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### Connected Health Empowers Patients and Providers

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**Author:**

**David Pettigrew**

*Sector Manager for Patient Care*

*Sagentia*

Connected health is poised to transform the way services are delivered. Sagentia's David Pettigrew examines how technology innovation is successfully making the transition to commercial reality.

Ageing populations and the growing prevalence of chronic diseases are placing healthcare infrastructure under greater pressure than ever before. The UK's Department of Health estimates these issues could require £5 billion in additional expenditure by 2018, yet NHS budgets are currently allocated on a flat-cash basis.

At a time of significant budgetary constraint, healthcare providers must find new ways to reduce costs and increase the efficiency and quality of care. Treating patients quickly and effectively frees-up hospital beds and critical resources. Ensuring underlying health issues are properly addressed and encouraging lifestyle improvements drives reductions in both the number of people visiting healthcare providers and repeat visits.

Technology is proving a key enabler in realising these aims, particularly in the form of connected health. Broadly defined as the use of technology to provide healthcare at a distance and improve speed of response, connected health is seeing new levels of capability being realised in areas such as user interfaces, storage, smartphones, low power connectivity, and data processing and analytics. These are being combined with medical sector advances around novel sensing and imaging technologies, as well as microfluidics, haptic feedback, and robotics, to deliver practical solutions to some of the most pressing healthcare issues.

#### **Making the Connection**

Connected health is an evolution from existing delivery models such as telehealth and telemedicine services, which are focused on the transmission of raw data between two locations – for example, the electronic transmission of drug prescriptions to a patient, or medical images between clinicians. Connected health takes this further by abstracting these data using sophisticated context-aware algorithms to provide actionable information to the patient, payer or clinician.

It is this ability to provide real-time data management and decision support that distinguishes connected health. It can be as simple as a bedside monitor linked to a nursing station that alerts nurses to a critical event, or a series of networked devices collecting clinical data that is stored together with patient records and other administrative and financial data within a central clinical information system (CIS).

More advanced connected health solutions combine the latest advances in smart sensing technology, fixed and wireless networking, and cloud computing. They also employ sophisticated algorithms and centralised storage (either locally or via remote servers) to enable the mining and analysis of 'big data' to uncover trends and insights, and generate decisionmaking outputs.

Crucially, connected health solutions can be applied at any point in the care pathway, from a patient's first contact with a healthcare professional, service, or organisation, through to the completion of their treatment and subsequent aftercare. Moreover, they can be delivered in the home, between the home and surgery, within a surgery or even between surgeries, in areas including vital signs, sleep, and medication compliance monitoring.

#### **A Technology Applied**

Monitoring and prevention are two promising areas for connected health. Commercial examples include solutions for monitoring diabetes (blood sugar levels, insulin administration) and for preventing co-morbidities through the monitoring of blood pressure, cholesterol, and weight. There

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are also PT/INR self-testing solutions (Prothrombin Time/International Normalized Ratio) allowing patients taking medication such as coumadin or warfarin to measure their blood's anti-coagulation level (i.e. how long it takes their blood to 'clot'), as well as cloud-based platforms that log patient data and refine algorithms to enable more accurate diagnosis in areas such as cardiology and image analysis.

Arrhythmia detection is another major area of focus, as it is important for patients to be able to monitor and record their heart rate outside of the surgery. An electrocardiogram (ECG) rhythm monitoring technology has been implemented by AliveCor for example, in the form of a hand-held device consisting of two finger-pads embedded in an iPhone cover. The ECG data acquired via this device can be transferred to a secure online server for review by a clinician.

Although AliveCor's system is approved for clinician use only at present, the next step could be to put this device in the hands of patient for recording their own ECG traces for remote review in-between their appointments. This would significantly increase the likelihood of detecting relatively rare arrhythmia events.

Another connected health innovation under development is the Endotronix system, which uses an implanted sensor to communicate pressures from inside the patient's heart to a smartphone app via a transmitter. The system is able to accurately capture internal heart pressure data at any time and communicate it securely from a remote location to the patient's care team. It will be possible for both patients and clinicians to view the data in various formats, and on multiple devices.

### **Delivering Successful Outcomes**

Some connected health solutions are already providing doctors with new levels of visibility of their patient's progress, and empowering patients to take more responsibility for their own health and care. 'Health Buddy', for example, is a personal and interactive communications device developed by Health Hero Network (now part of Bosch Healthcare). It enables a doctor or nurse coordinator to send a set of queries to the patient each day via the Internet. The patient answers them by pressing one of four buttons. The device automatically transmits this data to a processing centre, where it is analysed and published to a secure website for review by the coordinator.

Piloted as part of a computerised interactive asthma self-management and education programme in the U.S., the device was found to increase self-management skills while reducing the number of urgent calls to the hospital. There are now more than 20 clinical trials of the Health Buddy system in post-acute and chronic care coordination, with consistent demonstration of positive outcomes across a variety of disease states and settings. One Health Buddy programme that is supporting chronically ill patients has achieved spending reductions of approximately 7-13 percent (\$312-\$542) per intervention patient per quarter.

The U.S. has been an early adopter of connected health solutions and digital health technology in general. Electronic health records (EHRs) are subsidised under 'ObamaCare', while VC funding for digital health is on track for another record year, with start-up incubator Rock Health reporting a 35 percent increase during the first quarter of 2013 compared with Q1 2012. Last year, total annual VC funding in the digital health industry stood at \$1.4 billion and \$968 million in 2011.

In Europe, take up has been slower, but industry commentators believe all the elements are now in place for connected health to make the transition from small-scale pilots to mass market implementation. According to the European Connected Health Alliance, the path for connected medical devices will be smoother in Europe than in the US, because it is easier and faster to get over the regulatory hurdles and the process is better understood.

### **Fit for Purpose**

The regulatory landscape in the U.S. remains highly uncertain, with the FDA due to publish its final guidelines on mobile medical apps shortly. FDA draft guidelines released at the end of 2012 stipulate that certain types of medical mobile apps will be regulated, placing a large burden on R&D in terms of managing risk. There are also considerable challenges around protecting the privacy and security of personal health information, and concerns over the impact on development schedules and costs should products require FDA approval.

Nevertheless, the 510(k) number issued by the U.S. Food and Drug Administration (FDA) is considered the 'gold standard' for solution developers globally due to the rigour of the regulatory process, and the fact it clears medical devices for sale in a market where providers, payers, and physician groups are forecast to spend over \$69 billion on healthcare-related IT and telecommunications services between 2012 and 2017, according to analysts at Insight Research Corporation.

Functionality of connected health devices varies and is based on their technical sophistication, but their success will depend on end user acceptance. This explains the rising prominence of smartphone apps, which at first glance, would appear to provide an easy route for manufacturers to deliver a 'consumer friendly' user interface for their connected systems. However, manufacturers and regulators are increasingly concerned about how rapid changes in smartphone hardware and operating systems will affect the intended function of their medical devices.

Depending on the level of risk of the intended connected health system, it can still be cheaper and less risky in the long run to develop a platform-independent system that they can control entirely. Alternatively, a model explored by many companies involves the use of custom 'smart sensors', which perform the 'high risk' data processing functions using sophisticated embedded algorithms. These devices can in turn transmit the result to the smartphone, which displays the data to the user. In this way, the usability of a smartphone interface is brought to bear without adding in the extra risk of using 'unregulated' hardware and software to generate the data.

#### **Connecting the Future with the Present**

Additional challenges remain, particularly in respect of the networking technologies employed in connected health applications and their respective power requirements and data rates. Using Wifi or broadband for example, has the advantage that the medical device can be connected to a backbone of wireless hotspots using an existing hospital network, and the investment will be relatively low from a technology perspective.

The drawback of this approach is that it is power hungry and cannot be used if the device is battery powered and has very limited dimensions. In this case, Bluetooth Low Energy (Bluetooth Smart®) is often the preferred solution as it has low-power consumption but also means a low data rate. This constrains the amount of information that can be transmitted back and forth in real time and thus limits the application. This is an area in which leading manufacturers continue to innovate by embedding processes within the portable device so that less data is being exchanged.

Given that connected health bridges the consumer and healthcare space, development of robust and interoperable platforms is essential. Recent FDA regulations and harmonised global standards are driving manufacturers to increasingly focus on usability engineering, in order to develop devices and services that minimise the risk of patient harm through user error. Considerable progress in terms of interoperability has been made by the Continua Health Alliance, which is developing a system of interoperable personal connected health solutions.

As these challenges are addressed, connected health will enable efficiencies and improve patient outcomes. It will also free-up healthcare professionals to focus triage on patients where it is needed most. And as people become more open to owning their own healthcare, advances in connected health mean they will have a growing range of tools at their disposal. Ultimately however, the transition to connected health will be borne out of necessity, as conventional healthcare and its associated costs become less feasible in respect of fiscal and demographic pressures.

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