensing process for telehealth providers and how to develop a comprehensive MaineCare telehealth policy.

Although outside the parameters of this study, it may be worthwhile to explore opportunities to include a RPM component under Maine's home and community based waiver program for the elderly. Assessment data for these participants indicate a high percentage with CHF or diabetes. There is flexibility under the waiver program to include services that are not otherwise available to the general MaineCare population. Also, the limited number of participants would reduce the state's financial liability and could serve as a contained study to assess its impact on outcomes and cost.

¹⁵ More information on the demonstration and specific projects is available at: <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp#TopOfPage>; accessed August 22, 2006.