ST+D; the EXPERIENCES of a SMALL/MEDIUM ENTERPRISE (SME)

Alan Watts[1], Michael Caulfield, Eric McAdams, John Anderson, Jim McLaughlin.

Sensor Technology + Devices Ltd,
4, Heron Road, Belfast, BT3 9LE, Northern Ireland, UK
[1]Alan.Watts@stnd.com

***Abstract*— Sensor Technology and Devices Ltd, a sensor-based business spun out from the University of Ulster in Belfast 7 years ago, has found that a specific set of technologies it has developed during that period now sits at the epicentre of a well defined clinical/technological watershed. *Wireless vital signs monitoring* solutions have moved from development to clinical trial to the excitement of both the healthcare and technology communities.**

I. INTRODUCTION

The percentage of the population classified as being elderly has been predicted to increase dramatically in size over the next 30-40 years. Figures produced by the World Health Organisation (WHO) anticipate an increase from around 600 million in the year 2000 to close to 2 billion by the year 2050 [1]. By 2050, 22 percent of the world's population will be over 60 [2] – in Europe it will be over 30 % [3]. In addition, according to the WHO, approximately 10% of the population experience some form of disability. Already 21% of people above the age of 50 have severe vision, hearing and/or mobility problems.

The prevalence of diabetes and cardiovascular disease increases with advancing age. Additionally, the age-related demographics of these diseases are changing and they are affecting people at progressively younger ages. As a result we are now witnessing a shift in the burden of illness from acute to chronic conditions which has given rise to a generation of people living with long-term illness and disability.

The combination of an ageing population and the increased need for chronic disease management is driving up health costs and making significant demands on an already stretched health and social care provision. According to the Continua Health Alliance, in developed countries, between 40 to 70% of healthcare spending is related to the care of chronic conditions, especially those affecting the elderly.

According to the WHO, chronic diseases and their risk factors now pose a serious threat to global health. "*Health care is heading toward one of the biggest societal crises that we* (the US) *can imagine, both here and abroad. Because health care already accounts for 15% of the GDP in the U.S., we can't, as a society, afford to devote any more of our economy to it.*" [4]

There is a widely recognised need to radically change Healthcare provision, presently based on an acute care model, to make it more suited to the ongoing management of chronic disease and hence move towards a preventative care model. This has to involve changing the existing Health Care systems and their associated technologies.

Modern healthcare systems have generally evolved around the treatment of acute disease and are therefore largely organised to cope with patients' episodic and acute needs. Chronic conditions have now overtaken acute problems, constituting the major, and growing, healthcare burden. Unfortunately, using a reactive acute care model to address the needs of a population that now suffers primarily from chronic conditions, i.e. waiting until something goes seriously wrong rather than optimally managing the chronic condition on an ongoing basis, leads to excessive, inefficient and ineffective use of secondary care services. As a consequence, chronic conditions now consume up to 75-85% of health and social care spend in developed countries, causing a growing economic strain on the world's healthcare systems [3].

It is widely agreed (e.g. by the WHO and the EC) that it is imperative that healthcare leadership implement a more sustainable form of care, improving healthcare quality while reducing unnecessary costs. This is to be achieved by shifting away from today's reactive model of care to an integrated approach which enables, encourages and supports individuals and their families to continuously monitor and manage their health from the comfort of their homes, cars, work place, etc., avoiding, to a great extent, costly acute intervention. The emphasis now is therefore on "self-management", "personalised health", "pervasive healthcare" and "preventative healthcare"; terms reflecting key aspects of the new approach.

It has been shown that home-based or Ambient healthcare delivery, where appropriate, is much less costly coupled and the patient's perceived quality of life is generally much higher. Home-based care is less expensive on a 'per day' basis and more appreciated by the patient. More importantly, it is generally more effective, therapeutically and financially, to encourage and support the patient to manage their chronic condition at home; to detect and act on symptoms as early as possible.

A. Potential Solutions

The development of sensor and related technologies that enable the monitoring of a patient's health and lifestyle at home and 'while on the move' promise major improvements to the quality of healthcare while driving down costs. There is therefore a need of revolutionary 'Ambient Assisted Living' (AAL) systems which involve novel sensor technologies, mobile technology, home-based medical equipment, embedded systems, wearable systems, ambient intelligence,

etc. which are capable of conveniently, discreetly and robustly monitoring patients in their homes and while performing their daily activities without interfering significantly with their comfort or lifestyle. Early studies indicate that these technology-enabled, personalised programs can, with further developments, form a complete solution for sustained, efficient, quality health care.

It has been estimated that the prevention and effective management of chronic conditions is 20% medicine – 80% 'other' [5]. By concentrating on the 80% non-medicinal aspects, better healthcare can be provided without the escalating cost. Solutions to the monitoring and treatment of many chronic diseases can therefore be offered from a number of technological perspectives, all of which aim to provide a level of independence within the home environment (and beyond) and the effective early detection and treatment of conditions before they necessitate costly emergency intervention. According to the EC definition, AAL is the consolidation of the necessary technologies, systems and services required to delivery this new healthcare provision.

One of the key goals of AAL is the delivery of preventative support rather than (simply) reactive intervention. This involves the intelligent processing of information gathered concerning the patient's environment, lifestyle and vital signs. The patient (and/or family) is/are effectively encouraged to take some responsibility for their healthcare, and medical conditions can be more effectively managed to the benefit of all concerned. The services which AAL can offer within the home environment should also be available once the person leaves their home, goes for a walk, gets into their car, goes to their GP, etc. Future health care must be 'Personalised' and 'Connected'. It is important to stress the 'at work' and 'in community' parts of AAL – this is one of the main ways that it delineates itself from its 'Tele' predecessors.

B. Barriers to the success of Ambient Assisted Living

Although early trials, pilot studies and a few major programs have had promising results, the widespread adoption of such 'telemonitoring' and AAL has to date been very slow – much too slow to radically improve health and quality of life and dramatically reduce healthcare costs. Several key barriers exist to the more widespread use of such exciting technology.

These include

1. Suitable Sensor & Associated Technologies
2. Device Interoperability
3. Connected HealthCare Systems
4. Routes to Market

II. ST+D's EXPERIENCES

A. Suitable Sensor & Associated Technologies

A major remaining stumbling block to the successful design and development of monitoring systems capable of being applied to and functioning reliably on real patients, under real conditions for an extended period of time with sufficient robustness is the design of the sensors [6], [7].

This rather surprising observation is a consequence of the standard approach taken by engineers while designing wearable/portable monitoring devices. Invariably the engineers involved, who are generally specialists in IT, Electronics etc., start with the monitoring device, hardware, software, telemetry, etc and leave the 'simple' sensors to be added on at the end. Unfortunately, electrodes are not just 'pieces of conductive metal' as is often evidently assumed (for example, silver chloride, the best electrode material for most non-invasive biosignal monitoring applications, is in fact very resistive), nor are all sensing problems miraculously solved by making sensors smaller. Key problems to be overcome include the convenient attachment of sensors in their correct locations, the comfortable and discrete wearing of the sensors for prolonged periods and the avoidance of motion-induced artefacts.

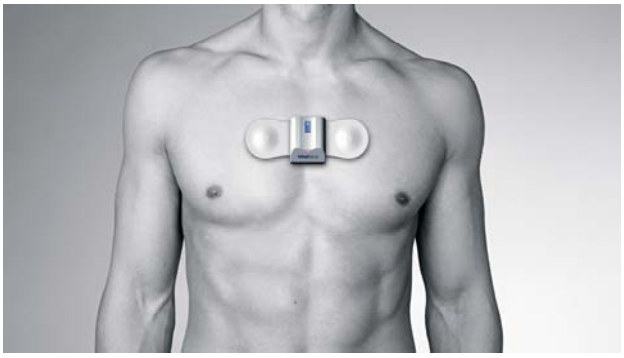

Fig. 1 ST+D's Wireless Vital Signs Monitor

ST+D is a technical innovator in the AAL field. One of ST+D's key product ranges is the body-worn sensor patch and telemetry system. The associated technology has been developed for personalised healthcare and provides :

- Miniaturised wireless telemetry
- Reduced motion artefact
- Multiple combinations of vital signs integrated into a single, disposable, low-cost sensor patch.
- On-body processing and recognition algorithms allowing a huge reduction in the data sent, thus improving battery life and ease of data assimilation by clinicians
- Unique patient identification 'biometric' derived from the vital signs for security and privacy

Some of specific technologies developed include:

- Motion tolerant ECG, up to 3 leads
- Low-power processing of ECG arrhythmia recognition algorithms – 10 arrhythmia types recognised
- Motion tolerant respiration from chest patch (no band round the chest)
- $SP0_2$ measurement from the same chest patch, presently through proof-of-concept development.
- 3-axis motion and temperature measurement.
- Patented user identification from ECG
- Range of wireless protocols/combinations for use in various monitoring applications – hospital, at home,..

B. Device Interoperability

If sophisticated monitoring devices and associated systems are to be successfully introduced into the general Healthcare, the devices must be fully interoperable with each other and with other information sources. 'Interoperability' is the ability of a system or a product to work with other systems or products without special effort on the part of the patient/customer. For medical devices to be able to function efficiently with other products they all have to adhere to some form of widely accepted standards. No standards presently exist that fully define interoperability among medical devices and systems, thus the market is unable to fully exploit the technical solutions presently available. International interoperability standards will require the collaboration of all the key participants involved in the Healthcare provision and will involve the development of public policy, regulations, re-imbursement, etc. without which such standards will not gain widespread acceptance. Policy makers, regulators and industry leaders must collaborate to remove policy barriers to standards development worldwide and create new policies and incentives to advance harmonisation

The Continua Health Alliance was formed in 2006 by technology, medical device and health and fitness industry leaders with the aim of "establishing an ecosystem/market of connected personal health and fitness products and services making it possible for patients, caregivers and healthcare providers to more proactively address ongoing health care needs"[3] and to thus accelerate the healthcare technology transformation. The alliance now includes over 100 of the top companies, including IBM, Philips, Dell, Welch Allyn, Partners HealthCare, GE, Medtronic, Intel, Boston Scientific, Motorola and Samsung. By bringing together all the different levels of healthcare technology, from the devices up to the healthcare providers, the Alliance is creating a system of standards using currently available technologies. The Continua Health Alliance recently announced the production of its first set of guidelines which will enable most available devices to seamlessly function together. Products are now being certified and marked with the Continua Health Alliance symbol to indicate that a given device is compatible with all other Alliance certified products**.** ST+D have already been working with some of the major players in the Continua Health Alliance, developing novel technologies for future markets, and since late 2007 has been a member of the Alliance.

C. Connected HealthCare Systems

Any single organization or group does not have the resources needed to address the complex public health issues that need to be resolved to facilitate the introduction and implementation of effective and efficient management of chronic disease and the ageing. New 'Connected Health' coalitions will need to be established between the various sectors involved to ensure that the advancements in prevention, control, and treatment of chronic diseases benefit all. Fortunately, the critical mass of interest and political will is now coming together in many countries, including in the EU – with the goal of connecting the various elements of Healthcare provision required for this 'disruptive' approach. [A disruptive technology or innovation is one that, when introduced, either radically transforms markets, creates wholly new markets or destroys existing markets for other technologies/strategies.]

The 'European Centre for Connected Health' was recently established in Northern Ireland by local Government, with the encouragement of the EC, 'linking up' of all of the relevant 'players' in HealthCare. "The European Centre for Connected Health, based...in Northern Ireland, will focus on developing the region as a connected health economy, introducing new technologies and working closely with the health and social care system to deliver this" [8]. It is anticipated that, once successfully implemented in Northern Ireland, which is effectively a good-sized, real-world, test-bed for the introduction of new systems and technologies, the 'Connected Health' model will be eventually be adopted throughout Europe and possibly elsewhere following adaptation of aspects of the model to make it compatible with the varying social preferences and the regulatory issues which exist on the national or regional level across Europe**.**

ST+D has been actively involved in supporting the creation of the European Centre for Connected Health in Belfast and sees in its creation an ideal opportunity for SMEs to get their innovations introduced into clinical settings. Further collaborations within Europe and between Europe and the US are also key opportunities accruing from this new centre.

D. Taking it to Market

It is one thing to technically innovate, it is quite another to take these innovations successfully onto the complicated and conservative medical market. ST+D are taking a multi-pronged approach to address this challenge.

The Belfast Hospital Trust, including the world-famous Royal Victoria Hospital (RVH), has an impressive record in medical innovation - including the development by one of the ST+D founders of the world's first portable defibrillation service. Work is presently underway in the RVH on the post operative monitoring of heart patients using ST+D devices. To enable a reduced post-operative stay in the hospital, a miniature chest-worn vital signs monitor is being assessed. The patient will complete their recovery at home while still being monitored remotely by the hospital. There are a number of significant issues to be addressed within this trial in order to enable the hospital to retain responsibility for patients who are no longer physically within the hospital.

ST+D gratefully acknowledge the assistance provided by the European Community in the form of several multi-centre research projects. These projects have not only provided welcome funding, but also the opportunity to collaborate with other leading, often large, companies as well as with key clinicians and academics. This greatly facilitates the development of clinically-viable devices and helps raise the profile of an SME such as ST+D, its research and its devices.

Many of the projects are in niche monitoring areas where the route to market may be less challenging.

The ProeTEX 6th Framework IST Integrated Project involves the development of textile-based integrated sensor systems for emergency personnel to monitor their wellbeing and their environment and to thus improve their safety. Additionally, patch-based systems are being developed to monitor rescued, possibly injured, civilians at the emergency scene in order to facilitate and optimize their survival management. It is envisaged that these developments will eventually lead to monitoring systems suitable for a wide range of other markets including extreme sports, building workers and general healthcare [9].

DIAdvisor is a 7th Framework Programme involving the development of a unique tool for diabetics to better predict and thereby control their blood glucose levels. The prediction-based tool will use past and easily available information to anticipate how blood glucose levels will develop short term and thus optimise the therapy for type I and type II diabetes. In addition to blood glucose level and insulin dosing, measurements of the patient's vital signs will be used to assist the predictions [10].

ST+D regard nonotube array technology as one of the key emerging technologies for its sensor development roadmap. DEsign, SYnthesis and Growth of Nanotubes for Industrial Technology (DESYGN-IT) is 3 year EU-funded STREP (Specific Targeted Research Projects) project which commenced in 2004. The primary scientific and technical objective of this project is to pioneer in Europe the design, synthesis, growth and application of nanotubes, nanowires and nanotube arrays for industrial technology. ST+D's contribution is particularly in the areas of medical diagnostics, sensors and mobile appliances [11].

As an SME, ST+D has long believed in forming strategic alliances with major companies who have the where-with-all to get the shared technology clinically assessed and into the market. This pragmatic approach is not without difficulties, however, as often large companies can be relatively slow to move and may suddenly put what to them is a minor project on the 'back burner'. Obviously, to a small company, this can be problematic.

ST+D has however successfully cooperated with several major companies on projects including Welch Allyn and one major US chip company.

The Center for Innovative Technology for Medicine (CIMIT) is a clinically based consortium of Boston-area hospitals and engineering schools which includes Harvard Medical School, MIT and Partners Healthcare. CIMIT has a strong track record in pioneering new medical technologies and has recently signed an MoU with ST+D. Under this, co-operative work is being done to develop a miniaturised patient-worn monitor providing information on a patient's heart, respiration, temperature and movement. The devices will use the existing hospital wireless networks to give an immediate indication of change directly to the clinical teams even as patients move around the hospital. This contrasts with traditional monitoring which is based around hospital beds.

As stated above, the Centre for European Connected Health was recently announced to be set up in Belfast, Northern Ireland. The Northern Ireland Health Minister has allocated £46m to introduce new approaches to chronic disease management with the target of monitoring 5,000 patients remotely within 3 years. This world-leading initiative is being leveraged by the local development agencies to create a remote healthcare technology cluster and ST+D is well positioned to be involved.

III. Conclusions

Healthcare delivery is set to dramatically change in the near future – "a social necessity and an economic opportunity". Although there are many challenges facing the introduction of the 'disruptive' technologies and systems required, many of the underpinning structures are now being put in place.

Acknowledgments

ST+D acknowledge with gratitude the support of the EC in the following projects- DESYGN-IT, ProeTEX & DIAdvisor.

The assistance of Dr Chris Nugent in researching the background to AAL and its challenges is gratefully acknowledged

References

[1] Ageing and life course,World Health Organization, http://www.who.int/ageing/en/.
[2] United Nations "Population Aging 2002".
[3] http://www.continuaalliance.org/
[4] Andy Grove, Fortune, April 2003
[5] Nakita Vodjdani, 1st Global Village Workgroup, February 7th, 2008 Paris, France.
[6] Wearable eHealth Systems for Personalised Health Management: State of the Art and Future Challenges. Studies in Health Technology and Informatics. Editors, Andreas Lymberis and Danilo de Rossi; IOS Press. 2004
[7] Personalised Health Management Systems: The Integration of Innovative Sensing, Textile, Information and Communication Technologies. Studies in Health Technology and Informatics. Editors, Chris D. Nugent, Paul J. McCullagh, Eric T. McAdams and Andreas Lymberis; IOS Press. 2005V
[8] http://www.eu-cch.org/index.htm
[9] http://www.proetex.org/
[10] http://cordis.europa.eu/fetch?CALLER=PROJ_ICT&ACTION=D&DOC=77&CAT=PROJ&QUERY=1205498990663&RCN=85459
[11] http://www.tcd.ie/Physics/desygnit/index.php