EMPOWERING HEALTHCARE PATIENTS WITH SMART TECHNOLOGY

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Continua Health Alliance is developing a set of technical interoperability guidelines for personal telehealth systems that will make it possible to better monitor high-yield microevents over time and thereby enable timely lifestyle adjustments.

Bob is a savvy new employee at a high-tech firm. He grew up an avid user of the Internet and took to electronics at an early age. Although Bob is only 20 years old and watches his weight, he has just been diagnosed with diabetes mellitus type 2 (DMII). Consequently, he is about to contribute to this year's record-high US healthcare costs. According to the most recent Towers Perrin Health Care Cost survey (www.towersperrin.com), employer-sponsored medical benefit costs will rise 7 percent in 2010 and exceed an average of $10,000 per employee.

Young people with DMII fail to make the news today, yet just two generations ago they would have startled the medical community. Sadly, stories similar to Bob's have become all too common. In some communities, nearly half of pediatric diabetes cases are DMII.

Surely Bob must have a family history of diabetes. His chart, however, is unremarkable; his great uncle may have had diabetes the year before his death at 88. No, Bob—and indirectly his employer—are victims of a more insidious problem: a steady accumulation of unmonitored health-related microevents such as poor nutritional choices and lack of exercise that have resulted in the premature onset of DMII, not by weeks or months but by decades.

Continua Health Alliance (www.continuaalliance.org), a nonprofit open industry group of nearly 240 healthcare and technology companies dedicated to reducing costs and improving outcomes, is developing a set of technical interoperability guidelines for personal telehealth systems that will make it possible to better monitor such high-yield microevents over time and thereby enable timely lifestyle adjustments. A product certification program with a recognizable logo signifies compatibility with other Continua Certified solutions. Complementary Continua initiatives include working with government regulatory agencies, educating and equipping policymakers with data and benefit analysis, providing training, promoting the alliance and member products at international events, and matchmaking between purchasers and manufacturers.

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THE FUTURE OF HEALTHCARE

"At the Center for Connected Health, we believe four cornerstones support a successful connected health strategy. First, collecting accurate physiologic data from patients rather than relying solely on self-reported data. That drives the next three cornerstones: enabling patients to access this data, offering coaching personalized to each patient, and then optimizing provider involvement. Across our programs we are proving that leveraging these elements in combination can produce measurable behavior change, improve adherence, and increase engagement.

"Connected health tools provide great resources for population health management. My favorite example in our own system is our Connected Cardiac Care program. Heart-failure patients thought to be at risk of readmission are given a set of technologies (hub, weight scale, blood pressure, and oximetry) and asked to upload their vital signs daily. We now have more than 250 patients on the program at any given time. Three or four nurses manage the dashboards and reach out to patients whose readings are out of parameter. This enables preventative and proactive care, and encourages patient self-care. The result has been a 52 percent drop in readmissions in the cohort we've followed over a year or so. We're applying the same principles now to the management of diabetes and hypertension and having great success with these as well."

Dr. Joseph C. Kvedar, Director, Center for Connected Health, Partners HealthCare

"The use of in-home wireless and mobile devices to connect patients with chronic diseases and their family members/caretakers to their providers will certainly change the way medical care is delivered in the future. Monitoring patients' vital clinical parameters in real time and proactively intervening will avoid unnecessary trips to the emergency department and expensive hospital admissions or readmissions. Empowering patients and their loved ones with education about their disease process and helping them to manage their ongoing care and medications better will reduce the overall costs of healthcare significantly. Data and device interoperability is an important part of the necessary ecosystem."

Dr. Alan D. Snell, Chief Medical Informatics Officer, St. Vincent Health

"Prevention is now one of the key buzzwords for the [UK] National Health Service. We are seeking a huge growth in the use of remote monitoring, but there are signs that technology is actually holding back adoption. The UK is probably the world leader in use of technology to support independent living for older people, and the NHS has invested heavily to establish evidence of what works in chronic disease management. While proprietary solutions have shown the way, there is a real need for robust and consumer-friendly standards for interoperability to provide genuine choice, so that people can have the technology that best fits their needs and that information can be presented in a way that helps clinicians deliver care effectively. Most current services only meet the needs of people who clearly need care now. By harnessing the potential of eHealth 2.0, it should be possible to reach out to other groups and help healthcare become genuinely preventative."

Dr. George MacGinnis, a telehealth advisor to the UK National Health Service

INTEROPERABILITY GUIDELINES

In developing its interoperability guidelines, Continua begins with use-case collection and refinement. After agreeing upon a limited set of use cases, it extracts requirements from these and selects standards. Next, Continua profiles over the standards and creates interoperability guidelines that serve as a basis for product certification.

Collect use cases. Converging on a set of priority use cases for each iteration is a challenge. To deal with this, Continua maintains a rigorous process consisting of the following steps:

- consolidate and generalize use cases to eliminate redundancy and group like-minded companies together to describe a broader, consolidated industry need;
- augment each use case with an analysis of technical feasibility and market implications;
- review in light of the Continua mission and analysis, and adjust the scope as necessary; and
- conduct a review cycle with end users and domain experts to ensure use cases represent real requirements and represent solutions that will be purchased and used.

Develop requirements. Once the use cases are complete, Continua defines personal telehealth system requirements. This entails analyzing each use case to pull out actors, identify actions, clarify assumptions, and elaborate with sufficient detail.

Select standards. Continua next seeks out existing standards development organizations (SDOs) and standards that best satisfy the system requirements and desired characteristics. Where no standard is available, Continua selects an SDO to host a new standard and applies resources to create and obtain its approval. The standard-selection process considers many criteria, including the level of adoption and maturity of a standard, whether it's international, and how well it harmonizes with other domain standards.

Develop guidelines. Because international industry standards address a broad range of applications and interests, they can be somewhat general. To keep solutions as simple as possible and tightly focused on the personal health domain, Continua creates guidelines that profile over the standards to address any remaining gaps, minimize options, and facilitate tight interoperability. This constraint steers vendors in a common direction.

Create test tools. Continua then fashions procedures to verify that a product complies with the appropriate

standards and guidelines. These procedures serve as the basis for automated test tools that members can use to quickly evaluate products under development.

Host plugfests. Continua offers quarterly "plugfests" that let companies test the interoperability of products under development and to surface defects in the products or specifications. These events also make available system simulators, error generators, stress testers, a library of certified products and services to test against, transport testing tools, and debug resources to ensure rigorous product evaluation leading up to certification.

Provide certification labs. Continua currently has several certification labs and will expand their number and locations as the market demands. At these labs, independent third parties can thoroughly validate devices against the guidelines to guarantee interoperability. Once product testing produces a satisfactory result, Continua will certify the product and can use the Continua Certified logo for marketing purposes. Figure 1 shows one such product.

Figure 1. Designed to meet the specific needs of healthcare professionals, Panasonic's Toughbook H1 rugged mobile clinical assistant (MCA) is the first Continua Certified application hosting device supporting Bluetooth. It features a 10.4-inch, dual-touch, 500-nit display that accepts input from a stylus or finger touch. Hot swappable twin batteries provide limitless hours of use.

E2E REFERENCE ARCHITECTURE

Continua's end-to-end (E2E) reference architecture provides a high-level structure and terminology for the interoperability guidelines. It also introduces topology constraints for a Continua personal healthcare ecosystem. As Figure 2 shows, the E2E architecture references five device classes and four interfaces based on the following communication needs:

- personal area network interface (PAN-IF)—measurement exchange around a person;
- local area network interface (LAN-IF)—measurement exchange at a location;
- wide area network interface (WAN-IF)—measurement exchange across the globe; and
- health-reporting network interface (HRN-IF)—health reporting to other enterprise systems.

The network interfaces are key to achieving the interoperability goals and form the basis for most Continua certification targets. These targets will be extended by device guidelines addressing high-level behavior aspects required for E2E interoperability.

PAN-IF connects a sensor or actuator to an application hosting device (AHD), such as a personal computer, cell phone, or monitoring hub, located around the person using the sensor or actuator. LAN-IF connects sensors and actuators to an AHD at the same building or facility. WAN-IF connects an AHD to a WAN device, such as a personal

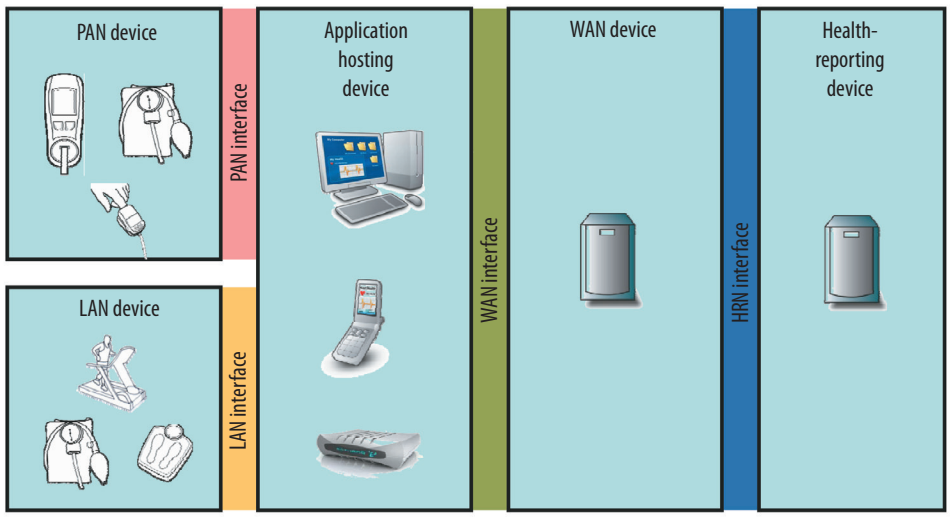

Figure 2. Continua end-2-end (E2E) reference architecture.

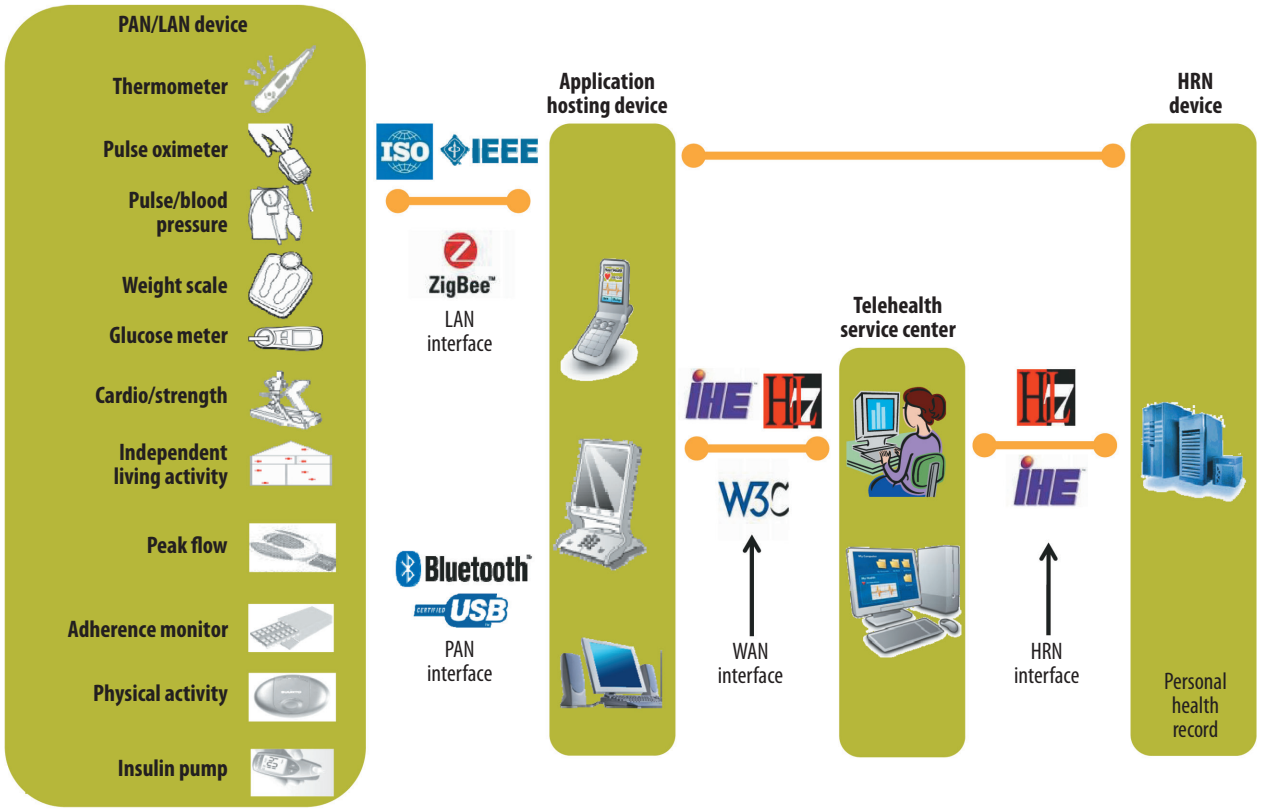

Figure 3. Continua relies on well-established standards to ensure a successful interoperable telehealth system.

telehealth service provider's back-end server. AHDs often are aggregators that share and upload data from the bound PAN or LAN devices, but they also can implement sensing functionality itself and thus act directly on WAN-IF. HRN-IF enables patient-centric reporting from a WAN device to an HRN device, typically at the personal telehealth system boundary. This is in contrast to the other interfaces, which support more device-centric, measurement-oriented communication.

All Continua network interfaces have one component encompassing open-systems-interconnection layers 1-4 (physical, data link, network, transport) and another encompassing OSI layers 5-7 (session, presentation, application). Both lower and upper layers must be specified to achieve true device interoperability. This separation of concerns is illustrated by the two PAN-IF instantiations, one wired based on USB and one wireless based on Bluetooth. Both use the same transport-independent exchange protocol created by the IEEE 11073 Personal Health Data (PHD) Working Group. Instantiations of the LAN for ZigBee-based sensors also leverage this exchange protocol. Finally, the exchange protocols used for WAN-IF and HRN-IF don't depend on the underlying transport mechanism—it could be GPRS, Wi-Fi, Ethernet, or a plain telephone line.

Another important aspect of the E2E architecture is that the interfaces are domain agnostic. Many use cases are at the border of, or cross, the three application domains Continua addresses: aging independently, health and wellness, and disease management. To ensure interoperability, the standards adopted are the same across the domains.

To support the different domains and corresponding use cases, the Continua architecture is highly flexible. Various devices within the device reference classes can implement the interoperability guidelines; in fact, even a single device can implement the guidelines of multiple reference device classes, enabling it to play multiple roles within the architecture.

INTERFACE STANDARDS

The key to a successful interoperable system is careful description of the interfaces, which ensures that participating parties understand the information being exchanged. As Figures 3 and 4 show, Continua relies on well-established interface standards. It also provides a comprehensive guideline to specify and constrain as much remaining system "looseness" as possible.

PAN-IF

The PAN interface is based on the ISO/IEEE 11073 standards family—particularly IEEE 11073-20601, which

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0x20 0x07 0x12 0x06 0x12 0x10 0x00 0x00
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PAN interface

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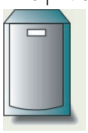
WAN interface



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HRN interface

Figure 4. Systolic value of a blood pressure reading as it progresses through the protocols of each Continua interface.

specifies the data and protocol for communication between medical devices and the aggregating computer. For each device, there is a corresponding IEEE 11073-104xx specification that details how it utilizes IEEE 11073-20601 to accomplish its function. This family of specifications continues to grow as the PDH Working Group defines additional devices. PAN-IF supports the popular Bluetooth wireless and the ubiquitous USB wired technologies. In both cases, the interface uses a new communication profile specific to health information.

Figure 5. Companies and products involved in 22 different Continua-based solutions exhibited at an event in Tokyo in early 2010.

LAN-IF

A recent addition to the Continua ecosystem, LAN-IF introduces a plethora of new devices of all sizes and functions. The core underlying technology is the rapidly growing ZigBee standard for low-cost, low-power wireless communications. As data flows into the ecosystem, LAN-IF transforms it to correspond with normal IEEE 11073-20601 PAN payloads.

WAN-IF

The WAN interface sends aggregated data from the patient's location across the Internet to the professional environment. To accomplish this, WAN-IF uses the PCD-01 transaction of the IHE Device Enterprise Communication (DEC) profile, which articulates how raw device data is transformed into a Health Level Seven (HL7) V2.6 message. At this point the payload will be in one of the most widely accepted formats. WAN-IF then sends it to the target system by means of a Web service based on a set of Web standards, the core of which is WSI-Basic. Ancillary standards specify additional transport mechanisms such as security, delivery reliability, and logging.

HRN-IF

The HRN interface is typically found in a professional setting—for example, communicating patient information between a telehealth service and a health records center. A leading solution is the HL7 Clinical Document Architecture (CDA) V3 family of standards. Continua uses the Personal Health Monitoring Report (PHMR), a close cousin of the widely used Continuity of Care Document (CCD) with specific changes to accommodate device data monitoring. The chosen transport technology is again a modern Web service based on the IHE Cross-Enterprise Document Reliable Interchange (XDR) standard; the IHE Cross-Enterprise Document Media Interchange (XDM) profile allows for simpler e-mail or physical media transport.

MARKET DRIVERS

Despite large investments in the development of personal telehealth devices, they're only now becoming widely available in the market. This is due to a combination of factors, including increased consumer awareness, globalization, the availability of ultra-low-power wireless technologies, and emerging interoperability standards. In addition, as regulatory changes shift liability from insurers to caretakers, connected health devices are becoming increasingly critical for risk management. To assess this risk, researchers have initiated various clinical trials involving patient use of these devices and are now publishing associated clinical outcomes.

Aging independently

Personal telehealth systems have the potential to let seniors live independently longer. While clinical studies demonstrating the cost savings of these systems compared to hospitalization will drive Medicare reimbursement, positive clinical outcomes will motivate family members to choose such systems over more traditional approaches.

Risk factors are commonly used to determine whether a specific medical procedure is reimbursable. If a telehealth device or service can be correlated to an existing billing code in the reimbursement system, the process of determining the relative valuation of the new billing code associated with the telehealth system can readily be determined by comparing the effectiveness of the new treatment or technology with that of more expensive procedures.

Increased consumer awareness of independent-living technologies' effectiveness will accelerate their deployment. For example, consumers will be likely to use devices that automatically detect physiological changes and trig-

ger medical treatments if they reduce the probability of traumatic injury and premature death.

For wearable activity-monitoring devices to be widely adopted, they must be easy and comfortable to use. If a wearable sensor requires a large battery to reduce the frequency of recharge or battery replacement, seniors are unlikely to use it. In addition, the associated wireless sensing technologies must be robust. If the device interprets stomping on a bug as a fall, the frequency of false alarms will quickly lead seniors to discontinue their use.

Health and wellness

The distribution of health- and wellness-monitoring devices is likewise driven by both consumer self-pay and institutional reimbursement models. Corporate-sponsored studies continue to demonstrate the benefits of encouraging workers to exercise more regularly through interactions with peers and family. Consequently, employers are increasingly reimbursing employees who use health- and wellness-monitoring devices. In addition, various clinical studies have shown that exercise reduces stress, one of the leading causes of metabolic disorders such as diabetes. As consumers become increasingly aware of regular exercise's many benefits, systems that quantify calorie consumption or physical activity and thereby help reduce stress will become more popular.

Disease management

Disease-management devices such as glucometers and heart-rate monitors are widely used today, and the reasons for wirelessly connecting them vary. Family members concerned about loved ones might purchase a telehealth disease-management device to ensure they're properly taking care of themselves. In addition, as the healthcare system struggles to meet the growing staff demands of baby boomers, and as consumers become more aware of the complications and risks associated with understaffed hospital care, they'll become more open to portable wireless devices that can help them manage existing conditions wherever they are.

LESSONS LEARNED

Continua standards are being instantiated in numerous real-life, end-to-end solutions based on certified products, with uptake on the rise. For example, the Japanese government is encouraging development of personal telehealth systems to facilitate early detection and avoidance of the growing problem of metabolic syndrome, a condition with symptoms including obesity, elevated cholesterol, and high blood pressure. Figure 5 depicts the companies and products involved in 22 different Continua-based solutions exhibited at an event in Tokyo earlier this year. Continua is growing strong and hopes to double the number of Continua Certified devices by the end of 2010.

Several key lessons have emerged from its work developing interoperability guidelines for personal telehealth systems during the past three years.

The world is "flat," and *companies increasingly want international solutions to provide consistency for their global work force and to increase market potential*. While this sounds straightforward, it's actually difficult to achieve as there are many regional SDOs and policy initiatives. An organization must be unwavering in its quest for a global solution despite the inevitable debates, complexity, costs, and delays that arise.

Stick to market-viable use cases and requirements. Instead of leading with technology, focus on solving real-world problems. This involves gauging market support: How many companies are ready to implement a personal telehealth system? How many are ready to purchase one?

Continua standards are being instantiated in numerous real-life, end-to-end solutions based on certified products, with uptake on the rise.

Keep the customers and domain experts involved in the process. Because personal healthcare is a nascent field, many of the technology and consumer electronics companies involved are relative newcomers and may not be aware of the real-world environment's nuances and constraints that they must address to be successful.

Carefully constrain scope to determine the appropriate focus. As the number of companies grows, so will the appetite for new capabilities. Given limited resources, it's important to concentrate on the highest-priority capabilities.

To keep aligned with other companies and meet expectations, *an organization should identify and communicate its strategy and philosophical underpinnings*. For example, what's the relative importance of a predictable development schedule compared with additional features? Should certain geographical areas be prioritized over others?

Continua's interoperability guidelines for personal telehealth systems will make it easier to connect the high-yield microevents consumers experience that, left unchecked, contribute to many of the adverse health outcomes responsible for growing healthcare costs.

Managing such microevents can significantly reduce this burden. Consider a US company that currently spends about $6 million per year on healthcare for its approximately 40,000 workers. This employer has invested $6-8 million on employee wellness programs for standard

health-risk assessment and coaching programs. The return on investment is difficult to assess reliably but is probably around 3:1. Providing Continua Certified personal telehealth systems may double the company's annual investment to $12 million but will drive the ROI closer to 6:1.

Disease management will become increasingly person-centric. For example, Bob will connect his glucometer to his phone and use an online system to help manage his diabetes. By maintaining close and constant contact with the right micro-information environment, Bob will avoid unnecessary emergency visits. He will minimize the progression of renal, retinal, and other complications. An activity tracker will ensure that Bob breaks his insidious cycle of prolonged inactivity. High-yield microevents that slipped under the radar will be actively tracked and his personal health record (PHR) will link to a Web-based management solution. Early data suggests a fourfold health benefit improvement with a dynamic online solution versus medication therapy alone.

When patients are enabled with technology, avoiding the avoidable becomes a core functionality of personal health.

Avoiding the accumulation of adverse microevents is also important in achieving wellness. Connect a PHR to an activity monitor and mix in a simple and secure user interface, and the result is an irresistible platform for action. All too often, today when an employee does the right thing, such as using the stairs instead of the elevator, his effort goes unrecognized and he eventually loses his motivation to repeat this excellent behavior. But if this same employee can capture the steps on a low-cost, easy-to-use device and link this data to his PHR he can garner employer recognition for his effort and even compete against his peers. The emerging social networking functionality of PHRs creates an irresistible stimulus for citizen-driven health reform.

During the recent H1N1 pandemic, we were shocked that health authorities couldn't reliably distinguish stable flu cases from those that would progress to critical. Without any technology for tracking flu victims, their prehospital health experience wasn't captured and future flu victims didn't benefit from the incremental knowledge that could have been generated.

Fast forward to a connected community united against H1N1 and armed with PHRs and low-cost flu-tracking patches. The patches are worn at the onset of flu-like symptoms and transmit heart-rate variability, temperature, and oxygen saturation to a PHR hosted on the person's cell phone. The number of clinic, hospital, and other visits are linked in the PHR, securely de-identified from the users, and organized in a community registry. In the space of a single flu season, knowledge of the flu's natural history in the community has advanced, dramatically increasing resilience against future outbreaks. The next year's patches are even better, improving the markers that matter most and dropping the ones that don't seem to make a difference.

In short, when patients are enabled with technology, avoiding the avoidable becomes a core functionality of personal health.

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