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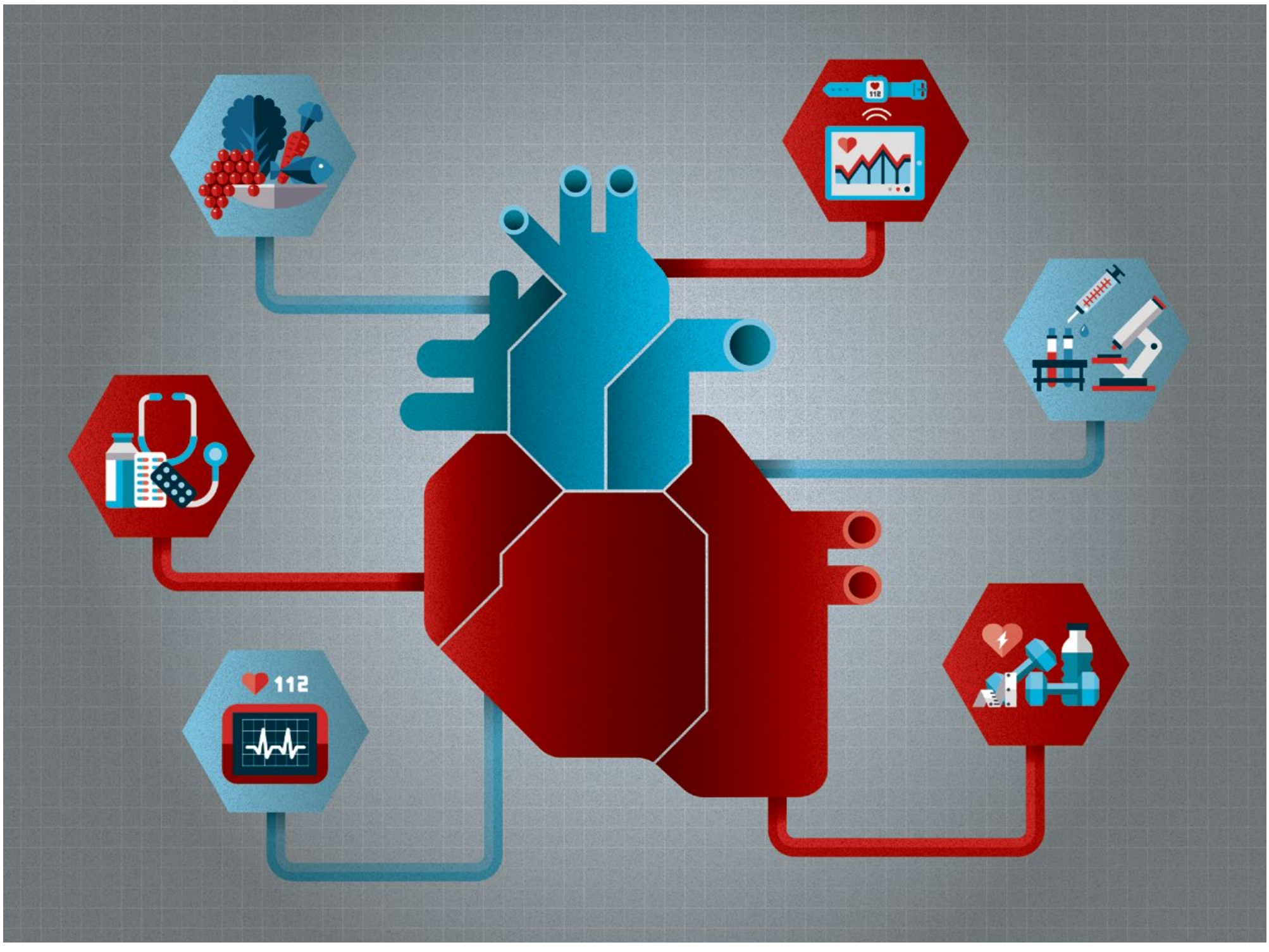
# CARDIOVASCULAR HEALTH





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# Battle to beat heart disease...

*Despite improvements in survival rates, more needs to be done to save an ageing population from cardiovascular disease*

◆ OVERVIEW

● NIGEL HAWKES

Doing well, but could do better. That's the report card on cardiovascular care in the UK. It is hard to cavil at data that shows a 36 per cent reduction in deaths from cardiovascular disease between 2001 and 2010 – by any standards that is an impressive result.

"We have seen a fantastic reduction in cardiovascular mortality," says Professor Huon Gray, national clinical director for heart disease at NHS England. "But the job's far from being done."

Cardiovascular disease still causes almost a third of all deaths and an ageing population multiplies the risks. "By 2022, the 85-plus age group will have increased by 44 per cent and we'll have nearly a million people living with heart failure," says Professor Gray. Rising obesity, if left unchecked, could chip away at the gains that have been made. The UK still lags behind other European countries, and within the UK regional and local inequalities remain stubbornly wide.

Most of the improvements have come from better control of the risks, which remains the focus of the strategy launched in 2013. All cardiovascular diseases have a common origin – atherosclerosis (furring or stiffening of the walls of the arteries) – so they should be seen as a single family of diseases. Many patients with one disease commonly suffer another, but this can be missed or care provided in a disjointed way.

**425**
people die from cardiovascular disease each day in the UK

**7m**
are living with cardiovascular disease

**Source:**
British Heart Foundation

A major worry is whether those at higher risk are being picked up early enough

A major worry is whether those at higher risk are being picked up early enough. To improve case finding, the last Labour government introduced NHS Health Check, which was supposed to provide 15 million adults between the ages of 40 and 74 with a cardiovascular examination by their GP. But by 2013 it had reached only a fifth of its target population; less than 5 per cent of patients were identified as high risk and of these only a third were getting the right treatment, according to a study commissioned by the Department of Health.

Public Health England relaunched the programme, ignoring criticisms from the Royal College of General Practitioners, among others, that it lacked evidence of effectiveness. The Department of Health rejected a suggestion from the House of Commons Select Committee on Science and Technology that the National Screening Committee should review the programme.

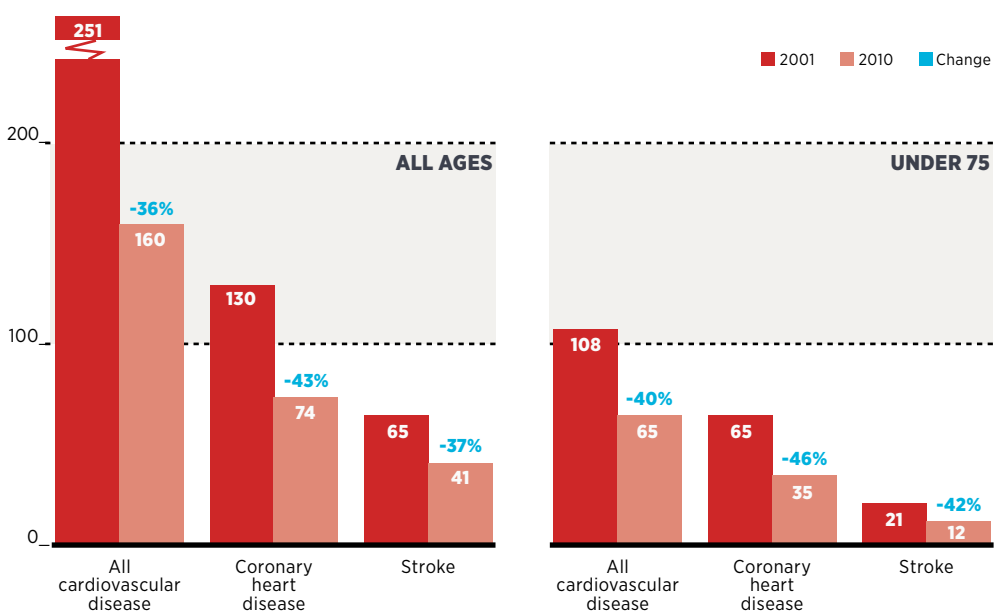
Dr Matt Kearney, a GP and a national clinical adviser to NHS England, says the programme is "a legitimate, rational response" to the problem. "We don't have the luxury of waiting for 15 years for randomised controlled trials to tell us this is going to work," he told a Westminster Forum seminar on cardiovascular services in July.

One GP who's not at all surprised it hasn't worked so far is Dr Azhar Farooqi, co-chairman of Leicester City Clinical Commissioning Group (CCG). "Only 8 per cent of practices achieved the numbers they were supposed to and 22 per cent of practices didn't do any checks at all. In Leicester our performance was really low," he says. So the CCG redesigned the scheme with templates to ensure GPs did the right checks and acted on them. Instead of inviting people in, GPs did the checks opportunistically when a patient of the right age attended for some other issue. £400,000 a year was provided to run the scheme.

This worked a lot better, he says, with many more patients seen and 13 per cent of them identified as high risk. Overall a third of patients checked had either high blood pressure, diabetes or a high risk of cardiovascular disease requiring action. But the scheme depends on public health funding, which comes from local authorities and is not ring-fenced. At least one county council has already stopped payments to GPs half way through the financial year.

New guidance suggests that anybody with a 10 per cent risk of developing

**UK MORTALITY FROM CARDIOVASCULAR DISEASES (DEATHS PER 100,000 POPULATION)**




**Source:** Office for National Statistics 2014

cardiovascular disease within a decade should be given the option of taking statins. But many with a much higher risk as a result of an inherited condition – familial hypercholesterolemia or FH – remain undetected. Of the almost 200,000 estimated cases in England, only 15 per cent have been identified.

This is despite guidelines being in place since 2008 that show how to do it. It is a genetic condition so whenever a case is identified, close relations should have their DNA tested for the gene responsible, in a process called cascade testing. "Here we are in 2015 and it's not happening," says Dr Peter Weissberg, medical director of the British Heart Foundation. "It's frustrating. Specialist commissioners said it wasn't their job because the condition was too common, while local commissioners said it wasn't their job either because it was too rare. It fell between two stools."

Although the foundation's job is supporting research, not filling in the gaps where the NHS has failed, it has made an exception in this case, co-funding a programme in Wales, and in 2014 deciding to pay for specialist FH nurses in 13 sites in England and Scotland. "We've identified 215 cases already, although we've only just started," Dr Weissberg says. "We aim to show the testing scheme is cost effective."

> **Although people dread a heart attack, many don't realise that the chance of survival is high**

Although people dread a heart attack, many don't realise that the chance of survival is high – around 90 per cent. Confusion arises because people confuse heart attacks with cardiac arrest, a different and much more lethal condition. In a heart attack, blood flow is blocked and heart muscle may be damaged, but in cardiac arrest the heart stops beating altogether. Fewer than 10 per cent of people survive a cardiac arrest that occurs outside a hospital.

Survival is much higher where more people are trained in cardiopulmonary resuscitation (CPR) and use it promptly. In public places the availability of defibrillators can help, but 80 per cent of cardiac arrests take place at home. Calling 999 quickly and providing CPR is the best a relation or bystander can do, and it might double the survival rate. The British Heart Foundation supplies training DVDs and kits to all secondary schools, and aims to train two million people a year in CPR. That could save 5,000 lives, says Dr Weissberg.

## 10 STRATEGIC POINTS OF ACTION

Strategy agreed in 2013 sets out ten key actions to improve cardiovascular health in England. But how likely are they to be achieved?

**01 IMPROVE MANAGEMENT OF CARDIOVASCULAR DISEASE (CVD) AS A FAMILY OF DISEASES**
This needs new service models crossing primary, acute and community care. NHS Improving Quality was supposed to be managing the process, but it has since been abolished.

**02 IMPROVE DATA ON RISK FACTORS TO REDUCE INEQUALITIES**
Healthier lifestyles would be a major gain, but the strategy relies on persuasion and voluntary change by the food industry. Taxes on unhealthy foods are ruled out. This may not be enough, critics say.

**03 IMPROVE IMPLEMENTATION OF THE NHS HEALTH CHECK**
Six years after it began, the Heath Check lacks professional buy-in and evidence of effectiveness. Poor implementation so far and the doubtful commitment of local government make success a long shot.

**04 IMPROVE NG IN PRIMARY CARE**
Software packages can help GPs identify patients at risk, but not all use them. Improvement should be possible.

**05 IMPROVE IDENTIFICATION OF INHERITED CARDIAC CONDITIONS**
NHS England will work with the chief coroner to improve processes for identifying inherited conditions. But is the death certification process in England up to it?

**06 IMPROVE MANAGEMENT OF CVD IN PRIMARY CARE**
There is plenty of scope for recasting incentives for GPs to manage care better. The best already do a good job, so this is more a case of chasing up laggards and narrowing variation.

**07 IMPROVE ACUTE CARE**
Training in cardiopulmonary resuscitation or CPR, providing maps showing where defibrillators are and awareness programmes are one leg. The other is providing fast access to the right treatment in hospitals, seven days a week.

**08 IMPROVE CARE OF THOSE LIVING WITH CVD**
Rehabilitation after a heart attack is variable and often poor. There is plenty of room for improvement, but not much clarity on who will be responsible for the assessments and care plans promised.

**09 IMPROVE END-OF-LIFE CARE**
Palliative care has been largely restricted to cancer patients, but others could benefit. Some pioneering regions have already shown it can help.

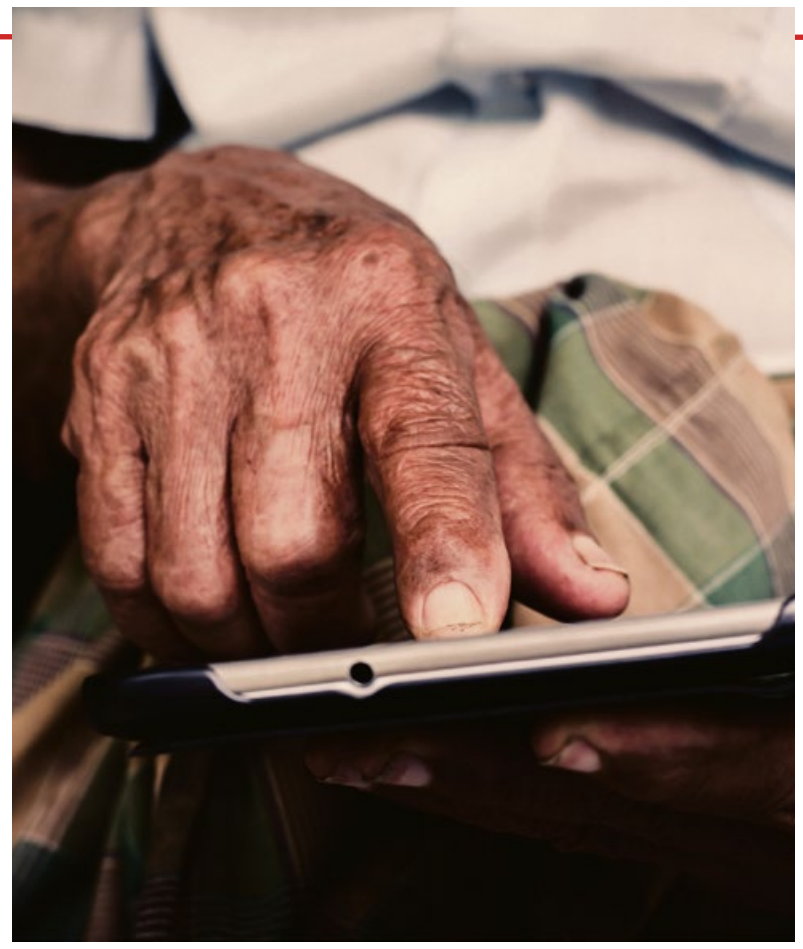
**10 IMPROVE THE USE OF INFORMATION TO DRIVE IMPROVEMENT**
Transparency drives improvement, the government believes. If so, plans to make lots more data on quality and outcomes public are a good idea.

# Technology is a se

*The ubiquitous smartphone, leading the way for mobile technology, is on the cusp in the self-management of their conditions*

◆ **SELF-MANAGEMENT**

● **DANNY BUCKLAND**



Mobile technology may sometimes appear a refuge for the gaming obsessive and fitness fans who can recite their personal bests for treadmill runs and oblique crunches more accurately than their children's birthdays.

But its use as an effective diagnostic tool and early-warning system is gathering pace as we learn how to stay healthy by harnessing the power of microchips that can be smaller than a grain of rice.

The number of health apps has doubled in two years to more than 160,000 and 70 per cent of the UK population owns a smartphone that can now deliver precise and engaging advice from asthma to yeast infections. We are beyond a tipping point where it is easy, and safe, to locate and use digital health information.

The growth factors of self-management are clear: a creaking NHS and fears about later-life health have combined with heightened innovation and increased trust in online information to create a motivating potion. And everyone knows it. GPs are using digital monitoring and directing patients to supporting apps, and pharmaceutical companies are investing heavily – their number of apps jumped 63 per cent in 2014 compared with 2013.

"Digital's ability to change the way people view their own health is just getting started as we move well beyond fitness and activity tracking to medical apps, such as those obtaining electrocardiogram, blood pressure or glucose readings to diagnosing ear infections in kids or sleep apnea in adults," says Dr Eric Topol, a cardiologist and director of the Scripps Translational Science Institute, who wrote *The Patient Will See You Now*, which highlights the rising potency of patient empowerment.

"Those using these medical apps and hardware are feeling quite empowered and excited to take more charge of their care with respect to diagnosis and monitoring. Good examples are patients doing their blood pressure frequently through their smartphone and taking a much more active role.

"When patients are doing their own routine observations and many diagnostics through their smartphones, the work for doctors will be decompressed, leaving more time for interpretation, guidance and formulation of treatment options."

But Dr Topol believes the pace of change is not fast enough and that patients should have a civil right to own their medical data so they can become more involved in managing their health and treatment.

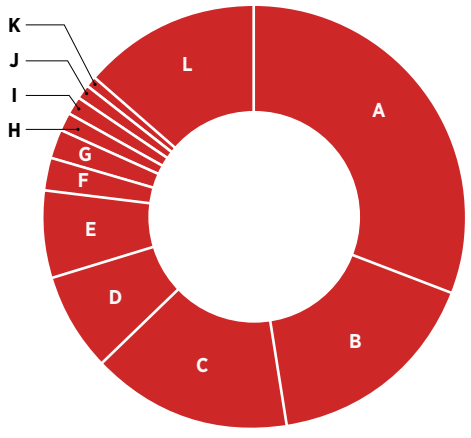
The government has fixed digital technology at the heart of its *Five Year Forward View* to reboot the NHS and minister for life sciences George Freeman told the recent NHS Expo in Manchester: "We need to transform healthcare in the NHS from a 20th-century model in which health is something done to you, to a 21st-century world in which we empower people to take more responsibility over their own health and life choices."

He predicts the UK's digital health industry will grow by nearly £1 billion over the next three years, but the amount it shaves off public expenditure by encouraging people to manage their conditions without seeing their GP is just as important. The NHS is facing a funding crisis with an additional £5 billion needed by 2018 and a further £30 billion by 2021 to cope with rising demand from an ageing population.

Boosting the nation's health economy is valuable, but people still need encouragement and guidance to pick up their smartphone and log on rather than dialing the GP receptionist at the first sign of a snuffle. There are an estimated 165,000 apps already available in an arena dominated by lifestyle, fitness and wellness – the choice is bewildering.

Initiatives from the Department of Health, which is exploring a kite mark system, and the European Commission, which created the European Directory of Health Apps, will provide signposts and GPs can underscore which app to choose.

**SHARE OF DIGITAL HEALTH APP MARKET 2014**




| | | |
|---|---|---|
| A | Fitness | 30.9% |
| B | Medical reference | 16.6% |
| C | Wellness | 15.5% |
| D | Nutrition | 7.4% |
| E | Medical condition management | 6.6% |
| F | Electronic health records | 2.6% |
| G | Continuing medical education | 2.1% |
| H | Compliance | 1.6% |
| I | Diagnosis | 1.4% |
| J | Reminders and alerts | 1.1% |
| K | Remote consultation and monitoring | 0.6% |
| L | Others | 13.6% |

**Source:** Deloitte 2015

# lf-help remedy

*of transforming healthcare by increasingly involving patients*

### SINGLE MOST IMPORTANT SERVICE HEALTH APPS SHOULD PROVIDE

Asked of patients with a long-term condition

| | | |
|---|---|---|
| 01 | Give me understandable information on symptoms/medical conditions | 23% |
| 02 | Help me communicate with my doctor/nurse | 17% |
| 03 | Allow me to examine my health records/medical tests online | 16% |
| 04 | Help me to track any medical symptoms | 14% |
| 05 | Help me track activities to improve my health, or keep me healthy | 13% |

**Source:** Deloitte 2015

### TOP BENEFITS OF DIGITAL HEALTH FOR PROVIDERS


**Source:** Deloitte 2015

"Doctors are increasingly recommending health apps to help people understand the impact of their behaviour," says Karen Taylor, director of Deloitte's Centre for Health Solutions. "If you are diagnosed as a high risk for cardiovascular disease or have had a heart attack or atrial fibrillation then there is a clear incentive to do something and advances in digital health have made it easier to track your condition in real time.

"If you have something on your wrist on a smartphone app that can give you readings and advice at the touch of a button, it is easy to manage your health, and we have seen notable changes of behaviour in some groups."

> **Digital's ability to change the way people view their own health is just getting started as we move well beyond fitness and activity tracking to medical apps**

But she adds there is still a huge task to connect with the hard-to-reach groups of society, which have been impervious to healthcare advice. The challenge is to take digital beyond the groups who are comfortable with changing their health regime and improving their fitness.

A survey by Patient View notes that 69 per cent of the public rate trust as the most important aspect of online health information delivery, followed by ease of use at 66 per cent and data safety at 62 per cent. The entrance of tech giants Apple and Google into health is expected to improve trust ratings as their devices start to make a difference. The new Apple Watch has already been credited with alerting a wearer to his dangerously high heart beat in time for life-saving treatment.

"There is increasing evidence of improved outcomes from using technology and that will drive it even further," says Taylor, co-author of Deloitte's 2015 *Connected Health* report. "Digital start-ups are now bringing clinicians together with app developers as it is clear they will not endorse a product unless they are involved or engaged in developing the technology.

"But doctors are becoming savvier at using technology and, although there may be some concern that their professional knowledge may be undermined, we still need clinicians. If you are having a heart attack, then no number of apps is going to stop it – you will need clinical intervention."

### 5 OF THE BEST HEALTH APPS

**01 HEALTHY HEART 2**
A prevention and monitoring app for patients with high blood pressure or high cholesterol, it tracks blood pressure, pulse, cholesterol, blood glucose and potassium readings as well behavioural and environmental factors. It helps motivate a healthy lifestyle, while the data aids doctors to identify conditions and monitor the effect of treatments. **FREE.**

**02 WORLD WALKING**
Promotes increased activity through walking with the aim of reducing the risk of heart disease. Devised by Scottish cardiac rehabilitation group, the Inverclyde Globetrotters, it provides virtual maps of global destinations for people to reach, while just walking locally. The Globetrotters have walked more than 160,000 kilometres through 100 countries without leaving their home town of Greenock. **FREE.**

**03 BHF POCKET CPR**
The app follows the British Heart Foundation's successful Staying Alive advertising campaign, providing easy-to-follow instructions to learn and practise cardiopulmonary resuscitation first aid. **FREE.**

**04 SLEEP CYCLE**
Monitors sleep patterns, revealing how long you are in a deep or light sleep and wakens you from a light phase to promote a relaxed feeling at the start of the day. Developed by North Cube, of Sweden, it is credited with helping people sleep better and promotes improved health throughout the day. It also has a measuring device that detects heart rate. **79p.**

**05 DIABETES RISK CHECKER**
Developed by UK doctors and academics, it calculates the risk of developing type 2 diabetes over the next ten years through a series of questions. Using data from the NHS and thousands of GPs, it can encourage behaviour change by providing accurate percentage analysis of future risk. **79p.**

# UK lags behind in using the latest treatments

*Lives are being lost and blighted in the UK as we lag behind other Western nations in introducing innovative procedures and new drugs*

◆ **UK COMPARISONS**

● **NIGEL HAWKES**

There are no secrets in cardiovascular care, no magic treatments that doctors or hospitals keep to themselves and deny to others. Everything that works is published, promoted and shared. But the speed with which national health care systems adopt the best care varies hugely, with the UK all too often lagging behind the rest.

Much has been made of the improvement in heart attack survival in the UK, but a study last year put it into perspective. Compared with Sweden, a third more UK patients died within a month of having a heart attack. More than 11,000 deaths could have been prevented between 2004 and 2010 if UK care standards had been as good as Sweden's.

Why? In a nutshell, the NHS does slowly what others do fast. Professor Harry Hemingway from University College London, who led the study published in The Lancet, says: "The uptake and use of new technologies and effective treatments recommended in guidelines has been far quicker in Sweden. This has contributed to large differences in the management and outcomes of patients."

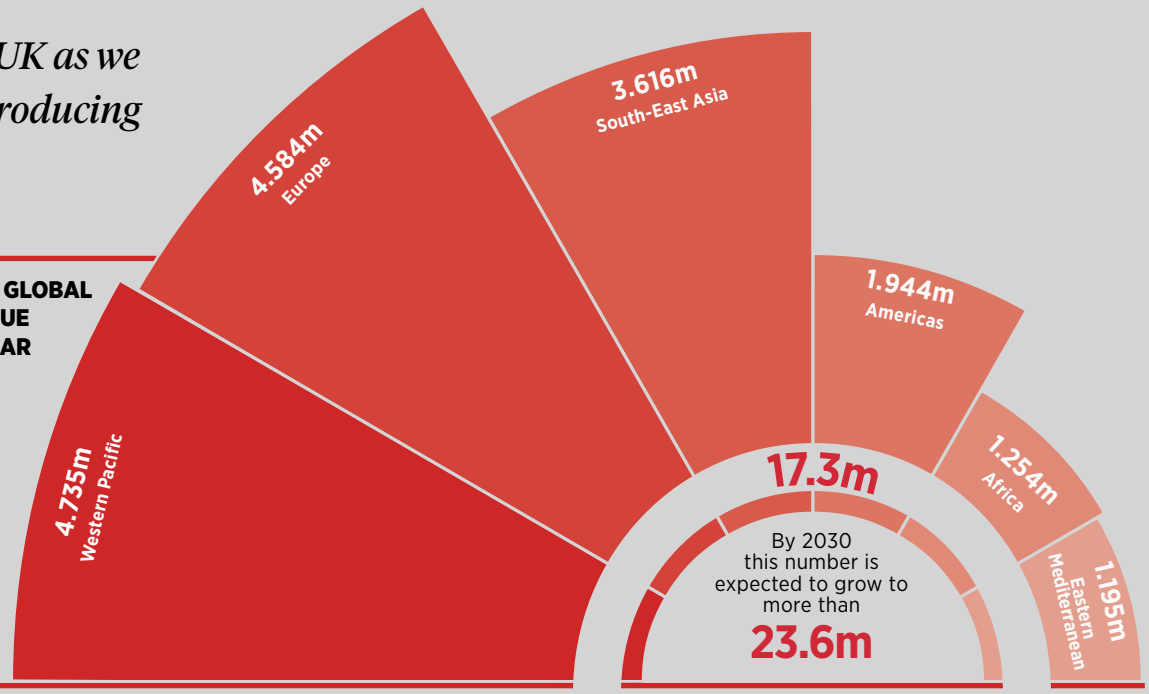
In this case, the key may have been the speed with which the two countries adopted angioplasty – opening up constricted coronary arteries – as an emergency treatment. In Sweden, 59 per cent of patients had this treatment; in the UK it was 22 per cent.

The same pattern can be discerned across the board, with almost every new innovation taking longer to be adopted here than abroad. By the end of the study, the gap had narrowed, but this is a small consolation because by then we had failed to adopt lots of other new technologies. The waves of innovation that carry others on almost always leave the NHS disconsolately paddling in their wake.

The treatment of heart rhythm disturbances is a textbook example. In drugs, surgical treatments and even in its public health response, the UK lags. Nor is this a small unimportant corner. "Sudden cardiac arrest is the number-one killer in the UK and in Western Europe," says Trudie Lobban, founder of the Arrhythmia Alliance. "It kills 100,000 people in the UK every year, more than breast cancer, lung cancer and Aids combined."

The commonest cause of cardiac arrest is atrial fibrillation (AF), a heart rhythm disturbance. Audits show that UK patients are less likely to get treatment for such conditions than they would in

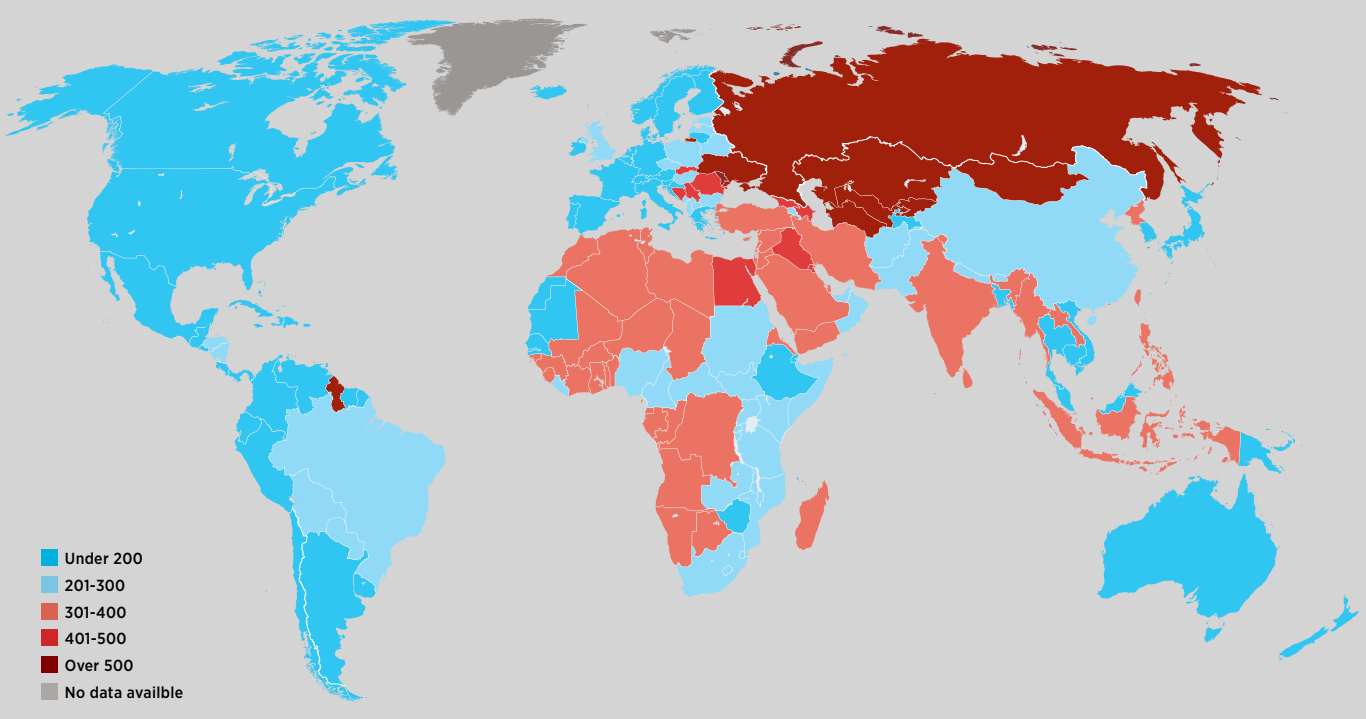
**TOTAL NUMBER OF GLOBAL ANNUAL DEATHS DUE TO CARDIOVASCULAR DISEASE (CVD)**




**Source:** World Health Organization (WHO) 2014

**Source (centre):** American Heart Association

**GLOBAL MORTALITY RATES FROM CVD PER 100,000**




**Source:** WHO

**LOWEST CVD MORTALITY RATES PER 100,000**

| | |
|---|---|
| Japan | 82 |
| Israel | 86 |
| France | 86 |
| Canada | 89 |
| Australia | 92 |

**HIGHEST CVD MORTALITY RATES PER 100,000**

| | |
|---|---|
| Turkmenistan | 712 |
| Kazakhstan | 636 |
| Mongolia | 587 |
| Uzbekistan | 578 |
| Kyrgyzstan | 549 |

**Source:** WHO 2014

**UK CVD MOR**

157 – 266
267 – 300
301 – 338
339 – 400

**AVERAGE A FROM CVD**

England

Scotland

Wales

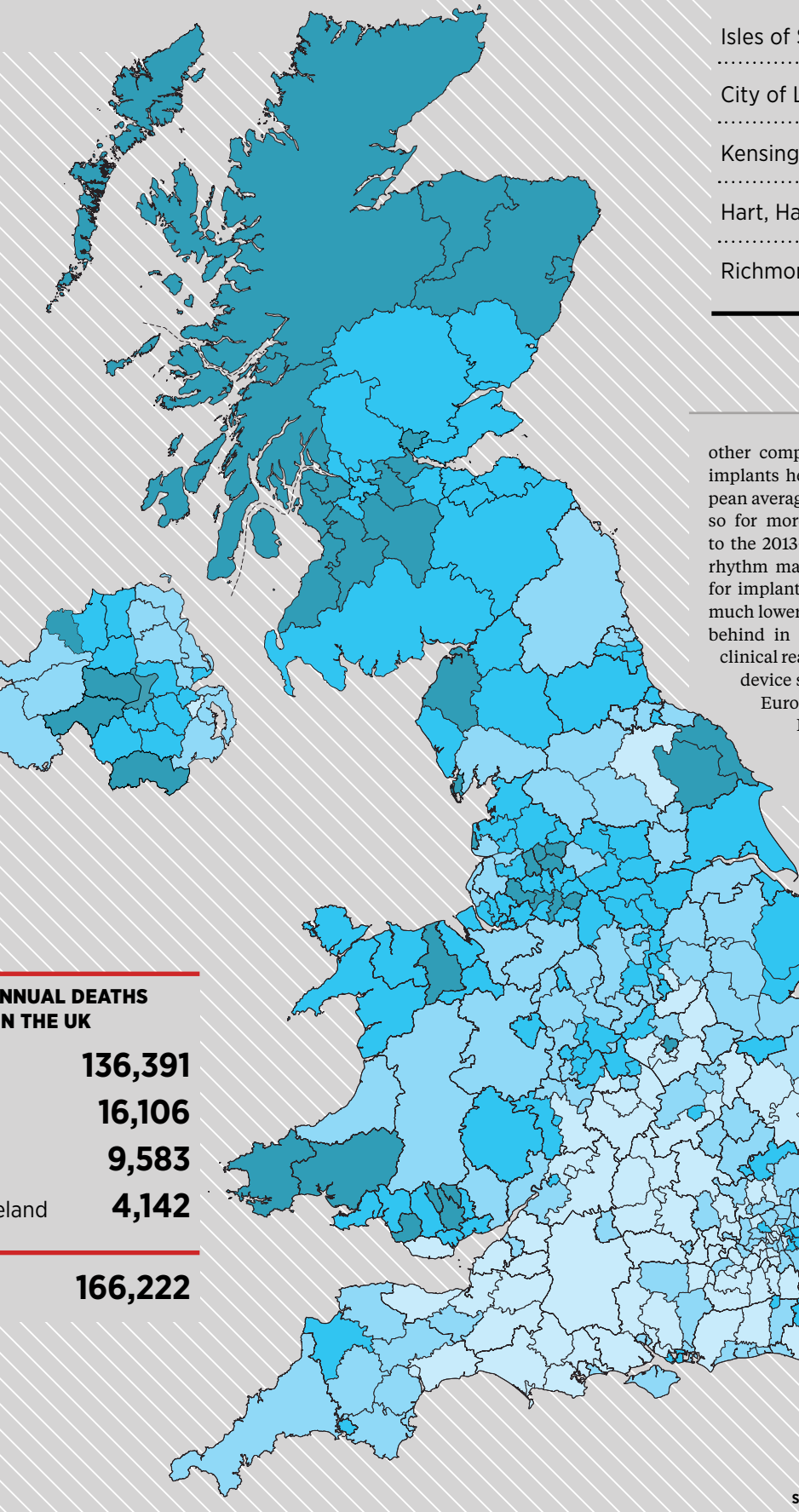
Northern Ire

UK total

**UK CVD DEAT**

50,000
40,000
30,000
20,000
10,000
0

## TALITY RATES BY LOCAL AUTHORITY PER 100,000



## NNUAL DEATHS N THE UK

| | |
|---|---|
| | 136,391 |
| | 16,106 |
| | 9,583 |
| eland | 4,142 |
| | 166,222 |

**Source:** British Heart Foundation 2014

## LOWEST UK CVD MORTALITY RATES PER 100,000

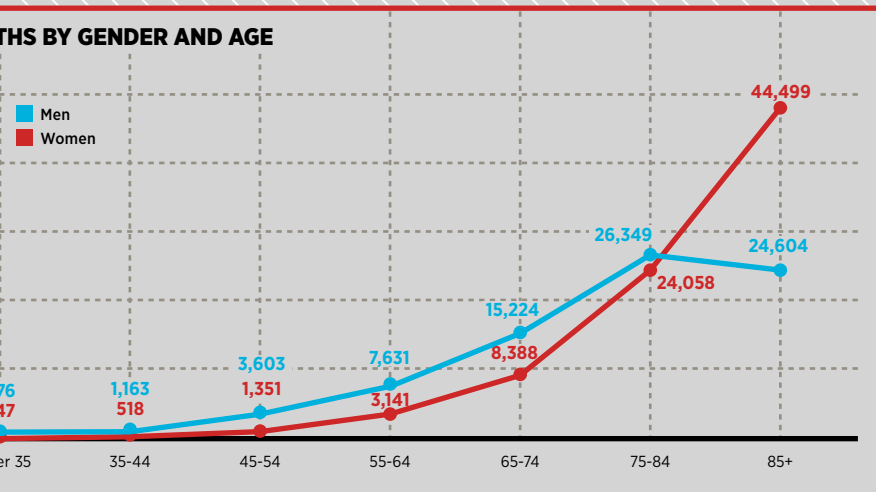
| | |
|---|---|
| Isles of Scilly | 157 |
| City of London | 178 |
| Kensington and Chelsea | 197 |
| Hart, Hampshire | 213 |
| Richmond upon Thames | 213 |

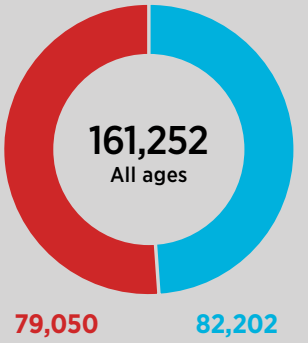
## HIGHEST UK CVD MORTALITY RATES

| | |
|---|---|
| Glasgow | 400 |
| Hyndburn | 395 |
| Blaenau Gwent | 395 |
| Tameside | 394 |
| Blackburn with Darwen | 393 |

**Source:** British Heart Foundation 2014

## THS BY GENDER AND AGE




**Source:** British Heart Foundation 2014

other comparable counties. Pacemaker implants here are well below the European average and have been consistently so for more than a decade, according to the 2013-14 national audit of cardiac rhythm management devices. The rate for implantable cardiac defibrillators is much lower and has been falling further behind in recent years. There are no clinical reasons why the need for either device should be lower here than in Europe, the audit reports.

Exactly the same is true of transcatheter aortic valve implantation (TAVI) in which heart valves are replaced through a catheter, a procedure suited to elderly and infirm patient too ill to risk open-heart operations. In 2011, one study showed, 36 per cent of suitable patients in Germany were treated by TAVI, compared with 9 per cent in the UK.

Catheter ablation, a technique for treating and usually curing heart rhythm disturbances using fine electrodes threaded into the heart through veins, shows a parallel pattern. "Sadly, we lag behind Europe," says Ms Lobban. She's right: the rate for the procedure in the UK is at the bottom of the Western European average. Denmark performs nearly three times as many ablations for AF, Switzerland almost twice as many, Germany 44 per cent more.

The uptake of new drugs tells the same tale. New medicines to thin the blood and reduce the risk of strokes in AF patients have been on the market for several years, are approved by the National Institute for Health and Care Excellence (NICE), but are little used. Audits show uptake much lower than NICE expected.

> **Lengthy regulatory processes are another cause of delay, most commonly for drugs that need both evidence of effectiveness and cost effectiveness**

In the House of Commons last November, MP Barry Sheerman, whose wife has AF, asked: "What is the good of innovation if we do not use it? For the one million people who suffer from atrial fibrillation, these three new NICE-approved drugs are a life-saver; they make life worth living. But only about 6.5 to 7 per cent of people have been prescribed the new drugs, as they are being blocked by clinical commissioning groups and GPs. What will the minister do about that?"

Life sciences minister George Freeman replied that he had launched a review, now called the Accelerated Access Review and chaired by Sir Hugh Taylor, a former permanent secretary at the Department of Health. It aims to identify how regulation, payments systems and uptake could be reformed to speed the process. Don't hold your breath: in 2011 the NHS launched Innovation, Health and Wealth, a strategy designed "to make innovation and its spread central to what we do". Three years later the Medical Technology Group found that it had made very little difference.

Barbara Harpham, chair of the group and also director of Heart Research UK, blames conservatism and the operation of a tariff system for some of the delays. She points out that one intervention that is now widely used in the NHS is stenting – opening up clogged arteries and introducing a tiny expandable cage to keep them open.

"Stents are a cash cow," she says. "Patients are in and out in a day. You can do ten stents in a day and it's easier than a TAVI. Hospitals are more likely to do the procedures that get easy money."

Proposed cuts to the tariff – the payment to a hospital for each procedure carried out – could make things worse. "NHS England is proposing tariff cuts of between 17 and 45 per cent," says Ms Lobban of the Arrhythmia Alliance. "What will happen if these go through is that the UK won't be able to implant the latest technology – it will be like implanting an old mobile phone rather than an iPhone 6. Some of the newer devices last ten to eleven years, while the older ones last three to four years, so in the long term it will cost the NHS more." UK specialists have signed a letter opposing the changes.

Lengthy regulatory processes are another cause of delay, most commonly for drugs that need both evidence of effectiveness (a licence) and cost effectiveness (approval by NICE). Two new cholesterol-lowering drugs, Amgen's Repatha and Sanofi's Praluent, have recently won licences for use in the UK, but their high price compared with statins is likely to mean NICE will approve them for very few patients.

Much more encouraging is the Early Access to Medicines scheme, which aims to fast track promising drugs and make them available before they are licensed. In September, the first non-cancer drug was accepted on this scheme, Novartis' LCZ696 (sacubitril valsartan) for heart failure. "Based on what we've seen so far, access to this new medicine will help patients live longer and keep them out of hospital, compared to currently available treatment," says Iain Squire, Professor of cardiovascular medicine at Leicester. Heart failure affects 550,000 people in the UK and costs the NHS £2.3 billion a year.

But this is just a small thread of optimism in a canvas woven in sombre colours. If you are going to suffer any heart disease, the UK is not the best place to choose.

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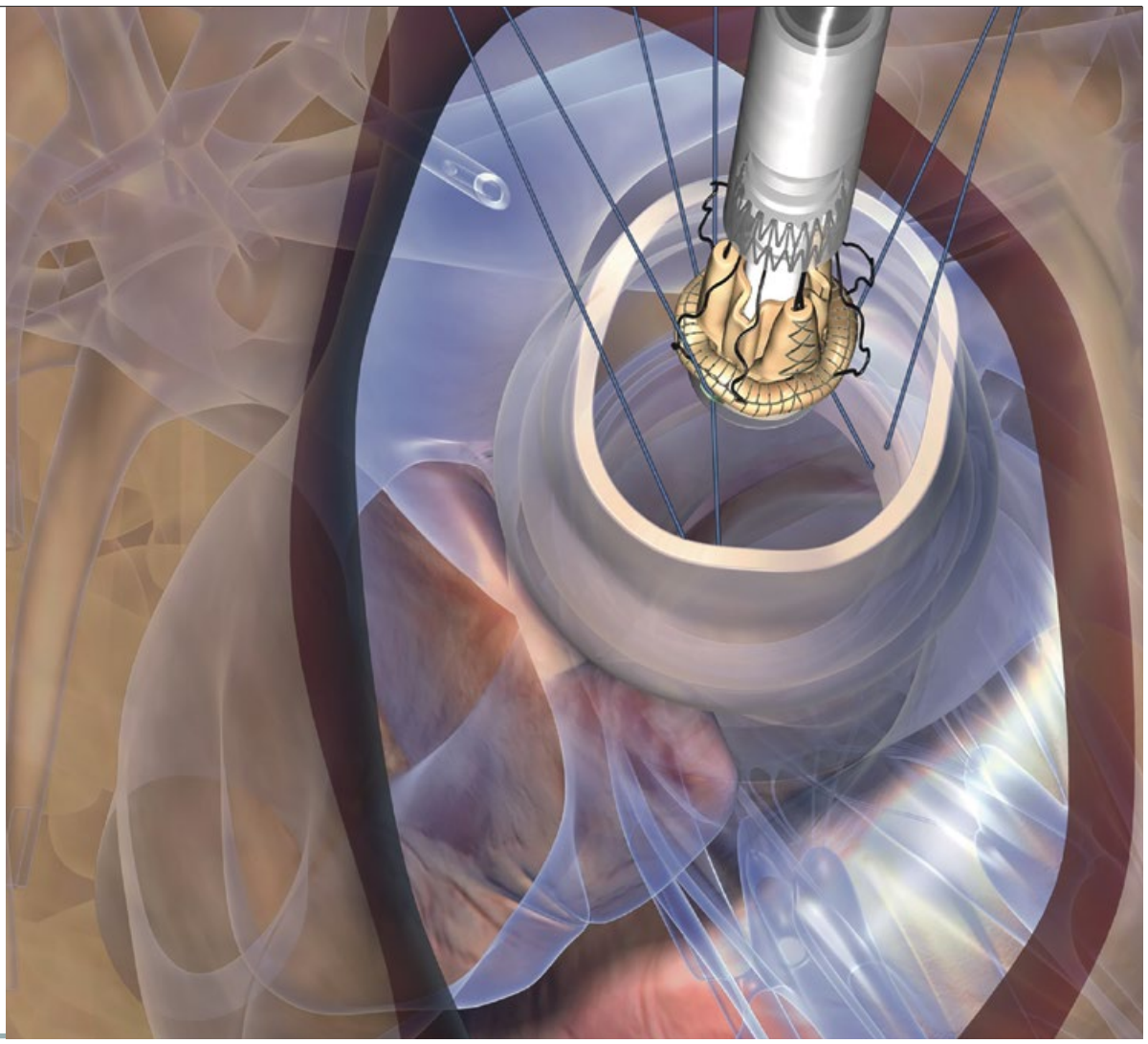
COMMERCIAL FEATURE

# MAJOR ADVANCE IN HEART SURGERY

*An innovative sutureless tissue valve is revolutionising heart surgery around the world by reducing critical surgical time and healthcare costs*



SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

Sorin's Perceval valve, which has a self-anchoring frame so surgeons can replace diseased aortic valves without sutures, is proving a major technological advance and is moving rapidly towards being the standard of care.

The device, which has been used successfully in more than 12,000 patients in 48 countries, reduces operation time, the risk of complications and has been shown to improve patient outcomes.

Its ingenious design enables rapid deployment and offers a significant boost to the 1.68 million people in Europe who suffer from aortic stenosis, a condition where a heart valve leaflet becomes calcified and suffers reduced flexibility and efficiency.

Aortic stenosis, which forces the heart to exert greater force to circulate blood, is the most common heart valve disease and has a mortality rate of 30 to 50 per cent in severe cases within a year of diagnosis.

Replacing the damaged valve traditionally requires 15 to 18 permanent sutures, but the Perceval comprises a bovine pericardium inserted in a super elastic that adapts to the anatomy of the aorta and to follow its movements, relieving the stress on the leaflets at each cardiac cycle and targeting an enhanced durability.

Its flexibility and simplicity of use means that operation trauma is reduced and more than 100 clinical papers have demonstrated benefit across factors such as surgical duration, the length of post-operative hospital stays, blood-flow dynamics, transfusions and healthcare costs.

> Sorin's Perceval valve reduces operation time, the risk of complications and has been shown to improve patient outcomes

It can be precision-placed with a reproducible surgical technique in both minimally invasive cardiac surgery (MICS) and conventional surgery. It can also more than halve the critical cross-clamp time taken in traditional aortic valve replacement procedures to 30 minutes.

The advantage of Perceval was characterised in a report by Dr Kevin Phan's Collaborative Research Group, published in the *Annals of Cardiothoracic Surgery* in April 2014, which said: "Sutureless aortic valve replacement (SU-AVR) has emerged as an innovative alternative for treatment of aortic stenosis. By avoiding the placement of sutures, this approach aims to reduce cross-clamp and cardiopulmonary bypass (CPB) duration, and thereby improve surgical outcomes and facilitate a minimally invasive approach suitable for higher-risk patients."

Its success was underscored by results from a five-year follow-up from three prospective clinical trials, which followed more than 700 patients across 25 European centres between 2007 and 2012 to evaluate feasibility and valve safety. Its report, published by Malak Shrestha in the *European Journal of Cardio-Thoracic Surgery* earlier this year, said: "This European multi-centre experience, with the largest cohort of patients with sutureless valves to date, shows excellent clinical and haemodynamic results that remain stable even up to the five-year follow-up.

"Even in this elderly patient cohort with 40 per cent octogenarians, both early and late-mortality rates were very low. There were no valve migrations, structural valve degeneration or valve thrombosis in the follow-up. The sutureless technique is a promising alternative to biological aortic valve replacement.

"In summary, this study reports the widest and longest experience with a sutureless valve and highlights its safety and efficacy even in an elderly population. The Perceval valve implantation could be easily performed by offering a significant reduction of cross-clamping and CPB times compared with both the traditional valve prostheses and the other sutureless prostheses available on the market even when performed via a minimally invasive approach.

"Therefore, in patients needing aortic valve replacement with or without concomitant procedures, this device could have an advantage compared with conventional sutured valves. The continuation of the patient follow-up will provide further assessment of long-term valve performance."

Professor Vinnie Bapat, a consultant cardiac surgeon at London's Guy's and St Thomas' Hospital, highlights that future reinterventions with transcatheter aortic valve implantation (TAVI) valves are safe and feasible with the Perceval, thanks to its unique design.

Sorin, which has a track record for innovation in cardiac surgery and cardiac rhythm management, and has more than one million patients treated with its devices every year, developed Perceval after an intensive research and development programme into improving outcomes for aortic valve replacement patients.

The Perceval has innovation at its core to give it a unique mode of action and tests showed its durability as it recorded no failures after two billion cycles, the equivalent to 50 years of natural heart life.

More than 12,000 implants


Publications to date

Available in 48 countries worldwide

Thanks to its ease of implant and encouraging results, the Perceval has the potential to become the valve of choice to treat patients eligible for aortic valve replacement with biological valves.

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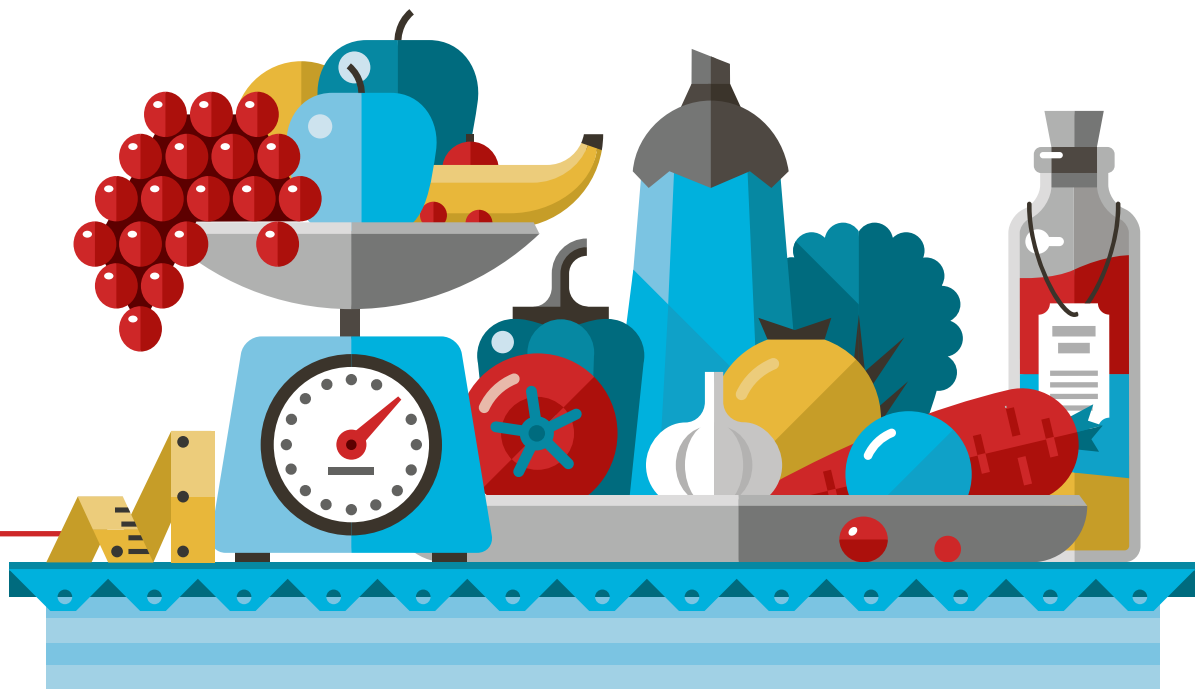
# Campaign to make food heart-healthy

*Regulation and voluntary initiatives by food manufacturers have combined to improve nutrition, but areas for improvement remain*



◆ BRANDS

● CORRINE SWAINGER

Over the past 40 years significant clinical advances have been made in treating heart disease; however, the focus has now switched to preventing ill-health through lifestyle changes, such as stopping smoking, increasing exercise and eating healthy food. This has led to a greater demand for improved nutrition.

Linda Main, lead dietician for HEART UK, the cholesterol charity, says this demand has been driven by various factors, which include new UK and European Union regulations, scientific evidence, and improved public awareness about the importance of nutrition in heart disease.

"In response, many manufacturers have reformulated their food products and revised their branding for consumers," she says. October, for example, is National Cholesterol Month.

An early factor driving consumer product changes was the 2003 Scientific Advisory Committee on Nutrition's report on salt and health, which set initial salt reduction targets. Since then, the average daily salt intake in the UK has fallen by 15 per cent. This is mainly due to manufacturers reformulating the salt content in a wide range of products.

Consumer awareness of trans-fat content has also forced many UK manufacturers to reduce the amount of this substance in their food products. Trans-fats can damage health by increasing the levels of LDL – "bad" cholesterol – and reducing levels of HDL – "good" cholesterol. The UK consumption of trans-fats has decreased from 2.1 per cent of average energy intake in 1985 to an estimated 0.7 per cent in 2012.

In addition, many food manufacturers have signed up to the elimination of trans-fats under the Department of Health's 2010 Responsibility Deal, which relies on voluntary action by producers and retailers to tackle diet-related ill-health.

In line with this, several companies, including Mars, Kellogg's and McDonald's, have changed their product recipes. In January, Britvic also announced it would be axing all full-sugar lines from its Fruit Shoot squash range. In addition, it will be carrying out a rebranding launch of its no added sugar range. According to Britvic, the company has made these decisions after "listening and responding to parents' needs, and implementing our own plans to support voluntary initiatives to encourage healthy lifestyles".

> **Many manufacturers have reformulated their food products and revised their branding for consumers**

The UK's voluntary traffic light food labelling system, rolled out in 2013, has also had a major impact on the reformulation of food products. Developed by the Food Standards Agency, this scheme was designed to make it easier for consumers to make healthier choices. The system uses red, amber and green signals on the front of packages to show whether a product is high, medium or low in fat, saturated fat, sugars and salt.

Many large UK retailers and manufacturers have since adopted this colour-coded system. Ms Main from HEART UK points out: "After Tesco started using it, they saw that customers were spending more time comparing these nutrition labels across different brands and often opted for the healthier option." As a result, Tesco changed the ingredients in many of their own products to reduce their use of red labels.

In July 2014, HEART UK trademarked its Product Approval Scheme logo across the EU as a benchmark for cholesterol-lowering foods available for consumers. The logo can now be used on packs and in advertising and other promotional materials by food products that pass stringent tests overseen by the HEART UK Product Approval Working Group.

Several products have now received this approval, such as Benecol, a range of spreads, yogurts and mini-drinks fortified with plant stanols. Studies show a daily intake of Benecol lowers cholesterol by 7 to 10 per cent in two to three weeks, as part of a healthy diet and lifestyle. Other approved HEART UK products include Alpro, MornFlake, Shredded Wheat and Oatwell.

However, not all brands have been so successful. In 2014, Kellogg's withdrew cholesterol-lowering cereal Optiva, after eight years on the UK market, following poor retail sales. According to food industry experts, Optiva struggled to find its brand identity.

Brand specialists Thrive Unlimited stress that consumer healthcare marketing should be "accessible, chatty, natural brands that talk to people, rather than those that dictate and shout about their health credentials".

Research shows that marketing plays a significant role in influencing children's dietary choices. The current self-regulatory system for non-broadcast advertising is weak and allows products which are outlawed from children's television to be marketed to children online.


Benecol yoghurt drink with HEART UK product approval logo

Websites for food and drinks almost exclusively promote products that are high in sugar and/or fat and/or salt, often using techniques which children will find difficult to identify as advertising, for example "advergames", downloads and competitions. Studies show that advergames, which are currently unregulated, are even more powerful than traditional advertising.

Malcolm Clark, co-ordinator of the Children's Food Campaign (CFC) says: "Marketing plays a significant role in influencing children's food choices." In 2014, the CFC and the British Heart Foundation jointly delivered a 30,000-signature petition to 10 Downing Street calling for a ban on junk food adverts before the 9pm watershed.

"The industry was given a chance to regulate itself voluntarily, but there was a patchy response to this," says Mr Clark. "Now they need firm leadership and regulations from the government that force them to comply, and approval from outside the Advertising Standards Association (ASA)."

Authorities are now requiring rigorous proof of any health claim. The ASA, for example, has banned some Actimel TV advertising, claiming it was "misleading", and the European Food Safety Authority required Danone to withdraw health claims about Actimel.

The CFC also launched a Junk-Free Checkouts campaign to remove junk food at supermarket tills and queuing aisles. This was initially met with resistance. However, earlier this year Lidl became the first UK supermarket group to comply with this request. Other major UK supermarkets have since followed suit. But this initiative has yet to be widely adopted by non-dedicated food retailers.



**UNDERSTANDING THE TRAFFIC LIGHT SYSTEM**

| | Sugars | Fat | Saturates | Salt |
|---|---|---|---|---|
| What is HIGH per 100g? | Over 15g | Over 20g | Over 5g | Over 1.5g |
| What is MEDIUM per 100g? | Between 5g and 15g | Between 3g and 20g | Between 1.5g and 5g | Between 0.3g and 1.5g |
| What is LOW per 100g? | 5g and below | 3g and below | 1.5g and below | 0.3g and below |

**Source:** Food Standards Agency

RISK FACTORS FOR CARDIOVASCULAR DISEASE IN THE UK

**25%** of adults consume five portions of fruit and vegetables each day

**25%** are obese and more than a third are overweight, in terms of body mass index

**50%+** have high blood cholesterol levels of five millimoles per litre or above

**22,000** deaths from cardiovascular disease each year can be attributed to smoking

**33%+** of men and 25 per cent of women regularly exceed the recommended limits for alcohol intake

**Source:** British Heart Foundation 2015

# Man's mission to repair hearts

*Stimulating the heart to repair itself is within scientific touching distance, thanks in large part to the work of Professor Paul Riley (pictured) and his team at Oxford University*

◆ **REGENERATIVE MEDICINE**

● **DANNY BUCKLAND**

Almost 500 people suffer a heart attack every day in the UK and seven out of ten survive. But the uplifting statistic masks a deeper problem in that most will join the 550,000-strong ranks of people living with debilitating heart failure.

Heart transplants are rare – only 181 were performed in 2014 – so the Holy Grail in cardiology is the ability to stimulate the heart to repair itself and regrow naturally.

It seems that nature has been kind by ensuring some of the cells that cause the heart to form in the embryo persist in adulthood, although they stay dormant during the ageing process when the heart deteriorates.

But scientists have discovered a method of re-activating some of the cells to create new heart tissue that could have a curative impact on diseased hearts and generate an improved quality of life to those who normally would have been consigned to a slow-paced decline.

"It is very exciting and, although we are not near a cure yet, we are heading in the right direction," says Professor Paul Riley, of the University of Oxford, whose work has identified the trigger to get the cells from the epicardium, the outer layer of the heart wall, to regrow blood vessels and heart muscle.

His team's laboratory work found the protein thymosin beta-4, which is an important factor in cell proliferation and migration, could effectively be used to remind the adult heart about its embryonic programme and start producing the cells that could repair damage from heart attacks.

Research in the United States at Stanford University has identified another protein, also naturally present in the epicardium, which they hope can be placed into a patch on the heart after an attack to minimise the scarring and improve function. Its first clinical trials are slated for two to three years' time.

"People are increasingly living with heart failure after surviving their initial heart attack and it is a huge burden on society. The figures for loss of productivity and the cost to the NHS are pretty horrendous," adds Professor Riley, who has the chair of development and cell biology, Department of Physiology, Anatomy and Genetics at Oxford.

"Our focus is understanding how the heart develops in the embryo during pregnancy. We are trying to understand how the heart is built in the first place so that we can rebuild it in the diseased adult setting. The embryo and foetus give us all the clues we need.

"We have focused on cells that still reside in the heart, but have switched off most of their function because they are not required for further growth. They have simply done their job and now lie dormant."

Encouragement that heart cells could regrow naturally was given a boost in the US by Professor Kenneth D. Poss, a cell biologist at Duke University, who discovered the zebrafish has a way of regenerating its heart after damage and that the epicardium played an essential role in this process.

In reports published in the journals *Nature* and *eLife* earlier this year, Professor Poss and colleagues explained that the molecule, neuregulin1, made heart muscle cells divide in response injury in zebrafish. A key finding was that the heart could be stimulated into creating more muscle cells by boosting this molecule even without injury.

> **Our research discoveries could trigger a revolution in cardiovascular medicine – my vision is a world where heart damage is temporary and repairable**

"Studies of the epicardium in various organisms have shown this tissue is strikingly similar between fish and mammals, indicating that what we learn in zebrafish models has great potential to reveal methods to stimulate heart regeneration in humans," says Professor Poss.

Unwinding the complex trail from the zebrafish and Professor Riley's clinical work could lead to a process where human heart regrowth could be primed both before heart attack, as a preventative measure for vulnerable populations, and after to save lives and improve the quality of life.

Identifying a route to kick-start cell regrowth is only the beginning as Professor Riley, and others, also have to decode complex relationships between cells, proteins, molecules, scar tissue and the immune system, which becomes significantly active during and immediately after a heart attack.

The heart's response is to patch up damage with scar tissue which is less flexible than the original tissue and causes the heart to work harder to function and this can lead to heart failure.

"We have to consider challenges such as reducing the scarring process, without risking rupture, to enable more room and compatibility for new cells to integrate and create new tissue," says Professor Riley, who is also British Heart Foundation professor of regenerative medicine. "You cannot just stimulate these cells to repair and not worry about the inflammatory process and the local environment."

But the reaction of the lymphatic system, which is forced into emergency action during a heart attack, has provided a further bonus. It is prolific at fluid drainage and lipid transport through its blind-ended vessels, but could also have a key role in moderating attacks.

"When a heart attack is induced these vessels expand and undergo something called lymphangiogenesis, which leads to sprouting as a compensatory mechanism to help get rid of the oedema and fluid retention, and clear damaging immune cells after an injury to the heart. It is a natural injury response and we have found that, with added growth factor to improve this process, heart function was improved by up to 50 per cent in our animal models," says Professor Riley.

"We don't yet know at what time point this happens, but we are currently trying to understand the mechanisms so that we can provide the right stimulus at the right time.

"The relief for those people living with heart failure downstream from heart attacks is likely to be a cocktail of treatments that stimulate a range of tissue restoring cells along with modulating the immune response and control of the scarring.

"It could also be used as a preventative treatment to strengthen hearts by giving thymosin beta-4 to people identified with high blood pressure, high cholesterol, potentially hypertensive and those with a genetic history of heart disease. There are many issues to solve such as ensuring the treatment does not interfere with other organs, but it could be used to prime people at risk."

Drug development time is notoriously lengthy and full of setbacks, but Professor Riley believes that repurposing existing drugs could halve the time taken from discovery to approval.

Further work is being carried out and fundraising is under way for a unique £35-million Institute of Developmental and Regenerative Medicine in Oxford, as a collaboration between the university and the British Heart Foundation. The new institute would bring 200 researchers together working across different organ systems, immunology and paediatric medicine.

"If the institute becomes a reality, our research discoveries could trigger a revolution in cardiovascular medicine," says Professor Riley. "My vision is a world where heart damage is temporary and repairable."

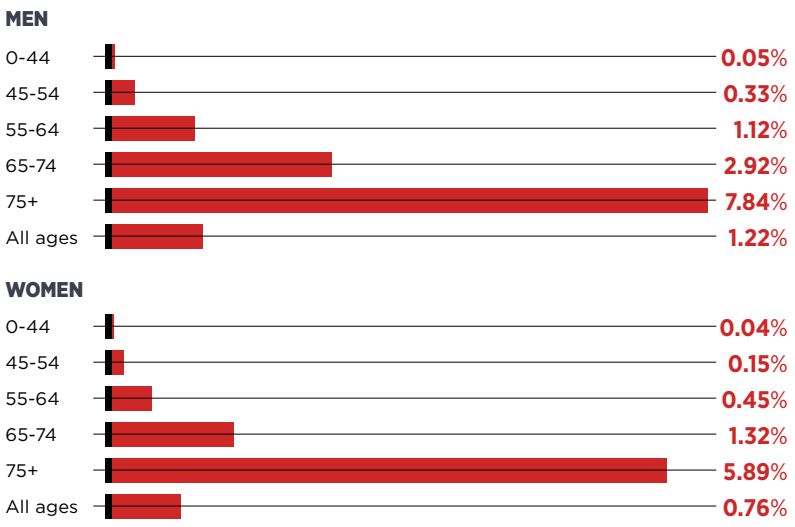
The British Heart Foundation, which supports his work, concludes: "Professor Riley's research offers the hope that within a decade we will be able to teach damaged hearts to repair themselves so that we can help the UK's heart-failure sufferers."

**£19bn**

annual cost to the UK of premature death, lost productivity, hospital treatment and prescriptions relating to cardiovascular disease

**Source:** British Heart Foundation

**PREVALANCE OF HEART FAILURE IN THE UK, BY GENDER AND AGE**




**Source:** British Heart Foundation

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- Don't smoke. Smoking can greatly increase the risk of heart problems.
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