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The public healthcare sector in England

Overview and attractiveness as a new market for the Finnish medical device manufacturer Medieta Oy

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The purpose of the thesis is to provide an overview of the public healthcare system in England, as well as identify factors that would influence the demand or complicate market entry for Medieta Oy, a Finnish medical device manufacturer and commissioner of the work. Medieta's product is a system for early risk recognition consisting of a wearable monitoring device and compatible software intended for clinical use.

Data for the research is sourced mainly online from websites of official bodies, think tanks and public organisations, databases allowing access to peer-reviewed journals, and media outlets. The material collected is used in a review describing the demography of England, public healthcare with a focus on the National Health Service (NHS), as well as monitoring and regulation of medical devices and the NHS. After the review, findings are discussed in the context of the research issues and, finally, conclusions are drawn.

The thesis finds that the public health system in England is under severe operational and financial pressures that are set to continue into the future. Significant contributory factors include demographic trends, increased patient volumes, curbed public expenditure on healthcare, efficiency savings requirements, quality of care demands, and HR challenges.

The research concludes that the public healthcare system in England would be a suitable new market for Medieta with demand for such a device. Nevertheless, in addition to proving clinical efficacy, the device must be shown to deliver benefits at an acceptable cost if the device is intended to be purchased by the NHS.

Keywords	England, health technology, medical devices, National Health Service, public healthcare, United Kingdom,

Tekijä Otsikko Sivumäärä Aika	Jenni Jokinen Julkinen terveydenhuolto Englannissa – Yleiskatsaus sekä kiinnostavuus uutena markkinana suomalaiselle terveysteknologia-alan yritykselle Medieta Oy:lle 47 sivua + 1 liite 20.4.2015
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Tämän opinnäytetyön tarkoitus on tarjota perustason kuvaus Englannin julkiseen terveydenhuoltoon, sekä tunnistaa ne tekijät, jotka voisivat vaikuttaa Medieta Oy:n—työn tilaajan ja terveysteknologia-alan yrityksen—tuotteen kysyntään markkinoilla tai hankaloittaa markkinoille pääsyä. Medietan tuote on kliiniseen käyttöön tarkoitettu, rannelaitteesta ja yhteensopivasta ohjelmistosta koostuva järjestelmä varhaista riskien tunnistamista varten.

Tutkimusaineisto on kerätty pääasiassa virallisten tahojen, ajatushautomoiden ja julkisten organisaatioiden verkkosivustoilta, vertaisarvioituja julkaisuja sisältävistä tietokannoista, sekä mediasta. Koottua materiaalia käytetään katsauksessa, jonka aiheina ovat Englannin väestö, julkinen terveydenhuolto (erityisesti National Health Service (NHS) -organisaatio), sekä lääketieteellisten laitteiden ja julkisen terveydenhuollon valvonta ja sääntely. Tätä seuraa löydöksiä käsittelevä pohdintaosio sekä lopuksi yhteenveto.

Tutkimuksesta selviää, että Englannin julkinen terveydenhuoltojärjestelmä on kovien operatiivisten ja taloudellisten paineiden alla. Tilanne jatkunee myös tulevaisuuteen. Huomionarvoisia vaikuttavia tekijöitä ovat väestölliset suuntaukset, lisääntyneet potilasmäärät, supistunut terveydenhuollon julkinen rahoitus, tarve saavuttaa tehokkuussäästöjä, hoidon laatua koskevat vaatimukset ja henkilöstöhaasteet.

Yhteenvetona, Englannin julkinen terveydenhuolto vaikuttaa soveltuvan uudeksi markkinaksi Medietalle ja markkinoilla olisi kysyntää yrityksen laitteelle. On kuitenkin huomioitava, että mikäli tavoitteena on NHS:n hankkivan laitteita julkisen terveydenhuollon käyttöön, täytyy yrityksen pystyä osoittamaan laitteen toimivuuden lisäksi se, että laitteen kustannukset ovat hyväksyttävät laitteen tuomiin hyötyihin nähden.

Avainsanat	Englanti, Iso-Britannia, julkinen terveydenhuolto, lääketieteelliset laitteet, National Health Service, terveysteknologia

Contents

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Glossary

A&E: Accident and emergency (department)
CCG: Clinical commissioning group
CQC: Care Quality Commission
DH: Department of Health
EC: European Commission
GP: General Practitioner
HM Treasury: Her Majesty's Treasury
HSCIC: Health and Social Care Information Centre
ISO: International Organization for Standardization
MDD: Medical Device Directive
MDR: Medical Devices Regulation
MHRA: Medicines and Healthcare Products Regulatory Agency
NAO: National Audit Office
NHS: National Health Service
NHS TDA: NHS Trust Development Authority
NICE: National Institute for Health and Care Excellence
OECD: Organisation for Economic Cooperation and Development
ONS: Office for National Statistics
PMI: Private medical insurance
QALY: Quality-adjusted life year

[Note: Throughout this thesis figures and statistics are expressed in the format "YYYY/YY" (e.g. 2013/14) for financial year data—running form 1 April to 31 March—and "YYYY" (e.g. 2014) for calendar year data.]

1 Introduction

Providing healthcare to citizens may be considered one of the hallmarks of a welfare state. The World Health Organization (WHO) even regards it as a "fundamental right of every human being" (WHO, 2015). Unfortunately, many countries are struggling and especially in the European Union the costs of providing public healthcare seem overly high, considering the recent economic events and turmoil. The situation is exacerbated by the severe pressures brought on by factors such as an aging population and influx of lifestyle conditions in much of the western world.

Simultaneously many technology industries are booming and major advances are constantly made in various areas. One of these is the health technology industry, which in Finland seems to do exceptionally well. This thesis intends to assist a health technology start-up, Finnish medical device manufacturer Medieta Oy, in bringing their innovation to new markets where it will hopefully help ensure that healthcare is delivered not only efficiently, but safely and effectively, and bring cutting-edge technology to a field that could immensely benefit from it.

The present research aims at providing a comprehensive overview of the public healthcare market in England in the context of it being a potential new market for Medieta. The goal is to provide an understanding of the system and its components, determine if there would be demand for the type of product Medieta is offering, and identify potential requirements that might act as barriers to entry. This is accomplished by conducting reviews on significant demographic factors, the National Health Service (NHS) of England, as well as the regulation and monitoring of medical devices and the NHS. Finally, the key findings are summed up in a discussion and conclusions are drawn.

2 Background to the study

2.1 Commissioner of the thesis and selection of topic

The commissioner of the present thesis is Medieta Oy, a Finnish medical device manufacturer. Medieta's product is a wearable, wireless bracelet for monitoring vital signs with accompanying software to alert medical staff of any concerning changes—in other words, a system for early risk recognition in patients under medical supervision. Due to data being transmitted wirelessly, the device may be used to monitor patients after they have been discharged as well, in addition to having possible applications in various types of units such as care homes for the elderly. The device is being currently tested in selected Finnish hospitals in order to attain clinical data. While the product is not on the market yet, a CE marking and ISO certification have been obtained for the software already.

The idea for the thesis stemmed from discussions with the CEO of Medieta, Jouni Ruoppa, who expressed interest in the possibility of taking the product abroad to other markets and receiving a study on a market of interest. Europe and the United Kingdom emerged as viable options, so, in order to limit complexity, England was selected as the geographical area. Originally the thesis was to consider the entire healthcare system, along with relevant external factors, but it soon became evident, the focus should be narrowed down in order to avoid a superficial end product lacking proper detail. Thus, the public health sector, which is vast and accounts for the majority of all healthcare expenditure, was selected as the core topic. It was also decided that the thesis would focus on aspects most relevant to a medical device manufacturer, while still offering a comprehensive overview of the public health system. All proprietary information—including product specifics and financial data—were to be excluded.

2.2 Medieta's device in the EU market

The European Commission (EC) defines a medical device in the *Council Directive 93/42/EEC on Medical Devices (MDD)*, as follows

> 'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; (Council Directive 93/42/EEC)

The EC additionally divides medical devices into four classes—I, IIa, IIb, and III—separated into these groups "essentially for the purpose of conformity assessment procedures" (Council Directive 93/42/EEC). Since Medieta's product is a system composed of a mobile monitoring and diagnostic device along with software for monitoring vital signs, it is considered class IIa-IIb, depending on the functions made available, and defined as an "active device" according to rule 10 (Council Directive 93/42/EEC: 10–11, 42).

Considering Medieta's product is a mobile, sensory device worn on the wrist with compatible software for data management, it is necessary to emphasise the distinction between such a system intended for clinical use in the healthcare system and numerous wellness and fitness wearables with compatible software available freely on the market for consumers. The latter include especially smartwatches, activity bracelets and heart rate monitors (e.g. Apple Watch, Fitbit, Jawbone UP, and Nike Dualband) combined with computer programmes or phone "apps", which do not have the same stringent requirements and standards as medical devices, nor are they intended for diagnostic purposes or use in medical establishments.

2.3 Overview of the medical device industry in Europe

Medical devices and medical technology make up a sizeable, growing industry in Europe. The key characteristics and latest figures on the European medical technology industry—presented by MedTech Europe (2014), an alliance of European medical

technology associations device industry consisting of Eucomed and European Diagnostic Manufacturers Association (EDMA)—are as follows:

- Market size of roughly €100 billion (around 28% of the global market).
- Average growth 4% per annum.
- Positive trade balance of €15.2 billion in 2013 (excluding in vitro diagnostics), more than a twofold increase since 2006. (In comparison, the United States trade surplus is €5 billion.)
- United States was the major export destination (41% of exports) as well as supplier to the European medical technology market (65% of imports)
- Almost 25,000 companies, of which around 95% are SMEs with less than 250 employees.
- Industry employs 575,000+ overall.
- Around 500,000 medical technologies currently available.
- Average product life-cycle of 18–24 months.
- 10,668 patent applications were filed with the European Patent Office (EPO) in 2013 (~7% of all applications).
- On average EU Member States spend 10.4% of their GDP on healthcare and medical technology accounts for only 7.5% of total healthcare expenditure. The 7.5% may be further divided into 6.7% expenditure on medical devices and 0.8% on in vitro diagnostics.

Regarding the above data, it should be noted that medical technology, as used by MedTech Europe (2014: 6), refers to "medical devices, in vitro diagnostics, imaging equipment and e-health solutions used to diagnose, monitor, assess predispositions and treat patients suffering from a wide range of conditions"—unless otherwise specified—and, thus, medical devices make up only a portion of the cited figures.

The medical device industry faces a number of challenges, but the following have stood out in several industry reports and news articles. First, due to governments aiming to curb healthcare expenditures, companies must be able to demonstrate enough benefits to justify the costs (Eucomed, 2014). This is not a simple task and failure to do so would likely inhibit market access. Second, the EU is currently revising the medical device directives and proposing for a Regulation on medical devices to replace directives 90/385/EEC and 93/42/EEC (EC, 2014b). The new Regulation was

intended to be adopted in 2014 and come into effect in 2015–2019 (EC, 2012), but at the end of 2014 several outstanding issues requiring further discussions persisted and the matter remained uncompleted (European Parliament, 2014 & 2015). Nevertheless, when concluded new expenses impacting especially European SMEs would be created. (Eucomed, 2013) Third, medical device security and cybersecurity concerns have been raised over the last years. The issue has received notable media coverage after the U.S. Food and Drug Administration (FDA) issued a warning regarding cybersecurity for medical devices and hospital networks on 13 June 2013, and numerous reports by information security experts on the ease of hacking medical devices have emerged (FDA, 2013; Halperin, et al., 2008; Robertson, 2012; Basu, 2013; Zetter, 2014).

3 Demography of England

3.1 Population structure and life expectancy

According to the Annual Mid-year Population Estimates, 2013, published by the Office for National statistics (ONS) (2014a), the population in the UK as a whole grew to 64.1 million—growth of 0.63% from the previous year and well above the EU average of +0.21%—and in England to 53.9 million—growth of 0.70%. Immigration was responsible for 46% of the increase and natural change (i.e. births minus deaths) for 53% (ONS, 2014a). With this dataset one may state England's population to have formed approximately 84% of the UK population in 2013. The report further states England to have had the greatest 10-year average population change of the four UK countries in percentage terms with +0.79%. According to ONS, the UK population is projected to reach 68.5 million in 2023, 72.5 million in 2033, and 82.4 million in 2063 (2014b).

The population structure for the UK is displayed as a population (or age) pyramid in Figure 1. One should note that the pyramid displays UK data, not England alone, and is flat on top since "the pyramid stops at age 89" (ONS, 2014a: 10-11). Population pyramids are used to "track and compare changes in population age distribution over time" and looking at Figure 1 we see a block-resembling shape typical of an industrialised society with low death-rates, and indicative of effective public health measures and good socioeconomic conditions (Merrill, 2010). As one may observe, the number of people aged 65 and over has increased over the decade, more so in men than women, and the number of births has increased lately. Despite the pyramid neglecting to give a comprehensive view of the most elderly population in the UK, other data convey the significance of the "very old"; in 2013 there were more than 0.5 million people aged 90 and over living in the UK and the number of centenarians went up by 71% in the decade leading up to 2013 (ONS, 2014c). The population aged 90 and over made up just 0.8% of the population in 2013, but the trend appears upwards both in absolute terms as well as relative to other population groups (ONS, 2014c), which relates to the topic of an ageing population discussed more in the next sub-section.

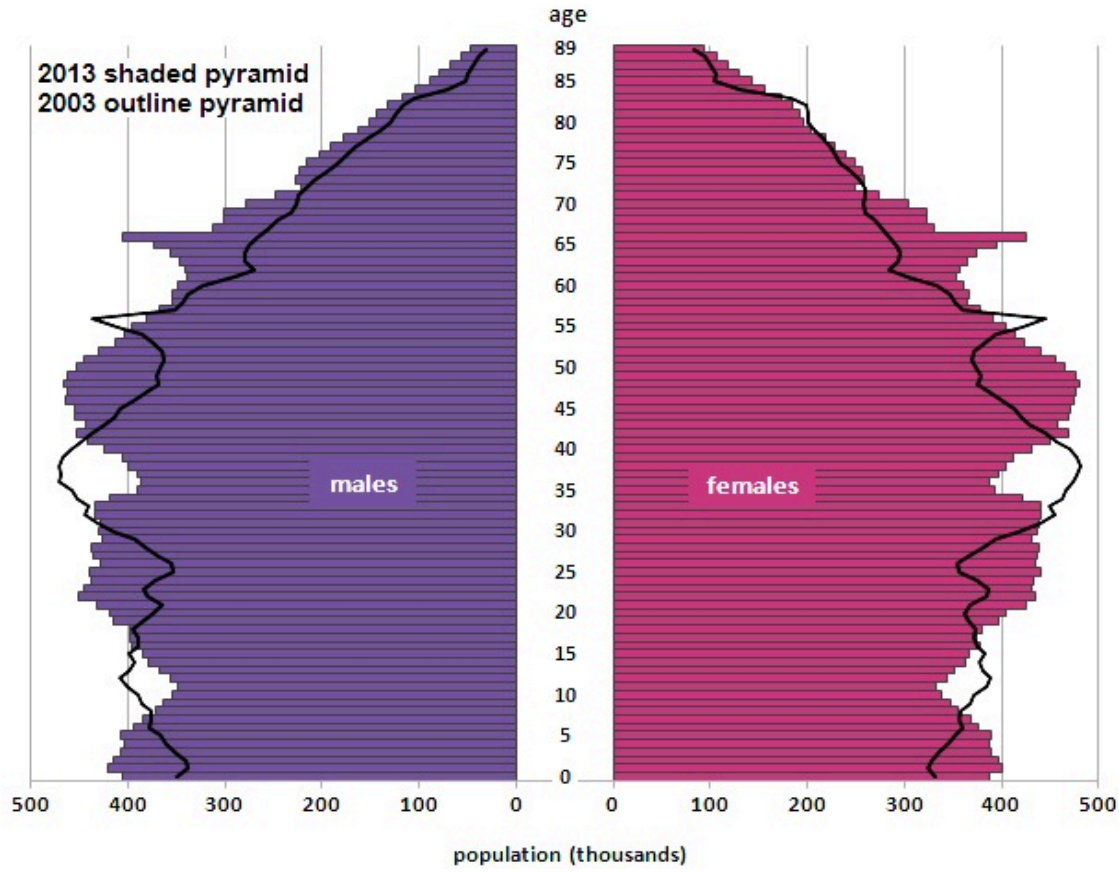


Figure 1: Population structure in the UK, 2013 (ONS, 2014a: 10)

In general, England has fared well when it comes to improving life expectancy, which may be considered to reflect a functioning health service system among other properties of a welfare state. Based on data for England 2011–2013, a newborn boy could expect to live 79.21 years while a newborn girl 82.96 years—figures, which were 76.13 and 80.68 for 2001–2003 data, and 73.59 and 78.98 for 1991–1993 data (ONS, 2014d). However, geographical variations do exist especially between London and the Northern regions, with the former having some 2.5 years higher life expectancies for both baby boys and girls, despite the latter experiencing more rapid increases in life years since the 1990s than the southern areas (excluding London) (ONS, 2014e).

The increasingly long lives also impact the causes of death, the most common of which are conditions mainly diagnosed at an older age. According to ONS (2014f), there were 506,790 all cause deaths—51.5% women and 48.5% men—in England and Wales in 2013. (Data for England alone is unavailable.) The five most common causes of death and their proportion of all deaths in the order of prevalence are as follows.

- neoplasms (i.e. cancer) 28.7%
- diseases of the circulatory system 27.7%
- diseases of the respiratory system 14.6%
- mental and behavioural disorders (incl. dementia) 7.5%
- diseases of the digestive system 4.8%

There have been some changes in the statistics from a decade ago. In 2003 in the same population set there were a total of 538,254 deaths with diseases of the circulatory system as the most common cause (38.2%), neoplasms second (25.9%), diseases of the respiratory system third (14.0%), diseases of the digestive system fourth (4.6%) and external causes of morbidity and mortality fifth (3.1%) (ONS, 2004). As one may observe cancer deaths have increased slightly in both absolute and relative terms, while deaths from diseases of the circulatory system have decreased. Deaths assigned to mental and behavioural disorders are up by over 150% and 97.6% of them in 2013 were due to various forms of dementia (ONS, 2014f).

3.2 Notable trends and their impact on demand for health services

When discussing demographics it is important to observe significant factors and prevalent trends in order to understand how the population is changing. This is meaningful to the main topic of the thesis since the aforementioned has a significant impact on the health of the nation and, thus, demand of various types of health services.

First, the population is ageing and the King's Fund (2015a) projects the number of 65–84 year-olds to increase by 39% to 10.9 million and the number of over 85 year-olds 106% to 2.6 million in 2012–2032. They further state that, despite population growth in lower age groups as well, this would bring the old age dependency ratio—i.e. ratio of those under the working age or over the state pension age to those aged 15–64 who are in the labour force—up from 31.4% to 34.9% during the same time period even if higher state pension ages were implemented (although they did not elaborate on the possible new pension age).

This trend will inevitably increase healthcare costs, considering most people over 65 have a chronic condition, most of those over 75 have two or more, and co- and multimorbidity tends to increase with age (Oliver et al., 2014:10). This is further illustrated in figure 2, which displays data derived from Scottish medical practices and local patients making up approximately a third of the Scottish population (Barnett et al., 2012). (It should be noted that individuals living in highest levels of socioeconomic deprivation saw onset of multimorbidity 10–15 years earlier than the most affluent ones.) With older people experiencing a higher incidence rate of certain severe conditions such as dementia which independently are associated with longer hospital stays, as well as having complex co- and multimorbidities, it is not surprising the mean length of stay for all hospital admissions increases with age-group and the over 65 year-olds account for nearly 80% of the emergency admissions staying in the hospital for longer than two weeks (HSCIC, 2013a: 38; Poteliakhoff and Thompson, 2011: 3).

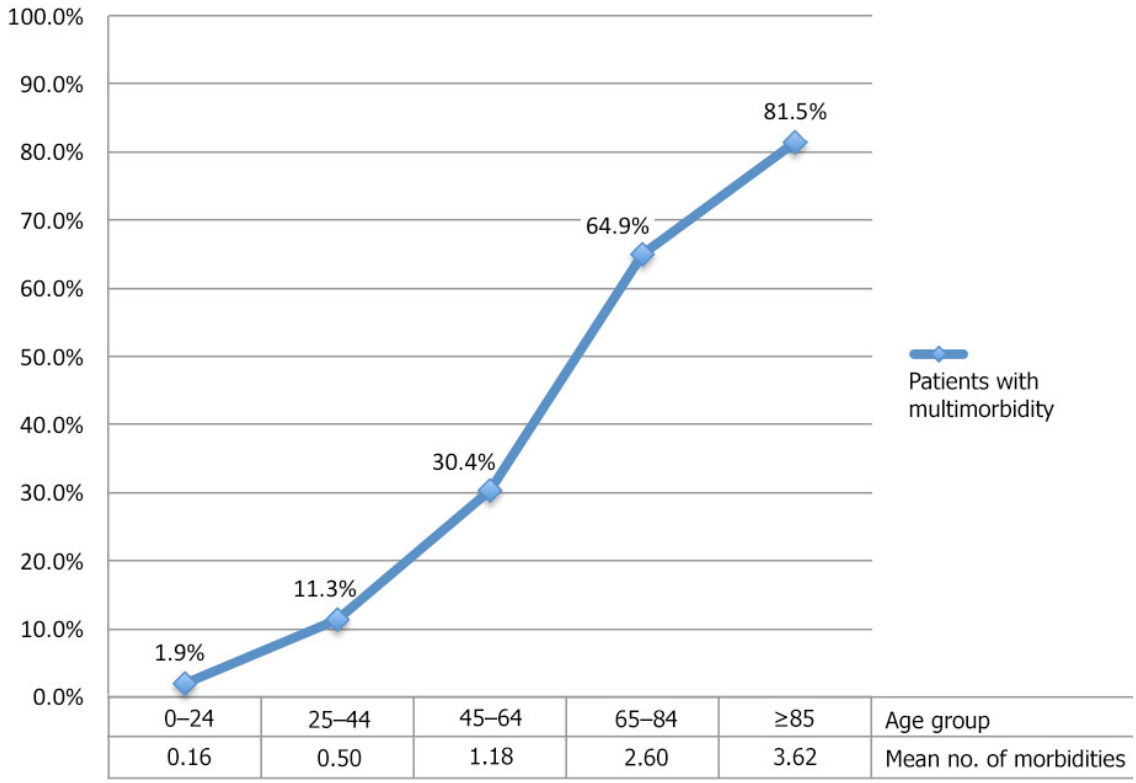
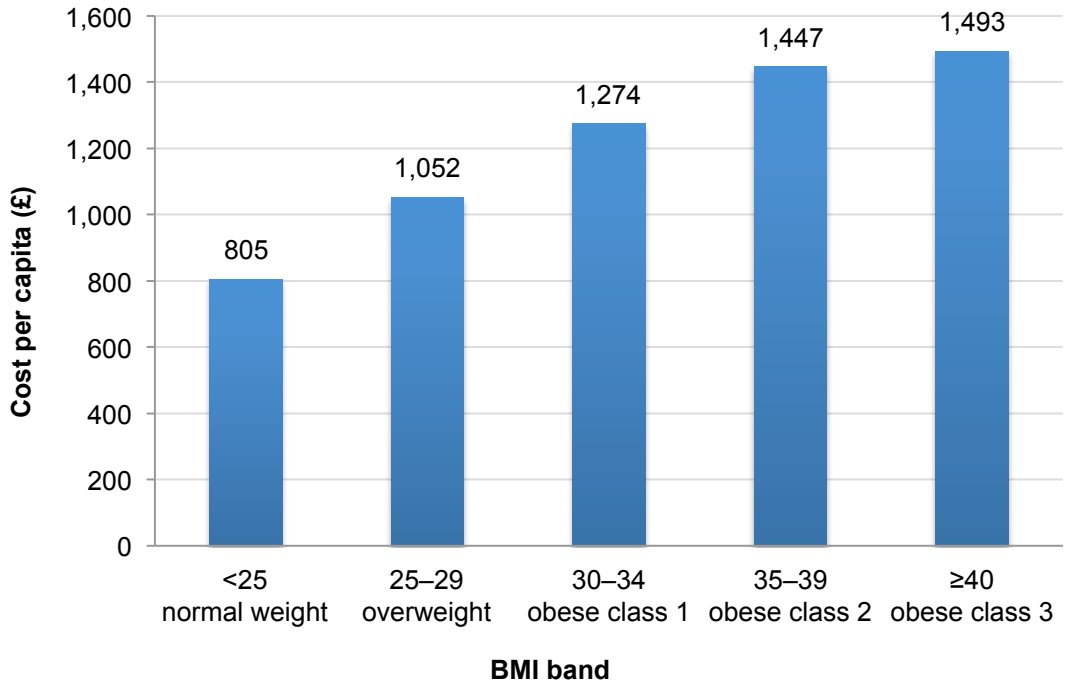


Figure 2: Prevalence of multimorbidity in Scottish patients by age group (Adapted from Barnett et al., 2012)

In addition to ageing, a prominent demographical trend worth mentioning is the increasing proportion of overweight and obese people. According to a report by the

Health and Social Care Information Centre (HSCIC, 2013b), 65% of men, 58% of women, and around a third of children aged 2 to 15 in England in 2011 could be classified as either overweight or obese. These figures are alarming since statistically medical costs increase as a person's body mass index (BMI) increases (figure 3). Spending on direct medical costs of conditions related to being overweight or obese are around £6 billion (equal to some 5% of NHS's budget), not to mention the £10 billion spent on diabetes (Dobbs et al., 2014: 22) and other costly conditions associated with excess weight. According to some projections the number of obese people in the UK will increase by a further 11 million by 2030 (Wang et al., 2011). As well as bringing up costs, this worrying development will exert substantial pressure on health services.



Note: "Includes primary care, general practitioner prescriptions, hospitalization, accident and emergency, and outpatient care. 2003 values taken from Tigbe et al. (2013) adjusted using 2012/13 Fédération Internationale de Médecine du Sport and Health Examination Survey data on per capita UK costs in each category"

Figure 3: UK medical costs by BMI group, 2012 (Adapted from Dobbs et al., 2014: 21)

Finally, other factors commonly considered to putting the English population's health at risk include alcohol consumption and binge drinking, tobacco use, high blood pressure

and cholesterol levels, and insufficient activity levels. Boyle (2011: 11) reports alcohol consumption to have increased among both men and women between 1998 and 2003—perhaps most worryingly as binge drinking among young women—raising the number of alcohol related deaths. Chief Medical Officer for England Dame Davies (2012: 196) states smoking to be "the single greatest cause of preventable illness and early death in England, and a major contributor to health inequalities" with 79,000 deaths a year being attributable to smoking along with a price tag of £5.2 billion in 2005/06 for the NHS. Despite the worrying statistics she states smoking to have decreased significantly over the last three decades. Tying together with obesity and poor dietary choices, high blood pressure and cholesterol are mentioned by Davies (2012: 205–207) as further risk factors. These have been linked with chronic conditions such as cardiovascular disease, which, as established earlier, is a major cause of death in England. Lastly, she raises concerns over low levels of physical activity. Due to exercise and an active lifestyle reducing risk of several medical conditions—physical and mental—the figures stating that in 2008 an average of 39.2% of men and 28.7% of women met the recommended level (i.e. 150 minutes of moderate intensity activity over a week) may be considered less than ideal.

4 England, the British Government, and responsibility for health services

England is a part of the United Kingdom (UK)—a Western European Commonwealth realm consisting of four countries: England, Northern Ireland, Scotland, and Wales. The UK is a constitutional monarchy with Queen Elizabeth II as the head of state and Prime Minister David Cameron, Leader of the Conservative Party, as the head of government (CIA, 2014). Developing and implementing policy and drafting laws are done by the government—also known as the *Executive*—which, in essence, runs the country, whereas the parliament—also known as the *Legislature*—scrutinises the work of the government, debates and passes all laws, and sets taxation. The prior is formed by the Prime Minister and a number of Ministers chosen by him from the House of Commons and the House of Lords, which then together form the latter (UK Government, 2014; UK Parliament, 2014a). The current Conservative/Liberal coalition government was formed on 10 May 2010 (UK Government, 2014), but a general election is to be held on 7 May 2015, which may bring about change (UK Parliament, 2015).

Since devolution in 1999, responsibility for certain policy areas, such as health, has lain with the devolved administrations (UK Parliament, 2014b; UK Government, 2014). Due to this the public health services are provided by separate systems in each country and the ultimate responsibility for healthcare lies with the UK Government in England, the Northern Ireland Assembly in Northern Ireland, the Scottish Government in Scotland, and the Welsh Assembly Government in Wales (NAO, 2012; NHS, 2015a). Respectively, the public health services are called the *National Health Service* (NHS), *Health and Social Care in Northern Ireland* (HSC), *NHS Scotland*, and *NHS Wales*, but because the present thesis focuses on England alone, "NHS" will only refer to the NHS in England from this point on, unless further specified. While the Department of Health (DH) is responsible for strategic leadership and funding for health and social care in England, the Secretary of State for Health—Jeremy Hunt MP since September 2012—has overall responsibility for the work of the DH (NHS, 2015b).

5 Public health services in England

5.1 Overview of the system

In England public healthcare is delivered by the National Health Service (NHS)—an independent body separate from the government—which was established on 5 July 1948, to provide health services for all UK citizens free at the point of delivery. The NHS provides a wide coverage of primary, secondary and specialist services, including

- general practitioner (GP) services
- hospital services
- emergency and urgent care (i.e. A&E)
- mental health services
- dental services
- eye care services
- pharmacy services
- social care

(NHS, 2015c)

A GP is typically the first point of contact for a patient and individuals must register with a GP practice primarily in their catchment area. If deemed necessary, the GP will then refer the patient to a hospital or specialist (NHS, 2015d).

Services are commissioned by Clinical Commissioning Groups (CCGs) and NHS England—a public body not to be confused with the NHS—who may acquire services from any service provider that meets the criteria. Commissioning services is examined more closely in section 5.3.1.

In general the founding principal of the NHS, "free at the point of delivery", is applicable, but some services such as ophthalmic and dental services, and outpatient medications require payment (Boyle, 2011: 96). Depending on a patient's financial situation, however, those in low-income brackets may be able to fully or partially reclaim the money spent or receive service vouchers (NHS, 2015e).

In addition to the public healthcare, private sector health services are widely available in England as well. A patient may acquire care directly from a private provider or receive NHS-funded care provided by one (King's Fund, 2014). Private health services are mainly paid for by voluntary health insurance, as "out-of-pocket" payments by individuals, or by the NHS for its patients. This topic will be further discussed in section 5.3.3.

Finally, it should be mentioned that due to the new *Health and Social Care Act 2012* a massive reorganisation of the public health system took place on 1 April 2013, when the legislative changes came into effect (NHS England, 2014: 7). The event saw some components of the old system abolished, new ones created, and responsibilities of certain bodies altered. This thesis focuses on the post-reform settings, although in some cases the old system is mentioned and data from time before the transformation used.

5.2 Healthcare expenditure

Statistics on healthcare expenditure are published for the UK as a whole. According to ONS (2014g), total spending on healthcare in the UK grew at an average annual rate of 8.1% in 1998–2009 before slowing down to 1.6% in 2010–2012. In monetary terms this translates to an increase from £54.6 billion in 1997 up to £144.5 billion in 2012. Considering population growth and other factors, some increase would be anticipated, but—within the same timeframe—per capita spending more than doubled as well, from £936.61 to £2268.12 (Postins and Payne, 2014: 4).

As a proportion of GDP (%), healthcare spending in the UK used to be relatively low when compared internationally, but reached the EU average in 2006 and is currently slightly above it (table 1) (OECD, 2014a: 122). This increase was influenced primarily by Labour government policy to increase public spending on healthcare in the early 2000s (Boyle, 2011: 72). Additionally, in the late 2000s the financial crisis slowed down GDP growth, even turning it negative in 2009, which raised the proportion of healthcare spending, although naturally this affected other nations in the EU as well and has somewhat reversed as the economy has recovered (Postins and Payne, 2014: 5).

Table 1: Total health expenditure as a share of GDP in 2000–2012, selected European countries (OECD, 2014b & 2015)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
UK	**6.9**	**7.2**	**7.5**	**7.8**	**7.9**	**8.1**	**8.3**	**8.4**	**8.8**	**9.7**	**9.4**	**9.2**	**9.3**
EU28	7.3	7.5	7.7	8.0	8.0	8.2	8.1	8.1	8.4	9.0	8.8	8.7	8.7
France	10.1	10.2	10.6	10.8	10.9	10.9	10.9	10.8	10.9	11.6	11.6	11.5	11.6
Germany	10.4	10.5	10.7	10.9	10.7	10.8	10.6	10.5	10.7	11.8	11.6	11.2	11.3
Italy	7.9	8.1	8.2	8.2	8.5	8.7	8.8	8.5	8.9	9.4	9.4	9.2	9.2
Spain	7.2	7.2	7.3	8.2	8.2	8.3	8.4	8.5	8.9	9.6	9.6	9.4	9.3

(Note: France, Germany, Italy and Spain have been chosen for the comparison by the author, because they are the four EU countries closest to the UK in terms of population size.)

In the UK public expenditure makes up 84.0% and private 16.0 % of the total health expenditure (Postins and Payne, 2014: 11). Some fluctuation has occurred over the years—influenced, for example, by the aforementioned policy decisions—but public sector has always been responsible for the majority of healthcare spending. Looking at other countries, the share of public financing is higher in just three European countries—the Netherlands, Denmark and Norway—as is the share of health expenditure from the total government expenditure, which in the UK stood at 16.2% in 2012 (OECD, 2014a: 129).

Overall, the UK has a similar or lower total health expenditure than its European peers. The share of public expenditure is high, as is the share of health spending from all government spending. Although this is the current situation, government policy and the economic climate, among other things, have considerable impact on the matter, which may result in significant changes. This should be kept in mind when considering the near future, especially with a general election approaching in May 2015, as well as some friction in the UK-EU relations with even a referendum on the UK's EU membership conversed (Oliver, 2013).

5.3 The National Health Service (NHS)

5.3.1 Basic structure and commissioning of services

Many public health services in England, such as hospitals, are managed by *trusts* and *foundation trusts*—not to be confused with the similar legal term—which are organisational units that provide health and care services of a certain function. Foundation trusts differ from trusts in that they are independent legal entities with unique governance arrangements where local people can become members or governors, and a board of governors is involved in strategic planning (NHS, 2015f). They are self-standing and self-governing organisations, which may raise capital from the public or private sector and retain financial surpluses. Trusts on the other hand are directed by the government in strategic decisions and are financially accountable to the government (NHS England, 2014: 15). Foundation trusts are overseen by Monitor, whereas trusts are overseen by the NHS Trust Development Authority (NHS TDA) that additionally assists a trust in its transition to foundation trust status.

Local services from the trusts and foundation trusts are commissioned by clinical commissioning groups (CCGs), which consist of clinicians like GPs and nurses. The CCGs are a novel component of the system and were established in 2013 when the NHS underwent a large-scale reorganisation as a result of the new Health and Social Care Act 2012. Prior to this the task of planning and commissioning services was mainly done by primary care trusts (PCTs), which no longer exist, but are mentioned in older materials. A key objective in giving these duties to CCGs was that the clinicians that form them were considered closer to the patients in their area and, thus, more attuned to their healthcare needs (King's Fund, 2013). Locally commissioned services include most secondary care services (e.g. planned hospital care, urgent and emergency care, community health services, and mental health services) and may be commissioned from any service provider (e.g. NHS hospital, private sector provider, social enterprise, or charity) as long as they meet NHS standards and costs, the guidelines provided by the National Institute of Health and Care Excellence (NICE), and data on service providers by the Care Quality Commission (CQC) (NHS, 2015b). In 2013, responsibility for planning and delivering primary care and specialist services was taken on from the PCTs by NHS England, originally known as the NHS Commissioning

Board—an executive non-departmental public body of the DH—that additionally oversees and allocates financial resources to the CCGs (NHS, 2015f; NHS England, 2015a).

The latest figures provided by the NHS Confederation (2014) regarding the number of providers and commissioners of NHS services in England are as follows:

> - 211 clinical commissioning groups […]
> - 156 acute trusts (including 101 foundation trusts)
> - 56 mental health trusts (including 41 foundation trusts)
> - 34 community providers (16 NHS trusts, 2 foundation trusts and 16 social enterprises)
> - 10 ambulance trusts (including 5 foundation trusts)
> - c. 8,000 GP practices
> - 853 for-profit and not-for-profit independent sector organisations, providing care to NHS patients from 7,331 locations

5.3.2 Funding and spending

Health services in England are financed through general taxation, national insurance contributions (NICs), and some patient payments, which in 2011 accounted for 80.9%, 17.9%, and 1.2% of the NHS funding, respectively (Hawe and Cockcroft, 2013: 51). Despite some slight fluctuations, general taxation has always been the greatest source of finance for the NHS.

The flow of funding in public health services is displayed in figure 4. Money is allocated by HM Treasury to the DH that retains a proportion for expenses and funding of other bodies, and then allocates the majority of what was received to NHS England. NHS England, in turn, retains money for funding nationally commissioned services and allocates about 60% of the initial total to CCGs—and in a much lesser extent to local authorities—that commission some local health services (NHS England, 2014: 11).

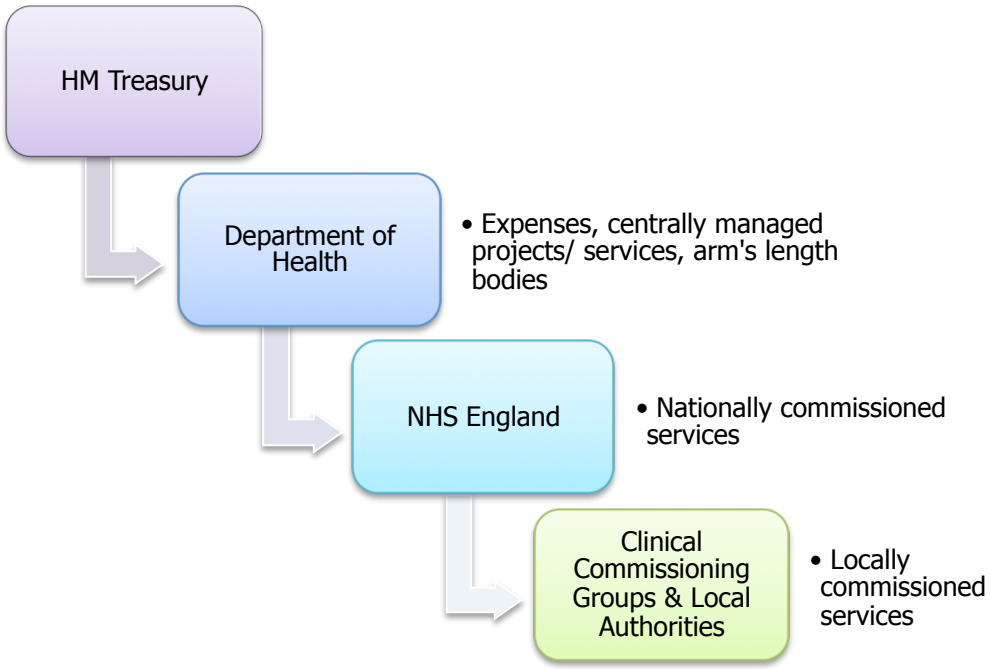


Figure 4: Flow of funding in public health services (adapted from NHS England, 2014: 11)

In 2013/14, NHS England received £95.6 billion—80.0% of the total £119.5 billion spent by the DH—and it was allocated as follows:

- £65.5 billion to CCGs (incl. £0.9 billion for local authorities) for commissioning local services
- £25.4 billion to NHS England for commissioning national services
- £1.8 billion for NHS England's public health responsibilities on behalf of Public Health England (incl. immunisation and screening)
- £1.2 billion surplus carry forward, to be allocated to CCGs and NHS England for future investment
- £1 billion for central health programmes to be administered by NHS England
- £0.7 billion for technical accounting adjustments

(NAO, 2014a: 9; NHS England, 2015b)

Significantly, staff costs made up £48 billion and purchase from non-NHS bodies £10 billion of the total (£119.5 billion) (NAO, 2014a: 11).

The DH ran surpluses in 2011/12 and 2012/13, but spending requirements are projected to go up and according to NAO (2014a: 18), "NHS England recently estimated that continuing with the current model of care will result in a total gap between spending requirements and resources available of around £30 billion by [2020/21]". Furthermore, £20 billion in efficiency savings are expected to be delivered by the NHS between 2011/12 and 2014/15 through the Quality, Innovation, Prevention and Productivity (QIPP) programme (HM Treasury, 2013: 35). Fortunately, the Parliament has confirmed that, despite austerity measures, health funding will be protected until 2015/16—unlike funding for many other departments facing cuts—but this means an increase of just 0.1% (in real terms) at a time when public health services are under mounting pressures (discussed in section 5.3.4) and certain demographic trends—such as the ageing population mentioned earlier—will contribute to increasing demand in the future as well (NAO, 2014a: 13, HM Treasury, 2013: 30).

Furthermore, grave concern has recently been expressed over the financial state and outcomes of trusts and foundation trusts. As detailed by Murray et al. (2014: 3), the system appeared to operate rather well until 2013/14, and meet demand efficiently while simultaneously maintaining quality of care, but in 2013/14 several overspends occurred; the NHS Trust Development Authority (TDA) reported a net deficit of £241 million for the NHS trusts—instead of the planned £76 million—and just over 25% of the trusts (25 trusts) ended the financial year in deficit, compared to a mere 5% in 2012/13. In the same time period the foundation trusts, which unlike trusts are "not required to break even every year", were experiencing something similar; 27.9% of them (41 foundation trusts) reported deficits taking their gross deficit to £309 million for 2013/14 compared to 21 foundation trusts running a deficit and a gross deficit of £160 million in 2012/13 (Monitor, 2014a). The situation has not shown signs of improvement, rather quite the opposite, and a recent Quarterly Monitoring Report conveyed the pessimism and worry of NHS trust finance directors with 36.7% (n=90) forecasting that their trusts will end 2014/15 in deficit (Appleby et al., 2014).

All in all, growth of government spending on public health services has slowed down in the last years. The NHS is facing challenges in managing efficiently at a time of austerity, and coping with various requirements and pressures. Sustainable ways of

achieving long-term savings, while maintaining quality of care, are needed in order for the NHS to fulfil its mandate and secure the delivery of public health services.

5.3.3 Health service commissioning from the private sector

Public health spending on non-NHS bodies was £10 billion in 2013/14, and, as established, commissioners of public health services may purchase services from private sector companies, as long as the provider meets set criteria. The "formal expansion of non-NHS provision" started in 2003 with independent sector treatment centres (ISTCs)—private sector units providing services only to NHS patients—and continued in 2008 with the Any Qualified Provider (AQP) policy—extending patient choice for elective care to all compliant providers (Arora et al., 2013: 14) This was aimed at reducing waiting times (by increasing capacity), improving patient choice, introducing competition in order to encourage NHS providers to develop their services, and allowing the NHS to utilise private sector capacity more cost-effectively (Naylor and Gregory, 2009: 2).

In 2012, NHS purchase accounted for 27.5% (or £1.2 billion) of private hospital revenue in the UK, up from just under 10% in 2004 and projected to reach nearly 29% in 2013 (LaingBuisson, 2013; King's Fund, 2014: 2). The remainder (in 2011) came from private medical insurance (PMI), individuals paying "out-of-pocket", and overseas patients—generating approximately 56%, 15%, and 2.8%, respectively—with some fluctuation in the ratios over the years. While private expenditure on all healthcare (in the UK) decreased on average 2.1% per annum in 2007–2011 and treatments paid by individuals out-of-pocket declined, spending by the NHS on non-NHS providers in England increased by 55% from £5.60 billion in 2006/07 to £8.67 billion in 2011/12 (Arora et al., 2013: 8, 12). Thus, despite recent decline in overall private health expenditure influenced by the financial crisis and, potentially, increase in public spending and volume of NHS activity in the 2000s, private sector providers have strengthened their position as suppliers of NHS-funded healthcare.

In the near future, as projected by Blackburn (LaingBuisson, 2013), the severe financial pressures of the NHS are expected to result in flat demand for health services

from non-NHS providers. Nevertheless, private provision of publicly funded health services has become a solid feature of the healthcare system in England.

5.3.4 Contemporary issues and challenges

As one might expect, a large organisation such as the NHS is not without its problems and challenges. The financial difficulties were already discussed in part 5.3.2, but three more topics are examined in this final sub-section on the NHS: Demand and increased volumes; staff and staffing; and quality of care. These were selected, because they have been prominently mentioned in industry reports and media publications.

5.3.4.1 Demand and increased volumes

Demand for public health services has increased significantly over the years and figures provided by NHS England (2013: 15–16) convey the magnitude of the upward trends:

- The average number of consultations in general practice per patient rose from 4.1 to 5.5 per year between 1999 and 2008 indicating greater demand and complexity in primary care.
- There were 6.8 million attendances at walk-in centres and minor injury units in 2012/13, and activity at these facilities has increased by around 12 per cent annually since data was first recorded a decade ago.
- Attendances at hospital A&E departments (officially referred to as Type 1 and Type 2 A&E) have increased by more than two million over the last decade to 16 million.
- The number of calls received by the ambulance service over the last decade has risen from 4.9 million to over 9 million.
- Emergency admissions to hospitals in England have increased year on year, rising 31 per cent between 2002/03 to 2012/13.

Health service providers are under severe pressure from acute cases whilst the waiting lists are expanding. This results in breaching targets. Recently the NHS has failed to meet target waiting times frequently in A&E, elective treatment, and cancer screening services, in addition to ambulance services missing target response times for the most urgent calls (Dorsett and Shi, 2014: 1-2; Campbell, 2014; Nuffield Trust, 2014a: 10–

11). The total waiting list for elective treatment stood at 3.13 million patients in October 2014, although the actual figure might be as high as 3.30 million if non-reporting trusts submitted their figures (Appleby et al., 2014). One should note that in 2014 the National Audit Office (NAO) (2014b: 20–28) identified inconsistencies (i.e. local variations and errors) in some trusts' methods of recording waiting times for elective care—resulting in under- and over-recording—which is why these figures should be viewed with caution and may not be directly comparable. Nevertheless, the NAO found waiting times to have been under-recorded in 129 cases and over-recorded in 22, with the net effect of errors being an under-recording of 21 days (mean), which may suggest a more severe problem than published statistics let on and, thus, the lack of fully reliable data on the subject should not be basis for disregarding the presence of an issue.

Overall, NHS England (2013: 16) state that considering the significant increases in demand and the trend setting to continue as people live longer with increasingly complex comorbidities, their current services are unsustainable.

5.3.4.2 Staff and staffing

Due to government policy the number of clinical staff has gone up since 2000 (Boyle, 2011: 194). The NHS hospital and community healthcare staff (medical and dental) per 10,000 population increased from 13.00 in 2001 to 18.70 in 2011 (Nuffield Trust, 2015), and the NHS employed 23,531 nurses more in 2013 than it did a decade prior (NHS Confederation, 2014). This has brought statistically low numbers of doctors and nurses (relative to population) higher and closer to OECD and EU averages, although the number of practicing physicians still remains rather low at 2.8 per 100,000 population compared to the EU28 average of 3.4 (OECD, 2013: 65, 77; 2014a: 63, 67). Additionally a UK nursing labour market review, commissioned by the Royal College of Nursing (RCN) (RCN, 2014: 10), points out that growth in the number of NHS England qualified nursing and midwifery staff (full-time equivalent) ceased in 2009/10 and the figures have been in decline ever since. They also call attention to ageing of the nursing workforce; in 2012, 44.8% of the NHS qualified nursing staff in England was aged 45 or over and once individuals in this sizeable group reach retirement age, significant replacement requirements will ensue.

Moreover, the use and reliance on agency staff has increased lately and raised concerns over the costs of this tactic at a time when efficiency gains and savings are desired. As Dorsett and Shi (2014: 1, 21) argue in their quarterly report on NHS foundation trust sector performance,

> An increase in the number of patients being treated combined with high use of contract and agency staff and a need to make cost savings, has put NHS foundation trusts (NHSFTs) under unprecedented financial and operational pressure.

They further state that although the foundation trusts have aspired to curb expenditure on contract and agency staff, they actually spend double the planned in Q1 of 2014/15 (i.e. £391m vs. £189m), and that, overall, agency staff costs as a percentage of total staff costs has increased by around 20% annually in the last two years. Table 2 below displays annual spending by NHS on agency and contract staff (including locums) since May 2010. Besides cost, over-reliance of unregistered and temporary staff may present a quality-of-care issue, because there are often limitations on the clinical tasks temporary staff may perform (Keogh, 2013: 22).

Table 2: Spending on agency and contract staff (incl. locums) in the NHS since May 2010 (Poulter, 2014)

Year	Foundation trusts (£ million)	Trusts (£ million)
2010/11	854.7	n/a*
2011/12	907	n/a*
2012/13	1,101.0	n/a*
2013/14	1,396.2	1,209.1
Total	4,258.9	1,209.1

*Before 2013/14 the expenditure of agency and contract staff was not provided separate from "non permanent NHS staff".

Finally, concerns over work morale and welfare of the workforce have been raised. The percentage of NHS staff reporting they have been ill due to work-related stress has increased significantly since 2008/09, averaging 38% in 2013, across all NHS organisations with higher figures in individual trusts (Nuffield Trust, 2014a: 17). In addition, a recent Quarterly Monitoring Report—based on an online survey of 90 NHS trust finance directors and 43 CCG finance leads—showed that staff morale was the

most often selected option to the question, "Which aspects of your organisation's performance are giving you most cause for concern at the moment? Please select top three" (Appleby et al., 2014). This is troubling, because research suggests a strong relationship and even a causal link between the wellbeing of healthcare staff and performance outcomes (Boorman, 2010; Maben et al., 2012).

5.3.4.3 Quality of care

When compared with EU averages or Western European countries with the most similar size populations, the UK falls behind in several quality of care indicators, such as infant mortality, avoidable hospital admissions from asthma and chronic obstructive pulmonary disease (COPD), as well as survival rates for certain cancers, heart attacks and ischemic strokes (appendix 1) (OECD, 2014a; De Angelis et al., 2014). Looking more closely at the avoidable admissions, Blunt (2014: 12-13, 17-18) described that in 4/2001–3/2013 potentially avoidable emergency admissions for ambulatory care sensitive (ACS) conditions—i.e. a specific subset of 27 conditions where emergency admissions may be avoided by preventive management in the community—accounted for 20% of all emergency admissions and went up 48% versus 34% for non-ACS conditions. Highest incidence rates occurred in the elderly, children under 5 years of age, and the most socioeconomically deprived groups.

In addition, England has seen scandalous revelations regarding quality of care in individual healthcare establishments. During the last decade, a number of public inquiries have been launched to conduct reviews into the quality of care of several NHS hospitals with abnormally high mortality rates, perhaps the most prominent of which was the Francis inquiry into failings at the Stafford hospital run by Mid Staffordshire NHS foundation trust (Francis, 2013). The final report published in 2013 highlighted numerous issues—stemming from, for example, cost-cutting, understaffing and focusing on things other than quality of care—as well as offered 290 recommendations aimed at changing culture and practice in several health service related organisations (BBC, 2013; Nuffield Trust, 2014b: 7). Official responses have been issued by the Government, along with a number of the organisations mentioned in the report, and most of the recommendations made by Francis were accepted by the DH in full (DH, 2014; Nuffield Trust, 2014b: 4).

Nevertheless, one should acknowledge that—despite the UK being unable to catch up to its European counterparts—improvements in the quality of care indicators mentioned earlier have been made over the years. Moreover, out of the four UK countries, England does best on some significant indicators such as life expectancy and rate of amenable mortality—i.e. premature deaths (under age 75) avoidable through better care and "a good indicator of quality of care at the system level"—while having less nurses per 1,000 population and lower healthcare spending per person than the other UK countries (Bevan et al., 2014).

6 Monitoring and regulation

Healthcare services and medical devices available in England are monitored and regulated by several bodies in the EU and England/UK. For the purpose of this thesis only those concentrated on areas relevant to Medieta as a medical device manufacturer, along with the principal national bodies responsible for monitoring NHS activities are included. The first section briefly introduces the EU regulation and is kept short seeing as Medieta has already acquired both a CE marking and ISO certification, while the second looks at national bodies responsible for monitoring and regulating the NHS.

6.1 EU regulation and quality assurance relating to medical devices

As a member of the European Union (EU), the UK must abide by EU regulations and directives including the *Council Directive 93/42/EEC* concerning medical devices and *Council Directive 90/385/EEC* relating to active implantable medical devices. While EU regulations apply directly and do not need to be transposed into national law, all EU administered directives and amendments are currently implemented by four sets of UK regulations as stated below (MHRA, 2013a; MHRA, 2014a).

- Statutory Instruments 2002 No. 618 (Consolidated legislation)
- The Medical Devices (Amendment) Regulations 2003 No. 1697 (Amendments to cover the re-classification of breast implants and additional requirements covering devices utilising materials from TSE susceptible animal species)
- Medical Devices (Amendment) Regulations 2007 No. 400 (Amendment to cover the re-classification of total hip, knee and shoulder joints)
- Medical Devices (Amendment) Regulations 2008 No. 2936 which transpose Directive 2007/47/EC into UK law

Nevertheless, change is under way and EU has planned on replacing the aforementioned council directives with new regulation on medical devices, as mentioned in section 2.3. When in effect, this would impose new requirements on device manufacturers.

Currently, in order for a medical device manufacturer to place their product on the market in the European Economic Area (EEA), the device must bear a CE marking to indicate it complies with set standards (Council Directive 93/42/EEC). A CE marking may be obtained from a Notified Body in any EU country, appointed by a Member State to carry out conformity assessment (EC, 2014a).

In addition, numerous voluntary medical device standards exist. These have been published by the International Organization for Standardization (ISO), as well as the European standardisation organisations the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) (ISO, 2014a; EC, 2013).

6.2 National monitoring and regulation of medical devices and public health services

The Medicines and Healthcare Products Regulatory Agency (MHRA) is "responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe". (MHRA, 2014b) In essence, the MHRA is gatekeeper to market when it comes to medicines, medical devices and healthcare equipment, in addition to which it investigates harmful incidents regarding the aforementioned (MHRA, 2014c). The MHRA also oversees and audits UK's notified bodies (as the competent authority) and must be notified of any clinical trials within the UK, which aim at obtaining CE marking (MHRA, 2013b, 2014d). If non-compliance is detected or if adverse incidents or security concerns regarding medical devices are reported to the MHRA, an investigation will be launched (MHRA, 2014e).

Recommendations on several healthcare topics—e.g. treatment on specific conditions, pharmaceuticals, and use of health technologies—are given to the NHS by NICE, a Non Departmental Public Body (NDPB) accountable to its sponsor department the DH (NICE, 2014). In order to avoid confusion between the activities of NICE and MHRA it should be noted that,

> MHRA is concerned about the relationships between benefits and risks; NICE is concerned, inter alia, about the relationships between benefits and costs. As a considerable over-simplification, MHRA says a product can be sold while NICE says it can be bought (by the NHS) (MHRA, 2008).

When it comes to health technologies, NICE assesses their "clinical and cost effectiveness" through technology appraisals and gives guidance accordingly (NICE, 2013a, 2013b: 8). Evidence on various aspects of a technology are required—such as clinical evidence and an economic evaluation—in order for quality-adjusted life years (QALYs) to be estimated and economic analyses—including cost-utility analysis and cost-effectiveness analysis—to be conducted (NICE, 2013c). A technology costing less than £20,000 per QALY is considered cost effective, while one costing £20,000-30,000 per QALY may be considered cost effective under conditions. Beyond that a very strong case has to be made in order for the technology to be considered efficient use of NHS resources (NICE, 2013c).

The final decisions of NICE fall into four categories:

- **Recommended** for use in line with marketing authorisation from the European Medicines Agency (EMA) or MHRA, or with how it is used in clinical practice in the NHS.
- **Optimised**, meaning recommended for a smaller subset of patients than originally stated by the marketing authorisation.
- **Only in research**, meaning recommended for use only in the context of a research study (e.g. a clinical trial).
- **Not recommended**, due to for example, lack of evidence for clinical effectiveness, or increased cost-effectiveness compared with current NHS practice.

(NICE, 2015)

Between 3/2000 and 12/2014 NICE published a total of 328 technology appraisals and made 540 resulting decisions, of which 335 (62%) were in the "recommended" and 97 (18%) in the "optimised" categories (NICE, 2015). While a marketable device is being appraised, NHS organisations should make decisions on the use of the device locally, but once NICE issues national guidance, local recommendations are replaced by them. The technology appraisals are typically enforceable three months from the date of publication and the NHS is required to provide funding and resources for the medicines and treatments recommended (NICE, 2013b).

Monitor is an executive non-departmental public body of the DH whose key responsibilities include regulating NHS foundation trusts, setting required standards to all NHS providers, ensuring essential services are provided in an area where a provider has encountered severe difficulties, ensuring efficiency and equality of the payment system for NHS services, and optimising procurement and competing services (Monitor, 2014b: 3–4). They work closely with regulatory partners such as the NHS, NHS TDA, CQC, National Quality Board, and Competition and Markets Authority.

The CQC regulates numerous health services in both public and private sectors including, but not limited to, areas such as hospital care, mental health, primary and community services, dental care, and ambulance services (CQC, 2014a: 10). In order to ensure the safety, efficiency and quality of care, they register health services that meet standards, carry out inspections, and publish reports and performance ratings (CQC, 2014b: 5–8). Where non-compliance is met the CQC may issue a warning notice or, in more severe cases, prosecute breaches of fundamental standards without a warning (CQC, 2014b: 119-120). In 2013/14 there were a total of 39,567 inspections (incl. follow-up and responsive) leading to 1,456 warning notices (CQC, 2014a: 11).

7 Methodology

7.1 Research objectives and design

The objective of the present thesis is to provide an overview of the public healthcare system in England, as well as to explore the factors present in the market and within the public healthcare system that might influence the demand for Medieta's product or complicate market entry. The work may be classified primarily as a descriptive study, because its purpose is to "gain an accurate profile of events, persons or situations" (Saunders et al., 2012: 171). In addition, elements of an explanatory study and feasibility study are present, since the thesis is concerned with explaining the factors that affect the public healthcare system in England, along with evaluating the possibility of market entry, despite excluding specifics of aspects such as Medieta's future plans, finances and product.

7.2 Data collection and analysis

Data collection focused on qualitative and quantitative data, obtained primarily from well-regarded official sources, such as the UK Government, DH, ONS, OECD and NAO; two UK-based charity think tanks the King's Fund and Nuffield Trust; and peer-reviewed journals. Descriptive data on public bodies—such as the NHS England, MHRA and NICE—was primarily retrieved from the organisation's own website. Despite some concerns when it comes to secondary data—i.e. it may be originally collected for different purposes, the scope may be unfavourable, and there may be problems with accuracy—the advantages when doing research on a national, non-domestic market and a complex industry are immense, and data collected by international organisations and governments may be considered reliable and of high quality due to expertise and rigorous methods (Ghauri and Grønhaug, 2010).

Material was searched primarily through Google, EBSCOhost (that displays e.g. Elsevier's publications), and search functions on the organisational websites outlined in the previous paragraph. Boolean phrases were used when possible and searches included terms such as:

commissioning	monitoring
efficiency	National Health Service
England	NHS
European Union	population
expenditure	private
funding	public
health indicators	quality of care
health technology	regulation
health technology assessment	statistics
healthcare	trends
medical devices	United Kingdom

Material was collected, aside from few exceptions, before 31 December 2014. No material published later was accepted, although some websites and online documents were accessed after that point as well. This was a necessary cut-off as new material is constantly generated in volumes. Furthermore, due to oversupply of material and constant developments of the public health system—including a massive reorganisation of the NHS in 2013—reports published in 2013-2014 were favoured. Few sources pre-2009 were included, but his was mainly due to a great volume of recent, high-quality data, rather than systematic excluding of older sources. Naturally, necessary historical data and statistics were used.

8 Discussion

8.1 Demand factors for Medieta's product in public healthcare in England

The public healthcare system in England is under severe pressure and faces numerous challenges now and in the future. The population continues to grow as well as age. Life expectancy is up and although this is a positive trend, people living longer and the absolute and relative number of the old and very old increasing translates to more demand for public services, including those provided by the healthcare sector. The older tend to have more comorbidities and complex conditions commanding longer hospital stays. In addition, growth of the proportion overweight or obese people, as well as poor health habits—smoking, alcohol use and insufficient physical exercise, among other things—contribute to costly lifestyle conditions and increased patient volumes. While the NHS is already struggling to meet demands, whilst not exhausting current resources (incl. staff), maintaining quality of care and managing costs, further improvements should be made in order to achieve better health outcomes on par with EU peers.

It is easy to see a market for Medieta's device here. The healthcare system requires improved efficiency and cost savings, but cannot afford to compromise on care quality, which already is an area of concern. A wearable monitoring device that transmits data wirelessly for clinical staff to be viewed wherever, accompanied by intelligent software that displays the data and automatically alerts of worrying changes in the patient's condition before their health status deteriorates, would have many applications within the public healthcare system in England. Based on what is written in the previous sections on the demographic trends impacting the demand of health services and the current situation and challenges of the system, some possible areas of care and patient groups that might benefit from Medieta's device (referred to as "the device" in this section) are:

- Geriatric patients (in hospitals, care homes and home care): Many older patients have complex comorbidities and conditions, which may be very difficult to treat and command for longer hospital stays. The device would allow care staff to be alerted and react promptly to worrying biosignals, whether the individual was at home or at a care unit. Thus, care could be delivered earlier,

potentially resulting in a better outcome. Additionally, the GPS tracking feature might prove useful when caring for and needing to locate an elderly patient—or any patient in general—suffering from memory loss or confusion, such as someone with dementia.

- Patients requiring emergency care (i.e. those using A&E and ambulance services): Using the device, ambulance and A&E nursing staff could monitor and collect data from a patient even before they can be seen by a physician. This might assist in determining the patient's health status and prioritising those most in need of urgent medical care, which in turn would help avoid unnecessary deterioration of the patient's condition while they wait.

- Individuals with severe, long-term conditions or comorbidities who require continuous management (e.g. patients with cancer, coronary heart disease, asthma, diabetes, or a combination of conditions): These patients are already receiving care and being monitored, however the device would allow continuous monitoring instead of only obtaining data at certain intervals and provide more insight into how the measurements change over time. It might help identify patients who require closer care in order to avoid worsening of their condition, especially to the point where it would require an expensive hospital admission and treatment in an intensive care unit. On the other hand, the device could allow reduce unnecessary appointments for patients whose condition and treatment are in balance.

- Post-operative patients and patients who have been treated for a serious event (e.g. heart attack or ischemic stroke): The device could bring extra help in deciding whether or not a patient is ready to be discharged and allow patients to be discharged earlier as well as called back if the device warns of worrying changes in the patients condition.

Overall, the key benefit and aspiration with the use of Medieta's device is to shift focus increasingly toward preventive care and allocating care where and when it is most needed. It also allows for convenient monitoring of patients who might benefit from it, but are not continuously monitored under the current system. With the patient

volumes up and projected to increase further, early medical intervention and attaining stability for patients—especially those with long-term conditions—would make a contribution to avoiding the more labour intensive—and hence expensive—types of care such as inpatient hospital care and intensive care, as well as relieving pressures on clinical staff and highly busy departments, such as emergency care. Additionally, catching negative health events early on and delivering care before a more severe or critical state ensues would help decrease need for future treatment caused by unnecessary complications or even permanent disabilities due to delayed care, thus, contributing to quality of care.

8.2 Key requirements for market access and encouraging purchase of Medieta's device by the NHS

Naturally, all legal requirements for medical devices must be met in order to gain market access. Medieta has already obtained a CE marking and relevant ISO certification for the software, which must be done for the wearable monitor as well. Still, this does not guarantee adoption of the device by the NHS. In order to do so Medieta must conclusively show the quality and benefits of the device, but, even more crucially, that the purchase and use of the device may be done at an acceptable cost.

It is possible that the NHS would purchase the device of their own accord, but in this case the decisions would be made locally. On the other hand, obtaining a recommendation for the use of the device from NICE would necessitate the NHS as a whole to make the device available and used if a patient's doctor considered it to be clinically appropriate. Since NICE is concerned with the cost and benefit of the new technology, a recommendation would not be awarded if a QALY gained through the use of the device came at too high a cost. Therefore, Medieta must have high-quality data proving both the positive clinical outcomes for patients and the costs in relation to these being low enough.

Looking ahead, the European legal framework is likely to experience updates in the near future, which may create additional responsibilities and costs to medical device manufacturers. On a national level, the new UK government that will be formed after the fast approaching general election may bring changes to healthcare policy and

funding, impacting NHS purchase among other things. Thus, a European medical device manufacturer aspiring to enter the public health services market in England must acknowledge and prepare for the possibility that new requirements and priorities emerge.

8.3 Limitations of the study and suggestions for future research

Composing a study on the public healthcare sector is challenging in several ways. First, everything is live and the situation keeps updating constantly, with new data being generated on a daily basis. For this reason it was necessary to select a "cut off date", i.e. 31.12.2014, meaning data published after this would not be accepted. Unfortunately it takes time for statistics to be made available so, despite using latest figures, most of them are some two or three years old. Furthermore, the large-scale reorganisation of the NHS in 2013 may have created special circumstances, which generate initial, short-term fluctuations in statistics, or conversely result in meaningful, permanent changes, which cannot be identified at such an early stage.

Second, data quality and comparability present an issue when working with secondary data. What complicates the matter further is England being a part of the UK. Some statistics are available for England alone, while some are obtainable only for the entire UK. Similarly, some data is presented for a calendar year—e.g. statistics from OECD and ONS—while some data is displayed for the UK financial year running from 1 April to 31 March—e.g. NAO and financial data in general. Whether the data regards England or the UK, and calendar or financial year is noted throughout the thesis, but this results in poorer comparability.

Finally, due to the vastness and complexity of the subject some data and subtopics had to be excluded. This was in order to provide a comprehensive overview of the system without being too superficial and still giving attention to areas of special interest to the thesis' commissioner. Selection of data and aspects to focus on more closely were primarily at the author's discretion, which impairs objectivity and may even result in omission of significant material. Furthermore, hardly using secondary/tertiary sources such as news articles and reputable blogs may have left out valuable interpretations or sides of a story. Despite improved reliability when using an original data source instead

of another author's understanding and presentation of that same data, popular publications may significantly shape public views and opinions, which makes them meaningful. As the so-called "Thomas theorem" states, "If men define situations as real, they are real in their consequences".

For future research—closer to the possible market entry—a comprehensive feasibility study on England/UK market entry, including necessary technological detail, might be of great benefit for Medieta. In addition, Medieta would benefit from a study using actual financial data, aiming at quantifying the savings attained by the NHS when using Medieta's device compared to existing practices. Being able to prove this in addition to functionality and accuracy would facilitate market entry and contribute to receiving a NICE recommendation for the use of the product within the NHS.

9 Conclusions

A number of demographic trends and the immense pressures already experienced by the public health services in England would support there being current and future demand for Medieta's early risk recognition system. The device could provide better monitoring for a variety of patients—especially the kind who might not otherwise be as comprehensively monitored—which would allow for earlier detection of health status deterioration. This would allow a shift of focus towards preventive and more timely delivery of care, which would ideally contribute to increased quality of care, more informed and earlier discharging of patients, and decreased need for emergency and intensive care services.

Nevertheless, entry into public healthcare and purchase by the NHS may not be considered certain even if the clinical efficacy of the device can be proven. The costs in relation to the benefits must be considered acceptable as well and failure to do so would inhibit obtaining an important recommendation from NICE. Furthermore, improving efficiency and realising savings is even more important at a time when government expenditure on public healthcare is rather flat and a number of NHS trusts and foundation trusts are struggling with their finances.

To sum up, if the device can be comprehensively shown to benefit patients at an acceptable cost, it would be fair to assume the public healthcare sector in England is a suitable new market with sufficient demand, and the device could be purchased by the NHS.

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Selected quality of care indicators in the UK and four other EU countries

Variable	Year	United Kingdom	EU average	Germany	France	Italy	Spain
Infant mortality (deaths of children <1 year of age per 1,000 live births)	2012*	**4.1** [a]	4.0 [b]	3.3	3.5	2.9	3.1
Asthma hospital admissions (adults; age-sex standardised rates per 100,000 population)	2011*	**61**	51 [c]	20	37	11	40
Chronic obstructive pulmonary disease (COPD) hospital admissions (adults; age-sex standardised rates per 100,000 population)	2011*	**227**	199 [c]	212	102	90	211
Case-fatality within 30 days after admission for acute myocardial infarction (AMI) in adults aged 45 and over (admission based; age-sex standardised rates per 100 admissions)	2011*	**7.8**	7.8 [d]	8.9	6.2	5.8	8.5
Case-fatality within 30 days after admission for ischemic stroke in adults aged 45 and over; age-sex standardised rates per 100 admissions)	2011*	**10.4**	9.6 [e]	6.7	8.5	6.5	10.2
Cervical cancer, five-year relative survival (%)	2007-12**	**60.9**	62.4 [f]	64.5	n/a	n/a	n/a
Breast cancer, five-year relative survival (%)	2007-12**	**82.0**	82.9 [f]	85.0	n/a	n/a	n/a
Colorectal cancer, five-year relative survival (%)	2007-12**	**54.5**	58.5 [f]	64.3	n/a	n/a	n/a

* or nearest year; ** or nearest period
[a] England: 4.0 (ONS, 2014h); [b] EU28; [c] EU21; [d] EU21/12; [e] EU20/11; [f] EU15

(OECD, 2014a: 30–31, 86–101)