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04	Foreword
05	The Painful Truth Executive Summary
06	Introduction
07	Living with pain day-to-day
80	A heart-breaking impact on loved ones
10	Economic woes: a burden to individuals and society
11	A lack of understanding from healthcare professionals
12	A painful experience with treatment
13	Surgery failing those with back pain
14	An urgent need for improvement
15	Cost savings in a cash-strapped economy
16	The time is now
17	Acknowledgements
18	Supporters and references

THE PAINFUL TRUTH

Study report

FOREWORD



hronic pain is pain that persists for 6 months or more. It has a detrimental effect on the lives of those affected, impacting not just the sufferer, but also those that care for and interact with them. There are 95 million people living with chronic pain in Europe, which is greater than the number of people living with diabetes (60 million), and it places a significant burden on the economy and society.

Perhaps because there are several causes of chronic pain, healthcare systems have struggled to appreciate the enormity and growing challenges that chronic pain presents. For many sufferers, conventional approaches with physical therapy, medication or surgery is not the answer and we need to be exploring the use of innovative and cost-effective technologies as they emerge.

The Painful Truth campaign aims to drive better understanding of chronic pain and highlight its impact on sufferers so that we can work towards a better outlook for people with chronic pain. It provides healthcare professionals with an opportunity to gain insights into their patients' perspective so they can evaluate the true challenge of chronic pain facing us all.

This European survey has revealed that despite receiving several treatments and in some cases several surgeries, many patients continue to suffer with their severe chronic pain on a daily basis. We need to see an improvement in the way people with chronic pain are managed.

I often see patients who for many years (on average 7 years) have been unsuccessfully managed with physical therapy, pharmacological treatment or surgery, despite the availability of nonmedicinal options such as rechargeable spinal cord stimulation (SCS). SCS may in the longer term not only improve the sufferer's pain, but may also reduce the burden on the health economy by getting the right treatment to the right individual at the right time. Unfortunately many sufferers have to see their doctor several times before they are referred to a specialist and unless sufferers see the right specialists, it is unlikely they will be informed of all the options available.

I hope that this campaign will encourage people with chronic pain, their friends and family as well as healthcare professionals and policy makers, to look at chronic pain in a new way and be motivated to make a positive change to the process and resources of providing care. I am optimistic that this initiative will lead to improved awareness and understanding for people with chronic pain across Europe, facilitating a change in management.



Dr Simon Thomson, Consultant in Pain Management Basildon and Thurrock University Hospitals NHS Foundation Trust, UK

Europe is suffering...

Chronic pain affects

1 in 5 adults in Europe⁴

On average, people live with their chronic pain for up to **7 years**⁵

68% of survey respondents are still in pain for more than **12 hours a day** despite treatment³

The total cost to healthcare systems across Europe is estimated to be as high as €300billion⁶

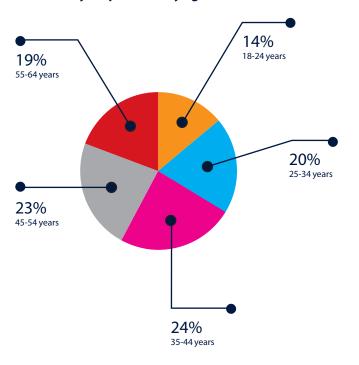
Nearly **one third** of patients claim they have been poorly informed about new options to better manage their pain⁵

THE PAINFUL TRUTH EXECUTIVE SUMMARY

The Painful Truth campaign has been launched to build awareness of the issues facing people with chronic (non-cancer) pain to drive for an improvement in how people with chronic pain are diagnosed, and to enhance access to innovative and cost effective treatment options to those who would benefit.

Key third party groups from across Europe have come together to support this research to create a call for action. The Painful Truth Survey³ not only reveals further insight into the impact of chronic pain on sufferers' lives, but also explores their experiences with treatment, unveiling the true and significant unmet need in optimal pain management.

Total Survey Respondents by Age



METHODOLOGY

Random sample of 1,010 adults aged 18 to 64, who define themselves as chronic pain sufferers





Chronic pain is defined as pain lasting 6 months or longer, excluding those with cancer

Respondents comprise 57% women and 43% men



An average of 200 interviews conducted online per country throughout May 2012

Interviews nationwide throughout France, Germany, Italy, Spain and the UK



INTRODUCTION

The full picture of chronic pain is largely misunderstood. It disrupts the lives for the millions that suffer and can cause intense physical and emotional anguish. Affecting one in five adults in Europe, 4 chronic pain reduces quality of life more than almost any other condition 7 and is thought to be one of the most common conditions for which people seek medical attention.8

Types of chronic pain

Chronic pain can be caused by a variety of physical and psychological factors, however, the subjective and personal nature of pain makes it difficult to measure and define. It can occur when no obvious cause can be found and is thought to be due to changes in the nervous system. ¹⁰

Chronic pain is generally divided into two classifications; however some people may suffer from a combination of both types: 8

• Nociceptive - associated with tissue damage, for example a cut, burn or broken bone.

 Neuropathic pain - occurs with nerve damage or problems with the nervous system. It is often described as numbness, tingling or like an electric shock.⁸

While most people will experience nociceptive pain at some point, neuropathic pain is often under-diagnosed and under-treated. ¹¹ It is a debilitating condition commonly affecting the back and legs, which is associated with severe disability and psychological illness. ¹²

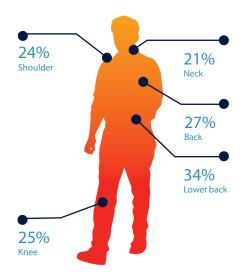
A lifelong condition

A third of people with chronic pain are in constant pain and many sufferers live with their chronic pain for an average of seven years. 5 Over a fifth will endure pain for 20 years or more. 4

Over a fifth will endure pain for 20 years or more.4

The Painful Truth Survey found that 63% of survey respondents believe that their chronic pain cannot be cured while only 37% believe that their condition will improve with medication, highlighting the lack of hope for the future.

Areas of the body most affected by pain, by survey respondents³



Almost two thirds (61%) state that the back and lower back are the most common areas to experience pain

FAST FACTS

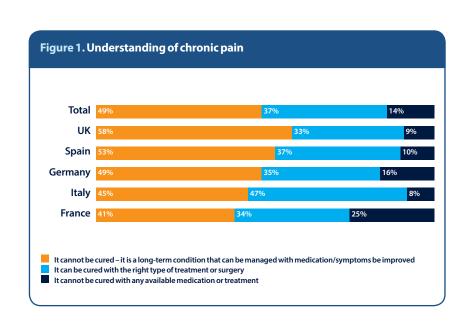
In Europe, backache is the most commonly reported location for chronic pain⁴

The causes of back pain can be very complex and it is difficult to obtain an accurate diagnosis¹³

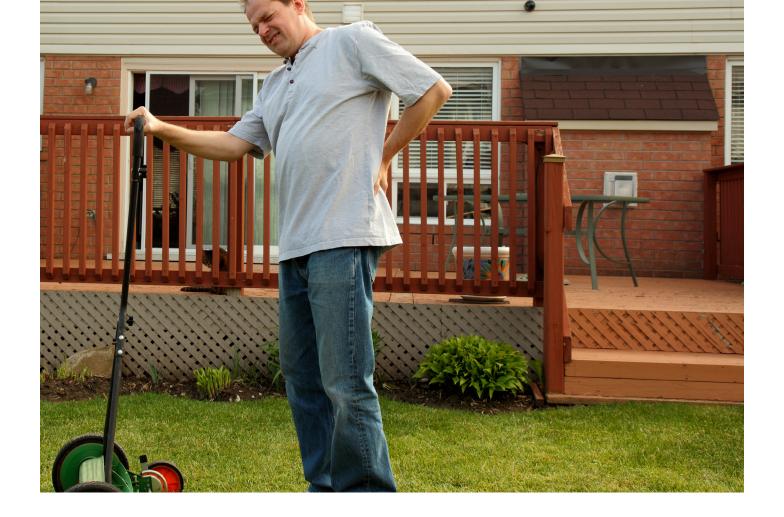
Pain may be a result of earlier injury or trauma or may be caused by arthritis or spinal disc abnormalities

Some sufferers have Failed Back Surgery Syndrome, which is persistent low back and leg pain in those who have not achieved a successful outcome with spinal surgery, or who are unwilling to undergo surgery

In many cases the cause of the pain cannot be determined



Chronic pain is defined as continuous long-term pain that has lasted for more than six months.⁹



LIVING WITH PAIN DAY-TO-DAY

The impact of chronic pain on a sufferer's quality of life can be devastating. Not only can it cause significant disability but it can also increase the risk of psychological disorders such as depression and anxiety. Without relief, or the hope for relief, many sufferers lose the ability to sleep, work, and function normally.⁴

The Painful Truth Survey revealed that more than a third of survey respondents report difficulty in managing simple routine daily tasks. These include activities such as showering/ bathing, getting dressed, cleaning and shopping. The ability to exercise is affected by chronic pain the most, with 79% finding this difficult to manage.³

Participation in social activities can be difficult as more than a third have difficulty driving or even leaving their home,³ something many of us can take for granted.

Being in pain for a long time can have a devastating impact resulting in isolation for the sufferer. Many people with chronic pain will be prone to depression and drug dependency. When their treatment fails, people with chronic pain can feel that committing suicide is a solution, and the risk of suicide in chronic pain sufferers is at least doubled. 14

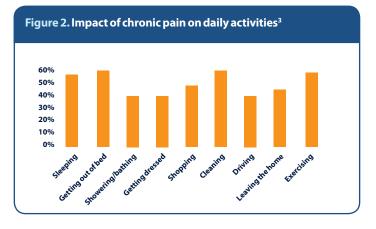
Tiredness and exhaustion add to the burden of chronic pain, with over half of survey respondents reporting they have difficulty sleeping.³



When my pain was at its worst, it was like this deep, hot sensation that you just can't get to; it became so hard to cope with everyday life. Something as simple as bending down to put my shoes on became incredibly difficult. The pain was always there, even at night, which meant that I had problems sleeping. I was exhausted, emotionally, physically, I just couldn't function. I struggled around the house trying to look after my two beautiful daughters. I couldn't get out of bed to get them ready for school. I wasn't able to cook for them because I didn't have the strength to pick anything up or I would drop things. I couldn't even take them out of the house.











Chronic/persistent pain is a debilitating and disabling condition and can interrupt all aspects of a persons' life, which can lead to physical deconditioning, psychological distress and social isolation. Those caring for people with chronic pain need to be aware of the impact of pain on the life of the sufferer, in order to have an understanding and empathy for the individual in pain, while providing helpful support. More education and awareness of the impact of chronic pain for both health care professionals and those caring for people in pain is needed.



Carol Banks, Nurse Specialist Basildon and Thurrock University Hospitals NHS Foundation Trust, UK



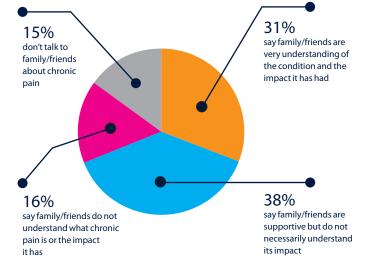
A HEART-BREAKING IMPACT ON LOVED ONES

Whilst the impact of chronic pain on the individual sufferer can, to a degree, be imagined, some of the silent more discreet impact can often go unnoticed, particularly the strain on loved ones.

Due to the debilitating nature of chronic pain, experts believe many sufferers may become physically and emotionally dependent on others, which can lead to changes, particularly as family members may be required to take on additional household responsibilities. ¹⁵ The emotional impact of chronic pain may impact the entire family and those with children are faced with additional strain.

More than 1 in 10 survey respondents (12%) have either separated or experienced a negative impact on their relationship due to chronic pain. This rises to 17% in the UK.³

Figure 3. Support from family and friends



'My pain has ruined my marriage'

It can be extremely difficult for a partner to watch and live with a loved one who is suffering. Earlier research findings have shown that many may by worried or uncertain about the future condition of their partner and may experience a lack of hope or feel helpless, as they try to understand their partner's chronic pain. ¹⁵

Opportunities to interact as a couple can be compromised and many survey respondents report that sex and intimacy are areas of relationships most impacted (16%), as are opportunities to enjoy activities together (30%).

'I can't talk to my friends and family'

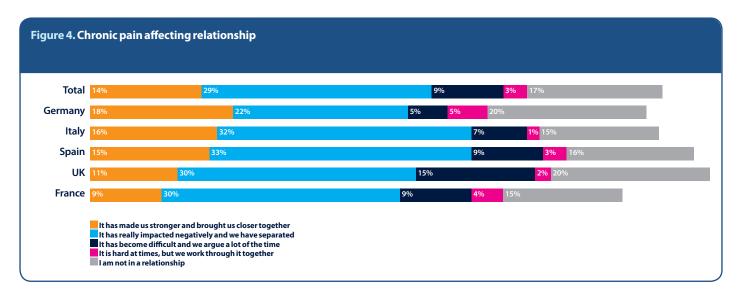
Although a third of survey respondents say that their friends and family are very understanding of the condition, 38% report that although they may be supportive, they do not necessarily understand the impact that chronic pain has. A further 31% of survey respondents highlight that their family and friends do not even know what chronic pain is, and that they do not even talk to their loved ones about their condition.³



Chronic pain goes beyond just simple aches and pains. When a person has been living with their pain for such a long period of time, the effects will be seen in all aspects of their life. We often talk about the economic burden or how people are unable to work, but we should not forget the impact on personal relationships; the strain that it can place on intimacy with your partner, how looking after your own children becomes an arduous task or how it can become impossible to have any sort of active social life. All of this is a fate that people should not have to bear; with the right treatment and support, chronic pain sufferers can live life to the full and so much can be achieved. We must push for access to innovative therapies to ensure that chronic pain sufferers everywhere get to live the life they deserve.

Action on Pain, UK

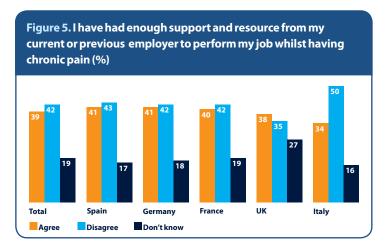




ECONOMIC WOES: A BURDEN TO INDIVIDUALS AND SOCIETY

In the current economic climate European healthcare systems, now more than ever, face challenges to reduce the healthcare expenditure in an effort to reduce public sector deficits. 16 With chronic pain sufferers often seeking medical attention,8 a recent report estimated the total cost to healthcare systems due to chronic pain across Europe to be as high as €300billion.6 An estimated 90% can be attributed to indirect costs such as lost productivity, social security and welfare payments.6

The impact to individuals is also high; over a third of survey respondents believe chronic pain affects working life more than anything else. While many sufferers do continue to work, the Painful Truth Survey found that 42% of respondents do not feel that they have had enough support or resources from employers to perform their jobs whilst suffering from chronic pain. Survey respondents report missing an average of 12 days off work in the last 12 months due to their condition. Just over a third (36%) also say that they have missed out on opportunities at work.3



Around a third claim their chronic pain has negatively impacted their household income with an average decrease of 31% across Europe (equating to approximately 5,000 euros*) leading to further strain on sufferers' situations.3 This is particularly worrying as some people with chronic pain may find they need to pay for support with activities they can no longer complete, such as housekeeping.



Chronic pain can be considered as a very common and costly chronic disease in its own right. People sometimes consider it as merely a symptom when the reality is that continuing pain has a multitude of consequences such as lack of sleep, anxiety, isolation, dependence on pain medication and depression. This can cause a financial burden to society in the form of increased healthcare costs from conventional pain medications, low productivity and absenteeism causing a loss for employers and strain to welfare systems with having to compensate those unable to contribute to the economy. Chronic pain deserves to be prioritised in Europe with balanced consideration within the health care policies and budgets of all



Of the people who say their income has been impacted, the largest average decrease is in the UK, where nearly 4 in 10 survey respondents say the impact has resulted in a 37% decrease on their household income.3

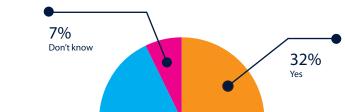
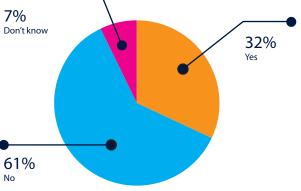
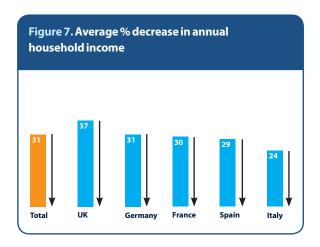


Figure 6. Has chronic pain negatively affected your household income





*4,822 Euros based on average salary across UK, Germany, France, Spain and Italy. Society at a Glance 2011: OECD Social Indicators - © OECD 2011

A LACK OF UNDERSTANDING FROM HEALTHCARE PROFESSIONALS

Despite the advances in treatment and ongoing movement to improve the standard of care for chronic pain sufferers, there is still a significant unmet need for millions of sufferers across Europe who, despite trying several treatments and in some cases numerous surgeries, report they continue to suffer with their debilitating pain condition on a daily basis.³

People with chronic pain visit a healthcare professional an average of 13 times in six months, double the average number of visits made by the general adult population. Although the majority of chronic pain sufferers turn to their doctor for an initial consultation, over a fifth of those surveyed report feeling frustrated after their first conversation and almost a quarter (24%) say their doctor was dismissive of their symptoms or not proactive in helping them. Only one in five respondents came away from the conversation feeling hopeful about their chronic pain.

Due to this lack of understanding of chronic pain among healthcare professionals, sufferers often experience lengthy delays with diagnosis and referrals, meaning their pain may not be effectively managed for some time.



to specialist and nobody gave me a solution. They would give me simple pills which had no effect, and every three months I would go back insisting I was still in pain. For eight years I suffered like this, eight very painful years... it wasn't a life. It wasn't until I was referred to the pain clinic and informed about the spinal cord stimulation system, that my life started to change completely.

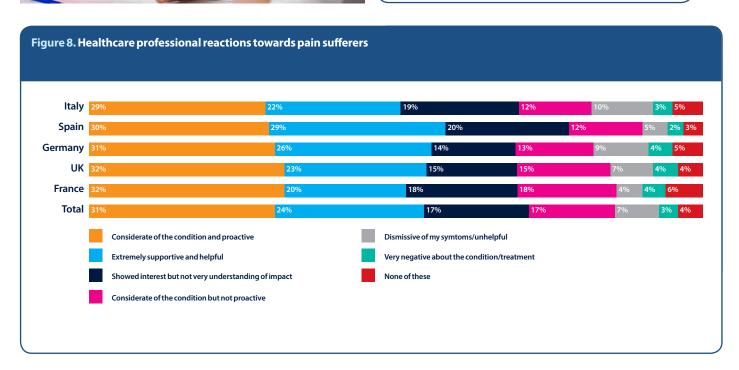
Francisco, aged 54, Spain





Diagnosis is extremely slow with only 8% of survey respondents actually being referred onto a specific Pain Specialist following their initial consultation, while on average 7% of survey respondents have not yet been referred at all.³

Although most say their healthcare professional is quite supportive, 41% of survey respondents seem unhappy with the way they are treated and almost a quarter, (24%) say their HCP is not very understanding of the impact or dismissive of their symptoms.³



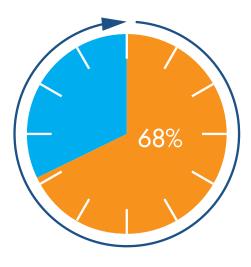
A PAINFUL EXPERIENCE WITH TREATMENT

The Painful Truth Survey findings reveal that less than half of survey respondents feel they have had a good experience with conventional medication.³

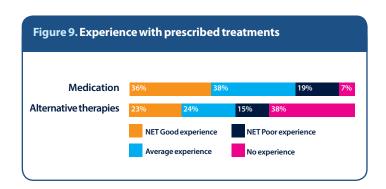
Although there have been several advances in treatment for chronic pain over the years, conventional medications, such as non-steroidal anti-inflammatory drugs (NSAIDs), anti-neuropathic agents and opioids continue to be the mainstay of treatment.³ However, research from the US found that nearly one in

five sufferers who use opioids in the long-term report having concerns about not being able to control their medication. 17 The drug dependency seen with opioid use can be an additional burden to healthcare systems. 8

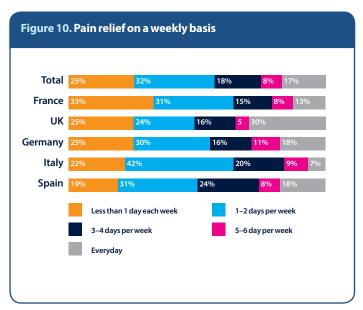
The results also reveal that a third have tried three or more prescribed treatments for their chronic pain, yet more than half only experience pain relief for 1-2 days per week with 68% of respondents still in pain for 12 hours or more a day despite treatment.³



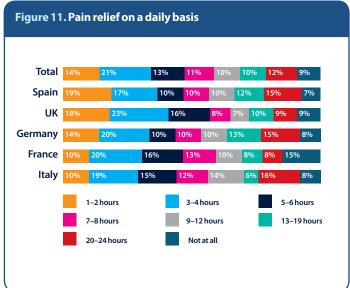
68% of pain sufferers are still in pain for 12 hours or more a day despite treatment.³



Only a third (36%) are satisfied with pharmacological treatment



More than half (57%) only experience pain relief for 1-2 days per week



1 in 10 do not experience any pain relief at all



SURGERY FAILING THOSE WITH BACK PAIN

On average, the Painful Truth Survey found that one in ten (14%) of those who have back or lower back chronic pain have had back surgery. Of these, 3% have experienced at least one failed back surgery.³

A recent review of available literature revealed that the percentage of sufferers experiencing failed surgery may in fact be much higher, as repeat surgeries after one or more spinal operations can be common. In some cases up to 19% of sufferers may undergo re-operation after surgery on their spine. Those sufferers that have one re-operation also have an increased risk of further spinal surgery, which could lead to many more failed operations.¹⁸

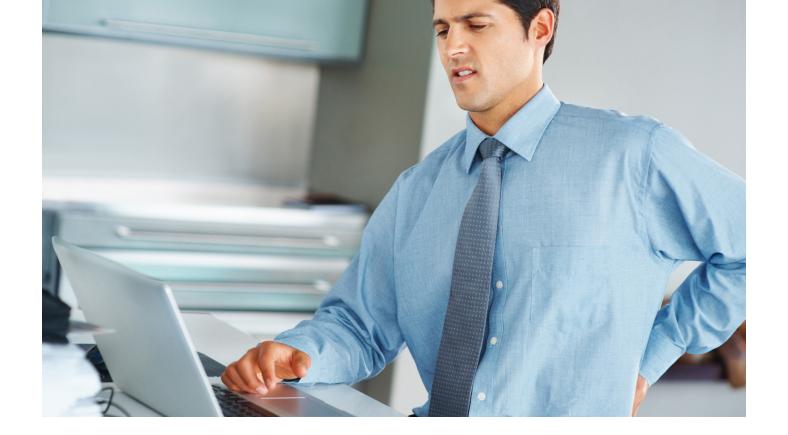
A further review has also shown that when their treatment fails, people with chronic pain can feel that committing suicide is a solution and the risk of suicide in chronic pain sufferers is at least doubled, ¹⁴ further highlighting the urgent need for improved care and pain management options. Earlier considerations of SCS from the onset of chronic pain symptoms may result in improved outcomes for sufferers. ¹⁸ Where initial use of medication or surgery has not been successful, SCS may be a more effective alternative to a repeat operation or increased opioid use. ¹⁹



Spinal surgery is now recommended more frequently than ever and many of the procedures have become much more complex. The frequency and the fact that these procedures are almost always performed in an elaborate manner should not hide the fact that they are invasive to the spine and can be traumatic for the patient, especially if unsuccessful. Often patients do not undergo just one operation, but can find themselves having to repeat surgery several times to no avail. This can have a detrimental effect on the patient's quality of life. We know that there are often disappointing results with repeat surgery or long-term medical treatment, so alternative options need to be considered much earlier.



Dr. Hartmut Neumann, Munich, Germany



AN URGENT NEED FOR IMPROVEMENT

The Painful Truth Survey revealed that one fifth of survey respondents have a chronic pain diagnosis that could be treated or managed with new innovative treatment options, such as rechargeable spinal cord stimulation (SCS).³

Despite availability across Europe, two thirds (61%) of survey respondents who could benefit from rechargeable SCS have never heard of the treatment, even though it is particularly beneficial for sufferers with back pain or neuropathic pain, both of which are difficult to treat. Separate research reveals that 87% of sufferers try at least 4 different treatment options before they are even considered for SCS. 12

Whilst in some instances, clinical guidelines do recommend SCS as a treatment option, ¹⁹ uptake and awareness among healthcare professionals is low. Of those sufferers that had heard of SCS, few had been informed by their doctor or specialist, with the majority hearing about it through television.³



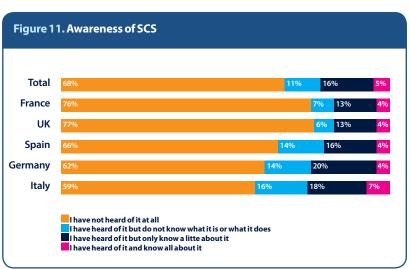
Chronic pain is considered a disease that should be treated effectively. It has been proven that poor treatment of pain will not only impact on the quality of life of patients and their environment, but can also lead to patients losing hope that their condition can ever be managed properly. It is estimated that less than 5% of chronic pain patients are treated in a specialised Pain Clinic. Patients are also not always informed about the side effects of treatments or the alternative options that are available to them. It is important that better efforts are made to keep patients and their families informed and that communication with healthcare professionals is improved.

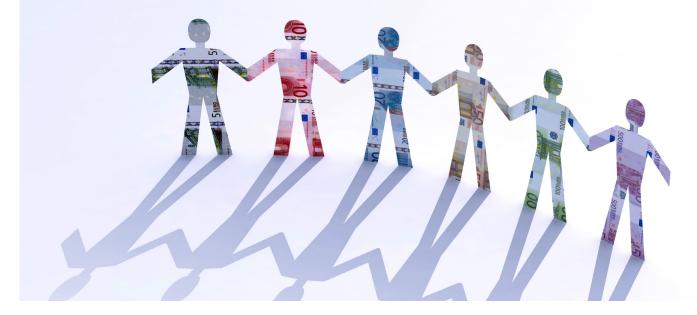
EFHRE Sine Dolore, Spain





87% of sufferers try at least 4 different treatment options before they are even considered for SCS.¹²





COST SAVINGS IN A CASH-STRAPPED ECONOMY

The economic benefits that newer technologies such as rechargeable SCS can offer also need to be considered. Not only can options such as rechargeable SCS halve the pain that sufferers experience and in some cases completely control the pain, but they can also reduce the need for daily medicinal treatment. ²⁰

Results from a health economics study comparing chronic pain sufferers receiving conventional medical management (CMM) only versus SCS patients, found that the initial upfront cost of SCS is offset by 15% within six months due to reduced use of pain medication and non-drug therapies.²¹

In the SCS group, it was found that: 21

- · Opioids were used an average 11 days less
- Non-steroidal anti-inflammatory drugs (NSAIDs) were used an average 38 days less
- · Anti-depressants were used for almost two weeks less
- Physical therapy was used by 7%, compared with 44% in the CMM group

FAST FACTS

- Spinal cord stimulation (SCS) may be an option for people with chronic pain who have not achieved adequate pain relief using drug or surgical treatment approaches.
- The technique involves a small device being implanted beneath the skin's surface, which electrically stimulates specific nerves of the spinal cord where pain signals to the brain can be intercepted resulting in an inhibition of pain sensation.
- The frequency and duration of the stimulation is controlled by the individual with a remote device. SCS can be used to treat sufferers with pain in more than one area.

ARE ALL SCS DEVICES THE SAME?9



A rechargeable (RC) device is charged by the sufferer at home. RC systems have a battery life of 10-25 years.



A non-rechargeable (NRC) device requires the battery to be replaced via surgery every 2-5 years.



Rechargeable systems may have greater capability to provide clinical benefits, including extended therapeutic longevity and avoiding frequent surgeries and the complications that may arise from such surgeries.



The costs of a rechargeable SCS system compared to a non-rechargeable system can be offset 4.1 years after implantation.



On average over a span of 15 years, a RC system could allow treatment of 6 more patients annually in a typical hospital setting.²²



The goal of treatment should be to improve function and enable individuals to participate in daily activities and return to work without pain. However, it is very difficult to relieve or cure chronic pain and many sufferers are still in pain despite drug treatment. Urgent action is needed to ensure people with chronic pain have access to newer innovative treatment options, which offer effective and cost efficient pain management.



Dr Ma Luisa Franco Gay, Bilbao, Spain





ACKNOWLEDGEMENTS

DRSIMONTHOMSON

Dr Simon Thomson is a Consultant in Pain Medicine and Neuromodulation at Basildon and Thurrock University NHS Foundation Trust since October 1992. He holds an interest in multidisciplinary pain management, clinical research, education, refractory angina management and implantable neuromodulation for pain and other chronic disorders.



He was founding president of the Neuromodulation Society of UK and Ireland (NSUKI) in 2001 and has been Secretary of the International Neuromodulation Society (INS) since 2003 to 2007, president elect to 2009.

He is current President of the INS since September 2009. He has been elected to serve a second term as President of the INS until September 2015. He was chair of scientific committee of biennial scientific meetings of the INS in London 2011 and Berlin 2013.

DRMª LUISA FRANCO GAY

Dr Ma Luisa Franco has been a Consultant at the Pain management Unit in Cruces Hospital Bilbao, Vizcaya, Spain since 1986. In 2011 she also became a Director at a private clinic pain management in Bilbao.

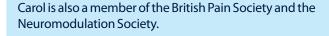


She is a specialist in interventional procedures and is a member of the International Neuromodualtion Society (INS), the Spanish Pain Society (SED) and also president of the Section of Pain at the Medicine Academy of Bilbao.

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DRHARTMUT NEUMANN

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He has led more than 10,000 major and minor operations specialising in infiltration of the cervical, thoracic and lumbar spine, as well as open disc surgery, herniotomia, discolisis with ozone, nucleoplasty, neuromodulation and epidural endoscopy. He also has specific experience with interspinal devices, nearly all kinds of nervous blocks and thermocoagulation as well as SCS, Peripheral Nerve Stimulation and Occipital Nerve Stimulator implants, having fitted more than 500 implants.



Action on Pain, UK

Action on Pain is a national UK charity established in 1998 by lan Semmons, the Chairman, as a result of his own frustration that it took so long to get treatment for his pain. That frustration was heightened by the fact that when he eventually discovered Pain Clinics some three years after his injuries the treatment he received was superb. During that journey he met many others in a similar position so knowing that complaining to the NHS was a pointless exercise he was determined to do something positive to help others who were faced with a similar challenge.



The Spanish Association for Pain Patients

"Sine Dolore" is a non-profit organisation which was established in 2004 to make the population and in particular the authorities aware of the need to treat pain because it not only alleviates the patients' suffering, but also improves their quality of life - this aim became the Association's motto "Treating pain, alleviating suffering: Improving quality of life". According to the World Health Organization (WHO), pain is a disease affecting 20% of the population, so one of the main objectives of this Association is to welcome all social groups: patients, families, friends, doctors, nurses, scientists, psychologists, philosophers, journalists, politicians, etc to make everybody aware that "Without Pain [Sine Dolore] you can live a better life". The Association's belief is that the fight against pain involves us all as sooner or later we are all going to reach a moment of our lives when we will be affected by pain and only if we prepare ourselves today will we be able to avoid it tomorrow.



German Pain League, Germany

The German Pain League (Deutsche Schmerzliga), founded in 1990, is the largest chronic pain patient organization in Germany. It is a non-profit and non-governmental organization with more than 5,000 members and runs more than 100 regional self-help groups. The German Pain League is also a member of the International Alliance of Patients' Organisations (IAPO). The mission of the "Deutsche Schmerzliga" is to improve the situation and life of pain patients. Above all, this means improving the general framework of health care policies and opening up therapeutic channels for patients suffering from chronic pain.

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