The increasing prevalence of chronic disease as the population ages is placing an unprecedented strain on our healthcare system, including our hospital resources. Chronic disease and conditions include diabetes mellitus, hypertension, asthma, heart failure, chronic lung and kidney disease, arthritis, dementia, and a range of disabling neurological conditions. Data from the United Kingdom’s Department of Health shows that about 80% of healthcare consultations relate to chronic disease. Patients with a chronic disease or complications account for over 60% of hospital bed days. The care of people with chronic conditions consumes a large proportion of health and social care resources.

Moving certain healthcare services from the hospital to the home is a potential solution to help reduce this resource burden, while improving patient health outcomes. However, the effective management of these chronic conditions and their associated therapies presents enormous challenges. Foremost it requires developing and testing new models of care delivery to overcome the shortcomings and barriers of the present system.

In this article we report on development of several next-generation remote patient monitoring systems. We highlight our research conducted at the University Health Network (UHN) in Toronto, where a new model of healthcare service delivery was developed that helps people to take an active role in managing their own care in a manner that enables the patient and their care providers to make better healthcare decisions. In particular, we feature the advances in information and communication technology and telemonitoring that provide the capabilities of enhancing patient self-management, such as the use of Bluetooth-enabled medical devices to collect vital signs in the home. Such technologies allow the information gathered by patients to be made available to healthcare providers at the time of office visits in a format that aids clinical-decision making.

Remote Monitoring for Chronic Disease Self-Management
Remote patient monitoring (RPM) technology has existed for many years on proprietary, purpose-built hardware platforms. They typically consist of medical devices deployed in the home that transmit vital signs through a data hub, desktop console, or set top box. Server side systems allow for storage and eventual retrieval of the data by care providers. There have been studies that indicate that these systems are able to reduce costs and improve health outcomes by providing more timely and efficient care. However, adoption of the technology has been relatively low in many jurisdictions and remains on the fringes of day-to-day healthcare service provision. The reasons for this are numerous, but mostly relate to the high capital cost of the equipment and the additional clinical staff required to monitor the transmitted data and act on alerts when necessary.

In our development of a next-generation RPM system, we elected to develop a chronic disease remote monitoring system based on a mobile phone platform that would allow the automatic wireless transfer of measurements from medical devices (e.g. weight scales, blood pressure monitors, glucometers, etc.). There is little compromise...
in electing to use mobile phones over purpose-built hardware, as mobile phones typically have greater computational power than these platforms, as well as built-in broadband Internet access, and are priced as a commodity. This last attribute allows the ability to scale the system to reach many more patients than would normally be possible on systems based on purpose-built hardware that cost significantly more to produce. Although tiny screens and buttons present a design challenge, these can be overcome using a user-centered design process that focuses on developing prototypes for optimizing the user experience of the patients.

In our original clinical studies with the system, patients were provided with Bluetooth-enabled, clinically-validated blood pressure and blood glucose monitoring devices and a mobile phone running a Java-based remote monitoring application. For the patient, the device acted as a personal medical diary, logging all of their home measurements and displaying trends that were used to generate reports. The patients were asked to take their blood pressure levels at least twice weekly in the morning and evening and glucose twice per day three days of the week at meal times, as recommended by the provider based on their particular condition. The system was designed to remind patients by automated phone calls to take their home readings if they failed to adhere to the preset schedule.

The user-centered design and operation of the system emphasized simplicity. The patients placed the blood pressure cuff on their arm and pressed a button to start the recording. Everything thereafter was done automatically. The blood pressure device transmitted the reading wirelessly to the mobile device. The reading was captured, and the mobile phone automatically recorded the time and date of the measurement and transmitted it to the hospital server for processing and storage. Similarly, blood glucose measurements were taken as the patient would normally, with no difference in routine other than prompting the patient for when the reading was taken (i.e. pre- or post-prandial readings).

It our first pilot in hypertension, patients experienced a significant drop in systolic and diastolic blood pressure, lowering their risk of cardiac mortality by 25%. We hypothesize that these results were more as a result of self-care than increased management by the physician.

These findings are currently being validated through a randomized controlled trial. Other trials to determine the health outcomes of home monitoring using this system are being conducted for blood sugar control, diabetes during pregnancy, and heart failure.

### Consumerism in Self-Management: There’s an App for That

Although the system described above was designed to greatly expand the use of remote monitoring to more patients, there now exists a new consumerism in mobile phone applications that has exploded in popularity recently and that has the potential to proliferate RPM technology to even greater levels. Online mobile phone application stores from Apple, Google, Research In Motion, and Microsoft have created an outlet for developers to create health and medical applications for clinicians, and more commonly the consumer patient. Mobile apps for weight loss, asthma management, fitness, and diabetes care now number in the thousands.

Together with Toronto’s SickKids Hospital, we developed our own iPhone application named bant to address the challenge of managing adolescent Type 1 diabetic patients who are transitioning from care provided by their parents exclusively, to learning the lifelong skills necessary to manage their condition. (The name of the application references the heritage of institutions involved in its development of the technology, where Sir Frederick Banting discovered and successfully tested the use of insulin for the treatment of diabetes mellitus.) The tool offers automated data transfer from the patient’s glucometer, trending of readings, storage on their Google Health personal health record, and diabetes social networking support through Twitter. (See Figure 1.)

The resulting platform incorporates the automatic capture of blood glucose readings through the iPhone’s standard 30-pin connector, avoiding the barriers and issues of manual data entry. Other novel elements include
a private Twitter-like micro-blogging feature to connect adolescents through a social networking community where they can share their experiences in managing their condition. The sharing of personal experiences related to diabetes management on Twitter is already a common occurrence as patients self-organize personal support groups online. By adding this functionality to bant, we plan to simply facilitate a similar social support community on a private network. As well, the system rewards adherence with self-monitoring and participation in the community through the issuing of iTunes redemption codes as an incentive.

Given the popularity of the device together with the use of social networking, and the novel rewards system, we hypothesize that there may be a natural fit between the system and the target population. The intervention may be helpful in improving glycaemic control, enhancing diabetes-related communication between adolescents and their families and their care teams, increasing adherence to recommended self-care practices, improving self-efficacy and personal empowerment. Clinical trials are underway at the time of this publication.

Remote Monitoring as a “Virtual Ward”
In addition to promoting self-management, the mobile phone-based remote monitoring platform is currently being investigated as a means to create a virtual ward. A virtual ward enables healthcare providers to closely monitor patients with complex medical needs at home, rather than in the more costly hospital setting. Nearly 20% of all Medicare patients discharged from hospital will be readmitted within 30 days, with as many as 34% readmitted within 90 days. These readmissions are often unplanned emergencies that are unnecessarily costly to the patient’s overall well-being and can require extended stays in the hospital for recovery. As well, post-surgery patients could potentially recover safely in the comfort of their own homes instead of having extended hospitalization for several days or weeks for observation.

In our first study utilizing the concept of a virtual ward, a system was developed to enable monitoring of patients with heart failure. Heart failure is a prevalent chronic condition with about a quarter of patients being readmitted to the hospital within a year. However, an estimated third to a half of hospital readmissions are preventable with proper patient monitoring and management, including medication titration. Previous studies suggest that remote monitoring could substantially reduce the cost of heart failure. In particular, remote monitoring enables healthcare providers to intervene at the earliest sign of deteriorating health, which can reduce costly re-hospitalizations.

In this study, heart failure patients in the virtual ward take their weight and blood pressure daily and an ECG periodically (e.g. weekly) with Bluetooth-enabled medical devices (Figure 2). They also indicate daily any symptoms that they are experiencing by answering yes/no questions on the mobile phone. The physiological measurements and symptom entries are automatically sent to the hospital servers. The appropriate healthcare providers and patient are alerted immediately if there is cause for concern according to predetermined clinical algorithms. Patients are able to inform their healthcare providers of any deterioration in health throughout the day by entering symptoms and measurements. An email alert is sent automatically to a healthcare provider (e.g. on a smartphone) when a patient’s parameters are abnormal. The email alert includes the patient’s measured parameters, symptoms, normal threshold ranges, medications, and contact information. The healthcare provider receiving the alert is able to phone the patient as required. Secure website access is available for patients and their healthcare providers to view all collected data. Healthcare providers can also document on the website any clinical actions taken due to alerts. In addition, the monitoring system sends an automated reminder phone call to patients who do not take their daily measurements.

Figure 2. Mobile phone based remote patient monitoring. Bluetooth-enabled consumer medical devices connect to a patient’s mobile phone to facilitate self-care and clinical management of chronic conditions. Shown here are a Bluetooth-enabled single-lead ECG monitor, blood pressure monitor, and weight scale. A Java application on the mobile phone turns the device into a monitoring hub within the home, relaying data back to healthcare providers and returning instructions and advice to the patient.
The system is currently being evaluated through a randomized controlled trial of 100 patients, with 50 in the control group and 50 in the intervention group (ClinicalTrials.gov identifier: NCT00778986). The patients were recruited from the UHN Heart Function Clinic between September 2009 and February 2010. Patients were asked to take their weight, blood pressure, symptoms, and ECG as described above. After six months of using the monitoring system by the intervention group (completion in fall 2010), hospital records of the intervention and control groups will be compared to determine any differences in hospital readmission rates, length of hospital stay, and number of heart function clinic and emergency room visits. Differences in the measured parameters (e.g., blood pressure and weight) will be compared, as well as changes in blood test results (e.g., Brain Natriuretic Peptide (BNP), creatinine, and potassium). For the trial, email alerts are being automatically sent to cardiologists on their mobile phone, who contact the patients directly as required. For long-term deployment of the monitoring system, it is proposed that a nurse practitioner would attend to the alerts.

Preliminary results indicate that a large majority of remotely monitored patients are strictly adhering to taking daily measurements. This may be in part due to the automated phone calls sent to the patients’ home phones to remind them to take their measurements if they have not adhered. The most significant clinical management actions from the remote monitoring have been medication titrations, and a few patients have been instructed to go to the emergency department. Patients have stated that by using the system, they have greater physical self-awareness and understanding of the impact that lifestyle choices, such as salt intake, have on their condition.

Although the results so far have been promising, the creation of a virtual ward is not without its challenges. The following summarizes some of the major barriers to adoption:

- **Workflow changes:** A healthcare provider will need to be on call 24/7 to respond to alerts. The duties of existing healthcare providers will have to be expanded or additional staff will be required. This added responsibility would have associated costs involved that would need to be factored into the development of a virtual ward.
- **Medicolegal concerns:** Healthcare providers could have an obligation to act immediately on any alerts generated by their patients. Healthcare providers may be concerned that they would be legally liable for a patient’s health deteriorating further because of a delayed or inappropriate response to an alert.
- **Privacy/security:** Patients’ health information being transferred from the home to hospital must have the appropriate privacy and security measures in place.
- **Determining appropriate patients:** A virtual ward will not be suitable for all patients for reasons such as physical or mental impairments, language, area of residence (e.g., no cell phone reception for a mobile phone-based monitoring system), etc. For example, some patients may not be able to perform the necessary measurements at home because of a lack of manual dexterity. Patients would have to be carefully screened to ensure that they could be safely monitored at home, perhaps with the help of family members.
- **Data integration:** The information from a virtual ward should be linked with the patient’s other health information to provide a complete profile of the patient’s health status. Integrating the data from a virtual ward into the existing health record (electronic health record or paper chart) could pose significant logistic challenges.
- **Fear of technology:** Many patients, especially elderly patients, may be uncomfortable with the use of sophisticated technology. The monitoring system must be as easy to use as possible, training must be adequate, and technical support must be made available.
- **Perceived benefit of the virtual ward:** If patients do not find immediate benefit from using the monitoring system (e.g., from clinical intervention or improved awareness of their lifestyle choices on their health), they will not continue to send their measurements as directed.
- **Trust in the virtual ward:** For continued use of a virtual ward, both the patients and healthcare providers must have confidence that the information and alerts from the monitoring system are accurate and appropriate. For example, frustration will result if false alerts are constantly generated due to errors in data entry, or if patients receive instructions from the monitoring system that are unclear or not actionable. The monitoring system must be developed in a way to minimize such occurrences.
The intent is to use the experience gained from the heart failure trial to mitigate these issues in order to operationalize the remote monitoring system at the UHN Heart Function Clinic. Future plans include applying the system to remotely monitor post-operative cardiac patients as they complete their recovery at home.

**Advanced RPM for the Hospital-at-Home**

Whereas the previous example was a means to keep patients from unplanned re-hospitalization, there is also the potential to completely eliminate the need for the hospital setting in the delivery of a complex therapy.

Most notable in recent years is the advent of home hemodialysis (HHD) as a viable therapy that can be delivered solely by the patient or family caregiver. HHD is a simple variant of conventional, hospital-based hemodialysis. It is essentially a more frequent therapy that is delivered for longer periods of time, and in most cases nocturnally. This increase in duration and frequency of treatment has a dramatic improvement in health outcomes. Patients enjoy improved cardiovascular health (without the need of hypertension medication), improved peripheral circulation, improved sleep quality (despite undergoing dialysis treatment), and the elimination of dietary restrictions.\(^{16, 17}\) Despite the capital costs of providing a dedicated hemodialysis machine in the patient’s home, the cost-effectiveness of nocturnal hemodialysis is clear when factoring in the greatly reduced nursing care and the reduction in medications.\(^{18}\)

Despite these positive outcomes, there are a number of patient-perceived barriers to adopting the therapy. These include a lack of self-efficacy in performing the therapy, lack of confidence in self-cannulation, as well as a perceived burden on family members and fear of a catastrophic event.\(^{19}\)

To address some of these concerns, we developed a more advanced form of RPM that had the potential to facilitate the delivery of complex therapies in the home. The system consisted of the acquisition, transmission, storage, and processing of patient vital signs (heart rate, blood oxygenation, and blood pressure) and selected hemodialysis treatment parameters of the hemodialysis machine (Figure 3). Decision support rules were developed through discussions with domain experts including nephrologists, nursing staff, and renal technologists. These rules were applied to the data in real-time and alerts were generated as needed. These alerts were sent to an on-call technologist who received the alerts and assisted the patients as necessary. The patients also had access to an IP-based call-bell system, just as if they were inpatients at the hospital. On-call staff would receive alert messages on their mobile device if the call-bell was activated.

Finally, a large liquid-sensitive pad was developed to detect the loss of blood in the event the patient’s cannula was dislodged. Although reportedly a rare event, this is a major concern of patients undergoing the therapy. In our limited trials of the use of the pad, there were two instances that the pad detected blood loss over a one-year trial, with only four patients being monitored. This suggests that the occurrence of blood loss is under-reported and that the need for such monitoring is greater than has been previously indicated.

The system was found to be particularly supportive of family caregivers, in that the monitoring acts as a surrogate for the nursing care they would have normally received in a hospital setting. Patients remarked on how the system was used to check on details of their treatments, such as the amount of ultrafiltration being performed and their resulting weight and blood pressure. Nursing staff were able to react and advise adjustments to their prescription in a more timely manner. Patients also felt that there was some security and comfort knowing that they were being monitored and that the nursing staff would call when they noticed problems with their treatments. Though the system was proposed for only transitional use, there was at times an unwillingness to have it removed. Even those patients with an uneventful transition from conventional hemodialysis to HHD continued to insist on remaining on remote monitoring.

Figure 3. Home Hemodialysis Remote Monitoring System, consisting of real-time monitoring of hemodialysis parameters, physiological data through a wireless oximeter, call-bell system to alert on-call staff, and blood-loss detection pad in the event of cannula dislodgment.
Care providers should be aware that patients perceive remote monitoring as a safety feature and its removal can generate anxiety among patients who have developed an unexpected dependency.

**What’s Next?**

Although some of these technologies are beginning to see mainstream use, we are still in the very early stages of delivering traditional healthcare services in the home. There continue to be barriers to wider dissemination, including interoperability issues with medical devices, lack of reimbursement for these services, and the potential for greater regulatory requirements of mobile consumer health applications.

The Continua Health Alliance, made up of more than 230 industry players and organizations, has been working to address these barriers. Interoperability is being addressed through the establishment of guidelines for manufacturers that encompass existing standards and those facilitated by Continua. In particular, the establishment of the Bluetooth Health Device Profile (HDP) will open up the marketplace for numerous Bluetooth-enabled medical devices in the coming year. Regulatory and reimbursement issues are also being addressed collectively through the Alliance.

The last few years have shown great promise in the acceleration of technology development to enable patient self-management, with the vision of enabling patients to take greater control of their care in a climate of diminishing resources. This should not necessarily be viewed with negative connotations, as the above examples here have shown there is the potential for greater efficiencies and improved health outcomes.

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