THE WORK FOUNDATION

PART OF LANCASTER UNIVERSITY

Adding Value: The Economic and Societal Benefits of Medical Technology

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Background

The current pressure to dramatically reduce public expenditure has led the NHS to review the efficiency of its services; this may in some cases include designating certain medical procedures as 'low value'. The study of chronic conditions demonstrates that quick-fix solutions for long-term illnesses – although incurring a low immediate cost – will be inadequate to deal with the longer-term impact of chronic disease on an ageing labour force, and associated costs to the welfare system. In order to reduce the societal burden of long-term conditions and maximise the cost-effectiveness of health and social care services, policy makers need to **invest in medical innovations that enable individuals to continue to live fulfilling working and family lives, and prevent their premature withdrawal from the labour market**.

Innovation and technology can deliver tangible improvements to important social outcomes, including the **healthy extension of working lives, increased job retention and return to work, and improved daily functioning** – all before the individuals are affected by the long-term consequences of disease. This report examines the positive impact that medical technologies like artificial hip/knee replacements, implantable cardioverter-defibrillators (ICDs) and insulin pumps can have on both quality of life and labour market participation as the UK workforce ages. It also examines the consequences of delaying access to such interventions, and the extent to which this may have the effect of increasing costs to patients, the health care system and the economy overall.

The coalition government's welfare reforms and the new NHS Outcomes Framework both aim to encourage individuals with long-term or chronic conditions to stay in or return to work, and therefore offer the opportunity to reduce both the payment of out-of-work benefits and lost societal productivity. Many of those receiving benefits are unemployed due to chronic disease and yet, ironically, active employment is known to improve health outcomes and quality of life at the individual level. Interventions, particularly **early and preventative interventions involving medical technologies, may help those individuals regain active employment status**, thus contributing to the retention of skills and improved societal productivity, while reducing the demand for the government to make payments to those individuals in the form of welfare benefits.

The study

In order to investigate the impact of these medical technologies on a number of outcomes, we explored the key questions below.

1. How can medical technologies be used as interventions to help improve:
    a. Labour market participation and work productivity?
    b. Quality of life through participation in society for people with chronic health conditions and independent living among those who have left the workforce?
    c. The efficiency of the NHS?

2. Is there an economic case for wider adoption of some of these technologies? If so, what is it?
3. What factors contribute to the adoption of medical technologies in the UK?
4. What policy changes are needed to increase efficiency of the health and social care services through supporting longevity and workability of individuals with long-term conditions?

We adopted the following methods:

- Desk-based literature review examining the costs and benefits of medical technologies;
- Qualitative interviews with stakeholders and experts who know and use the three technologies;
- Expert focus group/workshop to examine the costs and benefits of increased adoption of medical technologies from a stakeholder perspective.

Main Findings

Used appropriately, we found considerable evidence that medical technology offers a number of benefits for physical, social and psychological well-being. This study has looked in detail at three medical technologies to assess their current use, their impact of quality of life and labour market participation and the economic arguments for their use to be increased:

Artificial hip/knee replacements prevent disability and allow patients to keep their jobs – 31 per cent of women and 42 per cent of men receiving an artificial hip are of **working age**. Around 32 per cent of women and 33 per cent of men had a knee replacement procedure before they were 65 years old. Further knock-on effects of treatment are associated with **preserved capacity of individuals to lead independent lives and return to work**: relieved burden of caregivers, improved opportunities of return to employment among patients, as well as the benefits associated with participating in family roles. In 2009 in the region of 11,000 people in England and Wales were enabled to return to work by a hip replacement surgery, saving the UK welfare system £37.4 million each year of their working lives.

Implantable cardioverter-defibrillators offer crucial advantages by extending lives of people with heart conditions at risk of sudden cardiac death. ICDs can be regarded as an insurance policy for those known to be at high risk for it, as the device has been shown to prevent death from sudden cardiac arrest 98 per cent of the time **The majority of patients receiving the device were able to return to work**. Given the severity of their disease state, this an achievement in and of itself, but the fact remains that the patients' recovery reduces systemic burden on resources when such individuals can begin again to function in accordance with their previous lifestyles and levels of employment. Return to work following implantation of an ICD

reduces the burden to the UK welfare system by £3.5 million each year. If the number of people with ICDs was to match the European rate, the savings would increase to £7.1 million a year.

Insulin pump therapy provides greater **lifestyle flexibility (including that of relevance to working life**) and reduces risk of diabetes complications through improved control over blood glucose levels. Insulin pumps have been shown to support cognitive development and improved psychological adjustment of young patients, justifying the possibility of **early use of the intervention among children**. Numerous studies and volumes of empirical data advocate their use in order to better maintenance of safe insulin levels and in avoiding or mitigating some of the more severe health consequences of diabetes. As a result, individuals with diabetes require fewer adjustments within the work environment and can remain in work. If the number of pumps was increased by 7 per cent to reach the 12 per cent benchmark set by NICE in 2009, additional savings just on consultants' visits and hospital admissions would add up to between £37.2 and £62.5 million per year.

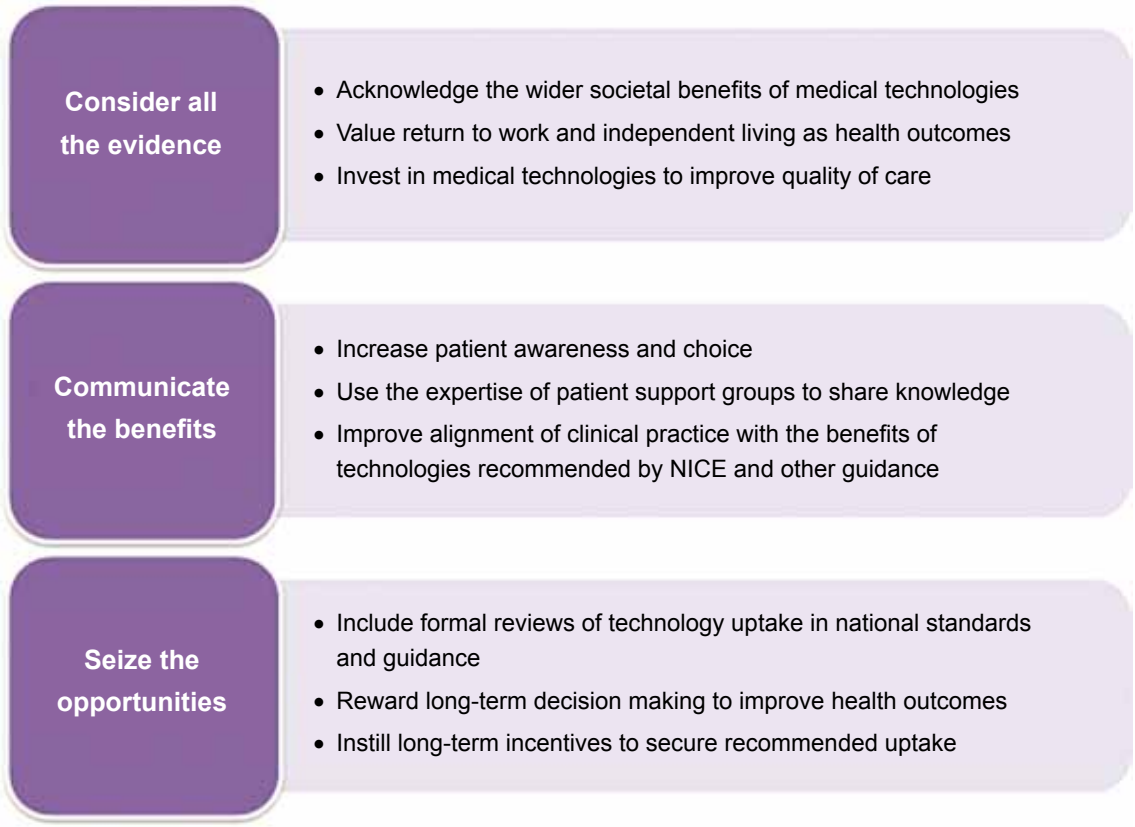
Overall, we identified three areas of benefits from medical technologies:

- Improvements in health care (quality, efficiency and the empowerment of patients);
- Improving quality of life and independent living (reducing fears and anxiety, increasing flexibility, and reducing the need for informal care and the burden on informal caregivers);
- Labour market participation and productivity (increasing labour market participation, retaining skills and improving productivity).

The study concludes that the long-term effects of medical interventions are rarely taken into consideration in health technology assessments. A focus on short-term priorities coupled with a lack of policy coordination and the related failure to recognise the variety of benefits offered by medical interventions often hamper their wider utilisation. Commissioners and specialists involved in the decision-making process need to address cultural conservatism in the uptake of valuable medical technologies.

A 'Call to Action'

Medical interventions should be regarded by clinicians and health care managers as investments in future benefits and cost reductions. As a result of our study we propose the following '**Call to Action'**.



Recommendations to improve adoption of valuable technology

A. Improving data on medical technology use and effectiveness

1. With currently available data it can be difficult to measure the return on investment in medical technology. This report identifies a number of variables that may impact analyses and decisions related to medical technologies and **these should be adopted by NICE and the Department of Health in setting strategic investment priorities**. Better data collection and availability will allow for more informed assessments of the costs and benefits associated with the effective use of innovative medical technologies. Reliable measures of quality outcomes and long-term effects would be required to conduct accurate estimations of the impact of medical technologies on economy and labour market.

2. The Department of Health should conduct research to **monitor and evaluate the adoption, clinical and cost-effectiveness and labour market outcomes of wider adoption of medical technologies** – including international comparisons. The results of this work should inform clinical guidelines, care pathways and early intervention strategies, especially in the domain of long-term conditions.
3. The Department of Health should make more explicit provision within the **NHS Outcomes Framework to evaluate clinical and labour market outcomes** in relation to the use of medical technologies to inform innovative best practice.

B. Enhance education about medical technologies

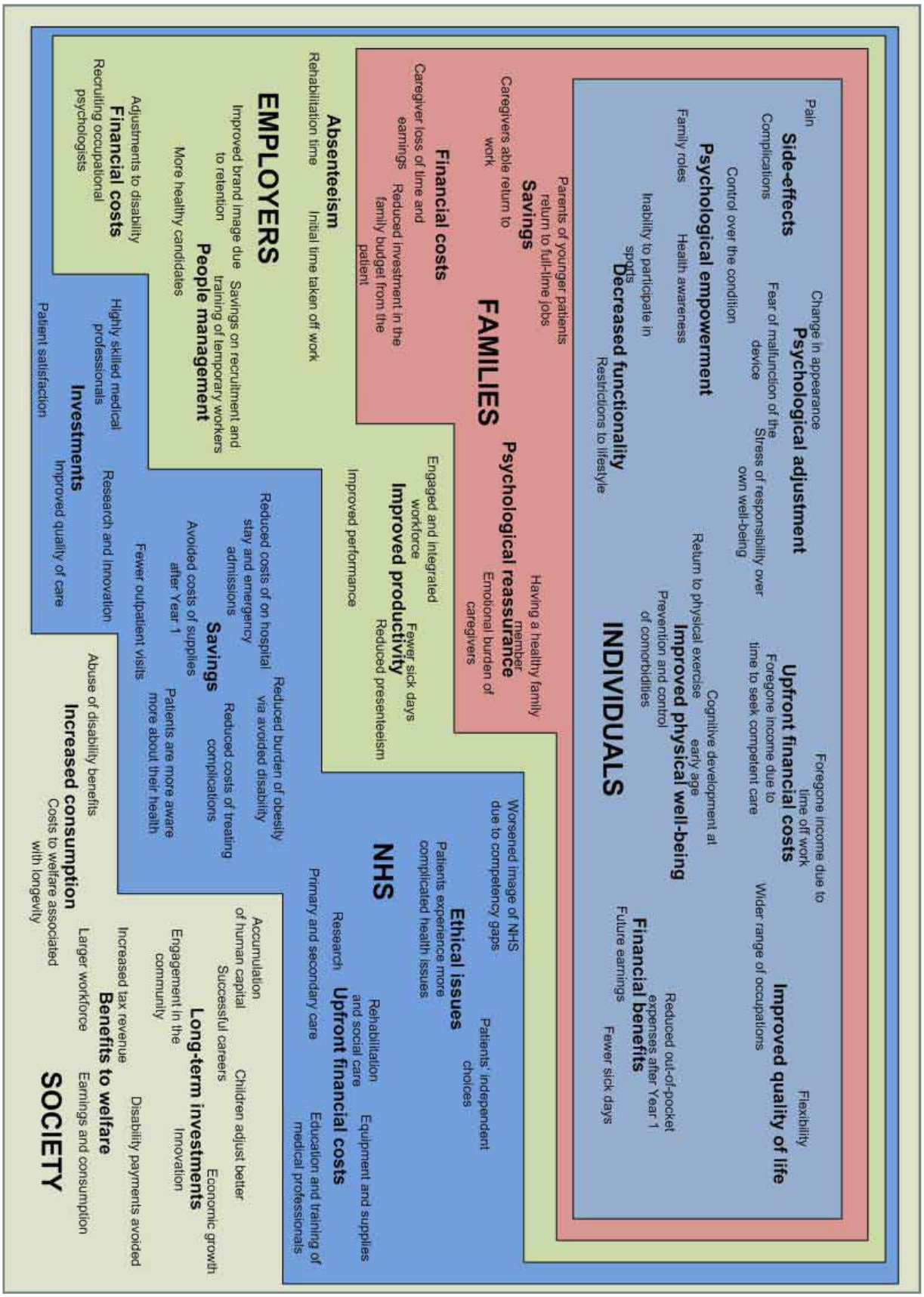
1. Both patients and health care professionals need to improve their awareness of currently available and innovative medical technologies. Raising patient awareness and their confidence in making health care choices would take into account quality of life and labour market outcomes on par with clinical effects of technologies. **The Department of Health should work in partnership with patients, industry and commissioners, and in conjunction with the Ministerial Medical Technology Strategy Group (MMTSG) to develop guidance which increases patient awareness and choice over treatment, therapies and medical devices**.
2. The Department of Health should **appoint expert users** of a range of medical devices (including those of working age) to be part of and advise the national HealthWatch body.
3. The NHS must **invest in the education of medical professionals** to challenge conservative approaches to innovation and to introduce incentives for the wider acceptance of medical advancements and their use, where appropriate, as part of earlier interventions to improve quality of life and labour market participation. Trainee and practicing doctors should be provided with **education and training on the features and benefits of medical devices which are cited in NICE or other professional guidance**. This would enable them to support patients through treatment and at the same time learn from the experiences of intervention users, especially if the technology has wider quality of life or labour market benefits.

C. Recognise the long-term benefits of medical technologies

1. For many medical technologies, health professionals and commissioners appear resistant to use them because of the high upfront costs associated with the uptake. However, the long-term benefits of improved health outcomes, quality and length of life and participation at work and in wider society should also be considered. **Where possible, NICE should be free to comment on the wider societal benefits of medical technologies as part its technology appraisal process**.
2. At the very least, **NICE quality standards should highlight the appropriate use of medical devices and aim to achieve the recommended uptake** where it has previously been outlined in NICE guidance.
3. In the interest of the wider economy and society, uptake of cost-effective, efficacious and beneficial medical technologies could provide long-term savings and benefits through improved health outcomes, NHS efficiency and participation in society. **Consideration could be given to some type of systemic modification that rewards long-term decision-making** or incorporates improved long-term health care and quality of labour market outcomes in the budgeting calculus at the local level.

Not having the intervention is often 'more of a cost' to patients, the health care system and the society. Evidence and experts consulted for this report suggest that further cost and benefit components should be considered when making treatment decisions, refining the cost-effectiveness models by including both short-term and long-term outcomes.

Costs and benefits of medical interventions: beyond the usual benefits framework – expert opinions



1. Background

The current pressure to dramatically reduce public expenditure has not bypassed the NHS. Like many other public institutions it is changing its priorities in order to increase the efficiency of services and save on costs. This can lead to uncomfortable choices from reducing staff numbers to designating some medical procedures as 'low value'. Yet, these austere measures have come with a wider acceptance of some difficult truths about the future delivery of health care. These include the need for greater emphasis on prevention and primary care, but also the need to embrace integrated care and maximise the benefits of the health care service.

The case of chronic conditions, among other things, illustrates that current patterns of provision will be inadequate to deal with rapidly accelerating demand for NHS services. Quick-fix solutions for long-term illnesses may be low in immediate cost, but offer few benefits over time. It is prompting a realisation that clinical practice and the organisation of health care will need to change radically to focus on the long-term effects of interventions and their capacity to prevent individuals withdrawing from work and family roles.

In order to deliver cost-effective health care to an ageing population policy makers and health care professionals will have to harness innovation and technology. It is already clear that a range of innovative medical initiatives on e-Health and Telecare support delivery of high-quality and cost-effective care in the right circumstances. This is especially the case if the technology can deliver tangible improvements to important outcomes such as quality of life and the healthy extension of working lives.

1.1 Medical technologies

Medical technologies are a broad category of devices, procedures and diagnostic and information gathering tools that assist with the delivery of health care. Medical technologies include innovative interventions designed to improve quality and outcomes of treatment and range from syringes to pacemakers to life-support machines. Medical technologies can improve diagnosis, extend life, reduce morbidity and improve quality of life. Some technologies which prove to be more convenient for individuals to administer treatments may improve patients' compliance with treatment regimens and thus reduce further complications in the long-run. Medical technologies offer other benefits that may 'spill-over' to other sectors outside health care as well.[1]

[1] An example provided through an expert interview was the x-ray which was developed for medical diagnoses is also used in airport security. Goldman, Lakdawalla, Philipson and Yin (2010) in an editorial on health technology assessment recognise the potential for spill-overs. As with the initial x-ray multiple iterations and improvements have led to even more sophisticated uses of the technology, such as CT scans or even radiation therapy to treat cancer

While medical technologies can improve health outcomes, some also have the potential of increasing health care costs, particularly in the short term. For example, in addition to costs associated with the technologies, costs may increase as a result of more check-up appointments or simply by virtue of the fact that the technology keeps people living for longer. This is an obvious benefit if the health status is improved, but can also lead to an increase in health care resources consumed because the patient is living for additional years beyond what they otherwise would have been.[2] On the other hand, savings mechanisms associated with new technology are many, including reduced costs associated with improved health outcomes, reduced treatment costs, reductions in long-term complications and co-morbidities, and better diagnoses which lead to more appropriate and timely treatment with less waste of resources. Medical technology improves recovery times and increases the functional capacity of patients. As noted above, this allows more patients and their caregivers to return to work, potentially reducing the economic burden associated with disability and work-limiting incapacity.

1.2 Burden of chronic health conditions

Chronic health conditions and ill-health place a significant burden on individuals – limiting their quality of life and their ability to participate in daily activities such as employment. The costs of ill health to the UK economy already add up to £100 billion a year (Black, 2008) and are likely to increase in coming years. Ill health adversely affects individuals, families, workplaces, health care and society. Poor health can lead to sickness absence,[3] as well as sickness presence, incapacity benefits, unemployment and underemployment. A few key points related to the costs of ill health are highlighted below.

- Poor health in childhood has negative outcomes for employment opportunities, family income, household wealth, individual earnings and labour supply that continue into adulthood (Smith, 2009).
- People with chronic health problems have a harder time gaining and maintaining employment (Schuring, Burdorf, Kunst and Mackenbach, 2007; Suhrcke, Nugent, Stuckler and Rocco, 2006).
- Studies have shown widespread deterioration in aspects of physical and mental wellbeing among those who lose their jobs, which can persist for many months (Armstrong, 2006; Brinkley, Clayton, Coats, Hutton and Overell, 2008; Strully, 2009).
- In 2001 around six million people in the UK reported providing care on an unpaid basis for a relative, friend or neighbour (Census 2001, 2002). The economic burden of alternative care would cost the health care system up to £87 billion a year (Buckner and Yeandle, 2007).

[2] Expert interview
[3] The Confederation of British Industry (CBI) suggests long-term absence costs £3.7 billion (CBI, 2010

Looking forward to 2050, it is clear that choices made now about how health care is delivered will affect the health and quality of life of future generations and the viability of the NHS as a system. The case of long-term conditions is a sobering example in this regard.

Box 1.1: Long-term conditions

There are currently around 15 million people living with a long-term condition in England. People with long-term conditions are disproportionately higher users of health services and account for around 70 per cent of overall health and social care spending, representing 50 per cent of GP appointments, 60 per cent of outpatient and A&E attendances and 70 per cent of inpatient bed days. Today 77 per cent of bed days are due to exacerbations of long-term conditions.

Over the two years to 2013, there will be a 60 per cent increase in the number of patients with two or more long-term conditions The rise in over 65-year-olds that will occur by 2050 is projected to increase the number of people with long-term conditions by 252 per cent.

Source: Department of Health. Millions of patients set to benefit from a modern NHS
http://www.dh.gov.uk/en/MediaCentre/Pressreleases/DH_125042

The burden of chronic health conditions is increasing steadily year on year and the associated costs are rising significantly. As a result, interventions that alleviate or allow patients to better manage their chronic conditions, improve health outcomes, reduce morbidity and mortality might mitigate some of the costs associated with ill health. Advances in health care through the development of interventions and medical technologies have contributed to improvements in health outcomes and life expectancy. Some of these technologies can impact quality of life as well as an individual's ability to continue working and participating in society.

A number of stakeholders including policy makers, clinicians, employers and patients have to support the cultural shift in their approach to health care from a reactive management of the consequences of the chronic conditions towards more insightful, long-term planning. Decision-makers have to embrace the need to think proactively about reducing the societal impact of long-term conditions and consider improvements in quality of life and societal benefits, when assessing the value and benefit of innovative medical technologies.

1.3 Purpose of the report

This report highlights some of the considerations policy makers, health care providers, as well as commissioners of health and social care should address when making decisions regarding the adoption of medical technologies. It seeks to address the wider social and economic considerations, as well as the value, that medical technologies provide. In this context, the report explores the following three technologies, already approved for clinical use by NICE:

- Artificial hip/knee replacements;
- Implantable cardioverter-defibrillators (ICDs);
- Insulin pumps.

In order to investigate the impact of these medical technologies on a number of outcomes, we explored the key questions below.

1. How can medical technologies be used as interventions to help improve:
   a. Labour market participation and work productivity?
   b. Quality of life through participation in society for people with chronic health conditions and independent living among those who have left the workforce?
   c. The efficiency of the NHS?
2. Is there an economic case for wider adoption of some of these technologies? If so, what is it?
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4. What policy changes are needed to increase efficiency of the health and social care services through supporting longevity and workability of individuals with long-term conditions?

1.4 A multi-method approach

In order to address the questions above, we employed a variety of methods, including a literature review, qualitative interviews with stakeholders and experts who know the technologies, and an expert focus group.

Desk-based literature review: Costs and benefits of medical technologies

A short, desk-based review was carried out to explore the role of medical technologies and their impact on work, functional capability, independent living and NHS efficiency and to identify existing evidence on costs and benefits for each of the technologies.

Qualitative interviews: Stakeholders and experts who know and use the three technologies

Qualitative interviews were conducted with two to three individuals per medical technology under investigation to explore their experiences of their condition(s), including how (if at all) they felt it has affected their work and quality of life, and how the medical technology impacted outcomes, including workability. Interviews were also conducted with experts who have knowledge of the medical technologies under investigation to supplement the literature and gain further expertise on each of the medical technologies.

Expert focus group/workshop

We invited a group of professionals from a range of backgrounds including research, policy, medical practice and the third sector to take part in a half-day focus group discussion (see Appendix A). Small and large group discussions focused on the each of the technologies and their impact on outcomes and their costs and benefits. The expert focus group and expert interviews informed the economic assessment of medical technologies.

All of this information and data have been used to inform the content of this report, which is geared towards policymakers and opinion leaders focusing on health and innovation.

1.5 Structure of the report

This report seeks to provide answers to the questions above. It focuses on three medical technologies: artificial hip or knee joints, ICDs and insulin pumps. For each of these interventions we explore how they work and what the costs and benefits associated with the interventions are. The outline of the report is as follows:

- Section 2 considers with the wider value of medical interventions;
- Section 3 discusses the economic case for adopting the specific medical technologies;
- Section 4 assesses the evidence towards adoption of medical technologies in the UK;
- Section 5 provides conclusions and recommendations from the project to key stakeholders.

2. Considering the economic value of medical technology

It has been hypothesised that a significant proportion of the economic growth of the UK over the last 100 years can be attributed to advancements in health care (Hickson, 2008). Health may contribute to economic growth through a number of factors, many of them with knock-on effects. For example, avoided disability reduces the weight of welfare benefits but also contributes to a larger workforce when individuals or caregivers are able to return to work. Given the recognised enormous economic burden of poor health and disability, the NHS has sought to encourage innovation of the health care system, which may project savings through increased efficiency of the service (Office of Life Sciences, 2009). Equal and timely implementation of medical technology is one possible way to improve the health conditions of patients and increase their further participation in the economy and society.

2.1 Assessing costs and benefits

Along with safety and efficacy, costs of medical technologies contribute to utilisation decisions of medical technologies. Health economics research and analysis seeks to quantify the cost of illnesses and the cost and benefits associated with interventions. Many cost-of-illness studies divide costs into the following three categories (Suhrcke, et al., 2006; Bevan, Passmore and Mahdon, 2007):

- **Direct costs** including medical expenditure, such as the cost of prevention, detection, treatment, rehabilitation, long-term care and ongoing medical and private expenditure;
- **Indirect costs** including lost work output attributable to a reduced capacity for activity, such as lost productivity and human capital, lost earnings, lost opportunities for family members, lost earnings of family members and lost tax revenue;
- **Intangible costs** including psychosocial burden resulting in reduced quality of life, such as job stress, economic stress, family stress and suffering.

These costs vary considerably depending on the condition, on the severity of the symptoms, and whether these cause short or long-term absence or disability as well as the type of interventions offered. However, the data suggest that indirect costs comprise about half – if not more – of the total cost figures for many health conditions (Suhrcke et al., 2006; Bevan et al., 2009). These indirect costs are frequently unaccounted for when assessing the value of medical technologies through cost-effectiveness mechanisms.

Cost-effectiveness is defined as the cost of a medical intervention per unit of health benefit (Suhrcke et al., 2006). Several measures are available to contrast costs and benefits in cost-effectiveness models, which attempt to provide a universal system of assessing both quantitative and qualitative components of the analysis. Two of the most frequent measures,

which have become accepted as helpful tools to make comparative judgements across medical conditions and internationally, are **disability adjusted life years (DALYs)** – equal to the number of years of healthy life lost – and **quality adjusted life years (QALYs)** that give a measure of how many extra months or years of life of a reasonable quality a person might gain as a result of treatment and helps in the assessment of the cost-utility of this treatment.

Another frequently cited calculation in the health economics literature that is used to compare interventions is the **incremental cost effectiveness ratio (ICER)**. An ICER is a specific measure applied to medical interventions, calculated as the ratio of the additional costs associated with the intervention treatment compared with the next best alternative therapy, per QALY. Therefore, it is a relative measure rather than an absolute measure. The calculation seeks to quantify the gain in health outcomes, usually measured by QALYs, resulting from the change of treatment.

With limited resources available to pay for interventions, cost-effectiveness measures are used to guide decisions on the use of interventions. The National Institute for Health and Clinical Effectiveness (NICE) uses cost-effectiveness analyses, including QALYs, along with other information to evaluate medical technologies (Dakin, Devlin and Odeyemi, 2006; Raftery, 2001). NICE's role has been regarded by some as controversial (Timmins, 2010). Part of the controversy occurs over the criteria that NICE uses to evaluate new health technologies. Although NICE considers the clinical and cost-effectiveness of interventions, no mechanism is available to consider some of the costs and benefits to the wider society.[4] While the tools have been developed to assist with quantifying, evaluating and comparing technologies, the limitations of those instruments mean that they have not yet been incorporated in the health care commissioning framework.

2.2 Focus on long-term outcomes of medical interventions

With the data on clinical effectiveness and ongoing costs at hand, currently little evidence is available on the potential long-term outcomes for the economy and society. While the direct impact on the health care system may be expressed, for instance, in the price of equipment to purchase and number of bed-stays, indirect costs and benefits which result as a consequence of an illness, premature death or treatment of an illness, are difficult to measure and are often not accounted for in the available economic analyses (Cutler, 2007). Additionally, the majority of studies collect data for only a few years – at most – which reduces the ability to assess the long-term impact of technologies without modelling.

[4] The Health Services Commission has requested for NICE to consider the broader societal costs, and there is an expectation that the projected move to a 'value-based' pricing mechanism may allow greater latitude here

In an attempt to examine the costs and benefits of medical technologies – those that have been quantified and those that are intangible – the following three specific technologies are highlighted:

- Artificial hip/knee replacements;
- Implantable cardioverter-defibrillators (ICDs);
- Insulin pumps.

All three technologies are approved for clinical use by NICE. However, the current cost-effectiveness model does not compare short-term costs against many unpredictable, indirect and intangible future benefits of implementing the three medical interventions. Indeed, putting a price on the value of independent living and working and changes in quality of life is a difficult task (Pinkerton, Johnson-Masotti, Derse and Layde, 2002). As a result the three technologies are only recommended as cost-effective for specific groups of patients, who would benefit from the intervention immediately, limiting access to the technologies for some individuals, who could equally benefit from the use of the intervention in the long run.

Experts consulted for this report suggest that frequently *not* having the intervention was 'more of a cost' to patients, the health care system and the society. The discussion of qualitative outcomes of interventions for stakeholders identified further cost and benefit components that should be considered when making treatment decisions. Figure 2.1 illustrates in detail that taking into account the current and future perspectives will refine the cost-effectiveness models by including both short-term and long-term outcomes.

Many of the positive outcomes associated with the use of innovative medical technologies result from the improved ability of individuals to stay in or return to work. Not only preserved workability supports individuals' physical and psychological well-being, but it also maintains financial sustainability of households, helps employers retain skills in organisations and contributes to the long-term savings for the welfare system. At the health care system level, early and more efficient intervention reduces future costs of more invasive – and more costly – medical procedures.

Failure to recognise long-term outcomes of medical innovation decreases efficiency of NICE policies due to ongoing losses associated with delayed implementation of beneficial technologies. For instance, Perry (2008) suggests that financial and emotional demands of care-giving can have a negative impact on child development, as carers reallocate financial

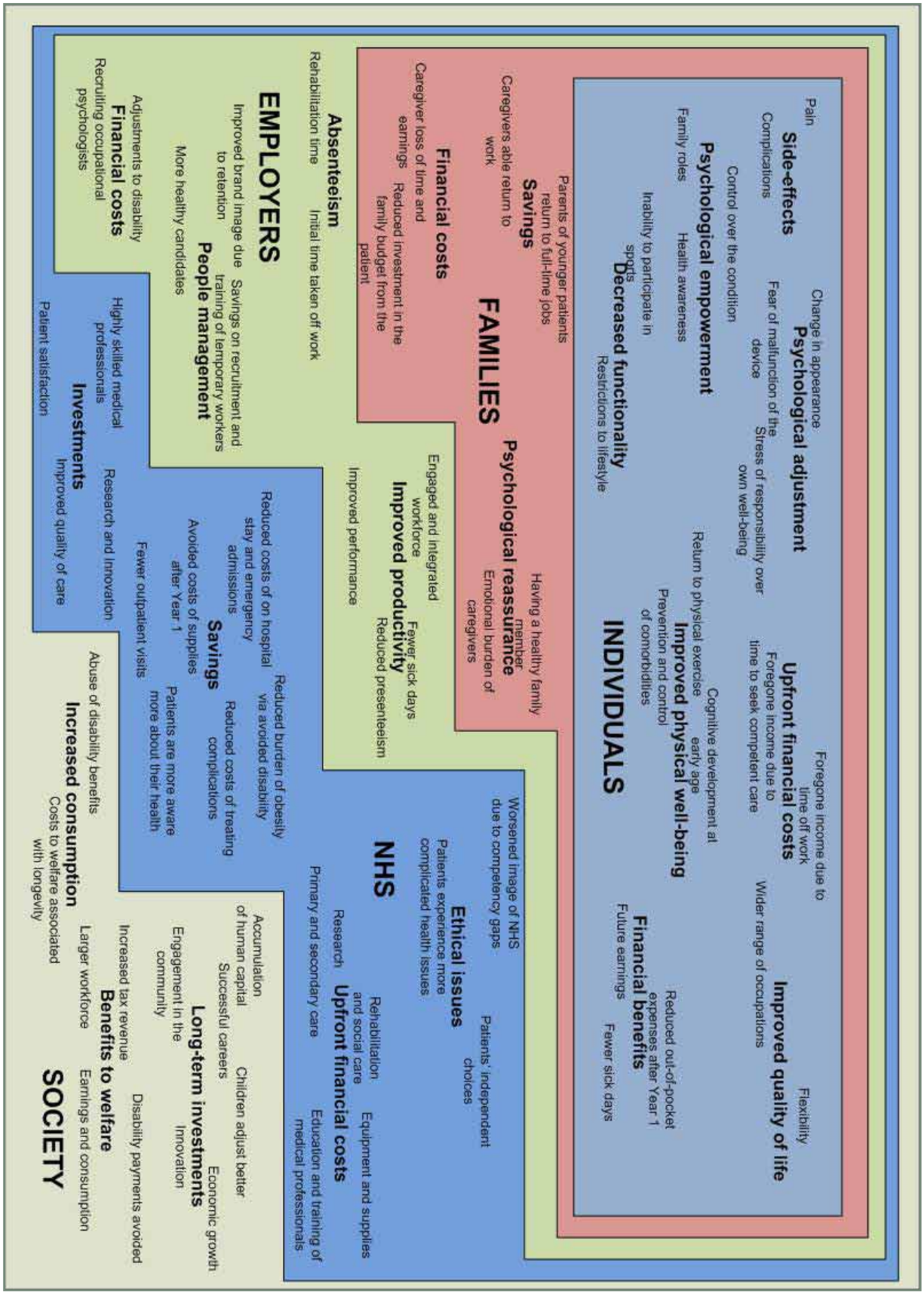


Figure 2.1: Costs and benefits of medical interventions: beyond the usual benefits framework – expert opinions

and time resources toward the sick and away from other family members. From a societal perspective, long-term effects may offer the greatest recovery of costs from investments in medical technology (Krumholz et al., 2002).

2.3 Conclusion

Improvements in health and advancement in health care have contributed to economic growth through various avenues – including continued participation of individuals in the labour market and reduced burden of disease on the health care and welfare system. Equal and timely access to medical interventions, such as medical technologies, may contribute to further improvements. Due to limited resources, however, cost-effectiveness studies are critical. Health economists have developed metrics that seek to assess the impact of interventions, such as medical technologies. Limitations in data quality hinder the ability to make an assessment that considers many of the indirect costs and societal benefits associated with improvements in health as a result of a medical technology. Furthermore, poor understanding of the long-term effect of the interventions may limit access to the technology even for those who are eligible for innovative medical treatment under NICE recommendations.

Additional costs and benefits that may be associated with a specific medical technology are currently not considered in cost-effectiveness analyses. Improved tools that lend to a better understanding of the costs and benefits associated with new medical technologies are needed. Taking into consideration the long-term effects of interventions will support NHS efficiency through the improved individual and societal outcomes of the treatment.

Section 3 explores the costs and benefits of the three specific medical technologies in detail.

3. Costs and benefits of specific medical technologies

As mentioned, the costs and benefits of medical technologies can be direct, indirect and intangible. Direct costs associated with medical technologies can include the cost of the technology and health care resources associated with using the technology. The most tangible benefit is improved health outcomes, such as reduced morbidity and mortality. However, indirect and intangible benefits may also occur through quality-of-life improvements for individuals, including better psychological and social wellbeing, or even for reduced burdens on informal caregivers. If the long-term effects of medical technologies are not taken into account now, individuals and society as a whole may forego some of the future benefits of innovative treatment.

Provision of some medical procedures may be capped by care providers for budget considerations. However, those concerns are based on potentially incomplete cost-effectiveness models. In the following paragraphs we highlight the health conditions associated with the technologies, describe the technologies and explore the existing evidence toward quantifiable and unquantifiable costs and benefits for different groups of stakeholders.

3.1 Artificial hip and knee replacements

Artificial hip and knee joints are medical technologies that replace damaged hip and knee joints. Often the damage occurs from osteoarthritis or rheumatoid arthritis, but damage may also occur from infections or fractures. The joints are replaced through orthopaedic surgery that requires general anaesthesia and a few days stay in the hospital (National Institute for Health and Clinical Excellence (NICE, 2003).

Over 90 per cent of recipients of hip and knee replacement joints have joint damage as a result of osteoarthritis. This condition '*affects joints in the body and is characterized by damage to the surface of the joint. The main symptoms are pain and, sometimes, mild stiffness. The condition is sometimes referred to as osteoarthrosis, arthrosis or degenerative joint disease.*'[5]

[5] See Arthritis Research UK
http://www.arthritisresearchuk.org/arthritis_information/arthritis_types__symptoms/osteoarthritis.aspx

Box 3.1: The burden of musculoskeletal disorders on the UK society

Lost productivity attributable to bone and joint disorders is expected to grow beyond the current levels and will continue to have significant economic and societal impact – particularly with the growth of obesity and the ageing population. Musculoskeletal disorders (MSDs), including osteoarthritis, are the most common type of work-related illness in the UK (Health and Safety Executive, 2010). Estimates suggest that the prevalence of MSDs will only increase in the coming years:

- More than 6.5 million cases of MSDs are present among the individuals of working age in the UK; by 2030 that number will increase up to more than 7 million cases (Vaughan-Jones and Barham, 2009).
- MSDs comprise the second largest percentage of cases of Incapacity Benefit claimants in the UK: 18.2 per cent of claimants in November 2009. Overall, MSDs cost the UK economy £7 billion each year (Bevan et al., 2007).

Osteoarthritis is the most common cause of disability in the UK, incurring considerable societal costs:

- About 80 per cent of people with the condition have some degree of limitation of movement and 25 per cent cannot perform their major activities of daily life (World Health Organization (WHO), 2003).
- Each year, over 2 million adults visit their GP because of osteoarthritis. Of those over 45 years of age, 5 per cent have an osteoarthritis-related GP consultation in the course of an average year (Arthritis Research Campaign, 2002).
- For over 93 per cent of people having hip procedures and 97 per cent of those undergoing knee procedures in 2009 the primary indication was osteoarthritis.
- The total cost of osteoarthritis to the UK economy is estimated at 1 per cent of GNP per year (Arthritis and Musculoskeletal Alliance, 2004; Levy, Ferme, Perocheau and Bono, 1993; Doherty, 1995). In 1999/2000, 36 million working days were lost due to osteoarthritis alone, at an estimated cost of £3.2 billion in lost production. About £43 million was spent on community services and £215 million was spent on social services for individuals with osteoarthritis.

Hip replacements

In a total hip replacement (THR), part of the thigh bone (femur) including the ball (head of femur) is removed and a new, smaller artificial ball is securely fixed into the rest of the thigh bone, while the surface of the existing socket in the pelvis is roughened to accept a new artificial socket for the ball component.[6] Depending on the degree of joint degeneration, invasive treatments of hip osteoarthritis may be required. Those may include replacing one (hemiarthroplasty) or both halves of the joint (total hip arthroplasty, THA) with prosthesis, while installing an artificial stem into the femur bone. A less radical solution is hip resurfacing, which caps the surface of the patient's bone without amputation and presumes fewer restrictions to lifestyle.[7]

A variety of techniques and materials are available to fit the required level of activity of the patient; some prostheses allow a greater range of movement. This may be particularly important for patients who wish to remain in employment or return to their jobs after the procedure. In 2009 the percentage of patients under 65 years (broadly, of working age) was 31 per cent among women and 42 per cent among men (National Joint Registry for England and Wales (NJR), 2010).

Further data gives the most comprehensive and up to date picture of the nature and extent of hip surgery in the UK (NJR, 2010). Key points from the Registry show that:

- 72,432 hip procedures were conducted in the UK in 2009 (1 per cent more than in 2008). Of these, 65,229 (90 per cent) were primary hip replacement procedures and 7,203 were revisions to procedures conducted in previous years. Almost 3 per cent of patients require a revision within 5 years of a primary procedure.
- The average age of people undergoing total hip replacement (THR) was 66.7 years and 56 per cent were female.
- Hip-resurfacing accounted for 6 per cent of all procedures and were received by three times as many men as women. The average age of these patients was 54.6 years.
- The average BMI of patients increased from 27.4 to 28.4 in the five years to 2009, and the percentage of patients with a BMI between 30 and 39 also increased. The NJR reports no change in the age bands within which hip patients fall since 2003. It concludes that the increase in BMI and the reduction in fitness among patients is 'not due to an ageing patient cohort'.

[6] See Arthritis Research UK. http://www.arthritisresearchuk.org/arthritis_information/arthritis_surgery/hip_surgery.aspx?gclid=CPngmtbju6cCFQod4QodeVsj_Q#non

[7] See American Physical Therapy Association. http://guidetoptpractice.apta.org/

Knee replacements

Most total knee replacement operations (TKR) involve replacing the joint surface at the end of the thigh bone (femur) and the joint surface at the top of the shin bone (tibia). Most surgeons prefer to leave the surface of the kneecap (patella) in its natural state because the natural patella is stronger than a resurfaced one and the prosthesis is less likely to cause pain during movement. Similar to the hip joint replacement procedures, a good proportion of TKR patients are of working age: 32 per cent for women and 33 per cent for men (NJR, 2010).

Again, the National Joint Registry (NJR, 2010) provides an overview of the number and nature of knee replacement procedures carried out in the UK in 2009:

- A total of 77,545 knee replacement procedures were carried out in 2009 (2.5 per cent more than in 2008). Of these, 4,565 were revisions (a 12 per cent increase on 2008). A total of 3.6 per cent of patients who have TKR require a revision within 5 years.
- The average age of patients in 2009 was 67.5 years and 57 per cent were women.
- The mean BMI of patients receiving knee replacements in 2009 was 30.5 (from 29.4 four years earlier). This represents an increase of 1.85 kg for a person of average weight. Thus, the average knee replacement patient in 2009 by BMI measurement was clinically obese.

3.1.1 Costs and benefits of joint replacements

Hip and knee joint replacements offer lifestyle benefits to the individuals receiving the intervention. Certain costs are associated with the initial adjustments of lifestyle and work environment to the new health status of the patient. However, many recipients reported the long-term benefits of improved social participation, including preserved ability to work. Below are some key costs and benefits associated with hip and knee arthroplasty.

Patients

As with other patients with chronic physical health problems, those with osteoarthritis who have received joint replacements are also vulnerable to depression or anxiety due to the stigma associated with disability or reduced mobility post-operation. On the other hand, several studies of the psychological wellbeing of these patients (Dorr and Chao, 2007), have concluded that high levels of surgical ‘success’ in reducing chronic pain have positively affected the emotional wellbeing of patients. Research suggests that expectations have a considerable impact on the perceived outcome of the surgery – those with lower subjective quality of life appeared to experience greater improvement after the operation (Ethgen, Bruyère, Richy, Dardennes and Reginster, 2004).

Employment

A systematic review of the return to work literature (Kuijer, de Beer, Houdijk and Frings-Dresen, 2009) found only three studies which met the criteria for inclusion in the review. In general, the review found evidence that more than 60 per cent of those people **already working** prior to their THR or TKR procedures had subsequently returned to work (Mobasheri, Gidwani and Rossan, 2006). These findings are supported by research conducted by Lyall, Ireland and El-Zebdeh (2009). The time elapsed prior to returning to work also varies significantly between studies. Studies have reported times ranging from a little over a week (Espehaug et al., 1998) to several months (Mobasheri et al., 2006).

It seems that the advice given to patients by clinicians about return to work is both very variable and widely adhered to by patients. A study examining patterns of return to work after surgery (Clayton and Verow, 2007) found that the advice on return to work times among patients who had undergone hip resurfacing procedures varied between 4 and 15 weeks. The research found that the average period of absence from work after surgery was 90 days, though this period varied considerably, and adhered very closely to what they had been advised by their surgeon or GP. As one expert told us:

> *'The advice patients get about return to work times varies according to clinical assessment, though my experience is that some doctors are considerably more cautious than others – they seem to think patients have to be 100 per cent fit before returning to work, which is rarely necessary.'*

Of course, one of the factors which can speed up return to work is the willingness of employers to make adjustments to the workplace or to the working time of the employee to accommodate their reduced mobility and fatigue during rehabilitation. Clayton and Verow found that 43 per cent of patients had been the beneficiaries of such adjustments by their employers. By contrast, a survey conducted by Palmer, Milne, Poole, Cooper and Coggon (2005) in the UK suggested that less than 2 per cent of workers who underwent hip or knee surgery received extra training, supervision or physical adjustments to their workplace to maintain their professional status. However the majority of former patients could share job responsibilities with co-workers, reduce working hours or transfer to different tasks.

In a study examining international differences in return to work patterns among those having had joint replacements Bieleman, Oosterveld, Oostveen, Reneman and Groothoff (2010) suggest that work itself can bring health benefits, especially if the demands or work are adjusted to support phased rehabilitation until recovery is secured.

Health care system

NICE guidance has estimated the costs of an artificial hip at £400-£2,000 with additional costs of between £1,200 and £9,000 for operation and treatment (NICE, 2000). On the other hand, many studies agree that THA is a cost-effective procedure for improving quality of life and relieving the disability-related costs to the health care and welfare systems (eg Heiner, Mauerhan, Masonis and Heath, 2008).

3.1.2 Cost-effectiveness and implications

For some time, hip and knee replacements have been regarded as both clinically successful and economically cost-effective. Several studies have examined the cost effectiveness of THR and TKR procedures from a clinical and a 'quality of life' perspective (Dong and Buxton, 2006; Krummenauer, Günther and Witzleb, 2008; Montin, Suominen, Katajisto, Lepistö and Leino-Kilpi, 2009; Slover, Hoffman, Malchau, Tosteson and Koval, 2009). Various studies have sought to estimate the cost of each QALY gained as a result of hip or knee joint replacement.

One study argues that the costs of both knee and hip replacement compare favourably with other medical or surgical procedures (Navarro Espigares, 2006). Total cost of knee replacement was €6,865 (€1,596 per QALY), gaining more QALYs than hip replacement at the cost of €7,891 (€8,768 per QALY).

A recent study arrived at a much lower incremental cost-effectiveness ratio associated with the THA treatment strategy of £1,000 per QALY (Devlin and Appleby, 2010). In the case of the conventional technology for TKR, the average NHS cost for elective primary TKR was £5,197; and the costs of 'complex revision', 'simple revision', and 'other treatments' were £7,326, £6,234 and £2,844 respectively (Devlin and Appleby, 2010).

Di Tanna et al. (2009) compared the incremental cost effectiveness ratios (ICER) of both cementless and hybrid THR replacements. Table 3.1 below illustrates that the **earlier the procedure is carried out the more revision-free life years are gained for patients.**

Table 3.1: THR: Revision-free life years, Costs per life year gained and ICER at different ages

	Cementless			Hybrid			
Age at THR	Costs (€)	Revision free life years	Costs (€) per life year gained	Costs (€)	Revision free life years	Costs (€) per life year gained	ICER (€)
30	4,422	20.1907	219	4,548	17.9767	253	Cementless dominates
35	4,357	19.5934	222	4,436	17.678	251	Cementless dominates
40	4,285	18.8757	227	4,312	17.2743	250	Cementless dominates
45	4,203	18.0053	233	4,175	16.7234	250	22
50	4,116	16.9847	242	4,029	16.0126	252	89
55	4,022	15.7997	255	3,879	15.1128	257	208
60	3,925	14.4528	272	3,730	14.0109	266	442
65	3,827	12.8877	297	3,586	12.6394	284	968
70	3,733	11.1579	335	3,458	11.0435	313	2,402
75	3,648	9.3119	392	3,351	9.275	361	8,028
80	3,579	7.5139	476	3,271	7.5104	436	87,839
85	3,526	5.7072	618	3,216	5.712	563	Hybrid dominates
90	3,494	4.4073	793	3,185	4.4106	722	Hybrid dominates

Mean costs for strategy and revision free life years gained, cost effectiveness ratio and ICER for age at first implant

Source: Di Tanna et al., 2009

Despite the evidence on cost-effectiveness, the current climate in the NHS is causing some commissioners to re-examine what are now being called ‘Procedures of Limited Clinical Value’ where reductions in the number of procedures are being considered. In some parts of the UK hip and knee replacement surgery, and revisions, are seen as *effective interventions with close benefit-risk balance in mild cases*.

Evidence indicates that 30.4 percent of hip replacement patients of working age are able to work. At least 60 per cent of those working before the hip replacement procedure return to work after the surgery without the need to claim Employment and Support Allowance of just under £3,400 per person per year (at 2011 prices). That means that just in 2009 about 11,000 people in England and Wales were enabled to return to work, saving the UK economy £37.4 million per year of their working lives, or £187 million over the next five years and £374 million over the next ten years. This takes no account of the income tax which these workers will be contributing when they return to work.

Re-emergence of quotas for the surgery or enhanced waiting times with cost-control as the paramount objective ignores the proven benefits described above, leading to losses in longevity and productivity with harmful societal ramifications. These developments point to a need to emphasize more prominently the wider economic benefits of hip and knee procedures in terms of quality of life and extended labour market participation and the productivity consequences.

3.2 Implantable cardioverter defibrillators (ICDs)

Implantable cardioverter-defibrillators (ICDs) are medical devices that are implanted into an individual's upper chest below the left shoulder. Usually the procedure requires local anaesthesia and a few days (2-4) stay in the hospital. Leads are connected to the heart that pace, sense and defibrillate. The ICD monitors the heart rate and recognises when an arrhythmia – an irregular, usually faster, heartbeat – occurs. When an arrhythmia occurs, a shock is delivered to the heart to restore the heart's normal rhythm (NICE, 2007).

Secondary prevention using an ICD occurs when the ICD is implanted after an individual experiences a life-threatening arrhythmia to prevent future events, and primary prevention occurs when the ICD is implanted in an individual who is at increased risk for life-threatening arrhythmias (Mark et al., 2008).

Box 3.2: The burden of cardiovascular disease on the UK population

Cardiovascular disease is the leading cause of death in the UK (Scarborough, Wickramasinghe, Smolina, Mitchell and Rayner, 2010; National Health Service (NHS), 2000). It is an umbrella term for a number of different cardiovascular problems, including heart attack, stroke, arrhythmias and heart failure. The prevalence and cost of cardiovascular disease is significant:

- Health care costs comprise around 47 per cent of the overall cost, whereas lost productivity due to mortality and morbidity (27 per cent) and informal carer costs (26 per cent) comprise around 53 per cent of the overall bill (Scarborough et al., 2010).
- For mortality in particular, coronary heart disease results in about 150,565 working years lost in England and Wales with the majority of the deaths occurring in men aged 45 to 64 years (Liu, Maniadakis, Gray and Rayner, 2002).
- Estimates of cases of coronary heart disease to 2030 suggest that there will be more than one million cases in the working age population, which is about 100,000 more than 2006 estimates (Vaughan-Jones and Barham, 2009).

Cont.

Cont.

Within the category of cardiovascular diseases, arrhythmias leading to sudden cardiac death and heart failure comprise a good proportion of morbidity and mortality:

- More than 700,000 people in England have cardiac arrhythmia, which may be an inherited problem or an acquired condition (NHS, 2005).
- Sudden cardiac death is an unexpected death as a result of cardiac causes, usually within one hour of symptom onset – mostly as the result of the first recognised arrhythmic event (NICE, 2006). About 95 per cent of those who experience sudden cardiac arrest die before reaching the hospital.[8] Those who do survive are at high risk of further episodes with about half being re-hospitalised within one year (NICE, 2006).
- The prevalence of heart failure was 0.9 per cent for males and 0.7 per cent for females in 2009 (NHS, 2009). A significant increase – about 50 per cent – in heart failure hospital admissions is projected over then next 20 years (Petersen, Rayner and Walstenholme, 2002). In the UK, the total costs of heart failure to the NHS are about £625 million per year with hospital inpatient care the largest contributor (60 per cent) (Petersen, Rayner and Wolstenholme, 2002).

3.2.1 Costs and benefits of implantable cardioverter defibrillators

ICDs significantly reduce mortality (Epstein, 2008), with at least 66 per cent of patients reporting that the intervention 'saved their lives' (Buxton et al., 2006). ICDs have been shown to prevent death from sudden cardiac arrest 98 per cent of the time (Zipes, Camm, Borggrefe, Buxton, Chaitman et al., 2006). Many patients requiring the intervention are of working age. According to one review of the literature on ICDs, the majority of ICD recipients are men between the ages of 45 and 64 years (Buxton et al., 2006). Some data suggest that about 10 per cent of ICD recipients are below the age of 50 (Sears, Burns, Handberg, Sotile and Conti, 2001). However, some lifestyle adjustments may be required following ICD implantation. Evidence towards costs and benefits of ICDs is summarised below.

[8] See Heart Rhythm Society. Sudden Cardiac Arrest Facts
http://www.hrsonline.org/News/Media/fact-sheets/Sudden-Cardiac-Facts.cfm

Patients

The evidence supporting the clinical effectiveness of ICDs in reducing mortality is well-established (Bardy et al., 2005; Bryant et al., 2005; Camm, Klein and Nisam, 2007; Ezekowitz, Armstrong, and McAlister, 2003; Thomas et al., 2006). Clinical trials have shown a 20 per cent to 30 per cent reduction of mortality over more than a 10 year period as a result of an ICD compared with other interventions (Epstein, 2008). High levels of satisfaction are reported for ICDs with more than 90 per cent of individuals recommending the therapy to other patients (Buxton et al., 2006). Experts interviewed for this report likened the ICDs to insurance highlighting that the main purpose of an ICD is to reduce mortality:

> *'Either it is there as a treatment for people who have already survived an event or it can be regarded as an insurance policy for those known to be at high risk for it.'*
>
> Expert interview

With this added security, some adaptations to the lifestyle may be needed (Buxton et al., 2006). Younger ICD patients report that their quality of life and emotional functioning were affected after the procedure, although their general health is better (Sears et al., 2001; Sears and Conti, 2002). One potential limitation associated with ICDs is that they may restrict driving (Ezekowitz et al., 2003).[9] This may impact the ability of an individual to get to work.

When ICDs are compared with other treatments, such as drug therapy or a pacemaker, quality of life outcomes are often similar (Thomas et al., 2006).[10] However, shocks delivered by the devices to restore heart rhythm may affect individual's psychological status (Thomas et al., 2006). One of the patients interviewed explained:

> *'Being with people and being shocked – I'm not looking forward to it when it happens. If I am in somewhere quiet, like theatre, or one of the children's school performances, I would've yelped out loud, it would be a bit embarrassing.'*

However, the majority of individuals with ICDs do not experience inappropriate shocks. Data from a clinical trial indicate that about 11.5 per cent of ICD patients may experience an inappropriate shock during an 18 month time period; they most commonly occur among individuals with a history of atrial fibrillation, smoking and/or diastolic hypertension as well as among those with experiences of appropriate shock occurrences (Daubert et al., 2008).

[9] Reiterated in patient and stakeholder interviews

[10] Thomas et al. (2006) report that seven studies have compared ICDs with alternative treatments. Six of seven report similar quality of life outcomes for those with and without ICDs. One study found that individuals with ICDs reported better quality of life compared with pharmacological therapy, whereas another study found that individuals with ICDs reported a worse quality of life when compared with coronary artery bypass graft surgery (CABG)

Families

While ICDs provide improved security against sudden cardiac death, fears or catastrophic thinking – particularly related to shocks – may inhibit individuals from fully participating in social activities that the ICD is meant to enable (Sears and Conti, 2002).

With implantation of ICDs, support systems and programmes also need to be put in place to support adjustment to life with a life-threatening condition. A number of psychosocial interventions have been developed to support of individuals with ICDs, their partners and family members in dealing with anxiety (van den Broek, Habibović and Pedersen, 2010); more work is needed to educate health professionals to assist patients with psychosocial adjustment (Sears and Conti, 2002). The experts we consulted confirm that both technological solutions, such as remote monitoring,[11] and patient education strategies were available to prevent potential stress. Additionally, experts highlighted how talking with patients about the ICD helps to make them aware of the risks and benefits. One expert explained:

> *'The reaction of patients depends critically on the time taken to explain to the patient what has happened to them and what might happen to them and why the ICD is something that could in fact be life saving for them.'*

Employment

Few studies have examined the impact of ICDs on work outcomes.[12] However, as mentioned before, mortality associated with cardiovascular conditions leads to considerable losses in working years (Liu et al., 2002). Since ICDs extend lives, their use may lead to reductions in the loss of working years. With that said, of those participating in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) only 27 per cent were employed (Mark et al., 2008) and of those participating in a Dutch study examining quality of life 21 per cent were employed (Kamphuis, de Leeuw, Derksen, Hauer and Winnubst, 2003). On the other hand, the few studies that have examined this issue found that the majority of individuals who were employed prior to receiving an ICD were able to return to work after the procedure, thus improving quality of life outcomes (Kalbfleisch et al., 1989; Gurevitz et al., 2003). The majority of ICD recipients who want to work should be able to continue working, and this could have positive implications for quality of life (Sears and Conti, 2002) as well as on the overall economy.

[11] A remote monitoring system offers additional assistance in monitoring the performance of the ICD and can reduce the occurrence of inappropriate shocks and ICD malfunction.
[12] Reiterated in an expert interview

While some indirect costs result from having to take time off work to undergo surgery to receive an ICD, one of the experts marked reduction in absenteeism among patients implanted with an ICD:

> *'Employees can continue working… without being sick all the time, or having to leave their jobs…A person with an ICD shouldn't have more time off work than any other person without [a heart condition].'*

Health care system

Boriani et al. (2009) explain that while ICD treatment incurs high up-front and maintenance costs on the health care system, there are considerable clinical benefits that compensate for the 'affordability' factor. The authors argue that other minimally invasive treatments do not generate the same degree of survival probability in the long-term, as compared to major interventions, like ICDs, which significantly reduce the risk of sudden cardiac death.

3.2.2 Cost-effectiveness and implications

NICE (2006) found ICDs to be a cost-effective intervention in a wider patient population compared to the recommendations of 2000, particularly due to the increase in the battery life of ICDs. A recent article by Cowie et al. (2009) suggests that the cost-effectiveness of ICD therapy when compared with conventional therapy is €31,717 per QALY gained with the cost-effectiveness ratio of ICDs below €50,000 per QALY. Cowie et al. (2009) indicate that 70 per cent of the per person cost for an ICD is related to the device and implant procedure costs, which confirms the high up-front costs of an ICD with benefits 'likely to accrue well beyond the duration of the clinical trial.'

Experts interviewed for this report confirm that the cost-effectiveness of an ICD increases with the length of time the ICD is implanted. The validity of the studies is often limited by a number of assumptions about future outcomes, such as lifespan of the device or the probability of sudden cardiac death. Some variables that most influence the cost-effectiveness of an ICD are ICD efficacy, time to replacement, utility and patient age at implantation (Cowie et al., 2009). Further technological advances would lead to improved cost-effectiveness due to improvements in the length of time before a replacement ICD is needed (Hauser, 2005; Ramachandra, 2010). In the long run ICDs may be 'a worthwhile investment not only for individual patients but for society as a whole' (Boriani et al., 2009).

While the rate of implantation of ICDs has increased in the UK (Buxton et al., 2006; Connelly, 2001; Cunningham, Charles, Cunningham and de Lange, 2009), it is still one of the lowest rates of ICD implantation per million inhabitants (Cunningham et al., 2009). The implantation rates also vary regionally with the rate in Wales being considerably lower compared with England.[13]

The Heart Rhythm Devices UK National Clinical Audit collects annually ICD implant rates in the NHS. In 2009 the ICD implant rate was about 80 per million population, well below the guide of 100 implants per million population and the European average of 160 devices pmp. In the current year it would mean that up to 5,000 people in UK are implanted with ICDs. Considering that about 21 per cent of people with ICDs are employed and are not claiming the Employment and Support Allowance, it is saving the UK economy £3.5 million each year. If the number of people with ICDs was to match the European rate the savings would increase to about £7.1 million a year.

Some potential reasons for the lower rate of implantation in the UK are that there are fewer implanting centres and electrophysiologists (Camm and Nisam, 2010).[14] Additional barriers include lack of awareness among physicians about the effectiveness of ICDs for individuals at risk of sudden cardiac death as well as misunderstanding about the costs-effectiveness of ICDs.[15]

Evaluations of the cost-effectiveness of the intervention suggest that the number of patients that need to be treated to avoid one death decreases the longer an ICD is implanted (Camm et al., 2007). Therefore, when an ICD is initially implanted the number of patients that need to be treated to achieve cost-effectiveness is greater than when an ICD has been implanted for a few years.[16] The MADIT-II trial suggests that only eight patients need to be treated to save one life after eight years of follow-up (Goldenberg et al., 2010). Very few therapies for cardiovascular disease have such a low effectiveness cost. If the device implantation rates increased beyond that goal, even more savings could be realised through reductions in mortality rates and improvements to NHS efficiency.

3.3 Insulin pumps

Insulin pumps (continuous subcutaneous insulin infusion (CSII) therapy) are medical devices that deliver insulin through a subcutaneously placed cannula – a tube that is inserted under the skin – or a small needle. The pump is programmed to deliver a specific amount of insulin

[13] See British Cardiovascular Society. National variations in the provision of cardiac services in the United Kingdom http://www.bcs.com/pages/news_full.asp?NewsID=17115455
[14] Reiterated in an expert interview
[15] Expert interview
[16] Reiterated in an expert interview.

throughout the day, and it can also be initiated through the push of a button. The cannula should be replaced by a patient or carer and repositioned every three days. The devices are typically worn 24 hours per day (NICE, 2008).

Insulin pumps are recommended as a treatment option for patients with Type 1 diabetes when control of hypoglycaemia or high blood glucose levels has continued to be poor on best insulin injection regimes (NICE, 2008). The pump imitates the insulin secretion patterns from the pancreas of a person without diabetes, enabling the patient to maintain blood glucose levels that are closer to normal than can often be achieved during injection treatment, without increasing the risk of hypoglycaemia often seen with intensive insulin therapy. In children, insulin pumps may be considered for achieving good diabetes control when multiple daily injections of insulin (MDI) are judged by the doctor to be impractical or inappropriate (NICE, 2008).

Box 3.3: The burden of diabetes on the UK society

Diabetes is a chronic health condition associated with excessive amount of glucose in the bloodstream, normally regulated by the hormone insulin. There are two main types of diabetes – Type 1 and Type 2.[17] Type 1 diabetes is an autoimmune disease associated with the failure of the body to produce the hormone, and accounts for between 5 per cent and 15 per cent of all cases. Occurring more commonly, Type 2 diabetes is often an outcome of environmental and lifestyle changes, including sedentary lifestyle and overeating (Wild, Roglic, Green, Sicree and King, 2004).

- Complications associated with both types of diabetes may result from fluctuations in blood glucose levels, which can impact cardiovascular, renal and neural systems (American Diabetes Association (ADA), 2008) and lead to comorbidities and disability.
- WHO (2009) estimates that deaths from complications associated with diabetes will double between 2005 and 2030.
- Diabetes affects more than 1.2 million individuals of working age in the UK; the number of cases is projected to reach more than 1.3 million by 2030 (Vaughan-Jones and Barham, 2009).
- Many individuals are diagnosed with Type 1 diabetes as children, therefore presenting a lifelong demand for health care (Helgeson, Honcharuk, Becker, Escobar and Siminerio, 2011).

Cont.

[17] See Diabetes UK. (2010a). *What is Diabetes?* Retrieved 3 August 2010 from: http://www.diabetes.org.uk/Guide-to-diabetes/Introduction-to-diabetes/What_is_diabetes/

Cont.

Treatment of symptoms and complications associated with this lifelong condition is a significant burden to the health care system:

- At least 1 in 14 diabetes patients in the UK require emergency response for one or more episodes of severe hypoglycaemia annually (Leese et al., 2003).
- The costs of medical care of diabetic patients are estimated at £2 billion or 5 per cent of NHS budget each year (National Economic Research Associates (NERA), 2004).
- Some evidence indicates that people with diabetes have two to three times the rate of sickness absence as other workers (Bramley-Harker and Barham, 2004), with over 55 per cent of sick days attributed to comorbidities, including depression, musculoskeletal and respiratory problems (Kivimaki et al., 2007).
- In the United States, the burden of diabetes to the national productivity is almost a third of total estimated costs (ADA, 2008). No comparable estimation is available for the UK economy.

3.3.1 Costs and benefits of insulin pumps

Some of the benefits of insulin pump therapy over MDI directly impact patients through improved health, wellbeing and quality of life. At the same time there are costs of switching onto insulin pumps from daily injections, as well as indirect costs during the adjustment period.

Patients

Insulin pump therapy is reportedly beneficial for overall physical health, reducing the number of severe hypoglycaemia episodes (Misso, Egberts, Page, O'Connor and Shaw, 2010). As the insulin pump allows continuous control over blood sugar levels, it helps minimise a pre-breakfast hyperglycaemia (known as the 'dawn phenomenon'), improve sleeping patterns (eg Pickup and Keen, 2002) and reduce overall fear of hypoglycaemia (Hoogma et al., 2006; Hammond, Liebl and Grunder, 2007).

> *'I can't imagine waking up in the morning thinking I am a slave to where my blood sugar is.'*
>
> Patient interview

Some diabetes patients may become depressed and discouraged to control their blood sugar levels. As a result exacerbated health condition incurs further treatment costs (Das-Munshi et al., 2007). On the other hand, patients who perceived themselves to be positively affecting their treatment were less likely to develop depressive symptoms and reported higher treatment satisfaction and quality of life (Aberle et al., 2009). With an insulin pump patients would need to spend less time on adjusting the dose of insulin intake with every injection, as well as perceive themselves to be in control of the treatment process.

> One patient reported that the insulin pump improved mental wellbeing by allowing her to *'not [live] in the shadow of diabetes all the time'*
>
> Patient interview

Modern insulin pumps allow precise adjustment of the insulin infusion rates according to the feedback received from measuring the blood glucose and active insulin levels. Some pumps allow continuous monitoring of blood glucose, or even indicate how much insulin boost is needed at different times of the day. Recent evidence suggests that patients learned to independently maintain their blood sugar levels within normal limits after three months of using an insulin pump, while gaining flexibility in times and size of meal intake, as well as expanding the variety of available daily activities (Rubin, Borgman and Sulik, 2011). The pumps may be particularly useful in cases of unpredictable daily schedules, such as shift work and frequent travel, or for patients with abnormal eating behaviour (Hammond, Boardman and Greenwood, 2006). Of individuals who have experienced both MDI and CSII therapies, the majority of patients opt for the use of the insulin pump, as reported by one of the experts:

> *'Once they've got it, they wouldn't go back to what they have before, that's universal… they just wouldn't go back. Convenience, that's what they want, they feel much better, they don't have to go through highs and lows, and it gives so much independence.'*
>
> Expert interview

Some costs are associated with the use of the insulin pump at the patient level. Due to lack of funding and slow uptake of the technology, some patients may have to carry the costs of the equipment, as well as the travel costs to the clinic where insulin pump therapy is available. Indirect costs may include time to adjust to the pump, as well dealing with low social awareness of the insulin pumps associated with its narrow adoption. For instance, one patient interviewed reported negative experiences of going through security lines when travelling:

> *'Every time it's like 'here we go again'. I learned to travel in clothes, where I can easily lift up my shirt to show it.'*
>
> Patient interview

Some people could be physically and emotionally uncomfortable about the visibility of the device, in particular adolescent female patients (Kakleas, Kandyla, Karayianni and Karavanaki, 2009). However, Skladany, Miller, Guthermann and Ludwig (2008) further explore the dilemma, concluding that concerns over appearance do not correlate with gender and are alleviated by increased reliability and discreetness of modern patch devices. According to one interviewee, the ease of administering insulin in fact attracted less attention to the pump user:

> *'A pump makes life more convenient. Yes, you have to carry the thing around with you, but at the touch of the button, you do it discreetly.'*
>
> Patient interview

Several studies have examined the changes to weight experienced by some patients and have yielded mixed results depending on age and gender distribution of the sample (Linkeschova, Raoul, Bott, Berger and Spraul, 2002; Ahern et al., 2002). A meta-analysis has shown that the majority of the trials report weight change to be insignificant (Weissberg-Benchell, Antisdel-Lomaglio and Seshadri, 2003).

Families

Some evidence suggests that CSII therapy should be recommended to women with diabetes in the preconception period to reduce blood glucose fluctuations and hypoglycaemia, and lower overall blood glucose levels during pregnancy, thereby reducing the risk of neonatal morbidities in the baby and obstetric complications for the mother (Mukhopadhyay, Farrell, Fraser and Ola, 2007; Shetty and Wolpert, 2010).

> *'In reference to pregnant women with diabetes, 'preconceptually they tend to get better control, and they are running into fewer complications during the pregnancy. They are less likely to experience hypoglycaemia, which is a common problem. Also better control of insulin levels during delivery.'*
>
> Expert interview

Additionally the treatment offers some benefits for the patients' family (Cummins et al., 2010), in particular caregivers of diabetic children, who may have to break up their work day to administer insulin injections at school lunch times. Not only does CSII therapy prevent early onset of complications in young patients, but is also conducive to a more flexible lifestyle and reduced fear of hypoglycaemia among parents (Weinzimer et al., 2006). The value of preventing comorbidities for family and work life was often highlighted in patients' interviews:

'For the sake of the job, keeping your blood sugar under tight control is important, because you are not going to lose your sight, take early retirement you're going to be able to keep up with kids...rather than you can't feel your feet.'

Patient interview

Employment

As mentioned earlier, the decreased productivity and high rates of sickness absence among the working adults with diabetes is a worrying issue for many concerned with the economic burden of the condition (Burton, Conti, Chen, Schultz and Edington, 1999; Goetzel, Hawkins, Ozminkowski, and Wang, 2003; Goetzel et al., 2004). Von Korff et al. (2005) suggest that many diabetes patients are unemployed not only due to the deteriorated health, but also because job demands and the work environment are not flexible enough to accommodate the tight control necessary to maintain normal blood sugar levels, such as regular injections of insulin and rigid meal times. Insulin pump therapy allows more flexibility of lifestyle, assisting accommodation of individuals with diabetes at the workplace.[18]

It is reported that 60 to 70 per cent of people with diabetes experience neuropathy – sensory impairment or pain in their limbs, which could affect performance (ADA, 2008). Successful treatment of diabetes with the CSII therapy may reduce neuropathy in patients (Kesavadev and Rasheed, 2007), contributing to reduced sick absences and presenteeism through relieving diabetes complications and the improved psychological state.

Health care system

A number of studies have compared cost-effectiveness of insulin pumps with MDI treatment, confirming a gain in QALYs at an increased cost. Indeed, the upfront marginal cost of CSII compared with MDI is between £3,571 and £3,878 with additional £2,715 for training medical professionals (Colquitt, Green, Sidhu, Hartwell and Waugh, 2004). Mean direct lifetime costs add up to be £19,407 ± £1,727 higher with CSII treatment compared to MDI (Roze, Valentine, Zakrzewska and Palmer, 2005).

Good blood glucose control helps to reduce long-term tissue complications such as eye, kidney and nerve disease, with fewer number of primary and secondary care contacts needed for diabetes patients .Transition to insulin pump therapy would see accumulating savings on treatment of long-term diabetes-related complications, including blindness, limb loss and kidney failure, which may require costly amputations and transplants (Cohen et al., 2007).

[18] Patient interview

Ulahannan, Myint and Lonnen (2007) project avoided costs of consultant appointments and hospital admissions of between £22,684 and £38,181 per 100 patients each year. Discounting future costs of diabetes is one of the challenges for the cost-effectiveness model of insulin pump therapy, particularly for young patients.

Society

A less obvious advantage associated with the use of insulin pumps among children is better social and psychological adjustment of those put on the CSII therapy. School children learned to manage glucose levels faster (Doyle et al., 2004) and showed further improvement in their cognitive abilities when tighter control over blood glucose was achieved (Cummins et al., 2010). Successful physical and psychological adjustment in childhood and adolescence may improve career opportunities and participation in various aspects of the society, including family and public roles for diabetic children (Helgeson et al., 2011).

3.3.2 Cost-effectiveness and implications

Assessing the costs and outcomes of CSII therapy for the health system and patients Scuffham and Carr (2003) concluded that insulin pumps were most cost-effective for Type 1 diabetes patients who experience more than two severe hypoglycaemic events per year and are admitted to the hospital at least once every year, at an ICER of only £11,461 per QALY. This evidence is reflected in the NHS Guidelines on CSII, which recommend the device for patients with high risk of hypoglycaemia (NICE, 2008). However, this guidance may be indirectly restricting the number of diabetics who would receive the treatment and therefore reducing the health and cost benefits associated with wider adoption of insulin pumps. In addition, many who qualify for insulin pump treatment under the NICE guidelines are unable to receive an insulin pump due to practitioners' unfamiliarity with the device and subsequent delays in referrals.[19]

Most cost-effectiveness analyses of insulin pump therapy take into consideration short-term benefits in reducing the costs associated with hypoglycaemia episodes; however, they fail to quantify the long-term effect of improved quality of life and added QALYs attributed to the reduced complications of diabetes (Hoogma et al., 2006; Ulahannan et al., 2007). The gap in data is partially explained by the lack of consistent measures for quality of life among diabetes patients, particularly with respect to treatment satisfaction, treatment impact, diabetes-related anxiety and perception of mental health (Speight, Reaney and Barnard, 2009). While the current CSII cost-effectiveness model does not include lifestyle and psychological benefits, the reported ICER is still inline with other interventions accepted by NICE (Roze et al., 2005).

[19] Expert interview

Savings on improved clinical effectiveness of the insulin pumps slightly decrease the ICER of the CSII therapy for general population to about £20,648 to £36,587 per QALY depending on the projected effectiveness of treatment in reducing long-term complications (Cummins et al., 2010). Interviewed experts and users report insulin pump use provides long-term qualitative benefits, including social benefits missed by health-related quality of life measurement, that are not currently included in cost-effectiveness evaluations:

> *'There are benefits for the health care systems. Reduced amounts of service, reduced outpatient visits. hospital stay, reduced long-term complications. Ultimately you can probably offset a lot of the costs. Again the savings you make are more difficult to see... The pump and consumables are staring in the face and they are the only budget. The other are more intangible, you know the cost of people coming in, but the savings of them not coming in are more difficult to assess.'*
>
> Expert interview

Meltzer, Egleston, Stoffel and Dasbach (2000) attempt to estimate the potential quality of life benefits for young adults with intensive control over blood glucose levels, predicting that improved earning capacity together with longer life expectancy would bring the cost-effectiveness of intensive therapy down from $31,893 to $13,599 per discounted life-year and from $22,576 to $9,626 per discounted QALY.

Given the reported evidence towards the benefits of insulin pump therapy, it is surprising that only about 1 per cent of individuals with Type 1 diabetes in the UK were using CSII at the time of the most recent NICE Technology Appraisal (NICE, 2008), and probably still less than 5 per cent in 2011, while the benchmark set by NICE (2009) recommended an uptake by at least 12 per cent of patients with Type 1 diabetes. Lack of awareness of the long-term benefits associated with insulin pumps, funding shortages, as well as low patient voice in the treatment process may have contributed to the ongoing conservative approach among doctors (Pickup and Keen, 2002). For instance, early anecdotal reports on possible increased risks associated with use of the device has not been confirmed by subsequent controlled trials (hypoglycaemia is in fact markedly reduced by pump therapy), yet these beliefs appear to have discouraged the spread of CSII use in the UK (Colquitt et al., 2004; Rodrigues, Reid, Ismail and Amiel, 2004).

Budget constraints and misinformation about the outcomes of insulin pump therapy may have led to disagreement about which diabetic patients should be treated with CSII (Pickup, 2006). Diabetes patients with significant fluctuations of blood glucose levels, who would benefit most

from stable control provided by an insulin pump, are paradoxically required to achieve that level of control through MDI to be considered for alternative therapy. In fact, 'CSII therapy is contraindicated when the patient does not demonstrate the necessary commitment and competence to use such therapy effectively.' (Hammond et al., 2006, p.398). One of the clinicians explained the reasoning behind rigid eligibility criteria for pump use:

> *'[Consultants] wouldn't consider some people for the pump therapy unless they are already competent in carbohydrate counting...If we put someone who is not committed on the pump, they would be getting better control in terms of less hassle, but they wouldn't be getting the best out of the pump therapy.'*

Considering the target benchmark of 12 per cent uptake (NICE, 2009) and evidence presented above, it is clear that more could be done to reduce the burden of diabetes on the UK society. Evidence suggests that between £23,000 and £38,000 is saved each year on every 100 patients who use insulin pumps. If the number of pumps was brought up by 7 per cent to reach the 12 per cent benchmark set by NICE, additional savings just on consultants' visits and hospital admissions would add up to between £37.2 million and £62.5 million per year.

3.4 Conclusions

For the three technologies under investigation, some of the key points are highlighted below.

- **Artificial hip/knee replacements** suggest improvement in the recipients' social lives, as such surgeries are considered to be cost-effective in preventing disability (Heiner et al., 2008). Further implications of the intervention may, however, be drawn from the knock-on effects associated with the costs of disability: relieved burden of caregivers, improved opportunities of return to work among patients, as well as benefits of participating in family roles should be included in the cost-effectiveness model. In addition, with an extension to the working lives of many UK citizens forecast over the next 20 years, joint replacements will allow an increasing proportion of the workforce to stay in, and return to, work. Indeed in 2009 approximately 11,000 people in England and Wales were enabled to return to work by a hip replacement surgery, saving the UK welfare system £37.4 million per year for the remainder of their working lives.

- **Implantable cardioverter-defibrillators** offer crucial advantages in extending lives of people with chronic heart conditions. While the quality of life of ICD patients may be decreased as a result of treatment (Sears et al., 2001), the devices offer a single most effective response in emergency cardiac episodes, effective in 98 per cent of cases of sudden cardiac arrest. The intervention is thus considered to be cost-efficient among

patients with high risks of sudden cardiac death. Return to work following implantation of an ICD reduces the burden to the UK welfare system by £3.5 million each year. If the number of people with ICDs was to match the European rate, the savings would increase to £7.5 million a year.

- **Insulin pump therapy** is one technology, which offers not only improved blood glucose levels and reduced risk of hospital admissions following diabetes complications, thus reducing time taken off work, but has also shown significant psychosocial benefits for patients with poor disease management. Additionally, there is evidence that insulin pump therapy may support cognitive development and improved psychological adjustment of young patients (Doyle et al., 2004), justifying the possibility of early use of the intervention among children. If the number of pump users was brought up by 7 per cent to reach the 12 per cent benchmark set by NICE, additional savings just on consultants' visits and hospital admissions would add up to between £37.2 million and £62.5 million per year.

4. Expanding the cost and benefits model

Evaluating cost-effectiveness of medical interventions is recognised to be a challenging task. With the current tools, which are highlighted in Section 2, a number of variables are not included in cost-effectiveness models. Frequently these assessments do not consider the impacts on families, employers and society. Where the assessments do consider individuals, they do not consider some of the intangible impacts. A similar case can be made for the NHS as well. Inconsistencies in the existing evidence are further exacerbated by the gaps in state policy on the implementation of medical technologies in the UK.

4.1 Summary of quantitative evidence: an example of insulin pump therapy

As mentioned earlier, diabetes poses a significant cost to a wide range of stakeholders. For example, some costs associated with Type 2 diabetes have been quantified and are listed below (NERA, 2004).

- Carers: Carers report losing an average of about £11,000 per person per year.
- Employers: The current average cost of absenteeism is £476 per employee per year. Diabetic employees are reported to have 2-3 times higher sickness absence than non-diabetic employees.
- Social services: The average annual cost of social services is £2,450 per person per year. For the purpose of extrapolation, it should be noted, however, that only 1 in 20 of those with diabetes use social services.

In addition there are costs to the health care system associated with short-term and long-term impact of diabetes:

- Estimates suggest that the total annual direct costs associated with severe hypoglycaemia events among Type 1 and Type 2 diabetes patients could reach about £13 million in the UK (Leese et al., 2003).
- Significant costs are associated with treating diabetes complications. One study has found the cost of diabetic peripheral neuropathy to be around £250 million (Gordois, Scuffham, Shearer, Oglesby and Tobian, 2003). NICE reports that up to £600 million are spent each year to treat diabetic foot problems, including amputations (NICE, 2011).

If health outcomes of individuals with diabetes were improved, then some cost savings may be realised. With incomplete data on potential costs and savings associated with medical interventions, it is difficult to provide a comprehensive estimation or forecast the impact of technology implementation for the future. The following statistics provide some examples of how the effect of insulin pump use may be quantified.

For CSII treatment, the mean direct lifetime costs add up to be £19,407 ± £1,727 higher compared to MDI (Roze et al., 2005). The additional expenditure derived from reported costs to the health care system assesses immediate costs; only scarce data on long-term consumption associated with longevity are available (Meltzer et al., 2000). Some direct medical costs associated with the use of the insulin pump compared to MDI include the following (Colquitt et al., 2004):

- Education of the patient: £147.54 in year 1;
- Education of professionals: £2,715 per centre in year 1;
- Cost of pump: £2,350 to £2,562 in year 1;
- Maintenance costs per year: £176.25;
- Consumables per year: £947.15 to £1,226.42.

The data on savings resulting from switching onto insulin pump therapy is frequently calculated as avoided costs of treating complications and emergency episodes (Ulahannan et al., 2007). For example, reducing the number of severe hypoglycaemia events could offer some costs savings. Below are some quantified savings associated with using insulin pumps.

- Reduced insulin intake and savings on MDI supplies per year: £88.72 per patient (Colquitt et al. 2004);
- Reduced cost for treating hypoglycaemia (estimated at one episode fewer per patient per year): £39.70 per episode (Colquitt et al., 2004);
- Reduced number of consultant appointments and hospital admissions: £22,684 to £38,181 per 100 patients each year (Ulahannan et al., 2007);
- Reduced consultant hospital diabetes outpatient visits: £88 per visit (0.20 vs 0.11 appointments per month, $p<0.001$) (Ulahannan et al., 2007);
- Reduced hospital admissions: £757 per severe hypoglycaemia episode or £1,932.50 with complicating conditions (0.03 vs 0.00 admissions per month, $p<0.002$) (Ulahannan et al., 2007);
- Reduced total primary care contacts (Ulahannan et al., 2007);
- Reduced primary and secondary care contacts for treating comorbidities (Cohen et al., 2007):
  - Incidence of severe vision loss, or blindness reduced by 12 per cent;
  - Incidence of end-stage renal disease reduced by 16 per cent;
  - Incidence of peripheral vascular disease reduced by 16 per cent;
  - Incidence of myocardial infarction reduced by 4 per cent.

Some clinical trials suggested the following improvements for quality of life (Battaglia, Alemzadeh, Katte, Hall and Perlmuter, 2006):

- Higher Diabetes Quality of Life Measure scores (M = 77.89 ± 9.65) than the MDI group (M = 69.37 ± 14.67);
- Higher Self-Efficacy for Diabetes scores (M = 178.05 ± 16.71) than the MDI group (M = 163.54 ± 24.21).

Linkeschova et al. (2002) report statistically significant improvement in quality of life parameters among patients, summarised in Table 4.1. The patients' wellbeing was assessed with Diabetes-Specific Quality of Life Scale (Diabetes-Specific Quality of Life Scale) prior and after switching to CSII therapy.

Table 4.1: Quality of life parameters before and after initiation of CSII*

	Intensified conventional insulin treatment	CSII
Social relations	79	85
Time flexibility	71	82
Physical complaints	68	81
Worries about future	37	51
Diet restrictions	60	77
Daily hassles	54	66
Fear of hypoglycaemia	54	68
Burden of hypoglycaemia events	50	69
Blood glucose fluctuations	40	65
Self-efficacy	70	79
Treatment satisfaction	51	71

*Higher scores mean better quality of life

Source: Linkeschova et al., 2002

What these data points suggest are that while the immediate costs of insulin pumps might be slightly higher compared with the costs associated with MDI, the reduced demand for primary and secondary care among diabetes patients, combined with improvements in long-term outcomes and quality of life, provide a strong argument for supporting the economic case for insulin pumps.

4.2 The biopsychosocial model and medical technology

Along with the general additions to the list of inputs for the considerations for assessing the costs and benefits of medical technologies, the expert group opinions highlight particular strengths associated with the biopsychosocial model for each of the considered interventions.

The biopsychosocial model (Engel, 1977) advocates that clinicians, occupational health professionals and others consider the interplay between the **biological** (eg disease, joint damage), the **psychological** (eg disposition, anxiety) and the **social** (eg work demands, family support). It is evident that the interaction of the biological, psychological and social dimensions can have a significant impact on health outcomes. Problems in one of the areas may affect wellbeing in other aspects of health, which requires a complex approach to diagnosis and treatment.

Biological: ICDs and reductions in mortality

The life-saving quality of **ICDs** was identified by the experts as its primary and most salient feature. Significant increase in projected life expectancy underscored the **life extending** benefits provided by the device, making it particularly cost-effective among patients with high risks of SCDs. One of the interviewees projected that older cardiac sufferers may choose better quality of life, while younger patients agree to adjust their life-style to invest in longevity:

> *'There is 4 per cent chance that they will need it in their life…a number of people say I'll just take my chances…Younger people would accept more hassle, more quality of life disadvantages, for the safety of life.'*

Although the extended life came at the cost of potential reductions in quality of life, one of the experts emphasised the considerable advantage of the device in reducing mortality:

> *'An ICD is a life-saving device. In the UK, for example, there are 100,000 sudden cardiac deaths each year. 80 per cent of those…could be avoided, if [patients] were treated with an ICD.'*

Psychological: Insulin pumps and patient empowerment

In the experts' opinion the **psychological empowerment** of patients, resulting from switching on **insulin pump** therapy, is one of the major benefits associated with insulin pump therapy.

It is argued that the flexibility of lifestyle gained through the use of an insulin pump provides independence from the rigid schedule of meal intake, exercise and mood changes. The patients acquire better control over the fluctuations in blood glucose levels with significant improvements

to the quality of life, as they no longer have to have an extra injection or wait until the next mealtime to make adjustments to their insulin intake.

> *'Convenience, that's what they want, they feel much better, they don't have to go through highs and lows, and it gives so much independence.'*
>
> Expert interview

Another source of empowerment comes from patients' education and improved ability to manage the disease on their own. Insulin pump users learn to monitor their condition and track causal relationships between their activity and relevant health indicators, taking progressively more control over their wellbeing, even as compared to diabetes consultants. One of the diabetes patients observed the psychological effect of the use of insulin pump:

> *'That was a big mind shift, the idea that I had to take control.'*

The flexibility and increased confidence patients gain from insulin pump use are the result of freedom from daily injections and improved insulin management. As a consequence, many patients and parents of young patients are able to return to employment more quickly. The improved wellbeing from better management of the patients' condition is reported to lead to better performance, as well as opportunities to learn new skills and demanding occupations, such as those requiring shift patterns. Patients become more flexible in their choices of jobs and work environments as employers would no longer struggle to accommodate the requirements of the condition. For example, one patient explained that it is:

> *'…difficult to maintain stable glucose control if your activity levels change without notice. For people, whose jobs require them to be active a period, and then go back to desk work or vice versa, it would be difficult to achieve that without a pump.'*
>
> Patient interview

Social: Hip and knee replacements and increased societal participation

Improved mobility associated with **hip arthroplasty** may offer considerable diversity to the patients' **family and social life** through the increased range of physical activity, return to work and consecutive relief of caregiver burden.

The technology has a strong potential to reduce disability among patients otherwise restricted to a sedentary lifestyle. It is estimated in some studies that up to 100 per cent of individuals who were working prior to receiving a joint replacement return to their working lives

subsequently (Kuijer et al., 2009). Participation in the labour market suggests benefits both at the macroeconomic and at the household level, through avoided disability benefits and relieved caregiver burden, as patients regain capability of independent living.

In order to maximise the benefits of hip/knee arthroplasty, it is important that the intervention is offered to the patient in due time. Lengthy referral periods delay rehabilitation and reduce future earnings and DALYs post-operation.

> *'I wish I'd had the procedure on my hip earlier. I just thought the pain was something I had to tolerate as a result of my arthritis, but now I know better. Giving people a joint replacement earlier would make so much difference to their quality of life.'*
>
> Patient interview

Increased participation in social life means that a wider variety of activities are available for the recipients of the intervention, particularly physical activities and hobbies. Return to an enjoyable life style increases the quality of life and contributes to improved psychological wellbeing.

> *'I've had both knees replaced and now I can go dancing in six inch heels! I pay for it the day after, mind you!'*
>
> Patient interview

At the same time the procedure itself may incur some quality of life choices. One of the experts mentioned that a patient hesitated before undergoing a joint replacement procedure, as an artificial hip would restrict him from participating in his favourite sport.

4.3 Barriers to the spread of medical technologies in the UK

The three cases highlight some of the differences between the technologies in terms of the benefits associated with them. However, due to low awareness of reported benefits of the therapies and potential for spill-over effects, limited groups of patients in the UK have access to the three medical technologies. Structural differences in the health care systems and sources of funding provide only some explanation for the disparities of intervention availability across countries demonstrated in the Box 4.1 below.

Box 4.1: Access to interventions in Europe and US

ICDs

- **UK:** 80 per million population (Cunningham et al., 2009);
- **Western Europe:** 160 per million population (Cunningham et al., 2009);
- **US:** 416 per million population (Ruskin, Camm, Zipes, Hallstrom and McGrory-Usset, 2002).

Insulin pumps

- **UK:** only 1 per cent of Type 1 diabetes patients (Pickup, 2006); less than 2,000 diabetes patients (Barlow and Burn, 2008);
- **Germany:** over 40,000 diabetes patients (Barlow and Burn, 2008);
- **US:** 200,000 Type 1 and Type 2 patients (Chait, 2005); 20 per cent of diabetes patients (Pickup, 2006).

Hip/knee arthroplasty

- **UK:** 109,892 NHS and 47,953 independent surgeries in England and Wales in 2010;[20] 195 hip replacements per million population and 146 knee replacements per million population (Organisation for Economic Co-operation and Development (OECD), 2010);
- **Germany:** 289 hip replacements per million population and 206 knee replacements per million population (OECD, 2010);
- **France:** 220 hip replacements per million population and 114 knee replacements per million population (OECD, 2010);
- **US:** 165,000 hip replacements and 326,000 knee replacements in 2001 (FDA, 2004); over 1 million joint replacement surgeries in 2006.[21]

[20] See National Joint Registry, Stats Online.
http://www.njrcentre.org.uk/njrcentre/Healthcareproviders/Accessingthedata/StatsOnline/tabid/117/Default.aspx
[21] See American Joint replacement registry, Factsheet. http://orthodoc.aaos.org/ajrr/AJRR%20Fact%20Sheet_AJRR.pdf

As this suggests, several barriers exist to the wider spread of the medical technology in the UK. Barriers appear to result from inefficient decision-making processes within the health care system and nurturing of a cautious approach to innovation among medical professionals (Barlow and Burn, 2008). In particular, the opinions from the stakeholders interviewed for this report suggest the following barriers:

- **Lack of funding**. Limited budget is a primary counterargument against the wider spread of medical interventions. Consultants are often not willing to apply for funding approval for devices, having to follow the guidance issued by NICE on the recommended quota of patients using the therapy and cost-effectiveness threshold set at £20,000 to £30,000. Experts highlighted general prejudice against more expensive technologies among the medical professionals acting as gatekeepers to medical technologies within budget silos. Commissioners of health care services should not just focus on the immediate cost of medical technologies, but consider their long-term value in reducing the number of outpatient visits and hospital admissions, that would provide savings to the NHS in the long run.

- **Data limitations**. A rigid cost-effectiveness threshold needs to draw recommendations from existing evidence (Chalkidou, Hoy and Littlejohns, 2007). A conservative approach to innovation may be explained by the responsibility of the health care system to prevent the potential negative impact of premature decisions.

  Early trials of medical technology implementation often report complications among users due to the lack of experience among patients and consultants, and may inform misleading health technology assessment. Analysis conducted by Dakin et al. (2006) criticised the 'yes, but…' approach of NICE guidelines, which impose some restrictions on groups of patients subject to intervention treatment. For example, one expert explained that:

  'There was bad experience in the 80s with the pumps, which was very crude...There was a professional resistance to using pumps, when we first started using them... That's becoming less of an issue. Larger barriers are around the costs...I see [NICE Guidance] as a barrier, because it limits the number of patients, who fulfil the criteria.'

  Expert interview

- **Rigidness of criteria**. Failure to include more indirect costs and benefits in cost-effectiveness analyses means that eligibility for interventions is based primarily on clinical criteria rather than other benefits. Patient participation in the treatment process could potentially expand the scale of access to interventions. One expert mentioned that the indicators used to monitor progress of therapy and ultimately make decisions about implementation of interventions does not consider variations in health status. For instance, diabetes patients may achieve good control over blood glucose on average, but experience critical fluctuations of its levels throughout the day at the expense of quality of life. Furthermore, the analysis of the costs and benefits of medical technologies do not account for the potential and spill-over benefits to the NHS (Claxton et al., 2009).

- **Conservatism of clinicians**. General practitioners and some specialists may not know the cost-effectiveness of some interventions – or even know about the existence of particular interventions. This may delay or prevent the referral of patients to most appropriate consultants.

  'It is the physician involved in the first care of the patient and their acceptance of the technology, rather than the implanting cardiologist and the patient, who considers the costs.'

  Expert interview

  The experts highlighted that medical professionals need to adopt a 'more proactive mentality' to challenge poor communication across the echelons of the health care system. It is unclear, who would be responsible for making the judgements, or even, who would be capable of adequately assessing the indirect benefits for patients to reflect those in the cost-effectiveness analysis.

  'I don't think it's a question of access, it's a question of people delivering it to patients.'

  Expert interview

- **Limited knowledge**. Expertise among general practitioners and specialists may delay uptake of certain medical technologies as well as limit availability of technologies in certain areas of the UK. For example, varied expertise of diabetes consultants, as well as restricted budgets, can enrol the patients into a 'postcode lottery', where accidental factors define their chances to receive appropriate treatment. For instance, the NHS Atlas of Variation revealed that only 32 per cent of Type 1 diabetes patients received

all the nine key care checks outlined by NICE with drastic variation in the treatment decisions across geographic areas: patients in the South West of England receive twice as many amputations because of diabetes complications as patients in the South East (Diabetes UK, 2010).

'People are doing it on the whim...[you think] the person you might see is a specialist and they know what they are doing…they may actually not have any proper training whatsoever.'

Patient interview

Consistently the recommendation to improve awareness and education was offered by interviewees. This has implications for continuing education in the NHS, but also for patient advocacy. Both patients and clinicians need to equip themselves with information regarding new therapeutic options. Cox et al. (2007) have shown that greater patient participation in the treatment process is associated with better health outcomes and with improved satisfaction with the health care system.

*'Making people who are eligible for pump therapy more aware of it. Making sure that everybody is following the NICE guidance to **consider** pump therapy for everyone with Type 1 diabetes.'*

Patient interview

- **Inefficient decision-making process**. The combination of the obstacles to informed assessment and implementation of medical interventions may lead to inefficiently organised and poorly timed medical care. The specialists directly involved in making decisions may not be equipped to do so, while the policy-making structures may lack evidence to lobby appropriate changes. An improved policy framework in the cost-saving climate would recognise the benefits of investment in the medical technologies to reduce long-term societal impact of chronic disease.

- **Short-term perspective.** Funding cycles, short-term priorities, and crises influence how policy makers and commissioners prioritise technologies. Upfront expenditures, such as costs of equipment and training of medical professionals seem to discourage policy-makers focused on short-term budgeting. This may reduce their ability to value the long-term benefits associated with certain technologies.

'Uptake of technology is a fairly long-term game. You have to work at it quite hard. You have to horizon scan, you have to identify, you have to do procurement, you have to implement it and you have to see if it works. Now that is a two year cycle at least…. So you need a stable organisation for something like two to four years to plan it, implement it and role it out. And if that is not there, then how do you do it?...The answer is that you need settled organisations that are confident in making decision, have a long enough term view in order to devise strategy and implement it and then have the competence to carry out what they say what they are going to do'.

Patient interview

4.4 Conclusion

Growing amounts of evidence support the preventive value of medical interventions, which should be regarded as an investment and precursor to savings in primary and secondary medical care. (Ulahannan et al., 2007). Innovative technologies offer significant benefits to physical, psychological and social wellbeing at early stages of disease, offsetting the burden of treating co-morbidities for the health care system (Claxton et al., 2009), and even to employers and taxpayers through the benefits system.

In addition to being approved by NICE as cost-effective for certain patients, the three technologies highlighted in this report have benefits to individuals, the health care system and society. Taking the biopsychosocial model, we have highlighted a particular benefit of each technology from life saving to increasing control and empowerment to improving the ability to return to work and participate in society.

We have also identified a number of barriers that may inhibit the use of these technologies. Providing further education for patients and clinicians and looking beyond immediate priorities and budgets may improve the ability of the NHS to adopt new technologies and offer patient's high quality care that meets their needs.

5. Conclusions, recommendations and a 'Call to Action'

Poor health – especially as a result of long-term or chronic conditions – significantly impacts the UK society through costs to individuals, the health care and welfare systems, the labour market and wider economy. Around 15 million people in England are currently living with a chronic disease. Over the next two years to 2013, the number of patients with two or more long-term conditions is expected to increase by 60 per cent. People living with long-term conditions are disproportionately higher users of health services – representing 50 per cent of GP appointments, 60 per cent of outpatient and A&E attendances and 70 per cent of inpatient bed days. The NHS has to consider how innovative medical technologies could help reduce the burden of chronic disease, which currently accounts for around 70 per cent of overall health and social care expenditure

Preventative or early intervention to mitigate the impact of worsening health not only improves health and quality of life outcomes, but can also save money at a time of austerity. In addition timely intervention improves workforce participation as the working age population gets older and inevitably spends longer at work.

A number of medical technologies have been developed to support people with long-term conditions. The technologies and devices highlighted in this report have been found to be cost-effective from a clinical and an NHS perspective for specific groups of patients. This report suggests that there are even greater benefits which can accrue from the use of these technologies for a wide-range of stakeholders – including individuals, families, employers, the NHS and the wider society. Some of these benefits are highlighted below.

5.1 Improvements in health care

Many medical technologies offer benefits to the NHS through improved efficiency and improved quality of care. Our research suggests at least three main benefits if access to medical technologies was widened:

- **Improving the quality of care:** Appropriate implementation of innovative technologies can contribute significantly to more efficient time use among physicians and consultants. Additionally, reductions in revisions, readmission and morbidity improve health outcomes, and may even improve the experience of care.

- **Enhancing efficiency:** Many medical technologies can reduce the need for emergency visits and unplanned hospital admissions, and can reduce average length of stay. Medical technologies can also help patients arrive to desired clinical outcomes that are difficult to achieve otherwise.

- **Empowering patients:** Medical technologies can give patients more control over their care, which reduces the time health care professionals may need to spend treating them, and allows patients to achieve positive outcomes as they acquire active role in the management of their condition.

5.2 Quality of life and independent living

Medical technologies offer the opportunity to improve quality of life, independent living and healthy/active ageing which may also impact upon patient satisfaction. While the specific outcomes differ depending on the technology, some of the potential benefits are listed below.

- **Reducing fears and anxiety** among patients and family members: Medical technologies may improve the quality of care individuals receive and improve their health outcomes. They may also provide 'insurance' by reducing mortality and morbidity.

- **Increasing flexibility:** Individuals may have an increased ability to live active lives, take part in social activities, spend less time at the hospital and focus more on living their lives rather than on their health care regime.

- **Reducing the need for informal and social care and burden on informal caregivers:** Families and informal carers may have more time to take part in other aspects of life – by having full and fulfilling working lives, for example – because their caring responsibilities are reduced with the use of medical technologies. In addition, the demand for social care may be reduced if more individuals with long-term conditions were enabled to live independently through the use of medical technologies that improve patients' quality of life.

5.3 Labour market participation and productivity

Medical interventions may offer improvements in health that benefit patients as workers. Employee health and wellbeing, and especially long-term and chronic conditions, often impact their performance and participation in the labour market (Bevan, 2010). Several positive outcomes for employment may be associated with the wider spread of medical technology, some of which are highlighted below:

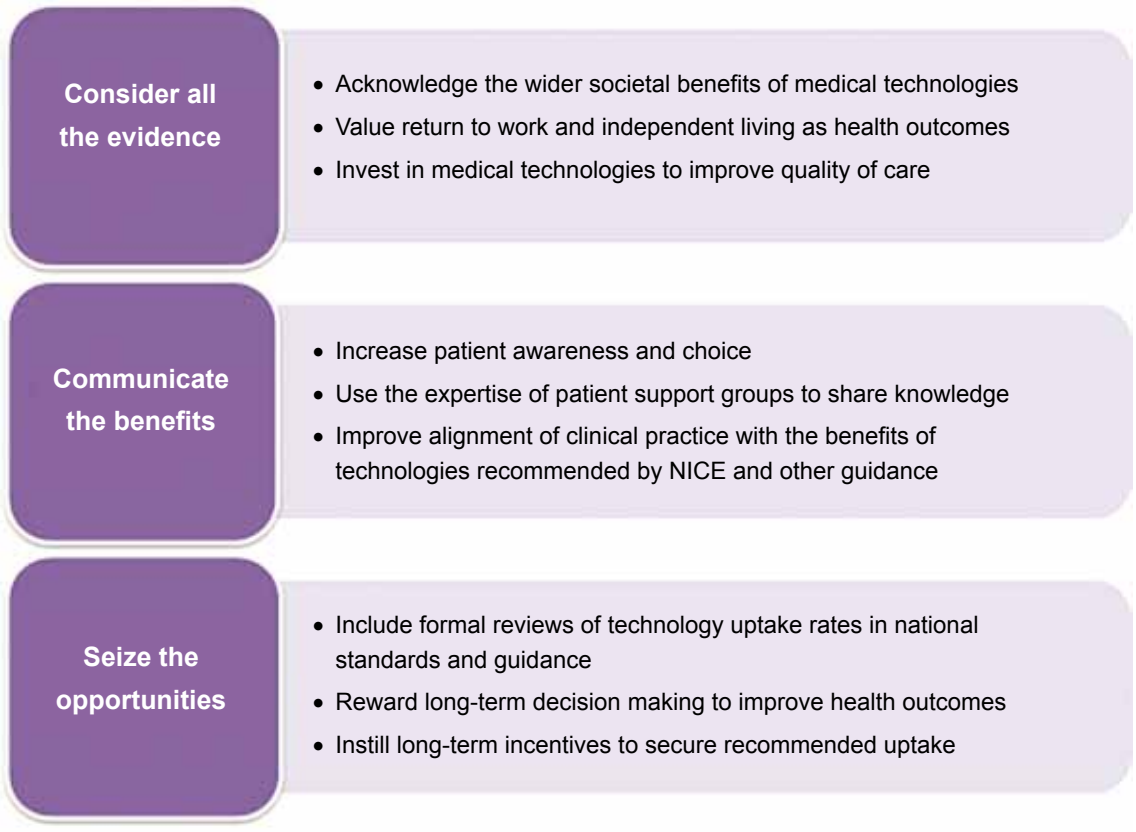
- **Increasing labour market participation**: Improved health outcomes among the working age population may increase the number of people able to access the health benefits of work, thereby reducing dependence on benefits, improving the ratio of people of working age who are tax payers rather than tax consumers and giving employers access to a greater skilled workforce.

- **Retaining skills**: Improved health outcomes resulting from greater use of medical technology can reduce the risk of people with chronic conditions leaving the labour market prematurely and provide improved opportunities for employers to retain the skills and talent in which they have previously invested.

- **Improving productivity**: Reduced the frequency and duration of sickness absence from work, together with dysfunctional sickness presence could contribute to improved availability, performance and productivity of staff with savings to both employers and the welfare system.

5.4 Recommendations and a 'Call to Action'

With the NHS set to cut spending (Timmins, 2010) cost-effective medical interventions may offer benefits for the patients' quality of life and improve their labour market participation and productivity. **Medical interventions should be regarded by clinicians and health care managers as investments in future benefits and cost reductions**. As a result of our study we propose the following '**Call to Action'**.



A. Improving data on medical technology use and effectiveness

1. With currently available data it can be difficult to measure the return on investment in medical technology. This report identifies a number of variables that may impact analyses and decisions related to medical technologies and **these should be adopted by NICE and the Department of Health in setting strategic investment priorities**. Better data collection and availability will allow for more informed assessments of the costs and benefits associated with the effective use of innovative medical technologies. Reliable measures of quality outcomes and long-term effects would be required to conduct accurate estimations of the impact of medical technologies on economy and labour market.
2. The Department of Health should conduct research to **monitor and evaluate the adoption, clinical and cost-effectiveness and labour market outcomes of wider adoption of medical technologies** – including international comparisons. The results of this work should inform clinical guidelines, care pathways and early intervention strategies, especially in the domain of long-term conditions.
3. The Department of Health should make more explicit provision within the **NHS Outcomes Framework to evaluate clinical and labour market outcomes** in relation to the use of medical technologies to inform innovative best practice.

B. Enhance education about medical technologies

1. Both patients and health care professionals need to improve their awareness of currently available and innovative medical technologies. Raising patient awareness and their confidence in making health care choices would take into account quality of life and labour market outcomes on par with clinical effects of technologies. **The Department of Health should work in partnership with patients, industry and commissioners, and in conjunction with the Ministerial Medical Technology Strategy Group (MMTSG) to develop guidance which increases patient awareness and choice over treatment, therapies and medical devices**.
2. The Department of Health should **appoint expert users** of a range of medical devices (including those of working age) to be part of and advise the national HealthWatch body.

3. The NHS must **invest in the education of medical professionals** to challenge conservative approaches to innovation and to introduce incentives for the wider acceptance of medical advancements and their use, where appropriate, as part of earlier interventions to improve quality of life and labour market participation. Trainee and practicing doctors should be provided with **education and training on the features and benefits of medical devices which are cited in NICE or other professional guidance**. This would enable them to support patients through treatment and at the same time learn from the experiences of intervention users, especially if the technology has wider quality of life or labour market benefits.

C. Recognise the long-term benefits of medical technologies

1. For many medical technologies, health professionals and commissioners appear resistant to use them because of the high upfront costs associated with the uptake. However, the long-term benefits of improved health outcomes, quality and length of life and participation at work and in wider society should also be considered. **Where possible, NICE should be free to comment on the wider societal benefits of medical technologies as part its technology appraisal process**.
2. At the very least, **NICE quality standards should highlight the appropriate use of medical devices and aim to achieve the recommended uptake** where it has previously been outlined in NICE guidance.
3. In the interest of the wider economy and society, uptake of cost-effective, efficacious and beneficial medical technologies could provide long-term savings and benefits through improved health outcomes, NHS efficiency and participation in society. **Consideration could be given to some type of systemic modification that rewards long-term decision-making** or incorporates improved long-term health care and quality of labour market outcomes in the budgeting calculus at the local level.

Health and social care services already struggle to deal with the growing impact of long-term conditions on the individuals and the society. Reactive management of chronic disease may be a low-cost strategy, but is certainly a short-sighted approach to reducing the societal burden. To maximise cost-effectiveness and ensure rational use of public finances the health care system has to invest in medical innovations that enable individuals to continue fulfilling working and family lives.

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Appendix A. Interviews and consultation with experts

We interviewed or consulted the following people during the course of our research and we are very grateful for the time each spent with us. We have taken their views into account in writing this report, though their participation in the study does not in any way imply endorsement of the report's conclusions.

Leela Barham	Health economist
Dr David Cavan	Consultant Physician, Bournemouth Diabetes and Endocrine Centre
Dr Richard Charles	Emeritus Consultant Cardiologist, Liverpool Heart and Chest Hospital
Dr Peter Hammond	Consultant Physician, Harrogate District Hospital
Barbara Harpham	Heart Research UK
Professor Peter Hindmarsh	Developmental Endocrinology Research Unit, University College London
Tim Jones	Commissioner, Milton Keynes Primary Care Trust
Lesley Jordan	INPUT
Professor Peter Kay	Consultant Orthopaedic Surgeon, Wrightington Hospital President of the British Orthopaedic Association
Mike Kimmons	British Orthopaedic Association
Trudie Lobban	Heart Rhythm Charity
Ros Meek	Arthritis and Musculoskeletal Alliance
Dr Phillip Moore	Consultant Physician, Spire Harpenden Hospital
Federico Moscogiuri	Arthritis Care
Dr Chris Pepper	Consultant Cardiologist, Yorkshire Heart Centre
Dr Chris Plummer	Consultant Cardiologist, Freeman Hospital Cardiac Centre
Professor John Pickup	Diabetes and Metabolism, King's College London
Professor Keith Willett	National Clinical Director for Trauma Care

In addition, we spoke with a few individuals who have been using the three technologies to learn about their experiences. We are grateful for the time they spent with us.

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