Transforming healthcare services with connected health innovation

Healthcare providers must find new ways to increase efficiency and quality of care. As an evolution of telehealth and telemedicine services, connected health is seeing new levels of capability being realized in areas such as user interfaces, storage, smartphones, low power connectivity, and data processing and analytics. When combined with medical sector advances around novel sensing and imaging technologies, as well as microfluidics, haptic feedback, and robotics, it delivers practical solutions to some of the most pressing healthcare issues.

by David Pettigrew

Ageing populations and the growing prevalence of chronic diseases are placing healthcare infrastructure under greater pressure than ever before. At a time of significant budgetary constraint, technology is proving a key force in combating these growing problems, particularly in the form of connected health.

Broadly defined as the use of technology to provide healthcare at a distance, connected health is an evolution from existing delivery models such as telehealth and telemedicine services. The latter are focused on the transmission of raw data between two locations – for example, the electronic transmission of medical images between clinicians. Connected health takes this further by combining the ability to transmit data with powerful analysis capabilities to provide real-time data management and decision support.

Such solutions can be as simple as a bed-side 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 solutions combine the latest advances in smart sensing technology, fixed and wireless networking, and cloud computing. They also employ sophisticated algorithms and centralized storage (either locally or via remote servers) to enable the mining and analysis of 'big data' to uncover trends and insights, and generate decision-making 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 organization, 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.

Avoiding unnecessary interventions

The application of connected health technology will mean expensive and unnecessary interventions can be avoided. For example, when an asthma patient visits their GP surgery to report a deterioration in their condition, it is often assumed the current medication regime is not working correctly and that an intervention is required. Interventions can range from a short course of steroid tablets to a costly hospital admission. These interventions are usually effective in the short term, but do little to address the root cause of the deterioration in the first place – poor adherence to their medication regime.

In many cases, the patients take their inhaler medication regularly, but have developed 'bad habits' since they were trained and are using them incorrectly. With this scenario in mind, Sagentia has developed a novel invasive acoustic detection technology called 'Sensohaler' that is capable of detecting several key events during the administration of an inhaler dose (including events relating to patient compliance).

Building on the recent success of this sensor in clinical trials, Sagentia is now looking to realize a connected system designed to drive outcome improvements for patients called 'Smarthaler'. The system transfers data to a secure cloud-based server via a mobile medical app. The user interface of the app will be designed in such a way that clear actionable information (rather than raw data) is displayed to the user, for example to warn them that a dose has been taken incorrectly and to coach them to improve their technique.

By inspecting these data in the cloud, the clinician can review their patient's adherence to their treatment over a long period of time, evaluate the root cause of a patient's deterioration and take appropriate action – i.e. notify the patient. Using this approach, clinicians have a practical way of monitoring whether the patient is using their medication properly away from the clinic. This would also enable the patient to adjust their technique quickly and/or the clinician to be alerted well in advance of adverse symptoms appearing. If symptoms do appear, the doctor would be able to review the historical data with the patient and to eliminate poor adherence as a cause of the deterioration.

Monitoring and prevention

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 are also PT/INR self-testing solutions (Prothrombin Time/International Normalized Ratio) allowing patients taking

Handheld device records ECG data for remote review by clinician.

medication such as coumarin 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 patients 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 computerized 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 per cent ($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 subsidized under 'ObamaCare', while Venture Capital (VC) funding for digital health is on track for another record year, with start-up incubator Rock Health reporting a 35 per cent 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

Connected health solutions have great potential for increasing efficiency and improving patient outcomes.

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 harmonized global standards are driving manufacturers to increasingly focus on usability engineering, in order to develop devices and services that minimize 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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