

Optimising the National Health Service Through Remote Vital Signs Monitoring:

zensor January 2013



Global populations are increasing, life expectancy is moving towards three figures and chronic Cardiac, Respiratory and other long-term diseases are on the rise. Healthcare organisations globally are in need of transformational solutions to handle the increasing burden on their healthcare resources both in primary and secondary care provision.

Intelesens's non-invasive, wearable, wireless **zensor** is at the forefront of innovative technology that can help transform healthcare provision by providing at least part of the solution.

Transforming Your Care

Globally Healthcare is facing a revolution and it is universally agreed that technology will play a key role in the necessary change.

In the US, President Obama has stated, "We will restore science to its rightful place, and wield technology's wonders to raise healthcare's quality and lower its cost."

In 2010 the UK Prime Minister Cameron made a huge commitment to changing the healthcare paradigm - "We are investing a record £800 million in the best medical technology to advance diagnosis, prevention and treatment"

Closer to home, Health Minister Poots has thrown the full support of the NI Government behind the health technology revolution and has focused on Connected Health in particular. The Ministers for Health and for the Economy in Northern Ireland have actually signed a Health and Wealth Memorandum of Understanding to help facilitate the revolution.

"Connected Health is quite a simple concept - by using companies with innovative technologies and products, we enable more patients to manage their condition at home which means fewer visits to hospital and provides opportunities for local companies to reap the rewards."

In December 2011 the Minister published a full and comprehensive review, "Transforming Your Care (TYC)". The review focused on the assessment of the Health and Social Care (HSC) Services in Northern Ireland critiquing the quality and accessibility of services, and the "extent to which the needs of patients, clients, carers and communities are being met."¹ The Minister appointed John Compton (the Chief Executive of Health and Social Care Board) to officiate over the review. The findings of the report support show the burdens to the HSC and recommendations for a solution. It is the belief of Intelesens that the findings in the report confirm the

need for the remote monitoring device **zensor**.

Some of the key problems identified by TYC that are putting pressure on the HSC are:

- A Growing and Aging Population
- Poorer Health and Growth in Chronic Conditions
- Instability in the Health and Social Care System

As a result, the Review documented twelve “major principles for change, which should underpin the shape of the future model proposed for health and social care,” .¹

1. Placing the individual at the centre of any model by promoting a better outcome for service user, carer and their family.
2. Using Outcomes and quality evidence to shape services.
3. Providing the right care in the right place at the right time.
4. Population-based planning of services.
5. A focus on prevention and tackling inequalities.
6. Integrated care- working together.
7. Promoting independence and personalisation of care.
8. Safeguarding the most vulnerable.
9. Ensuring sustainability of service provision.
10. Realising value for money.
11. Maximising the use of technology.
12. Incentivising innovation at a local level.

To achieve these principal goals, the fast evaluation, treatment, and prevention of disease will require the pathway to change from hospitals to primary care and the home. **In 2011 a bed utilisation audit showed that on the day in question, up to 42% of the inpatients reviewed should not**

have been in the hospital.¹ The Review recommends a financial remodelling that will shift £83 million from hospital spend to reinvest into primary, community and social care services. This will be needed to support the aging population of Northern Ireland. With the population growth, chronic condition prevalence will also rise.

zensor

zensor can help meet these goals by monitoring patients in the community. It is a remote vital signs monitor with the following features:

- 3 Lead ECG
- 7 day full ECG disclosure and event monitoring in one device
- Symptomatic and asymptomatic arrhythmia event detection using on-device algorithms
- Monitoring of respiration, heart rate, and motion
- Wireless transmission of detected arrhythmias and rate limit breaches using a standard Wi-Fi or mobile hotspot to a remote database
- Battery swap in-situ for extended monitoring
- Patented patch design to reduce motion artefact
- Configurable pre and post event data reporting
- Generation of PDF reports
- Full disclosure download via USB
- Accelerometer to help analysis and diagnosis (i.e. was patient very active during event?)

The following Events are detected:

- Bradycardia
- Ventricular Tachycardia (VT)
- Supraventricular Tachycardia (SVT)
- Ventricular Fibrillation
- Atrial Fibrillation (AF)
- Asystole
- Patient activated event recording

- Respiration rate breaches
- Heart rate breaches

Traditional remote ECG monitoring consists of three options:

Holter Monitor: Worn for 24-48 hours. All ECG data is collected, then after monitoring the device is brought back to doctor or third party where the analysis is done through software and then corroborated by a qualified clinician. The results will be put into a report, which is sent back to the doctor. This can typically take a minimum of two weeks to get results back.

Event Monitor: Event monitors only record the events that are triggered by the patient. It can be work as a 3-lead, or used as a device that is held up to the chest when the patient feels palpitations. There are many different versions of event recorders, and transmission of data varies from device. In the European and American markets, there are telehealth companies that act as the service behind these monitors. When events occur, they are either recorded and the device is brought back to office as with a Holter, or can be transmitted through a cellular or landline phone.

Implantable Loop Recorder: The implantable loop recorder (ILR) is implanted subcutaneously through a minor surgery. The patient has an activator that they hold above the skin to record any event. The ILR can also be auto-triggered for certain arrhythmias, then the events can be transmitted wirelessly.

sensor takes the best qualities of the above monitors and puts them into one device: the full disclosure data from the Holter (7 days), the events (both auto-captured and patient activated) transmitted immediately from the Event and implantable loop recorders.

Chronic Diseases and Societal Costs

As chronic diseases rise (the demand), so does the need for more efficient pathways of care (supply). The Quality Outcome Framework (QOF) has identified some specific chronic conditions that are on the rise²:

- Prevalence of diabetes is increasing by 4% per year.
- The rate of Atrial Fibrillation (AF) prevalence is rising, (1.25% growth in 2006/07 to 1.33% of the population in 2009/10).
- This averages to an additional 1,500 patients with AF per year.
- Stroke and Transient Ischemic attacks have also risen, causing an additional 6,400 patients needing care from their condition.
- Demand for services is expected to grow by around 4% by 2015¹

The increase of demand has caused large cost constraints. The graph opposite is a general representation of a nationalized health service. The supply curve is vertical because the NHS has to operate with fixed resources irrespective of quantity demanded. (See Graph 1)

This is a theoretical representation, though in reality there is an excess demand or “economic shortage” as shown. The result of which is queuing, rationing, or private healthcare. According to the NHS Operating Framework in 2012, a patient has the right to start treatment with a consultant within 18 weeks. If a patient needs a surgery or procedure, the wait time can extend into years depending on urgency. However, between May 2010 and November 2011, the amount of patients who were not treated in this amount of time increased by 42.8% from 20,662 patients to 29,508 patients in England. The number of patients having to wait at least a

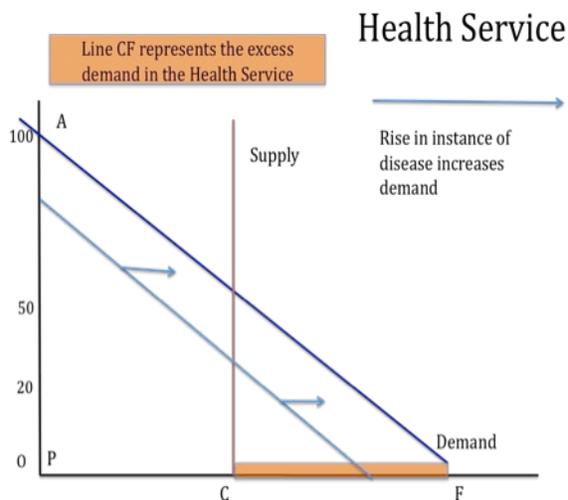
year also increased in the same time frame from 321 to 1,018.³

In Wales, where the health service is not bound by the maximum wait period, almost a third of patients waited longer than 18 weeks last year.⁴

According to the principles of economics, there are two ways to reduce the excess demand- and that is technological innovations, which decrease price or an increase in the price ceiling (higher subsidies or a fee for service). **Technological innovations** are the way to sustain the regulated medical market in the short and long run, which has been identified by “Transform Your Care” and other governmental and organisational studies.

By implementing **zensor** and monitoring patients at home, not only will wait times be shortened, but also quality of care and economic burdens will be improved.

Graph 1



Medical Market Breakdown

Both cardiologists and primary care physicians can help optimize the health service through the use of **zensor** and home vital signs monitoring. Current statistics and processes of Palpitations, Atrial Fibrillation, and syncope have been examined to demonstrate the need for a more efficient diagnostic pathway.

Palpitations

Palpitations are very common and are described as an “uncomfortable awareness of a heart rhythm.”⁵ They can be brought on by diet, exercise, or lifestyle. Palpitations are the most common complaint of outpatients presenting to internists and cardiologists.⁶ Of the patients presenting with palpitations in England, 700,000 of them are affected with arrhythmias. Of the patients presenting, according to a report in New York State (referenced by the NHS), 43% had a cardiac aetiology, and 31% had a psychiatric.⁷ According to the NHS and the “Palpitations Pathway” an ECG is always called for in patients presenting with palpitations.

Many palpitations will be eventually diagnosed as “ectopic beats” which can be treated through reassurance, advice, and the reduction of aggravating factors including anxiety management or Beta-Blockers. However, to diagnose the ectopic beat (rather than an arrhythmia) ECG correlation must be obtained. In the case that there are no high-risk features, the patient can stay in primary care. It is at this point (Step 4 on Palpitations Pathway flow chart) that **zensor** can be applied. As quoted by the NHS:

*Obtaining an ECG recording at the time of symptoms of palpitations, so called 'symptom ECG correlation' forms the mainstay of diagnosis. **This can be extremely difficult if episodes are infrequent and short lived.** It is important that the correct ambulatory ECG method is employed in order to maximise the chance of success. The choice of method depends on the frequency of symptoms and whether the individual would be able to activate a recording device should activation be necessary to make an ECG recording.*⁵

Confirmation of palpitations must be corroborated. **zensor** is an accurate, efficient, cost effective, and user friendly replacement to older generations of Holter and Event monitors. There is a clear use for home ECG and vital signs monitoring.

Atrial Fibrillation:

Atrial Fibrillation (AF) is the most common type arrhythmia (irregular heartbeat). It is caused by an irregular electrical activity in the heart, and the most common risk associated with AF is stroke, though other complications such as heart and valve disease and chronic fatigue can also be associated.

- AF can be linked to as many as 1 in 3 strokes.⁸
- In the UK 15,500 strokes a year can be attributed to AF.
- In a study weighing the economic cost of AF, it was found that there was a direct cost of £243.9 million pounds (UK 1995) and almost doubling by 2000.⁹
- 1 in 100 of the total population have AF, and in the elderly the ratio increases to 1 in 10.
- AF increases the risk of blood clot, leading to a higher risk of embolic stroke. People with AF are five

times more likely to have this type of stroke, and further have higher chance of morbidity or mortality.

Of the costs associated with stroke and AF, hospitalisation and community care costs account for a large proportion:

For example: the unit cost of the Stroke Unit (Guy's and St. Thomas') £164.8 *per diem* multiplied by the mean number of days stay: 34.4 equals £5,669.12. The patient may then need multiple tests, ranging from £85-£750 per patient per test. Once out of the hospital, the patient may go to a nursing home, which averages at £570 per week. Of the total costs in the UK associated with stroke, only .51% account for diagnosis.¹⁰

Stroke and AF Statistics:

- One stroke can cost the NHS an average of **£30,000** in direct costs.¹⁰
- The total societal costs of stroke amount to **£8.9 billion per year**, direct cost amounting to half that cost (and 5% of total NHS spend).¹⁰
- **152,000 strokes a year** in the UK according to NHS (1 in 3 can be *linked* to AF)
- **£148 million:** Cost of strokes associated with AF
- Third highest cause of death in UK
- AF is associated with higher severity strokes and higher hospitalization costs
- In England, 12,500 strokes are *directly attributable* to AF – potentially preventable¹¹
- 15% rise in stroke patients with GP in last 5 years
- **20% rise in AF** patients with GP in last 5 years (GP QOF Registry)²
- 27,000 patients with AF in GP database for Northern Ireland

- There are around 1.2 million stroke survivors in UK- many left with disabilities
- Stroke is the largest cause of complex disability in adults¹²

Percentage of Recurrence After First Stroke	
3% to 10%	30-Day
5% to 14%	1-Year
25% to 40%	5-Year

Table 1: "StopAfib.org"

NICE guidelines recommend either warfarin (anticoagulation) or aspirin to help prevent blood clots that could cause a stroke. The British Heart Foundation states that AF screening could increase detection by 60% thus dramatically reducing costs. If just half of patients with strokes attributed to AF were prevented through earlier detection, there could be a **direct NHS cost saving of £187.5 million**. (Figures extrapolated from NHS and BJMP)

Ablation

Ablation is a surgical procedure and alternative to drug therapy to treat AF. Many doctors consider it a last line of care for AF that is not controlled through medication. A catheter is placed into the patient's vein or artery, then radiofrequency energy is used to destroy the affected area in the heart that is causing the arrhythmia. The purpose is to block the abnormal electrical impulses of the heart.¹³

Each year, approximately 50,000 ablations are performed in the US, and 60,000 in Europe. The UK is roughly 12% of the European population (and has a higher percentage of heart disease) so there are approximately 7,300 ablations performed per year.¹⁴

The success rates vary depending on type of arrhythmia. Dr. James Edgerton, a cardiologist specializing in AF presented a report finding a "great variability between doctors regarding what is considered a successful intervention and how they monitor a patient after a procedure."¹⁵

What he found was that when using short term ECG monitors and patient self-reporting were highly inaccurate when being used to assess reoccurrence, which could lead to "inappropriate clinical decisions post ablation regarding one's care." The most reliable way of capturing AF post ablation was with a 14-day monitor at regular intervals in the year after the procedure. He tested the following:

- over the phone patient self report
- a single instance ECG
- 1-day monitor
- 7-day monitor
- 14-day monitor, and
- a 90-day monitor

There was no statistical difference between the 14-day and 90-day monitors. Long-term (7 days or more) monitoring was essential for detecting abnormal rhythms post ablation that could lead to stroke.

Other studies support these findings. The Emory Atrial Fibrillation Centre reported (2008): "'Spot' ECGs underestimate the incidence of recurrent AF after surgical ablation for AF and show poor agreement with the more reliable 1-week auto-capture event recording." At each follow up stage (3-month, 6-month, and 12-month) there was a statistically significant higher percentage of AF recurrences recorded with a week's monitoring than with the 12-lead spot follow-up.¹⁶

Syncope:

In an article published in The British Journal of Medicine, it was reported that NHS

hospitals in England had a total of 119,781 episodes of collapse/syncope in the financial year of 2008/09. Of those, roughly 80% of patients were admitted for an average stay of 3 days accounting for over 269,245 bed days. Hospitalisation is estimated to account for 75% of the costs.¹⁷

The diagnosis of the cause of the loss of consciousness (LOC) is difficult, as there is not a clear standard of care. Causes of syncope can be split into two categories: cardiac causes and non-cardiac causes. Because the initial evaluation leads to diagnosis less than half the time, it is clear that efficient tests must be undertaken. Cardiac causes can be caused by arrhythmias such as: SVT, VT, Brady arrhythmia among others. (All can be auto-triggered or patient activated with **zensor**)

It is the recommendation of Sankar *et al* (2010) that testing should be moved out of the hospital when possible into outpatient monitoring. There are multiple different tests, initially starting with a standard 12-lead ECG at the time of admission, blood tests, and a pacemaker check. However, ambulatory ECG monitoring is highly recommended for those patients who do not exhibit arrhythmias during admission (more than half the time).

Similar to the AF and Palpitation pathway, an at home ECG monitor is suggested. For patients with frequent LOC, a Holter may be recommended, but when less often (less than daily) event recorders (external loop recorder) are recommended. **zensor** has the capability to be used in either of these situations- with the potential to improve outcomes as the patient does not have to activate the device if an arrhythmia is occurring.

In addition to the proprietary algorithms that capture arrhythmias, zensor uses a hydra-gel electrode that decreases motion artefact and gives a better signal quality for

more accurate specificity and sensitivity of the on-board algorithms.



The implementation of **zensor** can help the quality and cost of patient care in the following ways:

- Cardiologists have more accurate information sooner, cutting down the amount of hospital visits and wait time
- Patient has peace of mind, knowing their course of care has been started
- “Filtering” of patients, keeping a higher proportion of patients in primary care
- Quicker turn-around time as data available immediately after arrhythmia occurs
- Quicker diagnosis leads to preventative care
- Auto-trigger for arrhythmias and rate breach or patient activated for highest possible detection rate

- Primary care: Service can include specialist analysis and reports via the web accessible secure cloud server
- Cardiologists: Accurate 3-lead traces for event analysis
- Sleep Apnea: At home (with SpO₂ application)

Application of zensor Ischemic Stroke

An ECG recording must corroborate an Atrial Fibrillation diagnosis for an ischemic stroke. As patients with paroxysmal (infrequent) AF and chronic AF have similar risk of ischemic stroke, a device that can detect both is needed. Approximately 40% of patients with this type of stroke do not have a cause on initial work up. In a study published by the American Heart Association, a majority of the patients had asymptomatic AF, only 6 out of 98 patients studied had activated the recorder with an AF event.¹⁸

As was shown in the above statistics, AF greatly increases chance of stroke, but after a patient has a stroke, the cause must be diagnosed. Because many of the patients have “silent AF” or asymptomatic AF, detection can be difficult. In a recent study comparing traditional 24 hour Holter monitors and continuous event monitoring, there was a wide disparity found among the patients that had AF:

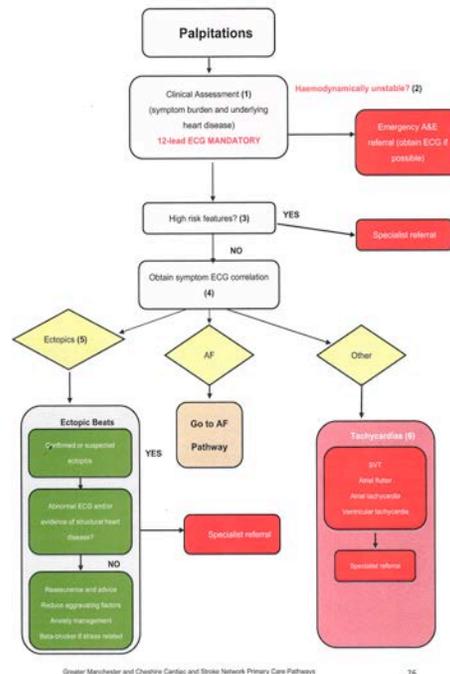
The 24-hour Holter monitor detected paroxysmal AF in 34.1% of the patients, and the continuous automated event recorder found 92.7% of AF events.¹⁹

zensor’s initial sensitivity and specificity tests support and improve on these findings due to the algorithms and hydrogel electrodes. Once the patient has been found to have AF, they can be treated

accordingly with anticoagulant therapy thus preventing future strokes and ending the diagnostic process of additional costly tests and bed days in a stroke clinic.

Palpitation Application:

The current palpitation pathway is shown here:



Step four shows the corroboration process where ECG and Event recording is currently done. The NHS uses a traditional 24-hour Holter or a 7-day Event monitor that is patient activated. Both have their respective drawbacks. As with AF, many palpitations do not present at time of recording, or in a 24-hour monitoring period. Studies show that Holter yields are between 33-35% and Event monitors yields are 66-83%.²⁰ While palpitations are usually symptomatic, there may be an underlying asymptomatic cause that would not be

picked up by the Event monitors currently used by the NHS. Patients can remain in the system for 9 months to a year while diagnosis of palpitations is sought.

zensor improves the quality of patient care while simultaneously lowering costs. AF, palpitations, syncope and post-ablation monitoring were shown as examples of how **zensor** can optimize the efficiency of the health service. The above use cases have been shown as specific examples of where **zensor** can be applied, however they are not the limit. Applications include:

- Asymptomatic or symptomatic arrhythmia detection
- Atrial Fibrillation detection

- Stroke prevention
- Stroke diagnosis
- Cardiac condition assessment
- Syncope of unknown aetiology
- Palpitations
- Sleep Apnea
- Respiratory diseases
- Post surgical monitoring
- Clinical Trials and Research

Ultimately, all aspects of the medical industry will need to work together to integrate more efficient technology to achieve cost savings and standard of care goals outlined in Transform Your Care. We at Intelesens play a small but vital role in the greater telehealth transformation that is currently in progress.



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